

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05P001	(X3) Date Survey Completed 05/14/2010
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)
Z0306	<p>REQUESTING CONSENT CFR(s): 486.342(a)</p> <p>An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following: (1) A list of the organs and/or tissues that may be recovered. (2) The most likely uses for the donated organs or tissues. (3) A description of the screening and recovery processes. (4) Information about the organizations that will recover, process, and distribute the tissue. (5) Information regarding access to and release of the donor's medical records. (6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body. (7) Contact information for individual(s) with questions or concerns. (8) A copy of the signed consent form if a donation is made.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the OPO did not ensure that the individual responsible for making the donation decision was informed about the options to donate organs including the list of organs that may be recovered; and the description of the recovery process. Finding includes: In three of 3 donation cases following cardiac death, review of donor records revealed the lack of documentation that the family member of the potential donor was provided information regarding certain aspects of donation after cardiac death (DCD), including the number organs that may be recovered specific to DCD; and that if cardiac arrest did not occur within the specified time frame, that organ donation would not occur. Review of the OPO's policy and procedure on Donation After Cardiac Death revealed that the "legal decision maker will be fully informed regarding donation options and procedures ...; "</p>

and that the patient's legal decision maker will be fully informed that if cardiac death does not occur within the time frame acceptable for organ recovery; usually within two hours of the withdrawal of support, organ donation will not occur and the patient will be transferred to a prearranged location for continued end of life care." Further, during an interview on 5/13/10, a staff member stated that in DCD cases, the OPO only recovered kidneys and liver. The staff added that lungs would also be recovered if it had indication that a transplant center would be willing to accept DCD lungs. In two of 3 donor records reviewed however, consent forms revealed that authorizations were also obtained to recover other organs "for transplantation or therapy," in addition to those that the OPO usually recovers during DCD.