

Submitter : Ms. Steve Kowske
Organization : Aurora Health Care
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

Issues

CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANSPLANTS

Submitter : Ms. Constance Marr
Organization : University of Maryland Medical Center
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3835-P-34-Attach-1.DOC



UNIVERSITY OF MARYLAND MEDICAL CENTER

UNIVERSITY OF MARYLAND MEDICINE

VIA ELECTRONIC SUBMISSION

Attachment #34

June 6, 2005

Centers for Medicare & Medicaid Services

Dept. of Health and Human Services

Attn: CMS-3835-P

P.O. Box 8013

Baltimore, Maryland 21244-8013

Re: DHHS/CMS/42 CFR Parts 405, 482, 488
Medicare Program; Hospital Conditions of Participation:
Requirements for Approval and Re-Approval of Transplant
Centers to Perform Organ Transplants; Proposed Rule
Fed Reg 70/23; Feb. 4, 2005

Dear CMS Officials:

Thank you for this opportunity to comment on the proposed CoPs referenced above. As one of the major transplant hospitals in the country, we support CMS' efforts to protect potential Medicare beneficiaries who are waiting for organs for transplantation; establish sufficient quality and procedural standards to ensure that transplants are performed in a safe and efficient manner; and reduce Medicare expenses by decreasing the likelihood that a transplant will fail. However, we feel strongly that several of the proposed changes will instead deny access to organs to Medicare beneficiaries and significantly increase the overhead burden to the transplant hospitals which will be passed through to Medicare thereby increasing expenses rather than decreasing expenses. Our specific comments are as follows:

CoP: NOTIFICATION TO CMS (Proposed section 482.74)

This notification proposal regarding significant changes in a program would be redundant for all transplant programs required to maintain OPTN membership. OPTN requires timely notification of significant changes within a transplant program. A second notification to CMS is redundant and administratively burdensome, increasing overhead expense. Monitoring and enforcement of OPTN membership requirements should be left to the agency developed for that purpose.

CoP: OUTCOME MEASURE REQUIREMENTS (Proposed section 482.80)

Under the proposed regulations, all OPTN data submission requirements must be met, including 95 percent of the required forms to be completed within 90 days of their due date during the 3-year approval period. OPTN already sanctions the Center if it falls below the requirement but does not terminate the program membership, allowing the program to redeem itself. Several factors can impact a program's ability to stay current with data submission including staffing vacancies or major illness in a small program. Would a transplant program lose Medicare approval if it fell below this requirement at some point in the prior 3 years but is current during the reapproval process? OPTN already oversees this outcome measure requirement and it would be redundant to adopt it as a CoP.

Under the proposed regulations, when a Center's observed patient and graft survival is lower than the expected patient and graft survival and the Center crosses over all three thresholds for a particular outcome measure, CMS would not consider the Center to be in compliance with the requirements for that particular measure and approval or reapproval would not be granted. **We feel strongly that transplant centers in urban areas will be placed at risk for reapproval as a result of the patient population served by the institution. Centers in demographic areas with a high concentration of indigent patients with limited income who have trouble paying for medications, and/or with poorer educational backgrounds and lack of support systems with resulting compliance issues will negatively impact survival rates and the transplant center will be penalized for serving this population. As a result, this population of urban patients will become underserved as transplant centers tighten selection criteria to ensure that only patients with solid financial means and social circumstances are accepted for transplantation.**

In addition, non-heart beating donor and expanded criteria organs, which have a greater likelihood of graft failure, will have a negative impact on center graft survival and the cloud of "decertification" will be a disincentive to use these organs. As a result, fewer patients will receive transplants nationally just as the use of these organs is expanding as a viable alternative to traditional donor organs for the thousands of patients on the waitlists.

We urge CMS to leave monitoring of data submission and graft survival rates to OPTN under its membership qualification requirements and associated review processes where special circumstances such as patient demographics and use of DCD or ECD organs can be adequately considered as factors that may impact graft survival.

CoP: PATIENT AND LIVING DONOR SELECTION (Proposed section 482.90)

In addition to requiring written patient and donor selection criteria, the CoPs would require that Centers must document in the patient's medical record the

patient selection criteria that were utilized. Patient and donor selection is made after an analysis of extensive medical work-up on individual patients and could vary in small but significant ways depending on the patient's overall health as determined by the physician, the patient's age, lifestyle, etc. compared to any other patient. While the use of basic selection criteria is necessary it would be extremely burdensome to document the complete analysis and selection criteria used that leads to a patient's selection decision. We feel that program policy to adhere to written basic program selection criteria during the selection process is adequate, and documentation of the process and all factors considered in each patient's chart would be overly burdensome on staff time and resources.

Additionally, the proposal that Centers would be required to make patient selection criteria available to patients either routinely or upon request is equally burdensome on staff time and resources, and it opens the Center up to arbitrary and capricious litigation from patients who take issue with the selection criteria determined by an individual transplant program. Basic criteria is subject to change and varies from Center to Center. If given to patients, it should be at the patient's request only.

Our medical center programs evaluate over 800 transplant candidates per year and 150 living donor candidates. The administrative and staff burden to meet the proposed CoPs on documentation and notification of patient and donor selection criteria is unreasonable and would add to the pre-transplant expense borne by Medicare.

CoP: PATIENT AND LIVING DONOR MANAGEMENT (Proposed section 482-94)

Patients evaluated for a transplant are evaluated, not treated, in the transplant program. This is according to existing Medicare regulations for transplant centers. Therefore, to propose that Centers have written patient management policies and patient care planning for pre-transplant patients is unreasonable and contrary to the scope of services provided by a transplant program. The pre-transplant management is performed by the patient's dialysis unit under the ESRD program guidelines for the patient's treating provider, and non-renal patients are followed by a private physician responsible for all patient care management. This is not a function of the transplant center and this requirement should be deleted.

JCAHO already mandates the use of patient care planning for inpatients through the discharge process, and surveys all hospitals for this requirement. This proposed CoP is redundant.

Related to the CoP stipulating that Centers must update waitlist patients' clinical information on an ongoing basis, the intent of that statement is unclear. As a very large transplant center, we project (based on median wait time) the patients most likely to receive an organ offer in the next year and concentrate our staff

and resources on keeping those patients medically ready for transplant. To use resources for repeat lab and diagnostic testing on patients who may not be transplanted for 2-7 years is not cost effective and would greatly increase the pre-transplant expenses billed to Medicare. The operational functions of transplant centers should be left to the Centers to manage and this CoP should be deleted.

The CoP proposed that Centers must remove patients from the UNOS waitlist when appropriate within 24 hours of such decision or notification is unreasonable and again redundant and overreaching into the monitoring functions of OPTN. There are times when staff will not have access to internet systems (such as weekends) to remove a patient from the waitlist and these activities must wait until return to work the following week. Additionally, monitoring of membership policies such as waitlist management should be left to OPTN which was developed for those purposes. We reiterate our perspective that monitoring and enforcement of OPTN membership requirements should be left to that agency and not micro-managed by CMS. A member in "good standing" with OPTN should be accepted as such by CMS without further oversight of those same requirements and guidelines.

This CoP would require notification to patients once per year of the patient's waitlist status, as well as notification to the renal patient's Dialysis Unit of the waitlist status, and documentation of such notice. This proposal would be extremely burdensome on large transplant hospitals such as ours with over 1400 total patients on waitlists. Patients are advised when evaluated and listed of the potential time to transplant and the median information is published annually by OPTN for each transplant center. In addition, dialysis patients frequently change Dialysis Units and do not communicate these changes to the transplant program, and the program cannot reasonably be held accountable for factors outside of our control. The staffing and resource burden of this proposed CoP would, again, increase the expenses of the organ acquisition fee to Medicare.

The proposed CoPs include a requirement that centers make available social and nutritional services to ALL transplant patients and living donors and social work services to patient families. This is currently a requirement for kidney pre-transplant patients only, but many institutions such as ours provide social work services for post-transplant patients as well when issues of medication compliance threaten the graft survival or health of the transplant recipient. The scope of this proposed requirement is very unclear in the CoPs. Why would a transplant center be required to assume "parental" obligation for these services for transplant patients but other medical specialties with patients with ongoing complex medical problems covered by Medicare have no such programmatic requirement? The responsibility for a transplanted organ belongs to the patient and transplant programs promote and teach independence in patients including encouragement to self monitor medical issues, medication use, and life skills for these patients who will have to manage their own transplant care for the life of

the organ or their lifetime. We request this requirement under the CoPs be deleted as an inappropriate expectation of transplant programs.

CoP: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)
(Proposed section 482.96)

This proposal would mandate that every Center develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate all transplantation services, including services provided under contract or arrangement. The information expected to be monitored and tracked under this CoP is staff and resource intensive and would be financially burdensome to transplant centers. As a large transplant hospital, we would need to dedicate at least a 1.0 FTE quality assurance staff person to implement such a comprehensive QAPI program, which will further add to the overhead cost of the program and be passed on to Medicare. Currently, basic QA functions exist in all hospital programs and are required by JCAHO. OPTN requires that transplant programs monitor and report additional information on a regular basis. Adoption of the proposed QAPI requirements further singles out transplant programs from other clinical programs with equally complex patients and places an unfair burden on resources of the institution. We submit that current QA mandated functions in hospitals are adequate and request that this CoP be deleted.

CoP: HUMAN RESOURCES (Proposed section 482.98)

This proposal arbitrarily requires that all Centers have one ABTC certified clinical transplant coordinator. What are the consequences if the certified transplant coordinator is terminated or takes another position outside of the program? It can take up to one year to certify another coordinator given that the educational program is given once per year generally, and the testing process takes several months. A more fitting requirement would be that all transplant clinical coordinators must be certified with two years of taking the position. Additionally, this educational process is extremely expensive and is covered by overhead expense at this time. To require this certification further increases expense pass-through to Medicare.

This CoP also requires that Centers must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team. OPTN already requires a certain level of staffing assignments for members and has designated those roles and responsibilities. This CoP is redundant.

CoP: PATIENTS' AND LIVING DONORS' RIGHTS (Proposed section 482.102)

This proposal would require that prior to transplantation or living organ donation, transplant centers must inform patients of their rights in a written informed consent process that addresses unique aspects of transplantation and donation, including eight (8) specific factors. We strongly protest the emphasis on factors (5) national and transplant center-specific outcomes such as graft and patient survival, and (7) organ donor risk factors of such a comprehensive nature, particularly for patients who have agreed to accept Expanded Criteria Donor

organs as designated by UNOS. Transplant center-specific outcomes such as “expected” survival differ greatly by institution and are again a factor of the population served by the institution and the use of ECD or DCD organs as a mechanism to meet the needs of patients who would otherwise not receive a transplant. “Expected” survival data is open to interpretation by patients who have limited knowledge of the factors involved in the outcomes reported, but which may dissuade them from listing with a Center that could more than adequately meet the patient’s needs. Using the same rationale, mitigating organ donor risk factors should be left to the transplant surgeon’s decision as to whether the donor risk factors are significant enough to discuss with the patient, following UNOS guidelines.

Regarding the proposal to adopt ACOT recommendations of ethical principles of consent to being a live organ donor, again we feel strongly that a consent process that includes information on factor (5), national and transplant center-specific survival rates, should not be mandated for the same reasons as stated above.

Regarding the proposal that an independent “donor advocate” position be mandated, is currently filled within the use of social workers for independent psycho-social evaluation of living donors and this requirement is redundant.

We also object strongly to the CoP proposal that Centers with a single transplant surgeon would be required to notify waitlist patients when the surgeon is unavailable to provide services and whether there is a covering surgeon available. This proposal is unrealistic and overly burdensome. A surgeon’s availability is affected by personal short-term sickness, normal vacation days, attendance at conferences, etc., and there may not be a covering surgeon available in small programs. Notification to patients of an extended period of surgeon unavailability (30 days or more?) is realistic, but notice of short-term unavailability is completely unrealistic for Centers to manage in a timely manner.

ALTERNATE PROCESS TO RE-APPROVE TRANSPLANT CENTERS

Our recommendation is that OPTN continue to monitor transplant programs for adherence to membership requirements and that a re-approval process by CMS be initiated only if the member Center fails to maintain “good standing” according to OPTN policies and procedures, and after all OPTN appeal processes and remedies have been exhausted.

LOSS OF MEDICARE APPROVAL

Our recommendation is that a transplant center that has submitted an acceptable correction plan NOT lose approval unless re-surveyed a year later and found not to have corrected the deficiencies from the prior survey. We object to the need to reapply for initial approval unless the deficiencies noted in the correction plan are not accomplished. Loss of Medicare approval, even if short-term, is disruptive to the patients and community served by the Center and every

opportunity to correct deficiencies should be given to a Center prior to this drastic action occurring.

EFFECT OF NEW COPS FOR TRANSPLANT CENTERS THAT ARE CURRENTLY MEDICARE APPROVED

The proposal is that a Medicare approved hospital would have to request initial approval for each organ specific transplant program, even for programs current approved. All Centers would be considered new centers for purposes of this proposal. We strongly protest this requirement and feel that all Centers currently approved should remain approved until determined by OPTN membership requirements or CMS regulations to be out of compliance.

COLLECTION OF INFORMATION REQUIREMENTS—INFORMATION COLLECTION REQUIREMENTS AND ASSOCIATED BURDENS

Specific comments:

- 1) Burden of notifying CMS of significant changes (CMS estimates 3 per center per year at 5 minutes each). The administrative time required here is significantly underestimated. These notices require the involvement of the program medical director, administrator, and appropriate clerical/support staff. Large centers will have a significant number of changes per year, perhaps as many as 6-12, involving 15-30 minutes of time per staff person listed above.
- 2) Documentation of Patient and Living Donor Selection Criteria—criteria used must be documented in each patient's chart. Written criteria adopted by the center should suffice; documentation in individual charts when it is the same criteria used over and over is redundant and burdensome on the staffing resources, taking at least 30 minutes of physician and staff time per patient or living donor.
- 3) Keeping waitlist up to date:
 - a. Updating all patients' clinical information on regular basis. Large centers "ready" a top list of patients likely to receive an organ offer based on time on the list. The expectation that large waitlists can be maintained in a totally "ready" status is unreasonable and a waste of staffing and financial resources on retesting, given the limited number of transplants that will occur in any given year.
 - b. Notifying OPTN within 24 hours of removal from waitlist (death or transplant). This does not take into consideration the unavailability of internet services to staff on weekends who are taking these organ offers from home "on call".
- 4) Patient Waitlist status—must notify patients:
 - a. Of placement status at least once per year is resource intensive and a significant burden to Centers with large waitlists; dollar figure quoted does not include management oversight time and expense.
 - b. Notify dialysis unit of patient's transplant status or changes in transplant status. See (c.) above. Also, transplant centers are rarely

notified by patients of changes in designated Dialysis Units making notification requirements unreasonable.

- c. Must maintain records of patient's pre-transplant and post-transplant multi-disciplinary team care planning. Pre-transplant care planning is under the purview of dialysis units, not transplant programs. Inpatient and discharge planning is already mandated by JCAHO.
- d. QAPI—centers must develop, implement, and maintain a written comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or by arrangement. A large center such as ours would require the dedication of an additional 1.0 quality assurance staff member to accommodate this requirement. Current JCAHO QA requirements should suffice.

Also, notice to patients about unavailability of transplant surgeon coverage for organ offers includes the drafting of a letter by administrator, approval by the surgeon, database queries of appropriate patients, clerical time and effort to prepare a mailing, and expense of the mailing. This would be an extensive and unrealistic undertaking for short-term absences of the surgeon.

TIME/RESOURCES NEEDED TO COMPLY WITH THESE REGULATIONS

Most of the burden to comply with these proposed CoPs will be on the transplant coordinator RN staff. The 2002 mean annual income of RNs of \$42,730 is woefully under-representative of the typical transplant coordinator RN income. Not only has a severe nursing shortage hit the country since the 2002, but clinical coordinators are generally highly experienced, trained and tenured, generally bachelors or masters prepared. They are frequently salaried rather than hourly employees, and salary rates vary significantly between geographical regions. The average national RN salary is not the appropriate salary to use to calculate the additional expense to the transplant programs, and is understated by at least 75% for Mid-Atlantic academic transplant centers.

In addition, the burden on staffing resources created by these regulations would serve to increase the organ acquisition fee rather than reduce Medicare expenses as is stated as an objective of the regulations, or increase the overhead of the hospital beyond the rates that facilities are able to contract for with managed care companies with a resulting inability to adequately serve the community.

The assumption that additional social work and nutrition services would not place additional resource burden on centers is erroneous. While these services are currently provided in hospitals the level of resource coverage will expand as a result of these regulations and additional staff will need to be hired to cover the additional scope of activities for the large volume centers, significantly increasing overhead expense.

Assignment of paid physician directors for each transplant program will increase the expense to the centers which will be added to the Organ Acquisition fee as well, therefore increasing the expense to the Medicare program.

CONCLUSION

The proposed requirements focus on an organ transplant center's ability to perform successful transplant and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. However, we are submitting numerous concerns about the resulting effect on patients in urban areas, and reduction in the number of organs accepted for transplantation if these CoPs are adopted. We are also concerned about the cost and staffing burden that the CoPs would encumber on the transplant centers, as well as our concerns about the redundancy of many of these factors given the OPTN charter and membership requirements already in effect. We strongly support the concept of OPTN as the oversight body for transplant center performance and limiting of CMS involvement to matters regarding reimbursement for clinical services provided.

Respectfully submitted,

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Submitter : Dr. Anthony D'Alessandro
Organization : University of Wisconsin Medical School
Category : Academic

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3835-P-35-Attach-1.TXT

CMS-3835-P-35-Attach-2.PDF

CMS-3835-P-35-Attach-3.PDF

ATTACHMENT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C1-09-06
Baltimore, Maryland 21244-1850



JAN 26 2005

Anthony M. D'Alessandro, M.D.
Professor of Surgery
Executive Director UWHC-OPO
600 Highland Avenue F8/121
Madison, WI 53792

Re: Reconsideration Request for Intestinal and Multivisceral Transplantation
Tracking #: CAG-00036R

Dear Dr. D'Alessandro:

Thank you for your interest and participation in the Medicare national coverage process. After a review of the materials you submitted in support of your request for reconsideration of the Medicare national coverage policy for Intestinal and Multivisceral Transplantation, we are unable to accept your request. CMS will soon post a draft Notice of Proposed Rule Making (NPRM) that will modify the requirements for intestinal transplant centers. It will be posted on the following site:

http://www.archives.gov/federal_register/public_inspection/public_inspection_list.html#regular
Once posted, there will be a 60 day public comment period. I encourage you to comment on the NPRM.

Again, thank you for your interest in the Medicare national coverage process and I hope that this letter has addressed all of your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Marcel Salive".

Marcel Salive, MD, MPH
Director
Division of Medical and Surgical Services
Coverage and Analysis Group
Office of Clinical Standards and Quality

Submitter : Ms. Janie Morrison
Organization : University Hospitals of Cleveland
Category : Other Health Care Professional

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

I applaud the efforts of CMS to pull together all of the regulations for transplantation into one concise regulation that addresses all solid organs. I also applaud CMS for utilizing the expertise and experience of the OPTN in formulating policies that are in sync with the OPTN's current by-laws and policies. However, "current" is the operative word that solicits my general comment regarding the proposed conditions of participation.

Fortunately, the OPTN policies change frequently in response to addressing specific areas, which improve clinical outcomes for the transplant recipient and donor. The CMS regulations are very specific and the degree of this specificity will quickly become out of sync with the OPTN's policies, requiring transplant centers to document for two sets of standards. I am sure that CMS does not intend for the regulations to become stifling to the advancements in transplantation nor is it desirable for the regulations to create undue hardship for transplant centers. I am proposing that since CMS contracts with the OPTN, that the regulations be simplified to state that Transplant Centers are required to adhere to the by-laws and policies of the OPTN; specifically in the areas of data submission, donor and patient management, patient outcomes, and personnel requirements. For example, the OPTN already has a process in place to allow for the remediation of transplant programs with less than standard outcomes. This process has enabled programs to address specific issues and to improve care while continuing to provide local access to beneficiaries in need of transplantation. CMS would not be required to have a separate review system for transplant centers but could tap the data from the OPTN, attend on-site reviews, etc. as necessary. This would allow the experts in the field of transplantation to be responsive to the health care needs of Medicare beneficiaries as they become evident. In the areas where the OPTN does not have specific policies that CMS feels are necessary, CMS should work with the members of the OPTN to develop them.

As a transplant administrator for the past 5 years and now working in my second transplant center, I am very concerned about the increased administrative responsibility placed on transplant centers while reimbursement continues to decline, creating an environment of limited resources. I encourage CMS to allow the transplant community to spend our efforts focused on promoting donation and improving patient care versus duplicating documentation of these efforts for both CMS and the OPTN.

I appreciate the opportunity to outline my concerns and to provide suggestions. If I can be of further assistance, please do not hesitate to call on me.

Sincerely,

Janie Morrison
Director, Transplantation
University Hospitals of Cleveland

Submitter : Miss. Denise D. Tharaldson
Organization : UC Davis Transplant Center
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the UC Davis Transplant Center, I have appended hereto as an attachment our comments to the proposed new regulations. Thank you very much for the opportunity to provide our feedback.

CMS-3835-P-37-Attach-1.DOC

Attachment #37

June 6, 2005

Dear Centers for Medicare and Medicaid Services:

Reference: File Code CMS-3835-P

On behalf of the UC Davis Transplant Center located in Sacramento, California, we appreciate the updating and collation of the renal and extra-renal transplant program regulations into a single segment of the Code of Federal Register (#42, Parts 405, 482, and 488). The following comments regarding each identified section are submitted for your consideration as CMS continues to refine the proposed new requirements for Transplant Centers:

482.80 Condition of Participation: Data Submission and outcome requirements for initial approval of transplants centers.

Section (4) (i) appears to provide Medicare approval if key members of a center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of one-year prior to the opening of a new center. In recognition of the number of team members required for successful patient outcomes at a transplant center, it is not clear how this requirement would permit a center to become qualified. For example, a transplant surgeon "taking" the patient outcome experience from one center with him/her to a new program does not seem sufficient to qualify the new center. We suggest that a more clear definition of team members and other important factors be taken into consideration for new program start-up, such as that which is reviewed by UNOS. We also question the validity of requiring only 9 transplants in the 2.5 year period and the validity of allowing a program to gain Medicare certification with only 1 month of data. Studies have shown a surgical specialty needs to perform a certain number of procedures per year in order to maintain proficiency and quality outcomes.

482.82 Condition of Participation: Data submission and outcome requirements for re-approval of transplant centers.

In order to ease the burden of recertification procedures upon CMS and the transplant centers, we recommend that those transplant centers which are already Medicare certified should be recertified upon meeting the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be incorporated into the scheduled UNOS on-site audit review of every program, approximately every three years. If a transplant program does not meet the first two CMS requirements, then a more urgent review is warranted. In this way, CMS would partner with UNOS, a federally approved contractor for administering the OPTN, to conduct the on-site audit. With its stringent process requirements, we would suggest that UNOS be considered for deemed status in the performance of these audits.

482.90 Condition of Participation: Patient and Living Donor Selection

Donor advocacy team for living donors: This would cause a hardship on small programs. Programs are dedicated to protecting the welfare of donors and if there is any problem or question the donor is deferred.

Patient selection: It is not clear how a center is supposed to meet the requirement that before a patient is selected (except for kidney) the transplant center must employ or consider all other appropriate medical and surgical therapies. Does this have to be stated in the patient's medical record, proven by "xyz?" When a patient is placed on the waitlist, the transplant center must document in the patient medical record the patient selection criteria used. What is expected by CMS by way of evidence to show this?

482.92 Condition of Participation: Organ Recovery and Receipt

The ABO policy is thoroughly covered by the OPTN policies and has been implemented and monitored through the OPTN listing systems.

482.94 Condition of Participation: Patient and Living Donor Management

In reference to the requirement for patient notification each year of their status on the list, this is redundant in that the current OPTN policy already requires notification at the time of listing and when a status change is made. Patients on heart and liver lists are followed closely, seen frequently, and know their listing status. Dialysis centers know if a patient is listed by having to get blood samples for PRA levels as requested by the listing transplant center.

482.96 Condition of Participation: Quality Assessment and Performance Improvement

We believe that several of the monitors suggested may not contribute to improving patient outcomes as may be intended. In addition to the outcomes measures tracked by the OPTN, we would suggest standard morbidity and mortality monitors, e.g. infections, re-transplants, deaths within one year of transplant, graft loss within one year of transplant, return to surgery events, urine leak rates (kidney), transplant admission lengths of stay, living donor complications, delayed graft functions, time on the waitlist, etc.

Protocols for adverse events are already a JCAHO requirement, and hospital sentinel event policies and reporting mechanisms are in place. Each is monitored by JCAHO as part of their site visit.

482.98 Condition of Participation: Human Resources

Regarding certification for transplant coordinators, there are several well-regarded professional nursing organizations that certify nurses; and we would recommend that

CMS should not single out one particular organization over the others which are equally well-respected, i.e. specifying ABTC certification.

Regarding the dietician requirement, this requirement can be met if it is for when the patient is an inpatient for the actual transplant process. If this is a requirement for the pre-transplant stage during the evaluation, it will be onerous for the extra-renal programs. Patients are cared for by their cardiologists and hepatologists. The transplant programs see these patients for their evaluation, make recommendations and return them to their primary physicians. Recommendations as to weight control or loss to meet selection criteria will be addressed in communication to the primary physician and the patient. A dietary consult at this stage will be too expensive and will fractionate the patient's care. Cardiac diets, etc., should be under the direction and monitoring of the primary physician.

482.102 Condition of Participation: Patient and Living Donor Rights

Our comments regarding the requirement that patients should be specifically educated to the selection criteria are as follows: Because each patient is unique and selection criteria need to be applied individually, transplant patient selection criteria are never absolute. We would recommend that CMS be less prescriptive regarding documentation of broadly applied patient selection criteria for each patient.

Regarding the requirement of informing patients of certain risks, this could be accomplished by way of an education checklist that each patient would be required to have checked off as he/she attends education sessions at which this information is presented. However, it is not clear how each patient could be alerted to specific donor risk factors. For example, in the case of a deceased donor it is a matter of hours before the transplant that the specific information about the donor is known. The patient is being brought in for transplant, taken to the OR, and prepped. The transplant coordinator is often not present. This is not the time to be discussing specific donor risk factors. We see this requirement to be difficult to implement.

Alternative Process to Re-approve Transplant Centers (page 162)

We agree it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN. As a federally contracted agency, the OPTN should be the entity to survey transplant programs as it is already reviewing programs every three years for compliance with transplant center facility and listing policies. The OPTN has the data and establishes the policies and standards for practice.

Transplant center programs which are already Medicare certified should be recertified with they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN arrives on-site for their scheduled review, thus completing the three-part process.

Cost to Administer/Implement

If the OPTN is not utilized to assess transplant center performance for the process requirements, then it would appear to require the establishment of a brand new monitoring entity currently unfamiliar with transplant programs and transplant policies. The learning curve would be steep. As such, the \$300,000 estimated additional expense may be underestimated.

In conclusion, thank you all once again for providing us with this important opportunity to submit our comments and suggestions about these proposed updated regulations. The hard work of all CMS staff involved in this extensive effort is most evident. We look forward to attending and participating in any additional town hall presentations that may be provided.

Best regards,

Denise D. Tharaldson
Manager
UC Davis Transplant Center
UC Davis Health System
2315 Stockton Blvd.
Sacramento, CA 95817

Cc: Dr. Richard Perez
Medical Director
UC Davis Transplant Center

Nabil Musallam
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Clinical Operations, Managed Care & Contracting
UC Davis Health System

Submitter : Ms. Shelley Ellison
Organization : Texas Children's Hospital
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3835-P-38-Attach-1.DOC

Attachment #38

Comments from:

Eileen D. Brewer, MD, Chief of Renal Services, Baylor College of Medicine
Shelley Ellison, Transplant Administrator, Texas Children's Hospital
Carrie Taylor, Financial Manager of Transplant Services, Texas Children's Hospital
Derek Kang, Director of Compliance Services, Texas Children's Hospital
June 6, 2005 response to CMS from Texas Children's Hospital

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

We appreciate CMS's efforts in recognizing the special needs of pediatric transplant patients and pediatric centers and for providing for separate approval of pediatric versus adult programs in the proposed Conditions of Participation. We agree that pediatric programs should not be asked to adhere to volume minimums for participation as transplant programs because the number of pediatric transplants is small relative to adult transplants. Requiring volume minimums for approval could adversely affect children's access to specialized pediatric care, including pediatric medical sub-specialists, pediatric intensive care and the special services offered by children's hospitals.

Specific comments include the following:

Proposed Section 482.76: Pediatric Transplants

It is important for pediatric programs to continue to transplant adolescents and young adults beyond the pediatric age range, especially those in the age range 18-25 years, to maintain continuity of care for established patients with onset of disease early in life and problems best addressed by a pediatric center until the patient is medically and developmentally ready for transfer to adult care.

Proposed Section 482.82: Data Submission and Outcome Measure Requirements for Re-Approval

It is unclear within the proposed regulations if data submission to CMS will be in addition to that which is already submitted to OPTN. As UNOS data requirements continue to grow, we hope that the requirement to provide 95% of the required data within 90 days can be met. Pediatric Hospitals will have more difficulty allocating appropriate support resources due to the financial burden of specialized pediatric transplant programs.

Proposed Section 482.94: Patient and Living Donor Management

We are in support of evaluation by qualified social workers and dietitians for patients and living donors. In addition, we would add further that the qualified social workers and dietitians should have knowledge of and ability to address specific pediatric issues.

Proposed Section 482.98: Human Resources

CMS may want to consider providing additional time for pediatric programs to meet the expected certification timetable for its coordinators. The proposed transplant coordinator

certification requirement will challenge pediatric centers; the current certification training certifies for "all solid organ" transplants. While we support the effort to insure uniformity and safety, many pediatric transplant coordinators do not have the exposure to adult transplant services that is part of the "all solid organ" certification. Providing additional time for pediatric program coordinators to prepare for elements of the certification that they previously have limited exposure to would help ensure their success.

Submitter :

Date: 06/06/2005

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3835-P-39-Attach-1.DOC

Attachment #39

Comments for File Code: CMS-3835-P

Special Requirements for Transplant Centers (Proposed Section 482.68)

- The OPTN/UNOS should be the entity charged with the responsibility to monitor and coordinate the procedures for approval or re-approval of transplant centers. Focusing this effort in one place saves money for both the government and the transplant centers by eliminating duplication. In addition to approval by the OPTN/UNOS each program undergoes multiple reviews by insurance companies and transplant networks on an annual basis. The staffing required to complete data requests is growing annually. If CMS wishes to add another layer of credentialing/approval on to the already existing system we will need a mechanism to increase reimbursement to transplant centers to account for the growing administrative cost burden.

Criteria For Centers Performing Living Donor Transplant:

- OPTN/UNOS should be responsible for approval or re-approval of transplant centers wishing to perform live donor procedures. It isn't practical or economical to add another layer of approval.

Condition of Participation: Notification to CMS (Proposed section 482.74)

- Transplant centers report any significant changes to OPTN/UNOS that would affect their approved status. Having more than one entity to report this information to is duplicative and is not economical.

Outcome Measure Requirements (Proposed Section 482.80)

- Quality standards are already established by OPTN/UNOS. Each center should be OPTN/UNOS approved. When outcomes fall below certain measures OPTN/UNOS is responsible for reviewing those centers. Additional review of this information would require duplication of effort and personnel. This would be an additional cost burden for both the government and the transplant centers.

Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.909) (Patient and Living Donor Selection)

- Documenting specific selection criteria applied to an individual patient in their medical record is a departure from current practice. This would require additional time and effort on the part of the clinical staff.

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

- Data is already required to be up-to-date for organ allocation purposes.
- Social worker requirements should not allow someone to substitute experience for the required educational (masters degree) requirements.
- Yearly notification of wait-list status will require monitoring to ensure that each patient is sent a yearly notice. This is another layer of administrative time and expense. Most transplant patients are in regular communication with their

transplant center – they are followed closely, seen frequently and know their listing status.

**Condition of Participation: Quality Assessment and Performance Improvement (QAPI)
(Proposed Section 482.96)**

- Protocols for adverse events are already a JCAHO requirement. Hospital already has a process for identification, reporting, analysis and prevention of adverse events.

Condition of Participation: Human Resources (Proposed section 482.98)

- The OPTN guidelines for program personnel requirements should be the industry standard. UNOS should be responsible for ensuring that transplant centers meet the requirements.

Submitter : Ms. Carrie Taylor
Organization : Texas Children's Hospital
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3835-P-40-Attach-1.TXT

CMS-3835-P-40-Attach-2.TXT

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Mr. John McWhorter
Organization : Baylor University Medical Center
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-3835-P-41-Attach-1.DOC

Attachment #41

June 6, 2005

VIA EMAIL:

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

RE: REQUIREMENTS FOR APPROVAL AND REAPPROVAL OF TRANSPLANT CENTERS TO PERFORM ORGAN TRANSPLANTATION; CMS – 3835-P

Baylor Regional Transplant Institute is pleased to have this opportunity to respond to the proposed rules establishing requirements for approval and reapproval of transplant centers, as published in the February 4, 2005 Federal Register.

Baylor Regional Transplant Institute encompasses the transplant services at Baylor University Medical Center in Dallas, Texas (liver, kidney, heart, lung, pancreas, small bowel) and Baylor All Saints Medical Center at Fort Worth (liver, kidney, pancreas). Since the program's inception in 1985, physicians and surgeons on the staff at these combined Baylor hospitals have performed more than 7,000 transplants, placing Baylor's transplant program among the largest and most successful multispecialty transplant programs in the nation.

We share CMS' interest in ensuring that transplant recipients and living donors receive the best possible care and treatment. While we agree with some aspects of the proposed rules, we have a number of suggestions and recommendations for CMS to consider that we believe will help improve the rules. Per the written instructions, we are using the requested captions for each comment section.

PEDIATRIC TRANSPLANT CENTERS

It is unclear whether centers seeking approval to perform pediatric transplants must specify personnel different than those listed on the adult application or whether overlap is permitted. It may be a hardship for a center performing predominantly adult transplants to hire different personnel to administer its pediatric program. It is frequently the same core team that does adult and pediatric transplants and it is often impractical, if not impossible, to find qualified pediatric-only transplant surgeons. The OPTN rules allow the same individuals who provide care to adults to provide care to pediatric patients, so long as such individuals are qualified.

Recommendation: We recommend that CMS clarify Section 482.76 to authorize the use of shared personnel for adult and pediatric transplant programs, consistent with existing OPTN requirements for pediatric transplants. In addition, we recommend that the Medicare approval status of pediatric and adult transplant programs operated by the same center impact each other

only if substantially the same transplant team is involved in performing both pediatric and adult transplants.

OUTCOME MEASURE REQUIREMENTS

We appreciate CMS' efforts to establish meaningful standards with respect to data submission and outcomes for transplant centers. In particular, we believe the current approach with respect to outcomes is an improvement over existing standards, which focus on volume and achievement of a fixed survival rate. We also commend the agency for its efforts to achieve consistency with OPTN standards.

Volume Requirement: Regarding the adult volume criteria, the proposed rule requires a minimum volume of 9 transplants in the 2.5 year cohort period. We feel that the volume is so low that it essentially eliminates a volume requirement completely, and is not in the best interest of transplant patients nationwide. Scientific literature is replete with studies from experts in the field of transplantation showing that outcomes for patients at higher-volume centers are better than outcomes at lower-volume centers. Although there are certainly centers with low volumes and good outcomes, the odds ratio for failure increase is much higher at a lower-volume center.

The difficult question is what should the minimum volume be? A recent paper by Robert Merion¹ offers guidance for establishing volumes for liver and kidney transplantation. Merion suggests a very low **median** volume is 20, low is 58, medium is 93 and large is 167. **We believe the minimum requirement should be 30 kidney transplants per year unless there is a geographical reason to accept fewer for the sake of access.** For instance, the minimum could be lower if the next closest center is more than 200 miles away. Regarding liver transplants, Merion's paper indicated a low **median** volume is 21, medium is 48 and high volume is 93. In the liver scenario, the spread for high odds ratios don't disappear until the volumes are much higher. **The stated purpose of CMS' efforts is to elevate transplant center standards with the ultimate goal of improving transplant outcomes in the U.S. To achieve that purpose, we recommend a minimum volume for liver transplants at 30 per year with a similar exception for isolated geographic locations. We suggest the current requirement of 15 for liver and kidney to be an absolute minimum.**

It is inarguable that a certain yearly minimum is required to have a basic level of proficiency. This is not just surgical proficiency, but more importantly a center's proficiency. The proposed volume of 9 totally disregards the published collective experience, and does not support CMS' stated purpose for the proposed rule.

Survival Criteria: In addition to the volume criteria, we also believe the one-year patient and graft survival threshold criteria do not support the stated purpose to ensure that transplant centers provide quality care to transplant recipients and not waste organs. For example, if a center performed 9 transplants in **one year** (which is **2.5** times the proposed minimal volume) and had an expected survival of 88% (8/9), then that center would need to have a 33% one-year survival before they failed one of the thresholds. This is clearly not in the best interest of patients requiring transplant.

¹ Axelrod DA, Guidinger MK, McCullough KP, Leichtman AB, Punch JD, Merion RM. Association of center volume with outcome after liver and kidney transplantation. Am J Transplant 2004; 4: 919-926.

Proposed outcome criteria states that even if a center's observed 1-year patient and graft survival rate is lower than its expected 1-year patient and graft survival rate, the center's patient and graft survival could still be acceptable, unless all 3 of the following thresholds are crossed:

- 1) $p\text{-value} < .05$
- 2) $O-E > 3$, and
- 3) $O/E > 1.5$

Recommendation: We believe this criteria is too lenient, and CMS should **consider a center's outcomes unacceptable if it fails to meet expected 1-year patient and graft survival, and fails 2 of the thresholds.**

DATA SUBMISSION

We are pleased that CMS is not proposing that transplant centers submit data beyond what is required by the OPTN. However, we oppose a requirement where failure to meet OPTN data submission requirements would be grounds for denial of approval or termination of Medicare approval. Also, the 95% standard needs further explanation. For example, does 95% compliance mean 95% of forms? 95% of patients? 95% of data fields? We request that CMS confer with the OPTN to clarify exactly what level of compliance is necessary to assure reliable application of the outcome measures and that this standard be set forth with specificity in the final regulations.

We strongly feel that if Medicare eligibility is tied to the strict adherence to the standard of 95% required data within 90 days of the OPTN's due date, then the quality of the data collected will go down dramatically. Even if most centers usually meet the 95% requirement, circumstances sometimes dictate that some data is not available when needed. If Medicare eligibility were at stake, centers would no doubt have to resort to marking individual data elements to 'UNKNOWN', and whole patient followups to 'LOST TO FOLLOWUP' much more often than is currently done. Currently, centers stretch the deadlines in order to have the best possible chance to collect good data. If these new CMS standards are enacted, then this will no longer be possible. Most importantly, it is important to realize that there is no evidence linking failure to submit data to the OPTN and poor outcomes.

The OPTN collects a wide variety of data related to donor and recipient characteristics and post-transplant follow-up care that is used for long-term follow-up and other purposes but is not used in the determination of one-year outcomes. We do not think Medicare conditions of participation should require compliance with OPTN data submission standards that have no relationship to the calculation of the Medicare one-year outcomes standard.²

Recommendation: We therefore recommend that the 95% standard for data submission be more specific, and based only on OPTN data used in calculating the center's one-year

outcomes. We recommend that CMS confer with the OPTN and the SRTR regarding which forms and which data fields relate to the Medicare one-year outcome calculation.

COMMUNICATION WITH OPTN

While we agree that transplant centers must submit data and be measured by their outcomes, and that centers with poor outcomes should not participate in the Medicare program, we note that the current OPTN outcome and data submission standards, which CMS would use to determine compliance with Medicare conditions of participation, were developed by the OPTN for quite a different purpose - as a tool for identifying centers with potential problems. Centers that do not meet these standards are flagged for investigation and remediation if necessary. The purpose of the OPTN outcome standards is to identify, investigate, and correct, if appropriate. The standards were not designed as a test for whether a center should qualify for participation in Medicare, or even as a proxy for determining that a center is providing substandard care. A center that fails the outcomes measures still may be providing high quality care. For that reason, we believe use of the OPTN standards as a pass/fail test for Medicare approval is entirely inappropriate.

We also note that, under the proposed regulations, compliance with the outcomes requirements will be based on a single data point that may be up to three and a half years old. Since the time of the submission of this data, a transplant center may have made significant changes in its program—changes which may have ameliorated or largely eliminated quality concerns. In light of the unavoidable lag between outcomes, the reporting of outcomes, analysis of any potential issue flagged through such reports, and amelioration, we believe that it would be entirely inappropriate to use failure to meet outcomes measures as grounds for termination, without the opportunity for explanation or remediation.

The OPTN has a rigorous and well-established procedure for enforcing its data submission and outcome standards (the same measures that CMS is proposing would apply to Medicare) and for identifying centers that do not meet those standards. If a center is found to be out of compliance with standards, it is referred to the Member Professional Standards Committee (MPSC) for investigation to determine if the low outcome rate may be accounted for by patient mix or some other unique clinical aspect of the transplant program in question. If a center's performance cannot be explained by such factors, a corrective action plan may be imposed. If a center cannot meet the standards after a reasonable opportunity to correct, then the OPTN implements sanctions against the center and informs the Secretary of the center's failure to meet OPTN requirements.

Recommendation: We strongly recommend that OPTN policies and standards should first be interpreted and enforced by the OPTN. Without such coordination, there is a very real risk that centers will be subject to inconsistent interpretations of the OPTN outcome standard. The following example illustrates this point: A center under investigation by the OPTN for poor outcomes would be given an opportunity to explain the reason for its poor outcomes or implement a corrective action plan under OPTN oversight. At the same time, based on the same evidence, CMS could deny Medicare approval or re-approval. The OPTN may subsequently conclude that there was a reason for the poor outcomes unrelated to quality or the center may be able to demonstrate that the cause of the poor outcomes has been ameliorated. However, that center would have already lost its Medicare approval. **CMS should defer any**

decision regarding data submission or outcomes requirements until OPTN review procedures have been concluded and should only consider termination of a center if the OPTN Board reports to the Secretary that it has made a final decision to take an adverse action against the center.

CONFIDENTIALITY OF OPTN DATA

The proposed rule is not clear as to how CMS would obtain outcomes data from the OPTN. We are concerned that the sharing of data between CMS and the OPTN could jeopardize the confidentiality of transplant centers' data submissions to the OPTN under applicable laws and regulations protecting peer review processes, and request that the regulation be clarified to state that the regulation is not intended to affect the confidentiality of the process in any manner. These issues have important implications for the OPTN compliance monitoring and privileged peer review process employed by the OPTN committees.

FREQUENCY OF ASSESSING CENTERS AFTER THEY ARE APPROVED

We support the proposed recommendation that transplant center approval would be granted for three years and that approvals would automatically be renewed for transplant centers that continue to meet the requirements. We do not see the purpose of surveying centers that do meet the standards. We believe it is more logical and more consistent with the goals of the proposed rule to survey the centers that do not meet the threshold requirements, but that file a plan of correction setting forth the actions that they will take to do so.

PATIENT AND LIVING DONOR SELECTION

1. Written Selection Criteria: The OPTN has patient listing criteria that centers are already required to follow. Although these are technically different than patient selection criteria, from a functional standpoint there is no reason for CMS to require the establishment of selection criteria that are different and separate than the OPTN listing criteria. Moreover, the field of transplantation is constantly changing, and any written selection criteria would have to be constantly updated, resulting in additional paperwork burdens. We disagree with CMS that centers already maintain such written criteria. **This would be a new recordkeeping burden with associated costs – costs which have not been included in the Regulatory Impact Analysis.**

2. Selection Criteria for Living Donors: With respect to selection criteria for living donors, the OPTN's *ad hoc* Living Donor Committee has developed living donor transplant care and management guidelines that have been approved by the OPTN board. **Therefore, we do not believe it is necessary for transplant centers to develop their own written selection criteria for living donors for Medicare purposes. We suggest that OPTN monitoring of adherence to its policies provides sufficient means for evaluating living donor program quality.**

3. Confidentiality of Medical Records: We also question the requirement that the living donor's suitability for donation be documented in the recipient's medical records. This raises confidentiality issues, such as how much of the donor's private medical information can be documented in another patient's record.

4. General Medical Ethics: The requirement that living donor selection must be consistent with general medical ethics is extremely vague. For example, there is a significant

divergence of opinion as to whether selection of a living donor via an Internet solicitation is ethical. **We suggest that this language be eliminated, and that centers be allowed to review each living donor situation for any ethical issues that may exist and resolve them on a case-by-case basis.**

5. Psychosocial Evaluation: We support the requirement that transplant candidates and living donors receive a psychosocial evaluation and that the center determine the patient's blood type.

6. Providing Selection Criteria to Patients: **We do not support the requirement to provide selection criteria to patients.** The decision to list a patient for transplantation is an extremely difficult and complex one. It requires a multidisciplinary team approach reviewing a combination of factors including the medical, social and psychological status of the patient. **We have grave concerns regarding this proposal because of the unrealistic expectations it would create as patients believe they meet the criteria, when in actuality the selection committee determined otherwise.**

PATIENT AND LIVING DONOR RIGHTS

We are concerned that the requirement for written policies does not advance quality of care and poses significant bureaucratic and administrative burdens on centers.

1. Center responsibility for pre- and post-transplant care: Subsection (a) of proposed section 482.94 requires that each transplant patient be under the care of a patient care team coordinated by a physician through the pre-transplant and discharge phases of transplantation. In many cases, waiting potential recipients are not managed by transplant centers but by local specialists. In the case of kidney transplantation, patients are frequently cared for at dialysis centers that are far away from the transplant centers, sometimes hundreds of miles. The same is true for extra-renal organ transplant candidates and recipients as well.

Further, many recipients are returned to their referring physicians after a transplant, where they are managed with little input from the transplant center. In fact, some Medicare intermediaries require that care be returned to the referring physician in cases where the center is not located in the patient's home state. It is not possible for centers to oversee such patients. Thus, pre-transplant and post-transplant care is not always within the control of the center, and it is impossible for the center to "ensure" the manner in which that care is delivered. **For this reason, we suggest that the proposed regulations be modified to require that pre and post transplant care for organ recipients be provided in conjunction with the local team.**

2. Waitlist Management: Wait list management is an extremely complex area and is already subject to substantial oversight by the OPTN, which examines a center's waitlist practices and determines if it has an excessive turn-down rate. Most of the proposed waitlist management requirements are, in fact, already part of OPTN policy. **Consequently, we do not believe the additional requirements in this section are necessary.** Moreover, to the extent that OPTN policies in this complex area change, and CMS policies lag behind due to formal notice and comment requirements, there is a possibility for a transplant center to be subject to inconsistent requirements.

3. Notification of Waitlist Status: We support the requirement that a transplant candidate (and dialysis center where appropriate) should be notified about his or her placement on the waiting list and if he or she is removed from the waitlist. **However additional yearly notification of a patient's place on the waitlist is not feasible.** The waitlist is extremely fluid and dynamic, particularly for extra renal organs. Yearly notification of a patient's place on the list would be meaningless since waitlist status can change rapidly during the course of a year. Moreover, the first-come, first-served system for extra-renal organs has been eliminated; thus notifying a patient of his or her place on the list at one point in time has little bearing on that patient's place on the list at future points in time. Further, it is impossible for a center to ensure that a patient receives notification of his status. Some patients move away without notifying their center; sometimes they have died; and some choose not to answer. Therefore, if the yearly notification requirement is not eliminated, the rule should provide that a center will be found to be in compliance with this requirement if it documents that it made a reasonable attempt to notify a patient, rather than requiring that the center actually succeed in notifying a patient.

4. Care by Multidisciplinary Team: OPTN policy stipulates personnel requirements for transplant centers. **Centers in compliance with OPTN requirements should be deemed to be in compliance with CMS requirements: Additional regulations relating to the composition of teams is likely to be either duplicative of or inconsistent with OPTN requirements.**

5. Nutritional Services: Regarding proposed section 482.94(e) related to nutritional services, we note that living donors are healthy, by definition. **Requiring that they receive a specific dietary prescription is burdensome, not medically indicated, and adds expense without improving outcomes.**

6. Written Informed Consent Policies: The requirement of additional written policies for informed consent in the transplant arena is burdensome and unnecessary. Most hospitals with transplant centers already have a comprehensive informed consent policy that provides guidance for the informed consent process, which would be applicable to transplants as well. At the very least, documentation in the medical record that informed consent was obtained, including the specifics of the discussion with each patient or donor should be sufficient evidence that such a policy exists. We agree that such discussions should include use of expanded criteria donors (ECD), transmission of disease from donor to recipient, potential outcomes, risks, benefits, alternatives, and the like, **but we do not believe this needs to be written down as a separate policy specific to transplant.**

7. Informing Transplant Candidates of Risk: Informing transplant candidates about potential risks should be done in general terms well before an actual organ is offered. This can be done by describing scenarios where disease could be transmitted, where a donor may have high risk behaviors but has tested negative for diseases, and by general descriptions of ECD characteristics. **It is reasonable to require documentation of these discussions; however it is impossible to cover all the potential scenarios.** At the time of an actual organ offer, known donor information can be discussed in the context of these initial discussions without disclosing donor identify. Documentation of these last minute discussions will be extremely difficult because often they are done over the phone, in the middle of the night and under rapid decision-making conditions.

8. Informing Living Donors of Risks: The proposed rule states that living donors must be informed of medical risks. In addition, CMS states, in the preamble, that potential donors should be informed of the long-term risks associated with kidney donation, such as renal failure. This requirement is impractical since there is no long-term living donor registry with which to provide such information, and without such a registry living donors cannot realistically be tracked. The OPTN has developed a plan for such a registry, but it has not been funded. **We strongly support the concept of informing not only potential kidney donors but all living donors of the short- and long-term risks; however a living donor registry must be funded and implemented before this will be possible.** We also question the statement in the preamble that mortality risk of living liver donation has been estimated at 1%. There is no citation for this estimate and we are not aware of peer-reviewed clinical literature supporting this estimate.

9. Living Donor Advocate: We do not support requiring a specific donor advocate at this time. However, we believe it would be appropriate for the transplant center to be required to offer the services of a transplant-educated health care worker who is not directly involved in the transplant procedure. Specifying the credentials for an individual advocate is problematic. In order to provide educated advice to the donor, the advocate should have a thorough knowledge of the risks and benefits of the donation procedure. This might indicate a physician or surgeon. However, those best qualified are likely to be less independent from the transplant team. **Further, an independent advocate probably is not necessary for living kidney donors, since the living donor and transplant procedures are often performed by the same team. This has been the practice in many centers for over fifty years.**

10. Notification of surgeon availability: We support the CMS proposed rule to require transplant centers with only one surgeon to notify patients when the surgeon is not available.

ORGAN RECOVERY AND RECEIPT

While we support CMS' objective of decreasing organ wastage and increasing the number of successful transplants, we are very concerned that the requirements in proposed Section 482.92 represent serious impediments to the timely placement and transplantation of deceased donor organs and could dramatically increase ischemia times.

1. Requirement that Transplant Surgeon Ensure Medical Suitability of Organ: We are concerned about the possible interpretation of the requirement that the "transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient." While we agree that the transplanting surgeon is ultimately responsible for the decision to proceed with the transplant, it is the OPO that is responsible for collecting accurate information and communicating it properly to the surgeon. In many cases, information such as blood tests, cultures, final pathology reports and autopsy data are not known during the window of transplantation. In order for a transplanting surgeon to be capable of "ensuring" the medical suitability of a donor organ, he or she would have to oversee all of the OPO's collection and recording of the donor data and possibly interview the family of the potential donor to verify the medical history of the donor. This may also involve waiting for the OPO data to be complete and communicated to the surgeon. If this is required, otherwise

acceptable organs will not be transplanted because the surgeon cannot “ensure” their suitability without such data. **We strongly urge that this language be modified, for example, to state that the transplanting surgeon is “responsible for determining, to the extent possible and based on the information reasonably available at the time, the medical suitability of the donor organs . . .”**

2. Review of Data Before Organ Recovery: Proposed section 482.92(a) requires that a transplant center’s organ recovery team “review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.” This will greatly jeopardize timely procurement and placement of viable organs and will result in increased organ wastage. In many cases, the procuring team is not the accepting team, and organs are procured before accepting transplant centers are notified of the organ’s availability. Requiring a center to review donor data before recovery takes place will delay organ recovery efforts, increase the time required to place organs, increase organ ischemia times, and, if Medicare participation is at stake, will result in many centers’ refusing otherwise acceptable organs because their team did not review the donor data before the procurement procedure started. Further, with respect to kidneys, many times the recipient has not yet been identified at the time of organ removal from a deceased donor. **We suggest, as an alternative, that the rule require that the accepting transplant team must review the donor data supplied by the organ bank with the recipient blood type and other vital data before accepting the organ.**

3. Protocols for Deceased Organ Recovery: We believe that the proposed requirement that centers have written protocols for deceased organ recovery should be clarified. It is not clear whether this means that there must be criteria for acceptable donors or that there must be protocols for recovery of organs from deceased donors. Strict delineation of acceptable donors would have to entail every possible scenario of donor risk vs. recipient need for every transplant type within a center. **Since it is not possible to anticipate all of these scenarios, this requirement is impractical and has little impact on quality.** Furthermore, outcome measures will reflect the adequacy of a center’s organ acceptance criteria. We also note that in large multi-center OPOs, protocols for recovery of deceased donor organs would be determined to a considerable extent by the OPO and not the transplant center.

4. Verification of Blood Type: We agree with the requirement in proposed 482.92 (b) that, upon arrival of the organ, the transplanting surgeon and at least one other individual verify blood type, intended recipient and other vital data. This is routine for the transfusion of blood products in most centers and is a reasonable requirement. **However, there should be an exception for intended ABO incompatible transplants.**

HUMAN RESOURCES

Director of Transplantation: The director of the transplant center is not well defined. It is unclear whether an individual meeting the OPTN’s definition of transplant surgeon or transplant physician would qualify to hold this position. **We suggest that either a physician or surgeon meeting the OPTN requirements for a designated transplant physician or surgeon would qualify as a transplant center director.**

Transplant Physician: The requirement that there be a transplant physician “responsible for providing and coordinating transplantation care” is vague. This function is carried out by the transplant surgeon in many, if not most, of the major transplant programs in the U.S. This should be coordinated with existing OPTN requirements for transplant physicians, by cross-referencing the OPTN definition. If CMS does not cross-reference the OPTN definition, provision should be made to update the CMS requirements for transplant physicians to be consistent with any modifications made by the OPTN, without the need to comply with notice and comment rulemaking procedures.

Transplant Surgeon: All new transplant surgeons at a center should be required to have completed an ASTS fellowship. Existing transplant surgeons without an ASTS fellowship but currently active should be grandfathered in.

Certified Transplant Coordinator: Proposed regulations require a clinical transplant coordinator certified by the American Board of Transplant Coordinators. However, most highly experienced, excellent transplant coordinators do not have ABTC certification; nor do we believe such certification is necessary or would improve transplant care. In addition, at the time of hire, almost no transplant coordinator has this accreditation, but obtains it later on. **We recommend that the Transplant Center be responsible for training transplant coordinators and ensuring that they have the necessary knowledge and skills.**

Transplant Pharmacologist: A much more reasonable requirement would be the inclusion of a transplant pharmacologist. Given the complexity of today’s immunosuppressive regimens and multiple drug interaction, **a dedicated pharmacist or pharmacologist with expertise in transplant care would contribute to increased patient and graft survival rates.**

PROVIDER VS. SUPPLIER STATUS FOR APPEALS

CMS has stated in the preamble that it intends that transplant centers be able to appeal denials of approval or re-approval. However, because transplant centers do not fit cleanly into the definition of either a provider or a supplier, as those terms are defined in the Medicare statute, it is unsure how to apply existing appeal requirements to transplant centers. Further, there is nothing in the proposed regulation that indicates that centers can appeal adverse decisions.

It is critical that transplant centers be given the same appeal rights as other entities providing services to Medicare beneficiaries, regardless of whether they are considered providers or suppliers. We believe transplant centers should have all of the due process and appeal rights set forth in section 498 of Title 42 of the Code of Federal Regulations and believe there is little difference between providers and suppliers when it comes to appeal rights. However, since transplant centers are part of hospitals which are considered providers under the Medicare statute, it would seem more logical to apply the same appeal rights that apply to hospitals. In any event, we believe CMS has the authority, through regulation, to apply the procedures set forth in section 498 to transplant centers and the final rule should contain such a provision. **We also believe that the final regulations should explicitly state that a transplant center shall remain eligible for participation in the Medicare program pending the exhaustion of any**

appeals, so long as it has in place an acceptable QAPI program and that its continued treatment of Medicare patients does not jeopardize such patients' health and safety.

In addition, we request that CMS clearly state that denial of initial approval as well as re-approval is an "initial determination" that triggers the appeal rights under section 498.

UTILIZING HOSPITAL QAPI PROGRAM AND STAFF

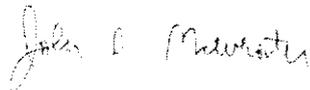
We believe the requirement for a "written, comprehensive data-driven QAPI program" should be eliminated. In this regard, we note that QAPI programs are required under Medicare conditions of participation for hospitals and by JCAHO. To the extent that a Medicare-approved transplant center is necessarily associated with a Medicare -approved hospital, the center will necessarily be part of an ongoing QAPI program.

The monitoring of outcome measures should adequately identify centers that are not keeping pace with advancing standards of care and should ensure that centers are improving over time. While we agree that centers should address adverse events, this is already a JCAHO standard and Medicare standard for hospitals generally and does not need to be duplicated. Implementation of a formal QAPI program might be appropriate as an aspect of remediation for a center that does not meet outcome standards.

SUMMARY

We appreciate the opportunity to comment on these complex and important regulations. We recognize the difficulty involved in finding an appropriate balance between protecting potential transplant donors and recipients and imposing duplicative, and potentially conflicting requirements on transplant centers, which are already among the most heavily regulated of providers.

Respectfully Submitted,



John McWhorter
President and CEO
Baylor University Medical Center

Submitter : Mrs. Denise D. Tharaldson
Organization : UC Davis Transplant Center
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the UC Davis Transplant Center, I have appended hereto as an attachment our comments to the proposed new regulations. Thank you very much for the opportunity to provide our feedback.

CMS-3835-P-42-Attach-1.DOC

Attachment #42

June 6, 2005

Dear Centers for Medicare and Medicaid Services:

Reference: File Code CMS-3835-P

On behalf of the UC Davis Transplant Center located in Sacramento, California, we appreciate the updating and collation of the renal and extra-renal transplant program regulations into a single segment of the Code of Federal Register (#42, Parts 405, 482, and 488). The following comments regarding each identified section are submitted for your consideration as CMS continues to refine the proposed new requirements for Transplant Centers:

482.80 Condition of Participation: Data Submission and outcome requirements for initial approval of transplants centers.

Section (4) (i) appears to provide Medicare approval if key members of a center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of one-year prior to the opening of a new center. In recognition of the number of team members required for successful patient outcomes at a transplant center, it is not clear how this requirement would permit a center to become qualified. For example, a transplant surgeon "taking" the patient outcome experience from one center with him/her to a new program does not seem sufficient to qualify the new center. We suggest that a more clear definition of team members and other important factors be taken into consideration for new program start-up, such as that which is reviewed by UNOS. We also question the validity of requiring only 9 transplants in the 2.5 year period and the validity of allowing a program to gain Medicare certification with only 1 month of data. Studies have shown a surgical specialty needs to perform a certain number of procedures per year in order to maintain proficiency and quality outcomes.

482.82 Condition of Participation: Data submission and outcome requirements for re-approval of transplant centers.

In order to ease the burden of recertification procedures upon CMS and the transplant centers, we recommend that those transplant centers which are already Medicare certified should be recertified upon meeting the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be incorporated into the scheduled UNOS on-site audit review of every program, approximately every three years. If a transplant program does not meet the first two CMS requirements, then a more urgent review is warranted. In this way, CMS would partner with UNOS, a federally approved contractor for administering the OPTN, to conduct the on-site audit. With its stringent process requirements, we would suggest that UNOS be considered for deemed status in the performance of these audits.

482.90 Condition of Participation: Patient and Living Donor Selection

Donor advocacy team for living donors: This would cause a hardship on small programs. Programs are dedicated to protecting the welfare of donors and if there is any problem or question the donor is deferred.

Patient selection: It is not clear how a center is supposed to meet the requirement that before a patient is selected (except for kidney) the transplant center must employ or consider all other appropriate medical and surgical therapies. Does this have to be stated in the patient's medical record, proven by "xyz?" When a patient is placed on the waitlist, the transplant center must document in the patient medical record the patient selection criteria used. What is expected by CMS by way of evidence to show this?

482.92 Condition of Participation: Organ Recovery and Receipt

The ABO policy is thoroughly covered by the OPTN policies and has been implemented and monitored through the OPTN listing systems.

482.94 Condition of Participation: Patient and Living Donor Management

In reference to the requirement for patient notification each year of their status on the list, this is redundant in that the current OPTN policy already requires notification at the time of listing and when a status change is made. Patients on heart and liver lists are followed closely, seen frequently, and know their listing status. Dialysis centers know if a patient is listed by having to get blood samples for PRA levels as requested by the listing transplant center.

482.96 Condition of Participation: Quality Assessment and Performance Improvement

We believe that several of the monitors suggested may not contribute to improving patient outcomes as may be intended. In addition to the outcomes measures tracked by the OPTN, we would suggest standard morbidity and mortality monitors, e.g. infections, re-transplants, deaths within one year of transplant, graft loss within one year of transplant, return to surgery events, urine leak rates (kidney), transplant admission lengths of stay, living donor complications, delayed graft functions, time on the waitlist, etc.

Protocols for adverse events are already a JCAHO requirement, and hospital sentinel event policies and reporting mechanisms are in place. Each is monitored by JCAHO as part of their site visit.

482.98 Condition of Participation: Human Resources

Regarding certification for transplant coordinators, there are several well-regarded professional nursing organizations that certify nurses; and we would recommend that

CMS should not single out one particular organization over the others which are equally well-respected, i.e. specifying ABTC certification.

Regarding the dietician requirement, this requirement can be met if it is for when the patient is an inpatient for the actual transplant process. If this is a requirement for the pre-transplant stage during the evaluation, it will be onerous for the extra-renal programs. Patients are cared for by their cardiologists and hepatologists. The transplant programs see these patients for their evaluation, make recommendations and return them to their primary physicians. Recommendations as to weight control or loss to meet selection criteria will be addressed in communication to the primary physician and the patient. A dietary consult at this stage will be too expensive and will fractionate the patient's care. Cardiac diets, etc., should be under the direction and monitoring of the primary physician.

482.102 Condition of Participation: Patient and Living Donor Rights

Our comments regarding the requirement that patients should be specifically educated to the selection criteria are as follows: Because each patient is unique and selection criteria need to be applied individually, transplant patient selection criteria are never absolute. We would recommend that CMS be less prescriptive regarding documentation of broadly applied patient selection criteria for each patient.

Regarding the requirement of informing patients of certain risks, this could be accomplished by way of an education checklist that each patient would be required to have checked off as he/she attends education sessions at which this information is presented. However, it is not clear how each patient could be alerted to specific donor risk factors. For example, in the case of a deceased donor it is a matter of hours before the transplant that the specific information about the donor is known. The patient is being brought in for transplant, taken to the OR, and prepped. The transplant coordinator is often not present. This is not the time to be discussing specific donor risk factors. We see this requirement to be difficult to implement.

Alternative Process to Re-approve Transplant Centers (page 162)

We agree it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN. As a federally contracted agency, the OPTN should be the entity to survey transplant programs as it is already reviewing programs every three years for compliance with transplant center facility and listing policies. The OPTN has the data and establishes the policies and standards for practice.

Transplant center programs which are already Medicare certified should be recertified with they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN arrives on-site for their scheduled review, thus completing the three-part process.

Cost to Administer/Implement

If the OPTN is not utilized to assess transplant center performance for the process requirements, then it would appear to require the establishment of a brand new monitoring entity currently unfamiliar with transplant programs and transplant policies. The learning curve would be steep. As such, the \$300,000 estimated additional expense may be underestimated.

In conclusion, thank you all once again for providing us with this important opportunity to submit our comments and suggestions about these proposed updated regulations. The hard work of all CMS staff involved in this extensive effort is most evident. We look forward to attending and participating in any additional town hall presentations that may be provided.

Best regards,

Denise D. Tharaldson
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Submitter : Ms. Anne McGinnis
Organization : Children's Hospital of Pittsburgh
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-43-Attach-1.WPD

CMS-3835-P-43-Attach-2.DOC

CHILDREN'S HOSPITAL OF PITTSBURGH
INTERNAL MEMORANDUM

TO: Jeanne Casilli
Demetrius Ellis, MD
Geoff Kurland, MD
George Mazariegos, MD
Victor Morell, MD
Len Merriman
Peter Michelson, MD
Ron Shapiro, MD
Steve Webber, MD

FROM: Anne McGinnis

DATE: March 22, 2005

RE: Proposed Rule: Conditions of Participation and Requirements for Approval/Re-Approval for Transplant Centers

Below please find a summary of a proposed ruling for the conditions of participation and requirements for approval/re-approval for transplant centers. Comments are due the Centers for Medicare and Medicaid Services (CMS) by April 5th. If you believe Children's should comment on any of the items in the proposal, please let me know. I will circulate a summary of responses prior to the April 5th deadline. I have also outlined what I believe our next steps should be. If I overlooked anything, please let me know.

The proposed rule would set forth the requirements that heart, heart-lung, intestine, kidney, lung and pancreas transplant centers must meet in order to participate as Medicare-approved transplant centers. The intent in developing and implementing such requirements is to insure Medicare-covered transplants are performed in an efficient manner in keeping with the importance of this scarce resource for individuals on organ transplant lists. It also serves to keep Medicare requirements current with the state of the art in transplantation. The proposed rule would not apply to the Medicaid program.

Current Medicare Policy

Kidney Transplant Centers

- Utilization Rates (annual volume): A center is granted a) unconditional status (15 or more per), b) conditional status (7-14 per year), c) time limited exception status (< 7 per year).
- Director of Renal Transplantation: A center must be under the direction of a qualified transplant surgeon or physician who is responsible for selection of suitable treatment modalities, ensuring tissue typing and organ procurement are available, staffing, training and supervision.
- Minimal Service Requirements: A center must a) be part of a Medicare-approved and participating hospital, b) be under the supervision of the hospital administrator and medical staff, c) participate in a patient registry program, d) utilize a qualified social worker to evaluate a potential recipient's psychosocial needs, participate in care planning and identifying community resources, e) utilize a qualified dietician to assess nutritional and dietetic needs of the patient, f) utilize a laboratory that is approved under 42 CFR Part 493 and that can perform cross-matching on an emergency basis and g) utilize the services of an OPO and have a written agreement with such an organization.

Heart, Liver and Lung Transplant Centers

- Patient selection: A center must have specific written patient selection criteria for each organ type and an implementation plan.
- Patient management: A center must have adequate patient management plans and protocols that include therapeutic and evaluative procedures for the waiting period, in hospital period and post transplant phase.
- Commitment: A center must make sufficient commitment of resources and planning for the center to demonstrate the importance of the center at all levels. Indications include: a) medical specialties such as hepatology, cardiology and pulmonology and b) general support in vascular surgery, anesthesiology, immunology, infectious diseases, pathology, blood banking, nursing, social services and radiology.
- Facility plans: A center must have facility plans, commitments and resources for a program that ensures a reasonable concentration of experience.
- Maintenance of data: A center must agree to maintain and when requested, submit data to CMS.
- Organ procurement: The center must be located in a hospital that is a member of the OPTN as a transplant hospital and abide by its approved rules. The center must also have an agreement with an OPO.
- Laboratory services: A center must make available, either directly or under arrangements, laboratory services to meet the needs of patients.
- Billing: A center must agree to submit claims to Medicare for Medicare covered conditions.
- Experience and Survival Rates: A center must demonstrate experience and success with organ transplantation. Adult heart and liver programs must have performed 12 or more transplants for covered conditions over a 12 month period. Heart centers must demonstrate actuarial survival rates of 73% for 1

year and 65% for 2 years. Liver centers must demonstrate a 1 year survival rate of 77% and a 2 year rate of 60%. Lung transplant programs must have performed 10 transplants over a 12 month period with a 1 year survival rate of 69% and a two year rate of 62%. Intestinal transplant programs (isolated intestine, liver/intestine and multivisceral) must have performed 10 transplants over a 1 year period with a 1 year survival rate of 65%. There are no survival standards in place for kidney, pancreas and heart-lung transplant centers.

Proposed Medicare Policy

Conditions of Participation: Process Requirements

Medicare approval will be given individually to centers that perform adult, pediatric or adult and pediatric transplants. A center that performs > 50% of its transplantation services to pediatric patients must obtain Medicare approval to perform both pediatric and adult transplants in order to be reimbursed for transplants performed on adult transplant beneficiaries. The loss of Medicare approval for adult transplants would not impact the center's Medicare approval to perform pediatric transplants while the loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would result in loss of Medicare approval to perform adult transplants.

Medicare approval will be contingent upon the following proposed patient and living donor selection guidelines:

- Centers will be required to utilize written patient selection criteria in making determinations regarding a patient's suitability for placement on the waitlist and a patient's suitability for transplant.
- Centers will be required to document in the patient's medical record the patient selection criteria that were utilized. There is a question around whether this information should be presented to the patient routinely or on request.
- Before a patient is selected for an extra-renal transplant, the center would have to consider or employ all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplant.
- All prospective transplant candidates must receive a psychosocial evaluation prior to placement on the waitlist.
- All prospective transplant candidates' medical record will contain documentation that the candidate's blood type has been determined. There is a question around how the documentation ensures the accuracy of vital data necessary to match the transplant candidate.
- Centers performing living donor transplants would have to use written living donor selection criteria to determine the suitability of candidates for living donation. Documentation of the donor's suitability must be contained in the donor's and recipient's medical records. Living donor selection criteria must be consistent with the general principles of medical ethics. The prospective living donor must also receive a medical and psychosocial evaluation and been given informed consent (which must be documented).

Medicare approval will be contingent upon following the proposed organ recovery and receipt guidelines:

- Transplant centers must have written protocols for organ recovery and organ receipt. Such protocols validates the donor's and the recipient's blood type and other vital data. The responsibility of ensuring medical suitability of donor organs will be assigned to the transplanting surgeon or the surgeon in the transplant center receiving the organ offer for his or her patient. Verification of suitability of donor and recipient must occur prior to recovery and after the organ arrives at the transplant center. The transplanting surgeon and at least one other person must verify the donor's blood type upon organ arrival and immediately before the removal of the living donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

Medicare approval will be contingent upon the following proposed patient and living donor management guidelines:

- Centers must have written patient management policies and patient care planning for pre-transplant, and through the patient's discharge from the hospital following transplant.
- Centers performing living donor transplant must have written donor management policies for the donor evaluation, donation and throughout the donor's discharge from the hospital following donation.
- All care must be coordinated by a physician during all phases of transplantation. This care must be completed by a multidisciplinary care team.
- Transplant centers will be required to reassess a patients place on their waitlist to ensure that a) the centers' information on the patient is accurate and b) the transplant is still medically indicated. Centers must keep their waitlists up to date and remove a patient from the list when the patient receives a transplant or dies. Centers must notify OPTN of the removal no later than 24 hours after such removal.
- Centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on the waitlist and who is admitted for organ transplant. Specifically, it is requested that the center must notify the patient of a) the patient's placement on the center's waitlist, b) the centers' decision not to place the patient on it's list or c) the center's inability to make a determination regarding the patient's placement of it's list because further clinical testing or documentation is needed.
- After a patient is placed on a waitlist, the center must provide waitlisted patients with an annual update of their waitlist status. This must be documented in the patient's record. If a patient is removed from the waitlist for any reason other than death or transplant, the center must notify the patient and document such within 10 days or removal. For dialysis patients, it is proposed such notification also be given to the patient's usual dialysis facility.
- Documentation of multidisciplinary care must appear in medical record.
- Availability of qualified social workers and dieticians to patients and living donors will be required.

Medicare approval will be contingent upon the following proposed quality assessment and performance improvement (QAPI) guidelines:

- Centers must develop, implement and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate all transplantation services, including services provided under contract or arrangement.
- Centers must include a written policy to address adverse events that occur during any phase of the organ transplant process. The policy must include the requirement of a thorough analysis of and document any adverse event and to utilize the analysis to effect changes in the center's policies and practices to prevent repeat incidents.

Medicare approval will be contingent upon the following proposed human resource requirements:

- Centers must be under the general supervision of a qualified transplant surgeon or physician. The director is responsible for training nursing staff, ensuring tissue typing and organ procurement services are available and ensuring that surgery is performed under the direct supervision of a qualified transplant surgeon.
- Centers must report both a primary transplant surgeon and a primary transplant physician.
- Centers must have qualified clinical transplant coordinators. Qualification would include obtaining certification by the American Board of Transplant Coordinators.
- Centers must identify a multidisciplinary team and the responsibilities of each team member.

Medicare approval will be contingent upon the following proposed organ procurement requirements:

- Centers must ensure that the hospital has a written agreement for the receipt of organs with an OPO designated by the Secretary.

Medicare approval will be contingent upon the following proposed patient and living donors' rights:

- Centers must have a written informed consent process that addresses living donation (where applicable). Two consent policies are offered for review (ACOT).
- Centers must have a written informed consent process that notifies patients of all aspects of and potential outcomes from transplantation, including, but not limited to: a) evaluation process, b) surgical procedure, c) alternative treatments, d) potential medical or psychosocial risks, e) national and transplant center-specific outcomes, f) future health problems related to the transplant may not be covered by the recipient's insurance and that the recipient's ability to obtain health, disability or life insurance may be affected, g) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used or the patient's possible risk of contracting the human immunodeficiency virus and

other infectious diseases if it cannot be detected in the donor and h) the right to refuse transplantation.

- CMS is requesting comments on a potential requirement for center's to provide the service of an independent donor advocate (or advocacy team) and what the individual or team's credentials should be.
- Centers that provide services with a single transplant surgeon or physician must inform patients of potential unavailability in an instance where an organ may come available for the recipient. Centers must also inform the patient whether or not a mechanism for providing an alternate surgeon or physician is in place if the primary providers are not available.
- Centers must assist patients in transferring waitlist time if the center is terminating Medicare approval.

Medicare approval will be contingent upon the following proposed additional requirements for kidney transplant centers:

- Centers must furnish directly, transplantation and other medical and surgical specialty services required for the care of the ESRD patients, including inpatient dialysis, either directly or under arrangement.
- Kidney transplant centers must cooperate with the ESRD network designated for its geographic area in fulfilling the terms of the network's current statement of work.

Data Submission & Outcome Requirements

Data Submission

All transplant programs will be required to submit at least 95% of required OPTN submissions no later than 90 days after the due date established by the OPTN. The required forms include:

- Transplant Candidate Registration Form (TCR): Due within 30 days of form generation date
- Transplant Recipient Registration Form (TRR): Due when the recipient is discharged from the hospital or 6 weeks following the transplant, whichever is first. Also, it is due within 60 days of form generation date.
- Transplant Recipient Follow-up Form (TRF): Due within 30 days of the form generation. Forms are generated 6 months post-transplant (except thoracic) and annually thereafter. If recipient dies or experiences graft failure, the TRF is due within 14 days of event.
- Post Transplant Malignancy Form: Due within 30 days of form generation date. Form is created when a malignancy is reported in the TRF.
- Living Donor Registration Form: Due within 30 days of form generation date.

- Living Donor Follow Up Form: Due within 30 days of form generation. Form created at 6 months and 1 year post transplant.

Outcome Requirements

A transplant program will be required to achieve separate patient and graft survival levels. This will be measured by comparing the expected patient and graft survival rates versus the observed rates. It is proposed that the evaluation system will rely on the SRTR risk-adjusted data. If a transplant program's observed rates are lower than the expected rates, the following SRTR tests would apply:

- P-value: the one sided p-value is less than 0.05
- O – E: observed minus expected events is greater than 3
- O/E: observed events divided by expected events is greater than 1.5

If observed patient and graft survival rates are less than those expected, the rates will only be acceptable if all 3 of the above thresholds are crossed over. This only applies to heart, liver, lung and kidney transplant centers. There are no outcome measurement requirements proposed for heart-lung, intestinal and pancreas centers. However, a heart-lung center must have Medicare certification for both its heart and lung programs in order to qualify, an intestinal center must have Medicare approval for its liver program in order to qualify and a pancreas center must have Medicare approval for its kidney program in order to qualify. None of these requirements apply to islet cell transplantation.

It is proposed that pediatric heart transplant programs have an alternative for approval. The center may be approved by meeting the following criteria:

- The center's pediatric transplant program must be operated jointly by the center and another facility that is Medicare-approved.
- The unified program shares the same transplant surgeons and quality improvement program, and
- The center demonstrates to the satisfaction of the Secretary that it is able to provide specialized facilities, services and personnel that are required by pediatric heart transplant patients.

Approval and Re-Approval

Current Medicare policies do not have criteria for re-approval of transplant centers. It is proposed that all programs will be granted Medicare approval for 3 years upon successful completion of all requirements. Every 3 years, each program will be reviewed for re-approval.

For a pediatric center, there are not a required minimum number of transplants (adult or pediatric) in order to qualify for Medicare approval. The OPTN requires that for a pediatric center to be functionally active, only 1 transplant per year is performed. An adult program will have to have performed at least 9 transplants of the appropriate

organ type during the 2.5 year period reported in the most recent SRTR center specific report.

Medicare approval is considered effective as of the date of the letter notifying the center of its approval.

Approved transplant centers will be required to comply with the data submission, outcome and process requirements at all times during the 3 year approval period.

Approval

New transplant center requesting initial approval:

- No later than 90 days after the due date established by the OPTN, heart, heart-lung, intestine, kidney, liver, lung and pancreas transplant centers must submit to the OPTN at least 95% of required data submissions on all transplants (deceased and living donor) performed at the center over the 3 year approval period.
- Transplant centers that have Medicare approval to perform pediatric transplants would not need to perform a minimum number of pediatric transplants.
- A center may use 1-month patient and 1-month graft survival data if the key members of the center's transplant team performed transplants at a Medicare-approved center for a minimum of 1 year prior to the opening of the new center. The survival data would be calculated on at least 9 transplants during the previous 1 year period for adult programs only. Pediatric programs would not have a volume criterion.
- Outcomes for pediatric and adult patients will be reviewed separately if a center has Medicare approval to perform pediatric transplants. The exception is lung transplant, which would be reviewed in combination with the adult program.
- Transplant center's observed outcomes must be higher than expected outcomes. If observed outcomes are less, all three SRTR thresholds must be crossed.
- Outcome measurement requirements are not applicable for heart-lung, intestinal and pancreas centers.

Re-approval

At least 180 days before the end of a transplant center's 3 year approval period, an evaluation of each center's data for compliance with the data submission and outcome requirements for re-approval will be performed. If the requirements are met, re-approval will be granted. If a center fails the data submission or outcome requirements, an onsite survey for compliance with the process requirements will occur. If the process requirements are satisfactory and not necessarily indicative of the quality of transplantation, the center would be re-approved. Alternatively, there is a proposal to also survey a transplant center for compliance with the process requirements and not solely rely on data submission and outcome requirements. The decision to survey would be based upon information provided by the OPTN.

Specifically, comments are invited on:

- How and if random surveys should be conducted
- Whether all centers should be surveyed every 3 years, regardless of their compliance with the data submission and outcomes requirements
- Whether it would be appropriate for CMS to base decisions about the need to conduct individual center surveys on information provided by OPTN

Requirements:

- No later than 90 days after the due date established by the OPTN, heart, heart-lung, intestine, kidney, liver, lung and pancreas transplant centers must submit to the OPTN at least 95% of required data submissions on all transplants (deceased and living donor) performed at the center over the 3 year approval period.
- Transplant centers that have Medicare approval to perform pediatric transplants would not need to perform a minimum number of pediatric transplants.
- Outcomes for pediatric and adult patients will be reviewed separately if a center has Medicare approval to perform pediatric transplants. The exception is lung transplant, which would be reviewed in combination with the adult program.
- Transplant center's observed outcomes must be higher than expected outcomes. If observed outcomes are less, all three SRTR thresholds must be crossed.
- Outcome measurement requirements are not applicable for heart-lung, intestinal and pancreas centers.
- Outcomes for heart, kidney, liver and lung centers would be evaluated on 1 year patient and graft survival data contained in the most recent SRTR center-specific report.

Loss of Approval

It is proposed that centers that have lost Medicare approval may seek re-entry into the program at any time. This request would be submitted and treated as if the center was a new center.

If a center is seeking re-approval due to sited deficiencies, the re-approval must document any changes or corrective actions the center has taken as a result of the loss of Medicare status.

Consortia

It is proposed that the current ruling that consortia are not approved collectively will remain.

Impact on Centers with Medicare Approval

It is proposed that centers with current Medicare approval will need to re-apply as a new center. Within 180 days from the date these regulations become effective, a center must submit a letter requesting Medicare approval for each individual program. If the center is determined to be in compliance with the data submission and outcome requirements, a survey will be scheduled to conduct an assessment of the conditions of participation. A program will be considered Medicare approved during the review of data and survey. Any change in status would be effective post-survey.

Next Steps

Identify which transplant programs have Medicare approval.

How many patients have Medicare as their primary payor.

Evaluate current process and determine where proposed changes may have significant impact (cost and operations).

Determine which programs currently meet the data submission and outcome requirements.

Cc:

Bernice Kula
Kathy Iurlano
Brenda Stinner
Kathy Lawrence
Amy Smith
Kim Haberman
Lynn Seward
Bev Kosmach Park
Pam Olesnevich
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Submitter : Mrs. Joan C. Arata

Date: 06/06/2005

Organization : LDS Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

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See attachment

CMS-3835-P-44-Attach-1.DOC

Reference: File Code CMS-3835-P

As transplant administrators representing a wide geographic area and both small and large transplant centers, we appreciate the updating and collation of the renal and extra-renal transplant program regulations into a single segment of the Code of Federal Register (#42, Parts 405, 482, and 488). An observation we have made is that it appears in many areas there has been extra burden placed on extra-renal transplant programs as a carry over from the ESRD regulations.

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Section (4) (i) appears to provide Medicare approval if key members of a center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of one-year prior to the opening of a new center. In recognition of the number of team members required for successful patient outcomes at a transplant center, it is not clear how this requirement would permit a center to become qualified. Nursing care is critical to the success of patient care, especially in complex cases as found in transplantation. Established programs have well oiled processes involving many professional within a transplant center. For example, a transplant surgeon "taking" the patient outcome experience from one center with him/her to a new program does not seem sufficient to qualify the new center. We suggest that a more clear definition of team members and other important factors be taken into consideration for new program start-up, such as that which is reviewed by UNOS. We also question the validity of requiring only 9 transplants in the 2.5 year period and the validity of allowing a program to gain Medicare certification with only 1 month of data. Studies have shown a surgical specialty needs to perform a certain number of procedures per year in order to maintain proficiency and quality outcomes.

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482.102 Condition of Participation: Patient and Living Donor Rights

Our comments regarding the requirement that patients should be specifically educated to the selection criteria are as follows: Because each patient is unique and selection criteria need to be applied individually, transplant patient selection criteria are never absolute. We would recommend that CMS be less prescriptive regarding documentation of broadly applied patient selection criteria for each patient.

Regarding the requirement of informing patients of certain risks, this could be accomplished by way of an education checklist that each patient would be required to have checked off as they attend education sessions at which this information is presented. However, it is not clear how each patient could be alerted to specific donor risk factors. For example, in the case of a deceased donor it is a matter of hours before the transplant that the specific information about the donor is known. The patient is being brought in for transplant, taken to the OR, and prepped. The transplant coordinator is often not present. This is not the time to be discussing specific donor risk factors. We see this requirement to be difficult to implement.

Alternative Process to Re-approve Transplant Centers (page 162)

We agree it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN. As a federally contracted agency, the OPTN should be the entity to survey transplant programs as it is already reviewing programs every three years for compliance with transplant center facility and listing policies. The OPTN has the data and establishes the policies and standards for practice.

Transplant center programs which are already Medicare certified should be recertified with they meet the first two requirements, i.e. data submission and outcomes. The third requirement, processes, can be reviewed when the OPTN arrives on-site for their scheduled review, thus completing the three-part process.

Cost to Administer/Implement

If the OPTN is not utilized to assess transplant center performance for the process requirements, then it would appear to require the establishment of a brand new monitoring entity currently unfamiliar with transplant programs and transplant policies. The learning curve would be steep. As such, the \$300,000 estimated additional expense may be underestimated.

In conclusion, thank you all very much for providing us with this important opportunity to submit our comments on these proposed updated regulations. The hard work of all CMS staff who were involved in this effort is most evident. We look forward to attending and participating in any additional town hall presentations that may be provided.

Best regards,

Submitter : Dr. James Boyer
Organization : American Liver Foundation
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment. Also kindly disregard previous submission; we have made one change. Thank you.

CMS-3835-P-45-Attach-1.DOC

| Attachment #45
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 American Liver Foundation (ALF) 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.

GENERAL COMMENTS

The American Liver 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, | ALF 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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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

- 1 -

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. ALF urges that the Final Rule make provision for Corrective Action Plans.

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, ALF 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 mental health care provider.

With regard to candidates for deceased donor organs, the psychosocial challenges faced by 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.

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The gravity of these psychosocial factors necessitates an evaluation/assessment conducted by a qualified mental health care provider. In addition, there should be an effort to standardize and codify the essential elements of the

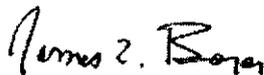
recommended psychosocial evaluation. This would facilitate the development of more valid and reliable interventions as well as psychosocial outcome measures.

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 mental health care provider. We believe that an independent donor advocacy team, that includes a qualified mental health care provider, would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. Mental health care providers have an established place in health care ethics committees and in helping patients make ethically appropriate decisions. A qualified mental health care provider 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.

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. ALF 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.

Sincerely,



James L. Boyer
Chairman of the Board

Submitter :

Date: 06/06/2005

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

We would like to comment on 3 sections of the proposed regulations:

Section 482.74, Notification to CMS.

The information requested in this section is either submitted to the OPTN (Change in key staff members; transplant volume) or published by the SRTR (survival rates). We would urge that CMS work with the OPTN and Scientific Registry to monitor transplant center status rather than require duplicative data submission, particularly given the large volume of data and information that transplant centers currently report to the OPTN.

Section 482.98 Human Resources; Standard: Clinical transplant coordinator.

The new standard would require that at least one coordinator be ABTC certified. It is recommended that some provision be made for adequate transition time for another coordinator to become certified in the event that a program has only one certified coordinator and that coordinator leaves the program. In our experience it is rare that a certified coordinator can be recruited to fill a vacancy.

Section 482.104; (b) Standard: Dialysis Services.

This proposed standard would require inpatient dialysis units to meet the full set of standards required for chronic dialysis facilities under part 405 subpart U. We believe this is an inappropriate requirement given the significant differences between chronic dialysis facilities and inpatient dialysis treatment units. Chronic dialysis facilities are intended to provide a particular type of care for patients over an extended period of time whereas hospital inpatient dialysis units in the context of this proposed rule are intended to provide isolated treatments within a 4-6 day inpatient stay. Many of the requirements of subpart U, such as patient care planning and the long term program, dialyzer reuse, nutritional and social work services, medical records, Governing body, etc. simply don't apply in this limited treatment inpatient setting. We strongly urge that subsection (b) be struck, and/or that standards specific to inpatient dialysis treatment units, irrespective of whether or not they are located within kidney transplant hospitals, be developed perhaps in conjunction with JCAHO.

Thank you for your attention.

Submitter : Ms. Rosalie O'Meara
Organization : Children's Hospital of Wisconsin
Category : Individual

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-47-Attach-1.DOC

CMS-3835-P-47-Attach-2.DOC

Attachment #47

June 6, 2005

Department of Health and Human Services
Centers of Medicare and Medicaid Services (CMS)
P.O. Box 8013
Baltimore, MD 21244-8013

RE: File Code CMS – 3835 – P

Dear Sirs,

Please consider the following comments regarding the proposed rules under 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 and 488:

Under Proposed Section 482.76 – Pediatric Transplants, Children’s Hospital of Wisconsin (CHW) supports CMS not requiring a minimum number of transplants in determining Medicare approval and allowing reimbursement for all pediatric heart, liver, lung and kidney transplant services. As stated in the proposed rules, by enforcing volume thresholds, access to these services for young Medicare beneficiaries would be limited since available pediatric organs are much less than those in the adult population. It is difficult for independent Children’s Hospitals to attain volumes comparable to the adult facilities. In addition, we ask that you consider increasing reimbursements for transplant services for Children’s Hospitals that are PPS-exempt and paid under the Tax Equity and Fiscal Responsibility Act of 1982, which is limited to a low target amount per discharge. A more fair reimbursement model would compensate for actual costs incurred for the provision of this tertiary care service.

Under Proposed Section 482.98 – Human Resources, CHW suggests that transplant centers have a qualified clinical transplant coordinator certified by the American Board of Transplant Coordinators and at least 12 months of work experience as a transplant professional OR be a state-licensed nurse with proficiency in complex professional and administrative skills usually acquired through 2-3 years of clinical experience related to the transplant program specialty.

Thank you very much for the opportunity to comment on the proposed rules. Please contact me at (414) 266-6223 with any questions.

Sincerely,

Rosalie O’Meara
Reimbursement Manager
Children’s Hospital of Wisconsin

Submitter : Ms. Rosalie OMeara
Organization : Children's Hospital of WI
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Ms. Rosalie OMeara
Organization : Children's Hospital of WI
Category : Hospital

Date: 06/06/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attached - second try

CMS-3835-P-49-Attach-1.DOC

Attachment #49

June 6, 2005

Department of Health and Human Services
Centers of Medicare and Medicaid Services (CMS)
P.O. Box 8013
Baltimore, MD 21244-8013

RE: File Code CMS – 3835 – P

Dear Sirs,

Please consider the following comments regarding the proposed rules under 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 and 488:

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Thank you very much for the opportunity to comment on the proposed rules. Please contact me at (414) 266-6223 with any questions.

Sincerely,

Rosalie O’Meara
Reimbursement Manager
Children’s Hospital of Wisconsin

CMS-3835-P-50

Submitter :

Date & Time: 06/07/2005

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3835-P-50-Attach-1.DOC

Attachment #50

CHILDREN'S HOSPITAL OF PITTSBURGH
CONDITIONS OF PARTICIPATION – TRANSPLANT CENTERS
COMMENTS

Section 482.76 Conditions of Participation: Pediatric Transplants

Comment: UNOS requirements should be the standard for pediatric hospitals when evaluating criteria to perform pediatric transplants.

Section 482.82 Condition of Participation: Data submission and outcome requirements for re-approval of transplant centers

Comment: We believe that the current survey process by UNOS, JCAHO and the state Department of Health is adequate to ensure quality and patient safety to our patient population. We do not believe an additional survey for the transplant services provided by the hospital is necessary.

Section 482.90 Condition of Participation: Patient and Living Donor Selection

Comment: Selection criteria should only serve as guidelines and should follow standards and published guidelines developed by the community of transplant professionals.

Section 482.98 Condition of Participation: Human Resources

Comment: We request clarification that each program needs only one certified clinical transplant coordinator. Each program must be allowed time for staff to obtain required certification and not be restricted to hire only certified coordinators. In addition, an individual with advanced training such as a CRNP, PA or CNS should be permitted to act as a clinical transplant coordinator without the certification.

Section 482.102 Condition of Participation: Patient and Living Donor Rights

Comment: This proposed process for consent for the evaluation process is unclear. The timing of such an act is not feasible given the standard flow of

medical treatment. Furthermore, we support and follow all CDC and UNOS guidelines for donor testing. If organ donor risk factors are to be part of a consent process, they must be developed by the transplant medical community. All donors carry risk factors by the very nature of cadaveric brain death.

Donor Advocacy:

Comment: We believe that the physical and psychosocial exam for a potential living donor be performed by an individual that is not part of the transplant team. An independent donor advocate (individual or team) is not a necessary component for a transplant program. Each transplant center should be able to define its process and structure for donor advocacy utilizing its existing trained professionals in a way that promotes an unbiased advocacy for living donors.

General Comment:

Policy development should not encourage the combination of adult and pediatric transplant programs. This is a retrograde step and goes directly against trends over the last 10 years. For small children and infants, the skills of dedicated pediatric surgeons are essential. All support services must also have a primary pediatric focus. Pediatric patients account for 7% of all transplants in 2004 (61% for intestinal transplant, 9% for liver transplant and 14% for heart transplant). Specifically, 25% of all pediatric heart transplants are performed on children less than 1 year of age. In this age group, two-thirds have end-stage congenital heart disease and require the skills of specialized congenital heart surgeons and pediatric cardiologists.

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Deleted: . It is imperative that these patients have the access to skilled surgeons and physicians in the treatments of congenital heart disease.