

## MEMORANDUM OF UNDERSTANDING

THIS MEMORANDUM OF UNDERSTANDING (“MOU”) by and between the **NORTH BROWARD HOSPITAL DISTRICT D/B/A BROWARD HEALTH**, an independent special district of the State of Florida as defined by § 189.012(3), Fla. Stat. (“Broward Health”), and **CITY OF FORT LAUDERDALE**, (the “Participating EMS Agency”), is entered into effective as of the date of the last signature of the Parties to this MOU (the “Effective Date”). Broward Health and the Participating EMS Agency may be individually referred to as a “Party” and collectively as the “Parties.”

### RECITALS

**WHEREAS**, Broward Health is a special taxing district duly organized pursuant to the laws of the State of Florida that provides health care services to the residents of the northern two-thirds of Broward County, Florida;

**WHEREAS**, the Participating EMS Agency provides fire rescue and emergency management services to various cities, towns, and all of the unincorporated areas of Broward County, Florida;

**WHEREAS**, the Participating EMS Agency employs several Emergency Personnel and is licensed, operates as, and provides Emergency Ambulance Services throughout Broward County, Florida;

**WHEREAS**, numerous articles, including in the New England Journal of Medicine and the Journal of Trauma and Acute Care Surgery, have found that exsanguination is the leading cause of preventable deaths among victims of trauma with nearly half of these patients dying in the prehospital setting;

**WHEREAS**, the current practice for prehospital treatment of trauma patients with hemorrhagic shock is the utilization of large boluses of clear IV fluids (saline or lactated ringers) for volume replacement, which have been shown to dilute blood and clotting factors leading to increased hemorrhage and worse overall clinical outcomes;

**WHEREAS**, literature suggests that when lost blood volume is replaced with either high-ratio blood products or whole blood, patients in hemorrhagic shock have better clinical outcomes, improved survival rates, and reduction of in-hospital complication risks, and the American College of Emergency Physicians has noted that prehospital blood transfusions has resulted in a 37% reduction in 30-day mortality for individuals suffering from hemorrhagic shock;

**WHEREAS**, the administration of prehospital blood transfusion by paramedics to treat patients suffering from life-threatening hemorrhagic shock is considered best evidence-based practice and has been endorsed by the American College of Surgeons, the American College of Emergency Physicians, the National Association of EMS Physicians, and the International Association of Emergency Medical Services Chiefs;

**WHEREAS**, several jurisdictions around the United States, such as in New York, Delaware, Virginia, and Texas have implemented a prehospital blood transfusion program with great success, and both Broward Health and the Participating EMS Agency wish to implement such a program whereby the Participating EMS Agency safely stores and carries Blood Components on its Emergency Ambulances and following such Emergency Ambulance’s use of

Blood Components for needy patients in a prehospital setting, Broward Health shall restock such Emergency Ambulance with new Blood Components; and

**WHEREAS**, both Parties wish to enter into this MOU to outline the respective agreement among both Parties to collaboratively work through the development, operation, and sustainment of a prehospital whole blood program to better patient outcomes, reduce mortality, and improve the survival rates of patients suffering from hemorrhagic shock in a manner consistent with Regulatory and Accreditation Standards.

**NOW THEREFORE**, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is hereby agreed by and between Broward Health and the Participating EMS Agency as follows:

1. **Recitals.** The Parties hereto acknowledge and agree that the above recitals are true and correct and are hereby incorporated by reference.
2. **Definitions.** For purposes of this MOU, the terms and acronyms below shall have the following meanings ascribed to them wherever they appear in this MOU, regardless of whether they are capitalized, unless (a) the context in which they are used clearly requires a different meaning; or (b) a different definition is prescribed for a particular section of this MOU. Words not defined shall be given their common and ordinary meaning unless the context in which they are used requires otherwise.
  - 2.1 **“AABB”** means the Association for the Advancement of Blood & Biotherapies.
  - 2.2 **“Blood Components”** means Low-Titer O Positive Whole Blood, high-ratio blood products, whole blood, or other blood components suitable for patients needing a blood transfusion on a prehospital emergency basis.
  - 2.3 **“Blood Supplier”** means the blood supplier or blood bank that Broward Health contracts with to provide Blood Components to Broward Health.
  - 2.4 **“Broward Health”** means the fictitious name of the North Broward Hospital District, an independent special district of the State of Florida.
  - 2.5 **“Broward Health’s Corporate Compliance and Ethics Program”** means Broward Health’s Compliance and Ethics Program and Broward Health’s Code of Conduct, both adopted by Broward Health’s Board of Commissioners consistent with the OIG’s General Compliance Program Guidance (available at <https://oig.hhs.gov/compliance>) in order to facilitate Broward Health’s compliance with federal and state laws and regulations including, without limitation, the federal Deficit Reduction Act of 2005 (Pub. L. No. 109-171, 120 Stat. 4), the Federal Anti-Kickback Statute, the Stark Law, and Florida’s Code of Ethics for Public Officers and Employees (ch. 112, pt. III, Fla. Stat.).
  - 2.6 **“Business Associate”** shall have the meaning ascribed to such term in 45 C.F.R. § 160.103.
  - 2.7 **“CMS”** means the Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services.
  - 2.8 **“Covered Entity”** shall have the meaning ascribed to such term in 45 C.F.R. § 160.103.

- 2.9 “**Effective Date**” shall have the meaning ascribed to such term in the preamble to this MOU.
- 2.10 “**Emergency Ambulance**” means an authorized vehicle designed and operated, as a part of a regular course business, for the transportation of sick or injured individuals in connection with the administration of prehospital medical or emergency care, if necessary, that responds to emergencies on an average of at least three times (3) per week.
- 2.11 “**Emergency Ambulance Service**” means the transport to Broward Health by Emergency Ambulance initiated as a result of a call through 911, another emergency access number, or a call from another acute care facility unable to provide the higher-level care required by a patient.
- 2.12 “**Emergency Medical Services**” means those prehospital functions and services whose purpose is to prepare for and respond to medical and traumatic patient care emergencies as a result of a call through 911, another emergency access number, or a call from another acute care facility unable to provide the higher-level care required by a patient.
- 2.13 “**Emergency Personnel**” means those medical First Responders, emergency medical technicians, and paramedics who are employed by the Participating EMS Agency and provide Emergency Medical Services throughout Broward County.
- 2.14 “**Exclusion Checks**” means the reviewing and screening of individuals and entities in the LEIE, SAM, and other applicable federal and state debarment databases (including, without limitation, the Florida Agency for Health Care Administration’s Sanctioned Providers List) to determine such individual or entity’s eligibility to participate in federal and state health care programs including, but not limited to, Medicare and Medicaid.
- 2.15 “**Federal Anti-Kickback Statute**” means Sections 1128A and 1128B of the Social Security Act as codified in 42 U.S.C. §§ 1320a-7a and 1320a-7b and the subsequent acts pertaining to federal fraud and abuse of federal health care programs, and all of the related and implementing regulations thereto.
- 2.16 “**FDA**” means the U.S. Food and Drug Administration.
- 2.17 “**FIPA**” means the Florida Information Protection Act of 2014, codified in § 501.171, Fla. Stat.
- 2.18 “**First Responder**” includes, but is not limited to, a fire department, paramedic service, or search and rescue squad that responds to an emergency call (through 911 or other emergency access number) and treats a patient but does not transport the patient to a hospital or other receiving facility.
- 2.19 “**HHS**” means the U.S. Department of Health and Human Services.
- 2.20 “**HHS-OIG**” means the HHS Office of Inspector General.

- 2.21 “**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and all the implementing regulations thereof.
- 2.22 “**HIPAA Rules**” means the Privacy, Security, Breach Notification, and Enforcement Rules of HIPAA promulgated at 45 C.F.R. Parts 160 and 164.
- 2.23 “**LEIE**” means the HHS-OIG’s List of Excluded Individuals/Entities available at <https://exclusions.oig.hhs.gov>, and any subsequent lists or hyperlinks established from time to time by the HHS-OIG, that provides individuals and entities the means for complying with their obligations for screening individuals and entities for exclusion, suspension, debarment, or the rendering of ineligibility to participate in any federal or state health care program (including, without limitation, Medicare and Medicaid) under Section 1128 of the Social Security Act, as codified in 42 U.S.C. § 1320a-7, and Section 1156 of the Social Security Act, as codified in 42 U.S.C. § 1320c-5.
- 2.24 “**MOU**” shall mean this Memorandum of Understanding entered into between Broward Health and the Participating EMS Agency.
- 2.25 “**Participating EMS Agency**” means the City of Fort Lauderdale.
- 2.26 “**Parties**” means both Broward Health and the Participating EMS Agency.
- 2.27 “**PHI**” means “protected health information” as such term is defined in 45 C.F.R. § 160.103.
- 2.28 “**Regulatory and Accreditation Standards**” means the relevant and applicable rules, regulations, and guidelines promulgated from time to time by the FDA’s Center for Biologics Evaluation and Research, CMS, the AABB, HIPAA, FIPA, the Federal Anti-Kickback Statute, and other federal and state law and accreditation body standards governing the procuring, storage, and preservation of Blood Components.
- 2.29 “**Safe Harbor Regulations**” means the safe harbor regulations of the Federal Anti-Kickback Statute delineated in 42 U.S.C. § 1320a-7b(b)(3) and 42 C.F.R. § 1001.952.
- 2.30 “**SAM**” means the U.S. General Services Administration’s System for Award Management available at <https://www.sam.gov>, and any subsequent lists or hyperlinks established from time to time by the General Services Administration, which contains debarment actions taken by various federal agencies.
- 2.31 “**Stark Law**” means the federal Ethics in Patient Referrals Act of 1989, promulgated at 42 U.S.C. § 1395nn, and its implementing regulations.
- 2.32 “**Term**” shall have the meaning ascribed to such term in **Section 3.1** (Term) to this MOU.

3. **Term and Termination.**

- 3.1 **Term.** The term of this MOU shall commence on the Effective Date and continue in full force and effect for one (1) year and shall automatically renew every year thereafter unless otherwise terminated by either Party as provided in this MOU (the “**Term**”).

3.2 Termination.

3.2.1 Termination Without Cause. Either Party may terminate this MOU without cause upon ninety (90) days written notice.

3.2.2 Termination for Cause. This MOU may be terminated by either Party for cause. For purposes of this **Section 3.2.2**, “cause” shall mean any act or omission of either Party which is contrary to the other’s business interests, reputation, or good will, or for any material breach of this MOU, and failure to cure such breach within seven (7) days following written notice of such breach.

3.2.3 Termination Due to Lack of Resources or Elimination of the Restocking Program. Broward Health may terminate this MOU at any time in the event that Broward Health determines, in its sole discretion and for any reason, that it is Broward Health’s best interests to discontinue the program for restocking Blood Components, or if circumstances arise which render Broward Health unable to continue restocking or replenishing the Emergency Ambulances of the Participating EMS Agency.

3.2.4 Termination Due to Cessation of Operations or Loss of Licensure. Broward Health may immediately terminate this MOU if the Participating EMS Agency loses its license to operate as an Emergency Ambulance Service, ceases operations, or moves outside of Broward Health’s hospital service areas.

3.2.5 Termination Due to Discontinuation of Relationship with Blood Supplier. Broward Health may immediately terminate this MOU if the Participating EMS Agency terminates its contract with the Blood Supplier or otherwise allows such contract to lapse.

3.2.6 Termination Due to Jeopardizing Events or Changes to Law. Notwithstanding anything to the contrary contained in this MOU, in the event the performance by either Party of any term, covenant, condition, or provision jeopardizes or adversely affects: (a) the licensure of Broward Health; (b) Broward Health’s participation in, or payment or reimbursement from, Medicare, Medicaid, or other reimbursement or payment programs; (c) Broward Health’s accreditation by The Joint Commission or any other state or nationally recognized accreditation organization; (d) Broward Health’s tax-exempt status under federal or state law; (e) Broward Health’s health care delivery system; or (f) if for any other reason said performance, whether currently or due to a change in or interpretation to law, is deemed by Broward Health to be unenforceable, unlawful, or in violation of any statute or ordinance, then Broward Health may, at its sole option, either: (i) terminate this MOU immediately; or (ii) initiate negotiations with the Participating EMS Agency to resolve the matter through amendments to this MOU and, if negotiations between the Parties are unsuccessful, Broward Health may terminate this MOU following any such unsuccessful negotiations.

3.3 Effect of Termination. In the event that this MOU expires or is terminated for any reason, the Participating EMS Agency shall immediately, and in no event later than

thirty (30) days after the termination or expiration date, return any and all unused Blood Components to Broward Health, and neither Party shall have any further obligation hereunder except for (a) obligations accruing prior to the date of termination; and (b) obligations, promises, and/or covenants contained herein, which are expressly or by the Parties' intent are made to extend beyond the term, including without limitation, those sections referenced in **Section 29** (Survival) of this MOU.

4. **The Participating EMS Agency's Duties and Responsibilities.** The participation in the replenishing and restocking of Blood Components on the Participating EMS Agency's Emergency Ambulances is contingent upon the Participating EMS Agency being responsible for and performing the following duties and obligations:

- 4.1 Ensuring and documenting, consistent with Regulatory and Accreditation Standards, that all Emergency Personnel authorized to transfuse and administer Blood Components, and are properly trained, and receive annual competency training thereafter, on (a) the administration and transfusion of Blood Components, (b) proper transfusion practices, procedures, and techniques, (c) proper handling and storage of Blood Components, (d) proper labeling of forms and specimens, (e) patient identification, and (f) the recognition, assessment, and management of adverse reactions (such as allergic, hemolytic, or anaphylactic reactions) to Blood Components;
- 4.2 Maintaining an adequate inventory of normal saline and medications, equipment, and supplies necessary for management of adverse transfusion reactions;
- 4.3 Restocking its Emergency Ambulances and other First Responder vehicles and contracting with the Blood Supplier to ensure that the Participating EMS Agency can restock its Emergency Ambulances and First Responder vehicles in the event that Blood Components are used on patients not transported by Emergency Ambulance or transported to a non-Broward Health hospital;
- 4.4 Properly handling and storing of the Blood Components on First Responder vehicles and/or Emergency Ambulances consistent with Regulatory and Accreditation Standards, in a manner that does not compromise the quality or serve to deteriorate the viability or functionality of the Blood Components, and which, without limitation, includes the following:
  - 4.4.1 Properly storing the Blood Components in a refrigerator, freezer, or other storage container with sufficient insulation and at a proper and adequate temperature consistent with Regulatory and Accreditation Standards and best practices (e.g.,  $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$ );
  - 4.4.2 Installing a temperature recording device on the refrigerator or freezer that monitors the temperature twenty-four (24) hours per day and contains an alarm that activates before Blood Components reach an unacceptable or compromising temperature;
  - 4.4.3 Connecting the refrigerator or freezer to a reserve power unit that contains an automatic and immediate switchover to the reserve power when there is a power failure of the main power supply; and

- 4.4.4 Ensuring that access to the Blood Components is restricted only to authorized Emergency Personnel and that the storage areas are clean and only used for the storage of Blood Components;
- 4.5 Performing quality improvement and validation reviews (and keeping adequate records thereof) of the storage, handling, and administration of the Blood Components, which includes, but is not limited to, the regular validation of the preservation, storage, and temperature control of the refrigerator, freezer, or container holding the Blood Components and other pertinent quality control documentation records;
- 4.6 Obtaining, if possible, informed written consent of the transfusion from each patient who is to receive a transfusion of any Blood Components and not transfusing patients who otherwise refuse a transfusion;
- 4.7 Having an identified, appropriately licensed physician with proper authority to prescribe transfusions of Blood Components;
- 4.8 Administering and transfusing, with proper rapid infusion warming equipment, Blood Components when rendering Emergency Medical Services on a prehospital basis on patients, as ordered, and as medically necessary and reasonable based on the patient's condition, and monitoring such transfused patients consistent with the current edition of the AABB's Standards for Out-of-Hospital Transfusion Administration Services, best practices, and established protocols and procedures;
- 4.9 Having a physician available in the event of adverse transfusion reactions and establishing protocols and procedures for Emergency Personnel to follow in the event of an adverse transfusion reaction;
- 4.10 Keeping and providing to Broward Health—following the patient's transport, or, if not transported, within a reasonable time following the patient's transfusion—as part of the Patient Care Record (as defined in Fla. Admin. Code R. 64J-1.001(14)) adequate and accurate records with details pertaining to the restocked and replenished Blood Components and the patient transport to which such restocked and replenished Blood Components related (which shall be included in the patient's medical record), and which shall, at a minimum, include:
  - 4.10.1 The patient recipient's name, the Blood Components used, and identifying information along with:
    - (a) The informed patient consent, as applicable;
    - (b) The date of the transfusion;
    - (c) The name and signature of the ordering physician who authorized the emergency use of the Blood Components;
    - (d) The name(s) of the Emergency Personnel who performed the transfusion and who attended the patient recipient during the transfusion;
    - (e) For each unit:
      - (i) The number and amount of units of Blood Components transfused;
      - (ii) The unit(s) identification code;

- (iii) The unit(s) ABO and Rh groups;
- (iv) The start time and completion time; and
- (v) The description of any adverse reaction and the results of related investigation; and

4.10.2 The inclusion of any other information requested or required from Broward Health, from time to time, to ensure that there is continuity of patient care and that the Parties are meeting all Regulatory and Accreditation Standards;

4.11 Disposing of used Blood Components and other biomedical waste in accordance with Regulatory and Accreditation Standards;

4.12 Cooperating in good faith with Broward Health to provide any information or data requested or required by Broward Health to account for the Blood Components provided to the Participating EMS Agency, as well as any information or data Broward Health deems necessary to ensure that Broward Health can comply with its Regulatory and Accreditation Standards, quality standards, Code of Conduct, Policies and Procedures, obligations to its patients, or for any other reason pertaining to the replenishing and restocking of Blood Components that Broward Health deems appropriate; and

4.13 Working and cooperating, in good faith, with Broward Health and any regulatory, licensing, or accreditation bodies who may be auditing, inspecting, or performing any investigation related to this MOU and the Blood Components Broward Health provides to the Participating EMS Agency to replenish its Emergency Ambulances.

5. **Broward Health's Duties and Responsibilities.** Broward Health shall be responsible for restocking and replenishing the Participating EMS Agency's Emergency Ambulances with Blood Components on a one-for-one basis, at no cost, following the Participating EMS Agency's prehospital and emergency use of Blood Components on patients requiring Emergency Medical Services who are subsequently transported to Broward Health, and subject to: (a) Broward Health's determination that a sufficient quantity of Blood Components is available for restocking; (b) Broward Health's determination that restocking the Emergency Ambulances will not compromise Broward Health's obligations and Broward Health's provision of patient care; and (c) Broward Health's determination that Broward Health is not compromising its, and is adequately maintaining a sufficient stock and inventory of, Blood Components at its hospitals for patient use consistent with Regulatory and Accreditation Standards.

6. **Representations and Warranties.** The Participating EMS Agency represents and warrants to Broward Health for both the Participating EMS Agency and all of its Emergency Personnel that:

6.1 The Participating EMS Agency is licensed as an advanced life support service to provide Emergency Medical Services and to operate Emergency Ambulances as required under § 401.25, Fla. Stat., and other Regulatory and Accreditation Standards;

6.2 The Participating EMS Agency is in compliance with all federal, state, and local laws and regulations pertaining to its Emergency Ambulances, personnel, and operating



an Emergency Ambulance Service including, without limitation, all required licensing, certification, and inspection standards;

- 6.3 The Participating EMS Agency and its Emergency Personnel have not been excluded, debarred, suspended, or otherwise rendered ineligible to participate in any federal or state health care programs (including Medicare and Medicaid) and the Participating EMS Agency is not employing any person who has been convicted of any criminal offense that is related to the provision of health care items or services or which could lead to such person being excluded, debarred, suspended, or otherwise rendered ineligible to participate in any federal or state health care programs (including Medicare and Medicaid);
- 6.4 The Participating EMS Agency and the Emergency Personnel are not under any investigation, and the Participating EMS Agency is not otherwise aware of any circumstances, which could reasonably be expected to result in the Participating EMS Agency or any of its Emergency Personnel being excluded, debarred, suspended, or otherwise rendered ineligible to participate in any federal or state health care programs (including Medicare and Medicaid);
- 6.5 The Participating EMS Agency shall conduct routine Exclusion Checks of all Emergency Personnel, consistent with the HHS-OIG's recommendations, to ensure that no Emergency Personnel has been debarred, excluded, suspended, or is otherwise ineligible to participate in any federal health care program or state health care program (including Medicare and Medicaid);
- 6.6 The Participating EMS Agency complies with all applicable federal health care program payment and coverage rules and regulations when transporting patients;
- 6.7 The Participating EMS Agency shall be subject to and at all times abide by Broward Health's Ambulance Restocking Policy, No. GA-016-010, as amended from time to time and in effect;
- 6.8 The Participating EMS Agency and its Emergency Personnel shall not bill any patient or third-party payor, including without limitation, Medicare and Medicaid, for the Participating EMS Agency and Emergency Personnel's use of any Blood Components on patients, and in the event the Participating EMS Agency receives any payment for such Blood Components provided to a patient, the Participating EMS Agency shall promptly return the payment to the patient or third-party payor, as appropriate;
- 6.9 The Participating EMS Agency and its Emergency Personnel shall not impede or interfere with Broward Health's compliance with Medicare and Medicaid's billing rules and requirements;
- 6.10 The Participating EMS Agency shall use the Blood Components only as a part of its emergency response and the rendering of prehospital Emergency Medical Services at the scene of an emergency or while in transport to Broward Health, and shall not resell them to any third party or use them for any other purpose;
- 6.11 The Participating EMS Agency shall ensure that its Emergency Personnel adhere to the Participating EMS Agency's obligations under this MOU, and shall adhere to all

Regulatory and Accreditation Standards governing the administration, transfusion, handling, storage, and recording of Blood Components, and the Participating EMS Agency shall be responsible for all acts and omissions of the Emergency Personnel and the use and administration of the Blood Components;

- 6.12 The Participating Agency shall comply with all applicable Regulatory and Accreditation Standards with respect to notification to Broward Health of adverse reactions to the transfusion of a Blood Component supplied by Broward Health;
- 6.13 The Participating EMS Agency shall immediately notify Broward Health, if for any reason (including, without limitation, any suspected labeling or testing error, damaged container, improper container, or improper container temperature) the Participating EMS Agency believes that any Blood Component is not suitable for its intended use, and if appropriate, shall delay or immediately suspend any transfusion or other use of such Blood Component pending determination of its suitability for the intended use;
- 6.14 The Participating EMS Agency shall immediately notify Broward Health of all pertinent details regarding any patient who has received any Blood Component supplied to the Participating EMS Agency by Broward Health when the Participating EMS Agency comes to know or is notified the patient has, or is suspected of having, a transfusion transmissible disease; and
- 6.15 The Participating EMS Agency shall comply with all applicable quarantine and notification requirements consistent with applicable Regulatory and Accreditation Standards, upon notification by Broward Health of potentially infected Blood Components, and shall notify any patient who has been administered such potentially infectious Blood Components, or such patient's attending physician, in a manner consistent with Regulatory and Accreditation Standards, and the Participating EMS Agency agrees that Broward Health shall have no duties with respect to the notification of such patient unless otherwise required under Regulatory and Accreditation Standards.

The foregoing representations and warranties shall be ongoing representations and warranties during the Term of this MOU, and the Participating EMS Agency shall notify Broward Health, no later than one (1) business day of the change in status of any of the foregoing set forth in this **Section 6**. If the EMS Agency shall be in breach of this **Section 6** or any of the obligations, representations, and warranties of this **Section 6**, Broward Health shall have the right to immediately terminate this MOU without any cost, liability, or imposition of damages.

- 7. **Special Circumstances Pertaining to Restocking First Responders**. In accordance with the Federal Anti-Kickback Statute's Safe Harbor Regulation governing Ambulance Replenishing at 42 C.F.R. § 1001.952(v)(2)(ii), the Participating EMS Agency may use the Blood Components provided by Broward Health to restock its First Responders who respond to a patient emergency via 9-11 or comparable emergency access number to render Emergency Medical Services and who administer and transfuse Blood Components on a patient, but who do not otherwise transport the patient to Broward Health via Emergency Ambulance; provided, however, that Broward Health shall not directly restock and replenish such First

Responders and shall only replenish and restock the Participating EMS Agency's Emergency Ambulances.

8. **Non-Exclusive and Equal Basis.** The Participating EMS Agency understands that, consistent with the Federal Anti-Kickback Statute's Safe Harbor Regulation governing Ambulance Replenishing at 42 C.F.R. § 1001.952(v)(3)(i), Broward Health's replenishing and restocking of Blood Components is done on a non-exclusive basis, the replenishing and restocking of Blood Components shall be offered on an equal basis to all not-for-profit, state, or local operators of Emergency Ambulances that provide Emergency Ambulance Services to patients brought to Broward Health, and the replenishing and restocking of Blood Components shall be conducted in an open and public manner consistent with 42 C.F.R. § 1001.952(v)(3)(i)(B).
9. **Availability, Quantity, and Waste of Blood Components.** The Participating EMS Agency acknowledges and understands that Blood Components are a perishable commodity that are often in short supply, and Broward Health's restocking of Blood Components is contingent on the amount of Blood Components that Broward Health has on hand and available after fulfilling its patient care obligations and storage requirements under Regulatory and Accreditation Standards and Broward Health's Policies and Procedures. The Participating EMS Agency agrees that it shall establish meaningful protocols and procedures consistent with the current edition of the AABB's Standards for Out-of-Hospital Transfusion Administration Services and best practices to ensure the proper use and to avoid the waste of any Blood Components provided to the Participating EMS Agency from Broward Health.
10. **Non-Discrimination.** Both Parties agree that, in the performance of the obligations under this MOU, neither Party may discriminate against patients based on such patients' payor status (or lack thereof), ability or inability to pay, race, color, creed, sex, age, national origin, ancestry, religion, marital status, handicap, disability, veteran status, or any other legally protected category of persons under federal or state law.
11. **HIPAA and Confidentiality.** The Parties acknowledge that the uses and disclosures of PHI under the terms and conditions of this MOU consist of communications pertaining to treatment, payment, and healthcare operations under HIPAA and, therefore, the Parties are Covered Entities and not Business Associates under HIPAA, are not required to enter into a business associate agreement, and, as Covered Entities, the Parties are subject to the applicable requirements set forth under the HIPAA Rules, including, without limitation, certain limits on uses and disclosures of PHI. The Parties agree to comply with HIPAA and its regulations, FIPA and other applicable law and regulations governing the confidentiality of PHI, medical records, and other confidential patient information with regard to any and all information directly or indirectly accessed or used by the Parties and their Emergency Personnel under this MOU.
12. **Disclaimer of Warranties.** THE PARTICIPATING EMS AGENCY UNDERSTANDS AND AGREES THAT, CONSISTENT WITH § 672.316(5) FLA. STAT., THE PROCUREMENT, PROCESSING, STORAGE, DISTRIBUTION, OR USE OF WHOLE BLOOD, PLASMA, BLOOD PRODUCTS, AND BLOOD DERIVATIVES FOR THE PURPOSE OF INJECTING OR TRANSFUSING THE SAME, OR ANY OF THEM, INTO THE HUMAN BODY FOR ANY PURPOSE WHATSOEVER IS DECLARED TO BE THE RENDERING OF A SERVICE BY ANY PERSON PARTICIPATING THEREIN

AND DOES NOT CONSTITUTE A SALE, WHETHER OR NOT ANY CONSIDERATION IS GIVEN THEREFOR; AND THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE NOT APPLICABLE. ACCORDINGLY, THE PARTICIPATING EMS AGENCY ACCEPTS THE BLOOD PRODUCTS AS-IS AND WITH ALL FAULTS, AND BROWARD HEALTH MAKES NO REPRESENTATIONS, GUARANTEES, AND WARRANTIES, AND FURTHER DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS OR IMPLIED, PERTAINING TO THE BLOOD COMPONENTS, THE CONDITION OF THE BLOOD COMPONENTS TO BE PROVIDED UNDER THIS MOU, THE SUPPLY AND AVAILABILITY OF THE BLOOD COMPONENTS, AND ANY OTHER REPRESENTATIONS, GUARANTEES, AND WARRANTIES PERTAINING TO THE BLOOD COMPONENTS INCLUDING, WITHOUT LIMITATION, ANY AND ALL WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

13. **Disclaimer of Liability.** The Participating EMS Agency understands and agrees that Broward Health is not involved in the transfusion of the Blood Components under this MOU, Broward Health is not providing transfusion services to the patients of the Participating EMS Agency, and Broward Health has no responsibility to obtain informed consent or to make any medical evaluation of the patients, the patients' condition, or the appropriateness of a transfusion of Blood Components. The Participating EMS Agency, by signing this MOU, understands and agrees that the Participating EMS Agency is solely responsible for all acts and omissions of itself and its Emergency Personnel, and Broward Health shall not be liable to the patients being transfused, the Participating EMS Agency for the supply of Blood Components, the Participating EMS Agency and the Emergency Personnel's use, administration, and transfusion of such Blood Components, the quality or condition of such Blood Components, the viability or safety of such Blood Components, the disposal of biomedical waste, or anything otherwise related to the Participating EMS Agency and Emergency Personnel's provision of Blood Components (including, without limitation, the negligent, intentional, or unauthorized disclosure of test results with respect to its patients), and that the Participating EMS Agency is responsible for all such acts as well as for complying with all applicable Regulatory and Accreditation Standards. The Participating EMS Agency represents and warrants that the Participating EMS Agency shall not seek any legal action against Broward Health for anything related to the Blood Components including, but not limited to, any actions seeking damages, contribution, indemnification, or any other legal action pertaining to the supply, receipt, condition, administration, or transfusion of the Blood Components, as well as the failure of the Participating EMS Agency and its Emergency Personnel's compliance with applicable Regulatory and Accreditation Standards. Further, Broward Health shall in no event be liable for personal injury or any incidental, special, indirect, consequential, or punitive damages whatsoever, including, without limitation, damages resulting from the supply, receipt, condition, viability, availability, type, quantity, safety, administration, or transfusion of the Blood Components, or any delay, loss of profits, loss of business or business opportunity, or other financial loss, arising out of or related to this MOU, however caused, whether under a theory of contract, warranty, tort (including negligence), products liability, or otherwise, regardless of whether or not the Participating EMS Agency has been advised of the possibility of such damages.

14. **Insurance and Indemnification.** Participating EMS Agency and Broward Health are governmental entities per the provisions of §768.28, Florida Statutes, and each Party agrees to be liable to the limits as set forth in §768.28, Florida Statutes, for its independent acts of negligence or omissions or intentional tortious acts which result in claims or suits against that respective Party and agrees to be liable to the limits set forth in §768.28, Florida Statutes, for any damages proximately caused by said acts or omissions. Each Party maintains its own insurance program. Each Party is insured up to its legal limits of liability. Nothing herein shall be construed as consent by either Party to be sued by third parties in any matter arising out of any contract. Nothing herein shall create or be construed to create an employer-employee, agency, joint venture, or partnership relationship between the Parties. Notwithstanding the foregoing, nothing in this section is intended to alter or waive Business Associate's entitlement to statutory or common law sovereign immunity, or to extend Business Associate's liability beyond the limits established in section §768.28, Florida Statutes, as amended.
15. **Sovereign Immunity.** Sovereign Immunity. Notwithstanding any contrary provision herein, the Parties hereto acknowledge that both Broward Health, as a special taxing district of the State of Florida, and the Participating EMS Agency, as a municipality of the State of Florida, enjoy the benefits of sovereign immunity, and nothing contained herein shall be construed as a waiver or limitation of such sovereign immunity. Whether such liability be in contract, tort, or other theory of liability, the liability of each Party shall not be more than the limits established in section §768.28, Florida Statutes. All terms and provisions in the Agreement, or any disagreement or dispute concerning it, shall be construed, or resolved so as to ensure each Party of the limitation on liability provided to political subdivisions of the State as established in section §768.28, Florida Statutes, as amended. Nothing in the Agreement shall be construed to require either Party to indemnify the other or insure the other for its negligence or to assume any liability for the other Party's negligence. Any provision in the Agreement that requires either Party to indemnify, hold harmless, or defend the other Party from liability for any other reason shall not alter either Party's waiver of sovereign immunity nor extend either Party's liability beyond the limits established in section §768.28, Florida Statutes, as amended.
16. **Access to and Maintenance of Books and Records.**
- 16.1 **Safe Harbor Regulations.** Consistent with the Federal Anti-Kickback Statute's Safe Harbor Regulation governing Ambulance Replenishing at 42 C.F.R. § 1001.952(v)(2)(ii), all records created under this MOU that pertain to the replenishment and restocking of the Blood Components and the patient transport to which such Blood Components related, along with the information delineated under **Section 4.9** of this MOU, shall be maintained for at least five (5) years, shall be provided to Broward Health within a reasonable time, and shall be provided promptly upon request to the Secretary of the HHS.
- 16.2 **Medicare Program Integrity Regulations.** In accordance with Section 1861(v)(1) of the Social Security Act (codified at 42 U.S.C. § 1395x(v)(1)), as amended by Section 952 of the Omnibus Reconciliation Act of 1980 (Pub. L. No. 96-499, 94 Stat. 2599), and its implementing regulations at 42 C.F.R. § 420.300 *et seq.*, until the expiration of four (4) years after the furnishing of services pursuant to any agreement, the Participating EMS

Agency shall, upon receipt of a written request, make available to the Secretary of HHS, the Comptroller General, and their duly authorized representatives, any agreement, books, documents, and records of the Participating EMS Agency that are necessary to certify the nature and extent of costs incurred by Broward Health under any agreement. If the Participating EMS Agency carries out any of the duties of any agreement through a subcontract with a value or cost of \$10,000 or more over a 12-month period, with a related organization, such subcontract shall contain a clause that the related organization, upon receipt of a written request, shall make available to the Secretary of HHS, the Comptroller General, and their duly authorized representatives, the subcontract, and books, documents, and records of such organization that are necessary to verify the nature and extent of costs incurred by Broward Health by reason of the subcontract.

17. **Audits and Inspections.** Broward Health shall have the right, but not obligation, from time to time to, and the Participating EMS Agency shall, upon Broward Health's request, provide Broward Health and its designated employees or agents, with access to, inspect and audit all Emergency Ambulances, First Responder vehicles, Blood Components, facilities, equipment, storage devices, books, records, protocols, policies, procedures, and documentation pertaining to the Blood Components so that Broward Health can verify compliance with Regulatory and Accreditation Standards and the terms of this MOU.
18. **No Ties to Referrals.** Both Parties understand and agree that Broward Health's replenishment and restocking of the Participating EMS Agency's Blood Components is not and shall not be conditioned on or otherwise take into account the volume or value of any referrals or other business generated between the Parties for which payment may be made in whole or in part by a federal health care program (other than the referral of the particular patient to whom the replenished Blood Components were furnished).
19. **Compliance with Federal and State Laws and Regulations.** The Parties to this MOU intend to comply with, have structured this MOU so as to comply with, and by entering into this MOU both Parties agree to comply with, all applicable federal and state laws and regulations, including, but not limited to: (i) those federal and state laws and regulations governing ambulance services and emergency services; (ii) those federal and state laws and regulations governing the provision of drugs and medical supplies and relating to the handling of controlled substances; (iii) those federal and state laws and regulations pertaining to patient confidentiality and PHI, including HIPAA and FIPA; (iv) the Federal Anti-Kickback Statute and the Safe Harbor Regulations promulgated thereunder; (v) the Stark Law and the regulations promulgated thereunder; (vi) state laws and regulations regarding anti-kickback, fraud and abuse, and/or self-referral; and (vii) all other Regulatory and Accreditation Standards and health care laws applicable to either Party's obligations or performance under this MOU. The Participating EMS Agency agrees to adhere to the codes, policies, and guidelines of Broward Health's Compliance and Ethics Program, as amended from time to time and in effect, and the performance by the Participating EMS Agency of its responsibilities in a manner consistent with Broward Health's Compliance and Ethics Program and its related policies and procedures, shall be elements of Broward Health's evaluation of the performance of the Participating EMS Agency under this MOU. The Participating EMS Agency understands that failure to comply with all applicable Regulatory

and Accreditation Standards and failure to adhere to Broward Health's Compliance and Ethics Program shall constitute a material breach of this MOU, which, in addition to any other remedy available to Broward Health at law or equity, shall entitle Broward Health to terminate this MOU immediately without any cost, penalty, liability, or damages. A copy of Broward Health's Code of Conduct and related policies and procedures of Broward Health's Compliance and Ethics Program can be found at <https://www.browardhealth.org/pages/Written-Policies-and-Procedures>, and is hereby incorporated herein by reference.

20. **Relationship of the Parties.** The Parties expressly acknowledge that nothing contained in this MOU shall be deemed or construed to create a partnership, joint venture, employer/employee relationship, or any other relationship between the Parties.
21. **Third Parties.** This MOU is entered into solely between the Parties hereto and their approved successors in interest and is not entered into for the benefit of any other person or entity. Without limiting the generality of the foregoing, this MOU shall not be construed as establishing, with respect to any third party, any obligation, duty, or standard of care or practice different from or in addition to whatever obligations, duties, or practices may exist separate and apart from this MOU.
22. **Assignment.** This MOU may not be assigned by the Participating EMS Agency except with the prior written consent of Broward Health in its sole discretion. Any assignment by the Participating EMS Agency without Broward Health's prior written consent shall be null and void and without force and effect. For purposes of this provision, an assignment shall include, without limitation, (a) an assignment to a direct or indirect subsidiary or affiliate of the Participating EMS Agency; (b) the transfer directly or indirectly of all or a portion of the assets, shares, stock, partnership interests or other ownership interests of the Participating EMS Agency in a single transaction or series of transactions; or (c) a change in control or management of the Participating EMS Agency. Broward Health may assign this MOU and its rights hereunder to any successor or entity owning or operating Broward Health, to a wholly owned subsidiary of Broward Health, to any entity in which Broward Health has an ownership interest, or to an entity which acquires substantially all of Broward Health's assets. To the extent this MOU is assigned to a person or entity that is suspended, excluded, debarred, or otherwise rendered ineligible to participate in a state or federal health care program, Broward Health may terminate this MOU immediately without cost, penalty, liability, or the imposition of damages.
23. **Successors and Assigns.** This MOU shall be binding upon the successors, legal representatives or permitted assigns of the Parties hereto.
24. **No Waiver; Remedies Cumulative.** Any failure by any Party to insist upon the strict performance of any covenant, agreement, term, or condition of this MOU or to exercise a right or remedy shall not operate as, or be construed to be, a waiver of any existing or subsequent breach of the same or other provision of this MOU and such Party shall be free to reinstate any such covenant, agreement, term, condition, right or remedy with or without notice to the other Party. The rights and remedies of the Parties to this MOU are cumulative and not alternative.

25. **Notice.** Whenever any notice, demand, or consent is required or permitted under this MOU, such notice, demand, or consent shall be written and sent by certified mail (return receipt requested), reputable overnight courier (e.g., Fed Ex, UPS, etc.), or hand delivery to the following addresses:

**To Broward Health:** Broward Health  
1800 NW 49th Street  
Fort Lauderdale, FL 33309  
ATTN: President and Chief Executive Officer

**With a copy to:** Broward Health  
1800 NW 49th Street  
Fort Lauderdale, FL 33309  
ATTN: Office of the General Counsel

**To Participating EMS Agency:** Fort Lauderdale Fire Rescue  
528 NW 2<sup>nd</sup> Street  
Fort Lauderdale, FL 33301  
ATTN: EMS Chief

**With a copy to:** City of Fort Lauderdale City Attorney  
One East Broward Boulevard, Suite 1320  
Fort Lauderdale, FL 33301

**With a copy to** City of Fort Lauderdale City Manager  
101 NE 3<sup>rd</sup> Avenue, Suite 2100  
Fort Lauderdale, FL 33301

Notice shall be deemed to have been delivered within seven (7) business days or upon actual delivery, whichever occurs sooner, including: (a) the next business day following deposit with the courier when delivered by a nationally recognized overnight courier; and (b) on the date given or otherwise refused by the recipient when such notice is delivered personally via hand delivery.

26. **Headings, Number, Gender, and Construction.** The headings contained in this MOU are for reference purposes only and shall not affect in any way the meaning or interpretation of this MOU. When the context requires, the gender of all words includes the masculine, feminine, and neuter, and the number of all words includes the singular and plural. The use of the term “including” and other words of similar import mean “including, without limitation” and where specific language is used to clarify by example a general statement contained herein, such specific language shall not be deemed to modify, limit, or restrict in any manner the construction of the general statement to which it relates. The word “or” is not exclusive and the words “herein,” “hereof,” “hereunder,” and other words of similar import refer to this MOU as a whole, and not to any particular section, subsection, paragraph, subparagraph, or clause contained in this MOU. The term “shall” is mandatory



and “may” is optional. The reference to an agreement, instrument, or other document means such agreement, instrument, or other document as amended, supplemented, and modified from time to time to the extent permitted by the provisions thereof, and the reference to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder.

27. **Force Majeure.** Neither Party shall be liable nor deemed to be in default for any delay or failure in performance of this MOU or other interruptions of service deemed resulting directly, or indirectly, from acts of God, pandemics, epidemics, civil or military authority, acts of public enemy, accidents, fires, explosions, earthquakes, floods, failure of transportation, strikes, supply shortages, or other interruptions or similar cause beyond the reasonable control of either Party.
28. **Entire Agreement.** This MOU, and all the attachments and documents referenced herein, supersedes all previous contracts concerning the subject matter herein, and constitutes the entire agreement between the Parties regarding the subject matter hereof. As between the Parties, no oral statements or prior written material not specifically referenced in this MOU shall be of any force and effect. This MOU may only be amended or modified, and no modification of any of the provisions of this MOU shall be binding unless it is, in a mutually agreed to writing, signed by both Parties to this MOU.
29. **Severability.** If any provision of this MOU is deemed to be invalid or unenforceable, the remainder of this MOU shall be valid and enforceable as though the invalid or unenforceable parts had not been included herein.
30. **Survival.** The following sections shall survive the expiration or termination (for any reason) of this MOU: (a) **Sections 4.11** and **4.12** (relating to cooperation with audits and legal obligations); (b) **Section 12** (Disclaimer of Warranties); (c) **Section 13** (Disclaimer of Liability); (d) **Section 14** (Insurance and Indemnification); (e) **Section 15** (Access to and Maintenance of Books and Records); (f) **Section 16** (Audits and Inspections); and (g) any other sections of this MOU which by their terms or the Parties’ intent are made to extend beyond the Term of this MOU.
31. **Legal Interpretation.** It is the intent of both Parties that this MOU be drawn up for the benefit of both the Parties hereto. Both Parties acknowledge that they have been represented by legal counsel in the preparation and execution of this MOU. As such, in the event of an ambiguity or if a question of intent or interpretation arises, this MOU shall be construed as if drafted jointly by the Parties and no presumptions or burdens of proof shall arise favoring any Party by virtue of the authorship of any of the provisions of this MOU.
32. **Governing Law, Jurisdiction, and Venue.** This MOU has been executed and delivered in, and shall be interpreted, construed, and enforced pursuant to and in accordance with the laws of the State of Florida, without regard to conflicts of law principles. All duties and obligations of the Parties created hereunder are performable in Broward County, Florida and federal or state courts within Broward County shall be the sole and exclusive venue for any dispute, litigation, special proceeding, or other proceedings as between the Parties that may, directly or indirectly, be brought or arise out of or in connection with or by reason of this MOU. The Participating EMS Agency hereby agrees to waive any jurisdictional,

venue, or inconvenient forum objections to the state and federal courts with jurisdiction in Broward County. Both Parties expressly agree to waive a trial by jury.

33. **Counterparts and Digital Signatures.** This MOU may be executed in two (2) or more counterparts, each of which together shall be deemed an original, but all of which together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof. Further, both Parties agree that this MOU or any other document necessary for the consummation of the transaction contemplated by this MOU may be accepted, executed, or agreed to through the use of a digital signature in accordance with state and federal law and any document accepted, executed, or agreed to in conformity with such laws shall be binding and shall have the same effect as handwritten signatures for the purposes of validity, enforceability, and admissibility. Both Parties hereby consent to the use of any third-party electronic signature capture service providers as may be chosen by either Party in conformance with the foregoing laws.

**IN WITNESS WHEREOF**, the Parties have executed this MOU having read, understood, and agreed to all the terms, conditions, obligations, rights, covenants, representations, and warranties herein and intending to be bound as of the Effective Date.

**NORTH BROWARD HOSPITAL  
DISTRICT D/B/A BROWARD HEALTH**

By: \_\_\_\_\_  
Alisa Bert, Chief Financial Officer

Date: \_\_\_\_\_

CITY OF FORT LAUDERDALE, a municipal  
corporation

By: \_\_\_\_\_  
RICKELLE WILLIAMS  
City Manager

Dated: \_\_\_\_\_

ATTEST:

By: \_\_\_\_\_  
DAVID R. SOLOMAN  
City Clerk

Approved as to Legal Form and Correctness:  
Shari L. McCartney, City Attorney

By: \_\_\_\_\_  
RHONDA MONTOYA HASAN  
Senior Assistant City Attorney