

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)
Z0188	<p>DONATION AFTER CARDIAC DEATH CFR(s): 486.344(f)(2)</p> <p>[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;</p> <p>This STANDARD is not met as evidenced by:</p> <p>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</p>

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.