



A Donate Life Organization

December 8, 2020

Marie Harrington
Mangum Regional Medical Center
1 Wickersham Drive
Mangum, OK 73554

Dear Ms. Harrington:

As you know, LifeShare Transplant Donor Services of Oklahoma, Inc., (LifeShare) is the federally-designated and certified Organ Procurement Organization (OPO) for the state of Oklahoma. The Center for Medicare & Medicaid Services (CMS) requires that each OPO enter into an agreement with each hospital in its donation service area (DSA). I reference the CMS standard detailing that requirement:

(Std) §486.322 (a) *Standard: Hospital Agreements.*

An OPO must have a written agreement with... the Medicare and Medicaid participating hospitals and critical access hospitals in its service area.....
The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death... and the requirements for hospitals at §482.45 or §485.643.”

The enclosed Agreement, describes the responsibilities of both Hospital and OPO and will be requested when you are audited by CMS, the Oklahoma State Department of Health or the Joint Commission.

Please note that LifeShare as an OPO, is not considered a “business associate” of the hospital. In regard to determination that as an OPO it is not a business associate of the Hospital, I refer to the *Federal Register*, Volume 65 page 82688. In comments on the Health Insurance Portability and Accountability Act (HIPAA), the following Federal response is found:

Response: We agree that OPOs and tissue banks are generally not business associates of hospitals.

It is on the basis of this response that our legal counsel believes it inappropriate for LifeShare to execute the various and detailed business associate agreements with which it is presented from time to time.

Your current agreement with LifeShare will expire soon. For your convenience and ours, the revised agreement, will be in effect for three years and if not terminated, will automatically renew for one additional year. It is my hope that the new agreements can be quickly signed and returned to LifeShare via DocuSign. Once returned, I will sign and forward a fully executed original electronic version for your files.

If in your review of these materials you have questions, feel free to call LifeShare at (405) 488-3540, the direct number of my assistant, Nora White.

I enclose with this cover letter the following documents for your review:

42CFR § 482.45 - Condition of Participation Organ, Eye and Tissue Procurement
42CFR § 485.643 - Condition of Participation Organ, Eye and Tissue Procurement

As I write this letter the national organ transplant waiting list has the names of nearly 113,000 Americans. At any given moment, more than 650 Oklahomans are on the list. Tissue transplants occur several times every day in Oklahoma, improving and enhancing the lives of the recipients.

We have enjoyed a long and successful relationship with your facility and on behalf of LifeShare and the many patients awaiting lifesaving transplant therapy, I thank you for your continued support of organ and tissue donation.

Respectfully,



Jeffrey P. Orlowski
President / CEO

JPO/nw

ORGAN AND TISSUE RECOVERY AGREEMENT

This AGREEMENT is made and entered into effective as of January 1, 2021 (the "**Effective Date**"), between Mangum Regional Medical Center with its principal place of business at 1 Wickersham Drive, Mangum, OK 73554 ("**Hospital**") and LifeShare Transplant Donor Services of Oklahoma, Inc., an Oklahoma not-for-profit 501(c)3 corporation, with its principal place of business at 4705 NW Expressway, Oklahoma City, Oklahoma 73132-5213, ("**LifeShare**"), with respect to the following circumstances:

WHEREAS, Hospital, being required by 42 CFR Part 482.45 to notify an organ procurement organization designated by the Secretary of the Department of Health and Human Services or third party designated by LifeShare, in a timely manner, of individuals for whom death is imminent or who have died at Hospital,

WHEREAS, LifeShare, being the Organ Procurement Organization ("**OPO**") designated by the Secretary of the Department of Health and Human Services for procurement of transplantable organs in Oklahoma,

WHEREAS, Hospital and LifeShare, desiring to facilitate the procurement of organs and tissues for transplantation and are committed to maximizing donation from suitable donors,

NOW THEREFORE, Hospital and LifeShare do agree as follows:

Section 1: Definitions

1.1 **Imminent Death**: A. Any patient on ventilator with Glasgow Coma Score ("**GCS**") of five or less and no sedation or paralytics. B. Any patient with brain death testing ordered. C. Prior to decelerating care or withdrawal of support on any ventilator patient. D. Any patient who experiences cardiac death.

1.2 **Timely Referral**: A referral by a Hospital is considered timely when made within sixty (60) minutes of determination that a patient meets clinical triggers for imminent death, or for patients not meeting such triggers within sixty (60) minutes following cardiac death.

1.3 **Tissue**: For purposes of this Agreement, the word "tissue" means bone, bone marrow, heart valves, skin, fascia, pericardium, nerve, tendon, cartilage, corneas/eyes, blood vessel and all other tissues as specified by applicable federal, state and local laws and/or regulations, and Joint Commission Standards or Det Norske Veritas Healthcare, Inc. ("**DNV**").

Section 2: Responsibilities of Hospital

2.1 Make a timely referral of all patients meeting clinical triggers for imminent death using the toll-free referral number (800) 241-4483;

2.2 Make a timely referral of all Hospital deaths using the toll-free referral number (800) 241-4483; (Note: Deaths which occur during transport from one hospital to another should be reported by the receiving hospital);

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2.3 Grant to LifeShare the exclusive right to coordinate organ and tissue donation for deaths referred during the term of this Agreement;

2.4 Work collaboratively with LifeShare in assuring all appropriate Hospital staff participate in training provided or approved by LifeShare on organ and tissue donation;

2.5 LifeShare has the responsibility to verify that employees and physicians functioning in roles for the purpose of organ recovery are qualified and have the appropriate licensure, credentialing as defined in paragraph 3.9 below;

2.6 LifeShare will perform as the designated requester for organ and tissue donation. LifeShare staff are the only personnel trained according to CMS regulation to approach families of medically suitable patients regarding the option of organ and tissue donation. Hospital staff will not be trained, or designated, as requestors;

2.7 In cooperation with LifeShare, protect the rights of every individual having made an anatomical gift through first person authorization (a right protected by state law: "...in the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor's body or part...") by honoring the deceased's first person authorization to donate in every case where said authorization is appropriately documented through a state or national donor registry;

2.8 In cooperation with LifeShare, protect the right of the legal next of kin to make or decline to make an anatomical gift in the absence of a first person decision to make or decline to make an anatomical gift;

2.9 In keeping with patient or family wishes, require that reasonable efforts be made to maintain physiological support and management of organ viability for a patient who is brain dead or for whom brain-death is considered imminent, to allow evaluation for organ donation;

2.10 Allow LifeShare staff full access 24/7/365 to all medical records including Electronic Medical Record ("**EMR**") remotely when possible, for evaluation of medical suitability, and to order lab tests, x-rays, diagnostic procedures such as bronchoscopy, etc. on patients who are authorized donors;

2.11 Encourage discretion and sensitivity with respect to the circumstances, views and beliefs of the families of potential donors;

2.12 Make medical records of deceased patients available, electronically and remotely when possible, for death record review as required by Centers for Medicare and Medicaid Services ("**CMS**"), Association of Organ Procurement Organizations ("**AOPO**"), United Network for Organ Sharing ("**UNOS**"), Federal Food and Drug Administration ("**FDA**"), and the American Association of Tissue Banks ("**AATB**");

2.13 The hospital will have a Donation after Circulatory Death Policy ("**DCD**") or a transfer policy to a facility that supports DCD. Evaluation of the patient for DCD will be performed by LifeShare staff in collaboration with the hospital healthcare team;

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2.14 Assure that Hospital and nursing service policies for organ and tissue donation are current and available to Hospital staff and LifeShare personnel and notify LifeShare of any change in credentials of any Hospital organ recovery surgeon or other recovery personnel from the hospital routinely recovering organs for LifeShare;

2.15 Provide LifeShare access to Hospital services such as laboratory and radiology, as well as ensure operating rooms and anesthesia services are made available 24/7/365 on a priority basis when organ recovery is planned;

2.16 Provide initial information to allow LifeShare to screen patients for medical suitability for organ and/or tissue donation;

2.17 Work cooperatively with, and actively participate in, LifeShare's comprehensive QAPI program related to donor referral/recovery including facilitating follow-up on occurrences identified and tracked by the LifeShare QAPI program; and,

2.18 In the event of a natural or man-made disaster in the Hospital's service area, Hospital shall to the best of its ability under such circumstances notify LifeShare of Hospital's status and shall provide LifeShare with continued access to referral sources and appropriate contacts at the Hospital.

Section 3: Responsibilities of LifeShare

3.1 In consultation with its Medical Director(s) determine medical suitability of potential donors for organ and/or tissue donation; in some cases LifeShare could transfer the patient to a central donation facility or other hospital in order to ensure that all needed services are available to maximize the donor's gift.

3.2 Work collaboratively with Hospital by providing programming and resource materials to educate members of Hospital staff regarding organ and tissue donation and provide orientation training for new Hospital staff as well as on-going training to current Hospital staff including DCD;

3.3 Make available to Hospital the services of appropriately trained LifeShare staff for timely communication and prompt response by LifeShare on a 24/7/365 basis;

3.4 A member of LifeShare staff will be available, with respect for family wishes, to discuss all options for donation of organs and tissue with the legal next-of-kin (NOK) in a sensitive, caring, and informative manner, to answer all questions the NOK may have, and when appropriate assure correct documentation of the NOK's authorization of donation. In cases of first person authorization, the LifeShare staff will verify the first person authorization by accessing the appropriate donor registry, will inform the NOK of the donor's pre-existing authorization for donation, and in a sensitive, caring, and informative manner discuss the process with the NOK including answering questions the NOK may have;

3.5 Provide, upon request, sample protocols for organ donation including DCD;

3.6 Meet all legal requirements regarding the use and disclosure of confidential patient information (HIPAA): This includes adherence to the HI TECH ACT of 2013, which addresses the security patient data;

3.7 Following declaration of brain-death, LifeShare staff will oversee medical management of the potential organ/tissue donor, coordinate the allocation of organs through the UNOS DonorNet system, and coordinate the retrieval of suitable organs and tissues;

3.8 For DCD donation, LifeShare staff determines whether the patient has the medical potential to become a candidate for DCD. If the patient is deemed a candidate, LifeShare staff will present the option of donation to the family, as applicable. Upon obtaining authorization for DCD, LifeShare will notify the Hospital staff. The Hospital staff and physicians then are responsible for the withdrawal of care, comfort care, and pronouncement of death per hospital policy and with no involvement from LifeShare staff or transplant surgeons. Following asystole, the attending physician, or his/her designee, pronounces the patient dead and the organ recovery team enters to coordinate the retrieval of suitable organs/tissues;

3.9 Ensure employees and physicians functioning in roles for the purpose of organ/tissue recovery are qualified and have the appropriate licensure, competency and the proper composition and credentials in the recovery teams;

3.10 Ensure organ and tissue recovery services are in compliance with all applicable standards, rules and regulations and provide these services with discretion, sensitivity and respect for the views and beliefs of the families of potential donors;

3.11 Notify Hospital of any LifeShare policy changes that affect recovery, perfusion or transport and provide timely communication and prompt response on a 24x7 basis;

3.12 Provide to Hospital administration a summary of deaths referred to LifeShare's toll-free referral number, 800-241-4483, manned 24/7/365 and the number of referrals that result in anatomical donation;

3.13 LifeShare will provide data reports on referral/conversion rate/timeliness of referral/donor activity with trends on a monthly, quarterly, or annual basis with frequency dependent upon volume of referrals (more referrals equates to more frequent reporting). These reports will include reports/data generated by the LifeShare QAPI process;

3.14 Upon pronouncement of death and consent for organ donation, LifeShare will assume and pay reasonable and customary charges at negotiated or discounted rates associated with donor evaluation, maintenance and surgical recovery of donor organs and tissues;

3.15 LifeShare will cooperate with the hospital's designated eye/cornea bank to facilitate ocular donation;

3.16 LifeShare will cooperate with the Oklahoma State Medical Examiner's Office to assure appropriate release for donation is obtained in cases where medicolegal investigation is to occur;

3.17 If pharmaceuticals are not readily available at Hospital, LifeShare shall provide those necessary for donor support; and,

3.18 LifeShare will ensure that proper documentation is prepared for the transplant program regarding the recovered organ(s) including blood type and other identifying information; and,

3.19 In the event of a natural or man-made disaster in the Hospital's service area, LifeShare shall to the best of its abilities under such circumstances i) provide notification to the Hospital of the status of the donor referral and recovery process and ii) provide donor referral services for screening and evaluation; including a) laboratory testing for infectious diseases and HLA, b) donor management as part of continued organ and tissue recovery services, c) adequate protection of potential donor PHI, d) resources for patient triage and care, and e) any other services that LifeShare can provide to serve the community. In the event of a natural or man-made disaster effecting LifeShare's corporate office functions and operations, LifeShare shall communicate with Hospital regarding the procedure LifeShare has adapted to deal with the impact such disaster has had on LifeShare's functions and operations and shall update Hospital as any of such disaster-response procedures are adjusted.

Section 4: Term and Termination.

4.1 This Agreement shall become effective as of the Effective Date set forth above and shall remain in effect until December 31, 2023 (the "**Initial Term**"), unless terminated as provided herein. Either party may terminate this Agreement at the end of the Initial Term by providing written notice of its intent to terminate to the other party within ninety (90) days of the expiration of the Initial Term.

4.2 Unless either party hereto provides the other party written notice of its intent to terminate this Agreement ninety (90) days prior to expiration of the Initial Term, this Agreement shall automatically renew for an additional one (1) year term (the "**Renewal Term**").

4.3 If at any time during the Initial Term or Renewal Term of this Agreement LifeShare fails to meet federal requirements as an Organ Procurement Organization, Hospital shall have the right to terminate this Agreement at that time.

4.4 If at any time during the Initial Term or Renewal Term of this Agreement Hospital loses its state license or is debarred as an eligible provider under any Federal Healthcare Program, LifeShare shall have the right to terminate this Agreement at that time.

Section 5: Indemnify and Hold Harmless

5.1 Hospital agrees to defend, hold harmless, and indemnify LifeShare, its directors, officers, employees or agents against any legal liability in respect to bodily injury, death, and property damage arising from the negligence of Hospital, its directors, officers, employees or agents during its performance of its responsibilities under this Agreement.

5.2 LifeShare agrees to defend, hold harmless, and indemnify Hospital, its directors, officers, employees or agents against any legal liability in respect to bodily injury, death, and

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property damage arising from the negligence of LifeShare, its directors, officers, or employees or agents during its performance of its responsibilities under this Agreement.

Section 6: Insurance

6.1 LifeShare and Hospital shall maintain malpractice and general liability insurance with minimum limits of \$1,000,000 per occurrence and \$3,000,000 in the aggregate throughout the term of this Agreement. Upon reasonable request of either party, the other party shall furnish the requesting party proof of adequate insurance. Such insurance shall be obtained from a reputable insurance company authorized to sell insurance policies in the State of Oklahoma and be satisfactory to the other party.

Section 7: Force Majeure

7.1 Neither party shall be responsible to the other for nonperformance or delayed performance of the terms and conditions hereof due to acts of God, acts of government, wars, riots, accidents and transportation, fuel shortages, or other causes (except strikes), in the nature of force majeure which is beyond its control.

Section 8: Independent Contractor

8.1 LifeShare is providing its services hereunder as an independent contractor. Nothing herein shall create any affiliation, partnership or joint venture between the parties hereto, or any employer/employee relationship. Neither is LifeShare, as an organ procurement organization, considered a Business Associate of the hospital as described in the Health Insurance Portability and Accountability Act ("HIPAA").

Section 9: Notices

9.1 All notices and other communications provided for hereunder shall be in writing and shall be mailed by certified mail, return receipt requested, sent by facsimile transmission, with a copy sent promptly thereafter by U.S. mail, overnight delivery or hand delivery, as follows:

If to Hospital: Name: Marie Harrington (Please print)
Title: _____
Mangum Regional Medical Center
PO Box 280
1 Wickersham Drive
Mangum, OK 73554
Telephone: _____
Email: ceo@mangumregional.org

If to LifeShare: Jeffrey P. Orłowski, President and CEO
LifeShare Transplant Donor Services of Oklahoma
4705 NW Expressway
Oklahoma City, Oklahoma 73132-5213
Telephone: (405) 840-5551
Email: LSHospitalDevelopment@lifeshareok.org

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Section 10: Applicable Law

10.01 This Agreement shall be understood in accordance with the laws of the State of Oklahoma, without giving effect to any conflict of laws principles.

Section 11: Entire Agreement. This Agreement and any addenda hereto sets forth the entire Agreement between the parties. Any prior agreements, promises, negotiations, or representations, either oral or written, relating to the subject matter of this Agreement not expressly set forth in this Agreement are of no force or effect. The obligations in these provisions shall survive the termination or expiration of this Agreement for a period of one (1) year.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized officers as of the date first written above.

"HOSPITAL"

Mangum Regional Medical Center

By: _____

Name: Marie Harrington

Title: _____

Date: _____

"LIFESHARE"

LifeShare Transplant Donor Services of Oklahoma, Inc.

By: _____

Name: Jeffrey P. Orlowski

Title: President and Chief Executive Officer

Date: _____

§ 482.45 - Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act ([42 U.S.C. 274](#)) and abide by its rules. The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under [42 CFR 121.10](#). No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given

the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under [part 486](#) of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[[65 FR 47110](#), Aug. 1, 2000, as amended at [66 FR 39938](#), Aug. 1, 2001]