



WE ARE BLOOD
DRAWN TOGETHER SINCE 1951

BLOOD & BLOOD PRODUCTS SERVICE AGREEMENT

PURPOSE:

The purpose of this Blood & Blood Products Services Agreement, hereinafter referred to as the "Agreement", is to establish an agreement by which blood and blood products are provided to:

**Williamson County, TX, a political subdivision of the State of Texas on
behalf of the Williamson County Emergency Medical Services
710 Main St.
Georgetown, TX 78626s**

hereinafter referred to as "Emergency Services Provider" by We Are Blood, hereinafter referred to as "Blood Center", and to clarify the responsibilities of the individual parties to such an agreement. Hereinafter, Emergency Services Provider and Blood Center may be referred to individually as a "Party" and collectively as the "Parties."

DEFINITIONS:

- A. Services means provisions of all acts related to preparation and making blood and blood products available for Emergency Services Provider to transfuse.
- B. Products means blood and components prepared from human blood including whole blood, red blood cells and plasma.

AGREEMENT:

I. RESPONSIBILITIES OF THE PARTIES REGARDING BLOOD INVENTORY MANAGEMENT

- A. Blood Center shall assume responsibilities for providing blood and blood products (hereinafter referred to as "Product" or "Products") in the following manner:
 - 1. All Products manufactured by Blood Center shall be collected from volunteer donors, processed, and labeled in accordance with the Code of Federal Regulations of the Food and Drug Administration and Standards established by the AABB.

2. Prior to providing Product to Emergency Services Provider, Blood Center shall perform or cause to be performed all tests required in accordance with the rules and regulations of the FDA, the Standards of the AABB and the Clinical Laboratory Improvement Amendments (CLIA). Blood Center reserves the right to perform or have other entities perform additional tests as it may deem appropriate.
3. Blood Center shall maintain a validated system to detect the presence of bacteria in platelet products and provide a process for notifying Emergency Services Provider of any products suspected of containing bacteria that have been distributed to Emergency Services Provider.
4. Blood Center shall maintain TRALI risk reduction measures for blood products by manufacturing plasma, apheresis platelets, and whole blood for allogeneic transfusion from males, females who have not been pregnant, or females who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
5. Availability of and demand for blood and blood products may vary widely and unpredictably. Blood Center will endeavor to equitably distribute the community blood supply at all times. As such, the Blood Center will establish regional inventory par levels and make reasonable efforts to maintain minimum inventory levels of blood and blood components for Emergency Services Provider. When established inventory levels are unable to be met, Blood Center will notify Emergency Services Providers and provide alternative options (e.g. packed red blood cells, plasma).
6. A packing list with identification of each individual Product shall be provided by the Blood Center with each shipment.
7. Blood Center shall be responsible for the transportation of Products between Blood Center and Emergency Services Provider during unforeseen circumstances.

B. Emergency Services Provider shall:

1. Be responsible for the routine transportation for Products between Blood Center and Emergency Services Provider.
2. Handle and store Products in accordance with all applicable standards and regulations of the AABB and FDA.
3. Establish back-up plan for Product storage in the event of blood storage equipment failure and notify Blood Center of any blood storage equipment failure event.

4. Establish policies and procedures related to appropriate inventory management and blood usage review. Such policies and procedures shall be made available to Blood Center upon request.
5. Make reasonable efforts to notify Blood Center in advance when special Products, unusual volumes, or extended treatments are needed so that Product can be put into production or obtained from outside sources.
6. Assume financial responsibility for Products delivered at the current published prices as contained in the Fee Schedule.
7. Submit full payment to Blood Center for Product and services rendered upon receipt of the statement issued by Blood Center on a monthly basis in accordance with Section I.D. of this Agreement.
8. Dispose of all biohazard waste relating to Products supplied to Emergency Services Provider in accordance with Federal, State and local laws, ordinances, and regulations.
9. Emergency Services Provider shall allow inspection and audit of its storage/monitoring devices, temperature records, calibration, quality control, preventive maintenance, validation records and Product storage procedures by Blood Center upon request.

C. Return, Credit and Redistribution

1. Blood Center shall return from Emergency Services Provider selected Products for credit and redistribution provided that the following conditions are met by Emergency Services Provider:
 - a. Products have been stored in strict accordance with the current Standards of the American Association of Blood Banks ("AABB") EQUIPMENT section, The Technical Manual of the American Association of Blood Banks, and the Bureau of Biologics of the U.S. Food & Drug Administration ("FDA"), as may be amended. Such conditions include, but are not limited to the following:
 - 1) Product storage devices, such as refrigerators, freezers, platelet incubators and coolers used by Emergency Services Provider must be qualified and validated by Emergency Services Provider for their intended use. Storage equipment shall have the capacity and design to ensure that the proper temperature is maintained.
 - 2) There shall be a process to monitor the temperature of the storage equipment continuously and to record the temperature at least every four (4) hours. If platelet components are stored in an open storage area, the ambient

temperature shall be recorded at least every four (4) hours.

- 3) Storage device alarms shall be set and validated to activate under conditions that will allow proper action to be taken before Product reaches unacceptable conditions. Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.
- 4) There shall be a process to investigate equipment malfunctions, failures, or adverse events.
- 5) There shall be a process for back-up storage of Product in the event of primary storage equipment failures.

b. Product containers meet the following criteria:

- 1) The container seal has not been broken or entered and/or Product contents or container has not been altered in any way.
- 2) The face label of the Product has not been altered.
- 3) Cellular Products have at least three (3) segments of numbered integral tubing remaining.
- 4) Cellular Products have at least fourteen (14) full days remaining to expiration. Exceptions may be made by Blood Center on a case-by-case basis and in Blood Center's sole discretion.

2. Blood Center will not accept for return for credit:

- a. Liquid Plasma; or
- b. Product that has been stored in an unacceptable or questionable manner as determined by Blood Center in its sole discretion.

D. Billing

1. Blood Center and Emergency Services Provider understand and agree that billing for Products represents compensation for Blood Center's processing services only, and does not reflect charges for human donor blood or blood products.
2. Deliveries will be billed at a flat rate as defined by the current fee schedule.
3. Fees for Product and services will be applied from the current Fee Schedule which may be amended from time to time upon thirty (30) days' notice.
4. If Blood center is required to implement any new tests or processes mandated after the date hereof at the request of Emergency Services Provider, by the FDA, AABB or another applicable regulatory agency, Blood Center may increase the fees on the Fee Schedule after providing Emergency Services Provider with thirty (30) days prior written notice.
5. Blood Center will render invoices to Emergency Services Provider after delivery of Product to Emergency Services Provider indicating the number of Products delivered and credited. Statements upon which payment is to be made shall be issued on a monthly basis and payment shall be due pursuant to and shall be services shall be governed by Chapter 2251 of the Texas Government Code. An invoice shall be deemed overdue the 31st day after the later of (1) the date licensee receives the goods under the contract; (2) the date the performance of the service under the contract is completed; or (3) the date the Williamson County Auditor receives an invoice for the goods or services. Interest charges for any overdue payments shall be paid by licensee in accordance with Texas Government Code Section 2251.025. More specifically, the rate of interest that shall accrue on a late payment is the rate in effect on September 1 of licensee's fiscal year in which the payment becomes due. The said rate in effect on September 1 shall be equal to the sum of one percent (1%); and (2) the prime rate published in the Wall Street Journal on the first day of July of the preceding fiscal year that does not fall on a Saturday or Sunday. .
6. Emergency Services Provider agrees to pay Blood Center at the rates provided on the current fee schedule as set forth in paragraph 5.
7. Special Products will be billed at current market rate.
8. Blood Center will issue credit for Products returned in accordance with Sections I.C.1 and I.C.2

E. Customer Service /Customer Complaint Process

1. Blood Center will provide a process for Emergency Services Provider to submit written complaints.
2. Technical and/or medical personnel are available 24 hours, 7 days a week to report customer concerns that require immediate attention, such as issues immediately affecting patient care.

II. RESPONSIBILITIES OF PARTIES REGARDING DONORS WHO SUBSEQUENTLY TEST POSITIVE FOR INFECTIOUS DISEASE

Blood Center has established policies and procedures with regard to responsibilities for notification in the event that a recent blood donor subsequently tests positive for HIV or any other infectious disease where notification is required by law or the regulations of the FDA or the AABB.

Where Blood Center identifies a donor who subsequently tests positive ("Seropositive Donor") for infectious disease(s), the Parties agree to the following:

- A. Blood Center shall:
 1. Determine past donation history of the Seropositive Donor(s).
 2. Notify Emergency Services Provider if it received any Products from prior donations of the Seropositive Donor(s) by identification of the product type and blood unit number in accordance with required lookback or regulatory procedures.
- B. Emergency Services Provider shall, when notified by Blood Center of a Seropositive Donor, comply with the following required lookback or regulatory procedures:
 1. Determine all recipients who have received Products from the Seropositive Donor.
 2. Notify the transfusing physician.
 3. Notify the recipient or the receiving hospital to ensure the patient, the patient's legal representative or relative of recipient if recipient is a minor, incompetent or deceased is notified.
 4. Inform Blood Center of recipient notification status on an ongoing basis and as requested by Blood Center.

III. RESPONSIBILITIES OF PARTIES WHERE EMERGENCY SERVICES PROVIDER IDENTIFIES A POSSIBLE TRANSFUSION TRANSMITTED INFECTION.

Where Emergency Services Provider identifies a possible transfusion transmitted infection, the parties agree to the following:

A. Emergency Services Provider shall:

1. Notify the Blood Center's laboratory of the incident as soon as possible and request an investigation form; and
2. Complete the form and forward to Blood Center within twenty-four (24) hours of initial notification.

B. Blood Center shall:

1. Determine past donation history of implicated donor(s);
2. Attempt to call implicated donor(s) into Blood Center for additional testing if needed;
3. Notify Emergency Services Provider if donors test positive for infectious disease; and
4. Notify all other facilities that received any Product from prior donations of positive donor(s) by product type and blood unit number in accordance with required lookback or regulatory procedures.

IV. RESPONSIBILITIES OF PARTIES WHERE EMERGENCY SERVICES PROVIDER IDENTIFIES A POSSIBLE CASE OF TRANSFUSION RELATED ACUTE LUNG INJURY

Where Emergency Services Provider identifies a suspected case of Transfusion Related Acute Lung Injury ("TRALI"), the Parties agree to the following:

A. Emergency Services Provider shall:

1. Notify the Blood Center's laboratory of the incident as soon as possible and request an investigation form; and
2. Complete the form and forward to Blood Center.

B. Blood Center shall:

1. Notify Blood Center Medical Director and forward the form;
2. The Medical Director will accept or reject the suspected TRALI case based on the information provided by Emergency Services Provider. Blood Center's laboratory will notify the Emergency Services Provider of the decision to accept or reject;

3. If the case is accepted, Blood Center will facilitate quarantine of Products, contact with implicated donors, testing for granulocyte and HLA antibodies if indicated and consented, and deferral of donors as appropriate; and
4. Notify Emergency Services Provider in writing of final results and conclusions.

V. NOTIFICATION TO PARTIES REGARDING TRANSFUSION FATALITY

- A. When Emergency Services Provider identifies a transfusion fatality or other serious, unexpected adverse event that is suspected to be related to an attribute of a donor or Product, parties agree as follows:
 1. Emergency Services Provider shall:
 - a. Immediately notify Blood Center QA Department, a VP, a Director or EVP/COO of such event by phone.
 - b. Notify Blood Center in writing within 3 business days of the event.
 - c. Notify CBER of a transfusion related fatality as soon as possible according to Section 606.170 of Title 21, Code of Federal Regulations. A written report of investigation of the fatality must be submitted to CBER within 7 days of the fatality.
 2. Blood Center shall:
 - a. Review applicable records for donor and product.
 - b. Submit final written summary of any investigation.

VI. NOTIFICATION TO PARTIES OF RETURNS, RECALLS, AND MARKET WITHDRAWALS

Where notification regarding returns, recalls and market withdrawals of Product are initiated by Blood Center, the Parties agree to the following procedure:

- A. Blood Center shall:
 1. Notify Emergency Services Provider of the need to quarantine and/or return existing Products or provide information about the final disposition of the Products; and
 2. Inform Emergency Services Provider of the need to notify the recipient of the Product included in the notification, when appropriate.

B. Emergency Services Provider shall:

1. Quarantine and/or return to Blood Center existing Product; and/or
2. Provide information to Blood Center of final disposition of Product that is the subject of the notification upon request by Blood Center.

VII. RESPONSE TO DISASTERS AND EMERGENCIES

The Parties recognize that in cases of regional, local or facility disasters or emergencies re-allocation of the blood supply may be necessary. To this end, Blood Center maintains a system to identify inventory levels at all facilities in the region and to manage fair and equitable Product distribution when abnormal usage or Product shortages dictate careful rationing of available Product. The following responsibilities apply to disaster and emergency situations.

A. Blood Center shall:

1. Make reasonable effort to notify facilities of need for re-distribution of Product;
2. Make reasonable effort to move Product to Blood Center for re-allocation;
3. Make reasonable effort to account for redistributed Product and issue credits and/or invoices as appropriate;
4. Make reasonable effort to obtain Product from outside sources as needed;
5. Make reasonable effort to recruit donors and collect blood as needed; and
6. Utilize Emergency Services Provider-provided emergency contact information to notify Emergency Services Provider of shortages, Product recalls or other events that warrant management attention and review.

B. Emergency Services Provider shall:

1. Provide timely and ongoing communication of the impact of the disaster to Emergency Services Provider, including Product needs and patient volumes.
2. Evaluate current inventory and, to the extent possible, release Product for re-distribution; and
3. Provide emergency contact names, phone and fax numbers and on-call protocols to ensure communications can be reliably transmitted. Changes to the emergency contact information should be routed through Blood Center's Hospital Services department.

VIII. OTHER TERMS

A. Health Insurance Portability and Accountability Act (“HIPAA”) Requirements

1. Blood Center respects the confidentiality of data relating to individual patients and visitors. Blood Center commits to undertake to meet the applicable legal requirements of medical/health information privacy and has internal policies and procedures to protect the confidentiality of same.
2. Both Parties hereto shall comply with all applicable laws, statutes, and regulations pertaining to the use and disclosure of Protected Health Information (“PHI”) as that term is defined in HIPAA which PHI is not for treatment, payment, or healthcare operations and for which authorization by the individual is required.
3. Emergency Services Provider agrees to disclose PHI only to extent it is necessary to enable Blood Center to fulfill its services hereunder. Only to the extent authorized under Texas law, Emergency Services Provider as a department of a political subdivision of the State of Texas agrees to defend and indemnify Blood Center for any claims arising out of the disclosure of PHI that is beyond minimally necessary as defined in 45 CFR Part 164 Subpart E.
4. Blood Center agrees to disclose PHI only to extent it is necessary to enable Emergency Services Provider to fulfill its services hereunder. Blood Center agrees to defend and indemnify Emergency Services Provider for any claims arising out of the disclosure of PHI that is beyond minimally necessary as defined in 45 CFR Part 164 Subpart E.

B. Representation and Warranty

1. Blood Center represents and warrants to Emergency Services Provider that Blood Center:
 - a. Is not currently excluded, debarred, or otherwise ineligible to participate in the Federal health care programs as defined in 42 U.S.C. Section 1320a-7b (f) (the “Federal health care programs”);
 - b. Is not convicted of a criminal offense related to the provision of health care items or services but has not yet been excluded, debarred, or otherwise declared ineligible to participate in the Federal health care programs; and
 - c. Is not, to Blood Center’s knowledge, under investigation or otherwise aware of any circumstances which may result in Blood Center being excluded from participation in the Federal health care programs. This shall be an ongoing representation and warranty during the term of this Agreement and Blood Center shall

immediately notify Emergency Services Provider of any change in the status of the representation and warranty set forth in this Section VII C 1 c. Any breach of this Section shall give Emergency Services Provider the right to terminate this Agreement immediately for cause.

2. Blood Center does not extend any warranties other than expressly provided herein including **NO WARRANTIES OF MERCHANTABILITY OF FITNESS FOR AN INTENDED PURPOSE OF THE PRODUCTS PROVIDED UNDER THIS AGREEMENT.**

C. Insurance

1. Each Party shall maintain a "claims-made" policy or policies of insurance in the amount of not less than \$2,000,000 per occurrence and \$5,000,000 in the aggregate for insuring against liability, which may be imposed arising out of its acts or omissions to include: 1) General Liability; and 2) Professional Liability. Each Party agrees to provide the other Party a certificate of insurance evidencing such coverage upon request and further agrees to provide written notice of any threatened cancellation of such coverage on or before ten (10) business days prior to such cancellation. The policy limits in this Agreement may be achieved through a combination of primary and excess coverages.

D. Indemnification

1. Blood Center agrees to indemnify, defend and hold harmless Emergency Services Provider, its officers, employees, managers and agents against and in respect of any claims, settlements, demands, losses costs, expenses, obligations, liabilities, damages, recoveries, and deficiencies, including without limitation, interest, penalties, reasonable attorneys' fees and disbursements that Emergency Services Provider (its owners, officers, directors, managers, members, employees and agents) may incur or suffer which result from Blood Center's negligence, gross negligence, or willful misconduct in connection with its obligations hereunder.
2. Only to the extent authorized under Texas law, Emergency Services Provider as a department of a political subdivision of the State of Texas agrees to indemnify, defend and hold harmless Blood Center, its officers, employees, managers and agents against and in respect of any claims, settlements, demands, losses costs, expenses, obligations, liabilities, damages, recoveries, and deficiencies, including without limitation, interest, penalties, reasonable attorneys' fees and disbursements that Blood Center (its owners, officers, directors, managers, members, employees and agents) may incur or suffer which arise, result from, or relate to, Emergency Services Provider's negligence, gross negligence, or willful misconduct.

3. In order for the Party claiming indemnification hereunder to be entitled to any indemnification with respect to a claim or demand made by a third party against such Party (a "Third Party Claim"), the Party seeking indemnification must notify the indemnifying Party in writing and in reasonable detail of the Third Party Claim as promptly as reasonably possible after receipt by the Party seeking indemnification of written notice of the Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided under this Agreement except to the extent the indemnifying Party has been actually prejudiced as a result of the failure to provide prompt and reasonably detailed written notice. Within five (5) business days after providing written notice as outlined herein, the Party requesting indemnification shall deliver to the party from whom indemnification is requested copies of all notices and documents (including court papers) received by the Party seeking indemnification relating to such Third Party Claim. No Third Party Claim shall be settled without the express written consent of the Party seeking indemnification, which consent shall not be unreasonably withheld. Furthermore, no settlement shall contain any admission of liability on the part of the indemnified Party without the express written consent of such Party, which consent shall not be unreasonably withheld.

E. No Waiver

No waiver of any provision of this Agreement will be valid unless in writing and signed by the person against whom such waiver is sought to be enforced, nor will failure to enforce any right hereunder constitute a continuing waiver of the same or a waiver of any other right hereunder.

F. Mutual Understandings

1. Independent Contractor Status. The Parties hereto agree that each is an independent contractor and each understands that this Agreement does not constitute nor shall it be construed as creating a joint venture, partnership or any other similar relationship. Neither Party shall hold itself out as an agent or act as agent of the other Party, nor may either Party bind or otherwise obligate the other Party in any manner without the written agreement of the Party to be bound.
2. Entire Agreement. The Parties agree that this Agreement and the documents referenced herein represent the entire agreement between the parties regarding the subject matter hereof and that it expressly supersedes any other agreement, whether written or oral, between the parties hereto regarding the subject matter hereof. Any amendments, modifications, or alterations to this Agreement must be in writing and signed by both parties.
3. Mediation. The parties agree to use mediation for dispute resolution prior

to and formal legal action being taken on this Agreement.

4. Venue and Governing Law. Venue of this Agreement shall be Williamson County, Texas, and the law of the State of Texas shall govern.
5. Right to Audit. Blood Center agrees that licensee or its duly authorized representatives shall, until the expiration of three (3) years after final payment under this Agreement, have access to and the right to examine and photocopy any and all books, documents, papers and records of Blood Center which are directly pertinent to the services to be performed under this Agreement for the purposes of making audits, examinations, excerpts, and transcriptions. Blood Center agrees that licensee shall have access during normal working hours to all necessary Blood Center facilities and shall be provided adequate and appropriate workspace in order to conduct audits in compliance with the provisions of this section. licensee shall give Blood Center reasonable advance notice of intended audits.

IX. TERMINATION OF AGREEMENT

- A. Term: This Agreement shall remain in effect for a three (3) year term beginning on **08-01-2022** and ending at midnight on **08-01-2025** and shall be renewed automatically for successive three (3) year terms thereafter, unless otherwise terminated as provided herein.
- B. Termination: Notwithstanding anything herein to the contrary, this Agreement may be terminated as follows:
 1. Whenever Blood Center and Emergency Services Provider mutually agree to the termination in writing; or
 2. By either Party upon 30 days prior written notice to the other Party; or
 3. Except as provided elsewhere in this Agreement, with cause by either Party upon the default by the other Party of any term, covenant or condition of this Agreement; or
 4. Upon the filing of voluntary or involuntary bankruptcy by either Blood Center or Emergency Services Provider; or
 5. Upon either Party's loss of license, accreditation, or certification; or
 6. Either Party may cancel this contract at any time if audits of procedure, practices or records reflect that the other Party has failed to comply with the provisions of this agreement.

X. NOTICE

Any written notification regarding this Agreement or any matter governed by this Agreement shall be made by registered mail, overnight courier, or certified mail return receipt requested to:

Emergency Services Provider Name

We Are Blood

Name of Officer

Title of Officer

Street Address

City, State, Zip

Marian Garrard

Name of Officer

CEO

Title of Officer

4300 N. Lamar Blvd.

Street Address

Austin, Texas 78756

City, State, Zip

NOW WHEREFORE, the undersigned Parties, as evidenced by their signatures hereto, hereby agree to the provisions of this Agreement between **We Are Blood** and **Emergency Services Provider**, as herein before described and agree that same are effective as of the Effective Date. The Parties further acknowledge that this Agreement has been executed in multiple counterparts, each of which constitutes an original for all purposes.

Emergency Services Provider

We Are Blood

By:

Bill Gravell
Bill Gravell (Jul 13, 2022 08:17 CDT)

Signature

Bill Gravell

Printed Name

County Judge

Title

Jul 13, 2022

Date

By:

Marian L. Garrard

Signature

Marian L. Garrard

Printed Name

CEO

Title

06-09-22

Date