

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03P001	(X3) Date Survey Completed 04/29/2010
Name of Provider or Supplier Donor Network Of Arizona	Street Address, City, State 201 West Coolidge, Phoenix, AZ	
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)
Z0237	<p>ADMINISTRATION AND GOVERNING BODY CFR(s): 486.324(f)</p> <p>The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the OPO did not ensure that it had procedures to ensure that members of the governing body complied with the policy and procedures for identifying and addressing potential conflict of interest. Finding includes: Review of the OPO's conflict of interest policy revealed that all members of the governing body as well as the medical executive committee "will be required to complete a conflict of interest disclosure statement upon affiliation with (the OPO) and to update the statement at least annually." Review of completed disclosure forms however revealed that of ten (10) members of the governing body, eight (8) did not have updated forms. Of eighteen (18) members of the medical executive committee, only five (5) had current disclosure forms; one (1) had an outdated form, and twelve (12) did not have evidence of signed disclosure statements.</p>
Z0263	<p>STAFFING CFR(s): 486.326(b)(2)</p> <p>The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.</p>

This STANDARD is not met as evidenced by:
 Based on record review and interview, the OPO did not ensure that it had sufficient number of staff to provide support to potential donor families and to conduct timely evaluation of the potential donor. Findings include: 1. In two of 7 SCD (donation by brain death criteria) cases, review of the donor records revealed that the OPO did not always ensure that organ recovery staff were onsite to provide consultation within 90 minutes following referral by the donor hospital of imminent death. In one case, the donor information form revealed that arrival time at the hospital for an on-site evaluation was after 12 hours; and in the other, after 2.5 hours. (Reference Donors 1 and 2 respectively.) Review of the OPO's policy on response to referrals revealed that an "ORC (organ recovery coordinator) will respond on-site to provide professional consultation of the referred candidate as soon as possible (not to exceed 90 minutes)" unless the potential donor "has a condition that precluded donation" or that the "candidate has no neurological injury that may present a potential for brain death or donation after cardiac death." During an interview on 4/28/10, an OPO staff stated that an ORC had to be onsite as soon as a referral is made and that any delay should be documented in the case notes. The staff added that the AOC (advisor-on-call) should also be notified. Further review of the donor records however revealed the lack of documentation to explain why the time frame for response was not met and whether the AOC was notified. 2. In one of three donation cases where the potential donor had first-person consent, review of the record revealed that on 12/09/09, the family requested "OR time either prior to 7 pm on 12/9/09, or after 10 pm on 12/9/09." Notwithstanding the request however, review of the record revealed that the potential donor was brought to the operating room at 7: 24 p.m. on 12/09/09 and that organ recovery occurred sometime at 9:41 p.m. (on 12/09/09). Further review revealed the lack of documentation as to whether the family's request was considered and accommodated; or that the family members were given the opportunity to be with the potential donor at the time frame requested. During an interview on 4/28/10, an OPO staff stated that supporting the family was an important responsibility and that the OPO continues to engage hospital staff including physicians, nurses, and the chaplain , for example, to help identify the family's needs, requests, and preferences, and how all these might be addressed. Review however revealed the lack of documentation of all these in the donor record. (Reference Donor 6.)

Z0306

REQUESTING CONSENT
 CFR(s): 486.342(a)

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.

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 of available options to donate organs of tissues or to decline to donate. Findings include: 1. In three of 3 cases of donation after cardiac death (DCD), review of donor records revealed the lack of documentation that the potential donor's family member was informed of the duration of time required to complete testing and make recovery assessments; the fact that recovery of organs must occur rapidly after death is pronounced; the possibility that the potential donor may not arrest within the allotted time frame and therefore organ donation may not occur; and that in DCD, the OPO only recovered kidneys, liver, pancreas and lungs. (Reference Donors 8, 9 and 10.) Review of the policy on "Organ Donation After Cardiac Death" revealed that OPO staff will approach the potential donor's family "taking care to explain the following: The organs and tissues that may be recovered (organs are usually limited to lungs, liver, kidneys and pancreas); the duration of time required to complete testing and make recovery arrangements; the fact that recovery of organs must occur rapidly after death is pronounced; the possibility that the patient may not arrest within the allotted time frame and therefore organ donation may not occur; and other procedures that may be necessary (including bronchoscopy, line placement, and medication administration) ... " During an interview on 4/28/10, an OPO staff stated that discussions regarding the use of Heparin and/or line placement in DCD cases were noted under "other," a data field on the consent form as required by the OPO's DCD policy and procedures. 2. Further review revealed that the policy above was not followed. In two of 3 DCD cases for example, the administration of Heparin prior to extubation was not noted in the appropriate section ("other") of the consent form to indicate that the family member was informed and consented to the use of the anticoagulant as required. While one of two records documented that the family member "(consented) to heparin for DCD purposes " on the "operational supplemental information" form, the documentation did not include what information was given and why Heparin was necessary. (Reference Donors 8 and 9.)

Z0318

TESTING
 CFR(s): 486.344(c)(2)

[The OPO must do the following:] (2) Ensure that screening and testing of the potential donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the OPO did not ensure that testing and screening of the potential donor including blood-typing, was conducted by a laboratory that is certified. Finding includes: In two of 10 donation cases, review of the donor records revealed that one of two ABO results did not identify the name of the hospital or laboratory where the test was performed. Without the identifier, determining whether the hospital or laboratory was certified could not readily be made. During an interview on 4/27/10, an OPO staff stated that while the ABO results when printed noted the potential donor's name, the medical record number, and date and time the sample was tested, it did not however, include the name of the hospital and/or any other information. (Reference Donors 2 and 10.)

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 were always followed. Finding includes: The OPO's policy and procedure for Organ Donation after Cardiac Death (DCD) stated that "at no time between the withdrawal of support and declaration of death may the surgical team be in the same room as the patient." The policy further noted that "withdrawal of support may occur (in) a pre-operative holding area ("induction room"), post-anesthesia care unit (PACU), or the OR (operating room) itself." During an interview on 4/28/10, an OPO staff stated that the family's wishes as well as hospital policy dictated where withdrawal of support was to be conducted. The staff added that regardless of the venue, the OPO did not allow any member of the recovery team inside the operating room or in the same room as the potential donor prior to death declaration. In three of 3 cases of donation after cardiac death, including one where withdrawal of support occurred in the operating room, review of the donor records revealed the lack of documentation by OPO staff that no member of the recovery team was in the same room as the potential donor during withdrawal of care and prior to death declaration. (Reference Donors 8, 9 and 10.)