

B.2 STATEMENT OF WORK

1.0. Background

The Department of Veterans Affairs (VA) provides prosthetic limbs and related services to veterans who are eligible for VA health care services and have medical needs for such items and services. This acquisition will supplement VA in providing comprehensive prosthetic care and support to the veterans in need. It is VA's intent to solicit proposals and award multiple contracts.

2.0. Scope

The Contractor shall fabricate all prosthetic limbs in strict conformance to the prosthetic prescription that has been provided by the VA Amputee Clinic Team. The VA will provide a list of approved L Codes for work to be provided by the Contractor for the specific prescription. The Contractor shall not add or substitute components or alter the veteran's limb prescription in any way without prior approval and written authorization from the Contracting Officer (CO). The solicitation only includes commercial items. Products that are not commercial items are considered experimental and purchase of experimental products shall not be authorized under this solicitation.

Comment [PS1]: Fillable – Default value is "CO". Users can modify this field and insert other information such as "Contracting Officer's Representative (COR)" or "VAMC Point of Contact (POC)" as appropriate.

3.0. Education and Training Requirements

3.1. General Education

The Contractor shall have a full-time American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) certified, or Board of Certification/Accreditation International (BOC) certified prosthetist(s) on staff in "good standing" at each of the proposed service locations throughout the contract period. "Good standing" is defined as participating and achieving appropriate continuing education credits and paying dues as determined by Certifying Agency such as ABC and BOC.

VA reserves the right to verify prosthetists' credentials anytime during the term of this contract. The Contractor shall provide current copies of certifications upon request of the COR. Failure to comply with this requirement may lead to adverse actions by the Government up to, and including contract termination in accordance with the contract clauses in the contract.

3.2. Special Education Requirements for Certain Prosthetic Limb Devices/Components

The fitting and alignment of prosthetic limbs device and associated services shall be performed under the supervision of a prosthetist who has met the applicable educational and training requirements covered under the manufacturing training program for that device. New technologies require proof of training and only those prosthetists specifically trained, or completing training for purposes of providing an item by the time of delivery of the item may provide the item and follow up services to a veteran. VA reserves the right to determine which technologies require specific training. VA will notify the Contractor when current technologies require specialized training from the manufacturer in order to provide to veterans.

4.0. Specific Requirements

4.1. Compliance with VA Prescription and Coding of Prosthetic Limb Devices/Components

The Contractor shall not add or substitute components or alter the veteran's prosthetic limb prescription in any way without prior approval and written authorization from the CO. Any changes to the veteran's prescription, components or codes require review and approval by the VA Amputee Clinic Team and shall be authorized in writing by the CO.

4.2. Contractor Facility Locations

All Contractor facilities as well as other fabrication facilities such as commercial central fabrication facilities that will be utilized for this contract shall be listed in the proposal. All work required under this contract shall be conducted at the facility locations included in the contract. The Contractor's facilities shall be accredited either by the Facility Accreditation Program of the ABC or the Accredited Facilities Program of the BOC at the time of proposal submission. VA reserves the right to conduct site visits of the facility and review accreditation and certification documents and standards at any time. The Contractor shall provide current copies of accreditation documents upon request of the COR. VA may conduct site visits as needed by the COR and other VA subject matter experts as determined by the COR. Throughout the duration of this contract, the Contractor shall notify VA of any facilities that are added, changed, or closed to the CO and the COR within 15 calendar days of any change. Approval for added or changed facilities must be obtained before those facilities may be used for this contract.

4.3. The Joint Commission and Other Special Requirements

The Contractor shall perform the required work in accordance with the Joint Commission (TJC) and ABC and/or BOC standards. All Contractor employees shall continuously meet or exceed TJC and ABC and/or BOC standards. The Contractor shall develop and maintain the following documents for each contractor employee working on this contract: credentials and qualifications for the job; a current competence assessment checklist (an assessment of knowledge, skills, abilities and behaviors required to perform a job correctly and skillfully, and including knowledge and skills required to provide care for certain patient populations, as appropriate); a current performance evaluation supporting ability of the contractor employee to successfully perform the work required under this solicitation; and, listing of relevant continuing education for the last two years. At the time of contract award, annually on the date of the contract award thereafter, and at any other time requested by the VA COR, the Contractor shall provide current copies of these records for each contractor employee working on this contract.

The Contractor shall be responsible for ensuring that contractor employees providing work on this contract are fully trained and completely competent to perform the required work.

When changes in contractor personnel are approved in accordance with the "Key Personnel" clause of the contract in section 5.1, the Contractor shall provide evidence of orientation, the current competence assessment, and current performance evaluation that supports the above.

Where the contract does not require TJC accreditation or other regulatory body requirements, the Contractor shall perform the required work in accordance with TJC standards. A copy of TJC standards

can be obtained from The Joint Commission, One Renaissance Blvd., Oakbrook Terrace, IL 60181 or <http://www.jointcommission.org/>.

4.4. Outcome Monitoring and Utilization

VA may prescribe and authorize an automated prosthetic utilization and function monitoring device for data collection and analysis for a new lower extremity prosthetic limb (transtibial, knee disarticulation, transfemoral and hip disarticulation level; does not include socket replacements). The utilization and function monitoring device will have the ability to record intensity, endurance, gait symmetry, dynamic function, including alignment, forces and moments with proven accuracy.

The device will monitor and continuously record the following:

- Stance and swing time for gait symmetry, dynamic function including alignment, forces, and moments;
- Cadence and cadence variability;
- Step count – continuous recording of total step count;
- Number of steps per selected time interval;
- Longitudinal, historical and objective analysis;
- Peak performance index, quantifiable into baseline and faster than baseline rate of walking, distance and variable cadence;
- Functional level assessment capability; and
- Measurement of socket load during gait.

VA may request “Veteran Outcome Reports” based on the data collected. The report shall contain narrative and graphical representation of the above variables.

4.5. Semi-Annual Service

The Contractor shall provide semi-annual service to each veteran for whom the Contractor is managing prosthetic limb care. For the purposes of this contract, semi-annual service is defined as a follow up visit for inspection of the prosthetic limb(s) and evaluation for fit and function for all VA-approved prosthetic limb(s) the patient owns and is actively using. Typically, semi-annual service includes inspection, testing, cleaning, and checking of the prosthetic limb(s) and/or residual limb(s) to include maintenance specific to the warranty of devices.

Semi-annual service shall not be incumbent upon the number of prosthetic limbs a patient owns. Two follow up visits per patient are required annually for a patient to whom the Contractor delivered a prosthetic limb(s) under this contract. The Contractor shall notify the CO for the required semi-annual service and receive written authorization prior to providing the semi-annual service to the veteran.

The following L-Code shall be used for semi-annual service:

- L7520 – Repair prosthetic device, labor component, per 15 minutes (not to exceed 4 units or 60 minutes)

4.6. Warranty

The Contractor shall warrant the prosthetic limb provided against defective material and/or workmanship for a minimum of 90 calendar days from the date of acceptance by VA. The minimum warranty period shall commence after the final check out at the VAMC by the Amputee Clinic Team and deliverable acceptance by the CO. Manufacturer's warranties of prosthetic limb and limb devices/components that extend beyond the minimum 90 calendar day period shall be in effect and be enforced. The Contractor shall furnish, without additional cost to the Government, all materials and labor necessary to correct defects that were detected during the warranty period. These conditions do not apply to adjustments incidental to wearing of the prosthetic limb, adjustments required by physical change of the wearer, or where there is evidence of deliberate misuse or alteration by anyone other than the Contractor.

Any prosthetic limb repaired or furnished as a "loaner" shall be subject to this clause to the same extent as a new prosthetic limb delivered. The warranty for a repaired limb or "loaner" limb shall be equal in duration to the term the Contractor is required to offer to a new prosthetic limb and shall run from the date of the acceptance of the repaired or "loaner" prosthetic limb by VA.

The Contractor shall warrant and imply that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract. The rights and remedies of the Government provided in this clause are in addition to, and do not limit any, rights afforded to the Government by any other clause of the contract.

4.7. Repair and Replacement

4.7.1. Minor Parts of Prosthetic Device and Labor

All parts procured or fabricated to replace existing parts or to modify a previously issued or fabricated device is considered a "repair," regardless of who fabricated or supplied the original part. Repair and replacement of minor parts may require adjustments to a prosthetic limb required by wear or a change in the veteran's condition. A minor repair or replacement means repair or replacement that does not significantly alter the function or essential physical characteristics of an item or component, or change the purpose of an item or component. Factors that will be considered in determining whether a repair or replacement is minor include the value and size of the repair or replacement, and the comparative value and size of the final product. Dollar values and percentages may be used as guideposts, but are not conclusive evidence that a repair or replacement is minor. The following L-Codes shall be used for repair and replacement of minor parts and for labor:

- L7510 – Repair prosthetic device, repair or replace minor parts (not to exceed \$500.00)
- L7520 – Repair prosthetic device, labor component, per 15 minutes (not to exceed 8 units or 120 minutes)

Repair and replacement of minor parts and labor requires prior approval and written authorization from the CO, except for repairs provided to veterans with VA Prosthetic Service Card (VA Form 10-2501) as described in section 4.7.2.

4.7.2. Use of Prosthetic Service Card (VA Form 10-2501)

Veterans may obtain repair services using a VA Prosthetic Service Card (PSC) VA Form 10-2501. A PSC is a pre-authorized card that can be used to receive needed repairs to the veteran's qualified prosthetic device up to the amount indicated on the PSC. For prosthetic limbs, veteran may obtain repairs up to \$500.00 with the PSC. For repairs or replacement of parts other than using a PSC or over \$500.00 shall be completed with prior approval and written authorization from VA and in accordance with the section 4.7.1.

The Contractor shall submit VA Form 10-2520 PSC Invoice (Attachment A) to the Prosthetic and Sensory Aids Service at the VAMC with the primary service area responsibility where the veteran resides for reimbursement. The Contractor shall obtain the veteran's signature acknowledging receipt of appropriate repair for invoices for such repairs under the authority of a PSC.

4.7.3. Other than Repair or Replacement of Minor Parts of Prosthetic Device and Labor

Repairs to a prosthetic limb are covered when necessary to make the prosthetic limb functional. If the expense for repairs exceeds the estimated expense of purchasing a new prosthetic limb or device, no payment can be made for the amount of the excess. Maintenance that may be necessitated by manufacturer's recommendations or construction of the prosthetic limb shall be performed by the Contractor covered as a repair.

Replacement of a prosthetic limb or replacement of a prosthetic limb device/component requires prior approval and written authorization from the CO. Replacement of a prosthetic limb or prosthetic limb device/component will be initiated if the VA provider (i.e., Amputee Clinic Team or VA provider) with granted prescription authority, and who is involved in veteran's amputation care, prescribes a prosthetic limb or device for the following reasons:

- (1) A change in the physiological condition of the patient; irreparable wear of the device or part of the device; or the condition of the device, or part of the device, requires repairs and the cost of such repair would be more than 60% of the cost of a replacement device, or of the part being replaced.
- (2) Damage to the prosthetic limb or device is not due to malicious damage, culpable neglect, wrongful disposition or use of device other than intended purposes.

4.8. Government Supplied Items

VA may provide certain supplies such as shrinkers, liners, sleeves, and socks to the veteran at the discretion of the VA. Any items or supplies provided to the veteran by the Contractor shall be pre-authorized by the CO.

4.9. Loaner Prosthetic Limb Requirements

The Contractor shall be qualified to furnish prosthetic devices such as, but not limited to, hydraulic knee units, micro-processor feet and knees, electronic hands and feet by completing special educational and training requirement for such devices as described in section 3.2 and the same requirement shall be applied to provision of a "loaner" unit. The Contractor shall provide a "loaner"

unit in the event that a veteran's prosthetic limb requires repair by the manufacturer. A "loaner" is defined as a suitable prosthetic device, fit for patient use during the repair period. VA will not reimburse for loaner units.

4.10. Recalls

The Contractor shall immediately notify all affected VAMC(s) and COR(s) in the event of a device recall, removal, required adjustment, or required modification that is suggested or mandated by the Contractor, distributor, manufacturer, or any regulatory or government agency. The following information shall be included in this notification:

- A complete item description and identification;
- Administrative identification data including contract number, order numbers and order date;
- Removal, adjustment, or modification reasons for recall; and
- Instructions for appropriate corrective action.

5.0. Special Contract Requirements

5.1. Key Personnel and Temporary Emergency Substitutions

The Contractor shall assign the following key personnel to this contract: all individuals providing items and related services to veterans and for whom information about education and training is required to be submitted as a part of the response to this solicitation including, but not limited to, those individuals who must meet the training requirements set forth in the Education and Training Requirements in Section 3.0.

During the first ninety (90) calendar days of performance, the Contractor shall make no substitutions of key personnel unless the substitution is necessitated by illness, death, or termination of employment. The Contractor shall notify the CO, in writing, within fifteen (15) calendar days after the occurrence of any of these events and provide the following information:

- Detailed explanation of the circumstances necessitating the proposed substitution;
- Complete resume for the proposed substitute; and
- Any additional information requested by the CO.

Proposed substitutes shall have comparable qualification to those of the persons being replaced. The CO will notify the Contractor within fifteen (15) calendar days after the receipt of all required information of the decision on the proposed substitutes. The contract will be modified to reflect any approved changes of key personnel. In the case where VA does not agree with the proposed substitutes and their qualifications, the contract may be terminated and the Contractor may not receive the minimum dollar amount specified in this contract.

For temporary substitutions where the key person will not be reporting to work for three (3) consecutive work days or more, the Contractor shall provide a qualified replacement for the key person. This substitute shall have comparable qualifications to the key person being replaced

temporarily. Any substitution exceeding a period of two weeks consecutively shall follow the key personnel replacement procedure described in paragraph above.

5.2. Confidentiality of Patient Records

[Insert necessary requirements and information in consultation with your Information Security Officer, CO, and Privacy Officer]

Example: The Contractor shall develop or operate a system of records on individuals, to accomplish an agency function subject to Title 5 United States Code (USC) 552a. Violation of the law may involve the imposition of criminal penalties. The Contractor may be required to enter into a Business Associate Agreement.

The Contractor is a VA contractor and shall assist in the provision of health care to patients seeking such care from or through VA. As such, the Contractor is considered as being part of the Department health care activity. The contractor is considered to be a VA contractor for purposes of the Privacy Act, Title 5 U.S.C. 552a. Further, for the purpose of VA records access and patient confidentiality, Contractor is considered to be a VA contractor for the following provisions: Title 38 U.S.C. 5701, 5705, and 7362. Therefore, Contractor may have access, as would other appropriate components of VA, to patient medical records including patient treatment records pertaining to drug and alcohol abuse, HIV, and sickle cell anemia, to the extent necessary to perform its contractual responsibilities. However, like other components of the Department, and notwithstanding any other provisions of the contract, the Contractor is restricted from making disclosures of VA records, or information contained in such records, to which it may have access, except to the extent that explicit disclosure authority from VA has been received. The Contractor is subject to the same penalties and liabilities for unauthorized disclosures of such records as VA. The records referred to above shall be and remain the property of VA and shall not be removed or transferred from VA except in accordance with U.S.C.552a (Privacy Act), 38 U.S.C. 5701 (Confidentiality of claimants records), 5 U.S.C. 552 (FOIA), 38 U.S.C. 5705 (Confidentiality of Medical Quality Assurance Records) 38 U.S.C. 7332 (Confidentiality of certain medical records) and federal laws, rules and regulations. Subject to applicable federal confidentiality or privacy laws, the Contractor, or their designated representatives, and designated representatives of federal regulatory agencies having jurisdiction over Contractor, may have access to VA 's records, at VA's place of business on request during normal business hours, to inspect and review and make copies of such records. Records created by the contractor in the course of treating VA patients under this contract are the property of the VA and shall not be accessed, released, transferred or destroyed except in accordance with applicable federal law and regulations. Upon the expiration of this contract or termination of the contract, the contractor shall promptly provide the VA with the individually identified VA patient treatment records. In any instance where the contractor transmits patient or sensitive data of any sort to VA, the contractor shall encrypt the data and provide it in an encrypted/secured manner.

5.3. VA Sensitive Information

[Insert necessary requirements and information in consultation with your Information Security Officer, CO, and Privacy Officer]

Example: VA sensitive information is all Department data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary information, records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy rule, and information that can be withheld under the Freedom of Information Act. Examples of VA sensitive information include the following: individually-identifiable medical, benefits, and personnel information; financial, budgetary, research, quality assurance; confidential commercial, critical infrastructure, investigatory, and law enforcement information; information that is confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney client privilege; and other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of federal programs.

6.0. Performance, Delivery, Inspection and Acceptance

6.1. Performance and Delivery

The Contractor shall complete initial delivery of items ordered under this contract no later than 30 calendar days after receipt of a delivery order. Initial delivery means an ordered item or service is complete and the item is provided to, and accepted by the patient. The Contractor shall provide a written notification to the CO within 7 calendar days of the receipt of a delivery order to show cause in the event the Contractor is unable to deliver the required items or services in accordance with the Government's required delivery date. Initial delivery shall not be construed as final delivery or acceptance of an item or service by the Government.

In the event the Government desires expedited delivery, the CO shall telephonically contact the Contractor and inquire into the feasibility of obtaining the device under this condition. The Contractor shall respond within 24 hours to such request and expedited delivery shall be mutually agreed upon. Expedited delivery terms and conditions, when required, shall be determined by the CO or COR and the Contractor on a case by case basis and stated in the individual task or delivery order. Any additional costs incurred by the Contractor for meeting this requirement shall be negotiated in accordance with 48 U.S.C. 52.212-4, Contract Terms and Conditions – Commercial Items. The total cost for the expedited delivery shall not exceed 1.5 times the cost of the normal delivery for the same or similar item with any applicable discounts. Failure by the Contractor to deliver the ordered items on an expedited basis, or otherwise fulfill the agreed upon requirements shall constitute an event of default, and the CO shall undertake any action authorized pursuant to the awarded contract, or otherwise in accordance with applicable statutes and regulations.

6.2. Inspection and Acceptance

Contractor performance shall be monitored by the Quality Assurance Surveillance Plan (QASP) located in Section X. The QASP matrix details performance indicators, the standard, the acceptable quality level, the method of surveillance and incentive/disincentives. The indicators are:

- Delivery time requirement
- Limb compliant with VA physician prescription
- Workmanship free of defect (socket fits appropriately, limb correctly aligned)
- Patient education
- Patient acceptance of the device in all aspects (cosmetically and functionally)

Payment shall be rendered for a prosthetic limb or service that satisfactorily meets all of the indicators. Payment shall be delayed for any prosthetic limb or service that does not meet one or more of the indicators. The Contractor shall correct all deficiency of non-compliant prosthetic limb or service within fifteen (15) calendar days of written rejection notification from the COR. The corrected prosthetic limb or service will be re-inspected for acceptance. No invoice shall be submitted until the Government accepts the item or service.

For new prosthetic limbs or socket replacement for existing prosthetic limbs, final check-out by the VA Amputee Clinic Team at the VAMC from which the task order was generated is required. Final delivery and check out shall be conducted at the VAMC, either by in person inspection or via Tele-health capabilities at an outlying VA facility. Final acceptance or rejection and authorization for payment shall occur with the final delivery and checkout of the prosthetic limb to ensure accuracy of prescription and acceptance by the veteran. CO will provide a written acceptance notification for any items accepted by the Government. Veteran prosthetic limb wearers may be measured and fitted and accept conditional or initial delivery of the prosthetic limb at the Contractor's facility. However, conditional or initial delivery shall not be construed as final delivery or acceptance of an item or service by the Government and authorization for payment.

Repair or replacement of prosthetic limb components other than socket replacement does not generally require final check-out by the VA Amputee Clinic Team unless VA determines and notifies the Contractor that the final check-out is required with the issuance of the task or delivery order. VA retains sole discretion to determine whether a final check-out is necessary for the task order.

7.0. Ordering Procedures

The Contractor shall not directly, or indirectly through agents, solicit eligible veterans. VA personnel shall not direct, guide or prompt a veteran to a specific contractor except when a physician determines that it is a medical necessary as documented in clinical notes.

Veterans are allowed to select a non-VA prosthetic limb provider from a list of VA approved contractors and this satisfies the requirement for fair opportunity. In some instances a VA clinician determines that it is medically necessary to select a certain contractor as documented in clinical notes, which would also satisfy the fair opportunity requirement of FAR 16.505(b)(1). Exceptions to the fair opportunity process are:

- The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
- Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

- The order must be issued on a sole-source basis in the interest of economy and efficiency because it is logical follow-on to an order already issued under the contract, provide that all awardees were given a fair opportunity to be considered for the original order.
- It is necessary to place an order to satisfy a minimum guarantee.
- For orders exceeding the simplified acquisition threshold, a statute expressly authorizes or required that the purchase be made from a specified source.
- In accordance with section 1331 of Public Law 111-240 (15 USC 644(4)), contracting offers may, at their discretion, set aside orders for any of the small business concerns identified in 19.000(a)(3). When setting aside orders for small business concerns, the specific small business program eligibility requirements identified in part 19 apply.

ABBREVIATIONS:

ABC	American Board for Certification in Orthotics, Prosthetics & Pedorthics
BOC	Board of Certification/Accreditation International
CMS	Centers for Medicare and Medicaid Services
CO	Contracting Officer
COR	Contracting Officer's Representative
DMEPOS	Durable Medical Equipment Prosthetics, Orthotics, and Supplies
FAR	Federal Acquisition Regulation
HCPCS	Healthcare Common Procedure Coding System
HIPAA	Health Insurance Portability and Accountability Act
NOC	Not Otherwise Classified or Specified
PSC	Prosthetic Service Card
QASP	Quality Assurance Surveillance Plan
TJC	The Joint Commission
VA	Department of Veterans Affairs
VAMC	VA Medical Center
USC	United States Code