DRAFT Statement of Work (SOW)
Blood & Blood Products
Veterans Health Care System of the Ozarks
1100 N. College Avenue
Fayetteville, AR 72703
Pathology & Laboratory Medicine Service (P&LMS)

I. Purpose: The Veterans Health Care System of the Ozarks (VHSO) Pathology and Laboratory Medicine Service intends to pursue a contract for the provision of blood and blood products to include the following: all blood components needed for transfusion (frozen plasma, frozen cryoprecipitate, leukocyte-reduced packed red blood cell units, apheresis platelets, irradiated blood products, CMV negative packed red blood cell units**,** reference laboratory and apheresis procedures. Contract would be for a base year (10/1/2022 – 9/30/2023), plus four option years.

II. Statement of Work

A. **Quality of the Product**

1. All blood components provided to patients in the Veterans Health Care System of the Ozarks (VHSO) medical center shall meet the requirements of the AABB (formerly known as the American Association of Blood Banks) and/or the Food and Drug Administration (FDA), Department of Health and Human Services.

2. Allogeneic blood/blood components shall be typed for ABO and Rho (D) in accordance with licensed methodologies and shall be tested for **all** transfusion transmitted disease markers currently required by **both** the FDA and AABB.

   a. All blood shall be collected by the closed system under aseptic conditions, processed in appropriate solutions and the container so labeled. The label shall also bear the expiration date of the contents, which shall not exceed the Food and Drug Administration (FDA) allowable limit for the type of anticoagulant in which the blood component is drawn.

   b. All blood supplied shall be free of hemolysis, clots, and excessive chyle.

3. Autologous blood/blood components shall be typed for ABO and Rho(D) in accordance with licensed methodologies and shall be tested for **all** transfusion transmitted disease markers currently required by the FDA.

4. The Contractor shall supply 100% "volunteer donor" blood as defined in 21CFR606.121(c)(5)(ii). All blood/blood components shall be collected from donors in accordance with the requirements of the AABB and the FDA.

5. In the event of a recall, Contractor shall promptly send copies of the recall request to the Blood Bank Medical Director at the VA medical center where the blood product was issued.

6. The VHSO medical center reserves the right to inspect the contractor's facilities at a mutually agreed upon date and time and has the authority to inspect quality, quantity and verify adherence by the contractor to the technical requirements of the contract.

B. **Changes in Testing Requirements for Transfusion Transmitted Diseases:** In the event that additional testing for transfusion transmitted diseases is nationally mandated by the FDA during the contract period, specific price adjustments may be requested by the supplier to address the cost for the additional testing. In the event that this should occur, a letter detailing the rationale for the price increase shall be submitted to the Contracting Officer Representative (COR) at least 30 days before the intended implementation date. COR will forward request to the Contracting Officer and request a modification after validation.

C. **Donor Requirements:**

1. The contractor shall maintain readily available blood donor lists, including names, addresses, and social security numbers. Such lists shall indicate whether, and on what date, blood of a particular donor was furnished to VHSO under this contract.

Offeror's donor identification numbers shall be unique to the donor unit and shall have a FDA-approved numbering schematic.

2. Donor selection shall be in accordance with criteria established by the FDA and/or the AABB.

3. Each unit of blood collected through voluntary donation shall minimally be tested and found negative for the following:

- Hepatitis B surface antigen (HBsAg)
- Antibodies to hepatitis B core (anti-HBc)
- Antibodies to hepatitis C (anti-HCV)
- Antibodies to human immunodeficiency virus, type 1 and type 2 (anti-HIV1 and anti-HIV2)
- Antibodies to human T lymphotropic virus, type 1 and type 2 (anti-HTLV-I and anti-HTLV-II)
- Genetic viral material to detect HIV type 1 and HCV by nucleic acid amplification
- West Nile virus
- Syphilis

4. Each platelet component shall be tested for bacterial contamination in accordance with AABB standard 5.1.5.1 effective March 1, 2004 and FDA Guidance for Industry, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion.

D. **Contractor Requirements**

1. The contractor shall possess current and maintain the following licenses and or registrations for throughout awarded contract. Contractor shall submit with technical quote copy of license and or registration:

a. The Contractor shall maintain an unrevoked U. S. License which is issued by the Director, Bureau of Biologics, FDA under Section 351 of the Public Health Service Act, as amended, 42 USC Section 262, as a source of supply for whole blood.

b. If the Contractor is involved in interstate shipment of blood or blood component is involved, the Contractor shall maintain approval authorized under Section 251 of the Public Health Service Act, as amended, 42 USC Section 262.

c. The Contractor's blood bank shall maintain registration and/or licensing with the Food and Drug Administration (FDA), Department of Health and Human Services pursuant to Section 510 of the Federal Food, Drug and Cosmetic Act, as amended, 21 USC Section 260 at all times during the contract period.

e. Certificate of Accreditation under the Clinical Laboratory Improvement Act of 1988 or current certification by the College of American Pathologists.

2. Contractor will protect any Veterans' personal and medical information required by the contractor to provide blood products which compromise the Veteran's information's security or privacy, exposing the Veteran to identity theft, credit fraud, and other financial woes. Certification and Accreditation requirements do not apply, and a Security Accreditation Package is not required.

E. **Orders/Deliveries**

1. Orders will be categorized into three types: routine, as soon as possible (ASAP) and STAT. These categories are defined as follows:

a. Routine - Shipments of blood products to maintain minimum inventory levels or blood products ordered to fulfill a standing request.

b. As Soon As Possible (ASAP) – Shipments of blood products to fill a request for a waiting outpatient, or a non-life threatening need, or to replenish a depleted inventory of a particular blood product which has been used since the previous routine delivery. ASAP orders shall be delivered within four (4) hours.

c. STAT – A need for blood products so acute that a patient's life could be jeopardized if the request for blood products is unfulfilled. STAT orders shall be delivered within one (1) hour.

2. Contractor shall make delivery services for blood and blood components available to VHSO site 24 hours per day, seven days a week, 365 days a year, subject to blood product availability and a lack of *force majeure* events as set forth in 48CFR52.212-4(f).

The Government hereby provides notice and Contractor hereby acknowledges receipt that Government personnel observe the listed days as holidays:

New Year's Day	January 1
Martin Luther King's Birthday	Third Monday in January
President's Birthday	Third Monday in February
Memorial Day	Last Monday in May
Juneteenth National Independence Day	June 19
Independence Day	July 4
Labor Day	First Monday in September
Columbus Day	Second Monday in October

Veterans Day	November 11
Thanksgiving Day	Fourth Thursday in November
Christmas	December 25

*If a holiday falls on a Saturday, the preceding Friday will be treated as a holiday for pay and leave purposes. If a holiday falls on a Sunday, for most Federal employees, the following Monday will be treated as a holiday for pay and leave purposes.

In addition to the days designated as holidays, the Government observes the following days:

- Any other day designated by Executive Order;
- Any other day designated by the President's Proclamation; and
- Any other day designated by Federal Statute.

3. The specific volumes distributed in a routine order will be established by the VHSO Medical Center Transfusion Service. Within ten days after contract award, the contractor shall submit a proposed delivery and route schedule, identifying specific times and room number(s) for approval. Schedule may be adjusted periodically.

4. Products will be leuko-reduced unless ordered on a site-specific basis.

5. Once units are received by the VHSO medical center, those units become the property of the VHSO medical center, and payment will be made appropriately, based on contract terms and proper invoicing. They are **not** to be treated as though they are on consignment. However, for inventory control purposes, efforts will be made by the VHSO medical center to assist the contractor and other facilities in meeting patient transfusion needs.

6. Invoicing: Contractor shall submit monthly invoices in the arrears. Invoices shall be itemized for the products delivered and accepted. Invoices shall include the Purchase order number and CLIN number invoiced against.

Invoice Instructions

• VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, Tungsten, Vendor Electronic Invoice Submission Methods. Facsimile, e-mail, and scanned documents are not acceptable forms of submission for payment requests. Electronic form means an automated system transmitting information electronically according to the accepted electronic data transmission methods below:

• VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, Tungsten, to transition vendors from paper to electronic invoice submission. Please go to this website: http://www.tungstennetwork.com/US/en/veterans-affairs/ to begin submitting electronic invoices, free of charge.

• A system that conforms to the X12 electronic data interchange (EDI) formats established by the Accredited Standards Center (ASC) chartered by the American National Standards Institute (ANSI). The X12 EDI Web site (http://www.x12.org).

7. The VA will comply with all requirements and regulations associated with the recall and withdrawal of blood or blood components from its inventory due to health and safety risks.

8. All deliveries will be made directly to: Veterans Health Care System of the Ozarks, VHSO Blood Bank, Room 3100, Building 21, 1100 N. College Avenue, Fayetteville, AR 72703.

F. **Shelf Life**

1. All blood/blood components shall be labeled, stored, and shipped in accordance with the current regulations of **both** the FDA and the AABB. In the event that these regulations change during the course of the contract, the contractor shall implement the necessary changes as directed /recommended by the regulatory and accrediting agencies.

2. For routine orders, allogeneic blood/blood components shall be supplied with appropriate remaining shelf life, as detailed below.

Allogeneic blood/blood components	Appropriate Remaining Shelf Life
Whole Blood	Shelf life more than 21 days, regardless of anti-coagulant
Red Blood Cells	Shelf life more than 21 days, regardless of anti-coagulant
Fresh Frozen Plasma	Shelf life more than 60 days
Platelets (random)	Shelf life more than 48 hours
Plateletpheresis	Shelf life more than 48 hours, if not ordered/collected for a specific patient
Cryoprecipitate	Shelf life more than 60 days

3. For ASAP and STAT orders, the contractor shall provide units with the appropriate remaining shelf life whenever possible, however, the VA understands that the urgency of the situation and the availability of the blood product may preclude this possibility.

4. When the VA returns units prior to expiration in accordance with the contractors return policy, the contractor shall credit the VA for units which are returned, as detailed in the Price Schedule.

G. **Definitions:**

1. ALLOGENEIC: Blood or blood components drawn from a non-related donor for subsequent transfusion to a patient (synonymous with homologous).

2. ANTIBODY WORK-UP: Serological work-up performed on potential transfusion recipients, per patient per episode (set of examples); may be defined as simple or complex.

3. AUTOLOGOUS: Blood drawn from a donor-patient for subsequent transfusion; in this case, restricted to pre-deposit units of blood, i.e., not including intra-operative or post-operative blood salvage.

4. BLOOD GROUP: ABO Blood group plus the Rho(D) type of the unit, specifically O+, O-, A+, A-, B+, B-, AB+, AB-.

5. CMV NEGATIVE: Unit from a donor who has been screened for antibody to Cytomegalovirus and deemed to be negative. Use of CMV negative blood components are indicated in those patients who are undergoing transplantation or are otherwise severely immunocompromised.

6. COMPONENT (BLOOD COMPONENT): Portion of a unit of whole blood which has been physically separated by some mechanical means, e.g., centrifugation.

7. CRYOPRECIPITATE: Plasma component which has been prepared to contain high concentrations of Factor VIII and fibrinogen. It is stored in the frozen state and thawed immediately prior to transfusion. Product is used for the treatment of specific coagulation factor deficiencies, such as von-Willebrand's Disease, hypofibrinogenemia and uremic thrombocytopenia which have been shown to be irresponsive to DDAVP treatment.

8. DERIVATIVE: Portion of a unit of whole blood or blood component which has been chemically separated by some type of fractionation process. Examples include albumin, plasma protein fraction, intravenous gamma globulin, and various coagulation products.

9. FRESH FROZEN PLASMA (FFP): Plasma component that is stored in the frozen state and is thawed immediately prior to transfusion. Used for the treatment of significant multiple coagulation factor deficiencies or congenital factor deficiencies not treatable by cryoprecipitate. These may be associated with massive transfusion, severe liver disease, disseminated intravascular coagulation, hemolytic uremic syndrome, or thrombotic thrombocytopenia purpura, but not as a volume expander. Fresh frozen plasma 24 (FP24) is plasma frozen within 24 hours of collection and contains reduced levels of Factor VII and normal levels of Factor V. FP24 may be used interchangeably with FFP unless used to treat Factor VII deficiency.

10. HOMOLOGOUS: Blood or blood component drawn from a non-related donor for subsequent transfusion to a patient (synonymous with allogeneic).

11. IRRADIATED COMPONENT: Blood component that has been subject to a minimum central dose of 2500 cGy of irradiation.

12. LEUKOCYTE-REDUCED BLOOD COMPONENTS: Cellular products prepared by an approved filtration method.

13. PLATELETPHERESIS: Platelet component which is drawn from a donor using apheresis equipment, is stored in the liquid state, and is roughly equivalent to six to eight units of random platelets. Used for the treatment of significant thrombocytopenia as indicated for random platelets; however, it offers the advantage of minimizing donor exposures to prevent the patient from becoming refractory and/or contracting a transfusion transmitted disease.

14. PLATELETS (RANDOM): Platelet component that is prepared from a single unit of whole blood and is stored in the liquid state. Used for the treatment of significant thrombocytopenia associated with a variety of other clinical conditions, including active bleeding, massive transfusion, disseminated intravascular coagulation, and scheduled invasive procedures.

15. RECALL: A request from the supplier of blood component to return a specific unit(s) which was inadvertently issued to the VA medical center, regardless of the reason, or was issued to the

VA medical center prior to the receipt of information about a donor which would have prevented such release.

16. RED BLOOD CELLS (RBC): Red cell components that remain in the liquid state, i.e., not frozen, regardless of anticoagulant. Used for the treatment of anemia which is not treated pharmacologically either due to etiology or time constraints.

17. ROUTINE ORDERS: Orders that are generally placed on a regular basis at a pre-established time to provide adequate inventory of specific blood components of specific blood groups.

18. SHELF LIFE: Number of days remaining prior to the expiration date from the date received in the facility.

19. SPECIAL TYPINGS: Typings for RBC antigens other than ABO and Rho(D); performed in order to find red blood cell units appropriate for patients who have developed unexpected antibodies.

20. STANDING ORDER: A type of routine order which allows for shipment of a specific volume of specific blood components according to an established delivery schedule; assists the supplier in projecting volumes of components required in order to improve recruitment and minimize waste.

21. VOLUNTEER DONOR: Person who does not receive monetary payment for blood donation. Benefits, such as monetary time off from work, membership in blood assurance programs, and cancellations on non-replacement fees that are not readily convertible to cash, do not constitute monetary payment.

I. **Period of Performance:** Period of performance shall be a estimated base year (10/1/2022 – 9/30/2023), plus four (4) option years.

J. **Estimated Supply Quantities:** The Contractor shall provide the following blood and blood components to the Veterans Health Care System of the Ozarks, Fayetteville, AR in accordance with the requirements and estimated quantities noted below. The quantities shown are estimates only and do not guarantee any order.

	Description	**Unit of Issue**	**Est. Qty**
1	Red Blood Cells (Human), Leuko-reduced	Unit	700
2	Platelet Pheresis, Irradiated	Unit	30
3	Platelet Pheresis, Leuko-reduced	Unit	75
4	Fresh Frozen Plasma, Type A, B, or O	Unit	35
5	Red Blood Cells (Human), Irradiated	Unit	25
6	Cryoprecipitated AHF	Unit	1
7	Red Blood Cells (Human), Washed	Unit	1
8	Red Blood Cells (Human), Leuko-reduced, CMV Negative	Unit	10
9	Red Blood Cells (Human), Antigen Negative	Unit	35
10	Glutaraldehyde Set	Set	6
11	On Call Service	Each	3
12	STAT Courier Fee	Each	10

13	Basic Antibody Identification	Each	5
14	Adsorption	Each	4
15	Special Techniques	Each	1
16	DNA Testing	Each	3