



DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
WESTERN CONSORTIUM
DIVISION OF SURVEY AND CERTIFICATION

Refer to: DSC-FOIA-DH (SAN FRANCISCO REGIONAL OFFICE)

August 3, 2006

Robert Finney
CounterPoint Communications
P.O. Box 230927
Encinitas, CA 92023-0927

Dear Mr. Finney:

This is in response to your Freedom of Information Act request dated July 21, 2006 to the Centers for Medicare & Medicaid Services (CMS) for a copy CMS' recent survey report on Kaiser Foundation Hospital's renal transplant program, along with the facility's plan of correction (POC) and correspondence associated with the survey. In a conversation with CMS staff, you clarified that you were limiting the scope of your request to the POC without its attachments.

All records within the scope of your request (i.e. 70 pages) possessed by the San Francisco Regional Office of CMS are hereby released and none are withheld.

There is no charge for processing this request.

Please let us know if the San Francisco Regional Office of CMS may be of further assistance. You may contact Dan Hersh at (415) 744-3731 for additional information.

Sincerely,

Jeff Flick
Regional Administrator

Enclosure

Denver Regional Office
1600 Broadway, Suite 700
Denver, CO 80202

San Francisco Regional Office
75 Hawthorne Street, 4th Floor
San Francisco, CA 94105

Seattle Regional Office
2201 Sixth Avenue, RX-48
Seattle, WA 98121

Hersh, Daniel I. (CMS/WC)

From: Chickering, Steven D. (CMS/WC)
Sent: Wednesday, June 14, 2006 2:18 PM
To: Hersh, Daniel I. (CMS/WC)
Subject: FW:

fyi

From: Lockey, Nicole M. (CMS/WC) **On Behalf Of** Flick, Jeff A. (CMS/WC)
Sent: Monday, June 12, 2006 11:03 AM
To: maryann.thode@kp.org
Cc: michael.r.alexander@kp.org; Chickering, Steven D. (CMS/WC); Flick, Jeff A. (CMS/WC)
Subject:

Mary Ann –

I am writing to confirm the fact that CMS is extending the due date on the CMS survey and certification plan of correction from 6/15/06 until 6/22/06. You are required to forward the plan of correction to us no later than the close of business on 6/22/06.

Please let me know if you have any questions, or if additional information is required. You may also communicate directly with Captain Steve Chickering as noted below.

Thanks,

Jeff

Jeff Flick: (415) 744-3501

Steve Chickering: (415) 744-3682

6/14/2006

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05-2312	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 05/12/2006
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NAME OF PROVIDER OR SUPPLIER KAISER FOUNDATION HOSPITAL RENAL TR	STREET ADDRESS, CITY, STATE, ZIP CODE 2425 GEARY BLVD SAN FRANCISCO, CA 94115
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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V 000 INITIAL COMMENTS

Renal transplant center (RTC) shall herein refer to the Kaiser Hospital Renal Transplant Center.

The following reflect findings of the Centers for Medicare and Medicaid Services during a complaint investigation survey:

V 110 405.2136 GOVERNING BODY AND MANAGEMENT

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility.

This Condition is not met as evidenced by: Based on record review and interview, the governing body did not ensure that the RTC adopted and enforced rules and regulations including those pertaining to quality assurance and performance improvement to ensure the delivery of quality care to patients (V112); did not develop and enforce rules and regulations relative to the general operation of the RTC (V114); did not appoint a chief executive officer who was responsible for the overall management of the RTC (V116); did not ensure that the Transplant Program Director maintained ongoing liaison among the governing body, and medical and nursing personnel and other professional and supervisory staff through meetings and periodic reports (V130); did not ensure that the Transplant Program Director coordinated the provision of services in accordance with delegations by the governing body (V134); and did not ensure that the RTC employed a sufficient number of qualified employees and that employees had

V 000

Kaiser Foundation Hospitals ("KFH") submits this response (the "Response") to the statement of deficiencies ("Statement") issued by the Centers for Medicare & Medicaid Services ("CMS") related to a survey of KFH's Renal Transplant Center (RTC), completed by CMS on May 12, 2006.

V 110

For purposes of this response, KFH focuses on demonstrating evidence of compliance and sufficient corrective actions that will enable compliant operation of the RTC and protection of the care and rights of KFH's transplant patients, rather than addressing the alleged facts recited or implied in this Statement. Accordingly, this Response does not express concurrence with or admission of the accuracy or completeness of the findings, nor is it an admission or concession on the part of KFH of wrongdoing or liability. KFH's primary concern was, and continues to be, the welfare of its patients.

KFH continues to provide services to patients, including renal transplant patients, in compliance with the requirements for the provision of ESRD services set forth in 42 C.F.R. Part 405. The Response includes evidence of compliance with applicable regulations and corrective actions designed to ensure such compliance. KFH voluntarily decided to provide patients on the RTC's wait list an opportunity to transfer to the renal transplant centers at the University of California, San Francisco ("TC1") and the University of California, Davis ("TC2"). By continuing to provide the continuum of care including renal transplant services, while taking necessary action to demonstrate

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE *R. Mohl* TITLE *SRUP / Area Manager* (X6) DATE *6/22/06*

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

V 000 (continued)

compliance and enabling patients to obtain services at other renal transplant centers, KFH is putting its patients' interests first.

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V 000 V110
Corrective Action:

To effectuate an orderly transfer that protects the rights of patients, including the accrued time on the United Network for Organ Sharing (UNOS) wait list, KFHP has developed a formal transition plan (Attachment 1 "Transition Plan") in collaboration with TC1 and TC2 in cooperation with UNOS, and subject to the supervision of the California Department of Managed Health Care ("DMHC"), which regulates Kaiser Foundation Health Plan, Inc. ("KFHP"). Representatives of the DMHC, KFHP, KFHP, TC1, TC2, and UNOS meet formally at least weekly to implement the Transition Plan. (Attachment 2 "RTC Transition Plan Action Log"). KFHP also continues to monitor its systems to ensure adequate oversight of the RTC.

V 110
Accountable Party: Area Manager (see next paragraph)

Monitoring: Weekly meeting minutes and issue tracking action log.

On June 21, 2006, the KFHP Board of Directors appointed the Senior Vice President/Area Manager ("Area Manager") to serve as the Governing Body of the RTC. (Attachment 3 "KFHP Board Resolution") (Attachment 4 available onsite - "Certificate of Board Approval of Resolution") Acting on behalf of KFHP, the Area Manager has full legal authority and responsibility for RTC operations. He is advised in this role by the RTC Governing Body Advisory Committee ("GBAC"). The

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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V 110 (continued)

Governing Body Advisory Committee includes the RTC Medical Director, Chief Executive Officer (CEO), transplant surgeon, dietician, social worker, KFH-San Francisco Chief of Staff, RTC patient and others (Attachment 5 "GBAC charter") (Attachment 6 "GBAC Minutes of June 21, 2006" – available onsite)

Accountable Party: Area Manager

Monitoring: GBAC meeting minutes

June 21,
2006

Effective June 21, 2006, the Area Manager adopted Policies and Procedures for the RTC. On an annual basis, the GBAC will review and revise as necessary the RTC policies and procedures, which shall be implemented by the RTC upon approval of the Area Manager. (Attachment 7 "RTC Policy and Procedure Manual")

Accountable Party: Area Manager

Monitoring: GBAC meeting minutes

With the assistance of the Renal Service Unit Team ("RSUT"), the Area Manager has developed a Quality Program Plan (see V112). The RSUT is a multidisciplinary inter-departmental quality improvement committee focused on end stage renal disease ("ESRD"), which includes review of care provided to RTC patients. The RSUT provides periodic reports to the Area Manager. (Attachment 8 "Renal Service Unit Team Charter") (Attachment 9 "Renal Service Unit Team Quality Plan") (Attachment 10

V 110 (continued)

"Renal Transplant Center Quality Program Plan") (Attachment 11 "Renal Service Unit Team Minutes" available onsite)

Accountable Party: Area Manager

Monitoring: RSUT meeting minutes

May 22,
2006

On May 22, 2006, the Area Manager prepared the initial Transition Plan for transferring KFH patients to TC1 and TC2 based on agreements reached through discussions with TC1 and TC2, supervised by the DMHC and with the participation of UNOS. This Transition Plan is an evolving document based on continuing dialogue between and among the parties addressing the needs of specific patients and similarly situated patients. Contingencies for the implementation of the Transition Plan are reviewed at the weekly meetings between DMHC, UNOS, TC1, TC2 and the RTC and at the regular meetings of the RTC Transition Team. (See V114)

Accountable Party: Area Manager

Monitoring:

Weekly meeting minutes and issue tracking action log

June 21,
2006

Effective June 21, 2006, the Area Manager appointed a CEO who is responsible for management and administration of the RTC.
(Attachment 12 "Letter of Appointment of CEO" – available onsite) (See V116)
The CEO is a registered nurse who

V 110 (continued)

meets the demonstrated competencies outlined in 42 C.F.R. Section 405.2102. The CEO's written position description identifies the CEO's accountabilities, qualifications, and reporting relationship to the Area Manager. The CEO's orientation program addressed the RTC program, staff, and operations.

The CEO reports to the Area Manager. The CEO works with the RTC Medical Director in implementing the Transition Plan. (See V130)

The CEO acts in accordance with the delegations outlined by the Area Manager. (See V130 and V134).

The CEO has employed sufficient qualified employees and has ensured that they have had appropriate orientation to their responsibilities in compliance with the requirements. (See V141).

Accountable Party: Area Manager

Monitoring:

Monthly reports of RTC Transition Plan progress from CEO to Area Manager. Evidence of achieving corrective actions stipulated in CMS Plan of Correction from CEO to Area Manager.

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V 110	Continued From page 1 appropriate orientation to their work responsibilities (V141). The cumulative effect of these practices resulted in failure of the RTC to deliver statutorily mandated services and comply with Federal requirements under Governing Body and Management.	V 110		
V 112	405.2136 GOVERNING BODY: HEALTH AND SAFETY The governing body adopts and enforces rules and regulations relative to the health care and safety of patients. This Standard is not met as evidenced by: Based on record review and interview, the governing body did not adopt and enforce rules and regulations including those relative to quality assurance and performance improvement to ensure the delivery of quality care to patients. Finding includes: Review of the RTC's Quality Improvement Program (with an "effective date" of 2004) revealed that, "with the integration of the kidney and pancreas services," the goal was "to provide ongoing assessment of Quality Indicators, implementation of Quality Improvement Program and ultimately, (and) delivery of improved member and provider services." Accordingly, the program goals included: a. evaluation of patients on the UNOS kidney transplant waiting list for outside medical programs regarding "time from evaluation to name placed on UNOS waiting list," as well as "time on waiting list;"	V 112	V 112 <u>Corrective Action:</u> The Area Manager has taken the following measures to assure that the RTC has an ongoing Quality Program Plan that continually monitors its operations and ensures the delivery of quality care to its patients. The RTC is managed by the CEO under the oversight of the Area Manager. The RTC has adopted a Quality Program Plan (See Attachment 12) and RTC Program Description (Attachment 13: "RTC Program Description") for pre and post transplant services. The Area Manager is responsible for assuring that a planned and systematic process for monitoring and evaluating the quality and appropriateness of patient care services is in place, implemented and effective. The GBAC will monitor and act upon data obtained through the Quality Program. The Quality Program goal is to continuously improve operational performance and quality outcomes by monitoring and acting on the following indicators:	June 21, 2006 June 21, 2006 June 21, 2006 and ongoing July 31, 2006 and ongoing

(V 112 continued)

- a. Evaluation of RTC patients' transition from the RTC to the Waiting Lists of the RTC Contracted Transplant Centers (TC1 and TC2)

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V 112	Continued From page 2	V 112		
	<p>b. evaluation of Quality Indicator data for the first year post transplant for patients who received kidney and/or pancreas transplant during the years 2002 and 2003 relative to "time on the waiting list to transplant," the "number of patients enrolled in pharmaceutical company sponsored studies and study outcomes," "rejection episodes," "incidence of opportunistic infections," and "hospitalization rate following discharge from transplant surgery;"</p> <p>c. evaluation of patient access for transplant candidate evaluation at non-RTC transplant programs from "time of evaluation referral to appointment," and "incidence of members referred and not seen;" and</p> <p>d. evaluation of member satisfaction with transition to transplant services at the RTC.</p> <p>Review of documents including minutes following each QUEOC (Quality Utilization and Oversight Committee) and QHIC (Quality Health Improvement Committee) meetings for 2003, 2004, and 2005 revealed the lack of documented evidence of any evaluation, monitoring, or resolution relative to the goals specified above. In addition, there was no evidence of any quality assurance and performance improvement plan for the RTC for 2005 and 2006 particularly following the transfer of patients from TC1 and TC2 from a process review perspective and potential effects on patient waiting times, continuity of care, and other outcomes.</p> <p>While transplant center staff interviewed during the survey stated that the RTC had "good" survival rates, there was no evidence that operations and other components of the program</p>		<p>V 112 (continued)</p> <p>b. Evaluation of clinical outcomes for the first year post transplant patient. July 31, 2006</p> <p>c. Comparison of RTC clinical indicators against regional and national centers supplied by the Scientific Registry for Transplant Recipients to ensure the delivery of quality care to RTC patients. July 31, 2006</p> <p>d. Evaluation of patient access for transplant candidate evaluation at contracted TC1 and TC2 from "time of evaluation referral to appointment" and "incidence of patients referred and not seen." July 31, 2006</p> <p>e. Evaluation of patient satisfaction with transition from transplant services at the RTC to the contracted TC1 and TC2 Renal Transplant Centers. July 31, 2006</p> <p>f. Evaluation of patient satisfaction with current services at RTC. July 31, 2006</p> <p>g. Rate of Organ declines by RTC. July 31, 2006</p> <p>h. Evaluation of the accuracy of the turn down codes used by the Organ Procurement Organization (OPO). July 31, 2006</p> <p>i. Audit of data accuracy of UNOS submissions. July 31, 2006</p> <p><u>Accountable Party:</u> Area Manager</p>	

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V 112: Continued From page 3

were being reviewed and evaluated to ensure the delivery of quality care to patients. Record review, for example, revealed the lack of evidence that the RTC periodically collected and analyzed data including rate of organ declines to determine how use of available organs could be maximized; the mortality of patients on the waiting list; the efficiency of record keeping including those pertaining to patient record information and other processes; as well as the accuracy of data transmitted to UNOS (United Network for Organ Sharing). In addition, there was no written indication that SRTR (Scientific Registry for Transplant Recipients) information, for example, was being reviewed to determine how the RTC compared with other centers regionally and nationally.

During an interview on 5-8-06, MS1 stated that the RTC was not monitoring its turn-down ratio (for kidneys) because the OPO (organ procurement organization) was already doing this for them. There was no evidence however, if this information was routinely obtained by the RTC particularly in that it has the option to revise the turn-down code (used by the OPO) if it did not agree with the OPO.

Further record review revealed that in 2003, TC1 transplanted 141 member patients (or 41% of its total volume of transplants performed). TC2 on the other hand was noted to have performed a total of 27 transplant for a combined total of 168.

In 2004 TC1 performed 140 transplants on member patients (or about 38% of its volume), while TC2 performed an additional 25 transplants for a total of 165 transplants.

In 2005, transplants on member patients at TC1

V 112

V 112 (continued)
Monitoring:

1. The GBAC is responsible for using the Quality Program indicators to ensure that the program has the capacity and capability to meet the needs of the RTC patient population, including access to organs, credit for wait time, prompt evaluation and integration of care with TC1 and TC2.
Accountable Party: CEO as co-chair of the GBAC
June 21, 2006
2. CEO will provide monthly reports to the Area Manager through the GBAC and KFHSF Quality Utilization and Oversight Committee (QUEOC) (Attachment 14: "KFH San Francisco Professional Staff Bylaws" available on site) on evaluation, monitoring and/or resolution relative to the indicators listed above (a through i). There will be an annual review of the Program Description and Quality Program Plan.
Accountable Party: CEO as co-chair of the GBAC
June 21, 2006
3. The Northern California Region Quality Oversight Committee (QOC) exercises oversight of the RTC Quality improvement process by requiring regular reports from the Area Manager. Reports will be required no less than quarterly to ensure program capacity and effectiveness.
Accountable Party: Co-Chairs of QOC
August 31, 2006

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V 112 Continued From page 4
dropped to 14 (or 6% of the volume) and no transplants were noted as performed on member patients at TC2.

While the RTC performed a total of 56 transplants in 2005, there was no evidence that the RTC conducted a program review involving its structures and operations, as well as its ability to continue to meet the needs of the increasing number of patients and those others already in the program, to prevent or minimize service interruptions and facilitate efficient delivery and continuity of care.

V 114 405.2136 GOVERNING BODY: OPERATION

The governing body adopts and enforces rules and regulations relative to the general operation of the facility.

This Standard is not met as evidenced by:
Based on record review and interview, the governing body did not develop and enforce rules and regulations relative to the general operation of the RTC (renal transplant center).

Findings include:

1. During an interview on 5-8-06, MS1 stated that the hospital previously contracted with TC1 and TC2 to perform renal transplants for its member patients. After the decision was made to terminate the contract in 2003, TC1 and TC2 were notified and the transfer to the RTC of "over 1500 patients" began in mid-2004.

Review of documents revealed the lack of written evidence of any governing body involvement in

V 112

V 114

On June 21, 2006, the KFH Board of Directors appointed the Area Manager to serve as Governing Body for the RTC.

V 114

The Policies and Procedures, Program Description, Transition Plan, and Quality Program Plan of the RTC were presented at the June 21, 2006 GBAC meeting. Effective June 21, 2006, the Area Manager approved the aforementioned documents for the RTC. These will be reviewed annually by the Area Manager.

1. Beginning on May 22, 2006, the Area Manager drafted a detailed Transition Plan in collaboration with the CA Department of Managed Health Care, UNOS and representatives from TC1 and TC2 for the purpose of transferring RTC patients to TC1 and TC2 respectively. The RTC developed the Transition Plan in order to ensure an orderly, effective, and patient centered transition.

June 21, 2006

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V 114 Continued From page 5
the planning, implementation and oversight of the transfer of these patients. While review of QUEOC (Quality Utilization Executive Oversight Committee) meeting minutes dated 5-3-05 revealed that the region to which hospital belonged to was "currently developing an internal transplant program for solid organs," there was lack of documentation of a plan relative to the manner with which the transfer was to be accomplished in light of the large number of patients involved; the effect to patients still being evaluated or already on the RTC's waiting list; consideration for the number of staff required and their level of training and experience to accomplish the task; consideration for the rights of patients and the potential consequences of such transfer; and the need to develop contingencies should any problems arise.

For example:

a. During separate interviews on 5-8-06, MS1 and PTC1 stated that the RTC was given a document in 2004 by their regional office containing names of patients to whom letters were to be sent informing them that they would financially be responsible for the cost of the kidney transplant performed outside of the renal transplant center after 9-1-04. Review of this list revealed 1964 patients' names which, according to staff interviewed, were not only on the waiting list at TC1 and TC2, but other patients receiving dialysis in outpatient clinics, being evaluated for transplants, or being evaluated by nephrologists for pre-chronic kidney disease. Further record review revealed the lack of consideration for any confusion particularly for patients who have not opted for transplantation and therefore may not be on the list; have not qualified for transplantation; or have not had any discussion

V 114 **V 114 (continued)**
On May 22, 2006, KFH amended contracts for services at TC1 and TC2. RTC completed transplant authorizations for patients who had remained on either the TC1 or TC2 wait lists, as of May 24, 2006. (Attachment 15 "UCSF Letter of Agreement" and "Transition Plan" Attachment 16 "UCD Letter of Agreement" and "Transition Plan" available on site)

Under the leadership and oversight of the Area Manager, the RTC began the Transition Plan. During the transition period, RTC continues to provide clinical services for patients currently wait-listed at RTC and for post-transplant patients. RTC also continues to perform transplant surgeries as deceased donor organs become available and living donors are identified and deemed clinically appropriate.

May 22, 2006
May 22, 2006

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V 114 Continued From page 6
about transplantation as a treatment option. During the same interview, PTC1 added that a "large number" of patients failed to respond to the letter, did not return required consent forms, and/or did not follow directions and faxed the consent forms to UNOS themselves.

b. Review of QUEOC meeting minutes revealed the lack of governing body involvement in the development of letters which, according to staff interviewed on 5-8-06 and 5-9-06, were sent to patients in June, 2004. Review of model letters made available by staff on 5-9-06 revealed one dated 6-22-04 that "beginning September 1, 2004, our Program, together with your (hospital) Nephrologists, will begin providing you with your transplant care." The same letter informed the patient that "you will be financially responsible for any kidney transplant services you receive from (TC1) after September 1, 2004."

Another model letter dated 6-23-04 which, according to staff in the same interviews was sent to patients, stated that "the opening of our Regional Kidney Transplant Program will result in a change in your current authorization for kidney care," and that "effective September 1, 2004, your current authorization for kidney transplant services provided to you by (TC1) will expire." The same letter added that "kidney transplant services at (TC1) on or before August 31, 2004 will continue to be covered as they have been in the past," and that "as a Medicare Cost member, or since Medicare is your primary payer, you may choose to use your medical benefits outside of the (hospital 's) network." The letter cautioned the patient however that "if you continue to use (TC1), you will be financially responsible for billed copayments and any charges not covered by Medicare."

V 114 V 114 (continued)

(Attachment 17 "RTC Transition Team minutes" available on site)

a. The comprehensive Transition Plan (embodied in the written document, "Transfer of Patients to Outside RTC Policy and Procedure" see Attachment 7) includes:

- The identification of RTC patients on the May 5, 2006 UNOS Wait List (UNOS center ID = CAKP);
- The identification of patients who are eligible for transplant wait listing but not yet wait listed for the RTC, based on review of the KP ESRD patient population database;
- The referral of newly identified patients who need pre-transplant evaluation to TC1 or TC2.

According to the Transition Plan, patients on the RTC Wait List will be transferred over time by category, based on clinical status and Wait List times. The RTC developed a sequential plan for transferring each patient that includes contacting the patient, preparing the medical record, sending a copy to the medical record to TC1 and/or TC2.

(Attachment 18 - "CAKP UNOS Wait List" available on site)

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V 114 Continued From page 7

During interviews on 5-8-06, MS1 stated that the letters were developed by herself, MS2 and TD1, and that the letter dated 6-23-04 was intended for patients who may have secondary payor sources.

While these letters informed patients that they would be financially responsible for kidney transplants performed at TC1 or TC2 after 9-1-04; and that arrangements were being made for their transfer to the RTC, there was no indication that patients were informed of their rights or of other available options as well as potential consequences of the transfer. Review of a list provided by the RTC on 5-12-06, for example, revealed the names of 95 patients described by staff as having secondary payor sources. Review of the letter dated 6-23-04 however revealed the lack of indication that these patients have been informed about how their secondary payor sources might be used to pay for kidney transplants should they elect to remain at TC1.

In addition, on 5-11-06, a copy of a letter dated 5-10-04 was obtained at TC2 detailing concerns by the transplant director that patients (at TC2) would have to wait longer for a kidney following their transfer to the RTC which is under the service area of another organ procurement organization (OPO). The letter addressed to MS2 noted that patients on the waiting list at TC2 "who in general have been on the waiting list for a relatively short time will have little chance of being transplanted at your center until they have accumulated more waiting time and rise to the top of your list." The letter added that patients on the wait list at TC2 "would have to wait an average of 1.5 to 3.6 years longer for transplantation, depending on the blood type."

V 114

V 114 (continued)

On or about May 9, 2006, it was agreed that for KFHP members who were already on TC1 or TC2 wait lists, transplants would be authorized if kidneys became available. This agreement is consistent with the May 10, 2006 Stipulated Agreement between DMHC and KFHP.

May 9, 2006

(Attached 19 "Stipulated Agreement")

Accountable Party: Area Manager

Monitoring:

Weekly report on Transition Plan implementation.

Monthly report of clinical outcomes at GBAC.

b. On May 22, 2006, letters were sent advising all known affected patients of the transition process. (Attachment 20 "RTC Transition Patient Packet") Just prior to each patient's transition, individual letters are sent advising him/her of the options, providing the UNOS "Wait Time Transfer Form" and soliciting the patient's preference for TC1 or TC2. (Attachment 21 "Template Patient Letters") DMHC approved all letters sent to patients.

May 22, 2006 and ongoing

Since May 13, 2006, RTC patients can contact a designated hotline via a toll-free phone number, staffed seven days a week, 24 hours/day to supplement the KFHP Member Services Call Center. The hotline promptly refers all calls requiring clinical follow-up to the RTC staff, who must contact the patient within 48 hours. DMHC approved scripts used by the hotline and RTC. (Attachment 22 "Scripts")

May 13, 2006 and ongoing

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V 114 Continued From page 8

On 5-10-06, TC2 staff provided a copy of a letter dated 6-9-04 from the RTC and signed by MS1, MS2, and TD1. This letter, according to the staff interviewed, was sent to a patient on the waiting list at TC2 announcing that "by early fall of 2004," the RTC "will provide care for members who need a kidney transplant." While the letter added that "during this transition, you will not lose your place on the kidney transplant waiting list," there was no indication that the patient was informed about how his/her chances for a kidney transplant might be affected moving from one OPO service area to another where the demand for available kidneys is higher and waiting lists at several transplant centers much longer.

During the survey, copies of actual letters sent to patients in June, 2004 were requested from RTC staff but none were received.

c. Review of documents further revealed the lack of written policy and procedures outlining how the transfer of over 1500 patients was to be accomplished taking into consideration the processes involved; the required documentation to complete each patient transfer; and the impact to new patients being evaluated and to the follow-up evaluations of patients already on the waiting list of the RTC.

During an interview on 5-8-06, MS1 stated that discussions and meetings were held at the administrative level about how the transfer of patients was to be implemented but that no minutes were kept of these meetings. In another interview on 5-9-06, TD1 stated that problems and other issues encountered during the transition were assigned to a specific transplant center staff. Problems with medical record

V 114

V 114 (continued)

Patients will be informed of their rights and responsibilities by letters approved by DMHC and CMS. (see V215, V222)

Accountable Party: Area Manager

Monitoring:

100% concurrent monitoring of transition of each patient by Compliance Officer/designee

July 15, 2006

Beginning June 20, 2006

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V 114 Continued From page 9

information, for example, were assigned to a pre-transplant coordinator for follow-up and resolution, and those relative to data entry were given to the data coordinator. TD1 added that instructions given to staff members were not always documented and that procedures were not always written.

During an interview on 5-9-06, DC1 explained that incomplete medical records were a significant reason for the delay in that without the required information, the patient could not be added to the RTC's waiting list even if the patient had completed and signed the wait time transfer form. DC1 added that she had to return each incomplete record to the pre-transplant coordinator who was responsible for making the necessary inquiries to obtain the information. DC1 stated that over a period of time, there were over "1000 incomplete records."

During another interview on 5-12-06, PTC1 stated that problems with incomplete medical records were ongoing and that TD1 was always notified. PTC1 added that TD1 and MS1 at times assisted in getting some of the necessary information. In spite of this however, there was no evidence that a written policy and procedure was developed defining how the flow of paper work was to be handled. In addition, there was no evidence that a responsible individual, for example, was identified to ensure that medical records were actually received in a timely manner and reconciled with requests made at TC1 and TC2. Review of a copy of an e-mail by TC2 staff dated 11-19-04 in response to the repeated requests for medical records urged the RTC "to re-review your list" as "I cannot afford the additional staff time to repeat work that was already been done."

V 114

V 114 (continued)

c. The RTC policies and procedures address the organization of the transition to TC1 and TC2, the documentation of the transition process, and communication with patients. The RTC Policy and Procedure manual has been revised, approved by the Area Manager on June 21, 2006 and all staff have been educated on the relevant policies and procedures for their roles. The Transition Plan approved by DMHC will govern transfers to TC1 and TC2.

Accountable Party: Area Manager

Monitoring:
Annual review of Policy and Procedure Manual by GBAC and approval by Area Manager

Audit of staff knowledge and implementation of policies by Compliance Officer/designee

June 21, 2006 and ongoing

July 31, 2006

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V 114 Continued From page 10

During the same interview on 5-9-06, TD1 stated that there had been some difficulty obtaining medical records from other centers and that several attempts were made to get this resolved with the center involved. Review of written communication between the RTC and TC1 revealed that while a letter dated 3-8-04 was sent by the RTC to TC1 regarding the delay in obtaining medical record information, this letter however was relative to the delay in obtaining post-transplant medical records and not pre-transplants.

In addition, review of RTC documents revealed the lack of evidence that policy and procedures were developed relative to data entry required for adding patients to the RTC's waiting list.

d. Notwithstanding that over 1500 patients were to be transferred to the RTC from their initial primary centers, review of QUEOC meeting minutes and other documents revealed the lack of consideration regarding the need for additional staff to enable the RTC to accomplish the task within the required timeframe for completion. Review of transplant center documents revealed a deadline of 1-31-05 by which all patients were to be on the RTC's waiting list including the transfer of accrued wait time from their initial primary centers.

During an interview on 5-8-06 and again on 5-12-06, PTC1 stated that she was the only pre-transplant coordinator at the time the transfers began and was involved in all aspects of the transfer including the mass mailing of letters, conducting follow-up calls, obtaining required medical record information, participating in pre-transplant evaluations, and answering questions from member patients regarding

V 114

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V 114 Continued From page 11 concerns they have about the process. PTC1 explained that in some cases, letters were mailed several times as patients had moved or had several addresses on file. PCT1 added that she was also new at her position at the time having just finished her orientation period. Sometime later, according to PCT1, another transplant coordinator was hired.

On 5-8-06, a list provided by RTC staff contained the names of 2080 patients on the waiting list for a kidney transplant as of 5-4-06. Review of the medical staff roster during the survey revealed that while the RTC had two transplant surgeons, there however was only one transplant nephrologist available for the care and follow-up of 91 patients already transplanted by the RTC; the postoperative care and follow-up of others transplanted at TC1 and TC2; the evaluation of new patients; and the evaluation and supervision of the medical care of patients being transferred from TC1 and TC2. In addition, the transplant nephrologist was also the medical director of the RTC with additional administrative responsibilities. Although there were two other transplant nephrologists on the roster, staff interviewed stated that 1 was "on leave" and the whereabouts of the other could not be determined. In light of this, there was no indication that the governing body was informed about how the lack of available nursing, administrative support, and medical staff might affect the continuing transfer of patients 20 months past 9-1-04 when patients were informed that they would be financially responsible for transplants performed at TC1 or TC2. During an interview on 5-12-06, MS1 stated that the transplant surgeons could also assist in the evaluation and care of pre and post transplant patients.

V 114 **V 114 (continued)**
On May 22, 2006, letters were sent to all known affected patients, advising them of the planned process (enclosures included UNOS Facts and Figures and DHHS HRSA Partnering with your Transplant Team). Just prior to each patient's transition, individual letters are sent advising him/her of the options, providing the UNOS Wait Time Transfer Consent Form and soliciting their preferences. The Department of Managed Health Care approved all letters sent to patients.

Since May 13, 2006, RTC patients can contact a designated hotline via a toll-free phone number, staffed seven days a week, 24 hours/day, to supplement the KFHP Member Services Call Center. The Call Center promptly refers all calls requiring clinical follow-up to the RTC staff, who must contact the patient within 48 hours. DMHC-approved scripts are used.

May 22, 2006 and ongoing

May 13, 2006 and ongoing

d. While the RTC is in transition additional medical staff have been credentialed and privileged (as indicated). Five additional transplant nephrologists were credentialed on June 14, 2006. The physicians and surgeons will provide pre-transplant and post-transplant care to patients until all RTC pre-transplant care to patients until all RTC pre-transplant patients are transitioned to TC1 and TC2.

June 14, 2006

Accountable Party: Medical Director

Monitoring:
Monthly reports regarding physician staffing/capacity to Area Manager from Medical Director

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V 114	<p>Continued From page 12</p> <p>e. Review of the personnel file of DC1 revealed the lack of written evidence of any training regarding UNOS data entry processes, the use of the database, and other policies and procedures relative to her responsibilities as data coordinator. During an interview on 5-12-06, DC1 stated that she has not had any training on the use of the UNOS database other than a one-hour training by "telephone" in 2004.</p> <p>Review of the job description of DC1 revealed several responsibilities including coordinating UNOS regulatory reporting and managing clinical data bases for tracking, monitoring clinical outcomes; data collection and reports; overseeing quality assurance and monitoring program outcomes; supervising onsite data collection; preparing study progress reports/data summaries; reviewing and updating files; submitting required patient data to UNOS; overseeing the validity of all data entered into the systems; and ensuring that "information met all guidelines/compliance."</p> <p>During the same interview, DC1 stated that while she was familiar with components of the database she routinely accessed, she nonetheless relied on UNOS staff for certain specific reports. At the time the transition began, DC1 stated that she had to learn how to add patients to the RTC's waiting list and that signed consent forms for transfer of patients' accrued wait times had to be faxed to UNOS.</p> <p>2. Review of RTC documents as well a QUEOC meeting minutes revealed the lack of indication that the governing body was involved in monitoring the transfer of patients from their initial primary center to the RTC to ensure that it was</p>	V 114	<p>V 114 (continued) (Attachment 23 "Credentials/Privileges Files" available on site)</p> <p><u>Accountable Party:</u> Area Manager</p> <p><u>Monitoring:</u> 100% concurrent monitoring of transition of each patient by Compliance Officer/designee</p>	<p>June 20, 2006 and ongoing</p>
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V 114	<p>Continued From page 13 efficient, effective, and completed within the timeframe specified.</p> <p>For example:</p> <p>a. While several RTC staff stated during interviews that there were still patients whose transfers have to completed, none knew the actual number of patients involved.</p> <p>During an interview on 5-8-06, PTC1 stated that of over 1500 patients involved, about 10 patients were still waiting to have their transfer to the RTC completed. PTC1 attributed the delay to a variety of reasons including failure to sign their wait-time transfer consent forms, incomplete medical record information, failure to contact the transplant center, death, or that patients may have obtained other primary healthcare coverage elsewhere.</p> <p>During a separate interview on 5-8-06, TD2 stated that she did not know the exact number of patients involved but that DC1 would be able to give the actual number.</p> <p>During another interview on 5-12-06, MGA1 stated that there were about 60 patients whose transfers have yet to be completed and that the status of these patients was "unknown."</p> <p>On 5-9-06, DC1 provided a list of patients whose transfers were still to be completed. Review of this list revealed the names of 86 patients whose status according to DC1 were still "unknown" twenty months after 9-1-04 when patients were initially informed that they would assume the financial costs for their kidney transplant if performed at TC1 or TC2. Review of RTC documents as well as interviews with staff</p>	V 114	<p>V 114 (continued) e. The RTC has revised its UNOS Wait List Policy and Procedures. On June 22, 2006, RTC staff completed additional training on UNOS Wait List Management Policies and Procedures via web-cast conducted by UNOS. The RTC has employed one additional FTE to complete data entry and data validation on the UNOS wait list, and implemented a process for tracking the status of each patient as they transition off the RTC wait list (with verification from UNOS). All data entry is conducted in compliance with UNOS timeframes as of June 20, 2006.</p> <p><u>Accountable Party:</u> CEO</p> <p><u>Monitoring:</u> Audit of compliance with UNOS Wait List Policies by Compliance Officer/designee on monthly basis</p> <p>2. The RTC has established processes for monitoring the transfer of patients and control of records under the Transition Plan supervised by DMHC.</p> <p><u>Accountable Party:</u> CEO</p> <p><u>Monitoring:</u> 100% concurrent monitoring of transition of each patient by Compliance Officer/designee</p>	<p>June 22, 2006</p> <p>July 31, 2006 and ongoing</p> <p>Beginning June 20, 2006</p>

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V 114. Continued From page 14

revealed that in spite of this, a written plan to expedite placement on the wait list and transfer accrued wait times, was not available. In addition, there was no indication that RTC staff periodically monitored their process so that no patient was left unaccounted for.

On 5-10-06, a list containing the names of 209 patients who were still on the waiting list at TC1 was obtained. The list according to TC1 staff interviewed contained member patients whose transfer to the RTC could not be verified (hence their showing on TC1's waiting list). The staff added that the list had been shared with the RTC on 5-5-06. When this information was conveyed on 5-12-06 and the discrepancy between this and the RTC's was pointed out, MGA1 stated that work on reconciling the list began "about a week ago."

b. Review of documents obtained at TC2 revealed an e-mail dated 11-10-04 by TD1 informing TC2 staff that authorization for kidney transplants at TC2 "are fully cancelled" and that the RTC "was in the process of transferring these patients to our wait list through UNOS." The e-mail added that the transfer "should be completed by 11-12-04 at the latest."

Following this announcement and in consultation with medical and surgical staff, TC2 thereafter began moving 65 remaining member patients on their waiting list to "UNOS Status 7." During an interview on 5-11-06, TC2 staff explained that "Status 7" meant putting the patients on the inactive status so that while these patients remained on the UNOS list, they however would not be offered a kidney when one became available (until they were back on the active status).

V 114 V 114 (continued)

a. All correspondence and phone contacts have been documented for each individual patient and are being tracked in a database to assure that all patients make an appropriate and complete transition. (Attachment 24 "Patient Contact Data Base" available on site)

Accountable Party: CEO

Monitoring:
 100% review of each patient transfer process by Compliance Officer/designee with monthly report to Area Manager

May 13, 2006 and ongoing

June 20, 2006 and ongoing

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V 114 Continued From page 15

On 11-16-04, another e-mail sent by TD1 informed TC2 staff that member patients on TC2's waiting list had "all (been) listed with our center effective 11-18-04," but that "it will take time to see them transferred out from your center to ours because of the volume." The e-mail added that "leaving them in Status 7 does not penalize them." It was not clear at this point whether these patients were still to be added to the RTC waiting list on 11-18-04 in that the e-mail date was 11-16-04, or whether their accrued wait time while at TC2 was transferred as well. Without transfer of their accrued time, the patients start at the bottom of the waiting list of the RTC.

Further record review revealed that notwithstanding TD1's e-mail above dated 11-16-04, eleven months later on 10-13-05, a list containing 11 patient names was faxed to MS1 by TC2 staff. The cover page on the fax transmission noted: "the following list of patients have not transferred off of our list." The note added to "let me know if a wait time transfer form has been completed."

Further interview with TC2 staff on 5-11-06 revealed that as of 5-1-06, six patients continue to remain on the waiting list at TC2; and since these patients remain on the inactive list, they will not be offered a kidney even if they have accrued time and were on top of the list (by allocation rules).

c. Review of additional information obtained at TC1 revealed a document identified by TC1 staff as a list from UNOS containing 947 patients' names and the dates the patients were transferred from TC1 to the RTC.

V 114 V 114 (continued)

b. The RTC has established a back-up authorization process with TC1 and TC2. In any instance where an individual transplant authorization is missing from a patient's medical record and an organ becomes available, the RTC will issue a retroactive authorization to ensure that any future organ offers are appropriately authorized.

Accountable Party: Area Manager

Monitoring:
Weekly meeting with DMHC, RTC and TC1 and TC2.

Member grievances regarding out-of-plan services

May 22, 2006 and ongoing

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V 114 | Continued From page 16

While patients were informed on June, 2004 that they would be responsible for the financial costs of a kidney transplant performed at TC1 (or TC2) after 9-1-04, the list referenced above noted transfer completion dates well into 2005 and 2006. Within this period and while on the waiting list at TC1, these patients therefore could not be transplanted even when a kidney was available unless they were willing to shoulder the financial cost themselves. Also, while these patients may have been added to the waiting list of the RTC, they still start at the bottom until after their accrued wait times are transferred. Consequently, because TC1 was informed that no further kidney transplants on member patients would be authorized after 9-1-04, and because of the delay in getting patients added to the RTC's waiting list and/or their accrued wait times transferred, these factors have prevented patients, especially those at the top of the list (by allocation rules), from receiving a transplant even if they were near-perfect match with available kidneys. During an interview on 5-10-06, a medical staff member from TC1 stated that several zero-mismatch kidneys were offered but that member patients were unable to avail of these kidneys because they may not have been added to the waiting list of the RTC and that while they may still be on the waiting list at TC1, authorizations have stopped and patients would not be able to shoulder the financial cost if the transplant was performed at TC1.

Review of a "refusal" list obtained from the OPO revealed 25 "zero-mismatch" kidneys offered to 24 member patients on the waiting list at TC1 between 1-22-05 and 12-2-05 that were refused. One member patient was noted to have been offered a zero-mismatch kidney twice (on 3-23-05

V 114 | V 114 (continued)

c. The RTC Quality Program Plan provides for monitoring the transition of patient wait time and organ disposition.

June 21, 2006

Accountable Party: Area Manager

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V 114 Continued From page 17 and 5-10-05) both of which were declined as well.

UNOS policy and procedures define zero-mismatch as "occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens," or a match "occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B and DR antigens when at least one antigen is identified at each locus." Thus, a zero-mismatch kidney represents the best possible match between the donor and the recipient.

Further review revealed that 13 member patients had their transfer to the RTC completed over a year from 9-1-04, the cut-off date for which authorizations for kidney transplants at TC1 stopped. In addition, fourteen (14) other names on the refusal list were currently on the waiting list of the RTC.

While the quality of the zero-mismatch kidneys described as "import offers" could not be determined or even whether they would have been acceptable for transplantation, the delay in completing patient transfers and the denial of authorization for transplants performed at TC1 (or TC2) after 9-1-04 have denied some of the patients the opportunity for available kidneys including zero-mismatch kidneys.

3. Even while problems were being encountered extending the transfer of patients past the deadline for completion, there was no evidence that the development of contingencies was considered and implemented so that patients who have accrued wait times but whose transfer to the

V 114

V 114 (continued)
Monitoring:
Copies of the delivered medical records and the associated evidence of receipt are maintained. June 1, 2006

Copies of all transplant authorizations for each patient are maintained. May 24, 2006

100% review of each patient transfer process by Compliance Officer/designee with monthly report to Area Manager June 20, 2006

100% review of organ disposition log on a weekly basis by Medical Director with monthly report to Area Manager June 26, 2006

See also V 112

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V 114 Continued From page 18
RTC have not been completed, were not disadvantaged.

During interviews on 5-10-06, TC1 staff stated that in spite of the deadline set for 9-1-04 when authorization stopped and member patients were informed that they would have to be financially responsible for their kidney transplant performed at TC1 (or TC2), that the RTC nonetheless continued to approve certain transplants after 9-1-04 including dual organs such as kidney and pancreas, as well as other "special cases" involving pediatric patients.

Further record review revealed that authorization for kidney transplants at TC2 were also extended by the RTC to 9-17-04 following a request by the OPO to until the "regional crossmatch trays expire on September 17, 2004 at 5:00 p.m." During the same interview on 5-11-06, TC2 staff stated that the RTC continued to approve certain transplants such as dual organs but not single, cadaveric kidney procedures.

During an interview on 5-9-06, TD1 stated that she was aware of several kidney transplants that were authorized outside of the RTC even after the 9-1-04 deadline. TD1 added that approval was based on communication between the RTC and the centers involved. Review of RTC documents however revealed the lack of written evidence that TC1 and TC2 were informed about this possibility and of certain situations where this might be considered and how authorization could be obtained.

V 114
V 114 (continued)

3. Contingencies for the implementation of the Transition Plan are reviewed at the weekly meetings, with DMHC, CMS, TC1 and TC2. May 22, 2006

Regular meetings of RTC Transition Team. May 22, 2006

Accountable Party: Area Manager

Monitoring:
Weekly reports to Area Manager on Transition Plan implementation by CEC

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V 116 405.2136 GOVERNING BODY: CEO

The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

This Standard is not met as evidenced by:
Based on record review and interview, the governing body did not appoint a chief executive officer who was responsible for the overall management of the RTC.

Finding includes:

Review of the organizational chart revealed that TD2 was identified as the Transplant Program Director of the RTC. During an interview on 5-8-06, TD2 stated that she was the Service Director and was responsible for overall administrative functions including the supervision of staff working at the RTC. TD2 added that she had just assumed the position sometime in March, 2006 following the departure of the previous Service Director whose tenure was "brief."

Review of the "position definition" of the Transplant Program Director (which was that for the Service Director) revealed several responsibilities including, "plans, organizes, directs, evaluates and coordinates inpatient nursing services and/or integrated outpatient-inpatient nursing services..." and works with the hospital and health plan group in "developing strategic plans, providing quality care, cost effective services which are aligned with federal, state, and local regulations." In addition, the Transplant Director was responsible for the "direct development and implementation of quality and utilization across the continuum of care to ensure coordinated plans of treatment,

V 116

V 116

Corrective Action

- The Area Manager has appointed the CEO. The Area Manager has taken the following steps to ensure that the CEO coordinates the provision of services in accordance with the CEO's position description and the delegations outlined by the Area Manager:
 - o Development and review of policies and procedures
 - o Oversight of daily RTC operations
 - o Ensuring that all RTC equipment is appropriately and safely maintained consistent with defined program standards
 - o Hiring, training, evaluation and, if necessary, termination of RTC staff
 - o Planning the operating budget and monitoring financial performance
 - o Ensuring the delivery of quality care to RTC patients and the maintenance of a quality improvement program
 - o Providing oversight for RTC services contracted to TC1 and TC2
- The Program Description establishes the CEO's role in ensuring appropriate provision of transplant services. These delegations include but are not limited to:

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June 21, 2006 and ongoing

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V 116 Continued From page 20
customer focused delivery of services and cost effective utilization of necessary services."

The "position definition" did not require the Transplant Program Director to have previous transplant center administrative experience.

During the survey, interview and record review revealed the lack of evidence that the Transplant Program Director was aware of the difficulties and excessive delay in the transfer of patients to the RTC's waiting list. Review of available documents revealed the lack of evidence of any involvement and/or intervention by TD2 in any process review or development of a plan to expedite the transfer and/or reconciliation of patients whose status were yet to determined 20 months after they were initially told that they would have to be financially responsible for transplant performed at TC1 or TC2. A list provided by the RTC on 5-9-06 revealed the names of 86 patients whose status were noted as still "unknown."

During the same interview, TD2 stated that while she has had previous experience as Service Director in both hospital inpatient and outpatient units, she did not, however, have transplant center administrative experience. During the survey, TD2 was often unavailable or unable to provide information referring requests for information instead to other RTC staff. A review of the personnel file of TD2 revealed multiple training in leadership skills, however, there was no evidence that TD2 had training specific to renal transplantation.

V 116

- o Review of all patient complaints and associated resolution of the complaints.

V 116
Corrective Action

- The RTC Program Description also describes that while delegating these functions described above, the Area Manager remains fully accountable for these functions. June 21, 2006
- The CEO's position description identifies the CEO's accountabilities, qualifications and reporting relationship to the Area Manager. June 21, 2006
- The CEO's orientation ensures that the CEO is fully familiar with the RTC, staff and operations. June 21, 2006

Accountable Party: Area Manager

Monitoring

1. Review and approval of all relevant RTC documents by the Area Manager June 21, 2006
2. Monthly oversight report by the CEO to the Area Manager including: July 21, 2006
 - RTC statistics
 - Quality outcomes
 - Staffing summary
 - Contract monitoring that addresses performance of TC1 and TC2.
3. Quarterly evaluation of the CEO's performance in accordance with the CEO's position description and delegations outlined by the Area Manager. After four quarterly evaluations, evaluation will occur annually. September 30, 2006 and ongoing

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V 130 405.2136(c) CEO: LIAISON

Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, the medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body.

This Standard is not met as evidenced by:
Based on record review and interview, the governing body did not ensure that the Transplant Program Director maintained ongoing liaison among the governing body, and medical and nursing personnel and other professional and supervisory staff through meetings and periodic reports.

Finding includes:

Review of QUEOC (Quality Utilization Executive Oversight Committee) and QHIC (Quality Health Improvement Committee) meeting minutes, as well as RTC policies and procedures revealed the lack of documented evidence demonstrating ongoing liaison by the RTC, the governing body and other professional and supervisory staff. Review of QUEOC and QHIC meetings for 2003, 2004, 2005 and 2006, revealed the lack of indication that TD1 and TD2 periodically reported to and/or appraised the governing body about problems and other difficulties including the excessive delay in the transfer of pre-transplant patients to the RTC's waiting list. Further record review revealed the lack of indication of any appraisal and/or monitoring conducted by the governing body relative to the operations of the RTC.

V 130

Corrective Action: (See also V110)

The RTC is managed by the CEO under the direction and oversight of the Area Manager. The CEO is responsible for coordination of operational and administrative services of the RTC.

The Program Description establishes the CEO's role in ensuring the appropriate provision of transplant services, consistent with the delegations outlined by the Area Manager.

The CEO's position description identifies the CEO's accountabilities for integration of department staff medical records, IT systems, and hospital and transplant services providers

The CEO, co-chair of the GBAC, evaluates and maintains program performance goals.

The GBAC documents its deliberations, decisions, actions, and recommendations through contemporaneous minutes. The minutes are signed and dated by the GBAC co-chairs to document that minutes are representative of discussions and decisions of the GBAC.

(See also V112)

The Area Manager has developed and implemented a detailed operational Transition Plan in collaboration with the DMHC, CMS, UNOS, and representatives from TC1 and TC2, for the purpose of transferring RTC patients from the RTC to TC1 and/or TC2

June 21, 2006

June 21, 2006

June 21, 2006

May 22, 2006

V130, con't The CEO participates in regular meetings of the RTC Transition Team and gives regular updates to the GBAC. The CEO and Medical Director work with the Transition Team to oversee the transfer of the patients on the RTC Wait List by category, based on clinical status and wait list times. (See Transition Plan, V 114) June 21, 2006

Accountable Party: Area Manager

Monitoring:

1. Review and approval of all relevant RTC documents by the Area Manager June 21, 2006
2. Monthly oversight report by the CEO to Area Manager. July 21, 2006
This report will provide at a minimum:
 - RTC statistics
 - Quality outcomes
 - Staffing summary
 - Contract monitoring to address performance of TC1 and TC2
3. Quarterly evaluation of the CEO's performance, in accordance with the CEO's position description and delegations outlined by the Area Manager. After four quarterly evaluations, evaluation will occur annually. September 30, 2006

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V 130 Continued From page 22
During an interview on 5-9-06, TD1 stated that while there were discussions, for example, among MS1 and other RTC staff regarding the difficulties in obtaining medical records from TC1 and TC2 which contributed to the delay in the transfer of wait times and addition of pre-transplant patients to the RTC's waiting list, that these discussions were often informal and not always documented. When requested however, no written documentation of these discussions was presented.

V 130

V 134 405.2136(c)(3)(i) CEO: IMPLEMENT/COORDINATE

The responsibilities of the chief executive officer include but are not limited to implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.

This Standard is not met as evidenced by:
Based on record review and interview, the Renal Program Director did not always coordinate the provision of services in accordance with delegations by the governing body.

Finding includes:

Review of a model letter dated 6-22-04 which, according to staff interviewed, was intended for patients on the transplant waiting list at TC1 revealed that "beginning September 1, 2004, our Program, together with your (hospital) Nephrologist, will begin providing you with your transplant care." The same letter informed patients that "you will be financially responsible

V 134

V 134
Corrective Action:

The Program Description establishes the CEO's role in ensuring the appropriate provision of transplant services, consistent with the delegations outlined by the Area Manager.

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V 134 Continued From page 23
for any kidney transplant services you receive from (TC1) after September 1, 2004."

Another model letter dated 6-23-04 which, according to staff in the same interview was mailed to patients, stated that "the opening of our Regional Kidney Transplant Program will result in a change in your current authorization for kidney care," and that "effective September 1, 2004, your current authorization for kidney transplant services provided to you by (TC1) will expire." The same letter added that "kidney transplant services at (TC1) on or before August 31, 2004 will continue to be covered as they have been in the past," and that "as a Medicare Cost member, or since Medicare is your primary payer, you may choose to use your medical benefits outside of the (hospital's) network." The letter cautioned the patient however that "if you continue to use (TC1), you will be financially responsible for billed copayments and any charges not covered by Medicare."

Interviews with RTC staff during the survey revealed that after the letters were mailed, the transfer of patients to the RTC's waiting list began. Review of documents revealed that the deadline at which the transfers were to be completed was 1-31-05.

Review of the "position definition" of the Transplant Program Director (which was for the Service Director) revealed several responsibilities including the planning, organizing, directing, evaluating, and coordinating "inpatient nursing services and/or integrated outpatient-inpatient nursing services across the continuum of care ...". Further record review however, revealed that while the transfer of patients exceeded the deadline of 1-31-05, there was no evidence that

V 134

(V 134 continued)
The Program Description also describes that while delegating these functions described above, the Area Manager remains fully accountable for them.

The CEO ensures coordination of renal transplant services.

The Area Manager and the CEO have developed a process to ensure that all patient letters undergo review by the Area Manager and subject matter experts.

The CEO has developed and the Area Manager has approved an "RTC Patient's Rights and Responsibilities" policy. This "RTC Patient's Rights and Responsibilities" will be mailed to all RTC patients. (See Attachment 7)

A process has been developed that outlines expectations for timely notification and resolution of patient grievances.

June 21, 2006

June 21, 2006

July 15, 2006

June 21, 2006

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V 134 Continued From page 24

TD1 and TD2 were involved in developing and implementing contingencies to prevent or minimize interruption of services and/or the delivery of care to patients. Record review revealed that while transplantation involving dual organs, for example, were authorized past 9-1-04, there was no indication that consideration for the same was extended to patients especially to those who have accumulated wait times but were still on the waiting list at TC1 and TC2 because their transfers have not been completed. Review of records obtained at TC1 revealed the names of 947 patients a large number of whom had transfers completed past 1-31-05. TC1 staff interviewed on 5-10-06 revealed that evaluation of member patients stopped after 9-1-04 and kidneys offered to patients after this date were declined including those that were zero-mismatched or near perfectly matched kidneys.

Further record review revealed that authorization for kidney transplants at TC2 were also extended by the RTC to 9-17-04 following a request by the OPO to until the "regional crossmatch trays expire on September 17, 2004 at 5:00 p.m." During the same interview on 5-11-06, TD2 staff stated that the RTC continued to approve certain transplants such as dual organs but not for single, cadaveric kidney procedures.

In addition, review of documents obtained at TC2 revealed an e-mail dated 11-10-06 by TD1 informing TC2 staff that authorization for kidney transplants at TC1 "are fully cancelled "and that the RTC" was in the process of transferring these patients to our wait list through UNOS." The e-mail added that the process "should be completed by 11-12-04 at the latest."

V 134

(V 134 continued)

- Letters of Agreement have been completed with TC1 and TC2 for the provision of renal transplant services.
Accountable Party: Area Manager

Monitoring:

1. Review and approval of all relevant RTC documents by the Area Manager. June 21, 2006
2. Audit plan for review of patient authorizations for appropriateness. Results of audits to be reviewed and approved at monthly GBAC meetings. June 21, 2006
3. CEO review of all patient complaints, grievances and appeals. Summary statistics presented to Area Manager through GBAC monthly. July 31, 2006

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V 134 Continued From page 25
Following this announcement and in consultation with medical and surgical staff, TC2 thereafter began moving 65 remaining member patients on their waiting list to "UNOS Status 7." During an interview on 5-11-06, TC2 staff explained that "Status 7" meant putting the patients on the inactive status so that while these patients remained on the list, they however would not be offered a kidney when one became available (until they were back on the active status).

V 134

During an interview on 5-9-06, TD1 stated that she was aware of several kidney transplants that were authorized for member patients to be performed outside of the RTC even after the 9-1-04 deadline. TD1 added that approval was based on communication between the RTC and the centers involved. Review of RTC documents however revealed the lack of written evidence that TC1 and TC2 were informed about this possibility and of certain situations where this might be considered and how authorization could be obtained.

V 141 405.2136(c)(3)(vii) CEO: STAFF TRAINING

V 141

The responsibilities of the chief executive officer include but are not limited to ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

This Standard is not met as evidenced by:
Based on record review and interview, the Transplant Program Director did not ensure that

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V 141 Continued From page 26
the RTC employed a sufficient number of qualified employees and that employees had appropriate orientation to their work responsibilities.

Findings include:

1. Interviews with staff during the survey revealed that over 1500 patients were to be transferred to the RTC's waiting list from their initial primary centers. Review of QUEOC meeting minutes and other documents however revealed the lack of discussion or consideration for the need of additional staff to accomplish the task within the deadline set for completion. While model letters dated 6-22-04 and 6-23-04 revealed that patients were to be responsible for the financial costs of transplantation performed at TC1 after 9-1-04, the deadline at which all patients were to be added to the RTC's waiting list, including the transfer of accrued wait time from their initial primary centers, was 1-31-05.

During an interview on 5-8-06 and again on 5-12-06, PTC1 stated that she was the only pre-transplant coordinator at the time and was involved in all aspects of the transfer including the mass mailing of letters, conducting follow-up calls, obtaining required medical record information, participating in pre-transplant evaluations, and answering questions from member patients regarding concerns they have about the process. PTC1 added that in some cases, letters were mailed several times as patients had moved or had several addresses on file. PCT1 added that she was also new at her position at the time having just finished her orientation period.

In addition, a list provided by RTC staff on 5-8-06

V 141

V 141
Corrective Action:

1. The CEO employs sufficient qualified employees and has ensured they have had appropriate orientation to their work responsibilities. Particular attention has been paid to the duties of the pre-transplant coordinators (PTCs) to assure that adequate staff is available. There are now three PTCs and based upon alignment of their duties, the PTC function is adequately staffed. ("Plan for Staffing Resources" Attachment 7). Additional physician staff has been added to address RTC patient care needs.

The CEO has completed the following steps to validate that the RTC has a sufficient number of qualified employees who have received the proper orientation and training for their respective work responsibilities:

A 100% audit of onsite RTC human resources (HR) files was conducted for HR requirements. (Attachment 25: "HR File Audits" Available on-site). If required documentation was not available in the RTC HR file, the information was reviewed with the employee and documentation was placed in the HR file. All HR files are 100% compliant. (see V114)

Accountable Party: CEO

Monitoring:

The CEO receives regular reports on availability of nursing, administrative

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V 141	<p>Continued From page 27</p> <p>contained the names of 2080 patients who were on the waiting list for a kidney transplant as of 5-4-06. While the RTC had two transplant surgeons, there however, was only one transplant nephrologist available for the care and follow-up of 91 patients already transplanted at the RTC, the care and follow-up of others transplanted at TC1 and TC2, the continuing evaluation of patients for inclusion into the waiting list, as well as other medical issues concerning those patients being transferred from TC1 and TC2. In addition, the transplant nephrologist was also the medical director of the RTC with additional administrative responsibilities. In light of this, there was no indication that the governing body was informed about how the lack of available nursing, administrative support, and medical staff might affect the continuing transfer of patients 18 months past 9-1-04 when patients were informed that they would be financially responsible for transplants performed at TC1 (or TC2).</p> <p>2. Review of the personnel file of DC1 revealed the lack of written evidence of any training regarding UNOS data entry processes, the use of the database, and other policies and procedures relative to her responsibilities as data coordinator. During an interview on 5-12-06, DC1 stated that she has not had any training on the use of the UNOS database other than a one-hour training by "telephone" in 2004.</p> <p>During the same interview, DC1 stated that while she was familiar with components of the database she routinely accessed, she nonetheless relied on UNOS staff for certain specific reports. At the time the transfer of patients began, DC1 stated that she had to learn how patients were added to the waiting list, and that consent forms signed by patients authorizing</p>	V 141	<p>support staff and medical staff to ensure the continuing transfer of patients to TC1 or TC2</p> <p>Audit of staff knowledge and implementation of policies by Compliance Officer/designee.</p> <p>2. An additional full time Data Manager was hired and both Data Managers were trained on UNOS wait list.</p> <p><u>Accountable Party: CEO</u></p> <p>3. Job descriptions (Attachment 7) have been distributed to staff, signed and placed in RTC employee files. All HR files are 100% complete.</p> <p>RTC HR files were reviewed for documentation of initial and annual competency assessments and/or education and training. Evidence of completed competency assessments and education/training, including nurses, was placed in each RTC HR file. The competency checklist includes the assessment and care of pre-transplant patients and skills necessary to care for RTC patients. If not available, staff competencies were re-assessed and documentation of the review was placed in the RTC HR file. All HR files are 100% compliant.</p> <p><u>Accountable Party: CEO</u></p> <p><u>Monitoring:</u> Any new staff that is hired will have their RTC HR files reviewed at 30, 60 and 90 days by the HR Compliance Consultant to assure all requirements have been completed and documentation is in the RTC HR file.</p>	<p>July 31, 2006</p> <p>June 21, 2006</p> <p>June 19, 2006</p> <p>June 19, 2006</p> <p>June 22, 2006</p>

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V 141 Continued From page 28

transfer of their accrued time had to be faxed to UNOS.

Review of the job description of DC1 revealed several responsibilities including coordinating UNOS regulatory reporting and managing clinical data bases for tracking, monitoring clinical outcomes; data collection and reports; overseeing quality assurance and monitoring program outcomes; supervising onsite data collection; preparing study progress reports/data summaries; reviewing and updating files; submitting required patient data to UNOS; overseeing the validity of all data entered into the systems; and ensuring that "information met all guidelines/compliance." A review of the personnel file of DC1 revealed an initial competency checklist that noted that training on data reporting skills relative to UNOS, OPO, and other sources was to "begin on 8/2004." Further review however revealed the lack of evidence of any follow-up to ensure that DC1 had indeed acquired the skills and was competent in data reporting.

During a separate interview on 5-12-06 at 3:15 p.m., a regulatory compliance staff revealed that the initial competency checklist was the only competency evaluation in DC1's personnel file and that there were no other checklists in the file.

3. Review of the personnel records of 3 of five registered nurses' initial competency evaluation checklists documented that they had little or no knowledge of the assessment and care of pre-transplant patients. In addition, there was no documentation in their employment files that their skills were reviewed and that a determination was made relative to their being able to perform the responsibilities required by their job description.

V 141

For existing hourly employees, RTC HR files will be reviewed on the employee's anniversary date: to assure all requirements are completed and documentation is in the RTC HR file. For non-union, non-exempt and exempt employees, files will be reviewed when organization-wide annual performance reviews are due. Both audits will be conducted by the HR Compliance Consultant or designee.

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V 187 405.2137(a) WRITTEN LONG-TERM PLAN

There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (i.e., home, self-care) for each patient.

This Standard is not met as evidenced by:

Based on review of medical records and policy and procedures, the RTC did not develop a written long-term program which ensured that patients selected for transplantation would be medically suitable at the time they were selected for transplantation.

Finding includes:

Seventeen of 17 medical records reviewed revealed the lack of evidence that multi-disciplinary long-term plans were developed to identify risk factors or changes in patient health status that would be communicated to the ESRD facility or patient's physician to trigger a notice to the RTC that may contraindicate transplantation once the patient had been selected for transplantation.

While further review of the policy and procedure manual revealed a "Long-Term Program Protocol" for "Post-Transplant Follow-up" that established guidelines for the long-term follow-up for kidney transplant recipients, there however, was no policy or procedure available for a multi-disciplinary long-term program pre-transplant.

V 187

V 187

Corrective Action:

The RTC has implemented a process to assure there is a written long-term program to ensure that patients selected for transplantation are suitable at the time they are selected for transplantation. The RTC collaborates with the community based nephrologists, RN renal case managers and hemodialysis units to assure integrated multidisciplinary care planning occurs. The plan of care for each dialysis patient is completed as a component of this community based care. The plan of care for non-dialysis patients is developed by the primary treating nephrologist. The care plan is updated on a regular basis by members of the interdisciplinary care team. This process includes participation by the patient and/or his representative.

The RTC Long-Term Care Program (Attachment 7) for wait-listed patients was revised and implemented on June 20, 2006. All current wait listed pre-transplant patients will have an RTC Long-Term Care Plan Update form in their medical record.

June 20, 2006

July 22, 2006

A presentation will be made to the Kaiser Permanente Northern CA Region Renal Case Managers peer group to confirm the Renal Care Manager's accountability for complying with the multidisciplinary long-term care plans and collaboration with the RTC staff.

June 29, 2006

Accountable party: CEO

A presentation will be made on July 5, 2006 to the Kaiser Permanente Northern CA Region Chiefs of Nephrology to confirm their accountability.

July 5, 2006

Accountable party: Medical Director and
CEO

June 21,
2006

Policies and procedures were approved by
the Area Manager on June 21, 2006.

Monitoring:

July 30,
2006

Audit of the RTC medical records for
evidence of multidisciplinary long term care
planning by Compliance Officer/designee.

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V 192 405.2137(b) PATIENT CARE PLAN: WRITTEN, ASSESSMENT BASED

There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see §405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

This Standard is not met as evidenced by:
Based on review of medical records and the policy and procedures, the RTC did not develop written multi-disciplinary patient care plans for ensuring that patients selected for transplantation would be medically suitable at the time they were selected for transplantation.

Finding includes:

Seventeen of 17 medical records reviewed revealed the lack of indication that multidisciplinary patient care plans were developed to identify, improve and/or monitor risk factors or changes in patient health status that would be communicated to the ESRD facility or patient's physician to trigger a notice to the transplant center that may contraindicate transplantation once the patient had been selected for transplantation.

While review of the policy and procedure manual revealed that provisions were available for "Patient Education Programs" for "Pre and Post Transplant and Patient Responsibilities Pre and Post Transplant," however, there was no policy or procedure available for a multi-disciplinary patient care plans.

V 192

V 192
The RTC has implemented a policy and procedure that addresses multidisciplinary patient care plans. The RTC collaborates with the nephrologists, RN renal case managers and hemodialysis unit staff to assure integrated multidisciplinary care planning occurs. The interdisciplinary plan of care is based upon the nature of the patient's illness, includes an assessment of the patient's needs, and is regularly updated. The plan for each dialysis patient is completed as a component of this community based care. The plan of care for non-dialysis patients is developed by the primary treating nephrologists.

The RTC Long Term Care Program for wait listed patients was revised and implemented on June 20, 2006. All current wait listed pre-transplant patients will have an RTC Long Term Care Update form in their medical record.

June 20, 2006

July 22, 2006

A presentation will be made to the Kaiser Permanente Northern CA Region Renal Case Managers peer group to confirm their accountability for completing the multidisciplinary long term plans and collaborating with RTC staff.

June 29, 2006

Accountable party: CEO

A presentation will be made on July 5, 2006 to the Kaiser Permanente Northern California Region Chiefs of Nephrology to confirm their

July 5, 2006

accountability.
V 192 Cont.

Accountable Party: Medical Director and
CEO

Policies and procedures were approved
by the Area Manager on June 21, 2006. June 21,
2006

Accountable Party: CEO

Monitoring:
Audit of medical records for evidence of
multidisciplinary long term care planning
by Compliance Officer/designee. July 30,
2006

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V 215 405.2138 PATIENTS RIGHTS AND RESPONSIBILITIES

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to §205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public.

This Condition is not met as evidenced by: Based on record review and interview, the governing body did not ensure that through the Transplant Program Director, written policies and procedures were implemented, as evidenced by failure by the RTC to inform patients of their rights, or of other available options as well as potential consequences of the transfer from their initial primary center to the RTC (V114); and did not ensure that patients were afforded the opportunity to participate in the planning of their medical treatment (V222). The cumulative effect of these practices resulted in failure of the RTC to deliver statutorily mandated services and comply with Federal requirements under Patients' rights and responsibilities.

V 215

V 215

Corrective Action:

The Area Manager has implemented policies regarding the rights and responsibilities of patients through the leadership of the CEO. The RTC is transitioning its patients to TC1 and TC2. Until each patient has been transitioned, clinical services continue to be provided to patients currently wait listed at the RTC and to post-transplant patients. Transplant surgeries continue to be performed as deceased donor organs become available and living donors are identified and deemed clinically appropriate. As patients transition out of the RTC, they are offered the choice of care at TC1 and/or TC2.

June 21, 2006

The RTC is managed by the CEO under the direction and oversight of the Area Manager. The GBAC recommends policies and procedures to the Area Manager. As authorized by the Area Manager, the GBAC provides input into the oversight and monitoring of the RTC to ensure compliance with the applicable requirements. This oversight includes monitoring of compliance with rules governing patient rights and responsibilities.

June 21, 2006

The RTC has developed and implemented a "Renal Transplant Center Patient's Rights and Responsibilities" policy and procedure which includes:

June 21, 2006

List of rights and responsibilities specific to renal transplant services

including the right to advance notice to ensure orderly transfer or discharge of patients and patients' opportunity to participate in the planning of their medical treatment.

Oversight by the Area Manager through the CEO and the GBAC.

Availability of the policies and procedures as requested by patients, guardians, next of kin, sponsoring agency(ies), representative payees, and the public.

"RTC Patient's Rights and Responsibilities" will be sent by July 15, 2006 to all RTC patients. July 15, 2006

The RTC has developed and implemented a complaint/grievance process specific to issues the RTC (Attachment 27 "Transplant Related Complaints/Grievances Policy") June 26, 2006

Accountable Party: Area Manager
Monitoring:
GBAC minutes July 31, 2006
KFHP Member Complaint and Grievance Data

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V 222 405.2138(b)(1) PARTICIPATION IN PLANNING

All patients treated in the facility are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research.

This Standard is not met as evidenced by:
Based on record review and interview, the RTC did not ensure that patients were afforded the opportunity to participate in the planning of their medical treatment.

Finding includes:

Review of model letters which according to staff interviewed were intended for patients and made available on 5-9-06 revealed one dated 6-22-04 that "beginning September 1, 2004, our Program, together with your (hospital) Nephrologist, will begin providing you with your transplant care." The same letter informed the patient that "you will be financially responsible for any kidney transplant services you receive from (TC1) after September 1, 2004."

Another model letter dated 6-23-04 which, according to staff in the same interviews was mailed to patients, stated that "the opening of our Regional Kidney Transplant Program will result in a change in your current authorization for kidney care," and that "effective September 1, 2004, your current authorization for kidney transplant services provided to you by (TC1) will expire." The same letter added that "kidney transplant services at (TC1) on or before August 31, 2004 will continue to be covered as they have been in the past," and that "as a Medicare Cost member, or since Medicare is your primary payer, you may choose to use your medical benefits outside of

V 222

Corrective Actions:

The RTC recognizes the importance of effective communication to ensure that patients are adequately informed about their rights, responsibilities, and options. Accordingly, the RTC has developed standard communication and documentation management processes.

May 22, 2006 and ongoing

Pursuant to an agreement with the DMHC, these letters have been or will be reviewed and approved by the DMHC. These letters include: the reason why the transition is necessary; the option of selecting care at TC1 or TC2; a suggestion to contact the patients' physicians to discuss care options; information from UNOS regarding how the UNOS program functions.

May 22, 2006 and ongoing

Accountable Party: Area Manager
Monitoring: Concurrent review of all patient transfers by Compliance Officer/designee.

Patients on the RTC wait list will be transferred over time by category, based on clinical status and wait list times. The RTC developed a sequential plan for transferring each patient that includes contacting the patient, preparing the medical record, sending a copy of the medical record to TC1 and/or TC2, along with pre-transplant and transplant authorizations.

The RTC has developed and implemented a "Renal Transplant Center Specific Patient's Rights and Responsibilities" policy and procedure, which includes: list of rights and responsibilities specific to renal transplant services, including the right to advance notice, to ensure orderly transfer or discharge of patients and patients' opportunity to participate in the planning of

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V 222 Continued From page 33

the (hospital's) network." The letter cautioned the patient however that "if you continue to use (TC1), you will be financially responsible for billed copayments and any charges not covered by Medicare."

During interviews on 5-8-06, MS1 stated that the letters were developed jointly by herself, MS2 and TD1, and that the letter dated 6-23-04 was intended for patients who may have secondary payor sources.

Notwithstanding these letters and notification that arrangements were being made for their transfer to the RTC, there was no indication that patients were informed of their rights or of other available options, as well as the potential consequences of the transfer. Review of a list provided by the RTC on 5-12-06 revealed the names of 95 patients described by staff as having secondary payor sources. Review of the letter dated 6-23-04 however revealed the lack of indication that these patients were informed about how their secondary payor sources might be used to pay for kidney transplants should they elect to remain with TC1.

Review of the RTC's policy and procedures regarding Patient Rights and Responsibilities revealed several rights of patients including the "right to be informed about and participate in the decisions regarding his/her care to patient (under consent)," as well as the right not to be transferred to another facility unless he/she or legal representative has received a complete explanation of the reason for the transfer and the alternatives to such a transfer ..."

During separate interviews with MS1 on 5-8-06 and again on 5-12-06, and with MS2 on 5-12-06, both stated that the transfer would not affect

V 222

their medical treatment; oversight by the Area Manager facilitated through the CEO and the GBAC; availability of the policies and procedures requested by patients, guardians, next of kin, sponsoring agency(ies), representative payees, or the public.

Policies and procedures related to patient rights and responsibilities were reviewed by the GBAC and recommended to the Area Manager for approval. June 21, 2006

Accountable Party: Area Manager
Monitoring: Concurrent review of patient transfers by Compliance Officer/designee

The Area Manager approved the Patient Rights and Responsibilities policies and procedures. June 21, 2006

The RTC Patient Rights and Responsibilities will be sent by July 15, 2006 to all RTC patients. July 15, 2006

Accountable Party: Area Manager
Monitoring: Concurrent review of all patient transfers by the Compliance Officer/designee.

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patients' chances for a kidney transplant and that no patient would be disadvantaged. On 5-11-06, a copy of a letter dated 5-10-04 was obtained at TC2 detailing concerns by the transplant director that pre-transplant patients (at TC2) would have to wait longer for a kidney following their transfer to the RTC which is under the service area of another organ procurement organization (OPO). The letter, addressed to MS2, noted that patients on the waiting list at TC2 "who in general have been on the waiting list for a relatively short time will have little chance of being transplanted at your center until they have accumulated more waiting time and rise to the top of your list." The letter added that patients on the wait list at TC2 "would have to wait an average of 1.5 to 3.6 years longer for transplantation, depending on the blood type."

During an interview on 5-10-06, TC2 staff provided a copy of a letter dated 6-9-04 from the RTC and signed by MS1, MS2, and TD1. This letter, according to staff interviewed, was sent to a patient on the waiting list at TC2 announcing that "by early fall of 2004," the RTC "will provide care for members who need a kidney transplant." While the letter sought to "to reassure you that during this transition, you will not lose your place on the kidney transplant waiting list," there was no indication that the patient was informed about how the transition might affect his/her chances for a kidney transplant following the transfer from one OPO service area to another where the demand for available kidneys is higher and the waiting lists of several transplant centers much longer.

Further, while patients were informed on June, 2004 that they would be responsible for the financial costs of a kidney transplant performed at

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TC1 (or TC2) after 9-1-04, the list referenced above noted transfer dates completed well into 2005 and 2006, more than a year from 9-1-04. Within this period and while on the waiting list at TC1, these patients therefore would not be transplanted even when a kidney was available unless they were willing to shoulder the expense themselves. Also, while these patients were added to the waiting list at the RTC but if their accrued wait times at their initial primary centers were not transferred, they start at the bottom of the list (until after their accrued wait time was transferred). Consequently, because TC1 was informed that no further kidney transplants on member patients would be authorized after 9-1-04; and because of the significant delay in getting patients listed and their accrued wait times transferred to the RTC, these factors have prevented patients especially those at the top of the list (by allocation rules) from receiving a transplant even if they were near-perfect match with available kidneys.

Review of a "refusal" list obtained from the OPO revealed 25 "zero-mismatch" kidneys offered to 24 member patients on the waiting list at TC1 between 1-22-05 and 12-2-05 that were refused. One member patient was noted to have been offered a zero-mismatch kidney twice (on 3-23-05 and 5-10-05) both of which were declined as well.

UNOS policy and procedures define zero antigen mismatch as "occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens," or a match "occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B and DR antigens when at least one

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antigen is identified at each locus." Therefore, a zero-mismatch kidney represents the best possible match between the donor and the recipient.

Further review of the list revealed that 13 member patients had their transfer to the RTC completed over a year from 9-1-04, the cut-off date for which authorizations for kidney transplants at TC1 stopped. In addition, fourteen (14) other names on the refusal list were noted to be currently on the waiting list of the RTC.

While the quality of the zero-mismatch kidneys described as " import offers" could not be determined or even whether they would have been acceptable for transplantation, the delay in completing patient transfers and the denial of authorization for transplants performed at TC1 (or TC2) after 9-1-04 have denied some of the patients the opportunity for available kidneys including zero-mismatch kidneys.

During an interview on 5-9-06, TD1 stated that she was aware of several kidney transplants that were authorized for member patients to be performed outside of the RTC even after the 9-1-04 deadline. TD1 added that approval was based on communication between the RTC and the centers involved. Review of RTC documents however revealed the lack of written evidence that TC1 and TC2 were informed about this possibility and of certain situations where this might be considered and how authorization could be obtained.

Cross-refer to V114(1)(b).

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V 243	<p>405.2139(a) MEDICAL RECORD: LAB REPORTS</p> <p>All medical records contain reports of laboratory and other diagnostic tests and procedures.</p> <p>This Standard is not met as evidenced by: Based on review of eight pre-transplant medical records, the RTC did not ensure that reports of all laboratory and other diagnostic tests and procedures were available in the medical record.</p> <p>Finding includes:</p> <p>Review of the RTC 's protocol entitled, "Kidney Transplantation: PRA Monitoring " revealed that if the HLA alloantibody titer is "0" or "100" that the patient sera is screened every 3 months for the presence of antibody, and if present, that methods to detect the specific HLA alloantibody were to be used.</p> <p>Review of the medical records belonging to Patients 22, 11, 24, 6, 23, 9, 10, and 5 revealed the lack of indication of the results of additional screening if these were conducted.</p>	V 243	<p>V243</p> <p><u>Corrective Actions:</u></p> <p>RTC has assigned staff to complete the medical record management and transition processes.</p> <p>The RTC has posted a position for a medical records manager and has engaged a contracted interim medical records manager, effective July 5, 2006. (Attachment 28 "Contract" Available on site)</p> <p>The policy and procedure for medical records management was revised and implemented on June 16, 2006.</p> <p>The RTC, in collaboration with TC1 and TC2, defined the required elements of the medical record.</p> <p>All pre-transplant medical records were assessed for the required elements by June 24, 2006.</p> <p>Each patient's medical record contains a checklist of these elements and each record is completed then couriered to the respective center based on an agreed time frame (25 records per day) beginning June 19, 2006. Effective June 19, 2006, the receiving center acknowledges receipt of each record.</p>
V 480	<p>405.2170 DIRECTOR OF TRANSPLANTATION CENTER</p> <p>The renal transplantation center is under the general supervision of a qualified transplantation surgeon (405.2102) or a qualified physician-director (405.2102), who need not serve full time.</p> <p>This Condition is not met as evidenced by: Based on record review and interview, the RTC did not ensure that the medical director was</p>	V 480	<p>July 5, 2006</p> <p>June 16, 2004</p> <p>June 24, 2006</p> <p>July 9, 2006</p> <p>July 31, 2006</p> <p>HLA/PRA results will be in all pre-transplant medical records by July 9, 2006.</p> <p><u>Accountable Party:</u> CEO</p> <p><u>Monitoring:</u></p> <p>Monthly audit of medical records for completeness by the Compliance Officer/designee reported to the GBAC</p>

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V 243 405.2139(a) MEDICAL RECORD: LAB REPORTS

All medical records contain reports of laboratory and other diagnostic tests and procedures.

This Standard is not met as evidenced by:
Based on review of eight pre-transplant medical records, the RTC did not ensure that reports of all laboratory and other diagnostic tests and procedures were available in the medical record.

Finding includes:

Review of the RTC 's protocol entitled, "Kidney Transplantation: PRA Monitoring " revealed that if the HLA alloantibody titer is "0" or "100" that the patient sera is screened every 3 months for the presence of antibody, and if present, that methods to detect the specific HLA alloantibody were to be used.

Review of the medical records belonging to Patients 22, 11, 24, 6, 23, 9, 10, and 5 revealed the lack of indication of the results of additional screening if these were conducted.

V 243

V 480 405.2170 DIRECTOR OF TRANSPLANTATION CENTER

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (405.2102) or a qualified physician-director (405.2102), who need not serve full time.

This Condition is not met as evidenced by:
Based on record review and interview, the RTC did not ensure that the medical director was

V 480 V 480

The RTC has taken the following steps to ensure that the Medical Director provides clinical oversight of Renal Transplant Center patients in accordance with the Medical Director's position description and the delegations outlined by the Area Manager, who is the RTC Governing Body:

The program description (attachment) establishes the Medical Director's role ensuring appropriate provision of

V 480 (continued)

transplant services, consistent with delegations outlined by the Area Manager who is the Governing Body.

June 22,
2006

1. The Medical Director's position description identifies the Medical Director's accountabilities, qualifications and reporting relationship to the Area Manager.

June 22,
2006

2. The Area Manager who is the governing body has appointed the Medical Director with the qualities and skills necessary for the position as required by regulation. §405.2102.

June 22,
2006

3. The Medical Director attended "Physician Orientation to the Kaiser Permanente San Francisco" in 2003. The Medical Director has been re oriented to the position accountabilities and reporting relationships and has attested to such by signing the Medical Director Job Description.

June 22,
2006

Accountable Party:

- Area Manager

Monitoring

- GBAC meeting minutes

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responsible for planning, conducting, and directing the renal transplant center (V481). The cumulative effect of these practices resulted in failure of the RTC to deliver statutorily mandated services and comply with Federal requirements under the Director of the Transplantation Center.

V 481 405.2170(a) PHYS RESP: MODALITY
The renal transplantation center is under the general supervision of a qualified transplantation surgeon (405.2102) or a qualified physician-director (405.2102), who is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to participating in the selection of a suitable treatment modality for each patient.

This Standard is not met as evidenced by:
Based on record review and interview, the RTC did not ensure that the medical director was responsible for planning, conducting, and directing the renal transplantation center to ensure that patients received the necessary care and services in accordance with their assessment, evaluation, and plans of treatment.

Finding includes:

1. Review of the "Medical Director Responsibilities" for the "Kidney Transplant Service" revealed several areas of responsibilities including program development consisting of evaluating, maintaining and communicating program performance goals;

V 480

V 481
The RTC is under the general supervision of a qualified Medical Director who reports to Area Manager.

The Medical Director is a member of the GBAC and is involved in evaluating and maintaining RTC performance goals.

June 21, 2006

V 481

The Medical Director job description delineates the responsibility for ensuring integration of RTC staff, medical records, IT systems and hospital and transplant services providers with regard to quality of care.

June 22, 2006

The Medical Director in conjunction with the CEO has reviewed and approved the policy and procedure: "The Renal Transplant Center Specific Patient's Rights and Responsibilities," which outlines the appropriate steps that must be taken to communicate a change in a patient's authorization of care.

June 22, 2006

While the RTC is in transition, physicians have been credentialed and privileged (as indicated). Four additional transplant nephrologists were credentialed on June 14, 2006. The physicians and surgeons will provide all phases of renal transplant care to patients until all RTC pre-transplant patients are transitioned to TC1 or TC2.

June 14, 2006

The Medical Director participates in regular meetings of the RTC Transition Team and, in conjunction with the CEO, gives regular updates to the GBAC. The Medical Director works with the Transition Team to oversee the transfer

June 22, 2006 and ongoing

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operations including ensuring integration of department staff with medical records, IT systems, and hospital and transplant service providers with regard to quality of care together with member and outside provider satisfaction; and patient selection and management and ensuring the high quality of service to patients and providers, and modifying policies based on reviews of transplant and patient outcomes.

During an interview on 5-8-06, MS1 stated that the hospital previously contracted with TC1 and TC2 to perform renal transplantation services for its member patients. After the decision was made to terminate the contract in 2003, TC1 and TC2 were notified and the transfer of patients from these centers to the RTC began in 2004 which involved "over 1500 patients."

During the same interview, MS1 stated that she was involved in the development of letters informing patients about the transfer. Review of these letters which, according to staff interviewed during the survey were intended for patients both at TC1 and TC2, revealed one dated 6-22-04 that "beginning September 1, 2004, our Program, together with your (hospital) Nephrologist, will begin providing you with your transplant care." The same letter informed the patient that "you will be financially responsible for any kidney transplant services you receive from (TC1) after September 1, 2004. "

Another model letter dated 6-23-04 which, according to staff in the same interviews was sent to patients who may have secondary payors stated that "the opening of our Regional Kidney Transplant Program will result in a change in your current authorization for kidney care," and that "effective September 1, 2004, your current

V 481

V 481 (continued)

of the patients on the RTC Wait List by category based on clinical status and wait list times.

The Medical Director as Co-chair of the GBAC recommends policies and procedures to the Area Manager. As authorized by the Area Manager, the GBAC provides input into the oversight and monitoring of the RTC to ensure compliance with applicable requirements.

Accountable Party: Area Manager

Monitoring: Regular meetings with Area Manager

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authorization for kidney transplant services provided to you by (TC1) will expire." The same letter added that "kidney transplant services at (TC1) on or before August 31, 2004 will continue to be covered as they have been in the past," and that "as a Medicare Cost member, or since Medicare is your primary payer, you may choose to use your medical benefits outside of the (hospital's) network." The letter cautioned the patient however that "if you continue to use (TC1), you will be financially responsible for billed copayments and any charges not covered by Medicare."

Review of available documents, including QUEOC (Quality Utilization Executive Oversight Committee) as well as QHIC (Quality Health Improvement Committee) revealed the lack of documented evidence of involvement by MS1 in the development of a written plan regarding how the transfer was going to be accomplished particularly in that it involved a large number of patients; required a lot of processes and procedures including knowledge, understanding and compliance with UNOS guidelines and directions; required clear understanding and cooperation by pre-transplant patients; and consideration for the number of staff, including medical staff, required to provide continuing care to existing patients and accomplish the transfer of new patients within the deadline specified, as well as the manner with which medical record information would be obtained. Interviews with staff revealed that problems associated with medical records were one of the primary reasons for the delay. During an interview on 5-9-6, DC1 stated that there were "over 1000 incomplete" records over a period of time delaying the addition of patients and transfer of their accrued wait times to the RTC's waiting list.

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In addition, a list provided by staff on 5-8-06 contained the names of 2080 patients who were on the RTC's waiting list for a kidney transplant as of 5-4-06. While the RTC had two transplant surgeons, there however, was only one transplant nephrologist available for providing post-transplant care and follow-up involving 91 patients at the RTC and those transplanted at TC1 and TC2, the evaluation of new patients for inclusion into the waiting list, and continuing evaluation and follow-up of other medical issues concerning those being transferred from TC1 and TC2. Review of medical staff configuration revealed that the transplant nephrologist was also the medical director of the RTC with additional administrative responsibilities. In light of this, there was no indication that MS1 was involved in any discussion regarding how the lack of available medical staff (as well as nursing and administrative support), might affect the care of existing patients as well as those newly added to the waiting list.

Further review of RTC documents revealed the lack of evidence that MS1 was involved in any discussion regarding how the transfer of patients from TC1 and TC2 might impact their chances for a kidney transplant. On 5-11-06, a letter dated 5-10-04 obtained at TC2 conveyed concerns by the transplant director that patients (at TC2) would have to wait longer for a kidney following their transfer to the RTC which is under the service area of another organ procurement organization (OPO). The letter which was addressed to MS2 noted that patients on the waiting list at TC2 " who in general have been on the waiting list for a relatively short time will have little chance of being transplanted at your center until they have accumulated more waiting time

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and rise to the top of your list." The letter added that patients on the wait list at TC2 "would have to wait an average of 1.5 to 3.6 years longer for transplantation, depending on the blood type."

During an interview on 5-10-06, TC2 staff provided another letter dated 6-9-04 from the RTC and signed by MS1, MS2, and TD1. This letter, according to staff interviewed was sent to a patient on the waiting list at TC2 announcing that "by early fall of 2004," the RTC "will provide care for members who need a kidney transplant." While the letter sought to "reassure you that during this transition, you will not lose your place on the kidney transplant waiting list," there was no indication that the patient was informed about how the transition might affect his/her chances for a kidney transplant following the transfer from one OPO service area to another where the demand for available kidneys is higher and the waiting lists of several transplant centers much longer.

In addition, record review revealed the lack of evidence that MS1 was involved in monitoring the transfer to ensure that it was accomplished within the timeframe specified. Review of documents revealed that the transfer of patients to the RTC's waiting list was to be completed on 1-31-05. Interviews with staff during the survey however, revealed that while there were still patients whose transfers have to be completed 16 months after the deadline, none knew the actual number of patients involved.

During an interview on 5-8-06, for example, PTC1 stated that of over 1500 patients involved, about 10 patients were still waiting to have their transfer to the RTC completed.

During a separate interview on 5-8-06, TD2

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V 481	<p>Continued From page 43</p> <p>stated that she did not know the exact number of patients involved but that DC1 would be able to give the actual number.</p> <p>During another interview on 5-12-06, MGA1 stated that there were about 60 patients whose transfers have yet to be completed and that the status of these patients was "unknown." On 5-10-06, a list provided by DC1 contained the names of 86 patients whose status, according to DC1, were "unknown" some 20 months after they were initially notified that they would assume the financial cost for their kidney transplant if performed at TC1 or TC2.</p> <p>In spite of this, review of transplant records revealed the lack of documented involvement by MS1 in any contingency planning to determine the patients' status, expedite their placement on the waiting list, and ensure that accrued wait times were transferred so that they would have been in a position to receive a transplant should a kidney be available. On 5-10-06, a list containing the names of 209 patients who were still on the waiting list at TC1 was obtained. The list, according to TC1 staff interviewed, were member patients whose transfer to the RTC could not be verified as completed (hence their showing on the waiting list at TC1). The staff added that the list had been shared with the RTC on 5-5-06. When this information was conveyed on 5-12-06 and the discrepancy between this list and the RTC's was pointed out, MGA1 stated that work on reconciling the list had began "about a week ago."</p> <p>While patients were informed on June 22 and 23, 2004 that they would be responsible for the financial costs of a kidney transplant performed at TC1 (or TC2) after 9-1-04, the list referenced above noted transfer completion dates well into</p>	V 481		

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2005 and 2006, more than a year from 9-1-04. Within this period and while on the waiting list at TC1, patients could therefore not be transplanted even when a kidney was available unless they were willing to shoulder the expense of the transplant themselves. Even while these patients were added to the waiting list but if accrued wait times at their initial primary centers were not transferred, they would start at the bottom of the list at the RTC. Consequently, because TC1 was informed that no further kidney transplants on member patients would be authorized after 9-1-04, and because of the excessive delay in getting the patient on the RTC's waiting list and/or their accrued wait times transferred, these factors have prevented patients, especially those at the top of the list from any consideration or evaluation for a transplant even if they were near-perfect match with available kidneys from 9-2-04 through the time their names were put on the waiting list at the RTC and transfer of their accrued wait times were completed. During an interview on 5-10-06, a medical staff member from TC1 stated that several zero-mismatch kidneys were offered but that member patients were unable to avail of these kidneys because they may not have been added to the waiting list of the RTC, and that while they may still be on the waiting list at TC1, authorizations have stopped and patients would not be able to shoulder the financial cost if the transplant was performed at TC1.

Review of a "refusal" list obtained from the OPO revealed 25 "zero-mismatch" kidneys offered to 24 member patients on the waiting list at TC1 between 1-22-05 and 12-2-05 that were refused. One member patient was noted to have been offered a zero-mismatch kidney twice (on 3-23-05 and 5-10-05) both of which were declined as well.

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UNOS policy and procedures define zero-mismatch as "occurring when a candidate on the Waiting List has an ABO blood type that is compatible with that of the donor and the candidate and donor both have all six of the same HLA-A, B, and DR antigens," or a match "occurring when there is phenotypic identity between the donor and recipient with regard to HLA, A, B and DR antigens when at least one antigen is identified at each locus." Therefore, a zero-mismatch kidney represents the best possible match between the donor and the recipient.

Further review of the list revealed that 13 member patients had their transfer to the RTC completed over a year from 9-1-04, the cut-off date for which authorizations for kidney transplants at TC1 stopped. In addition, fourteen (14) other names on the refusal list were noted to be currently on the waiting list of the RTC.

While the quality of the zero-mismatch kidneys described as "import offers" could not be determined or even whether they would have been acceptable for transplantation, the delay in completing patient transfers and the denial of authorization for transplants performed at TC1 (or TC2) after 9-1-04 have denied some of the patients the opportunity for available kidneys including zero-mismatch kidneys.

During interviews on 5-10-06, TC1 staff stated that in spite of the deadline of 9-1-04 when authorization for kidney transplants at TC1 for member patients stopped, that the RTC continued to approve certain procedures including dual organs such as kidney and pancreas transplants, as well as other "special cases" involving transplants for pediatric patients.

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Further record review revealed that authorization for kidney transplants at TC2 were also extended to 9-17-04 following a request made by the OPO to until "regional crossmatch trays expire on September 17, 2004 at 5:00 p.m." During the same interview on 5-11-06, TC2 staff stated that certain transplants were allowed past this date such as dual organs but not for single, cadaveric kidney transplants.

During an interview on 5-9-06, TD1 stated that she was aware of several kidney transplants that were authorized for member patients to be performed outside of the RTC even after the 9-1-04 deadline. TD1 added that approval was based on communication between the RTC and the centers involved. Review of documents however revealed the lack of written evidence of MS1's involvement in any communication with TC1 and TC2 of this possibility and of certain situations where this might be considered and authorized.

V 481

V 494 405.2171(c) RTC: DIETETIC SERVICES

The renal transplantation center ensures that each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (405.2102) who has an employment or contractual relationship with the facility.

This Standard is not met as evidenced by:
Based on interview and review of medical records and policy and procedures manuals, the RTC did not ensure that each patient was evaluated as to his/her nutritional needs by a qualified dietitian who has an employment or contractual relationship with the RTC.

V 494

V 494

The RTC hired a qualified dietician on June 12, 2006 and completed orientation on June 22, 2006.

Based on medical record review, patients who required a dietary evaluation were identified and a prioritized process developed for their receiving an evaluation.

In addition, the patients identified by the Statement have all received dietetic consultations by June 16, 2006.

June 22, 2006

June 12, 2006

June 16, 2006

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Findings include:

1. Review of ten of 17 medical records revealed the lack of evidence that a dietary evaluation had been conducted and that the patient's dietary needs relative to transplantation would be communicated to the ESRD facility or patient's physician to trigger a notice to the transplant center and/or contraindicate transplantation once the patient had been selected for transplantation.

The policy and procedure manuals did not contain a policy, process or procedure for a patient care plan or long-term program that included dietary evaluation.

2. During an interview on 5-9-06 at 9 a.m., TD2 stated that the RTC did not have a full time dietitian following her appointment as Renal Program Director two months prior. TD2 added that a hospital dietitian spends about 0.5 hours in the RTC.

During another interview on 5-9-06 at 3:30 p.m., a hospital registered dietitian stated that evaluations were conducted on a consultation basis only. She added that she only follows transplant patients when there is a request for consultation from the physician or a nurse, when a renal diet is ordered, or following the 11th inpatient hospital stay.

Review of the job description revealed that the Clinical Dietitian was responsible for the development, coordination, and performance of clinical nutritional activities to meet the needs of pre and post renal transplant recipients as well as living donors in the inpatient and outpatient settings.

V 494

V 494 (continued)

The RTC has implemented a policy and procedure that addresses dietetic evaluations. The Renal Transplant Center collaborates with the nephrologists, RN renal case managers and dialysis centers to assure integrated multidisciplinary care planning occurs. The plan of care for all dialysis patients is completed as a component of this community based care. The plan of care for non-dialysis patients is developed by the primary treating nephrologists.

June 22, 2006

A presentation will be given to the Kaiser Permanente Northern CA Region Renal Case Managers peer group to confirm their accountability for providing the current dietetic evaluations and collaborating with RTC staff.
Accountable Party: CEO

June 29, 2006

A presentation will be made to the Kaiser Permanente Northern CA Region Chiefs of Nephrology to confirm their accountability.
Accountable Party: CEO and Medical Director

July 5, 2006

Policies and procedures were approved by the RTC Area Manager on June 21, 2006.
Accountable Party: Area Manager

June 21, 2006

Monitoring:

Audit of medical records for evidence of dietetic evaluations by Compliance Officer/designee.

July 31, 2006

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V 494

3. During an interview on 5-9-06 at 11:30 a.m., Patient 1 who had a cadaveric kidney transplant on 3-8-06 stated that he was a diabetic and on a Weight Watchers program. The patient added that he did not see a dietitian before and after his transplant nor received any dietary follow-up or instructions from a dietitian. Review of the medical record revealed that Patient 1 had several diagnoses including post kidney transplantation, diabetes mellitus, hypophosphatemia, and chronic hepatitis C.

Further record review revealed that following the transplant clinic visit on 5-9-06, a physician's note (dated 5-9-06) revealed that postoperatively, Patient 1 had developed significant hyperglycemia with blood sugars over 400 (normal limits between 70 - 110 mgs/ml). At the time of discharge, record review revealed that Patient 1's NPH insulin dose was increased and that even with sliding scale coverage, his blood sugars still were over 350 at dinner and at bedtime. In addition, Patient 1 and his wife had been warned about compliance with a restricted calorie and concentrated sweet diet for both weight gain and diabetes mellitus control.

4. During separate interviews on 5-9-06 at 3:30 p.m., Patients 12 and 13 who were both immediate post-transplant recipients confirmed that they were not evaluated by a dietitian before and after their kidney transplant.

Record review revealed that Patient 12 had a kidney transplant on 5-5-06. During the interview, Patient 12 stated that he cannot "recall talking to a dietitian." When asked if he was aware of any dietary restrictions post transplantation, Patient 12 responded that he was not aware of any

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restrictions because he had not seen or talked to the dietitian before or after the kidney transplant. A review of the patient's hospital medical record revealed a dietary recommendation dated 5-7-06 that noted, "Renal diet and low Phosphorus diet. Will follow-up in 4 - 5 days to check progress. No restriction of protein."

5. Patient 13 was described in the medical record as having had a living donor kidney transplant on 5-3-06. During an interview on 5-9-06 at 3:45 p.m., Patient 13 and his wife who was the donor stated that there was no consultation session with the dietitian before and after the kidney transplant. At the time of the interview, a licensed staff stated that the patient and his wife "will be going home today," notwithstanding the lack of any dietary follow-up, consultation or instruction.

6. Review of the medical records belonging to pre-transplant Patients 22, 11, 24, 6, 23, 9, 10, 5, and 20 showed no evidence of assessment, evaluation, or follow-up by the dietitian.

Patient 20, for example, was described in his history and physical examination as having end-stage renal disease secondary to hypertension and diabetes mellitus. The patient was also noted to be on peritoneal dialysis since 9-18-02. Further record review revealed that Patient 20 had an initial transplant evaluation on 9-20-04. A letter sent to the patient dated 11-2-04 revealed a waitlist date of 10-28-04. The initial physical examination dated 9-30-04 identified the patient as a "high risk" due to obesity, diabetes mellitus and cardiomyopathy. A patient progress record dated 9-30-04 referenced the transplant evaluation conducted by the transplant surgeon, the transplant nurse coordinator, and a "pending" evaluation by the social worker. While the patient

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V 494	Continued From page 50 's body mass index (BMI) was noted to be "42" and that the patient was noted as a "high risk candidate," there was no written evidence of any evaluation conducted by the dietitian even in light of a "plan" to refer the patient to the dietitian.	V 494		
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