

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)
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 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</p>

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.)