DEC 19 2005

Rockville, Maryland 20857

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Grassley:

Thank you for your letter of November 29 conveying your remaining concerns regarding detection and prevention of fraudulent and/or improper allocation of organs and recently published reports regarding problems at the University of California Irvine (UCI) Medical Center transplant program. I am happy to address those issues for you.

Concerns Related to St. Vincent Medical Center:

You have asked whether the audit conducted by the United Network for Organ Sharing (UNOS), the contractor which operates the national Organ Procurement and Transplantation Network (OPTN), on June 15, 2005, identified problems with the liver transplant performed at St. Vincent's Medical Center (SVMC) on September 8, 2003.

The routine transplant program audits consist of two primary aspects: administrative and clinical. The clinical portion of the site survey is based on how well the medical records verify the urgent status of a patient listed and transplanted.

The clinical survey for a liver transplant program includes review of patient medical records for the following categories:

- Status 1 patients (maximum of 45 patients);
- Patients who are currently on the waitlist and were never listed with a risk of death severity score (known as the Model for End Stage Liver Disease or "MELD" score) of 20 or greater;
- All severity scores at time of transplant;
- Verification of pathology reports documenting evidence of Hepatocellular Carcinoma (HCC) status;
- Blood type (ABO) verification prior to implantation of organ;
- Patient notification; and,
- Accuracy of Reported Cause of Death/Accuracy of the Removal Code.

Records reviewed during the audit must meet the criteria above and are randomly selected by the auditors. Patient #2's transplant records were included in the sample because he received a liver transplant for HCC and the auditors were verifying whether the stage of

the tumor was accurately reflected in the medical records. At the time of the audit, medical records for Patient #2 were incomplete, so SVMC staff was asked to provide additional information to justify the patient's listing. This further inquiry into Patient #2's medical records prompted a staff member at SVMC to admit that false information about the recipient had been reported to the OPTN. We have since discovered that at the time of the transplant, SVMC sent the OPTN an altered pathology report falsely describing the liver to belong to Patient #2 instead of Patient #52.

You asked why the change in name of the liver transplant recipient did not trigger an investigation. Although is not common (approximately 0.1 percent of cases), transplant programs do submit requests to the OPTN to change the name of a patient who received a transplant from a particular donor, most often as a result of miscommunication between clinical staff and those entering the data into the computer system. In order to assure accuracy in data reporting, the OPTN performs a cross check between information submitted by the organ procurement organization (OPO) and information submitted by the transplant program to assure both entities agree on the identity of a transplant recipient. In this particular case there was no discrepancy and no reason to believe the transplant program was falsifying information. We are working closely with UNOS to explore options for collecting some type of evidence to validate recipient name changes in the OPTN database such as requesting a copy of the operative report from the transplant program that could be scanned into an electronic file and attached to the request.

After learning SVMC deliberately falsified information about a transplant recipient, UNOS immediately conducted a site visit of the OPO to determine whether it had prior knowledge of the discrepancy in reporting. After conducting this review, we are confident the OPO believed Patient #2, not Patient #52 received the liver transplant. Had the OPO been aware, OPTN bylaws would have required them to report this information to UNOS.

You also expressed concern about the percentage of non-resident aliens transplanted at SVMC. The OPTN/UNOS Ad Hoc International Relations Committee sent an inquiry to the SVMC's Liver Transplant Program on October 22, 2004, requesting an explanation of why the program transplanted greater than 5 percent non-resident aliens in 2002 (10 percent) and 2003 (8.3 percent). SVMC's response indicated that in 2002 the program transplanted 2 non-resident aliens out of 21 liver transplants performed and in 2003 transplanted 2 non-resident aliens out of 25 liver transplants performed. Subsequent to this inquiry, the number of non-resident aliens receiving transplants at SVMC was 1 out of 22 (4.5 percent) in 2004 and 2 out of 10 (20 percent) through October 31, 2005, when the program closed. If the liver transplant program had not already closed, the program would likely have been reviewed if it had exceeded the 5 percent limit by the end of 2005. The information you have specified in Question #4 of your letter is included with the materials accompanying this letter.

The number of annual liver transplant procedures performed at SVMC is very small. For the year 2002, the difference between meeting the OPTN non-resident alien cap and exceeding it was a single transplant. Because organ allocation policies are blind to resident status (as they are to race, gender, and economic status), programs cannot control when they will receive an organ offer for a non-resident alien. For this reason, the program must make a judgment call at the time an organ is offered as to whether the transplant is likely to put them over the annual cap while at the same time not knowing how many transplants will be performed by the program at the close of the year. While considering the impact of whether accepting the organ may put them over the cap, the program must at the same time consider the impact on a patient's life by accepting or not accepting the organ. As you can understand, this is a very fine medical and ethical line to walk, given the medical status of a potential transplant patient.

Concerns Related to the UCI Transplant Center:

You express concern regarding the performance of the UCI Transplant Center and whether the OPTN is capable of identifying functionally inactive transplant programs. Enclosed is a thorough description of the methodologies currently utilized by the OPTN to monitor transplant program activity, transplant outcomes, and to identify centers meriting review because they are under-performing.

Since the OPTN investigation of the UCI's Liver Transplant Program is still in progress, we still do not have all the facts yet. However, we are glad to share the information we know at this time. The matter of UCI's Liver Transplant Program performance has been under investigation by the OPTN since 2002. In 2002, through routine transplant outcomes analyses, the Membership and Professional Standards Committee (MPSC) found that UCI's liver transplant program had poorer outcomes than expected. The MPSC continued its review by asking the center to complete a questionnaire addressing all aspects of the transplant program, not just post-transplant outcomes. By the end of 2002, it was clear that the program's performance would not improve on its own, so the MPSC directed that a peer review site audit occur.

The peer review site audit is different from the routine audits and usually includes at least one transplant surgeon, one transplant physician, and a transplant administrator in addition to UNOS staff. The transplant professionals chosen for these site audits must be experienced individuals from the highest quality transplant programs. Therefore, there are often delays in pulling together a team with such credentials. The purpose of the peer review team is to assess the entire transplant program (not just the poor outcomes) and provide recommendations for improvement.

The peer review team went to UCI in mid-2003 and issued its audit report soon afterwards (enclosed). In response to the audit report, UCI proposed a corrective action plan which was accepted by the MPSC. Upon monitoring the progress of the corrective action plan, the MPSC did not feel that UCI was meeting its goals in the corrective action plan and

took actions to have the liver program inactivated in early 2004. Once these proceedings began, UCI proposed that Dr. Marquis Hart from University of California (UC)-San Diego would become the new primary transplant surgeon at UCI and be tasked with improving the program's performance.

The details of these events in 2005 are still being investigated by the OPTN but the review of the audit is not complete so it is not yet available. HRSA staff members attended the MPSC meeting, where Dr. Hart was proposed as the replacement surgeon and left with the clear impression that Dr. Hart would be leaving UC San Diego and moving full-time to UCI. Furthermore, in the application to change the primary surgeon from Dr. Sean Cao to Dr. Marquis Hart, UCI's Chief Executive Officer, Mr. Ralph Cygan certified that Dr. Hart would be on site at UCI 100 percent of the time after July 2004. Only around the time of the Centers for Medicaid and Medicare Services audit did we discover that Dr. Hart never left UC San Diego. It was also around this time that UNOS went back to UCI to investigate charges being made by a former patient, Ms. Elodie Irvine. As the details of this investigation unfold, we will be happy to brief you on the matter.

As a result of the concerns raised by the UCI audit, HRSA has requested its contractors for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) to develop more sensitive metrics for flagging unusually high turn down rates or unusually high wait list mortality rates.

Other Concerns:

Responses to Questions 8-11 are included in the materials accompanying this letter.

UNOS did not receive or investigate any allegations in calendar years 2000-2002. However, during this time period the OPTN was actively engaged in conducting site visits of OPOs and transplant programs and evaluating transplant program performance outcomes as required by the OPTN contract.

You have expressed concern regarding the robustness of the OPTN's auditing and corrective action practices and of HRSA's oversight of the OPTN.

Section 121.10(b)(iii) of the OPTN Final Rule, which became effective in April 2000, requires the OPTN to conduct ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with OPTN rules and policies. Subsequent to this regulation becoming effective, the OPTN contract, which went into effect on September 27, 2000, established the first formal requirement for the OPTN contractor to conduct site visits to assess compliance with OPTN policy. Over the next 2 years the depth and sophistication of the audits has rapidly progressed to the point to which metrics to better

understand and compare transplant program compliance and identify performance outliers are being developed so we can more quickly target programs requiring investigation. We would be happy to arrange for UNOS to brief your staff on this work.

You also have expressed concern regarding whether transplant recipients knew of potential problems with transplant programs that have been placed on probation. The issue of public disclosure of non-compliant transplant programs has been a subject of much debate within the OPTN and has focused on the very important patient protection issues alluded to in your letter. While keeping the interests of patients paramount, we must also balance the need to maintain a confidential transplant program review process that discloses all relevant information and allows objective conclusions to be reached. At the November 2005 meeting of the OPTN/UNOS Board of Directors, the board overwhelming voted to publicly disclose the name of any transplant program that is placed on probation. Probation is a lesser sanction than "Member Not in Good Standing" (which requires public disclosure) but has heretofore been implemented as a confidential action. This vote is an important step toward providing patients with information they should have when choosing a transplant program.

At this meeting, the Board also decided unanimously to raise the performance for the entire network by directing the MPSC to develop new membership standards and monitoring procedures. These include:

- changes to the OPTN Bylaws defining higher standards for the requirement of 100 percent transplant medical and surgical coverage;
- a new Bylaw provision requiring transplant centers to provide prompt notification to the OPTN (within 5 days) of a material or threatened change to a transplant program's status under Medicare or Medicaid;
- new Bylaw provisions to include organ acceptance/turndown rates and deaths on the waiting list as elements of center performance in addition to patient and graft survival. The MPSC and SRTR will develop a methodology that enables the MPSC to review turndowns with a mechanism that account for donor quality and recipient availability;
- additional metrics and internal OPTN process improvements to assess institutional performance with the goals of revealing indicators of potential noncompliance or quality issues earlier and addressing these issues promptly and effectively to ensure public trust in the system; and,
- implementing a telephone hotline and a confidential process to enable full and prompt disclosure by employees of OPTN member institutions or the public of actions needing review by the OPTN.

With respect to your concern that HRSA is not playing an active role in overseeing the OPTN contract with UNOS, I believe it is important for you to know that the implementation of the OPTN Final Rule has made it possible for HRSA to exercise extremely effective oversight of the OPTN that has produced significant results. Further, HRSA's contract to

operate the OPTN requires that HRSA staff be ex-officio, non-voting members of the OPTN/UNOS Board of Directors and all committees, including the MPSC, attend all meetings, and play a critical role in assuring the OPTN fulfills its obligations under the National Organ Transplant Act (NOTA), the OPTN Final Rule and the OPTN contract. Because of HRSA's oversight, the OPTN has made substantial gains in implementing organ allocation policies that have reduced waiting list deaths and facilitated more efficient organ placement, the method for identifying poor performing transplant programs has been significantly strengthened and data from lower performing transplant programs are peer reviewed on a quarterly basis and corrective action plans developed and implemented. Additionally, because of HRSA's oversight, patient and graft survival rates for every transplant program in the U.S. are posted on the Web site of the SRTR at www.ustransplant.org. For each of these programs, an assessment is provided as to whether the program's performance is consistent with what would be expected, lower than expected, or higher than expected. Any person in need of an organ transplant or any third party payer can view data for any transplant program leading to an informed decision regarding selection of a transplant program. Additionally, this Web site provides an assessment of whether waiting list deaths or transplant rates are consistent with what would be expected. The public availability of performance data regarding U.S. transplant programs is unparalleled in our Nation's entire healthcare system. We also will continue adding new data and performance measures to this site as they are developed.

You have expressed concern that the Department of Health and Human Services (HHS) has not yet designated any OPTN policies as mandatory. This concern stems from the impression that absent such designation, OPTN policies cannot be enforced. This is not the case. The OPTN has the authority to hold members accountable for compliance with OPTN policies. The accountability process is described in the OPTN bylaws previously provided to you. Should the OPTN determine that removal of a member's privilege to transplant organs is warranted for reasons of non-compliance with the Final Rule or threat to public health and safety, the OPTN is expected to make this recommendation to the Secretary of HHS for action. Because of the strength of the OPTN's peer review process, transplant programs would rather voluntarily withdraw than face removal of designation by the Secretary of HHS. As a result of the OPTN's peer review processes and HRSA oversight, 83 transplant programs (16 heart programs, 12 lung programs, 26 heart/lung programs, 13 pancreas programs, and 9 kidney programs) have voluntarily ceased transplantation since October 1, 2000. These programs cannot resume transplant activities without submitting a new application to the OPTN.

Despite these successes, we continue to identify opportunities for improvement as we work to better serve transplant patients. Several such opportunities are mentioned in your letter including: organ offer refusal data as a component of identifying under-performing transplant programs; refining OPTN bylaws and policies for appropriate coverage availability of transplant surgeons and physicians; and identifying opportunities to provide transplant candidates with information about organ acceptance trends at transplant programs. Developing appropriate means to achieve improvements in each of these areas creates great

challenges, but HRSA is committed to continuing its work with the transplant community to meet the needs of transplant patients.

I hope this letter and the enclosed documentation assists you in your review of the events of interest. My staff is working with your staff to arrange a briefing in January. If you require additional information you may contact Ms. Patricia Stroup, Director, Office of Legislation, HRSA, 5600 Fishers Lane, Room 14-37, Rockville, Maryland 20857; telephone 301-443-1890 or e-mail pstroup@hrsa.gov. Please let me know if you require additional information or assistance on this matter.

Sincerely,

Elizabeth M. Duke

Elizabeth M. Duke
Administrator

Enclosure

Enclosure

A description of the methodologies used by the MPSC to review functional inactivity as well as patient and graft outcomes is provided below. In addition, a summary of the application questions and bylaw requirements for coverage are provided below.

Methodology for Reviewing Functional Inactivity

Programs are identified to be functionally inactive if a transplant has not been performed during a specific period of time, defined by the MPSC. Heart, liver, and kidney transplant programs are reviewed if a transplant has not been performed in 3 months; lung and pancreas programs are reviewed if a transplant has not been performed in 6 months; and all pediatric programs are reviewed if they have not performed a transplant within 1 year. For those instances that a program is identified to be functionally inactive, organ turndown information is provided for the Committee to review. Currently, turndowns are not reviewed for any other purpose and have been used as supplementary information to aid the committee member in making a recommendation.

1. MPSC staff review preliminary reports of inactivity and turndown data provided by OPTN/UNOS Research Staff and will remove programs from consideration of inactivity review if any of the following conditions are met:

    a. Program is currently under MPSC review for either outcomes or inactivity.
    b. Program has been released from inactivity review within the preceding 6-months of MPSC review.
    c. Program has been released from outcome review within the preceding year of MPSC review.
    d. Program has inactivated or withdrawn (withdrawal requires that the program submit a new application to reactivate).
    e. Program has been active for less than 1 year (e.g. program recently reactivated/granted approval).

2. MPSC staff will provide to the MPSC turndown and inactivity information for those programs that remain on the reports. MPSC staff will also inform the MPSC of pending Personnel Change Applications that might have influenced activity.

3. Programs newly identified as being functionally inactive will be sent a survey of initial inquiry to be reviewed at the subsequent MPSC meeting.

4. MPSC staff will verify that no transplant has been performed prior to sending surveys to identified programs.

5. Initial inquiry and non-adverse action letters are addressed to the program director. Copies are sent to the medical director, transplant administrator, and the OPTN/UNOS representative. Adverse action letters are sent to all of the same personnel, with a copy also going to the CEO or Executive Director of the center.

6. Once a survey is received, transplant logs will be blinded and provided to the full committee. The unblinded survey will be assigned by the MPSC Chair to three MPSC members for review.

7. Once a program has performed a transplant, they are released from review UNLESS there is another issue that requires further monitoring (newly identified for outcomes, still need to address action plan items, etc).

Methodology for Reviewing Graft and Patient Outcomes

Using a statistically-driven method, the Scientific Registry of Transplant Recipients (SRTR) uses blinded data derived from UNet^{sm} to identify programs in which actual 1-year patient and/or graft survival falls below the expected rates given individual center donor and recipient characteristics. In brief, the SRTR provides the MPSC with a report (updated for every MPSC meeting) detailing program expected survival rates, observed survival rates, the ratio of observed to expected events (graft failure and/or death), and a p-value. If a program's observed minus expected events is greater than three (i.e., the program experienced an excess of three deaths/failures over the expected events); the observed events divided by expected events is greater than 1.5 (i.e., the program experienced 50 percent more deaths/failures than was expected); and the p-value is less than 0.05, the program will be identified for further MPSC review.

Current Cohorts for Analysis

Organ	2.5 year CSR Cohort	Actual time period
Kidney & Liver	Jan 05	July 1, 2001 – December 31, 2003
Kidney & Liver	Jul 05	January 1, 2002 – June 30, 2004
Heart & Lung*	Jan 05	January 1, 2001 – June 30, 2003
Heart & Lung*	Jul 05	July 1, 2001 – December 31, 2003

*Reporting schedule for thoracic follow up differs from abdominal reporting. The MPSC has requested the Thoracic Committee consider altering their reporting requirements to be consistent with the abdominal requirements and allow for a more current analysis.

Programs that are identified to have experienced lower than expected outcomes, in the most recent 2.5 year cohort, based on the SRTR analytical model adopted by the MPSC are requested to provide information for the MPSC to review. To initiate the review, the MPSC sends the program a letter detailing the data that reflects the program experienced lower than expected survival rates for patient, graft, or both. In addition to the letter, the program is sent a questionnaire that inquires into programmatic issues such as hospital/administrative support; surgeon, physician, and program administration; and ancillary support services. The questionnaire also asks the program to identify anything that may have contributed to the

lower than expected outcomes during the review period. Also, the program is asked to provide death/graft failure summaries for patients that died and/or graft failures within 1 year of transplant and to validate data the program submitted to UNet.

The MPSC Data Subcommittee reviews a program's submission to determine if further action is required. Possible actions the committee may take include release from reviews, continued monitoring, request for additional information, request for corrective action plan, offer of a site visit, and adverse actions such as probation and/or member not in good standing.

Programs that are offered and accept a site visit are requested to submit an action plan to address recommendations from the peer review team once the final report has been issued to the center. The peer review team consists of a UNOS staff member, a transplant surgeon, transplant physician, and transplant program administrator. The review team will meet with all key personnel for the transplant program as well as the CEO/Executive Director for the hospital, OPO representatives, and other personnel. The team is on site for 2 days. At the end of the second day, the review team provides a summary of the issues identified to the personnel. The review team then drafts a final report for the MPSC to issue to the center. When the MPSC issues the report to the center, it requests the program to develop an action plan to address the specific issues/recommendations identified within the report. The program is required to continue to submit updates to the action plan until all items have been satisfied. Programs that do not address items of the action plan may be recommended for an adverse action (such as probation or member not in good standing).

Once a program's outcomes have improved, the MPSC may release the program from further review.

The goal of the MPSC is to ensure that patients receive quality transplant services. Programs experiencing lower than expected outcomes are given the opportunity to improve their results prior to any adverse recommendation from the MPSC. This review process allows the MPSC to assist programs in improving their level of patient care. It takes more time to bring a program's performance up to an acceptable level, than it does to close them down. Typically, programs are under MPSC outcome review for a minimum of 1 year to allow time for improvements to be implemented and for more recent transplant data to be evaluated by the statistical model (need 1 full year of follow up completed before the analysis will be accurate).

Methodology and Bylaws for Reviewing Coverage

When a New Program or Key Personnel Change application is submitted, there are several questions on the application that deal with the issue of coverage. The following is a list of the questions that the UCI Medical Center had to answer on their Key Personnel Change application:

1. The primary surgeon must document their percentage of professional time on-site at the transplant center.

2. "Describe the surgeon's level of involvement in the program for which application is being made. If applicable, describe the surgeon's plan for coverage of transplant programs located in multiple transplant centers."

3. "Describe the plan to provide 100 percent surgical coverage by individuals credentialed by the institution and who provide transplant services for the program."

4. "Identify other transplant surgeons who will be prominently involved in the transplant program. Describe their involvement, as well as their transplant training and experience. List the number of transplants performed at each institution by the individual. Indicate for each the percent of professional time spent at the transplant center (include CV).

There are a set of pages to be completed for "additional surgeons" to give an overview of the type of surgical support at a program. However, "additional surgeons" are not required to meet the OPTN Bylaws criteria for primary surgeon.

There is not an ongoing monitoring process for coverage of a program. If an established program submits a Key Personnel Change (PC) application, they are required to answer the questions on the application pertaining to coverage, but the question will only be answered for the aspect of the program (surgical or medical) for which the Key PC application is being submitted (e.g., if a Key PC application is submitted for a change in primary physician, the center will answer the coverage questions only as they pertain to the primary physician's backup).

Additionally, OPTN Bylaws do allow for a facility to have a single transplant surgeon or physician. The Bylaws Appendix B, Attachment I, VI, states:

> "The transplant program must identify a qualified primary surgeon and primary physician, the requirements for whom are specified below. The program director, in conjunction with the primary surgeon and primary physician, must submit written documentation that 100 percent surgical and medical coverage is provided by individuals credentialed by the institution to provide transplant service for the program. A transplant program served by a single surgeon or physician shall inform its patients of this fact and potential unavailability of one or both of these individuals, as applicable, during the year."

Because of this sentence in the Bylaws, it is allowable for a center to state on the application that a single surgeon will provide 100 percent coverage for a transplant program. In this scenario, it would be expected of the center to remain in compliance with UNOS Bylaws by 1) notifying their patients via letter of the potential unavailability of transplants due to surgeon unavailability and 2) being aware of the definition of "functional inactivity" and voluntarily inactivating their program should they be unable to serve their patients for a sustained period of 15 days or more.