

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)
Z0235	<p>ADMINISTRATION AND GOVERNING BODY CFR(s): 486.324(d)</p> <p>The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the OPO did not ensure that it had bylaws for each of its boards that addressed potential conflict of interest. Finding includes: Review of the advisory board bylaws revealed that board responsibilities included agreeing "to completely disclose to the Board in writing any financial or other interests which may be perceived as a conflict of interest, and must sign a written acknowledgment to this effect." Further review revealed however that the bylaws did not define conflict of interest; did not identify situations that may constitute potential conflict of interest; and did not specify the timing and frequency the disclosures were to be made. During an interview on 5/13/10, an OPO staff member stated that members of the advisory board were not employees of the university (which owned and operated the OPO) so that the potential conflict of interest provision in the bylaw differed from that of the governing board's. The staff added that the provision will be revised to define potential conflict of interest for members of the advisory board and establish time frames for disclosures.</p>
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)</p>

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.

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 ...;" 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.

Z0307

REQUESTING CONSENT
CFR(s): 486.342(b)

If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

This STANDARD is not met as evidenced by:
Based on record review and interview, the OPO did not ensure that if the potential donor consented to donation before his or her death, that information about donation was provided to the family member. Finding includes: During an interview on 5/13/10, an OPO staff member stated that the family of every potential donor is provided the same information on organ donation regardless of whether or not the potential donor had first-person consent. The staff added that the family is also given a packet to reinforce organ donation information which had been discussed with the family. In

two of 3 cases however, where the potential donor had first-person consent, review of the donor record revealed the lack of documentation that the family member was given organ donation information.

Z0327

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:] (2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

Based on record review and interview, the OPO did not ensure that protocols dealing with withdrawal of support in donation after cardiac death were followed. Finding includes: The OPO's policy and procedure for Donation After Cardiac Death (DCD), under Withdrawal of Support, stated that "the procurement coordinator will assure that no member of the transplant team is involved with the end of life care process and only attends the patient after death;" and that when withdrawal of support occurred in the operating room that "the surgical recovery team will leave the room." During an interview on 5/13/10, an OPO staff stated that hospital policy usually determines where withdrawal of support occurs in DCD cases and that OPO staff's responsibility is to ensure that prior to death declaration, no member of the recovery team is in the operating room. In one of two DCD cases where the operating room was used for withdrawal of support, review of the donor record revealed the lack of documentation by OPO staff that no member of the recovery team was in the operating room during withdrawal of support and prior to death declaration.