

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05P001	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier Lifesharing	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies (Each deficiency should be preceded by full regulatory or LSC identifying information)
Z0120	<p>QUALIFICATIONS 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 OPO personnel interview and donor record review on April 10, 2018, the OPO failed to ensure that it had credentialing records to ensure that all physicians and other practitioners who recovered organs in hospitals with which the OPO had agreements were qualified and trained. Findings included: a. During an interview on April 10, 2018, OPO personnel stated that the OPO used the ACIN (AOPO Credentials Information Network) to establish the credentials of physicians who originated from outside the OPO's designated service area (DSA) that recovered organs on the OPO's behalf. The ACIN, an online database maintained by the AOPO (Association of Organ Procurement Organizations), enables OPO's to verify the credentials and/or qualifications and training of physicians prior to organ recovery. However, although ACIN information includes which organ (s) any given physician is credentialed to recover and the physician's license number, the ACIN does not include the expiration date of the physician's license to ensure that the license is current at the time of organ recovery. b. For two (ADBQ432 and ADDF424) of eleven randomly selected donor records from January 2016 to March 2018, the OPO used the ACIN to establish the credentials of physicians who originated outside the OPO's DSA, and did not verify whether these physicians had valid licenses at the time of organ recovery. For ADBQ432, OPO donor records indicated that on February 19, 2016 the OPO recovered a heart using a physician from outside the OPO's DSA. For ADDF424, OPO donor</p>

records indicated that on April 10, 2016 the OPO recovered a liver using a physician from outside the OPO's DSA.

Z0174

POTENTIAL DONOR EVALUATION

CFR(s): 486.344(b)(4)

[The OPO must do the following:] Review the potential donor's medical chart and perform a physical examination of the donor.

This STANDARD is not met as evidenced by:

Based on OPO personnel interview and donor record review on April 10, 2018, the OPO failed to perform a physical examination of a donor. Findings included: a. For one (ADAH241) of eleven randomly selected donor records from January 2016 to March 2018, the OPO donor record failed to indicate that a physical examination of a potential donor had been performed prior to organ recovery. OPO donor records for ADAH241 indicated that kidneys were recovered on January 9, 2016 without any documentation indicating that a physical examination of the potential donor had been performed. b. OPO documentation also indicated that the missing physical examination documentation for ADAH241 was discovered by the OPO during its quality assessment and performance improvement (QAPI) donor record review, and addressed appropriately.

Z0188

DONATION AFTER CARDIAC DEATH

CFR(s): 486.344(f)(2)

[If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:] Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

This STANDARD is not met as evidenced by:

1. Based on OPO personnel interviews and donation after cardiac death (DCD) protocol record review on April 10, 2018, the OPO failed to have comprehensive written protocols that addressed withdrawal of support including the relationship between the time of consent to donation and the withdrawal of support. Findings included: a. During an interview on April 10, 2018, an OPO organ procurement coordinator (OPC) explained that in addition to the "timekeeper," who is an OPO staff member designated to maintain complete information on any and all organs recovered, the OPC is also in the presence of the donor during the period of time between extubation and declaration of death. b. Although OPO DCD protocol ORCL-050 defined the role of the "timekeeper," this protocol did not define the role of the OPC as explained by the OPC on April 10, 2018. 2. Based on OPO personnel interview and donor record review on April 10, 2018, the OPO failed to ensure that the organ recovery team was not in the presence of the donor during the period of time between extubation and declaration of death. Findings included: a. It was the practice of the OPO to document in the donor record that the organ recovery team was not in the presence of the donor during the period of time between extubation and declaration of death. b. For one (ADAH241) of eleven randomly selected donor records from January 2016 to March 2018, the OPO donor record failed to indicate that the organ recovery team was not in the presence of the donor during the period of time between extubation and declaration of death. Donor records for ADAH241 indicated that kidneys were recovered on January 9, 2016 without any such

documentation. c. OPO documentation also indicated that the missing documentation for ADAH241 was discovered by the OPO during its quality assessment and performance improvement (QAPI) donor record review, and addressed appropriately.