An unannounced Medicare complaint survey was conducted onsite on June 7-8, 2011. An entrance conference was convened on June 7, 2011, at 8:30AM with the hospital's Administrators and Transplant Program Staff. The survey team leader introduced the survey team and explained the survey process and purpose, including expectations for document requests, interviews and observation needs to complete the survey.

An exit conference conducted on June 8, 2011, at 3:30PM included the hospital's Administrators and Transplant Program Staff. Per protocol, all deficiencies found throughout the survey process for the transplant program were identified to the attendees at the exit conference, allowing ample time for questions or discussion.

All citations are drawn from cases subsequent to the effective date of the Subpart E Requirements of June 28, 2007. Each deficiency statement includes a reference to the organ program(s) to which deficient practice applies. The complaint survey included the following types of organ transplant programs:

AKO - Adult Kidney Only
ALO - Adult Liver Only

X 001
AKO

482.68 SPECIAL REQUIREMENTS FOR TRANSPLANT CENTERS

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §482.72
**SUMMARY STATEMENT OF DEFICIENCIES**

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<th>ID TAG</th>
<th>DEFICIENCY REPORT</th>
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<tbody>
<tr>
<td>X 001</td>
<td>Continued From page 1 through §482.104 in order to be granted approval from CMS to provide transplant services. (a) Unless specified otherwise, the conditions of participation at §482.72 through §482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers. (b) In addition to meeting the conditions of participation specified in §482.72 through §482.104, a transplant center must also meet the conditions of participation specified in §482.1 through §482.57.</td>
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</table>

This CONDITION is not met as evidenced by:

Based on review of facility documents and interviews with staff (EMP), it was determined that the Adult Kidney Only (AKO) program failed to ensure that the facility met the conditions of participation specified in 482.90 Patient and Living Donor Selection by failing to follow written selection criteria in determining the suitability of a living donor candidate and failing to document relevant findings related to a living donor's suitability for donation.

Findings include:

1) Review of facility documents and interviews with staff revealed that the facility failed to identify that a living donor was Hep C positive prior to removal and transplantation of an adult kidney. See X051 and X059.

Recipient selection criteria policy and procedure applying to AKO transplant program updated by Transplant Compliance and Quality staff to include independent verification of serology and diagnostic testing as used to assess and determine the individual recipient’s suitability for placement on the center’s waiting list. Documentation of criteria utilized will be recorded in the recipient’s individual medical record and will be witnessed by a member of the multidisciplinary team. Documentation will also include completion of recipient evaluation checklist by assigned members of the transplant team (surgeon, nephrologist and clinical coordinator). When requested, a copy of the recipient selection criteria will be provided to individual patients. In-service educational training to all Transplant Faculty and applicable staff has been completed. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff.
### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

#### NAME OF PROVIDER OR SUPPLIER
UPMC PRESBYTERIAN SHADYSIDE

#### STREET ADDRESS, CITY, STATE, ZIP CODE
200 LOTHROP STREET, PITTSBURGH, PA 15213

#### PROVIDER'S PLAN OF CORRECTION
(EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)

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<td>Of the utilization of the recipient evaluation checklist will be performed monthly on all patients presented at the multidisciplinary patient selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). A summary report will be submitted annually to the Transplant Patient Safety Council. Responsible Person: Program Administrator</td>
</tr>
<tr>
<td>399801</td>
<td>Living Donor selection criteria policy and procedure applying to AKO transplant program updated by Transplant Compliance and Quality staff to include independent verification of serology and diagnostic testing as used to assess and determine the individual living donor’s suitability for donation. Documentation of criteria utilized will be recorded in the living donor’s individual medical record and will be witnessed by a member of the multidisciplinary team. Documentation will also include completion of living kidney donor evaluation checklist by assigned members of the transplant team (surgeon, nephrologist and live donor nurse coordinator). In-service educational training to all Transplant Faculty and applicable staff has been completed. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff of the utilization of the living kidney donor evaluation checklist and will be performed monthly on all living kidney donors</td>
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#### ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | COMPLETE DATE
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<td>399801</td>
<td>Of the utilization of the recipient evaluation checklist will be performed monthly on all patients presented at the multidisciplinary patient selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). A summary report will be submitted annually to the Transplant Patient Safety Council. Responsible Person: Program Administrator</td>
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<td>399801</td>
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<td>06/24/2011</td>
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**If continuation sheet 3 of 17**
**NAME OF PROVIDER OR SUPPLIER**
UPMC PRESBYTERIAN SHADYSIDE

**STREET ADDRESS, CITY, STATE, ZIP CODE**
200 LOTHROP STREET PITTSBURGH, PA 15213

**DATE SURVEY COMPLETED**
06/24/2011

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- Presented to the selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). A summary report will be submitted annually to the Transplant Patient Safety Council.

**Responsible Person:** Program Administrator

Living Donor Patient Safety Committee policy developed for the AKO and ALI programs and implemented by Chief, Division of Transplantation. In accordance with the policy, the Living Donor Safety Committee will review and discuss all cases presented to the multidisciplinary selection committee to ensure all requirements have been met for living donation. Decisions of the committee will be documented by the Chair on the Living Donor Evaluation Checklist as well as in the individual living donor’s medical records. The Chair of the Living Donor Patient Safety Committee is a Transplant Surgeon, but not the Transplant Surgeon who has been involved in the previous review and determination of the living donor as a potential candidate for donation. In-service educational training to all Transplant Faculty and applicable staff who will be involved in the Living Donor Patient Safety Committee has been completed. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff of the activities and decisions of the Living Donor Safety Committee. Results will be reported on a quarterly basis to the...
The transplant center must use written patient selection criteria in determining a patient’s suitability for placement on the waiting list or a patient’s suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

This CONDITION is not met as evidenced by:

Based on a review of facility policy, medical records (MR), and interview with staff (EMP), it was determined that the facility failed to follow written selection criteria in determining the suitability of a living donor candidate for one of 11 medical records reviewed (Sample G-MR1) for the Adult Kidney Only (AKO) program.

Recipient selection criteria policy and procedure applying to AKO transplant program updated by Transplant Compliance and Quality staff to include independent verification of serology and diagnostic testing as used to assess and determine the individual recipient’s suitability for
Findings include:

Review of "Living Donation ... Revision Date: January 2011" revealed "V. Procedure Each living donor is under the care of multidisciplinary team coordinated by a physician throughout the donor evaluation, donation and discharge phases of donation. ... Once a prospective living donor is identified the living donor team will conduct a comprehensive evaluation. This includes but is not limited to ... screening for evidence of a transmittable disease ... Upon completion of all testing and interviews by the multidisciplinary team the donor's data are presented at the selection meeting and a decision will be made regarding suitability for donation."

1) Review of the multidisciplinary selection committee meeting, held on March 23, 2011, revealed that the patient (G-MR1) was approved for living kidney donor donation. There was no documentation that the patient had abnormal Hepatitis C laboratory results.

2) Review of G-MR1 revealed that the patient had a nephrectomy on April 6, 2011, to provide their kidney for a living donor kidney transplant.

3) Review of G-MR1 revealed that on April 22, 2011, a "Quant HCV PCR" test was obtained, 16 days after the living donor kidney transplant. Further review revealed that the results of the test were received on May 2, 2011, with a positive result of a Hepatitis C infection.

4) Interview with EMP4 on June 8, 2011, at placement on the center’s waiting list. Documentation of criteria utilized will be recorded in the recipient’s individual medical record and will be witnessed by a member of the multidisciplinary team. Documentation will also include completion of recipient evaluation checklist by assigned members of the transplant team (surgeon, nephrologist and clinical coordinator). When requested, a copy of the recipient selection criteria will be provided to individual patients. In-service educational training to all Transplant Faculty and applicable staff has been completed. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff of the utilization of the recipient evaluation checklist will be performed monthly on all patients presented at the multidisciplinary patient selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). A summary report will be submitted annually to the Transplant Patient Safety Council.

Responsible Person: Program Administrator
approximately 9:30 AM confirmed the above findings and revealed "Hep C was not noted by the nurse or surgeon that reviewed the chart [prior to the living donor transplant]."

See X059

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<td>X 059</td>
<td>AKO</td>
<td>482.90(b)(2) DOCUMENT SUITABILITY FOR DONATION</td>
<td>Transplant centers must document in the living donor's medical records the living donor's suitability for donation.</td>
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</table>

This ELEMENT is not met as evidenced by:

Based on review of facility documents, review of medical records (MR), and staff interviews (EMP), it was determined that the facility failed to document relevant findings related to a living donor's suitability for donation for one of 11 medical records reviewed (Sample G-MR1) for the Adult Kidney-Only program (AKO).

Findings include:

Review of "Living Donation ... Revision Date: January 2011" revealed "V. Procedure Each living donor is under the care of multidisciplinary team coordinated by a physician throughout the donor evaluation, donation and discharge phases of donation. ... Once a prospective living donor is identified the living donor team will conduct a comprehensive evaluation. This includes but is not limited to ... screening for evidence of a transmittable transmissible
disease ... Upon completion of all testing and interviews by the multidisciplinary team the donor’s data are presented at the selection meeting and a decision will be made regarding suitability for donation."

Review of "Living Donor Selection ... Revision Date: ... January 2011" revealed "V. Procedure ... B. Patient Suitability The suitability of all potential living door candidates will be discussed upon completion of a comprehensive evaluation by the multidisciplinary team at regular selection meetings."

1) Review of G-MR1 revealed that the patient had laboratory tests performed on January 26, 2011, at 8:25 AM. Further review of MR1 revealed that a test for "Anti-Hepatitis C Virus Ab" indicated a possible infection, on January 26, 2011, at 3:39 PM, with recommended follow-up testing to be completed.


3) Review of a "Renal Living Donor Selection Outcome" form for G-MR1 revealed that on February 17, 2011, at a multidisciplinary selection committee meeting, the patient was approved to be a living kidney donor after a further diagnostic procedure would be completed. Further review of this form revealed no documentation under "Contraindications" of the January 26, 2011, abnormal Hepatitis C laboratory results.

Further review of this form revealed that at a

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| 000          | disease ... Upon completion of all testing and interviews by the multidisciplinary team the donor's data are presented at the selection meeting and a decision will be made regarding suitability for donation."
|              | Review of "Living Donor Selection ... Revision Date: ... January 2011" revealed "V. Procedure ... B. Patient Suitability The suitability of all potential living door candidates will be discussed upon completion of a comprehensive evaluation by the multidisciplinary team at regular selection meetings." |
| 000          | 1) Review of G-MR1 revealed that the patient had laboratory tests performed on January 26, 2011, at 8:25 AM. Further review of MR1 revealed that a test for "Anti-Hepatitis C Virus Ab" indicated a possible infection, on January 26, 2011, at 3:39 PM, with recommended follow-up testing to be completed. |
| 000          | 2) Review of G-MR1 revealed a "M&M Living Kidney Donor Presentation" form. Further review of this form revealed no documented evidence of the January 26, 2011, abnormal Hepatitis C results next to the "Abnormal lab results" section. |
| 000          | 3) Review of a "Renal Living Donor Selection Outcome" form for G-MR1 revealed that on February 17, 2011, at a multidisciplinary selection committee meeting, the patient was approved to be a living kidney donor after a further diagnostic procedure would be completed. Further review of this form revealed no documentation under "Contraindications" of the January 26, 2011, abnormal Hepatitis C laboratory results. |
|              | Further review of this form revealed that at a |

has been initiated by the Transplant Compliance and Quality staff of the utilization of the living kidney donor evaluation checklist will be performed monthly on all living kidney donors presented to the selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). A summary report will be submitted annually to the Transplant Patient Safety Council.

Responsible Person: Program Administrator

Please note that we have submitted a request for approval based on mitigating factors in response to CMS form 2567 for the Conditional level deficiency related to 42 CFR § 482.90 Patient and Living Donor Selection.
"Represent/Follow-up" multidisciplinary selection committee meeting, held on March 23, 2011, the patient was approved for living kidney donor donation. There was no documentation that the patient had abnormal Hepatitis C laboratory results.

4) Review of G-MR1 revealed a "Transplant Surgery Consultation" note, completed by EMP4, on April 1, 2011, [prior to the living donor transplant]. Further review of this note revealed no documented evidence of possible Hepatitis C infection.

5) Review of G-MR1 revealed that the patient had a nephrectomy on April 6, 2011, to provide their kidney for a living donor kidney transplant.

6) Review of G-MR1 revealed that on April 22, 2011, a "Quant HCV PCR" test was obtained, 16 days after the living donor kidney transplant. Further review revealed that the results of the test were received on May 2, 2011, with a positive result of a Hepatitis C infection.

7) Interview with EMP1 on June 7, 2011, at approximately 9:00 AM confirmed the above findings and revealed "Both [EMP12] and [EMP4] missed that the Hep C antibody test had come back as positive [prior to the living donor transplant] ... after the transplant, [EMP12] had noticed the Hep C test was positive."

8) Interview with EMP4 on June 8, 2011, at approximately 9:30 AM confirmed the above findings and revealed "Hep C was not noted by the nurse or surgeon that reviewed the chart [prior to the living donor transplant]."

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### STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

**NAME OF PROVIDER OR SUPPLIER:**

UPMC PRESTBYTERIAN SHADYSIDE  

**STREET ADDRESS, CITY, STATE, ZIP CODE:**

200 LOTHROP STREET, PITTSBURGH, PA 15213

**DATE SURVEY COMPLETED:**

06/24/2011

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#### SUMMARY STATEMENT OF DEFICIENCIES

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<tr>
<td>X 100 AKO</td>
<td>X 100</td>
<td>X 100</td>
<td>Completion Date: 06/29/2011</td>
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**482.96(a) COMPONENTS OF QAPI PROGRAM**

The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights.

This STANDARD is not met as evidenced by:

- Based on review of facility documents and staff interviews (EMP), it was determined that the transplant center's QAPI program did not use objective measures to evaluate living donor outcomes throughout the three phases of the living donor donation process (pre-donation, donation, and post-donation) for the Adult Kidney-Only (AKO) and Adult Liver (ALI) programs.

Findings include:

- Review of "UPMC Presbyterian Shadyside Quality Assurance / Patient Safety / Performance Improvement Program Transplantation Services April 2011" revealed "The scope of the Transplant Quality Plan includes the following services: ... Adult Living Liver Donors / Adult Living Kidney Donors ... d. Clinical Program Outcome Measures ... Living Donors (Kidney and Liver) Clinical Measures: 1. Length of Stay (LOS) 2. Re-operation rate 3.

Chief, Division of Transplantation has developed a formal and comprehensive Transplant Specific Quality Assessment and Performance Improvement (QAPI) plan. The scope of the Transplant QAPI includes the living donor programs affiliated with the AKO and ALI programs. Oversight of the Transplant QAPI plan is provided by the Transplant Patient Safety Council which reports to the UPMC Total Quality Council. Objective measures to evaluate living donor outcomes throughout the three (3) phases of the living donor donation process (pre-donation, donation and post-donation) have been incorporated into the plan. The Abdominal Transplant QAPI committee which is multidisciplinary in membership will be responsible for the implementation of the plan including analysis of the objective measures specific to the living donors,
NAME OF PROVIDER OR SUPPLIER
UPMC PRESBYTERIAN SHADYSIDE
200 LOTHROP STREET
PITTSBURGH, PA 15213

STATEMENT OF DEFICIENCIES
AND PLAN OF CORRECTION

PART I - SUMMARY STATEMENT OF DEFICIENCIES

Re-admission rate 4 % conversion from laparoscopic to open nephrectomy (kidney only)
5 Transfusion rate post-operatively.

1) Review of the previous "UPMC Presbyterian Shadyside Quality Assurance / Patient Safety / Performance Improvement Program Transplantation Services April 2010" revealed no documented evidence of "Clinical Program Outcome Measures ... Living Donors (Kidney and Liver) Clinical Measures" as listed in the most recent 2011 QAPI plan.

2) Review of "Transplant Patient Safety Council" meeting minutes from July 2010 to March 2011, and review of Abdominal Transplant QAPI Committee" meeting minutes from February 2010 to May 2011, revealed no documented evidence that any of the "Clinical Program Outcome Measures ... Living Donors (Kidney and Liver) Clinical Measures" were presented at any of the meetings.

3) Interview with EMP2 on June 8, 2011, at approximately 11:00 AM confirmed the above findings and revealed "We have been collecting the data [Clinical Program Outcome Measures ... Living Donors (Kidney and Liver) Clinical Measures] since January ... It had not been presented yet. It will be at the next meeting."

PART II - PROVIDER'S PLAN OF CORRECTION

implementation of recommendations for improvement and monitoring of performance to ensure improvements are sustained. The objective measures to evaluate living donor outcomes were presented to the Abdominal Transplant QAPI committee on June 29, 2011. Results regarding the living donor outcomes throughout the 3 phases will be routinely reported to the Abdominal Transplant QAPI Committee. A summary report will be submitted to the Transplant Patient Safety Council on an annual basis.

Responsible Person: Program Administrator

PART III - X 116

482.98(b)(1) SURGEON RESPONSIBLE FOR SURGICAL SERVICES

The transplant surgeon is responsible for providing surgical services related to transplantation.
Based on a review of facility policy, medical records (MR), and interviews with staff (EMP), it was determined that the transplant surgeon failed to ensure a living donor's suitability for donation for one of 11 medical records reviewed (Sample G- MR1) for the Adult Kidney Only program (AKO).

Findings include:

- Review of facility policy "Multidisciplinary Team" revised October 2010 revealed "IV. General Guidelines The team must be comprised of individuals with appropriate qualifications, ongoing training and experience in relevant areas of surgery, .... Transplant Physician/Transplant Surgeon: Provides and coordinates the individual care/services administered by other members of the multidisciplinary team. Ensures that the quality and appropriateness of the transplant donor or recipients (sic) care is monitored and evaluated. ...." 

- Review of facility policy "Patient Management Living Donor" revised September 2010 revealed "III. Purpose To ensure that each living donor is under the care of a multidisciplinary team coordinated by a physician throughout the donor evaluation, donation, .... V. Procedure Donor Evaluation Phase: ... In the evaluation process the potential living donor will be screened and evaluated by a transplant surgeon with a complete history and physical examination ...."

1) Review of G-MR1 revealed a "Transplant Surgery Consultation" note, completed by EMP4, on April 1, 2011, [prior to the living donor transplant]. Further review of this note revealed no documented evidence of possible Hepatitis C infection.
Interview with EMP4 on June 8, 2011, at approximately 9:30 AM confirmed that they did not note from G-MR1 laboratory reports that the patient had a possible Hepatitis C infection.

X 117

482.98(b)(2) PHYSICIAN RESPONSIBLE FOR TRANSPLANT CARE

The transplant physician is responsible for providing and coordinating transplantation care.

This ELEMENT is not met as evidenced by:

Based on a review of facility policy, medical records (MR), and interviews with staff (EMP), it was determined that the transplant physician failed to ensure a living donor's suitability for donation for one of 11 medical records reviewed (Sample G-MR1) for the Adult Kidney Only program (AKO).

Findings include:

Review of facility policy "Multidisciplinary Team" revised October 2010 revealed "IV. General Guidelines The team must be comprised of individual with appropriate qualifications, ongoing training and experience in relevant areas of surgery, .... Responsibilities and Roles of Multidisciplinary Team Transplant Physician/Transplant Surgeon: Provides and coordinates the individual care/services administered by other members of the multidisciplinary team. Ensures that the quality and appropriateness of the transplant donor or recipients (sic) care is monitored and evaluated. ..."

Policy and procedure Living Donor Team has been updated to clarify the roles and responsibilities of the Transplant Physician in making recommendations regarding the living donor’s suitability for donation. Documentation of the Transplant Physician’s assessment and recommendations will be done by completion of the individual living kidney donor evaluation checklist. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff of the completion of the living donor evaluation checklist by the Transplant Physician on all living donors presented at the multidisciplinary patient selection committee until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). Responsible Person: Program Administrator
**SUMMARY STATEMENT OF DEFICIENCIES**

Review of facility policy "Patient Management Living Donor" revised September 2010 revealed "III. Purpose To ensure that each living donor is under the care of a multidisciplinary team coordinated by a physician throughout the donor evaluation, donation, ... V. Procedure Donor Evaluation Phase: ... In the evaluation process the potential living donor will be screened and evaluated by a transplant physician and transplant surgeon with a complete history and physical examination ..." 

1) Interview with EMP1 on June 7, 2011, at approximately 8:30 AM revealed that the patient (G-MR1) was seen by the nephrologist (transplant physician) as part of the evaluation process.

2) Interview with EMP7 on June 24, 2011, at approximately 11:00 AM confirmed that the nephrologist saw the living donor patient (G-MR1) at time of the initial evaluation prior to the patient's laboratory testing being completed. The nephrologist did not see the living donor patient or review the medical record after the initial visit.

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<td>X 118</td>
<td>AKO</td>
<td>482.98(c) CLINICAL TRANSPLANT COORDINATOR</td>
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The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation.

This **STANDARD** is not met as evidenced by:

Completion Date: 05/18/2011
Based on a review of facility policy, medical records (MR), and interviews with staff (EMP), it was determined that the living donor transplant coordinator failed to ensure a living donor's suitability for donation for one of 11 medical records reviewed (Sample G-MR1) for the Adult Kidney Only program (AKO).

Findings include:

Review of facility policy "Patient Management Living Donor" revised September 2010 revealed "V. Procedure Donor Evaluation Phase: ... The living donor transplant coordinator will collect and screen all data and test results and prepare the medical record for presentation at the selection committee ..."

Review of facility policy "Multidisciplinary Team" revised October 2010 revealed " Responsibilities and Roles of Multidisciplinary Team ...Clinical Transplant Coordinator: is a Registered Nurse with advanced clinical knowledge and skills ... Coordinates, facilitates plans, implements, and evaluates all phases of care for living donors, ..."

1) Review of the multidisciplinary selection committee meeting, held on March 23, 2011, revealed that the patient (G-MR1) was approved for living kidney donor donation. There was no documentation that the patient had abnormal Hepatitis C laboratory results.

2) Review of G-MR1 revealed that the patient had a nephrectomy on April 6, 2011, to provide their kidney for a living donor kidney transplant.

3) Review of G-MR1 revealed that on April 22, 2011,
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<tr>
<td>X 156</td>
<td>AKO</td>
<td>482.102(a)(6) PATIENT INFORMED OF DONOR RISK FACTORS</td>
<td>X 156</td>
<td>Completion Date: 05/18/2011</td>
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Each patient is informed of organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

This ELEMENT is not met as evidenced by:

Based on a review of medical records and interview with staff (EMP), it was determined that the facility failed to inform an Adult Kidney-Only (AKO) transplant recipient of living donor risk factors that could affect the health of the recipient.

Findings include:

1) Interview with EMP1 on June 7, 2011, at approximately 8:30 AM revealed that an AKO

Document used for informed consent for potential transplant recipients for transplant procedures performed including living donor for AKO program reviewed to include language that each patient is informed of organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organ used, or the patient's potential risk of
transplant recipient received a living donor kidney (G-MR1) on April 6, 2011.

2) Review of G-MR1 revealed that on April 22, 2011, a "Quant HCV PCR" test was obtained, 16 days after the living donor kidney transplant. Further review revealed that the results of the test were received on May 2, 2011, with a positive result of a Hepatitis C infection.

3) Interview with EMP1 on June 7, 2011, at approximately 8:30 AM confirmed that the transplant recipient was not informed of the positive Hepatitis C infection prior to transplantation.

contracting the human immunodeficiency virus and any other infectious diseases if the disease cannot be detected in an infected donor.

In-service educational training to all Transplant Faculty and applicable staff has been completed. 100% audit/monitoring has been initiated by the Transplant Compliance and Quality staff off the utilization of the appropriate consent form and will be performed monthly on all patients seen in initial pre-transplant consultation until 100% compliance is achieved and sustained. Results will be reported on a quarterly basis to the Abdominal Transplant Quality Assessment and Performance Improvement Committee (QAPI). Responsible Person: Program Administrator