

SCHOOL OF MEDICINE

Department of Psychiatry

February 23, 2005

Centers for Medicare and Medicaid Services
Department of HHS
CMS-3835-P, P.O. Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I read with interest the proposed rules on Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants [70 Federal Register 6140]. I would like to address only one portion of this document as it pertains to my practice and clinical research to solid organ transplantation in the last thirty years. I am a clinical researcher and a clinician in this area. I have probably in my professional career made over 3,000 transplant evaluations of recipients, living and altruistic donors. I applaud the insistence that patients receive a thorough psychosocial evaluation. However, I believe that confining this only to clinical social workers is inadequate and that the document does not lead to the use of other specialists. I fully appreciate and understand that smaller transplant programs that are not located at university medical centers may not have access to clinical psychologists or psychiatrists. However, a good many patients who present for solid organ transplantation have past histories of psychological or psychiatric disturbance or presently have these problems. This is not just an academic question, but these past and present psychiatric status actually has much to say about the disease progression, adherence and final outcome of these surgeries. Patients who are clearly depressed and who have not received appropriate interventions either of the psychological or pharmacological nature are sometimes either precluded from being listed or receive transplants which may fail due to psychiatric/psychological reasons. Increasingly, in this organ pool are individuals who have had significant histories of substance abuse and alcoholism, making it difficult to attribute cognitive disturbances to either the progression of the organ disease or to a psychological or psychiatric status.

I am merely asking that the proposed rules be altered in a way that would suggest that further evaluations by clinical psychologists or psychiatrists may be necessary and that the initial evaluation could be done by social work or clinical psychologist or psychiatrists and that evaluations by a clinical psychologist or psychiatrist should be mandated for individuals who have histories of psychiatric illness or substance abuse.

Sincerely,



Barry A. Hong, Ph.D., FAACP
Professor of Psychiatry
Associate Professor of Medicine
Chief Psychologist, Barnes-Jewish Hospital

BAH/rh



March 10, 2005

By Federal Express

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
C5-11-24
Baltimore, MD 21244-1850

Re: Proposed Rule: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplantations; CMS-3835-P: Request for Extension of the Comment Period

Dear Dr. McClellan:

The American Society of Transplant Surgeons and the American Society of Transplantation are writing to request that the comment period for the above-referenced proposed rule be extended an additional 60 days. The comment period for this proposed rule is currently scheduled to end on April 5, 2005. Our organizations are working together to develop a coordinated response to this lengthy and complex proposed rule. This extension is necessary to allow our organizations to develop thoughtful comments which will be of use to the agency in its efforts to establish appropriate quality standards for Medicare-approved transplant centers.

We appreciate your consideration of this request.

Sincerely,

Richard J. Howard, MD, PhD
ASTS President

Jay A. Fishman, MD
AST President

cc: Sean Tunis, M.D.
Rachael Weinstein

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Department of Surgery
Medical School

11-200 Phillips-Wangenstein Bldg.
MMC 90
420 Delaware St S.E.
Minneapolis, MN 55455
Office: 612-625-1485
Fax: 612-624-7168
E-mail: grues001@umn.edu

February 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Proposed Outcome Measure Requirements for Intestine Centers
(CMS-3835-P Report, p. 92)

To Whom It May Concern:

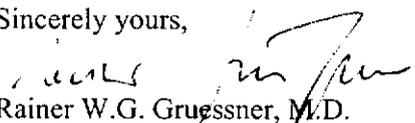
This letter is in strong support of the CMS recommendation to propose "that there not be any volume or outcomes criteria for **intestinal transplantation** ... [because such criteria would] ... further limit access to a rare procedure" (pp. 95-96).

We and other transplant centers that were initially not certified by CMS have previously argued that the 2000 CMS Medicare National Coverage decision for intestinal transplantation was based on a misinterpretation of the data available at the time from the International Intestinal Transplant Registry, directed by Dr. David Grant, Toronto, Canada. According to the Registry data, transplant centers that had performed ≥ 10 transplants *total* and not *per year* should have been certified. The 2000 CMS Medicare National Coverage ruling seriously disadvantaged new, potentially high-quality, intestinal transplant programs and potentially compromised the care of patients living in regions without CMS-certified intestinal transplant centers. In addition, updated Registry data show that the center volume no longer affects intestinal transplant outcome. Please see the attached letter dated October 10, 2003, that brought the issue of the 2000 CMS Medicare National Coverage decision for intestinal transplantation to the attention of Mr. T. Scully, previously Director of CMS. Unfortunately, Mr. Scully never responded to our request for a meeting to reassess the coverage decision.

The current proposal will allow greater access to this procedure and decrease financial burdens (e.g., travel costs, absence from work) for involved family members. Because half of potential intestinal transplant candidates also require a simultaneous liver transplant, the new proposal -- "which requires transplant centers to be located in a hospital that has Medicare approval to perform liver transplants" (pp. 95-96) -- will be supported by the majority of transplant centers.

In summary, this new proposal for CMS coverage for intestinal transplantation is favorable because it eliminates previously created disadvantages for low-volume intestinal transplant centers and financially burdened families.

Sincerely yours,


Rainer W.G. Gruessner, M.D.
Professor of Surgery
Vice-Chief, Division of Transplantation

RWGG/lcw
encl

New England Organ Bank

Yale-New Haven Transplant Center
333 Cedar Street-FMB 20
P.O. Box 208062
New Haven, CT 06520-8062

March 15, 2005

24-hour number: 800/446-NEOB
Office number: 203/785-4237
Fax number: 203/785-7162

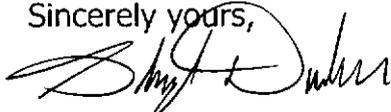
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

Quality patient care is vital to the transplant community, as is this mandatory requirement for professional certification of clinical transplant coordinators who perform direct patient care within the transplant community. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing level of clinical transplant coordinator competency.

Sincerely yours,



Sheryl Douless RN, BSN, CPTC
NEOB



March 17, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

Quality patient care is vital to the transplant community, as is this mandatory requirement for professional certification of clinical transplant coordinators who perform direct patient care within the transplant community. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing level of clinical transplant coordinator competency.

Sincerely yours,

Deirdre McAdams, RN, CPTC
Director of Quality Systems and Compliance
Tennessee Donor Services

1600 Hayes Street, Suite 300
Nashville, TN 37203
615 234 5251
888 234 4440 (OPO Office)
800 969 GIFT (24 hour donor referral)
615 320 1655 Fax
www.dcidonor.org

*A Division of DCI Donor Services
A Non-Profit Corporation*
Tennessee Donor Services
Golden State Donor Services
New Mexico Donor Services
Sierra Eye & Tissue Donor Services
Mountain Region Donor Services



American Board for Transplant Certification

P.O. Box 15384
Lenexa, KS 66285-5384
(913) 599-0198
(913) 599-5340 FAX
www.abtc.net

March 21, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, Maryland 21244-8013

Dear Messers:

This letter is submitted in support of the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. This letter further supports that a qualified clinical transplant coordinator be an individual receiving certification by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification). The American Board for Transplant Certification also supports that all licensed health care professionals functioning in the capacity as a transplant coordinator within Medicare facilities performing organ transplants be required to sit for the Certified Clinical Transplant Coordinator (CCTC) examination offered by the American Board for Transplant Certification. These proposed requirements will ensure that each organ-specific transplant program that may function in conjunction with, or independently of other facility organ-specific transplant programs, have available transplant coordinators employed which hold the title of clinical transplant coordinator certified by the American Board for Transplant Certification.

Quality patient care is vital to the transplant community, as is the requirement for professional certification of clinical transplant coordinators who perform direct patient care within a Medicare transplant facility. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing the competency level of clinical transplant coordinators. The proposed requirement for a Certified Clinical Transplant Coordinator, through the American Board for Transplant Certification, will also ensure a minimum level of regular continuing education. Supplemental information enclosed fully describes the psychometric methods utilized by the American Board for Transplant Certification for the development of each of its certification examinations and continuing education requirements.

Sincerely,

Richard E. Pietroski, MS, CPTC

President

American Board for Transplant Certification

Enclosure



AMERICAN BOARD FOR TRANSPLANT CERTIFICATION

CERTIFICATION PROCESS OVERVIEW

BACKGROUND:

American Board for Transplant Certification

The American Board for Transplant Certification (formerly known as the American Board of Transplant Coordinators) is an independent, not-for-profit organization with the mission of awarding voluntary non-governmental certification credentials. Currently, Certified Clinical Transplant Coordinator (CCTC), Certified Procurement Transplant Coordinator (CPTC), and Certified Clinical Transplant Nurse (CCTN) certificates are awarded to qualified transplant professionals that successfully demonstrate a given knowledge threshold based upon a 150 multiple-choice question certification examination. The CCTC examination establishes a national standard baseline competency for transplant center candidates that facilitate pre-transplant care and discharge planning of end-stage organ disease patients, the CPTC examination establishes a national standard baseline competency for organ procurement organization candidates that facilitate donor hospital activities that result in the facilitation of transplantable organs, and the CCTN examination establishes an international standard baseline competency for organ transplant center bedside registered nurses that administer perioperative surgical care to end-stage organ disease patients.

The American Board for Transplant Certification has been an incorporated organization in the states of California and Kansas since 1988. Under this incorporation, the ABTC maintains a board of governors that manage the organization's ongoing operations. In addition to the ABTC board positions of president, vice president, treasurer, and secretary, the ABTC has board positions which chair committees that oversee procurement examination, clinical examination, transplant nurse examination, judiciary, clinical credentials, and continuing certification. Two additional board positions are at-large representatives that are elected annually by the ABTC membership. Furthermore, the ABTC Board of Governors has resolved in January 2005, to add a third elected at-large member to the Board in 2005 as a means of ensuring that all examinations represent current and best practices.

Examination Development

The American Board for Transplant Certification clinical, procurement, and nursing examination committees meet face-to-face annually, and on a regular basis by telephone or Web conference calling, to develop examination items (test questions). Each ten-member committee consists of experts that represent a wide range of national procurement and transplant specialties. Additionally, two CCTN examination committee members represent the international transplant nurse field. The examination committees are structured to provide input into item development

that will ensure broad recognition of practice and limit regional practice variation that could advantage or disadvantage test candidates. All test items are specific to a test matrix which represents job functions consistent with national or international practice. The matrix guides the test development through the formation of items that test within a consistent distribution of practice areas for examination candidates. Equivalent job functions are determined through a job analysis that is typically performed every five to seven years. The national or international job analysis can be performed with greater frequency through the input of the ABTC Board of Governors, examination committees, or through communication from professional membership organizations. The ongoing requirement to perform a periodic job analysis is used as a method to gauge baseline practices nationwide and throughout the international transplant communities. If the job analysis determines that the baseline job functions have changed, or have become specialized to a limited geographic area, relevant examination items are either retired or rewritten to correspond with current and best practices.

Examination Administration

The American Board for Transplant Certification develops candidate examinations in conjunction with its test development contractor, Applied Measurement Professionals (AMP). ABTC has maintained a contractual relationship with AMP since 1988 for ABTC test development and for administrative services. Under the test development contract, AMP employs psychometric item analysis that statistically measures the baseline competency of procurement, clinical, and transplant nurse test candidates. Each test item is reviewed for item performance which allows for substantiating the competency of more proficient examination candidates and qualifying the limited proficiency for less able candidates.

A cut (passing) score is established for each examination based on the normal distribution of more to less qualified candidate scores and a calculated variability and precision index for the examination. Following each examination, Test Analysis Reports demonstrate the level of critical review that each examination receives by the ABTC examination committees and Board of Governors. The Test Analysis Report also validates that ABTC's recent change from paper-based to computer-based test administration has maintained examination reliability. Computer-based testing has allowed ABTC to simultaneously administer multiple 150-question examination forms from an extensive pool of test items to candidates in virtually all metropolitan statistical areas nationwide. Through ABTC's activity associated with the CPTC examination, procedures have been established to administer examinations at any secure location by means of the World Wide Web. Web-base computer examination has been found to be user friendly and cost effective for both the examination candidates and for ABTC.

To-date, the American Board for Transplant Certification has the experience of having administered approximately 4,000 examinations to candidates in the field of organ procurement and transplantation. Candidates that successfully demonstrate competency are conferred with the credentials of Certified Clinical Transplant Coordinator (CCTC), Certified Procurement Transplant Coordinator (CPTC), and Certified Clinical Transplant Nurse (CCTN). While the

overwhelming majority of candidates granted ABTC certification are based in the United States, there is also membership throughout the world.

The ABTC CPTC certification examination is the only certification currently recognized by the Association of Organ Procurement Organizations (AOPO) for meeting the AOPO accreditation administrative standard for demonstrating that OPO coordinators are sufficiently trained. The AOPO administrative standard states:

“Job descriptions should be reviewed. Review OPO’s methods of training organ recovery coordinators and documentation related to training process. The evidence of CPTC credentialing is deemed sufficient to determine that those individuals are trained. For those individuals not CPTC credentialed, look for other evidence of training.”
(www.aopo.org; Administrative Standard AS 2.3).

Recertification

In order to maintain American Board for Transplant Certification credentials, certificants may recertify by demonstrating a sufficient level of continuing education within their field of professional practice. Recertification requires that candidates achieve a minimum of 60 qualifying continuing education contact hours over each three-year period. One third of the contact hours must be in conjunction with ABTC approved programs. There are currently 1,607 persons that hold active CPTC (667), CCTC (778), and CCTN (162) credentials, and a limited number of individuals hold dual certification. Information regarding ABTC certification and recertification is located at www.abtc.net.

3-21-05



OSF

SAINT FRANCIS MEDICAL CENTER
A commitment to life.

March 23, 2005

Dear Sir or Madam:

The purpose of this letter is to notify you of concurrence with the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3845-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation; and the donor evaluation, donation and discharge phases of donation. We also support the requirement that a qualified clinical transplant coordinator is an individual, who is certified by the American Board of Transplant Coordinators.

Clinical Transplant coordinators perform direct patient care and it is imperative that an objective methodology for assessing level of clinical competency be in place. The proposed standard requiring certification of coordinators will aid in ensuring the public that the transplant community is doing everything possible to minimize medical errors associated with donation and transplant.

Sincerely:

Suzanne Faulkner
Director of Transplant Services
OSF/Saint Francis Medical Center



INOVA TRANSPLANT CENTER

A Service of Inova Fairfax Hospital

23 March 2005

*Outpatient Center
8503 Arlington Boulevard
Suite 200
Fairfax, Virginia 22031*

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

I am sending this letter as notification of agreement for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), as well as support for the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of donation and transplantation. This letter is also in support of the definition qualified clinical transplant coordinator as being an individual who is certified by the American Board of Transplant Coordinators.

I have been in the field of transplantation since 1987, and certified since 1993, and can certainly attest to the fact that patients, families, staff, and the community views certification of the coordinators as an affirmation of education, training, commitment, and expertise in the transplant field.

Quality patient care is vital to the transplant community, as is the mandatory requirement for professional certification of clinical transplant coordinators who perform direct patient care within the transplant community. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplantation, and that the transplant industry has an objective methodology for assessing the level of clinical transplant competency.

Sincerely,

Marion Stewart, RN, BSN, CNN, CCTC
Clinical Transplant Coordinator
Inova Fairfax Hospital
8503 Arlington Boulevard
Suite 200
Fairfax, VA 22031



THE ROGOSIN INSTITUTE
Centers For Medical Research And Health Care

Rogosin Kidney Center
Transplantation Division

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

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Sincerely yours,

A handwritten signature in cursive script that reads "Marian Charlton RN".

Marian Charlton, RN CCTC
Transplant Coordinator.



DEBORAH CROWE PhD
Laboratory Director

a division of Dialysis Clinic, Inc.
(a non-profit corporation)

JAMES M. LAPPIN
Administrator

March 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge of phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporation as the American Board for Transplant Certification).

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Sincerely,

A handwritten signature in black ink that reads 'Christina Bishop, MT, CHT'. The signature is written in a cursive style.

Christina Bishop, BS MT (ASCP, NCA), CHT (ABHI)
DCI Transplant Laboratory
1924 Alcoa Highway, 6 North
Knoxville, TN 37920

University of Tennessee Medical Center of Knoxville • Transplant Laboratory
1924 Alcoa Highway, 6 North • Knoxville, Tennessee 37920-1511

2917 Foster Creighton Drive, Nashville, TN 37204
1616 Hayes Street, Nashville, TN 37203

3300 Lemone Industrial Blvd., Columbia, MO 65201 • At Erlanger Medical Center, 975 East Third Street, Chattanooga, TN 37403

11

Department of Health and Human Services
Centers for Medicare and Medicaid Services
42 CFR Parts 405, 482, and 488
CMS-3835-P
RN: 0938-AH17

Medicare Program; Hospitals Condition of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants

I am going to divide my comments into 2 sections. First, I will give my overall opinion on the proposals. Then, I will comment on living donation with more details since I am a living donor.

I support these comprehensive proposals for transplant centers with requirements focusing on a center's ability to perform successful transplants and deliver quality care as determined by good outcomes plus sound policies and procedures. As stated, these proposals are to assure that transplant centers continually provide high-quality transplant services in a safe and efficient manner. This requires institutional support for resources and services as well as government oversight.

On p. 152, the document states that CMS or their designee will have the responsibility for monitoring and coordinating procedures for approval and re-approval. It is reassuring that the government is making a statement of authority and responsibility for oversight. It concerns me that UNOS policies are voluntary and that the no OPTN policy has been approved by the Secretary of HHS so not legally enforceable. Who protects the public or controls the scarce resource (organs) and oversees outcomes? To whatever authority will be responsible for compliance of these proposals, I suggest on-site audits for: any complaints by patients, families, public including the media, hospital staff or transplant colleagues; random surveys to keep centers on their toes; and if notified by the OPTN that there is a problem with data submission or problem with data (volumes, outcomes, etc.) It is not reasonable to think can audit all centers in a 3 year period, would be too labor-intensive.

Living Donation:

It is extremely important to ensure safe, high-quality services in safe/efficient manner for all living donors. CMS should monitor outcomes and policies/procedures.

This documents states that since 1990, living donation is the fastest growing source of organs. There is growing concern for safety of living donors? So why has nothing been done yet as far as mandatory requirements to protect the living donor.

Kidneys: low risk for death, but increased risk of donor morbidity

Living renal donation has long term risk that may not be apparent in the short term, which leads us to believe that donors should be informed of long-term risk. How can a center or the transplant community provide informed consent if there is no national living donor registry and the OPTN only plans to require a 6 month and 1-year follow-up? There is no source for long-term data.

Livers--1% risk of death (projected estimates 750 LDLT. Are we ready to accept 7-8 living liver donor deaths per year?)

p. 25--In the absence of national guidelines for donor selection, it is difficult to ensure that living donations are performed safely"--so why do you allow it to happen?? Why has the system of care for living donors failed to establish national guidelines and hold centers accountable?

The document states that accurate physical and psychosocial assessment is imperative to reduce likelihood of harm to health donors. Regardless, we are harmed by the very nature of having any surgery when not needed. Why not raise the bar for those who want to do living donation by making the rules tougher than we expect for deceased donors?

Concerns: lack of standardized recipient and donor selection criteria, lack of national outcomes database, lack of best practices in living donation procedure, variability in surgical expertise, volume and center resources given the growing number of living donor transplants

For living donors CMS has proposed minimum requirements!! This document states that living donation is 'very promising medical practice'--I find this troubling in light of just celebrating the first

kidney transplant over 50 years ago which was a living donation plus have allowed adult-to-adult living liver donation for over 7 years (adult-to-child much longer), living lung donations, etc plus have allowed anonymous living donation without mandatory national guidelines or safeguards. What has taken so long?

p 26 **CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS**

Each organ transplant center would be approved separately. I propose that if that particular center wants to do living donation, this also is approved separately. Just because a surgeon can implant an organ, does not guarantee skill with removal of an organ from a living donor. Living donor outcomes (mandatory review of all donor deaths) would be critical as well as volume and surgeon skills. There needs to be national criteria for centers performing living donor transplants. YES--protect the living with strict standardization.

CMS and the Secretary have the authority to establish standards necessary for the health and safety of individuals furnished services in hospitals. If you believe you have sufficient authority to prescribe rules for transplantation, please apply your authority to living donation.

p 113 **PATIENT AND LIVING DONOR SELECTION**

Living donors must be medically and psychosocially suitable to donate an organ.

p. 116—Living Donor Evaluation:

Propose: written living donor uniform, selection criteria to determine suitability
: document in both candidate and donor medical record

State that have not proposed specific living donor selection criteria because there are no established guidelines concerning the selection of living donors at this time. This is very concerning since allow a practice to put healthy people at risk without affording them any protections under the Federal laws. State that must document that given informed consent but what does this mean? Living donors need a uniform standard for informed consent.

p. 120--Patient and LD Management (separate out the living donor issues)

Propose: that centers performing living donor transplants **must have** written donor management policies for donor evaluation, donation, and through the donor's discharge plus a thoroughly documented discharge plan including who will follow this donor for the long-term.

What about post-discharge issues or complications? Mandate that centers cannot abandon this donor if harmed and that they are responsible for the care.

I support a multidisciplinary team coordinated by a designated physician whose primary interest is the living donor. Mandate a separate surgeon who does only the donor surgery to avoid conflict of interest. Are you aware that in some centers the same surgeon is operating on the living donor and the recipient?

In the postoperative period, provide a medical doctor to follow the living donor i.e., nephrologists if donated a kidney, hepatologist if donated a piece of liver, pulmonologist if donated a lobe of lung--all the attention is on the recipient--what about safeguards for the living donors?

I support the proposal that the social worker be at Masters' level and that will have a dietitian available to living donor.

p 128 QAPI specific to living donor issues

I support the requirement for QAPI--develop, implement and maintain written comprehensive, data-driven program designed to monitor and evaluate all transplant services. This data would be available for onsite audit by either CMS or the OPTN

For sure want a policy to address adverse events but should include the frequency of internal and external audits. I do not support a system of care in which audits are only complaint-driven.

There must be evidence of ongoing quality monitoring.

p 136--**PATIENT AND LIVING DONOR'S RIGHTS**

Informed consent is a unique aspect of living donation.

PROPOSE: have written informed consent process that addressed unique aspects of living donation plus require detailed documentation in the medical record. Important to know which MD obtained informed consent and what details were shared with the potential donor.

p 140--ACOT recommendations.

These are excellent but support that centers not just 'consider' them but follow them. Why waste all the time and expertise of this committee without implementing their recommendations? And make them requirements. Need a uniform standard of informed consent by organ just as ACOT did with living liver donation.

I support very comprehensive national, uniform criteria for assessment and informed consent for all living donors. I support mandatory compliance of requirements for Designated Living Donor Centers. I support making the rules very tough if want to do living donation. Need safeguards in place in order to protect the public.

Independent donor advocate—YES. The living donor should have a designated advocate who has access to their records, can manage their care, and oversees their care.

Since this is not yet available, I refer CMS to the website www.lodap.com for the Living Organ Donor Advocate Program which is resource for living donors.

I suggest this advocate, if from within the hospital, not be a member of the transplant team. Need to be independent from the team since not really independent of the interests of the hospital.

This individual can be either an MD or an RN and will be trained for their role specific to the risk, care needs of the living donor. Their sole purpose is oversight of donor care and follow-up.

What is needed?

1. Long-term registry with data submission mandatory for all living donors
2. Designated donor advocate
3. Living Donor rescue account costs accrued by donor or for lost wages, health care coverage, etc. Since the Frist/Kennedy bill did not get funded, there is no money available at this time.
4. Strict penalties under the law for centers who harm and abandon a living donor. Refer to www.iamnotacadaver.com or www.liverdonornightmare.com
5. On-site survey for:
 - any data submission problem or concerns regarding volume or outcomes
 - : death of a living donor
 - or: complaint filed by a living donor or family against a center or surgeon.

Submitted by:
Donna L. Luebke
Kidney donor, 1994

March 23, 2005

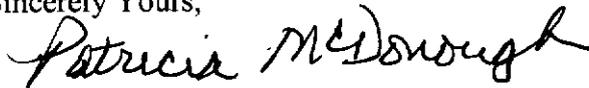
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

Please accept this letter as notification of my agreement with the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that **a transplant center must have a qualified clinical transplant coordinator** to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. And furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

Quality patient care is vital to the transplant community, as the transplant coordinator is on the front line of pre and post transplant care delivery it is as essential as physician certification, that the clinical transplant coordinator be certified in Transplantation. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing level of clinical transplant coordinator competency.

Sincerely Yours,



Patricia McDonough, RN, CCRN, CCTC, CPTC
Clinical Transplant Coordinator
Montefiore Medical Center

March 25, 05

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Service Attn: File Code CMS-3835-
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid:

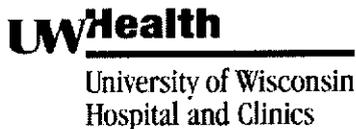
In the thirty years I have been a dialysis social worker, I have seen the enormity of business side grow. More and more individuals are diagnosed with ESRD and therefore receive hemodialysis treatments three times a week largely funded by Medicare and Medical dollars. As dialysis companies focus on their profits, their temptations lie in reducing costs like the social worker who usually is a masters level person well educated and equipped to treat and counsel patients undergoing a chronic disease. Let's make sure to keep this vital human function in place. With the ability to talk to a professional social workers, dialysis patients function better and are more able to contribute to society. For example, I have counseled people with job conflicts related to dialysis that has helped patients keep their jobs. I have also counseled patients in vocational directions that have led to dialysis patients obtaining jobs and thus, ceasing their dependence on government monies like SSI. Additional long term therapy and emotional support as well as assistance with concrete problem solving is vital to anyone undergoing a chronic disease. I therefore urge you to sustain proposal 494.14(proposal for dialysis centers. We want to keep a master's level social worker-preferably a social worker licensed by state, to assist the abundance (and ever growing numbers) of hemodialysis patients receiving treatments paid for by Medicare and Medical in dialysis centers all over the country.

Thanks for your attention to this.

Sincerely,



Susan F. Levine, L.C.S.W
221 Mira Mar Ave.
Long Beach, Calif. 90803



Electronically we can submit at <http://www.cms.hhs.gov/regulations/ecomments>

The Honorable Mike Leavitt
Department of Health and Human Services
Attention: CMS-3835-P
P. O. Box 8013
Baltimore, MD 21244-8013

<p>Official Copy submitted to DHHS Website on April 7, 2005</p>
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Dear Secretary Leavitt,

The University of Wisconsin Hospitals and Clinics Authority (UWHCA) is pleased to have the opportunity to comment on the Secretary's proposed modifications to the "Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants." As a hospital providing transplant services since 1966, we appreciate the desire to ensure that all transplant centers provide an acceptable standard of care for transplant recipients. As such, UWHCA respectfully submits the following comments to the proposal.

§482.82 Condition of Participation: Data Submission and Outcome Requirements for Re-approval of Transplant Centers

"Proposed Outcome Measures"

UWHCA agrees with the proposal to require that a transplant center's one-year graft and patient survival be lower than expected as reported by the Scientific Registry of Transplant Recipients AND that transplant center must meet all three of the following thresholds: 1) the one-sided p-value is less than 0.05; 2) the number of observed events minus the expected events (O-E) is greater than three; 3) the number observed events divided by the number of expected events (O/E) is greater than 1.5. This proposal is reasonable and will eliminate surveys of transplant centers based on data that is not statistically significant.

§488.61 Special Procedures of Approval and Re-Approval of Organ Transplant Centers

UWHCA agrees with the proposal for re-approval that would require transplant centers to meet the data submission and outcomes requirements for re-approval proposed at §482.82. UWHCA concurs that it is a prudent use of resources to only survey centers applying for re-approval that do not meet the requirements as stated in §482.82.

The Honorable Mike Leavitt

April 7, 2005

Page 2 of 2

“Alternative Process to Re-Approve Transplant Centers”

The Proposed Process Requirements are consistent with other Joint Commission on Accreditation of Health Care Organizations and Organ Procurement and Transplantation Network (OPTN) standards and policies for which transplant centers are currently surveyed. Performing random surveys and/or surveying every center as part of re-approval is duplicative and would divert center resources away from patient care for additional survey preparation work. UWHC supports §488.61 as written.

Additionally, UWHCA is concerned with the alternative proposal to survey transplant centers based upon feedback from the OPTN. The proposed regulation as written at §488.61 is based on statistically significant data as opposed to “feedback” that may or may not be relevant to the competency of the transplant center to provide transplantation.

Sincerely,



Donna Sollenberger
President and CEO
University of Wisconsin
Hospitals & Clinics Authority
608/263-8025

April 5, 2005

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services, Attn: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-3835-P, Proposed Rule: Medicare Program; Hospital Conditions of Participation:
Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants

Dear Mr. McClellan

The Transplant Social Workers of Iowa welcome the opportunity to offer comments regarding the proposed regulations for the Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to perform Organ Transplants (42 CFR Parts 405, 482, 488) which was published February 4, 2005. Our comments are motivated by the desire to ensure that Medicare beneficiaries and others needing organ transplant, as well as living organ donors, will have their psychosocial needs addressed by transplant centers. Specifically, we support the proposed process requirements that address quality of care for patients. We agree that adequate staffing is critical to transplant program efficiency and the resulting organ and patient outcomes. We approve of recognizing that the well being of living donors is as important as the well being of the transplant recipients.

We also support the proposed requirement that social services be provided by qualified social workers with Master of Social Work degrees to all living donors, recipients and their families. The specification that transplant centers provide qualified social workers to evaluate psychosocial needs, participate in care planning, and to identify community resources for patients and their families is very important. We welcome this proposal as it recognizes the importance of assisting and supporting all living donors, transplant recipients and their families in maximizing their social functioning and adjustment.

However, there is one element of this proposed requirement that actually lowers the standard for the qualified social worker when compared to the existing definition of the qualified social worker found in current kidney transplant center regulation 405.2171. The current regulations have stated that a qualified social worker is "a person who is licensed, if applicable, in the state in which practicing and:

(1) Has completed a course of study with specialization in clinical practice and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education. OR

(2) Has served for at least two years as a social worker, one year of which was in a transplantation program and has established a consultative relationship with a social worker who has obtained the education described above.”

Please note that (2) above seriously undermines the current standard of requiring transplant programs employ qualified social workers with masters' degrees. A recent study showed that of 312 transplant social workers in 411 transplant programs in 139 transplant centers, 96% had Master of Social Work degrees. With the inclusion of (2) above there is nothing to prevent a reduction over time of the standard to a lower rate of social workers with master's degrees in transplant programs. This would negatively affect the quality of care provided to transplant patients and living donors.

RECOMMENDATION: The Transplant Social Workers of Iowa recommend that the Final Rule define that standard for social services and qualified social workers as follows:

Page 6180 (d) Standard Social Services. The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the state which practicing, and

(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.

Please let us know if we can provide any additional information to substantiate this recommendation or to assist your agency in implementing it. Thank you.

Sincerely,

Laura Anderson Rice, LISW
Laura Anderson Rice, LISW

Iowa Methodist Transplant Program, Des Moines

Jane Blaton, LISW, CADC
Jane Blaton, LISW, CADC

Univ. of Iowa Hospitals and Clinics Transplant Program

Yuk Sum Chung, LMSW
Yuk Sum Chung, LMSW

University of Iowa Hospitals Clinics Transplant Program

Bruce Hoffmaster, LISW
Bruce Hoffmaster, LISW

Mercy Medical Center Transplant Center, Des Moines

Beth D. Houseal, MSW Student
Beth Houseal, BA

Univ. of Iowa Transplant Intern

Bronwyn Threlkeld-Wiegand, LISW
Bronwyn Threlkeld-Wiegand, LISW

University of Iowa Hospitals Clinics Transplant Program

Carol Winetroub, LISW
Carol Winetroub, LISW

VA Medical Center Transplant Program, Iowa City

University of Maryland Medical System

DEPARTMENT OF SOCIAL WORK



The Honorable Mark McClellan, Administrator March 14, 2005
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-3835-P, Proposed Rule: Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

Dear Mr. McClellan:

The Society For Transplant Social Workers have informed me of a subtle change in the above regulations that could lower the current standard of care for transplant patients (405.2171 [2]). The standard of practice that has already been established in the transplant social work community in the U.S. needs to be maintained. It is paramount that licensed masters degreed social workers from an accredited school of social work provide clinical services to this population as a result of the multiple high risk determinants of health (biological, behavioral, social and environmental) that the transplant patient have to live and cope with before and after transplantation.

I fully support the concerns and recommendations made by The Society For Transplant Social Workers and hope that we have your support to implement changes in the regulations to include these recommendations.

Thank you,

Gracie Moore-Greene, LCSW-C
Clinical Team Leader – Transplant Social Work
University of Maryland Medical Center
Department of Social Work
ggreene@uum.edu

March 25, 05

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Service Attn: File Code CMS-3835-
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid:

In the thirty years I have been a dialysis social worker, I have seen the enormity of business side grow. More and more individuals are diagnosed with ESRD and therefore receive hemodialysis treatments three times a week largely funded by Medicare and Medical dollars. As dialysis companies focus on their profits, their temptations lie in reducing costs like the social worker who usually is a masters level person well educated and equipped to treat and counsel patients undergoing a chronic disease. Let's make sure to keep this vital human function in place. With the ability to talk to a professional social workers, dialysis patients function better and are more able to contribute to society. For example, I have counseled people with job conflicts related to dialysis that has helped patients keep their jobs. I have also counseled patients in vocational directions that have led to dialysis patients obtaining jobs and thus, ceasing their dependence on government monies like SSI. Additional long term therapy and emotional support as well as assistance with concrete problem solving is vital to anyone undergoing a chronic disease. I therefore urge you to sustain proposal 494.14(proposal for dialysis centers. We want to keep a master's level social worker-preferably a social worker licensed by state, to assist the abundance (and ever growing numbers) of hemodialysis patients receiving treatments paid for by Medicare and Medical in dialysis centers all over the country.

Thanks for your attention to this.

Sincerely,



Susan F. Levine, L.C.S.W
221 Mira Mar Ave.
Long Beach, Calif. 90803

559131

March 25, 05

205 APR 15 11 09 AM

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, D.C. 20201

Re: CMS-3835-P-Medicare Program-Hospital Conditions of Participation :Requirments
for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

Dear Mr. McClellan:

The Society of Transplant Social Workers was formed over 20 years ago to make sure transplant donors and recipients receive professional attention for their psycho-social needs. As you probably know, Medicare is the primary payer for transplant process and therefore, you have a large input in making sure these patients and medicare recipients receive the high quality of care we all deserve.

I am therefore urging you to support the following:

1. A licensed (by the state) social worker be a member of the transplant team not only to assess donor and recipient's needs and feelings initially but also, to counsel during transplant process. Often people need emotional support just to cope with bewildering and depressing side effects from additional medications they must take during transplant process. And of course any major surgery generally causes a lot of fear and anxiety.

Bottom line—we want these costly and life enhancing surgeries to be successful. I strongly believe that a mandated law ensuring that donors and recipients be seen initially and during transplant process by master's level social worker (preferably licensed level) with experience in hemodialysis and transplant, will decrease percentage of rejection and therefore increase level of donor acceptance thereby creating a healthier society and returning more and more hemodialysis patients to the work force and off government assistance (SSI).

Thanks for listening. These comments are related to 42 CFR parts 405, 482, 488 which was published Feb, 04, 2005 as part of Requirements for Approval and Re-approval of Transplant Centers,

Sincerely,



Susan F. Levine, L.C.S.W. M.S.W.

Wine's



ORACLE
PACKAGING, INC.

221 Mira Mar Avenue
Long Beach, CA 90803



THE HONORABLE MAJOR McClellan, Adm
Centers For Medicare & Medicaid Services
200 Independence Ave S W

WASHINGTON, DC 20201



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WASHINGTON, DC 20515-2204
(202) 225-3661
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WORLD WIDE WEB:
<http://www.house.gov/camp>

DISTRICT OFFICES:
135 ASHMAN STREET
MIDLAND, MICHIGAN 48640
(989) 631-2552
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121 EAST FRONT STREET, SUITE 202
TRAVERSE CITY, MICHIGAN 49684
(231) 929-4711
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CTS - 55 881 -

DAVE CAMP
DISTRICT, MICHIGAN
COMMITTEE ON
WAYS AND MEANS
SELECT REVENUE MEASURES
CHAIRMAN
HUMAN RESOURCES
HEALTH

Congress of the United States
House of Representatives
Washington, DC 20515-2204

April 7, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. McClellan:

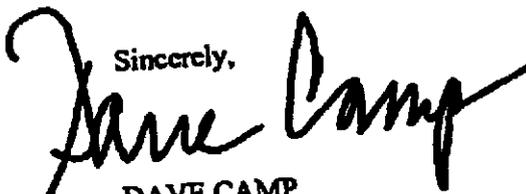
I am writing to express my concern regarding the proposed rule, CMS-3835-P, issued by the Centers for Medicare and Medicaid Services (CMS).

As you may know, in the 106th Congress I introduced H.R. 4592, to revise the performance standards and certification process of organ procurement organizations (OPO). I was pleased that this legislation was included in the final version of the Public Health Services Act of 2000, P.L. 106-505. This legislation requires the Secretary of Health and Human Services to adopt new standards to improve the certification process for organ procurement organizations by January 1, 2002. However, I am concerned that CMS is only now proposing these new regulations, nearly four years after P.L. 106-505 was signed into law, and only months before a new certification of OPOs are to take place. This leaves little time for the organizations to ensure that they are meeting all necessary regulations.

I am also concerned about the proposed implementation of a competitive model which would make OPOs compete every four years for the right to continue to serve its area. As I understand the proposed regulations, even the service areas of OPOs satisfying the new outcome and process measures would be subject to competition from other OPOs. I believe this would increase the level of uncertainty in the OPO certification process; directly contradicting the law's original intent.

Like you, I believe that we must continue foster positive relationships among the OPO community, and I am pleased that HHS, OPOs, and the nation's largest hospitals have undertaken the Organ Donation Breakthrough Collaborative. This initiative, based on joint accountability and best practices, has helped increased the number of deceased organ donors by nearly 11% in just the past 15 months. I believe it is in the best interests of everyone involved to continue to build on the existing collaborative structure.

Thank you for your time and efforts on this important issue, and I appreciate your serious consideration in this matter.

Sincerely,


DAVE CAMP
Member of Congress

2005 APR 7 PM 4: 59

Twelfth District, New Jersey

1019 Longworth Building
Washington, D.C. 20515
202-225-5801
Fax 202-225-6025

50 Washington Road
West Windsor, NJ 08550
609-750-9365
Fax 609-750-0618

website and e-mail:
www.house.gov/rholt



Congress of the United States

and the Workforce

Permanent Select Committee
on Intelligence

Member
Congressional Arts Caucus
Congressional Working Group on Children
Congressional Fire Services Caucus
Sustainable Development Caucus
Internet Caucus
Law Enforcement Caucus

05 APR 20 11 2:26

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, DC 20201-0004

Dear Dr. McClellan,

I am writing in regards to proposed CMS rules establishing conditions for coverage for organ procurement organizations (OPOs). The specific rule was published in the Federal Register on February 4, 2005 and is found on page 6136, §486.382, item 5.

The rule mandates that organ procurement organizations (OPO) must provide the family with, among other things:

- *Information (such as for-profit or non-profit status) about organizations that will recover, process, and distribute the tissue.*

I have heard concerns about this rule from constituents of mine in the 12th Congressional District of New Jersey who work for a business involved in the processing of human bone and connective tissue for transplantation. My constituents are concerned that the proposed rule may have damaging effects on the ability of for-profit organizations to continue fulfilling their important role in the tissue recovery, processing, and distribution system.

My constituents' objection to the referenced wording within the CMS proposed rule is that "such as for-profit or not-for-profit status" is at best inadequate, and at worst misleading, in an effort to provide informed consent for tissue donation. I have attached a position paper with their full comments for your review.

This business is also an innovator in the development and manufacturing of biologic, biomaterial, and device systems for musculoskeletal surgery. I believe it is important that any rule affecting for-profit organ procurement organizations takes into account the important research and development (R&D) work that these companies conduct. I ask you to take their comments under proper consideration as you evaluate comments on the proposed rule.

Thank you for your time and consideration of this matter.

Sincerely,


RUSH HOLT
Member of Congress

RH/md

Osteotech comments on CMS rule on organ procurement organizations (OPO)

CMS is taking public comment on proposed regulations affecting Organ Procurement Organizations (OPO). The proposed rule can be found on page 6086 of the Federal Register, Vol. 70, No. 23, Friday February 4, 2005. Comments on the rule are due by 5 pm April 5, 2005.

Osteotech is a firm that has researched, patented and developed several key products and processes using cadaver skeletal components to improve the lives of patients. It is a "for-profit" company, but it is involved with hospitals and doctors across the country, as well as several "non-profit" organ groups.

Background:

CMS is claiming this rule is required by Congress (Organ Procurement Organization Certification Act of 2000, section 701 of Pub. Law. 106-505; and section 219 of the Conference Report accompanying the Consolidate Appropriations Act, 2001, Pub. Law 106-554). Those Acts ordered CMS to draft rules dealing with 4 specific topics:

- 1) Increasing the re-certification cycle for OPOs from 2 to at least 4 years;
- 2) Establish outcome and process performance measures based on empirical evidence;
- 3) Establish multiple outcome measures; and
- 4) Establish a process for OPOs to appeal a de-certification.

Problems:

- 1) The proposed rule appears to go beyond the scope of the language issues identified by Congress. Specifically the proposed rule appears, in an effort to create "informed consent" for prospective donors, to choose between whether the organs should go to "for-profit" or "non-profit" entities. This draft rule is #5 on the list of HHS' draft. This seems outside the scope of Congress's request for regulations because Congress wasn't asking HHS to go into this area.
- 2) The proposed rules makes little effort to educate people about the similarities and differences between the "for-profit" and "non-profit" entities among OPOs. This confusion is very likely to lead donor families down a path of selecting "non-profit" recipients because of the potential confusion or mis-understanding among donor families. This will have a crippling impact on the "for-profit entities". Remember, in this area the designation of "non-profit" usually only implies the tax status of the organization, not that it works for free. Beyond the tax status, there are few differences between these "for-profit" and "non-profit" entities involved with this aspect of donation transactions.
- 3) The analysis used by CMS in justifying the regulation looks only at solid tissue organs such as the heart, lung, kidney and pancreas. For the most part these organs have little opportunity for "value added" processes before they are transplanted. Usually they are required to be transplanted as soon as possible, often time within hours of a positive identification. Conversely, skeletal donations and eyeballs can be harvested and transplanted with "value-added" processes between the time of donation and implanting. This necessitates the involvement of both "for-profit" and "non-profit" entities to study, develop and perfect those

"value-added" processes. Without the involvement of "for-profit" entities many of the technologies used today to transplant eyes and skeletal components would be unavailable. Misleading donors into choosing between "for-profit" and "non-profit" recipients will upset the current balance in the organ ID and delivery market.

4) The cost-benefit analysis used by CMS determines that there will be no cost to hospitals with the proposed rule change. Yet it fails to evaluate whether there would be a higher cost to hospitals or the federal government if many "for-profit" companies are put out of business as a result of donors electing not to send donations to the "for-profit" entities. We believe this lack of competition will end up raising prices on hospitals and the government.

5) The proposed rule fails to recognize that in many of these transactions there are likely to be a series of both "for-profit" and "non-profit" entities involved up and down the supply chain. This would include recovery, identification, processing, marketing and transplantation. Forcing a donor family to choose between "for-profit" or "non-profit" recipients does not take the reality of the entire supply chain into account. It unfairly helps "non-profit" entities by possibly misleading donor families.

6) There is some unofficial feeling that this rule is being pushed by a few "non-profit" entities that want to make it difficult for the "for-profit" entities to compete. They think if given the choice donor families will choose "non-profit" recipients, thereby drying up the supply for "for-profit" groups, putting them out of business. This will lead to less innovation and competition on the commercial side of the organ donation supply chain, where many "for-profit" and "non-profit" groups work together and in competition. This would be bad for the entire industry, although it would make a few on the "non-profit" side of the industry very wealthy.

March 29, 2005

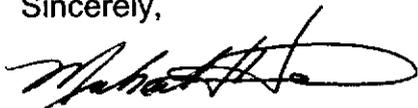
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

Please accept this letter as notification of concurrence for the Centers for Medicare and Medicaid Services Proposed Rulemaking (CMS-3835-P), and in specific support of the proposed standard that a transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. Furthermore, this letter is in support that a qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification).

Quality patient care is vital to the transplant community, as is this mandatory requirement for professional certification of clinical transplant coordinators who perform direct patient care within the transplant community. The proposed standards will aid in ensuring the public's awareness of elevated safeguards to minimize medical errors associated with donation and transplant, and that the transplant industry has an objective methodology for assessing level of clinical transplant coordinator competency.

Sincerely,



Michael J. Hill
Executive Director
Hospital Administration

April 26, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Proposed Rule: Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

I am writing to offer comments regarding the above referenced proposed regulations (42 CFR Parts 405, 482, 488), published February 4, 2005. Enclosed is one original and two copies. My comments are motivated by the desire to ensure that Medicare beneficiaries and others who need organ transplants, as well as living organ donors, receive the best possible psychosocial services addressed by the transplant centers. As a kidney and pancreas transplant social worker, I want to address these proposed regulations in detail as follows:

Issue Identifier: 482.90 Condition of participation: Patient and Living Donor Selection

Comment: I support the mandate of a psychosocial evaluation for all prospective transplant candidates. I suggest changing the language of this condition from "psychosocial evaluation" to "qualified social worker evaluation." My rationale is as follows: There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about mortality and morbidity, depression, anxiety, psycho-organic disorders, somatic complaints, lifestyle and economic pressures, access to insurance and prescription medications, employment and rehabilitation barriers, body image issues, and numerous losses (income, financial security, health, libido, strength, independence, mobility), social role disturbance, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon and Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2000; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment can lead to transplant immunosuppressive medication non-compliance (Russell & Ashbaugh, 2004). The gravity of these issues necessitates an evaluation and assessment conducted by a qualified social worker. Language such as "psychosocial evaluation" could be too ambiguous as to who conducts the evaluation. I also recommend an effort to standardize and uniformly include some of the essential elements of the recommended social work evaluation.

Issue Identifier: 482.90 Condition of Participation: Patient and Living Donor Selection

Comment: I also support the mandate of a psychosocial evaluation for all prospective living donors. As above, I recommend changing the language from "psychosocial evaluation" to "qualified social worker evaluation." I also support the requirement that transplant centers performing living donor transplants must provide the services of an independent donor advocacy team that includes a qualified social worker. Whenever possible, living donors and recipients

should have separate qualified practitioners conducting the social work and medical evaluations. The rationale for this recommendation is that meeting appropriate psychosocial criteria is essential to the success of the transplant. Qualified social workers must assess the prospective living donor in order to gauge any pressures on the donor that may influence the decision to donate an organ, motivation for donation, ability to make informed decisions, the nature of the relationship between the donor and recipient, and the donor's psychosocial status. The gravity of these psychosocial factors necessitates an evaluation and assessment conducted by a qualified social worker. As stated above, the use of the language "psychosocial evaluation" may be too ambiguous as to who will perform the evaluation. An independent donor advocacy team that includes a qualified social worker would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethical decisions.

Issue Identifier: 482.94 Condition of Participation: Patient and Living Donor Management

Comment: I support (d) Standard: Social Services ("The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors and their families. A qualified social workers is in an individual who meets licensing requirements in the State in which practicing") and (d)(1) ("Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.") However, I do not support (d)(2) ("Has served for at least two years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under 82.94") and urge that this be removed from the proposed changes.

My rationale for this is as follows: Transplant patients present with highly complex needs on an individual as well as systems level. Master's level social workers are trained to intervene within both areas of need that are essential for optimal patient functioning. The Masters in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. The MSW curriculum is the only curriculum that offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (BSW) degrees, or other mental health degrees (MA in counseling, or PhD in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems that is essential in transplant programs. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice. Under these same standards, the MSW degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance. Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990).

For these reasons, I strongly support (d)(1) of this regulation and strongly encourage the removal of (d)(2) of this regulation. This provision mirrors the "grandfather clause" that has been proposed to be removed from the End Stage Renal Facilities Conditions for Coverage. This

acknowledges that there is a need for the requirement that the social worker have a master's degree. Social work practice in transplantation does not lend itself to a diminution of professional qualifications and standards. The needs of transplant candidates, recipients, families and living donors are complex and deserve equal consideration for adequate care, and should only be provided by a qualified Master's level social worker.

Issue Identifier: 482.98 Condition of Participation: Human Resources

Comment: I support changing the language of this condition from "The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination and pharmacology: to "The team must be composed of individuals with the appropriate qualifications, training and experience in the relevant areas of medicine, nursing nutrition, **social work**, transplant coordination, and pharmacology." My rationale is similar to my comments above: the gravity of psychosocial factors related to transplantation necessitates Master's level qualified social work interventions. Utilizing language such as "social services" is not recommended because there is ambiguity about who provides such services. I recommend using the language of "social work" instead.

Thank you for the opportunity to provide comments on these proposed regulations. Please feel free to contact me should you have any questions.

Sincerely,

Jeff Harder, MSW, LICSW
Kidney/Pancreas Transplant Social Worker
5229 – 35th Ave SW
Seattle, WA 98126
206-598-4676
Email: Maxx11@comcast.net

Teri Arthur, MSW, LSW
6022 S. Drexel Avenue
Chicago, IL 60637
773-368-6429
teri@uchicago.edu

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

April 26, 2005

Enclosed you will find my response to the proposed Transplant conditions of coverage (one original and two copies). I am also enclosing a CD with the response included in case it is easier to have an electronic version of my response. Thank you very much for your consideration of my comments, which stem from my 10 years of experience in dialysis facilities across the country and extensive participation in nephrology organizations.

Sincerely,



Teri Arthur, MSW, LSW

Teri Arthur Comment
Proposed Transplant Regulations file code CMS-3835-P

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: I support the mandate of a psychosocial evaluation for all prospective transplant candidates. I suggest changing the language of this condition from "psychosocial evaluation" to "qualified social worker evaluation."

Rationale: There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2004; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as "psychosocial evaluation" is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a "qualified social worker evaluation" instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas' (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and may be used as a suggested template.

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: I support the mandate of a psychosocial evaluation for all prospective living donors. I suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.” I support a requirement that transplant centers performing living donor transplants must provide the service of an independent donor advocacy team that includes a qualified social worker. I suggest that living donors and recipients should have, whenever possible, separate qualified practitioners conducting the social work and medical evaluations.

Rationale: Living donor kidney transplants are increasingly popular. Meeting appropriate psychosocial criteria is essential to the success of the transplant. Qualified social workers must assess the donor in order to gauge any normative pressures on the donor that may influence the decision to donate a kidney, motivation for donation, ability to make informed consent, the nature of the relationship between the donor and recipient, and the donor’s psychosocial status (Fisher, 2003; Fox & Swazey, 1979; Leo, Smith & Mori, 2003). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; I recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation for living donors. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential elements and may be used as a suggested template for a social work assessment.

I believe that an independent donor advocacy team that includes a qualified social worker would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethical decisions. A qualified social worker is essential on an advocacy team to assess inappropriate motivations to or inadequate understanding of the related psychosocial issues of donation.

As transplant recipients and donors may have conflicting interests and motivation, it is strongly encouraged that living donors and recipients should have, whenever possible, separate qualified social workers to minimize potential conflict of interests.

Issue Identifier: 482.94 Condition of participation: Patient and living donor management

Comment: I would like to see language in these conditions which would outline the responsibilities of transplant centers and their responsibilities for following up and informing dialysis units of the transplant status of patients referred for transplant. I urge CMS to include the recommendations of the Transplant Referral Technical Expert Panel recently convened regarding transplant/dialysis facility communication and measures to facilitate cooperation.

Rationale: As per a motivation of creating the Transplant Referral Technical Expert Panel, it has been found that dialysis patients may not successfully navigate the transplantation referral process. Clear, standardized communication expectations of transplant centers to dialysis units are needed.

Comment: I support (d) Standard: Social services [The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing], and (d)(1) [Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.] However, I do **not** support: (d) (2): [Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 82.94], and urge that issue identifier: §482.94 (d) (2) be removed from the proposed changes. Additionally, I believe that there is need for ongoing access to qualified transplant social workers, who would ideally be dedicated to the transplant program.

Rationale: Transplant patients present with highly complex needs on an individual as well as systems level. Master's level social workers are trained to intervene within both areas of need that are essential for optimal patient functioning, and help facilitate congruity between individuals and their environments' resources, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum, which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems that is essential in transplant programs. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice

and requires a demonstration of skill or competency in performance (Anderson, 1986). Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of specialized, clinical training prepares the MSW to work autonomously in the transplant setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 1991; Rabin, 1983; Rosen, 1999; Soskolne & Kaplan-DeNour, 1989; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker

For these reasons, I strongly support (d)(1) of this regulation, and strongly encourage the removal of (d)(2) of this regulation. This provision mirrors the "grandfather clause" that has been proposed to be removed from the End Stage Renal Facilities Conditions for Coverage. The End Stage Renal Facilities Conditions for Coverage acknowledges that there is a need for the requirement that the social worker have a master's degree. Social work practice in transplantation as compared to End Stage Renal Disease Facilities does not lend itself to a diminution of professional qualifications and standards. The biopsychosocial needs of transplant candidates, recipients, families, and living donors are complex and deserve equal consideration for adequate care, and should only be provided by a qualified Master's level social worker.

I believe that there is need for transplant patients and donors to have ongoing access to qualified transplant social workers. This would allow for: patient continuity of care throughout the progress of each disease process; ongoing rehabilitation for planning to increase independence and lessen dependence on disability and Medicare/Medicaid (especially as these services often terminate after successful transplantation); and ability to address ongoing psychosocial concerns that impact on graft survival and patient quality of life. They can also assist patient with complex

coping issues and psychosocial status issues: results in 48 donors who were evaluated prior to surgery and again at 4 and 12 months showed a 29% incidence of DSM-IV psychiatric disorder developing over the first 12 months (Smith, G., Trauer, T., Kerr, P., et al., (2004). Skotzoto, C., Stowe, J., Wright, C., Kendall, K., and Dew, M. (2001) have shown support for pre-transplant, perioperative period, and post transplant psychosocial services. We urge that there be inclusion of language which would mandate additional social work provision for ongoing services.

Ideally, this person would be dedicated to the transplant program. Transplant social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. The United Network for Organ Sharing (UNOS) did a study that showed that 88% of transplant centers reported that social work coverage was adequate when social workers reported directly to transplant centers and only 58% reported adequate coverage when the social workers had to report to other departments (Thomas, 2003). Social workers who report to other hospital departments have increased non-transplant duties.

Issue Identifier: 482.98 Condition of participation: Human resources

Comment: I support changing the language of this condition from “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.” to “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology.”

Rationale: As discussed in my comments for identifiers 482.90 and 482.94, the gravity of psychosocial factors related to transplantation necessitate Master’s level qualified social work interventions. Utilizing language such as “social services” is not recommended because there could be ambiguity about who provides such services; we recommend using the language of a “social work” instead.

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May 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam:

I wish to express my **opposition** to the proposed standard that a transplant center must require their transplant coordinators be certified by the American Board for Transplant Certification (ABTC). The certification (C.C.T.C.) offered by ABTC *does not* qualify that a nurse is capable of the job. This is much better monitored by the hospital employing the R.N.

I have been working as a Transplant Coordinator since 1996. I am an expert in this field with outstanding reviews by my employer. I am concerned that ABTC has contacted the nurses they certified and no others. I expect that you will receive few responses from nurses such as myself thus greatly disadvantaging our opportunity to express our opinions and you receiving the vast majority of input from one side. I feel this raises many ethical concerns.

I appeal to you to **decline** the request to mandate C.C.T.C. for all transplant coordinators.

Sincerely,



Jill Salisbury, R.N., B.S.N.
Liver Transplant Coordinator

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244

Dear Sir or Madam:

I work as a Liver Transplant Coordinator and have a C.C.T.C. (Certified Clinical Transplant Coordinator) certification. I am asking you to **decline** the self-serving request by the American Board for Transplant Certification (ABTC) to make it mandatory that a nurse working in a transplant coordinator role have the certification offered by ABTC.

Please recognize this for what this is – their attempt at financial security placed on the backs of nurses.

If this statement is not true, would not ABTC be requesting all transplant surgeons obtain a F.A.C.S., transplant nephrologists a F.A.N.S., the ICU nurses caring for transplant patients a C.C.R.N? As you can see the list goes on and on but more to the point ABTC would not profit from these requirements.

There are many exceptional nurses working as transplant coordinators that do not carry the initial C.C.T.C. behind their names. This is a nice to have, not must have certification. It does not guarantee or qualify that a transplant coordinator will give excellent care.

Sincerely,



Sharlene Winters, R.N., B.S.N., C.C.T.C
Liver Transplant Coordinator
Oregon Health and Science University
Portland, Oregon

Comments on Proposed Rule CMS-3835-P: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants

We appreciate the opportunity to comment on these regulations. Our comments are divided into major comments and technical comments as follows.

Major Comments:

- 1. Re-approval of Transplant Centers should include surveying of process requirements.** We think that all of the process requirements that are included in this proposed regulation are important. These proposed regulations state that process requirements (e.g. minimum qualifications for the qualified surgeon, protocols for deceased organ recovery) are only reviewed on the initial approval and upon failure of a center to meet minimum outcome data rates. We suggest that the regulations specify that a center is expected to meet these requirements on an ongoing basis, and centers will be surveyed to assure that these requirements are being met on an ongoing basis.
- 2. Separation of patient information and of critical clinical staffing for potential and actual organ donors.** We are concerned about protecting the rights of organ donors. We are concerned not only about HIPPA laws that require protection of individual information, but we are also concerned about right of potential donors to make confidential and informed decisions about donation. This seems to be particularly important at a time when criteria for establishing the medical/clinical criteria for donation are expanding through the use of ABO-incompatible transplants and kidney donor exchanges. Therefore, we think that the regulations need to specify that confidential donor information is separate from the recipient information in the medical record. We also suggest that potential donors/recipients need to have separate key clinical staff that assist with donation decisions, including physicians and social workers.
- 3. Discharge planning should be included as a requirement.** The importance of multi-disciplinary follow-up care for transplant recipients and living transplant donors is well documented. We suggest that the minimum requirements for discharge planning need to be included in the regulations.
- 4. Renal transplant centers should be exempt from the requirement for one year of operation and a minimum of 9 transplants prior to certification.** Coverage for renal transplants is unique and legislated under the ESRD Program, and therefore Medicare provides coverage for almost all transplant recipients regardless of age, income, or prior disability status. Therefore, in order for ESRD transplant donors/recipients to qualify for coverage for both the transplant operation and the expensive post-transplant medications, the transplant needs to occur in a Medicare-certified transplant center. We suggest that initial approval for renal transplant centers continue with the current system of approval following an initial survey and certification.

Technical Comments:

- 1. Clarity about the extent to which a dialysis facility providing acute services to transplant recipients needs to meet all of the requirements for a chronic dialysis facility under the ESRD Program.** Currently, all dialysis facilities providing chronic care under the ESRD Program have a specific set of Conditions for Coverage in the ESRD Program. Currently, acute dialysis programs in hospitals are not covered by these Conditions. We feel that it would be helpful if the proposed regulations provided more clarity about the definitions/requirements for acute versus chronic dialysis facilities/services.
- 2. Consistency of basic minimum staff qualifications for social workers and dietitians with proposed ESRD regulations.** The proposed ESRD regulations change the current basic minimum staff qualifications for social workers and dietitians. We suggest that there be consistency for these minimum requirements in both the ESRD and transplant regulations. However, we think that it is appropriate to add an additional requirement for documented transplant training to the basic minimum staff qualifications.
- 3. Grandfather clause for staff qualifications.** Although minimum staff qualifications have been required by the ESRD Program for renal transplant centers, these requirements are new for other types of organ transplant centers. We suggest a grandfather clause for staff qualifications as a transition to these staff requirements.
- 4. Validation of blood donor type and other vital information by a licensed health care professional in addition to the transplant surgeon.** We suggest that the importance of the validation of blood donor type and other vital information requires validation by a licensed health care professional rather than "at least one other individual."

Thank you for the opportunity to comment:

Maria Ciccanti
Judith Kari
Michele Walton

March 24, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants

The New York Center for Liver Transplantation, Inc. (NYCLT) is a not for profit organization comprised of the five liver transplant programs in New York State. Established in 1988, our mission has been to assure the quality of care delivered to patients receiving liver transplant services. As such, we applaud CMS for its efforts in revising the requirements to ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner. While we agree with a great many of the proposed changes, we have several comments as outlined below.

OUTCOME MEASURE REQUIREMENTS (482.80/482.82)

- Patient and graft survival outcomes are appropriate measures of transplant center performance. However, the data collected by OPTN to be used in SRTR analysis of center-specific reports is not all-encompassing. For example, steatosis is not consistently or accurately captured for all liver donors on the OPTN data collection forms, yet literature shows steatosis may have an impact on liver transplant outcomes.
- Using the "average" or the norm as a measure of comparison is also problematic, specifically in those regions where access to quality organs, particularly livers, is limited. In these circumstances, organs having a higher relative risk are often used to prevent the death of a wait-listed patient. Factors such as the size of the waiting list, the number of organ donors and the number of deaths on the waiting list in each region need to be included in the analysis. Otherwise the proposed system may inhibit the use of organs having higher relative risk, thereby keeping outcomes high, but increasing the number of deaths on the waiting list at the same time.

PATIENT AND LIVING DONOR SELECTION (482.90)

- The selection of living liver donors in New York State is governed by state regulation. While medical suitability of the living donor must be ascertained and documented by the Independent Donor Advocate Team (IDAT), all such records and documentation must remain separate and distinct from the potential recipient medical record. The proposed requirement that documentation of living donor suitability for donation be in the potential recipient record is a breach of confidentiality and a violation of New York State regulation.

HUMAN RESOURCES (482.98)

- The first Condition of Participation in the proposed rule requires that a transplant center be a member of and abide by the rules and requirements of the OPTN. Currently, a member in good standing of the OPTN must meet professional standards and personnel requirements. As such, it would seem that the Condition of Participation related to Human Resources is redundant.

PATIENT AND LIVING DONOR RIGHTS (482.102)

- Potential living donors should have access to a multidisciplinary team whose main responsibility is to safeguard the interests and well-being of the donor. This Independent Donor Advocate Team can help to ensure continuity of care during the pre-donation, donation and post-donation phases.
- The informed choice process is a critical element of living donation and should be presented in a manner that is understandable to a potential donor and consistent with his or her language and educational level.
- Potential living donors should be given adequate time to understand and assimilate the information provided. For example, New York State regulation provides potential living liver donors with a minimum two-week reflection period between the time when a potential donor is informed of his or her suitability for donation and the time when the potential donor makes a final decision.
- All potential living donors should have the right to make this decision in an environment that is free from coercion.

SPECIAL PROCEDURES FOR APPROVAL AND RE-APPROVAL OF ORGAN TRANSPLANT CENTERS (488.61)

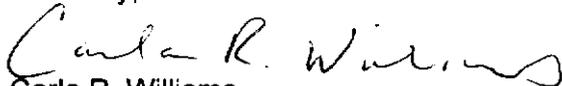
- Existing transplant centers are subject to UNOS surveys on professional standards and surveillance. Those centers who meet outcomes and submission requirements should not be subject to an initial CMS survey as this effort is duplicative. However, new or existing transplant centers who do not meet the outcomes and submission requirements should be subject to an initial CMS survey.
- The proposed rule should provide for a period of remediation during which a transplant center may develop, submit and implement a plan of correction. Upon completion of the remediation, a transplant center must meet 1-month expected outcomes and be resurveyed.

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

- Transplant centers should be approved based on graft and patient survival outcomes specific to each center. An alternate process of re-approval based on random surveys and OPTN input is not a consistent or efficient way to measure transplant center performance.

Thank you for your consideration of these comments.

Sincerely,



Carla R. Williams
Executive Director



June 2, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS- 3835-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Hospital Conditions of Participation -- Transplant Centers
RIN 0938-AH17
[CMS-3835-P]

Dear Dr. McClellan:

Temple University Hospital appreciates the opportunity to comment on the proposed rule setting forth requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare – approved transplant centers. We express our concerns below.

OUTCOME MEASUREMENT REQUIREMENTS

Condition of Participation: Data Submission and Outcome Requirements for Re-approval of Transplant Centers (Proposed § 482.82)

As a condition of participation, transplant centers must collect and submit transplant data to the Organ Procurement and Transplantation Network (OPTN), which is analyzed and reported by the Scientific Registry of Transplant Recipients (SRTR). CMS proposes to use the SRTR reports as the foundation for its outcome evaluation system for re-approval of transplant centers.

Unfortunately, the data collection and reporting process results in SRTR reports 1-3 years behind current data. Consequently, transplant centers are at risk of being evaluated based on outdated results. Although current data might reflect improved outcomes, the proposed rule does not allow consideration of current data in measuring outcomes.

As a result, the proposed rule would have the unintended consequence of sanctioning transplant programs with improved current outcomes. To avoid this harsh and unnecessary result, we suggest that the Final Rule allow consideration of recent results that better reflect the current ability of the transplant program to provide quality transplantation services.

In addition, CMS' use of aged data does not take into account that many of the patients cared for by the transplant program at the time of transplant may have moved and thus are no longer cared for by the transplanting center. Holding that transplanting center responsible for the long-term care of a patient who has switched caregivers may also not accurately reflect the current quality of care given by the original transplanting center.

Furthermore, because CMS is now demanding considerable follow-up of Medicare patients, we suggest that in addition to the costs associated with pre-evaluation and organ procurement, the new post-transplant costs should become a part of the Medicare Cost Report and be reimbursed on a cost-basis.

HUMAN RESOURCES

Condition of Participation: Human Resources (Proposed § 482.98)

The proposed rule provides that as a condition of participation, transplant programs ensure that all individuals providing services are qualified to do so. In particular, transplant programs would be required to have a qualified clinical transplant coordinator who is certified by the American Board of Transplant Coordinators (ABTC), which requires at least 12 months of work experience as a transplant professional in vascular organ transplantation. ABTC certification also requires successful completion of the certification examination, a process that can add more than 6 months to the certification process for application processing and test scheduling. We agree that the transplant coordinator must possess the high degree of knowledge and skills needed to provide quality care. Nonetheless, we believe that ABTC certification presents an undue burden on smaller transplant programs.

As an alternative, we suggest that non-certified transplant coordinators be required to receive certification within two years of hire. While undergoing the certification process, these coordinators would operate under the supervision of a fully certified lead transplant coordinator. In the unusual circumstance that a transplant hospital's individual transplant program experiences a period in which it is without a certified program coordinator, the transplant program would submit a plan for CMS approval indicating oversight of non-certified coordinators by a certified transplant coordinator of another transplant program within the same hospital.

For example, assume that a transplant hospital's liver transplant program employs one fully certified transplant coordinator and a second transplant coordinator who will be eligible for certification in 6 months. If the position of the fully certified liver transplant coordinator turns over, the hospital would arrange to have a lead coordinator from

another of its transplant programs provide oversight of the non-certified liver transplant coordinator while the hospital seeks to replace the certified liver coordinator. In this way, the hospital can maintain the quality of its transplant programs while it adjusts to legitimate workforce staffing and training constraints.

PROVIDER VS. SUPPLIER STATUS OF APPEALS

The Proposed Special Procedure for Approval and Re-approval of Transplant Centers (Proposed § 488.61)

The proposed rule states that centers that have lost their Medicare approval may seek re-entry into the program at any time following procedures outlined in the initial approval process. The proposed rule fails to address, however, how patients enrolled with a transplant center will be cared for if that center has lost its Medicare approval, and is particularly troublesome if it is likely that the transplant center will quickly be reinstated.

Current rules with the United Network for Organ Sharing (UNOS) states that patients be referred to a nearby transplant center if the listing transplant center cannot transplant for a significant period of time. This could be devastating to a program, particularly if the problems with the program have been reversed and reinstatement is likely.

For the above reasons, we urge the Centers for Medicare and Medicaid Services to reconsider its proposed requirements for approval and re-approval of transplant centers, and to incorporate our concerns into the final rule.

Sincerely,



Daniel J. Sinnott
CEO & Executive Director

NKF National Kidney Foundation®

Making Lives Better

June 3, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Sir or Madam:

I am pleased to provide the response of the National Kidney Foundation (NKF) with respect to the Proposed Rule: "Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants," CMS-3835-P, that was published in the *Federal Register* on February 4, 2005. NKF represents 4,443 transplant recipients and transplant candidates who are members of its "transAction" Council as well as 10,429 members of the NKF Donor Family Council, who have donated the organs of a loved one for transplantation, and 600 living donors. These comments also reflect input from the NKF Council on Renal Nutrition (CRN), which has 1500 members, and the NKF Council of Nephrology Social Workers (CNSW), with its 800 members.

GENERAL COMMENTS

The National Kidney Foundation and its patient, donor, and professional members applaud the agency's goals for this rulemaking: (1) to reduce organ wastage due to transplant failure, (2) to increase the efficient use of donated organs, and (3) to protect patients, and living donors. Nevertheless, NKF is concerned that many provisions in the Proposed Rule duplicate the oversight activities of the Organ Procurement and Transplant Network (OPTN). The OPTN already conducts ongoing and periodic reviews, site visits, and evaluations of each member transplant center for compliance with OPTN policies. This overlap of roles could result in conflicting requirements and that would not advance the stated goals for the Proposed Rule. The overlap is confounded because of a statutory requirement, (reflected in proposed section 482.72), that transplant hospitals must be members of OPTN in order to qualify for Medicare reimbursement.

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Conversely, these kinds of concerns might have been avoided if the Proposed Rule identified the agency or agencies that would have responsibility for the survey and certification process that is a typical component of an approval and re-approval system. However, the only reference to survey and certification in the draft regulation reads:

“We propose that, once this proposed rule is finalized, we, or our designee (e.g., a State survey agency or an accreditation organization with deeming authority for hospitals, such as the JCAHO or AOA), would have responsibility for monitoring and coordinating the procedures for approval or re-approval of a transplant center.”

Finally, a significant gap in the Proposed Rule is the failure to provide an opportunity for remediation for centers that do not meet requirements for approval or re-approval, as an alternative to termination. A policy for Corrective Action Plans is essential for the several hundred centers that have already been approved under existing Medicare policy and have been participating in Medicare. Terminating Medicare participation for such centers would result in unnecessary hardship for transplant patients who are receiving pre- and post-transplant care at those centers and substantial disruption for the transplant candidates on their wait lists. NKF urges that the Final Rule make provision for Corrective Action Plans.

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANPLANT

NKF recommends that, in developing the Final Rule, CMS take into consideration the recommendations from the U. S. Department of Health and Human Services Advisory Committee on Organ Transplantation, specifically Recommendations 1, 2, and 7, as well as the guidelines of the New York State Department of Health, published as “Quality Improvement in Living Liver Donation.”

OUTCOME MEASURE REQUIREMENTS

Proposed Sections 482.80 and 482.82 outline a process for initial approval and re-approval of a transplant center, provided that the center has 1-year post-transplant follow-up on at least nine transplants of the appropriate organ type during the previous 2.5 year period. NKF maintains that a history of nine transplants in a 2.5 year period is inadequate as a basis for approval or re-approval of a transplant center.

PATIENT AND LIVING DONOR SELECTION

CMS called for comments on whether transplant centers should be required to make patient selection criteria available to patients. In order to preserve public trust in the transplant system in the United States, and to ensure fair and non-discriminatory distribution of organs, the patient selection process should be absolutely transparent. Therefore, NKF recommends that transplant centers be required to make patient selection criteria for deceased donor transplantation available whenever requested. Similarly, we endorse proposed section 482.90 (a) (4), requiring transplant centers to document, in the transplant candidate's medical record, the patient selection criteria used in his/her case.

We also endorse proposed sections 482.90 (a) (2) and (b) (1) that make psychosocial evaluation of transplant candidates and prospective living donors a condition of participation. This psychosocial evaluation should be performed by a qualified social worker.

With regard to candidates for deceased donor organs, the psychosocial challenges faced by ESRD patients can affect graft survival and transplant outcomes. These include coping with chronic illness, concern about mortality and morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and medication issues, employment, and rehabilitation barriers, mood changes, body image concerns, social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life. In particular, psychosocial factors such as finances, depression, relationship changes, and employment problems lead to transplant immunosuppressant noncompliance.

The gravity of these psychosocial factors necessitates an evaluation/assessment conducted by a qualified social worker. In addition, there should be an effort to standardize and codify the essential elements of the recommended psychosocial evaluation. This would facilitate the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas' (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and we suggest their use as a template.

With respect to prospective living donors, we recommend a requirement that transplant centers performing living donor transplants must provide the services of an independent donor advocacy team that includes a qualified social worker. We believe that an independent donor advocacy team, that includes a qualified social worker, would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethically appropriate decisions. A qualified social worker is essential on an advocacy team to assess inappropriate motivations to donate or inadequate understanding of the related psychosocial issues of donation. Since transplant recipients and donors may have conflicting interests and motivation, it is strongly encouraged that living donors and recipients should have, whenever possible, separate qualified practitioners conducting the social work and medical evaluations.

Qualified social workers must assess the potential living donor in order to gauge any untoward pressures on the donor that may influence the decision to donate a kidney, and evaluate motivation for donation, ability to make informed consent, the nature of the relationship between the donor and recipient, and the donor's overall psychosocial status. In addition, there should be an effort to standardize and codify the essential elements of the recommended psychosocial evaluation. This would facilitate the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas' (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and we suggest their use as a template.

PATIENT AND LIVING DONOR MANAGEMENT

Proposed section 482.94 requires transplant centers to have written patient management policies for the pre-transplant, transplant, and discharge phases of transplantation, for both transplant recipients and living donors, including a standard for social work services. NKF's Council of Nephrology Social Workers maintains that transplant patients and living organ donors need ongoing access to qualified transplant social workers after discharge. Such access is necessary to assure continuity of care, facilitate rehabilitation planning so as to increase economic and personal independence, and strengthen ability to address ongoing psychosocial concerns that impact on graft survival, patient and donor outcomes, and patient quality of life. A random survey of Medicare beneficiaries who were transplant recipients, conducted by the NKF Patient Services Committee in 1988, substantiates the need for access to post-transplant social work services. We urge that the final provision for patient and living donor management mandate ongoing social work services.

Proposed section 482.94(d) (2) [*Standard: Social services*] that provides an alternative definition of a "qualified social worker" should be eliminated. This provision mirrors the "grandfather clause" that was included in the Conditions of Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services (*Federal Register*, June 3, 1976) and has been deleted in the Proposed Rule, "Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities," CMS-3818-P. The definition of a qualified social worker should be comparable in both CMS-3818-P and CMS-3835-P. The former Proposed Rule recognizes the need for the requirement that the social worker have a master's degree. The biopsychosocial needs of transplant candidates, recipients, families, and living donors are complex and deserve the same attention as the corresponding needs of dialysis patients. That attention can be adequately provided only by a qualified Master's level social worker. Ideally, the social worker would be dedicated to the transplant program. Transplant social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. The results of a study conducted by the United Network for Organ Sharing (UNOS) showed that 88% of transplant centers reported that social work coverage was adequate when social workers reported directly to transplant centers and only 58% reported adequate coverage when the social workers had to report to other departments. Social workers

who report to other hospital departments have increased non-transplant duties.

Proposed Section 482.94 (e) [*Standard: Nutritional Services*] should be revised to conform to the parallel provision in the Proposed Rule, “Medicare Program: Conditions for Coverage for End Stage Renal Disease Facilities,” CMS-3818-P, which reads: “Standard: Dietitian. The facility must have a dietitian who must--

- (1) Be a registered dietitian with the Commission on Dietetic Registration;
- (2) Meet the practice requirements in the State in which he or she is employed; and
- (3) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian.” (Proposed Section 494.140).

Qualified Dietitian

The Proposed Rule should specify that the minimum qualifications for ‘qualified dietitian’ should include dietetic registration according to the Commission on Dietetic Registration. The provision of medical nutrition therapy (MNT) for transplant patients is too complex for a dietitian who is RD eligible. Post-op complications require a considerable working knowledge of nutrition support in organ failure in order to follow the patient for rejection issues and other co-morbid conditions.

Nutrition Intervention

CRN supports the provision for transplant centers to make nutrition assessments and diet counseling services by a qualified dietitian to all transplant patients and donors. A registered dietitian has the expertise to provide MNT to address the potential for weight gain, hypertension, hyperlipidemia, food-drug interactions and post transplant diabetes mellitus which could impact the longevity of the transplant.

The language nutrition intervention “should be made available” should be changed to “must be provided” to ensure accessibility of nutrition services to transplant patients and donors. Given the present lack of long-term data about outcomes for living donors during the remainder of their lives, and widespread

concern that some donors might encounter health issues related to that donation at a later time, MNT at the time of a living donations is important.

The National Kidney Foundation endorses the provisions of Section 482.94 (c), [*Standard: Patient records*], that require the transplant center to notify the transplant candidate whether or not he/she has been placed on the center's waitlist and to notify the patient's usual dialysis facility of any changes in the candidate's transplant status. This section should be expanded to require the transplant center to notify the patient's usual dialysis facility when that patient is placed on its waitlist or a decision has been made not to place the patient on its waitlist. NKF frequently hears from patients who had assumed they were on the transplant waitlist but learned, by chance, that they had not been listed.

QAPI – Proposed Section 482.96 (a), [*Standard: Components of a QAPI program*]

Patient and graft survival must be addressed in every transplant center's quality assessment and performance improvement program.

HUMAN RESOURCES – Proposed Section 482.98

We recommend changing the language of this condition from: "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology," to: "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology."

PATIENTS' AND LIVING DONORS' RIGHTS

Proposed section 482.102(a)(7) would require the transplant center to have an informed consent process that provides information to the transplant candidate about organ donor risk factors that could affect the success of the graft or the health of the patient after transplantation. NKF recommends that this obligation to provide information about organ donor risk factors be limited to the point in time when a patient is placed on a transplant waitlist. It would not be practical

to require the communication of such information to the patient each and every time when a specific organ is offered for transplantation. This recommendation is similar to a recommendation from a National Conference on the Wait List for Kidney Transplantation, sponsored by the American Society of Transplantation, the American Society of Transplant Surgeons, the Division of Transplantation of the Health Resources and Services Administration, and the National Kidney Foundation, that was held March 4-5, 2002. The participants in the Expanded Donor Work Group at that conference recommended that the risks and benefits for the patient should be discussed prior to placing a candidate on the Expanded Donor Criteria (ECD) waitlist and that informed consent should be documented at that time. Minimum informational elements for patients contemplating acceptance of an ECD kidney should include: (1) The increased likelihood of delayed graft function (2) decreased graft survival when compared to a non-ECD kidney; (3) increased longevity compared to remaining on dialysis, (4) the potential for decreased waiting time; and (5) benefit of transplant prior to potential dialysis related morbidity and mortality.

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

The National Kidney Foundation recommends that transplant centers should be surveyed at random.

Sincerely,



David G. Warnock, M.D.
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Professor and Director, Division of Nephrology
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Melissa Fry, MSW Comment
Proposed Transplant Regulations file code CMS-3835-P

***Issue Identifier:* 482.90 Condition of participation: Patient and living donor selection**

Comment: We support the mandate of a psychosocial evaluation for all prospective transplant candidates. We suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.”

Rationale: There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2004; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and may be used as a suggested template.

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: We support the mandate of a psychosocial evaluation for all prospective living donors. We suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.” We support a requirement that transplant centers performing living donor transplants must provide the service of an independent donor advocacy team that includes a qualified social worker. We suggest that living donors and recipients should have, whenever possible, separate qualified practitioners conducting the social work and medical evaluations.

Rationale: Living donor kidney transplants are increasingly popular. Meeting appropriate psychosocial criteria is essential to the success of the transplant. Qualified social workers must assess the donor in order to gauge any normative pressures on the donor that may influence the decision to donate a kidney, motivation for donation, ability to make informed consent, the nature of the relationship between the donor and recipient, and the donor’s psychosocial status (Fisher, 2003; Fox & Swazey, 1979; Leo, Smith & Mori, 2003). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation for living donors. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations

http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential elements and may be used as a suggested template for a social work assessment.

We believe that an independent donor advocacy team that includes a qualified social worker would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethical decisions. A qualified social worker is essential on an advocacy team to assess inappropriate motivations to or inadequate understanding of the related psychosocial issues of donation.

As transplant recipients and donors may have conflicting interests and motivation, it is strongly encouraged that living donors and recipients should have, whenever possible, separate qualified social workers to minimize potential conflict of interests.

Issue Identifier: 482.94 Condition of participation: Patient and living donor management

Comment: We support (d) Standard: Social services [The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing], and (d)(1) [Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.] However, we do not support: (d) (2): [Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 82.94], and urge that issue identifier: §482.94 (d) (2) be removed from the proposed changes. Additionally, CNSW believes that there is need for ongoing access to qualified transplant social workers, who would ideally be dedicated to the transplant program.

Rationale: Transplant patients present with highly complex needs on an individual as well as systems level. Master's level social workers are trained to intervene within both areas of need that are essential for optimal patient functioning, and help facilitate congruity between individuals and their environments' resources, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum, which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems that is essential in transplant programs. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of specialized, clinical training prepares the MSW to work autonomously in the transplant setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality

& morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 1991; Rabin, 1983; Rosen, 1999; Soskolne & Kaplan-DeNour, 1989; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker

For these reasons, we strongly support (d)(1) of this regulation, and strongly encourage the removal of (d)(2) of this regulation. This provision mirrors the "grandfather clause" that has been proposed to be removed from the End Stage Renal Facilities Conditions for Coverage. The End Stage Renal Facilities Conditions for Coverage acknowledges that there is a need for the requirement that the social worker have a master's degree. Social work practice in transplantation as compared to End Stage Renal Disease Facilities does not lend itself to a diminution of professional qualifications and standards. The biopsychosocial needs of transplant candidates, recipients, families, and living donors are complex and deserve equal consideration for adequate care, and should only be provided by a qualified Master's level social worker.

CNSW believes that there is need for transplant patients and donors to have ongoing access to qualified transplant social workers. This would allow for: patient continuity of care throughout the progress of each disease process; ongoing rehabilitation for planning to increase independence and lessen dependence on disability and Medicare/Medicaid (especially as there services often terminate after successful transplantation); and ability to address ongoing psychosocial concerns that impact on graft survival and patient quality of life. They can also assist patient with complex coping issues and psychosocial status issues: results in 48 donors who were evaluated prior to surgery and again at 4 and 12 months showed a 29% incidence of DSM-IV psychiatric disorder developing over the first 12 months (Smith, G., Trauer, T., Kerr, P., et al., (2004). Skotzoto, C., Stowe, J., Wright, C., Kendall, K., and Dew, M. (2001) have shown support for pre-transplant, perioperative period, and post transplant psychosocial services. We urge that there be inclusion of language which would mandate additional social work provision for ongoing services.

Ideally, this person would be dedicated to the transplant program. Transplant social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. The United Network for Organ Sharing (UNOS) did a study that showed that 88% of transplant centers reported that social work coverage was adequate when social workers reported directly to transplant centers and only 58% reported adequate coverage when the social workers had to report to other departments (Thomas, 2003). Social workers who report to other hospital departments have increased non-transplant duties.

Issue Identifier: 482.98 Condition of participation: Human resources

Comment: We support changing the language of this condition from “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.” to “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology.”

Rationale: As discussed in our comments for identifiers 482.90 and 482.94, the gravity of psychosocial factors related to transplantation necessitate Master’s level qualified social work interventions. Utilizing language such as “social services” is not recommended because there could be ambiguity about who provides such services; we recommend using the language of a “social work” instead.

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6/6/05
J. N.W.

June 6, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3835-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: **Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Proposed Rule (CMS-3835-P)**

Dear Dr. McClellan:

The Federation of American Hospitals (“FAH”) is the national representative of investor owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural areas of the United States. FAH appreciates the opportunity to comment on the Medicare Proposed Rule on Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants (“Proposed Rule”). (See 70 Fed. Reg. 6,140 [Feb. 4, 2005].)¹

I. General Approach

FAH fully supports CMS’ decision to propose specific requirements that apply to all centers engaged in various types of transplantation services. The need for clarity through more definitive Medicare policy in this area is clear. We believe the Proposed Rule generally provides detailed, reasonable policies that will streamline the administrative processes regarding transplant center approval and re-approval, which will help ensure that Medicare beneficiaries receive high quality transplantation services. We also support CMS’ proposals to include these

¹ The Centers for Medicare & Medicaid Services (“CMS”) subsequently extended the comment period by 60 days. (See 70 Fed. Reg. 15,264 [March 25, 2005].) The Proposed Rule’s comment period now closes on June 6, 2005.

standards in the Hospital Conditions of Participation (“CoPs”) and to eliminate the old policies currently found in 42 C.F.R. Part 405. Most importantly, we support the proposed standards because they are driven by patient outcomes.

When considering final CoPs, we encourage CMS to strive for the goal of promulgating policy that is consistent with existing applicable federal requirements. In our view, the system will not be well served if the Medicare CoPs are inconsistent with existing rules. This will create confusion and ambiguity for centers when complying with these rules, with possible significant ramifications for non-compliance. In this regard, the Proposed Rule’s informed consent process for live donor situations and the proposed annual letter to recipients from transplant centers seeking status reports are topics where the proposed CoPs go beyond existing Organ Procurement and Transplantation Network (“OPTN”) and United Network for Organ Sharing (“UNOS”) requirements without a clearly compelling need to do so. In the latter case, the proposed annual letter is unlikely to facilitate the level of response and patient follow up that CMS desires.

II. Patient Donor Issues

We appreciate that CMS has proposed various CoPs that recognize the important and ever evolving role that living donors play in allowing transplant centers to provide high quality care to an increasing number of patients. While supportive of CMS’ proposed living donor policies, we believe that CMS should also formulate federal policy permitting and further addressing the concept of directed donations by living donors, who are both related and unrelated to their selected recipients. This issue is complex, as it involves a variety of policy and ethical issues that may not fall into line with the standard framework applicable to deceased donors.

However, the number of living donors is consistently on the rise and, in the area of kidney transplantation, the level of living donors has now surpassed deceased donors. Moreover, recent studies show that living kidney donations enjoy better clinical outcomes than donations from the deceased. Therefore, living donation should continue to be encouraged because it presents a positive outcome for the health care system as a whole. However, more comprehensive federal policy is necessary to properly address the unique issues presented by living donors.

We recognize that the OPTN and UNOS have sought public input on this issue, which signifies its importance to all interested parties. We ask that CMS also develop policy in this area, perhaps by addressing the issue in any final rule that it may issue to follow the Proposed Rule, provided the public has an opportunity to comment on that specific issue before binding federal policy is adopted.

III. Outcome Measure Requirements

FAH greatly appreciates CMS’ proposal to implement an evaluation system that relies on the Scientific Registry of Transplant Recipients’ risk-adjusted data. We believe that principles of equity and fairness support basing evaluations on risk-adjusted data, which minimizes the possibility of penalizing transplant centers with a high-risk patient population or that use organs from extended criteria donors. In this way, FAH fully supports the level playing field that is created by using an evaluation system based on risk-adjusted data. This approach will also help

ensure fair access to transplantation by removing barriers that make transplant centers sometimes reluctant to provide services to high risk or high severity patients.

IV. Coordinated Regulatory Oversight

Given the nature of their services, transplant centers are overseen and regulated by a number of organizations, including CMS, OPTN and UNOS. When the proposed CoPs are finalized, transplant centers will be required to comply with even more detailed rules than exist currently. While we support CMS' decision to propose these CoPs, FAH is concerned about the increasing potential for inconsistent rules and disparate enforcement policies that transplant centers may face given the number of agencies they must answer to.

Our cause for concern is real, as we see a proper analogy to current inconsistencies between CMS' general CoPs for hospitals and the hospital accreditation standards adopted by the Joint Commission for the Accreditation of Healthcare Organizations ("JCAHO"). To avoid a similar outcome, FAH recommends that CMS coordinate with the OPTN, UNOS and other organizations as appropriate to pursue the goal of uniform standards across the organizations. This will ensure that transplant centers provide high quality services without the risk of having to try to comply with conflicting standards.

Similarly, FAH is concerned about how CMS plans to audit transplant centers for compliance with any final CoPs standards. We understand state survey agencies will be tasked with conducting CoPs reviews on CMS's behalf. Also, we understand CMS interprets its statutory authority as permitting the agency to designate an accrediting body to exercise deeming authority to approve transplant centers for Medicare purposes. Given the nature of their expertise, FAH recommends that UNOS be selected as the appropriate accrediting body to perform these compliance audits. Two reasons support our recommendation. First, UNOS already audits every three years all heart and liver transplantation program for compliance with the wait list policy, which is a consistent timeframe with the period of approval proposed under the draft CoPs. Second, UNOS is very experienced with transplantation services, and is therefore we believe better suited than JCAHO to adjudicate transplant center compliance.

V. Financial Implications of Proposed CoPs

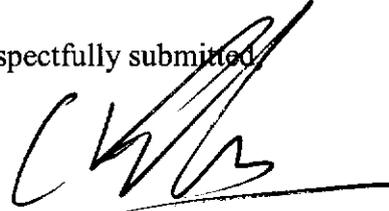
Given the nature of the transplant services, the recordkeeping and administrative burdens associated with administering a transplant center are significant. Existing data reporting requirements to the OPTN/UNOS already require up to thirteen different reports on an organ recipient that survives ten years. While the number of reports alone is substantial, this does not even account for the difficulty in persuading recipients to receive annual post-treatment follow up exams or the difficulty in obtaining information from community-based specialists that may follow these patient post-operatively. This last concern has been exacerbated since the implementation of final privacy and security rules under the Health Insurance Portability and Accountability Act of 1996.

FAH recognizes the need to collect this data in order to track patient outcomes and develop critical quality data. However, CMS downplays the impact of its proposed data reporting requirements because, in the agency's view, they are duplicative of the OPTN/UNOS requirements. In light of the operating reality, FAH believes that CMS' cost analysis in the

Proposed Rule and its assessment of the financial implications of the proposed CoPs misses the mark. We recommend that CMS implement a policy that seeks this type of data through the Medicare cost reporting process and allows for program payment beyond the current allocation allowed for a data coordinator position. In reality, this data collection process involves resources beyond just the data coordinator and, given the practical difficulties transplant centers face in obtaining such data, the public reporting process should help fund the significant operational costs that are incurred in meeting the OPTN/UNOS requirements as well as the Proposed Rule's proposed policies.

Thank you for the opportunity to provide input on this Proposed Rule. Should you have any questions about our comments, please contact Jeff Micklos of my staff at (202) 624-1521.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'C. Kahn III', written over a horizontal line.

Charles N. Kahn III
President



Memorandum

Centers for Medicare & Medicaid Services

Division of Survey and Certification

1301 Young Street, Room 833

Dallas, Texas 75202

Phone (214) 767-6301

Fax (214) 767-0270

Date: June 5, 2005

From: Glenda M. Payne, RN, MS, CNN
ESRD Clinical Lead, Regions 4 & 6

Subject: Comments on the Proposed Rule for Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants (CMS- 3835-P)

1. Regarding the Outcome Measurement Monitoring for Transplant Centers described in the section on page 6152 of the Preamble: who / what agency would be charged with doing this monitoring? I cannot see the state survey agencies being responsible for this work. Would HRSA do the calculations and refer outliers to the SSA or whatever entity is charged with doing these surveys?
2. I'm concerned about the change in timing of kidney transplant program approvals and what this will mean regarding availability of programs for patients covered by Medicare under the ESRD program. Currently, Medicare approval of a hospital for reimbursement for kidney transplants is granted without requiring a certain number of transplants or the program being in operation for a year. Since the majority of kidney transplant recipients are covered under the Medicare ESRD program (for both the surgery and three years of the immunosuppressive medications), requiring new kidney transplant programs to wait a year for certification may limit patient access to new programs.
3. **Regarding 482.04, (d) Standard: Social services:** I would encourage consistency in the personnel requirements for social workers with those current (and proposed) in the ESRD program. In describing an alternative to having a Master's degree in social work, you did not specify a time period for the accumulation of social work experience—the language at 405.2102(2) states "has served for at least 2 years as a social worker, one year of which was in a transplantation program," and does not state when that experience might have occurred.
4. **Regarding 482.94 Patient and living donor management:** I applaud clarity in the requirements for the transplant center regarding patients on waitlists, and hope that we can support the development of technology that will ease the burden of communication between transplant centers and referring dialysis centers.
5. **Regarding 482.104 Additional requirements for kidney transplant centers:** (b) Dialysis services: this language references the current Subpart U, which is under revision

concurrently with these new rules. The language here infers that the inpatient dialysis unit of a hospital doing kidney transplant must meet the requirements of Subpart U. Currently, hospitals doing only inpatient dialysis are not required to meet Subpart U, and are not surveyed by those requirements. Perhaps we should consider adding a Condition of Dialysis to the Hospital Conditions of Participation in order to provide regulatory guidance for this service in all acute settings.

6. **Regarding the special procedures for approval and re-approval of organ transplant centers:** As these requirements are revised for kidney transplant programs and new to other organ transplant programs, I would encourage routine survey of the process requirements on a three year cycle for a minimum of two survey cycles, to ensure implementation and maintenance of systems to assure these requirements are met.

Thank you for the opportunity to comment on these proposed rules.

200 First Street SW
Rochester, Minnesota 55905
507-284-2511

June 2, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, Maryland 21244-8013

Re: File Code CMS-3835-P
Comments to Requirements for Approval and Re-Approval of Transplant Centers to
Perform Organ Transplants

Dear Sir or Madam:

Mayo Clinic is pleased to have the opportunity to respond to the proposed rules to establish hospital conditions of participation requirements for approval and re-approval of transplant centers to perform organ transplants as published in the *Federal Register* on February 4, 2005.

Mayo Clinic currently has transplant centers located in Minnesota, Arizona, and Florida. Each year, our surgeons perform more than 1,000 transplants, the largest of any medical center in the United States. Through education and research, Mayo Clinic is dedicated to quality and excellence in the field of organ transplantation.

We applaud CMS's efforts to promulgate regulations to establish standards that will ensure that Medicare beneficiaries are receiving quality transplantation services from Medicare-approved transplant centers. It is our mission, along with other institutions in the transplant community, to provide the best possible care to both transplant recipients and living donors. We also understand CMS's position to address the report issued by the Office of Inspector General, which recommended CMS to expedite the development of standards for continuing Medicare-certified transplant centers.¹

Our primary concern with the proposed conditions of participation revolves around the possible conflicting regulatory requirements from both CMS and the Organ Procurement and Transplantation Network (OPTN). The OPTN was created under the National Organ Transplant Act (NOTA) of 1994. Under section 1138 of the Social Security Act, all hospitals that perform organ transplants are required to be members of and abide by the rules and requirements of the OPTN as a condition for participation in the Medicare and Medicaid programs. The regulations applicable to the operations of the OPTN are contained in 42 CFR Part 121. The OPTN, which is administered by the United Network for Organ Sharing (UNOS), contains legally binding rules and requirements that are enforceable on transplant centers. The OPTN is responsible for conducting ongoing and periodic reviews and evaluations of each member transplant hospital for compliance with regulations and OPTN policies. Section 121.10(c) states that the Board of Directors of the OPTN shall advise the Secretary of Health and Human Services of any reviews and evaluations that indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. This appropriate action

¹ U.S. Department of Health and Human Services, Office of Inspector General, *Medicare Approved Heart Transplant Centers*, February 2004

may include removal of designation as a transplant program or termination of a transplant hospital's participation and reimbursement under Medicare or Medicaid.

Therefore, we recommend CMS work collaboratively with the OPTN to establish or modify existing OPTN standards and provisions for transplant centers to develop a unified process for continued and initial Medicare approval for performing organ transplantation. Since there is already an established process that provides authority for the Secretary, with recommendations from the OPTN Board, to remove Medicare approval for transplant centers, the quality measures proposed by CMS should be added to the OPTN standards.

We also strongly recommend that the oversight of the conditions of participation be the sole responsibility of the OPTN and not shifted to the state agencies, JCAHO, AOA, or any other agency with deeming authority for hospitals. This would allow for the consistent interpretation of the conditions of participation for transplant centers. The uniqueness and complexity of transplantation should remain with a uniform enforcement body such as the OPTN.

If CMS proceeds with establishing its own set of conditions of participation for transplant centers, we have listed below our comments to sections of the proposed rule.

GENERAL REQUIREMENTS (§ 482.72 THROUGH § 482.76)

OPTN Membership (§ 482.72)

We agree that a transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the OPTN. We also agree with CMS's decision to not deem a transplant hospital out of compliance with section 1138(a)(1)(b) of the Social Security Act unless the Secretary has given the OPTN formal notice of approval of the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

Notification to CMS (§ 482.74)

We agree that it is necessary for each transplant center to maintain the resources and commitment to safely and efficiently perform transplants throughout its approval period. We also agree with maintaining the current requirement for transplant centers to notify CMS of any significant decreases in experience level or survival rates, the departure of key members of the transplant team, or any other major changes that could affect the performance of transplantation. However, we recommend the scope of this section be limited to reporting only adverse events and the departure of key members of the transplant team, which are the same circumstances for such notification to the OPTN. We believe that an unusually large number of early deaths may not significantly affect 1-year outcomes if the transplant center subsequently has increased volume with successful results. Also, any significant impact on 1-year outcomes will already be identified with the outcome requirements under § 482.82.

Pediatric Transplants (§ 482.76)

We disagree with the requirement for transplant centers to submit a separate request to perform pediatric transplants. We believe that a transplant center should be treated as a unified program, even if performing both adult and pediatric transplants. Also, in most if not all transplant centers, the core transplant team performs both types of transplants. The rules of the OPTN allow for the

same personnel to provide care to both adults and pediatrics so long as they are qualified. In the proposed rule, CMS provides justification for its requirement due to many centers that perform pediatric transplants are not jointly operated by another facility that is Medicare-approved. However, we disagree that there should be a separate approval request for the same transplant center in order to comply with the conditions of participation. Similar to Medicare-approved pediatric heart transplant centers, we recommend specified criteria in order to be approved to provide both adult and pediatric transplants. The criteria would include: (1) the unified program shares the same transplant surgeons and quality assurance programs (including oversight committee, patient protocol, and patient selection criteria); and (2) the hospital demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel required for those types of patients. We believe this criteria provides flexibility for those transplant centers that provide both adult and pediatric transplants.

DATA SUBMISSION AND OUTCOME REQUIREMENTS (§ 482.80 AND § 482.82)

Basis for Initial Approval and Re-Approval

The proposed rule specifies the same data submission and outcome requirements for transplant centers seeking initial approval and re-approval. Also, the proposed rule states that for transplant centers seeking initial approval and fail to meet the data or outcome requirements, application for approval would be denied and no survey would be performed. However, an exception is provided for those transplant centers seeking re-approval and fail to meet the data submission and outcome requirements. Specifically, CMS states that “under some circumstances, we believe that a transplant center’s inability to meet the data submission or outcome requirements can be influenced by factors that are not necessarily indicative of the quality of transplantation care.”²

CMS further states that “a successful survey may under certain circumstances make up for a center’s failure to meet one or more of the quantitative requirements.” However, in the context of the proposed rule, this exception seems to only be applicable for transplant centers seeking re-approval. Since CMS proposes to treat centers that are currently Medicare-approved as new centers that would need to meet the requirements for initial approval, we recommend that CMS provide a one-time exception to currently Medicare-approved transplant centers and allow for a survey if the center fails to meet the data submission and outcome requirements.

We also believe using the OPTN data and outcome standards as the sole basis for initial approval is inappropriate. We understand CMS’s purpose to require timely and complete submission of data that will ensure up-to-date and meaningful data. However, these standards developed by the OPTN were not intended for this purpose. We suggest that CMS allow the OPTN to enforce its own policies on member hospitals regarding the adherence to these standards and to not use the data and outcome standards as a condition for initial approval.

If CMS continues to use the data and outcome standards as conditions for initial approval, the transplant center should be provided an opportunity to develop a corrective action plan with approval from CMS and/or the OPTN. Since the SRTR reporting period spans six months, we recommend that the transplant center be provided no more than 180 days to correct any deficiencies and submit an acceptable plan of correction.

² Page 6167, *Federal Register*, February 5, 2005

Outcome Measure Requirements

We agree that it is necessary to establish outcome measure requirements for transplant centers in order to better ensure patient safety, and given the scarcity of donor organs, to ensure that organs are transplanted effectively and not wasted. CMS proposes to use the most recent center-specific SRTR report to determine compliance with the outcome measures. This report is also used by the OPTN to identify centers that may need further investigation. The SRTR report is published every six months and represents only a “snapshot” of patient and graft survival statistics performed anywhere between 1 and 3.5 years previously. We recommend that CMS consider the outcome standard be based on at least the two previous SRTR reports to identify trends. The use of more than one report may provide a better impression of a transplant center’s quality and performance.

CMS has also offered two other options for determining the requirements for outcome measures if the center’s observed patient and graft survival rate is lower than its expected rate. In option 1, the outcomes would be unacceptable if just two of the three tests are not met. Per CMS this option identified 15.7 percent of the heart, kidney, liver, and lung centers that perform adult transplants to be non-compliant. In option 2, only one of the three tests would have to be met of which CMS identified 41.6 percent of adult transplant centers to be non-compliant. The three tests were developed by the OPTN to measure risk-adjusted outcomes and to address the potential for inadvertently penalizing transplant centers for transplanting high-risk patients or using organs from extended criteria donors. These three tests used collectively assist the OPTN to identify transplant centers for further review. We believe it to be inappropriate for CMS to not use all three tests for determining compliance with outcome measures. Therefore, we recommend CMS not incorporate option 1 or option 2, and to utilize the three-pronged approach for the outcomes standards as proposed.

We also agree to the proposal to permit a new transplant center to use 1-month patient and graft survival outcomes for all transplants performed in the previous 1-year period in lieu of 1-year patient and graft survival outcomes if two conditions are met. Those two conditions are that the “key members” of the center’s transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center, and the transplant center’s team meets the human resources requirement under § 482.98. However, we recommend that “key members” of the transplant team be specifically defined and should include at a minimum the transplant surgeon.

PROCESS REQUIREMENTS (§ 482.90 THROUGH § 482.104)

Patient and Living Donor Selection (§ 482.90)

We disagree with the requirement that a transplant center must employ or consider all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation. In the final rule establishing the OPTN, there is a statement that says, “No provision of the final rule is intended to interfere with the discretion of individual health professionals and patients in medical decision-making.”³ However, we believe that the proposed requirement is contrary to this statement. We also believe that by requiring

³ Organ Procurement and Transplantation Network, *Federal Register*, October 20, 1999

transplant centers to document their consideration of "all other" therapies, it would place transplant centers at an undue risk for legal ramifications. For example, in an unfavorable outcome for a transplant recipient, a legal argument could be that the transplant center may not have considered "all other" appropriate therapies. The transplant center's consideration of "all other" therapies would have to be documented per the proposed rules rather than relying on medical judgment. We believe that transplant centers should support the decisions of its transplant team and rely on their judgment based upon their medical knowledge and experience. In practice, the transplant center, under the medical direction of a transplant physician, already seeks all appropriate therapies.

We also disagree with the requirement to document in the patient's medical record the patient selection criteria used. We do not support making available the patient selection criteria used to patients or any third party. Patient selection criteria are made up of several factors to include medical, social, and financial support. The decision for patient selection is based upon the collective input from highly experienced transplant professionals and is made in the best interests of the patient, both short-term and long-term. We also believe that this would again place the transplant center at an undue risk for legal ramifications.

We believe that the requirement should be removed that relates to requiring living donor selection criteria be consistent with the general principles of medical ethics. As stated by CMS, there are no established guidelines concerning the selection of living donors. Recently in the transplant community, there have been questions as to whether the use of an Internet website for matching donors is considered ethical.

We also disagree with documenting the living donor's suitability for donation in both the transplant candidate's and living donor's medical records. Our argument is similar to the requirement for documenting the patient selection criteria used.

Organ Recovery and Receipt (§ 482.92)

We support CMS's efforts to ensure that transplant centers are actively taking steps to avoid transplantation of mismatched organs throughout the organ distribution process along with preventing the waste of organs in the event a mismatch is discovered late in the process. However, we have concerns of the requirement to have the transplanting surgeon responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient. We agree that the transplanting surgeon is ultimately responsible for the decision to proceed with the transplant. However, the transplanting surgeon relies heavily on the Organ Procurement Organization (OPO) for the collection of accurate information and to properly communicate this information. In order for a transplanting surgeon to be capable of ensuring medical suitability, the surgeon would have to be involved and oversee the OPO's deceased donor processes. We recommend the language be modified to state that the transplanting surgeon ensures the medical suitability of donor organs, *based upon available information*, for transplantation into the intended recipient.

We also believe the requirement for the organ recovery team to review and compare donor data with the recipient's blood type and other vital data before organ recovery takes place should be revised. This proposed process will delay timely procurement and placement of viable organs, which could ultimately lead to wasted organs. In most cases, the transplant recipient has not yet been identified at the time of organ removal from the deceased donor. We recommend that the

requirement be changed from “organ recovery” to “organ acceptance.” Also, there needs to be an exception for intended ABO incompatible transplants whereby the donor and intended recipient will not have matching blood types. These types of transplants are performed in few transplant centers, but a provision needs to be made to account for non-matching blood types.

Patient and Living Donor Management (§ 482.94)

We believe the standard to require each transplant patient be under the care of a multidisciplinary patient care team coordinated by a physician be modified. In most cases, potential recipients are not managed by the transplant centers, but rather by local specialists. For example, kidney transplant recipients are frequently cared for at dialysis centers that are not in close proximity to the transplant center. Furthermore, many transplant recipients are returned to the referring physician for post-transplant care. As such, pre and post transplant care may not always be able to be provided by the transplant center. Therefore, we suggest the requirement to be modified to state that pre and post transplant care be provided in conjunction with the local specialists.

Quality Assessment and Performance Improvement (§ 482.96)

We disagree with the requirement for a transplant center to have a separate QAPI program. While we agree with CMS’s commitment to encourage continuous quality improvement for all Medicare providers, we do not believe that this should be a condition for participation. As noted by CMS in the proposed rule, the QAPI process is already required by JCAHO through its hospital accreditation standards. The decision to establish a transplant-specific QAPI program should be determined by each individual hospital. The monitoring of outcome measures should adequately identify those transplant centers that do not meet the standards of care. The implementation of a formal QAPI program would be appropriate for a transplant center that does not meet the outcome standards as part of a remediation process.

Human Resources (§ 482.98)

We agree with CMS in its view that transplant centers ensure all individuals who provide services and/or supervise services are qualified to do so. The OPTN has specific policies regarding the training and experience of transplant physicians and surgeons, and we compliment CMS for adopting this definition. However, we disagree with the requirement for clinical transplant coordinators to be certified by the American Board of Transplant Coordinators (ABTC). While we agree that the ABTC does ensure a standard of competency, knowledge, and skills for transplant coordinators, we do not believe it is a necessary requirement to ensure quality of care. Currently, there are many highly experienced transplant coordinators without ABTC certification. An alternative to the ABTC certification would be the addition of a “grandfather” clause whereby a clinical transplant coordinator must meet a minimum number of years of experience.

Organ Procurement (§ 482.100)

This section is an example of a duplicate requirement of existing regulations. Under 42 CFR § 121.9(a)(2)(i), in order for a transplant hospital to receive organs for transplantation, it must have letters of agreement or contracts with an OPO. Therefore, we believe it is unnecessary to create a separate condition of participation for hospitals to have a written agreement for the receipt of organs with an OPO.

Patient and Living Donor Rights (§ 482.102)

We agree with the proposed standards for informed consent to transplant patients and living donors. However, we disagree with the requirement to inform living donors of national and transplant-center specific outcomes for donors. Currently, there is no living donor registry to obtain the long-term history to satisfy this requirement. It is our understanding that the OPTN has developed a plan for such a registry, but the registry has yet to be funded. Therefore, we recommend removal of the requirement to provide national outcomes for living donors.

In response to the request for comments on whether there should be a requirement for transplant centers performing living donor transplants to provide the service of an independent donor advocate (or advocacy team), we believe that the use of a transplant-educated health care worker not directly involved in the transplant process, such as a medical social worker, would be sufficient. The advocate would be knowledgeable of the transplant process and be able to accurately convey the risks and benefits to the potential donor. Within the transplant community, there is general consensus that there should be some form of donor advocacy to apprise donors of the process of transplantation, the risks and benefits of living organ donation, and to protect and promote the interests and well being of the donor. However, the issue in the transplant community has centered on the power assigned to the donor advocate. The predominant view is that the donor advocate should advise and not have the ability to overturn a donor's decision of organ donation.

Additional Requirements for Kidney Transplant Centers (§ 482.104)

We agree that kidney transplant centers should have a direct relationship with the ESRD Network and dialysis centers. However, we believe it is unnecessary to create a separate condition of participation since most of these conditions are already addressed under 42 CFR Part 405, Subpart U. Also, the requirement for transplant centers to cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the Network's current statement of work is very generalized. We recommend that CMS further qualify this requirement.

SPECIAL PROCEDURES FOR APPROVAL AND RE-APPROVAL

Provider vs. Supplier Status for Appeals

We believe that it is paramount to have an appeal process should CMS decide not to approve or re-approve a transplant center. We also agree with CMS that transplant centers are unique entities that do not fit perfectly into either the provider or supplier category as defined in the Social Security Act. However, the definition of a provider under section 1861(u) of the Act specifically includes hospitals. Since Medicare-approved transplant centers must be operated within a hospital, we believe the appropriate categorization for a transplant center would be that of a provider.

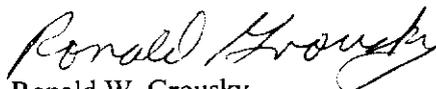
Alternative Process to Re-Approve Transplant Centers

We agree that a transplant center's adherence to the data submission and outcome measure requirements does not necessarily indicate that the center is also in compliance with the process requirements. We also agree that CMS or its designee should conduct random surveys each year to determine compliance with the process requirements. We recommend the sample be based upon the number of transplant centers and not differentiated by organ type. Depending upon the feasibility of using state agencies, JCAHO, or the OPTN to conduct the reviews, we recommend that at least 10 percent of the transplant centers be surveyed each year by random sample or approximately 23 hospitals per year for compliance with the process requirements. These random surveys would cover all organ types for that particular transplant center. We do not believe that all transplant centers should be surveyed every 3 years, as this would create an unfair burden to the surveyors due to the number of transplant centers. An alternative would be every 5 years. We also agree that any information provided by the OPTN that warrants further review of a transplant center should immediately result in a survey for compliance of the process requirements.

CONCLUSION

We appreciate the opportunity to comment on these very important proposed rules. At Mayo Clinic, we support CMS's efforts to ensure quality of services provided to Medicare beneficiaries for transplant services. However, we believe that these proposed requirements are only the initial steps in the rapidly changing transplant environment. In addition to our comments on the proposed regulations, we strongly recommend that CMS work collaboratively with the OPTN to establish or modify existing OPTN standards and provisions for transplant centers to develop a unified process for continued and initial Medicare approval for performing organ transplantation. If you should have any additional questions or comments, please feel free to contact either Robert Howey at (904) 953-2698 or me at (507) 284-4627.

Very truly yours,



Ronald W. Grousky
Director, Medicare Strategy Unit
Mayo Clinic

June 1, 2005

CMS
Dept. of Health and Human Service
ATTN: CMS-3835 P
PO Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I would like to submit my comments for the Transplant Conditions of Coverage. As a transplant social worker for 5 years, and a member of CNSW for 15 years, I support the attached CNSW proposals.

Sincerely,



Leanne Peace, MSW, LCSW
161 Moonglow Ln.
Columbia, MO 65201

**Council of Nephrology Social Workers Comment
Proposed Transplant Regulations file code CMS-3835-P**

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: We support the mandate of a psychosocial evaluation for all prospective transplant candidates. We suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.”

Rationale: There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2004; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and may be used as a suggested template.

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: We support the mandate of a psychosocial evaluation for all prospective living donors. We suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.” We support a requirement that transplant centers performing living donor transplants must provide the service of an independent donor advocacy team that includes a qualified social worker. We suggest that living donors and recipients should have, whenever possible, separate qualified practitioners conducting the social work and medical evaluations.

Rationale: Living donor kidney transplants are increasingly popular. Meeting appropriate psychosocial criteria is essential to the success of the transplant. Qualified social workers must assess the donor in order to gauge any normative pressures on the donor that may influence the decision to donate a kidney, motivation for donation, ability to make informed consent, the nature of the relationship between the donor and recipient, and the donor’s psychosocial status (Fisher, 2003; Fox & Swazey, 1979; Leo, Smith & Mori, 2003). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation for living donors. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations

http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential elements and may be used as a suggested template for a social work assessment.

We believe that an independent donor advocacy team that includes a qualified social worker would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Social workers have an established place in health care ethics committees and in helping patients make ethical decisions. A qualified social worker is essential on an advocacy team to assess inappropriate motivations to or inadequate understanding of the related psychosocial issues of donation.

As transplant recipients and donors may have conflicting interests and motivation, it is strongly encouraged that living donors and recipients should have, whenever possible, separate qualified social workers to minimize potential conflict of interests.

Issue Identifier: 482.94 Condition of participation: Patient and living donor management

Comment: We support (d) Standard: Social services [The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing], and (d)(1) [Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.] However, we do not support: (d) (2): [Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 82.94], and urge that issue identifier: §482.94 (d) (2) be removed from the proposed changes. Additionally, CNSW believes that there is need for ongoing access to qualified transplant social workers, who would ideally be dedicated to the transplant program.

Rationale: Transplant patients present with highly complex needs on an individual as well as systems level. Master's level social workers are trained to intervene within both areas of need that are essential for optimal patient functioning, and help facilitate congruity between individuals and their environments' resources, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum, which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems that is essential in transplant programs. The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of specialized, clinical training prepares the MSW to work autonomously in the transplant setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle,

economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 1991; Rabin, 1983; Rosen, 1999; Soskolne & Kaplan-DeNour, 1989; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker

For these reasons, we strongly support (d)(1) of this regulation, and strongly encourage the removal of (d)(2) of this regulation. This provision mirrors the “grandfather clause” that has been proposed to be removed from the End Stage Renal Facilities Conditions for Coverage. The End Stage Renal Facilities Conditions for Coverage acknowledges that there is a need for the requirement that the social worker have a master’s degree. Social work practice in transplantation as compared to End Stage Renal Disease Facilities does not lend itself to a diminution of professional qualifications and standards. The biopsychosocial needs of transplant candidates, recipients, families, and living donors are complex and deserve equal consideration for adequate care, and should only be provided by a qualified Master’s level social worker.

CNSW believes that there is need for transplant patients and donors to have ongoing access to qualified transplant social workers. This would allow for: patient continuity of care throughout the progress of each disease process; ongoing rehabilitation for planning to increase independence and lessen dependence on disability and Medicare/Medicaid (especially as there services often terminate after successful transplantation); and ability to address ongoing psychosocial concerns that impact on graft survival and patient quality of life. They can also assist patient with complex coping issues and psychosocial status issues: results in 48 donors who were evaluated prior to surgery and again at 4 and 12 months showed a 29% incidence of DSM-IV psychiatric disorder developing over the first 12 months (Smith, G., Trauer, T., Kerr, P., et al., (2004). Skotzoto, C., Stowe, J., Wright, C., Kendall, K., and Dew, M. (2001) have shown support for pre-transplant, perioperative period, and post transplant psychosocial services. We urge that there be inclusion of language which would mandate additional social work provision for ongoing services.

Ideally, this person would be dedicated to the transplant program. Transplant social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. The United Network for Organ Sharing (UNOS) did a study that showed that 88% of transplant centers reported that social work coverage was adequate when social workers reported directly to transplant centers and only 58% reported adequate coverage when the social workers had to report to other departments (Thomas, 2003). Social workers who report to other hospital departments have increased non-transplant duties.

Issue Identifier: 482.98 Condition of participation: Human resources

Comment: We support changing the language of this condition from “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.” to “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology.”

Rationale: As discussed in our comments for identifiers 482.90 and 482.94, the gravity of psychosocial factors related to transplantation necessitate Master’s level qualified social work interventions. Utilizing language such as “social services” is not recommended because there could be ambiguity about who provides such services; we recommend using the language of a “social work” instead.

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May 24, 2005

CMS
DHHS
ATTN: CMS 3835-P
PO Box 8013
Baltimore Md. 21244-8013

Enclosed are an original and 2 copies of my comments on the Proposed Transplant Regulation – file Code CMS – 3835-P

Thank you for your consideration.



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Proposed Transplant Regulations file code CMS-3835-P

Issue Identifier: 482.90 Condition of participation: Patient and living donor selection

Comment: We support the mandate of a psychosocial evaluation for all prospective transplant candidates. We suggest changing the language of this condition from “psychosocial evaluation” to “qualified social worker evaluation.”

Rationale: There are numerous psychosocial barriers to transplantation. The chronicity of End Stage Renal Disease and the intrusiveness of required treatment such as transplantation provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping to chronic illness, concern about mortality & morbidity, depression, anxiety, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Mapes, 2004; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizoni, 1997). Psychosocial factors such as finances, depression, relationship changes and employment lead to transplant immunosuppressant noncompliance (Russell & Ashbaugh, 2004). The gravity of these psychosocial factors necessitate an evaluation/assessment conducted by a qualified social worker- utilizing language such as “psychosocial evaluation” is not recommended because there could be ambiguity about who conducts such an evaluation; we recommend using the language of a “qualified social worker evaluation” instead. There should be an effort to standardize and uniformly include some of the essential elements of the recommended psychosocial evaluation. This would also allow for the development of more valid and reliable interventions as well as psychosocial outcome measures. The ESRD Network of Texas’ (2002) Social Services Practice Recommendations http://www.esrdnetwork.org/professional_standards.htm include recommendations for these essential social work evaluation elements and may be used as a suggested template.

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Comment: We support (d) Standard: Social services [The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing], and (d)(1) [Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education.] However, we do not support: (d) (2): [Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 82.94], and urge that issue identifier: §482.94 (d) (2) be removed from the proposed changes. Additionally, CNSW believes that there is need for ongoing access to qualified transplant social workers, who would ideally be dedicated to the transplant program.

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Ideally, this person would be dedicated to the transplant program. Transplant social workers who report to the transplant department, rather than other hospital departments, are better able to intervene. The United Network for Organ Sharing (UNOS) did a study that showed that 88% of transplant centers reported that social work coverage was adequate when social workers reported directly to transplant centers and only 58% reported adequate coverage when the social workers had to report to other departments (Thomas, 2003). Social workers who report to other hospital departments have increased non-transplant duties.

Issue Identifier: 482.98 Condition of participation: Human resources

Comment: We support changing the language of this condition from “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.” to “The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, **social work**, transplant coordination, and pharmacology.”

Rationale: As discussed in our comments for identifiers 482.90 and 482.94, the gravity of psychosocial factors related to transplantation necessitate Master’s level qualified social work interventions. Utilizing language such as “social services” is not recommended because there could be ambiguity about who provides such services; we recommend using the language of a “social work” instead.

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THE Transplant CENTER

PANCREAS • HEART • LUNG • ISLET • LIVER • KIDNEY • INT. STINE • LIVING DONOR

A Unique Partnership of University of Minnesota Physicians Transplant Program and Fairview Health Services

May 24, 2005

Mark McClellan, M. D., Ph.D.
Administrator
Center for Medicare and Medicaid Services
7500 Security Blvd.
C5-11-24
Baltimore, Maryland 21244-1850

Re: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplantation; CMS – 3835 – P

Dear Dr. McClellan:

The transplant programs at the University of Minnesota Medical Center and the University of Minnesota Children’s Hospital (Minneapolis, Minnesota) are pleased to have the opportunity to respond to the proposed rules establishing requirements for approval and re approval of transplant centers, as published in the February 4, 2005 Federal Register. We have performed over 9,000 transplant procedures (heart, lung, liver, kidney, pancreas, islet, intestine, and living donor) and are one of the oldest and largest programs in the world. The University of Minnesota has long been a pivotal leader in the field.

We support the response of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST). Our team has reviewed the ASTS/AST statement and concurs with most of the recommendations. In one area however, we offer an opposing viewpoint.

Proposed section 482.98 (c) requires a clinical transplant coordinator to be certified by the American Board of Transplant Coordinators (ABTC). This is reasonable and timely, even though many programs (ours included) employ clinical coordinators who have not achieved certification. Certification examinations were established (in 1988 by the ABTC) in order to standardize experienced clinical transplant coordinator care services for patients who seek or who have received transplants. The intent was that an independent agency would develop standards by which these services would continually promote clinical excellence. Introductory education courses for transplant coordinators who will be practicing in procurement and/or clinical transplantation are offered frequently, as are advanced practice educational opportunities to fulfill ongoing continuing education requirements. The advisory (clinical and procurement) committees which devise these testing competencies are composed of experienced clinicians whose goal is to safeguard the standard of care, not to rely on physicians or other care providers to “train” them.

To reiterate, we agree with the AST and ASTS that coordinator clinicians who are not certified are practicing in transplant programs, but this fact does not justify preventing implementation of a quality standard goal. Just as there are physicians and surgeons practicing transplantation without meeting standards of leadership outlined by the Organ Procurement and Transplant Network, it would be inappropriate to suggest that “trainers” outside the field of medicine and surgery expertise would keep them current in attaining transplant standards of practice.

CMS has taken the first step in ensuring that continuity of care of patients and living donors can be assured in transplant programs by having qualified clinical transplant coordinators (and procurement transplant coordinators in the organ procurement organizations). Certification by the American Board of Transplant Coordinators (now legally incorporated as the American Board for Transplant Certification), is the entity that promotes that effort. The public's awareness of elevated safeguards will minimize medical errors associated with donation and transplant and supports an objective methodology for assessing the level of transplant coordinator competency.

Sincerely,

Transplant Program Leadership
University of Minnesota Medical Center

Elizabeth Braunlin, MD
David Dunn, MD, PhD
Rainer Gruessner, MD
Bernhard Hering, MD
Cynthia Herrington, MD
Marshall Hertz, MD
Abnihav Humar, MD
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May 17, 2005

Mark B. McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-3835P
PO Box 8013
Baltimore, MD 21244-8013



RE: Hospital Conditions of Participation for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants- Proposed Rule

Dear Dr. McClellan:

Thank you for the opportunity to provide comment on 42 CFR Parts 405, 482, and 488 Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Proposed Rule, as published in the Federal Register on February 4, 2005.

Abbott Northwestern Hospital, the largest hospital in the Allina Hospitals and Clinics system of services, located in Minneapolis Minnesota, provides organ transplant services through Medicare approved programs for heart and kidney transplantation.

Overall, we were positively impressed by the thoughtful discussion and rationale provided for the proposed rules. A definite strength of the proposed rules is their close approximation to current policy and practice that has been developed through the years by the OPTN as administered by the United Network for Organ Sharing. OPTN /UNOS policy has been developed through a consensus process with broad participation of the entire transplant community. Congruence between CMS requirements and OPTN /UNOS policy is important in setting consistent and unified standards, and provides established infrastructure for performance monitoring and review mechanisms already in place within the OPTN.

Please give serious consideration to our comments in the following areas:

1. Outcome Measure Requirements: We are in agreement with the proposed data collection and outcome measure requirements for initial approval and re-approval of transplant centers. However, we caution CMS that patient data forms have grown in scope and complexity, requiring a significant amount of time for data submission. No where else in health care are data reporting requirements so extensive and burdensome. We urge CMS to support streamlining the data forms to require data that is deemed essential (patient and graft survival) rather than continue the proliferation of non-essential data fields as we have seen over the years (current insurance, employment status, activity level etc.).

2. Patient and Living Donor Selection: We are in agreement with the proposed requirements for written criteria for selection of transplant candidates and living donors, and for documentation and communication of those criteria. We are also in agreement with the organ recovery and receipt requirements to ensure proper matching between donor and recipient. We agree with the increased requirements for the transplant center's accountability to continuously update the status of patients on the waiting list. However, we believe that referring nephrologists who regularly see the patients should also have accountability for updating the transplant center with changes in the patient's medical status that would affect the patient's listing status. As written, the proposed rule places responsibility for communication of the patient's status on the transplant center. The referring nephrologists and dialysis unit staff are in a better position to be aware of changes in the patient's medical condition, and report these changes to the transplant center. We recommend that the final rules hold the transplant center, referring nephrologist and dialysis unit accountable to work as collaborative partners in communication regarding the medical and listing status of patients on the waiting list. This would greatly assist transplant centers remain updated regarding the patient's clinical information on an ongoing basis.

3. Human Resources: We are in agreement with the qualifications for transplant center staff as specified in the proposed rule, including the requirement of ABTC certification of clinical transplant coordinators. The rule should be flexible enough to allow for staff turnover, and recognize that obtaining ABTC certification will require a minimum of one year of clinical practice prior to eligibility to take the exam, and that preparation and completion of the certification process will take time. We suggest that the rule allow enough time for newly hired staff to meet these requirements. The rule should also specify whether the requirements could be met if a non-certified coordinator was under the supervision of a certified coordinator.

We also suggest greater clarity in the requirement for expertise in immunology. This requirement should be able to be met in a number of ways, i.e. availability of appropriately staffed histocompatibility laboratory with a qualified medical director, and by expertise in immunology and immunosuppression management by the transplant physician or surgeon. Few transplant centers have a specialized or designated "Immunologist", but all centers should have medical staff with expertise in immunology and immunosuppression management.

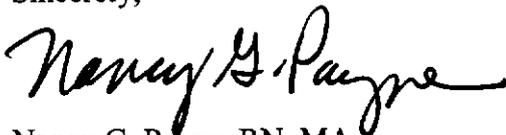
4. Patients' and Living Donors' Rights: We are in agreement with the emphasis of the proposed rules on patients' and living donors' rights. The informed consent process is essential in maintaining those rights. However, the proposed rule is highly prescriptive in listing the extensive technical content that needs to be included in the consent form. Our program already has a fairly extensive consent document in place, but the additional content required by the proposed rule will certainly challenge us to increase the length and detail of this document. It would be helpful for CMS or the OPTN to provide resources to assist centers in meeting these requirements such as providing education materials to include the essential content material with an explanation of risk much like the brochure that was developed for expanded kidney donors.

We are in agreement that transplant centers should have a process to ensure that living donors have an advocate within the system. However, we urge CMS to allow flexibility on how donor advocacy may be achieved. Employing an independent donor physician advocate would be costly. Centers should be able to specify an approach utilizing their established infrastructure to designate an advocate or advocacy team. The role of the advocate should be to provide input or oversight of the donor selection process, and be available for consultation in cases with concerns. It would be cumbersome to expect that an advocate or team would meet with every potential donor. Expertise for the role of advocate may be found in an independent physician, a patient representative, or an ethics committee.

Again, we appreciate the opportunity to comment on the proposed rule and hope that you will integrate our recommendations into the final rule. If you have any questions regarding our comments, please feel free to contact me at 612-775-9744.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Nancy G. Payne". The signature is written in a cursive style with a large, prominent "N" and "P".

Nancy G. Payne, RN, MA
Director Regulatory Affairs
Allina Hospitals and Clinics



Since 1984 — sharing organs, sharing data, sharing life.

700 North 4th Street, Richmond, VA 23219
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June 3, 2005

Walter Graham, Executive Director

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: OSORA - CMS-3835-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments Regarding the Centers for Medicare and Medicaid Services (CMS) Proposed Changes to the Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants

Ladies and Gentlemen:

The enclosed OPTN/UNOS comments on CMS' proposed changes to the Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants (File Code CMS-3835-P) focus clarification of certain current OPTN/UNOS policies and activities relating to OPOs and on identifying areas in which the national Organ Procurement and Transplantation Network (OPTN) can continue to collaborate and cooperate with CMS to promote continuous quality improvement in organ procurement.

UNOS is a Virginia non-profit corporation that operates the OPTN under contract with the Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), and pursuant to the National Organ Transplant Act of 1984, as amended (NOTA), and associated regulations. Among the duties assigned to the OPTN are responsibilities for developing and operating a national computer system for matching candidates in need of organ transplants with available donor organs and for establishing the medical criteria by which these donor organs are allocated among all candidates who are registered with the national matching system. UNOS also is tasked with providing input on proposed Federal regulations with potential impact upon the fields of organ procurement and transplantation as deemed relevant and appropriate by the OPTN/UNOS Board of Directors.

In accordance with these charges, OPTN/UNOS has developed organ-specific policies for the allocation of kidneys, livers, thoracic organs, pancreata (including islets), and intestinal organs. Also pursuant to these charges, OPTN/UNOS has established minimum procurement standards for organs that include requirements to assure organ procurement quality, safe packaging, and prevention of infectious disease transmission for diseases

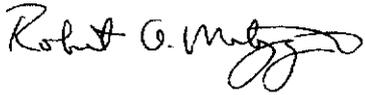
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Centers for Medicare & Medicaid Services
June 3, 2005
Page 2

such as AIDS and hepatitis. The standards anticipate challenges that result from multiple organ recovery from single donors, and try to maximize the number of transplantable donor organs.

We very much appreciate the opportunity to comment on this important proposal. If you have questions regarding our comments, or if we can provide information that would be useful to you as you reconsider the proposal, please do not hesitate to contact us.

Very truly yours,

A handwritten signature in black ink, appearing to read "Robert A. Metzger". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Robert A. Metzger, M.D.
President

**Comments to
CMS Medicare Program: Hospital Conditions of Participation: Requirements for
Approval and Re-Approval of Transplant Centers to Perform Organ Transplants;
Proposed Rule**

42 CFR Parts 405, 482, and 488
Fed. Reg. Vol. 70, No. 23, February 4, 2005.

File Code: CMS-3835-P

OPTN/UNOS Comments

NOTE: *The Proposed Rule text is in **Bold**, and the applicable comments follow in underlined, regular type.*

Preamble

Summary: This proposed rule would set forth the requirements that heart, heart-lung, intestine, kidney, lung and pancreas transplant centers must meet to participate as Medicare-approved transplant centers.

It appears that the term "liver" was omitted from the list, and it is recommended that it be added.

Section I Background – no comment

Section II Provisions of the Proposed Regulations

Special Requirements for Transplant Centers (Proposed Section 482.68) – no comment

Definitions (Proposed § 482.70) – no comment

Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed section 482.72)

Members of the OPTN, pursuant to the Preamble to the OPTN Charter and Bylaws, agree to abide by the voluntary Bylaws and Policies of the OPTN as well as the applicable statutes and the OPTN Final Rule. All transplant centers are members of the OPTN. The voluntary OPTN Bylaws and Policies represent standards of medical practice in organ transplantation, which cannot be kept up-to-date if they are locked into federal regulations. This is the same challenge as CMS describes regarding CDC guidelines to prevent the transmission of disease, which (at 70 Fed. Reg. 6086, at 6112, Columns 1 and 2) CMS is proposing to remove from its OPO regulations. It is clear that CMS expects transplant programs to abide by the standards of practice established from time-to-time by the OPTN. This is essential to the day-to-day relationship between the transplant programs and the OPTN. All of the OPTN's organ allocation policies are

voluntary standards of practice, as they must be to allow the policies to be kept up-to-date. The working relationship between transplant programs and the OPTN goes beyond the “rules” (i.e., federal regulations) approved by the Secretary and referred to in § 1138(a)(1)(B) of the Act.

OUTCOME MEASURE REQUIREMENTS

Proposed Transplant Center Data Submission and Outcome Requirements Condition of Participation: Data Submission and Outcome Measure Requirements for Initial Approval of Transplant Centers (Proposed Section 482.80)

A. Overview - no comment

B. Data Submission Requirements for Initial Approval of Transplant Centers

1. Current Medicare Data Submission Requirements - no comment

2. Data Collection and the OPTN - no comment

**3. The Scientific Registry of Transplant Recipients (SRTR) and the
Center-specific Reports - no comment**

4. Proposed Data Submission Requirements - no comment

C. Outcome Measure Requirements for Initial Approval of Transplant Centers

1. Current Medicare Outcome Measure Requirements - no comment

2. Appropriateness of Current Survival Criteria - no comment

**3. Proposed Outcome Measure Requirements for Heart, Kidney,
Liver, and Lung Centers**

We also propose to review adult and pediatric outcomes separately if a center other than a lung transplant center requests Medicare approval to perform pediatric transplants. For most organ types, the SRTR has developed separate Cox models for calculating expected patient and graft survival statistics for adult (18 and older) and pediatric (younger than 18) patients. For lung transplants, however, the SRTR stratifies recipient outcomes using other categories—(1) patients that are 12 and older or (2) patients that are less than 12. Since most lung transplants performed on pediatric patients, which is traditionally defined as patients that are younger than 18 years old, are performed on older children, we propose to use the 1-year patient survival data on patients who are at least 12 years old to assess both adult and pediatric outcomes.

The preamble to the proposed regulations discusses outcome measures for transplant centers, indicating that for centers other than lung centers requesting Medicare approval to perform pediatric transplants, adult and pediatric outcomes would be reviewed separately. For lung transplants, candidates would be stratified by age 12 years and older and less than 12 years. We acknowledge that this stratification replicates the protocol currently used by the SRTR in reporting lung outcome data to the Membership and Professional Standards Committee. We ask, however, that CMS re-consider this protocol as we will be asking the

Committee to do the same. We believe the age range for evaluating pediatric candidate outcomes should be maintained at less than 18 years across all organs. While allocation policy for lungs and livers combines certain groups of pediatric candidates with adult candidates in terms of operation of the policy, this is in response to characteristics or factors making this age break more beneficial to adolescents for allocation purposes. The general definition of pediatric remains age less than 18 years and should be used consistently in reporting and evaluating pediatric versus adult outcomes.

a. Proposed Outcome Evaluation Methodology

We are proposing that an adult transplant center requesting Medicare approval would have to have one-year patient and one-year graft survival follow-up data on at least 9 transplants of the appropriate organ type during the 2.5-year period reported in the most recent center specific report. In other words, centers that perform fewer than 9 transplants generally would not be eligible for Medicare approval under our proposal.

OPTN requirements are similar to those we proposed. The OPTN currently requires that heart, kidney and liver transplant centers perform a minimum of one transplant every three months which equals approximately 9-10 transplants over the course 2.5 years. Although lung transplant programs are required to perform only once every six months, there were only three lung centers that did not perform at least 9 transplants.

It is important to note that the OPTN does not require transplant centers to perform a minimum number of transplants. Programs are reviewed and may be considered “functionally inactive” if they have not performed a transplant within a specified period of time. The period of time that applies to the review of kidney, liver, and heart programs is three months. Pancreas and lung programs are reviewed on a six-month basis, and stand-alone pediatric programs are reviewed on a yearly basis.

We suggest that it would be helpful to transplant centers and to CMS for the CMS methodology for outcomes review to be consistent with the methodology being used from time to time by the OPTN. The goal of the OPTN, under the leadership of the OPTN/UNOS Membership and

Professional Standards Committee (MPSC), is to promote continuous quality improvement in organ procurement and transplantation, with guidance from HRSA. The MPSC is continually refining its system of analysis and feedback to transplant centers and OPOs. An example of this is that the MPSC is considering and will be reporting to the OPTN Board this June a modification to the process for reviewing small volume programs. The OPTN will provide CMS with the details of changes to its review methodology as they are approved by the MPSC and the Board. We welcome and encourage CMS to review the current status of MPSC processes before finalizing the amendments to its proposed transplant center regulations.

The current OPTN outcomes review methodology defines two thresholds for reviewing transplant program survival rates. "Large volume" programs will be defined as those programs that perform greater than 9 transplants in a 2-year cohort. "Small volume" programs will be defined as those programs that perform less than or equal to 9 transplants in a 2-year cohort. The MPSC will be providing a presentation to the OPTN/UNOS Board, at its June 2005 meeting, that clarifies the outcomes review methodology which the OPTN will use in its outcomes review process. We are providing a PowerPoint presentation that specifically describes this methodology as Attachment A to these comments. The time cohort of 2.5 years that CMS is recommending differs from the two year cohort that the MPSC is currently using for review purposes.

If the OPTN determines that a transplant center is functionally inactive, the transplant center is no longer eligible to receive organs for transplantation, and therefore can no longer perform transplants.

OPTN/UNOS By-Laws and Policies require, as a condition of membership in OPTN/UNOS, that all institutional members (including transplant hospitals) be active in the field of transplantation (By-Laws, Article 1.2). These By-Laws and Policies also stipulate that a transplant hospital, once approved as a member, must continuously meet membership requirements or elect to inactivate (for a period of up to 12 months), or terminate, any program that does not continue to meet the standards. (By-Laws, Appendix

B, V). Beginning in 1997 and on an ongoing basis the Membership and Professional Standards Committee (MPSC) has reviewed programs that do not perform a transplant during a specified time period. The time period of review for kidney, liver, and heart programs is three months. Pancreas and lung programs are reviewed on a six-month basis. Stand-alone pediatric programs are reviewed on a yearly basis.

The MPSC is concerned that such programs may not meet requirements for being active in the field of organ transplantation, which may result in the members of the transplant team not maintaining a current working knowledge in a particular organ. A letter and questionnaire are sent to each program identified in a report that is produced by OPTN/UNOS. The study is conducted in a blinded manner such that the identification of the center is not disclosed to the MPSC in the initial report and responses. The questionnaire requests the program to identify the how staff is maintaining a current working knowledge, the reasons for inactivity, and a plan for the coming year.

If the transplant program is not currently active, then the member is encouraged to either voluntarily inactivate or withdraw the membership of this program until such time as the circumstances affecting the status of the program have been resolved. The OPTN's determination of functional inactivity does not have any connection to any determination of a transplant center's eligibility to receive organs for transplantation. The OPTN's review of "functional inactive programs" would not, in and of itself, prohibit a center from receiving organs. However, transplant centers have usually followed a recommendation of the OPTN/UNOS MPSC by voluntarily inactivating the program in question.

- b. Evaluation of Alternatives to the SRTR Methodology –**
Concerns have been expressed by ASTS/AST and AOPO regarding the measurement of outcomes for ECD and DCD donor organs. We are confident that OPTN/UNOS and the SRTR will be able to develop an outcomes measurement methodology that fairly takes into account the type of donor.

Condition of Participation: Data Submission, and Outcome Measure Requirements for Re-approval of Transplant Centers (Proposed § 482.82)

A. Overview - no comment

B. Proposed Data Submission Requirements for Re-approval of Transplant Centers - no comment

C. Proposed Outcome Measure Requirements for Re-approval of Transplant Centers - no comment

D. Summary of Proposed Data Submission and Outcome Requirements for Re-Approval, by Organ Type – no comment

Proposed Transplant Center Process Requirements

A. Overview

B. Current Requirements

C. Proposed Process Requirements

1. Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90) - no comment

2. Condition of Participation: Organ Recovery and Receipt (Proposed Section 482.92) – no comment

3. Condition of Participation: Patient and Living Donor Management (Proposed Section 482.94)

The OPTN Ad Hoc Living Donor Committee has addressed this issue by creating evaluation guidelines for potential liver and kidney donors and recipients. The following guidelines were approved by the OPTN Board of Directors on June 24-25, 2004.

Living Liver Donor Evaluation Guidelines

1. Transplant candidate evaluation

a. Potential living liver donor transplant candidates should derive potential benefit from transplantation.

b. Potential living liver donor transplant candidates should under go evaluation process similar to deceased donor recipients.

c. Potential living liver donor transplant candidates should not have any absolute exclusionary criteria for liver transplantation at that transplant center.

2. Donor Evaluation

a. Donor team

i. Keeps well-being of the donor as paramount responsibility

ii. At least one member should have no connection with the candidates' medical care or decision-making

iii. The program has a responsibility to have available to the potential independent donor team that should consist of at least the following:

1. Physician/Surgeon

2. Transplant coordinator/nurse clinician

3. Medical social worker

4. Psychiatrist or psychologist (as appropriate)

5. Ethicist/Clergy (as appropriate)

iv. The team's status should not depend on the outcome of the donor evaluation

v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.

vi. The team should be experienced with donor evaluation.

vii. The team's function is:

1. to educate the potential donor regarding the potential risks and benefits of donation.
2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
4. to provide opportunities for the donor to "opt out" of the procedure without consequences.

viii. The team members should meet with the donor more than once during the evaluation process, separately from candidate appointments and without the presence of the candidate.

b. Medical evaluation: An attending physician and surgeon should screen all potential donors.

c. Psychiatric and Social Screening

i. Dedicated ~~medical social worker~~ mental healthcare professional familiar with transplantation and living donation should evaluate the potential donor for:

1. Psychosocial history
2. relationship between donor and candidate and potential areas where undue pressure or coercion may be applied.
3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
4. the existence of a financial incentive as motivation for the donor.
5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

i. Donor should undergo radiologic imaging to establish:

1. There is adequate donor liver volume to supply a graft of suitable size for the recipient.
2. There is adequate residual donor liver volume to support the donor in the immediate post-operative period.
3. Determine the vascular anatomy of the donor liver to ensure maintenance of inflow and outflow in the graft and in the donor residual liver remnant.

e. Anesthesia Evaluation

i. The potential donor should be evaluated by a staff anesthesiologist experienced in liver transplant anesthesia and post-operative pain consultation should be available.

Living Kidney Donor Evaluation Guidelines

1. Transplant candidate evaluation

- a. Potential living kidney donor transplant candidates should derive potential benefit from transplantation.
- b. Potential living kidney donor transplant candidates should under go evaluation process similar to deceased donor recipients.
- c. Potential living kidney donor transplant candidates should not have any absolute exclusionary criteria for deceased donor kidney transplantation at that transplant center.

2. Donor Evaluation

a. Donor team

- i. Keeps well-being of the donor as paramount responsibility
- ii. At least one member should have no connection with the transplant candidate's medical care or decision-making.
- iii. The program has a responsibility to have available to the potential donor an independent donor team that should consist of at least the following:

Physician/Surgeon

Transplant coordinator/nurse clinician

Medical social worker

Psychiatrist or psychologist (as appropriate)

Ethicist/Clergy (as appropriate)

- iv. The team's status should not depend on the outcome of the donor evaluation.
- v. The team should have enough medical sophistication and awareness of current center experience and results to explain these adequately to the potential donor.
- vi. The team should be experienced with donor evaluation.
- vii. The team's function is:
 1. to educate the potential donor regarding the potential risks and benefits of donation.
 2. to provide counseling and support for the donor regarding family, disability, intellectual, emotional, or other pressures.
 3. to determine that the donor's decision to donate is voluntary, without coercion from within or outside the transplant center.
 4. to provide opportunities for the donor to "opt out" of the procedure without consequences.
- viii. The team members should meet with the donor more than once during the evaluation process, separately from transplant candidate appointments and without the presence of the transplant candidate.
 - b. Medical evaluation: An attending physician and surgeon should screen all potential donors.
 - i. Donor kidney function should be tested to determine serum creatinine, calculated creatinine clearance, and urine protein excretion.
 - c. Psychiatric and Social Screening
 - i. Dedicated mental healthcare professional familiar with transplantation and living donation should evaluate the potential donor for:

1. Psychosocial history
2. relationship between donor and recipient and potential areas where undue pressure or coercion may be applied.
3. presence of psychiatric disorders. In cases in question, psychiatric or psychologist consultation should be readily available.
4. the existence of a financial incentive as motivation for the donor.
5. presence of physical or sexual abuse of the donor in the past or the presence of active substance abuse in the donor.

d. Radiologic Evaluation

i. Donor should undergo imaging studies to determine:

1. That there are two kidneys of normal size and appearance; and
2. To outline the renal vascular and urinary drainage anatomy.

ii. Donor should undergo assessment of surgical risk.

e. Anesthesia Evaluation

- i. The potential donor should be evaluated by a staff anesthesiologist experienced in renal transplant anesthesia and post-operative pain consultation should be available.

4. Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Proposed Section 482.96) – no comment

5. Condition of Participation: Human Resources (Proposed Section 482.98) – no comment

6. Condition of Participation: Organ Procurement (Proposed Section 482.100) – no comment

7. Condition of Participation: Patients' and Living Donors' Rights (Proposed Section 482.102) – no comment

8. Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed Section 482.104) – no comment

Special Procedures for Approval and Re-Approval of Transplant Centers

A. Initial Approval Procedures – no comment

B. Effective Dates for Initial Approval – no comment

C. Re-approval Procedures – no comment

D. Alternative Process to Re-Approve Transplant Centers – no comment

E. Loss of Medicare Approval – no comment

F. Applications from Consortia – no comment

G. Effect of New CoPs for Transplant Centers on Centers That Are Currently Medicare-approved – no comment

III. Collection of Information Requirements

Condition of Participation: Notification to CMS

Centers must notify CMS immediately of any significant changes related to the center's transplant program or that would otherwise alter specific elements of their application for re-approval.

It is recommended that CMS define the term "significant changes." CMS proposes that the multidisciplinary team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination and pharmacology. Would a change in the any of the individuals who comprise the multidisciplinary team, as required in section 482.98, constitute a "significant change" and need to be immediately reported to CMS? A number of OPTN members have indicated that they do not know who in CMS to notify regarding these significant changes. It would be helpful for CMS to describe the procedure for such notification. It is unclear what the impact or penalty would be for the program if a member fails to notify CMS immediately. It would be helpful to define "immediately" as within a specified period of time.

It would be helpful for CMS to describe how it would inform the OPTN of changes in primary surgeons and physicians reported to CMS.

Condition of Participation: Pediatric Transplants (Proposed Section 482.76) – no comment

Condition of Participation: Data Submission and Outcome Measure Requirements for Re-Approval of Transplant Centers (Proposed Section 482.82) – no comment

Condition of Participation: Organ Recovery and Receipt (Proposed Section 482.92) – no comment

Condition of Participation: Patient and Living Donor Management (Proposed Section 482.94) – no comment

Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (Proposed Section 482.76) – no comment

Condition of Participation: Human Resources (Proposed Section 482.98) – no comment

Condition of Participation: Organ Procurement (Proposed Section 482.100) – no comment

Condition of Participation: Patient and Living Donor Rights (Proposed Section 482.102) – no comment

Special Procedures for Approval and Re-Approval of Organ Transplant Centers (Section 488.61) – no comment

Section IV. Response to Comments – no comment

Section V. Regulatory Impact Statement

A. Overall Impact – no comment

B. Anticipated Effects

- 1. Effects on Transplant Hospitals or Centers**
 - a. **OPTN Membership – no comment**
 - b. **Notice of Significant Changes to CMS – no comment**
 - c. **Pediatric Transplants – no comment**
 - d. **Data Submission – no comment**
 - e. **Outcome Measures – no comment**
 - f. **Patient and Living Donor Selection – no comment**
 - g. **Organ Recovery and Receipt – no comment**
 - h. **Patient and Living Donor Management – no comment**
 - i. **QAPI – no comment**
 - j. **Human Resources – no comment**
 - k. **Organ Procurement – no comment**
 - l. **Patients' and Living Donors' Rights**

The team must be composed of individuals with appropriate qualifications, training, and experience in relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

The term "pharmacology" may be inaccurate in this context. Not all centers have pharmacologists, while all centers do have pharmacists.

m. Additional Requirements for Kidney Transplant Centers – no comment

C. Conclusion – no comment

List of Subjects – no comment

Proposed Text and Amendments to the Regulations

PART 405 – FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED
Subpart U – Conditions for Coverage of End-Stage Renal Disease (ESRD) Services – no comment

PART 482 – CONDITIONS OF PARTICIPATION FOR HOSPITALS
Subpart E – Requirements for Specialty Hospitals

Transplant Center Data Submission and Outcome Requirements
§482.80 Condition of Participation: Data submission and outcome requirements for initial approval of transplant centers.

For compliance with the data submission requirements we would expect the OPTN to review its statistics on data completeness for the previous calendar year and certify compliance with the data submission standards.

OPTN/UNOS collects data from transplant programs (1) to operate the wait list and the organ allocation algorithms; and (2) to analyze outcomes and inform OPTN/UNOS Policy evaluation and modification. Most data are submitted electronically through UNetsm. Some items are submitted by fax or email. Each transplant program is responsible for the accuracy and completeness of its own data. The transplant program has access to its data that was submitted electronically and can supplement or correct its electronic data at any time. The UNetsm system has prompts and error codes that reduce the incidence of data errors and omissions. OPTN/UNOS does not employ any other measures to verify or audit the accuracy or completeness of a transplant program's data submissions, other than selective medical record reviews (primarily focused on organ allocation policy compliance) during the three-year onsite audit cycle.

Transplant programs comply willingly with OPTN/UNOS data submission policies because they use the data in the operation of their transplant programs and derive benefit from up-to-date OPTN/UNOS Policies and SRTR outcomes analysis. A program might occasionally fall behind in data submission due to the unavailability of key personnel or other causes. OPTN/UNOS Policy requires the submission of 95% of a program's data within three (3) months of the due date and 100% of a program's data within six (6) months of the due date. At any time, OPTN/UNOS will be able to certify to CMS when a transplant program submitted its data and whether the submission was timely.

Attachment A

Process of MPSC Review of Program Performance

**OPTN/UNOS Board of Directors
June 23-24, 2005**

OPTN

A-1

UNOS
DONATE LIFE

Code of Federal Regulations 42 CFR Part 121

Public Health Service Act (42 U.S.C. 216, 273–274d)

63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999

OPTN Final Rule lists the following factors to guide development:

- Based on sound medical judgment
- Seek to achieve best use of donated organs
- Preserve medical judgment in acceptance or refusal of organ offers
- Specific for particular organ system
- Avoid organ wastage and futile transplants
- Promote patient access to transplantation and efficient organ placement
- Include provision for periodic review and revision as appropriate
- Include procedures for compliance monitoring
- Avoid using candidate place of residence or listing, except as required to meet the above-listed factors.

Code of Federal Regulations 42 CFR Part 121

Public Health Service Act (42 U.S.C. 216, 273-274d)

63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999

Allocation policies are to be in context of

- (i) **performance goals:** to achieve equitable allocation of organs include
 - (1) Standardizing the criteria for determining suitable transplant candidates by use of minimum criteria
 - (2) Setting priority rankings ... through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates. These rankings shall be ordered from most to least medically urgent (taking into account... that life sustaining technology allows alternative approaches to setting priority ranking for patients).
 - (3) Distributing organs over as broad a geographic area as feasible in order of decreasing medical urgency;
 - (4) Applying appropriate performance indicators to assess program performance.
- (ii) **performance indicators:** outcome analysis

MPSC Outcome Review Process

Large program (>9 transplants over 2 years) Analysis

- Statistical models (Cox Proportional Hazard) are produced for each organ that quantify the risk of graft failure/death associated with identified donor and recipient characteristics based on the national experience.
- The statistical models then adjust for these donor and recipient risk factors at a specific transplant program and calculate expected results.
- Actual (observed) and expected results are calculated for every program based on two-year cohorts.
- To be “flagged” for a cohort, a center must meet ALL THREE of the following for EITHER graft or patient survival:
 - Actual (observed) events (graft failures or deaths) – Expected events >3
 - Actual (observed) events (graft failures or deaths)/Expected events >1.5
 - Actual (observed) survival is significantly lower than expected survival ($p < 0.05$, Poisson distribution)
- To be identified for further review, a program must be “flagged” in two consecutive cohorts.

MPSC Outcome Review Process

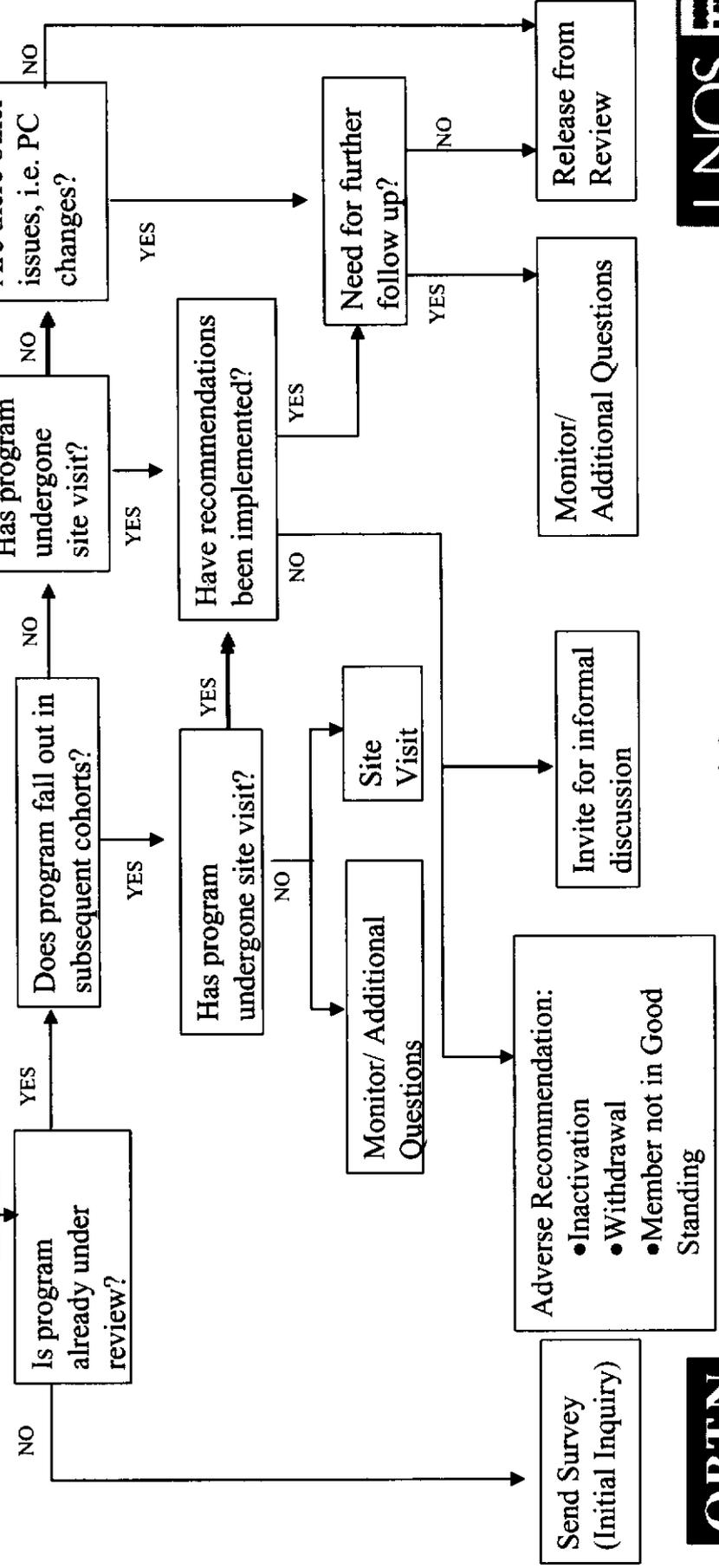
Large program (>9 transplants over 2 years) Analysis

- SRTR Report provided to MPSC annually
- Initial inquiry sent to all programs identified as not fulfilling performance measures, that are not already under MPSC review
- MPSC options for programs already under review:
 - Release from review
 - Continue to monitor
 - Offer/Proceed to site visit
 - Invite for informal discussion
 - Inactivation
 - Withdrawal
 - Member Not in Good Standing

Large Volume Program Outcome Review Process

Center XXXX ORGAN
 Over 2 consecutive cohorts for patient, graft, or both:

- Obs - Expected > 3
- Obs/Expected > 1.5
- P Value < 0.05



MPSC Outcome Review Process

Small program (≤ 9 transplants over 2 years) Analysis

- All small programs are analyzed based on the most recent 2-year cohort (for which data and follow-up are available).
- All programs with at least one death or graft failure within one year of transplant during the 2-year cohort are identified by SRTR.
- MPSC Staff provide the following information for consideration:
 - Actual 1 week, 1 month, 1 year graft and patient survival statistics
 - National 1 week, 1 month, 1 year graft and patient survival statistics
 - 5-year cohort data provided by SRTR
 - Cause of death/graft failure
 - Data on SRTR exclusions
 - Summary of subsequent yearly performance
 - Status of alternate component
 - Transplant volume summary and detailed logs

MPSC Outcome Review Process PROPOSAL

Small program (≤ 9 transplants over 2 years) Analysis

- Criteria for identifying small volume programs that warrant further inquiry will be developed by a subcommittee of the MPSC and with the assistance of SRTR representatives.

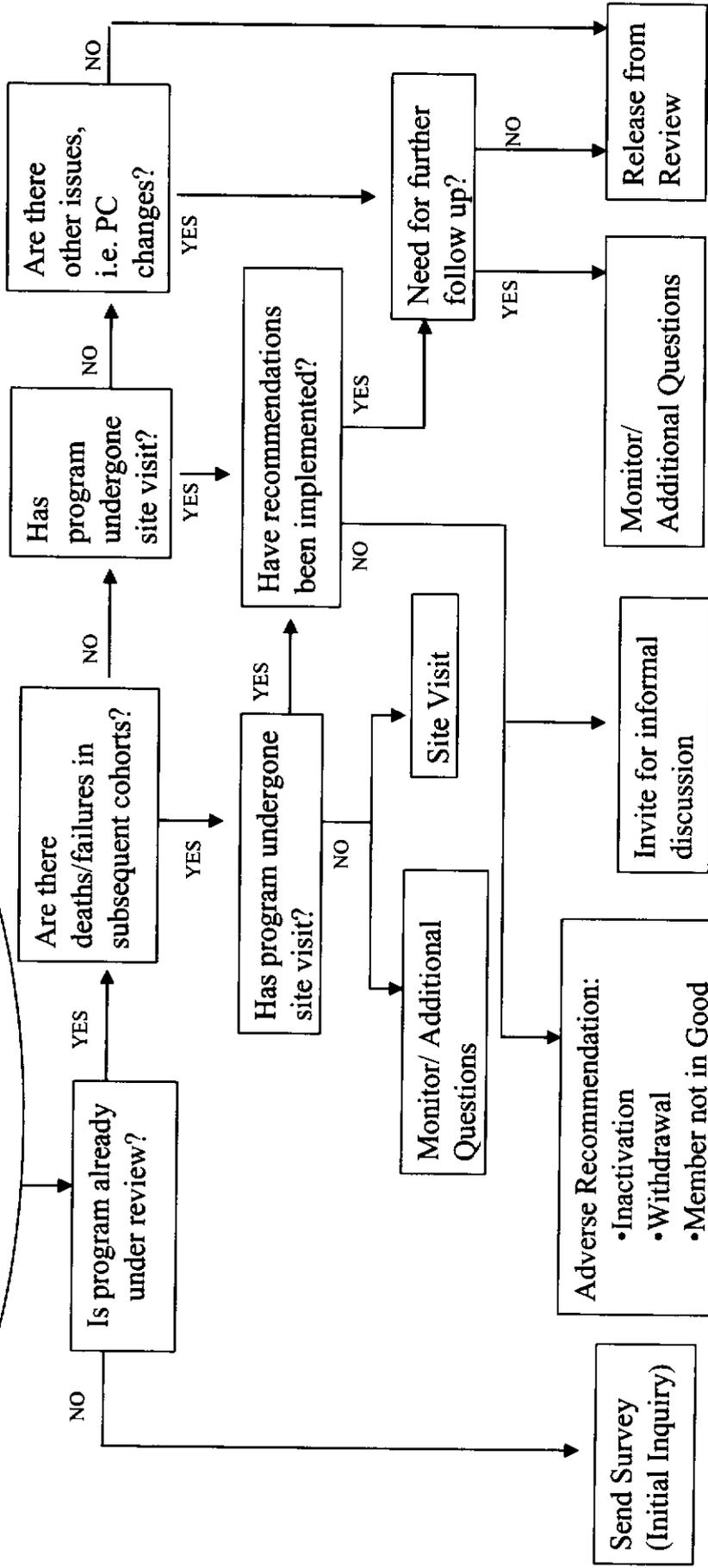
MPSC Outcome Review Process

Small program (≤ 9 transplants over 2 years) Analysis

- **MPSC options for programs already under review:**
 - **Release from review**
 - **Continue to monitor**
 - **Offer/Proceed to site visit**
 - **Invite for informal discussion**
 - **Inactivation**
 - **Withdrawal**
 - **Member not in good standing**

Small Volume Program Outcome Review Process

Center XXXX ORGAN
 Over 2 consecutive cohorts:
 • Performed ≤ 9 transplants
 • Experienced at least 1 death and/or graft failure within 1 year of tx.



OPTN

UNOS UNIVERSITY NATIONAL ORGAN FOR TRANSPLANT LIFE

AOPO
Association of
Organ Procurement
Organizations

June 3, 2005

Mark B. McClellan, MD, PhD.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O.Box 8013
Baltimore, Maryland 21244-8013

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Executive Director

Dear Dr. McClellan:

We are pleased to take this opportunity to respond to the proposed CMS rule (CMS-3835-P) regarding Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform organ Transplants. The Association of Organ Procurement Organizations (AOPO), as you know, represents all fifty-eight federally designated OPOs in the country.

Under separate cover, AOPO has responded to CMS-3064-P regarding Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations. Several of our comments which follow cross reference these two proposed regulations.

- (1) In the interest of advancing organ donation and transplantation, it is essential that there be regulatory incentives in these two rules which are positively aligned and do not conflict with one another. Specifically, the proposed OPO rules provide added outcome performance incentives for OPOs to recover organs from donation after cardiac death (DCD) and older donors. It would appear, however, that patient and graft survival measures advanced for transplant centers may not be in congruence in offering positive incentive for utilizing organs from these donors for transplant. We would strongly recommend remedying this conflict in a manner supportive of increased recovery and transplantation, that is, providing incentives in both regulations that positively reinforce recovery and transplant of organs from such donors.
- (2) Both rules are characterized by very detailed and prescriptive process measures. In the AOPO response to CMS-3064-P, we recommended that the proposed quality assessment and performance improvement (QAPI) provisions serve as a model for approaching process measures generally. This

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would apply to process measures proposed for both organ procurement organizations and transplant centers, as the science of procurement and transplantation continually evolves and an overall organ procurement and transplant network structure and framework already exist to achieve timely concordance between changing policy and practice.

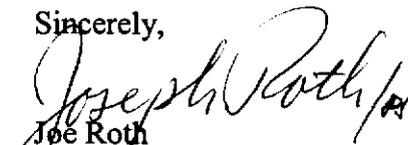
- (3) In view of the new, generally stated appeals approach advanced by CMS for organ procurement organizations, we note with interest the absence of any specific appeals mechanism proposal in the regulation regarding transplant centers. We would submit that there be symmetry between the appeals processes available to both OPOs and transplant centers. OPOs currently have the right to appeal a de-certification under §498. The proposed OPO regulations would replace the 498 appeals process with a separate, new appeals process. From a procedural standpoint, the 498 appeals process provides the OPOs with fairness and stability. We would submit that the 498 appeals process be the appropriate mechanism for OPOs and transplant centers alike.
- (4) There are occasions when OPOs have experienced difficulty in obtaining follow-up data on transplant recipients from physicians caring for these recipients or from some transplant centers. The reluctance is occasioned by an erroneous belief by some providers that providing such information would violate the Health Insurance Portability and Accountability Act (“HIPAA”). We would recommend that the rule clarify that follow-up data are essential for evaluation of outcomes, the refinement of organ allocation policies, the reporting of outcomes to UNOS, and the capability of OPOs to OPOs to anonymously inform donor families of the viability of their loved one’s organs, and that the release of the data to transplant centers, OPOs, and/or to the OPTN/UNOS does not constitute a violation of the HIPAA privacy regulations.
- (5) The regulations are dated regarding reference to “Department (of HHS) Activities Related to Organ Donation and Transplantation.” Specifically, the rule summarizes former Secretary Thompson’s multi-level approach to increasing organ, tissue, and marrow donation but makes no reference to either the ongoing HHS Organ Breakthrough Collaborative or the upcoming HHS Organ Transplantation Initiative. The latter has major implications for the participation of donor hospitals, organ procurement organizations, and transplant centers. We would recommend that the final rule incorporate reference to the initiative regarding increasing organs transplanted per donor and provide positive incentives for participation.
- (6) We note with interest the statement in the rule: “We (CMS) applaud the SRTR’s effort to strive for better ways to identify under-performing transplant centers.” We similarly applaud the work of SRTR regarding donation rate methodology and assessment and have brought that matter to the attention of

CMS in our response to CMS-3064-P. In both instances, we believe that determinations of “under performance” should not be solely based on approaches that arithmetically lead to organizations automatically falling out each performance cycle. The inclusion of a statistically-based methodology as part of outcomes measurement, such as the analytic work of the SRTR, remedies the shortcomings of any automatic fall-out approach.

- (7) The OPO regulations, in response to legislative mandates in the Pancreatic Islet Cell Act of 2004, include incentives for pancreas recovery for islet cell transplantation and research. The regulation for transplant centers, in contrast, exclude islet procedures from proposed pancreas standards.
- (8) We recommend that the proposed organ recovery and receipt requirements call for consistency with OPTN policies and procedures and not incorporate additional, prescriptive standards which are likely to evolve and be dealt with in the existing OPTN framework.
- (9) We support the provision requiring that transplant centers “establish and implement a written policy to address adverse events that occur during any phase of the organ transplant process.” A similar provision should be advanced for OPOs, rather than the proposed detailed reporting system outlined in CMS-3064-P. Here as well the principle of symmetry between OPO and transplant center regulations, to the maximum extent appropriate, should be pursued.
- (10) We support the proposal “to require that transplant centers ensure that the transplant hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary.”

Thank you again for this opportunity to comment.

Sincerely,


Joe Roth
President


Paul Schwab
Executive Director

Camille M. Yuscak, LCSW-R, ACSW
97 South Road
Holmes, NY 12531

May 31, 2005

Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P, PO Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I am a nephrology social worker and am writing in response to the proposed Transplant Conditions of Coverage. I support the position of the Council of Nephrology Social Workers and in addition make the following comments:

482.90 Condition of participation: Patient and living donor selection

CMS must recognize and direct that Master's level social workers are uniquely trained to intervene with patients to facilitate optimal patient functioning and adjustment. The use of the phrase "qualified social worker evaluation" as opposed to "psychosocial evaluation" demonstrates that CMS recognizes our training.

482.94 Condition of participation: Patient and living donor management

482.94 (d) (2) should be removed from the proposed changes. A consultative relationship with a qualified social worker does not take the place of a graduate degree from a school accredited by the Council on Social Work Education. Transplant patients, living donors and their families must have ongoing access to qualified transplant social workers who ideally would be dedicated to the transplant program.

482.98 Condition of participation: Human resources

The phrase "social services" always reminds me of a cruise director! It does a disservice to the profession of social work. Therefore, I recommend a change in language to "The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social work, transplant coordination, and pharmacology."

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Yuscak, Comments, page two

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Respectfully Submitted,



**Camille M. Yuscak, LCSW-R, ACSW, LCSW
Licensed Clinical Social Worker-R, New York
Licensed Clinical Social Worker, New Jersey
Academy of Certified Social Workers, National Association of Social
Workers**

National Association of Social Workers

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CA**EXECUTIVE DIRECTOR**

Elizabeth J. Clark, PhD, ACSW, MPH

GENERAL COUNSEL

Carolyn Polowy, JD

May 20, 2005

The Honorable Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-3835-P, Proposed rule: Medicare Program, Hospital
Conditions of Participation: Requirements for Approval and Re-Approval
of Transplant Centers To Perform Organ Transplants

Dear Mr. McClellan:

The National Association of Social Workers (NASW) welcomes the opportunity to offer comments regarding the proposed regulations for the Medicare Program, Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants, referenced as CMS-3835-P, published in the Federal Register on February 4, 2005 (42 CFR Parts 405, 482, and 488).

The National Association of Social Workers was founded in 1955, and with over 150,000 members, is the largest and most recognized membership organization of professional social workers in the world. Our Association works to promote, develop, and protect the practice of social work and social workers and to enhance the effective functioning and well-being of individuals, families, and communities.

NASW appreciates and supports the recognition by CMS of the highly complex medical, psychosocial, and ethical issues faced by organ donors and by recipients in the transplant setting. We support the proposed requirement that prospective transplant candidates must receive a psychosocial evaluation prior to placement on the waitlist to address social support, coping abilities, and the ability to demonstrate adequate adherence to a therapeutic regimen (Proposed Section 482.90, page 6159). We support the need for "social services, such as assisting and supporting patients and their families in maximizing the social functioning and adjustment of the patient" (Proposed Section 482.94, page 6161). We



agree with the current regulation 405.2171 requiring “centers to provide a qualified social worker to evaluate transplant patients’ psychosocial needs, participate in care planning of patients, and identify community resources to assist the patient and family” (Proposed Section 482.94, page 6161).

However, there is one element of the Proposed Section 482.94, on page 6180, which lowers the current standard for a qualified social worker, and subsequently could jeopardize care of the recipient and donor in this high acuity setting.

We **agree** with the first portion of the Proposed Section, which states:

“(d) *Standard: Social Services.* The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which practicing, and

1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education”

We **do not agree** with the second portion, which states:

“;or

2) Has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under 482.94 (d)(1).”

The proposed language of 482.94 (d)(2) threatens to dilute the standard of education and training, required for social workers in renal transplantation. It is our position that a master of social work degree from a graduate school of social work accredited by the Council on Social Work Education is the appropriate degree to prepare qualified social workers to provide the range of psychosocial services required by patients, donors, and their families, as described by CMS.

RECOMMENDATION: The National Association of Social Workers recommends that the final rule defines the standard for social services and qualified social workers as follows:

482.94 (d) *Standard: Social Services.* The transplant center must make available social services, furnished by qualified social workers, to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the state in which practicing, and

1) Has completed a course of study with specialization in clinical practice, and holds a master’s degree from a graduate school of social work accredited by the Council on Social Work Education.

Thank you for your consideration of our recommendation and of the needs of transplantation patients, donors, and their families. Please let us know if we can provide any additional

information to substantiate this recommendation or to assist your agency in implementation.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth J. Clark". The signature is written in a cursive style with a large, prominent "E" at the beginning.

Elizabeth J. Clark, PhD, ACSW, MPH
Executive Director
National Association of Social Workers

March 24, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants

The New York Center for Liver Transplantation, Inc. (NYCLT) is a not for profit organization comprised of the five liver transplant programs in New York State. Established in 1988, our mission has been to assure the quality of care delivered to patients receiving liver transplant services. As such, we applaud CMS for its efforts in revising the requirements to ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner. While we agree with a great many of the proposed changes, we have several comments as outlined below.

OUTCOME MEASURE REQUIREMENTS (482.80/482.82)

- Patient and graft survival outcomes are appropriate measures of transplant center performance. However, the data collected by OPTN to be used in SRTR analysis of center-specific reports is not all-encompassing. For example, steatosis is not consistently or accurately captured for all liver donors on the OPTN data collection forms, yet literature shows steatosis may have an impact on liver transplant outcomes.
- Using the "average" or the norm as a measure of comparison is also problematic, specifically in those regions where access to quality organs, particularly livers, is limited. In these circumstances, organs having a higher relative risk are often used to prevent the death of a wait-listed patient. Factors such as the size of the waiting list, the number of organ donors and the number of deaths on the waiting list in each region need to be included in the analysis. Otherwise the proposed system may inhibit the use of organs having higher relative risk, thereby keeping outcomes high, but increasing the number of deaths on the waiting list at the same time.

PATIENT AND LIVING DONOR SELECTION (482.90)

- The selection of living liver donors in New York State is governed by state regulation. While medical suitability of the living donor must be ascertained and documented by the Independent Donor Advocate Team (IDAT), all such records and documentation must remain separate and distinct from the potential recipient medical record. The proposed requirement that documentation of living donor suitability for donation be in the potential recipient record is a breach of confidentiality and a violation of New York State regulation.

HUMAN RESOURCES (482.98)

- The first Condition of Participation in the proposed rule requires that a transplant center be a member of and abide by the rules and requirements of the OPTN. Currently, a member in good standing of the OPTN must meet professional standards and personnel requirements. As such, it would seem that the Condition of Participation related to Human Resources is redundant.

PATIENT AND LIVING DONOR RIGHTS (482.102)

- Potential living donors should have access to a multidisciplinary team whose main responsibility is to safeguard the interests and well-being of the donor. This Independent Donor Advocate Team can help to ensure continuity of care during the pre-donation, donation and post-donation phases.
- The informed choice process is a critical element of living donation and should be presented in a manner that is understandable to a potential donor and consistent with his or her language and educational level.
- Potential living donors should be given adequate time to understand and assimilate the information provided. For example, New York State regulation provides potential living liver donors with a minimum two-week reflection period between the time when a potential donor is informed of his or her suitability for donation and the time when the potential donor makes a final decision.
- All potential living donors should have the right to make this decision in an environment that is free from coercion.

SPECIAL PROCEDURES FOR APPROVAL AND RE-APPROVAL OF ORGAN TRANSPLANT CENTERS (488.61)

- Existing transplant centers are subject to UNOS surveys on professional standards and surveillance. Those centers who meet outcomes and submission requirements should not be subject to an initial CMS survey as this effort is duplicative. However, new or existing transplant centers who do not meet the outcomes and submission requirements should be subject to an initial CMS survey.
- The proposed rule should provide for a period of remediation during which a transplant center may develop, submit and implement a plan of correction. Upon completion of the remediation, a transplant center must meet 1-month expected outcomes and be resurveyed.

ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

- Transplant centers should be approved based on graft and patient survival outcomes specific to each center. An alternate process of re-approval based on random surveys and OPTN input is not a consistent or efficient way to measure transplant center performance.

Thank you for your consideration of these comments.

Sincerely,



Carla R. Williams
Executive Director

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3835-P
7500 Security Boulevard
Baltimore, MD 12144-1850

RE: Proposed Rulemaking (CMS-3835-P)

To Whom This May Concern,

I strongly **OPPOSE the mandatory requirement of CCTC certification**. It by no means ensures or safeguards the care of transplant recipients. I have gone through extensive training to become a Registered Nurse. My professional degree and nursing experience have enabled me to care effectively and appropriately for transplant patients. It is only by chance that I hear about this proposed rulemaking. ABTC (American Board of Transplant Certification) has sent an email to all its constituents who are currently CCTC certified with a sample letter to reply in favor of this rule. The RN's who are not currently certified do not even know about the proposed rulemaking!

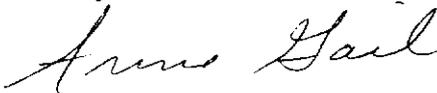
The task of taking one standardized test for a couple of hours does not in any way equal the years of training and experience that is required to perform this job, or any job safely. An employee's place of work has professional standards and qualifiers along with yearly performance reviews required under JACHO criteria that evaluate the effectiveness of an individual.

In addition there is intrinsic motivation by the company (ABTC) that promotes CCTC Exams whereby they will profit financially in this endeavor and have every reason to lobby for mandatory certification.

Finally, one might as well go ahead and require surgeons to obtain their FACS or nephrologists to obtain FANS – again this does not ensure the safe care of patients.

PLEASE DO NOT ADOPT THIS RULE!!!!

Sincerely,



Anne Gail, RN
Liver Transplant Coordinator
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3181 SW Sam Jackson Park Road
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