

STATEMENT OF WORK

1 Definitions:

AABB: American Association of Blood Banks

FDA: Food and Drug Administration

VAMC: Veterans Affairs Medical Center

VISN 1: Veterans Integrated Service Network, Region 1 (all VAMC facilities in 6 New England States)

JC: Joint Commission

2 Background:

Apheresis services are not currently available under contract at the VA Medical Center Boston. The contractor shall provide apheresis services at VA Medical Center Boston upon the request of VA staff physicians. The treatments will be provided in accordance with the VA physician's orders. In carrying out its responsibilities for apheresis services, the contractor shall provide all appropriate equipment. The equipment must be safe, effective, reliable, and shall be maintained by the contractor according to manufacturer's expectations.

3 Requirements:

The Boston VA Healthcare System has a requirement to provide therapeutic apheresis services to Veteran patients. The intended result of the solicitation will be to award a twelve month base contract with four 12-month option periods.

- 3.1 Use reasonable efforts to provide apheresis services at the locations defined in Paragraph 7.0. Such apheresis services will include the separation and removal of a blood component, reinfusion of the unused portion and the infusion of a suitable replacement fluid ("Apheresis"), if required, as well as other duties associated with therapeutic apheresis ("Associated Duties"). Apheresis and Associated Duties are collectively referred to as "Apheresis Services." The Contractor will perform the Apheresis Services in accordance with the written orders issued by the patient's ordering physician ("Ordering Physician") as documented in the patient's chart. Such written orders may include, without limitation, the treatment schedule, the patient's weight, the amount of blood to be processed, the amount and type of replacement fluid, if required, and instructions for the care of the lines after the procedure, including without limitation, heparinization (each, an "Order"). Contractor physicians will not write the orders for the Apheresis. Apheresis services shall include plasma exchange, therapeutic plasmapheresis, thrombocytapheresis, erythrocytapheresis, leukocytapheresis, photopheresis, LDL apheresis, and red blood cell exchange.

- 3.2 Before the performance of the Apheresis Services:
- 3.2.1 When necessary consult with the Ordering Physician to determine the medical necessity, type, and frequency of the required procedure and to schedule a time or times, and a place to perform the Apheresis Services ("Consultation").
 - 3.2.2 Obtain written informed consent for the performance of the Apheresis Services from the patient (or responsible guardian or parent) which will be kept with the patient's hospital chart. The vendor shall maintain patient confidentiality during its provision of the Apheresis Services and during the life of the contract, according to the Privacy Act.
- 3.3 Monitor the patient during the provision of the Apheresis Services and report any progress and/or complications to the Ordering Physician or the Customer's physician responsible for the patient during the procedure. Other than the Apheresis Services, under no circumstances will the Contractor perform patient care duties, which duties are the sole responsibility of the Customer.
- 3.4 Therapeutic apheresis is available to the VAMC on a 24/7 days a week basis. Ideally therapeutic apheresis procedures should be scheduled with as much advanced notice as possible (generally 24 hours) but are available on an emergency basis.
- 3.5 Provide qualified personnel, equipment, supplies and disposables for the performance of the Apheresis Services. The Contractor is responsible for proper equipment maintenance and documentation of Contractor-owned equipment, supplies and disposables.
- 3.6 Upon completion of the Apheresis Services, document on the patient's chart a record of the Apheresis Services including replacement solutions administered, if any, fluid balance, medications given, and adverse reactions, problems with vascular access, or any other non-routine or unexpected incidents/results if any, which occurred during the Apheresis Services.
- 3.7 Will provide to the VAMC, an electronic quality resource documentation book that is continually maintained by the Contractor, to address staff licensure and certification, training, ongoing professional education activities, and equipment maintenance records.

4 Responsibilities of the VA:

VA will:

- 4.1 When possible, ensure that the Ordering Physician contacts the Contractor by telephone in order to request Apheresis Services at least 4 hours in advance. The Ordering Physician will be knowledgeable of the patient's condition, as well as the

appropriate application of, and risks and benefits associated with, therapeutic apheresis.

4.2 During the Consultation, ensure that the Ordering Physician provides the Contractor with the patient's name, diagnosis, physical size and location, pertinent laboratory values, and the Ordering Physician's name and contact information.

4.3 Maintain responsibility for:

4.3.1 Making the final decision for the Contractor to perform the Apheresis Services following the Consultation, and

4.3.2 The patient's care at all times, including the period of time the Apheresis Services are provided by the Contractor.

4.4 Provide the Orders for the Apheresis Services with which the Contractor must comply. In addition, the Customer is responsible for obtaining the informed consent for the Apheresis Services as a treatment. The Customer understands and agrees that the Contractor cannot start the Apheresis Services without such informed consent.

4.5 Supply and prepare replacement fluids (other than the patient's own blood) prior to the performance of the Apheresis Services.

4.6 Make available at no additional cost a suitable site adequate for the performance of the Apheresis Services, support personnel, laboratory service accessibility, and emergency care, equipment and medical personnel.

4.7 Ensure that the Ordering Physician, or at least one designated physician from the primary care team familiar with the patient, is readily available throughout the Apheresis Services. Customer will also provide support staff as may be reasonably necessary to assist and care for the patient if a medical emergency arises during the provision of the Apheresis Services. Such support staff will include, without limitation, medical/surgical technicians and the resuscitation/code team.

4.8 Arrange for the insertion of a central line or other venous access if venous access other than peripheral veins is required for the Apheresis Services.

4.9 Dispose of any waste or biohazardous materials resulting from the Apheresis Services.

4.10 Upon discovery, report possible transfusion-transmitted infections or other serious complications associated with transfusion which may have resulted from the Apheresis Services ("Adverse Event"). Customer will cooperate with the Contractor's investigation of any Adverse Event and supply information concerning the patient to the Contractor, upon forms provided by the Contractor.

4.11 Keep complete and accurate records, as required by the Regulations, of patients supplied with Apheresis Services (product names, lot identifications and quantities), any therapeutic adverse effects and complaints and other information related to the Apheresis Services.

4.12 Provide the Contractor with emergency evacuation procedures and the Customer's code system.

5 Regulations

The Parties will comply with applicable laws and industry standards, including without limitation, requirements, regulations, standards, recommendations, specifications, guidelines and directives of the Food and Drug Administration ("FDA") and the Contractor; standards of the Joint Commission and AABB; U.S. economic sanctions; anti-terrorism and anti-money laundering laws; the USA PATRIOT Act; laws administered by the U.S. Treasury Department's Office of Foreign Assets Control; and Executive Order 13224 ("Regulations").

6 Payments

Shall make timely payment to the Contractor pursuant to the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) Circular A-125, Prompt Payment. See clause 52.212-4 Contract Terms & Conditions--Commercial Items.

7 VAMC Facility Addresses:

Provide the Apheresis Services to the Veterans Affairs Healthcare Network One ("VISN 1") medical Centers listed below (for additional information visit-<http://vaww.visn1.va.gov/intranet>):

MASSACHUSETTS

Boston VA Healthcare System
West Roxbury VA Campus
1400 VFW Parkway
West Roxbury, MA 02132
(617) 323-7700

Or

Boston VA Healthcare System
Brockton VA Campus
940 Belmont Street
Brockton, MA 02301

8 Administrative Requirements/Data

8.1 Records, Data, and Quality Management

8.1.1 The Contractor shall develop and maintain quality assurance activities.

- 8.1.2 The Contractor shall provide VAMC with a comprehensive Quality Improvement Plan related to the Apheresis Services, including the development of administrative and clinical monitors. Upon request Contractor shall submit quarterly quality improvement (QI) reports on findings and improvement initiatives. These activities might include the results of internal audits of therapeutic apheresis procedures that are presented to the quarterly transfusion practices committee, and results of monitoring activities which are presented and discussed at the transfusion practices committee.
- 8.1.3 Contractor shall comply with VAMC medical record documentation requirements and procedures.
- 8.1.4 Contractor shall adhere to VAMC clinical policies and procedures and the regulations of the medical staff bylaws.
- 8.1.5 The Contractor shall be certified by the FDA and the AABB minimum standards/qualifications. The Contractor's employees who perform the Apheresis Services shall be a registered nurse or an equivalent level professional and shall maintain current and active state licensure, in good standing, appropriate certification as qualified by education, training, and experience to perform apheresis according to the guidelines set forth for apheresis activities by the FDA and AABB.

9 Independent Entities

Each of the parties to this Contract shall be considered independent entities. Nothing herein shall create any relationship, association, partnership, or joint venture between the parties or an employer-employee relationship. Neither party, nor any of their respective agents, employees or representatives, shall be, or shall be deemed to be, the agent, employee, servant or representative of the other.

10 Credentialing Reviews/Privileging

- 10.1 The requirements of the government as stated in this Statement of Work are for the performances of professional medical services. The Director of VA Medical Center Boston grants privileges. As a prerequisite to performance under the contract, if a contract healthcare provider performs services at the VA Medical Center Boston, this HCP must be credentialed and privileged at VA Medical Center Boston. When applicable, compliance with the credentialing and privileging processes is essential to the performance under this contract. Any failure to meet these requirements is considered nonperformance and the basis for assessment of liquidated damages and/or termination for default.

- 10.2 The credentialing and privileging process is subject to the provisions of 38 U.S.C. 4104 (1); VHA Handbook 5005, Staffing; VHA Handbooks 1100.17 (National Practitioner Data Bank Reports) and 1100.19 (Credentialing and Privileging); VHA Directive 2006-067, Credentialing of Health Care Professionals, dated Dec 22, 06; and VHS&RA Supplements; Joint Commission, Medical Staff Bylaws and Memorandum 11-23. The Credentialing Committee, a subcommittee of the Clinical Executive Board established at the VAMC is the sole agency authorized to accept applications for privileges submitted by the contractor to the Chief of Staff and to make recommendations on the granting of privileges. The VA Medical Center Boston Director is the final authority for approving or denying clinical privileges for all contract clinicians.
- 10.3 Request for privileges and completed credential packets shall be submitted sixty (60) days prior to the clinician's scheduled start date.
- 10.4 Once privileges are granted, subsequent actions taken concerning the privileges of contract providers, including any limitation on privileges, will be governed by the procedures in 38 U.S.C. 4104 (1); VHA Handbook 1100.19 Credentialing and Privileging, and VHS&RA Supplements; VHA Handbook 1100.19 dated March 2001; Joint Commission, Medical Staff Bylaws and Memorandum 11-23.

11 Background Investigations

- 11.1 All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, Personnel Suitability and Security Program. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.
- 11.2 The Contractor will have and maintain access to digital certificates for all key staff for the safe electronic transmission of patient information via patient encryption (e.g. PKI). The VA can assist the Contractor in getting PKI badge access. Any initial or recurring costs that may be incurred are the responsibility of the Contractor.
- 11.3 Talent Management System (TMS) training requirements for contractor employees who come to the VA and process billing need to complete VA Privacy/HIPAA/Information Security (TMS 10203) and Rules of Behavior Training (TMS 1076). Copies need to be provided to the Contracting Officer and VISN COR.

12 Standards of Practice

- 12.1 Contract provider's standard of care shall cover the same standards and range of services as would be provided in a civilian medical treatment facility, and shall meet or exceed the standard of care required by all appropriate and applicable policies,

procedures and regulations of the VHA and the Boston VA Healthcare System to ensure compliance with Joint Commission (or equivalent) guidelines and standards.

12.2 The Contractor is responsible to ensure that contractor employees providing work under this contract are fully trained and are completely competent to perform the required work. The Contractor is required to maintain records that document competence and performance level of contractor employees working on this contract in accordance with Joint Commission and/or other regulatory body requirements.

13 Medical Records

13.1 Contractors providing healthcare services to VA patients shall be considered as part of the Department of Veterans Affairs Healthcare activity and shall comply with the following laws and government regulations: Public Law 93-579 the "Privacy Act of 1974" as implemented by 5 USC § 552a (as amended); Public Law 104-191 Health Insurance Portability & Accountability Act of 1996 (HIPAA) as implemented by 45 CFR Parts 160, 162 and 164; 45 C.F.R. 164.502 "Uses and Disclosure of Protected Health Information"; 38 U.S.C. § 5701 "Confidential Nature of Claims"; 5 U.S.C § 552 Freedom of Information Act (FOIA) as amended by PL104-231; 38 U.S.C. § 5705 "Confidentiality of Medical Quality Assurance Records"; 38 U.S.C. § 7332 "Confidentiality of Certain Medical Records".

13.2 Contractor must adhere to the provisions of Public Law 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the National Standards to Protect the Privacy and Security of Protected Health Information (PHI)

13.3 This contract and its requirement meet the exception of 45 CFR 164.502(e) that does not require a Business Associates Agreement (BAA) in order for a covered entity to disclose protected health information to a healthcare provider for treatment. Based on this exception, a BAA is not required for this contract. Treatment and administrative patient records generated under this contract or provided to the contractors by the VA are covered by the VA system of records for patient medical records.

13.4 Contractors must obtain permission from the VA Information Security Officer (ISO) before disclosing any patient information. Subject to applicable federal confidentiality and privacy laws, the contractor may have access to VA patient records at VA's place of business during normal business hours in order to provide healthcare services to VA patients. Contractor shall abide by all federal laws, regulations and VA policies regarding protected health information. Contractors and sub-contractors will be subject to the penalties and liabilities mandated by government laws or regulations for unauthorized disclosure of VA patient information.

13.5 The quality of medical practice shall meet or exceed reasonable standards of professional practice for the required services in health care. All patient medical care

shall be appropriately documented in the patient's medical records in accordance with standard commercial practice and guidelines established by VHA Handbook 1907.01 Health Information Management and Health Records. All medical record entries shall be maintained in detail consistent with good medical and professional practices so as to facilitate internal and external peer reviews, medical audits and follow-up treatments.

- 13.6 Upon completion of the procedure, the Contractor shall provide documentation for the patient's chart, a record of the procedure performed including replacement solutions administered, fluid balance, medications given, and adverse reactions, if any, which occurred during the procedure. The Contractor will also provide date; time, patient information and service performed will be submitted to the VA Blood Bank for the patient's medical record. Clinical or other medical records of VA beneficiaries treated by Contractor are considered VA records and will remain at the VA Medical Center.

14 Medical Liability

- 14.1 The Contractor shall furnish their own medical liability insurance and will hold certificate of insurance for general liability and malpractice insurance, workmen's compensation and vehicle insurance. Prior to award of the contract, the Contractor shall furnish to the VA a certificate of insurance evidencing that all required coverage has been obtained. The Contractor shall be responsible for maintaining this certificate/coverage for the duration of the contract. The coverage cannot be changed or canceled without written notice to the VA Contracting Officer. Under no circumstances will the contractor be considered a Boston VA Healthcare System employee nor will contractor be covered by VA liability insurance.
- 14.2 It is expressly agreed and understood that this is a non-personal services contract, as defined in Federal Acquisition Regulation (FAR) 37.101, under which the professional services rendered by the Contractor or its health-care providers are rendered in its capacity as an independent contractor. The Government may evaluate the quality of professional and administrative services provided but retains no control over professional aspects of the services rendered, including by example, the Contractor's or its health-care providers' professional medical judgment, diagnosis, or specific medical treatments. The Contractor and its health-care providers shall be liable for their liability-producing acts or omissions. The Contractor shall maintain or require all health-care providers performing under this contract to maintain, during the term of this contract, professional liability insurance issued by a responsible insurance carrier of not less than the following amount(s) per specialty per occurrence: \$1,000,000.00. However, if the Contractor is an entity or a subdivision of a State that either provides for self-insurance or limits the liability or the amount of insurance purchased by State entities, then the insurance requirement of this contract shall be fulfilled by incorporating the provisions of the applicable State law.

- 14.3 An apparently successful offeror, upon request of the Contracting Officer, shall prior to contract award, furnish evidence of the insurability of the offeror and/or of all health-care providers who will perform under this contract. The submission shall provide evidence of insurability concerning the medical liability insurance required by paragraph 2.3.3.1 of this clause or the provisions of State law as to self-insurance, or limitations on liability insurance.
- 14.4 The Contractor shall, prior to commencement of services under the contract, provide to the Contracting Officer Certificates of Insurance or insurance policies evidencing the required insurance coverage and an endorsement stating that any cancellation or material change adversely affecting the Government's interest shall not be effective until 30 days after the insurer of the Contractor gives written notice to the Contracting Officer. Certificates or policies shall be provided for the Contractor and/or for each health care provider who will perform under this contract.
- 14.5 The Contractor shall notify the Contracting Officer if it, or any of the health-care providers performing under this contract, change insurance providers during the performance period of this contract. The notification shall provide evidence that the Contractor and/or health-care providers will meet all the requirements of this clause, including those concerning liability insurance and endorsements. These requirements may be met either under the new policy, or a combination of old and new policies, if applicable.
- 14.6 The Act of June 25, 1936, 42 Stat. 1938 (40 USC 290), authorizes the constituted authority of the several States to apply workmen's compensation laws to all lands and premises owned or held by the United States. The Contractor agrees to procure and maintain while the contract is in effect, Workmen's Compensation and Employers Public Liability Insurance. The policy shall provide coverage for Public Liability limits of not less than the statutory limitations for any one accident, and at least meet the statutory limitations if more than one person is involved.

15 Qualifications

- 15.1 Personnel assigned by the contractor to perform the services covered by this contract shall provide to the VA a copy of the health care worker's license or certification (as appropriate) along with evidence that the contractor has validated clinical competencies for that area of clinical expertise in which the health care worker will be assigned. All contractor employees assigned to provide services under this agreement must have had at least one year of recent clinical experience in therapeutic apheresis procedures. Contractor personnel assigned to perform the services covered by this contract shall be licensed in a State, Territory or Commonwealth of the United States or the District of Columbia, and shall meet the professional certifications and qualifications required to perform the contracted services at the Boston VA Healthcare System. The qualifications of such personnel shall also be subject to review by the Boston VA Healthcare System Chief of Staff and approval by the Boston VA Healthcare System Director. The VA reserves the

right to approve the assignment of individual personnel furnished by the contractor to perform the functions specified in the contract.

- 15.2 The contractor is responsible for obtaining all necessary licenses and/or permits required to perform this work. He/she shall take all reasonable precautions necessary to protect persons and property from injury or damage during the performance of this contract. He/she shall be responsible for any injury to himself/herself, his/her employees, as well as for any damage to personal or public property that occurs during the performance of this contract that is caused by his/her employee's fault or negligence, and shall maintain personal liability and property damage insurance having coverage for a limit as required by the laws of the State of Minnesota. Further, it is agreed that any negligence of the Government, its officers, agents, servants and employees, shall not be the responsibility of the contractor hereunder with the regard to any claims, loss, damage, injury and liability resulting therefrom.