

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05P001	<b>(X3) Date Survey Completed</b>  03/17/2022
<b>Name of Provider or Supplier</b>  Lifesharing	<b>Street Address, City, State</b>  7436 Mission Valley Road, San Diego, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>  (Each deficiency should be preceded by full regulatory or LSC identifying information)
<b>E0000</b>	On behalf of the Centers for Medicare & Medicaid Services (CMS), an unannounced on-site Recertification Survey conducted at the above-named Organ Procurement Organization (OPO) from 03/14/22 through 03/17/22 resulted in substantial compliance respective to the Emergency Preparedness Program Condition of Participation under 42 CFR 485.625.
<b>Z0000</b>	An unannounced Medicare Organ Procurement Organization (OPO) Re-approval survey was conducted on site from 03/14/22 through 03/17/22. The entrance conference convened on 03/14/22 at 9:00 AM with the Interim Executive Director (IED), two Organ Clinical Supervisors, (OCS) a Quality Analyst (QA), and the Organ Quality Supervisor (OQS). An exit conference was conducted on 03/17/22 at 3:00 PM and included the IED, an OCS, the Director of Donation Development (DDD), the Financial and Operational Supervisor (FOS), the Lead Surgical Coordinator (LSC), and the OQS. This facility was found to be in substantial compliance with the Federal Conditions for Coverage (CfC) set forth in 42 CFR Part 486, Subpart G. The following standard deficiencies were cited. Z182 486.344(d)(2)(ii) and Z120 486.326 (a)(3).
<b>Z0120</b>	<p><b>QUALIFICATIONS</b> CFR(s): 486.326(a)(3)</p> <p>The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.</p> <p>This STANDARD is not met as evidenced by: Based on medical record review, policy review and interview, the Organ Procurement Organization (OPO) staff failed to show documentation that all Recovery</p>

Surgeon's (RS) credentials were valid prior to organ recovery. Of the 12 Donor records reviewed, there were 26 RSs that had to be verified as having valid credentials prior to organ recovery. The documentation for one of the 26 RSs in two records was deficient. Finding includes: Review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19, located in the EMR scanned documents for DCD4 revealed RS5 was listed on the OPO's "Pre-Recovery Verification Form," as the RS for the heart and lungs. RS5 was also listed as the lung RS for DCD4 in the EMR under the team tab. There were no ACIN credentials listing for RS5 in the EMR. A paper chart was provided and reviewed with the Organ Quality Supervisor (OQS) and the Lead Surgical Coordinator (LSC). It was confirmed that there was no ACIN search listed in the medical record prior to recovery of DCD4's organs. A review of the OPO's policy, Surgical Coordinators' Responsibilities in the Operating Room," Document Number: ORCL-029, effective date 10/07/19 states, "Print the documents needed to review case with donor hospital OR staff and transplant Recovery Surgeons. This will include at least: ...Surgeon credentialing document: Access the ACIN database to print verification of Recovery Surgeon credentials prior to organ recovery." The OPO's policy, "Recovery Surgeon Credentialing and Responsibilities," Document Number: ORCL-001, effective date 04/20/21 revealed that the OPO's policies did not address verifying credentialing for RSs who come in to recover organs from outside the OPO's Designated Service Area (DSA). In an interview on 03/17/22 at 2:15 PM, it was verified that RS4, RS5, and RS6 were listed as the primary RSs for lungs, heart and lungs, and kidney, liver, and pancreas respectively and confirmed in the Digital Donor electronic record system. RS5 had no ACIN credential listing in the medical record at all including a paper chart. This deficiency was identified in the OPO's reapproval survey completed 04/11/18. The OQS explained that he/she remembers getting a letter from AOPO stating that they acknowledge the opportunity for process improvement and would enhance a feature in their system to document the expiration date of recovery personal and practitioners. The corrections implemented for this deficiency in the 04/11/18 Reapproval survey have not been sustained.

**Z0182**

**COLLABORATION WITH TRANSPLANT PROGRAMS**  
 CFR(s): 486.344(d)(2)(ii)

[The protocol must ensure that:] If the \*identify\* (sic) of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual; (\*identify is a misprint in the regulation text and should be identity.)

This STANDARD is not met as evidenced by:  
 Based on medical record review, document review, policy review, and interviews, the Organ Procurement Organization's (OPOs) recovery staff failed to show documentation to support that a member of the OPO's recovery team verified the compatibility of the Donor and the intended Recipient's Antibodies Blood Group (ABO), prior to recovery of the organs. In nine of 12 Donor records reviewed, there were 45 organs recovered and 28 of those organs had intended Recipients for transplant that require ABO verification between the Donor and the intended Recipient prior to recovery. Records, Brain Dead Donor (BDD) 1, 2 and 4, First Person Consent Donor (FPCD) 1 and 2, and Donation after Cardiac Death Donor (DCD) 1 through 4 were deficient. Findings include: 1. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the electronic

medical record (EMR) scanned documents for BDD1, showed the heart and liver had compatible intended Recipients for transplant assigned prior to recovery. The heart was recovered on 12/26/21 at 9:59 PM and the liver was recovered on 12/26/21 at 10:03 PM. The Recovery Surgeons (RSs) and an OPO staff member signed and dated the verification form, but information required for verification prior to recovery, the Donor's and the intended Recipient's ABOs and United Network for Organ Sharing Identification (UNOS IDs), which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there was no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the organ recoveries. 2. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for BDD2, showed the heart, right and left lungs, liver, and pancreas had compatible intended Recipients for transplant assigned prior to recovery. All organs were recovered on 07/06/21. The organ recovery times were documented as follows; heart at 3:16 AM, lung, right and left at 3:31 AM, liver, left segment at 3:46 AM, right segment at 3:50 AM, and pancreas at 3:53 AM. The RSs and an OPO staff member signed and dated the verification form, but documentation to support verification of the Donor's and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there were no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the organ recoveries. 3. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for BDD4, showed that the heart, right lung, liver, and pancreas were recovered on 01/13/22. All organs had compatible intended Recipients for transplant assigned prior to recovery. The recovery times were documented as follows; heart at 5:31 PM, right lung at 5:40 PM, liver at 6:08 PM, and the pancreas at 6:23 PM. The RSs and an OPO staff member signed and dated the verification form, but documentation to support verification of the Donor's and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there were no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the organ recoveries. 4. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for FPCD1, showed that the heart, left lung, and liver were recovered on 12/24/21. These organs had compatible intended Recipients for transplant assigned prior to recovery. The recovery times for each organ were documented as; heart at 5:47 PM, left lung at 6:02 PM, and liver at 6:17 PM. The RSs and an OPO staff member signed and dated the verification form, but documentation to support verification of the Donor's and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there were no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the recovery of the organs. 5. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for FPCD2, showed the heart, right and left lungs, both kidneys, and liver had compatible intended Recipients for transplant assigned prior to recovery. All organs were recovered on 10/20/21. The organ recovery times were documented as follows; heart at 5:22 PM, both lungs at 5:38 PM, both kidneys at 6:14 PM, and the liver at 6:04 PM. The RSs and an OPO staff member signed and dated the verification form, but documentation to support verification of the Donor's and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there were no times documented by either the RSs or the OPO staff to support that the

verifications were performed prior to the recovery of the organs. 6. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for DCD1, showed the liver had a compatible intended Recipient for transplant assigned prior to recovery. The liver was recovered on 07/03/21 at 8:35 PM. The RS and an OPO staff member signed and dated the verification form, but information required for verification prior to recovery, the Donor's, and the intended Recipient's ABOs and UNOS ID, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there was no time documented by either the RS or the OPO staff to support that the verification was performed prior to the organ recovery. 7. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for DCD2, showed the liver had a compatible intended Recipient for transplant assigned prior to recovery. The liver was recovered on 11/10/21 at 2:03 AM. The RS and an OPO staff member signed and dated the verification form, but information required for verification prior to recovery, the Donor's, and the intended Recipient's ABOs and UNOS ID, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there was no time documented by either the RS or the OPO staff to support that the verification was performed prior to the recovery of the organs. 8. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for DCD3, showed the heart, right and left lungs had compatible intended Recipients for transplant assigned prior to recovery. The heart was recovered on 11/05/21 at 7:59 PM, and the right and left lungs at 8:15 PM. The RSs and an OPO staff member signed and dated the verification form, but information required for verification prior to recovery, the Donor's, and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there was no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the recovery of the organs. 9. A review of the OPO's, "Pre-Recovery Verification Form," effective date 03/13/19 located in the EMR scanned documents for DCD4, showed the heart, both lungs, both kidneys, liver, and pancreas had compatible intended Recipients for transplant assigned prior to recovery. All organs were recovered on 02/13/21. The organ recovery times were documented as follows; heart at 2:10 AM, both lungs at 2:22 AM, both kidneys at 2:30 AM, liver at 2:24 AM, and the pancreas at 2:26 AM. The RSs and an OPO staff member signed and dated the verification form, but documentation to support verification of the Donor's and the intended Recipient's ABOs and UNOS IDs, which is a unique identifier assigned to all Donors and Recipients, were not included on the form. Additionally, there were no times documented by either the RSs or the OPO staff to support that the verifications were performed prior to the recovery of the organs. In an interview on 03/15/22 at 1:00 PM, the Lead Surgical Coordinator (LSC) and the Organ Quality Supervisor (OQS) confirmed that there were no times documented for the verification of the Donors and the Recipients ABO and unique identifiers prior to recovery. The LSC stated, we removed the times from there [the "Pre-Recovery Verification Form"] for some reason but I can't remember why. The times used to be on there." The QSC stated, "I remember the times being on there [the "Pre-Recovery Verification Form"] before as well but I don't remember why they were removed." The OQS explained that the reason the Donor and Recipient's ABOs and UNOS IDs are not documented on the form is because they are looking at them on the computer. In an interview on 03/17/22 at 11:15 AM, the heart and lung RS2 was asked to describe how the ABO between the Donor and the Recipient prior to recovery are verified and how it is documented. RS2 responded, "I go to a table where the Lifeshare people already has the papers laid out and has

things highlighted, and I sign my name next to the organs that I'm recovering." When asked about documenting the date and time of the verification RS2 responded, "I don't know." In an interview on 03/17/22 at 12:25 PM, the heart and lung RS 3 was asked to describe how the ABO between the Donor and the Recipient prior to recovery are verified and how it is documented. RS3 responded, "We are presented at the site of procurement with some additional forms that they want us to sign. I do sign a form." RS3 was asked to clarify that, when recovering a heart or lungs, you always have an intended Recipient correct? RS3 responded, "Yes, always." The OPO's form, "Pre-Recovery Verification Form," effective date 03/13/19 was reviewed on 03/15/22 during medical record reviews. This form is used by the OPO's Surgical Coordinators and the RSs to document the verification that by viewing the Donor and the intended Recipient's ABOs from source documents, they are compatible or intended compatible. Additionally, by viewing the Donor and the intended Recipient's unique identifiers (UNOS ID), they are confirming that they are recovering for the correct Recipient. However, this information the ABOs and UNOS IDs were not included in the documentation they are signing and there is no time required on the form to verify that the verification has taken place prior to the recovery of the organs. A review of the OPO's policy, "Surgical Coordinators' Responsibilities in the Operating Room," Document Number: ORCL-029, effective date 10/07/19 revealed, "An additional verification will occur when the intended Recipient is known prior to organ recovery. Two Lifesharing QHP [Qualified Healthcare Professionals] complete the bottom of ORCL-F112 (Pre-Recovery Verification Form) to confirm the Donor [missing text] the following using the OPTN computer system: -Known intended Recipient's unique identifier - Known intended Recipient's blood type -Donor and known intended Recipient are blood type compatible (or intended incompatible)." The policy does not require the OPO staff and another QHP to sign, date, and time their verification to support that the verification was done prior to recovery.