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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

**42 CFR Parts 405, 482, and 488
Medicare Program; Hospital Conditions of
Participation; Requirements for Approval
and Re-Approval of Transplant Centers
To Perform Organ Transplants; Proposed
Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 405, 482, and 488

[CMS-3835-P]

RIN 0938-AH17

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

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth the requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. These proposed revised requirements focus on an organ transplant center's ability to perform successful transplants and deliver quality patient care as evidenced by good outcomes and sound policies and procedures. We are proposing that approval, as determined by a center's compliance with the proposed data submission, outcome, and process requirements would be granted for 3 years. Every 3 years, approvals would be renewed for transplant centers that continue to meet these requirements. We are proposing these revised requirements to ensure that transplant centers continually provide high-quality transplantation services in a safe and efficient manner.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 5, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3835-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments>. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human

Services, Attention: CMS-3835-P, PO Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Eva Fung (410) 786-7539. Marcia Newton (410) 786-5265. Jeannie Miller (410) 786-3164. Rachael Weinstein (410) 786-6775.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3835-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in

a comment. CMS posts all electronic comments received before the close of the comment period on its public website as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Key Statutory Provisions

The Medicare statute contains specific authority for prescribing the health and safety requirements for facilities furnishing end stage renal disease (ESRD) care to beneficiaries, including renal transplant centers, pursuant to section 1881(b)(1) of the Social Security Act (the Act). Section 1102 of the Act (42 U.S.C. 1302) authorizes the Secretary to publish rules and regulations "necessary for the efficient administration of the functions" with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title." In 2003, 13,278 donors (deceased and living) provided organs in the U.S., and 25,468 transplants (deceased and living donor) were performed, yet 83,731 patients waited for a transplant at the end of 2003. Given the relative scarcity of donated organs compared to the number of people on transplant waitlists and the critical need to use these limited resources efficiently, we believe the proposed conditions of participation (CoPs) for transplant centers are necessary to: (1) Protect other potential Medicare beneficiaries who are waiting for organs for transplantation; (2) establish sufficient quality and procedural standards to ensure that transplants are performed in a safe and efficient manner; and (3) reduce Medicare expenses by decreasing the likelihood that a transplant will fail.

Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with the CoPs. Responsibilities of States in ensuring compliance with the CoPs are set forth in regulations at 42 CFR part 488, Survey, Certification, and Enforcement Procedures. Under section 1865 of the Act and § 488.5 of the regulations,

hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed by State agency surveyors for compliance with the conditions but are deemed to meet most of the requirements in the hospital CoPs based on their accreditation. In order to receive deemed status, hospitals accredited by the JCAHO, the AOA, or other national accreditation programs with deeming authority under § 488.6 of the regulations must meet requirements that are at least as stringent as the Medicare CoPs. (See Part 488, Survey and Certification Procedures.) Therefore, an accreditation organization could apply for and receive approval of deeming authority for the proposed hospital CoPs for transplant centers if the accreditation organization demonstrates that it has requirements for transplant centers that are at least as stringent as the proposed CoPs.

B. Department Activities Related to Organ Donation and Transplantation

1. Department Commitment To Increasing Organ Donation and Transplantation

At the end of 2003, there were 83,731 Americans waiting for organ transplants. About 25,468 patients on the waitlist received organ transplants (deceased and living donor), and approximately 6,879 persons died waiting for an organ to become available. Promotion of organ donation, which would increase the number of transplant recipients by increasing organ availability, is of paramount importance to the Department of Health and Human Services (the Department). On April 17, 2001, Secretary Tommy Thompson launched his "Gift of Life Donation Initiative," a multi-level approach to increasing organ, tissue, and marrow donation. The Secretary has directed agencies within the Department to make organ, tissue, and marrow donation a top priority. The Secretary's initiative focuses on 5 elements: (1) A model donor card program, (2) a national forum on donor registries, (3) a national "Gift of Life" medal to honor donor families, (4) a model curriculum on organ donation for drivers' education classes, and (5) the "Workplace Partnership for Life" program, which involves collaboration with companies and employer groups to make information on organ donation available to all employees.

We are revising the current Medicare requirements for heart, intestine, kidney, liver, and lung centers and adding new Medicare requirements for

heart-lung and pancreas centers by proposing transplant center hospital conditions of participation. The proposed CoPs would ensure that all Medicare-approved transplant centers provide quality transplantation services so that organs, once recovered, are not wasted. This proposed rule would not apply to the Medicaid program.

2. Transplantation Criteria Town Hall Meeting

We held a Town Hall Meeting on December 1, 1999 (See 64 FR 58419) to discuss current medical and scientific evidence regarding potential criteria for approval of transplant centers for Medicare coverage. Approximately 150 people attended the meeting. Attendees included representatives from the Organ Procurement and Transplantation Network (OPTN), staff from transplant centers, health policy and clinical researchers, transplant recipients and their families, physicians and other clinicians, and government officials.

The format for the meeting included four subject-related panel presentations followed by an opportunity for comments from the attendees. The panel topics included: (1) Aspects of facilities linked to coverage, (2) methodologies for measuring outcomes, (3) data used for approving centers, and (4) thresholds for approving centers. In addition to the planned panel topics, the meeting provided for an open forum during which ideas not covered in the topic panels could be shared. To accommodate the views of those who could not attend the meeting, we provided an opportunity for members of the community to share their views in writing.

Comments from the Town Hall Meeting expressed widely divergent views. However, the ideas shared during this meeting and the written public comments were considered seriously and significantly influenced the development of this proposed rule. Our staff has also attended meetings, conferences and training to stay abreast of the latest advancement and issues associated with transplantation.

C. Current Medicare Policy Regarding Transplantation

1. Kidney Transplant Centers

Section 1881 of the Act authorizes benefits for individuals who have been determined to have ESRD, including dialysis and transplantation services. Section 1881(b)(1)(A) of the Act provides an explicit direction to the Secretary of Health and Human Services to develop requirements for kidney (renal) transplantation services under the Medicare program. We fulfilled this

responsibility through regulations published on June 3, 1976 (41 FR 22511). These requirements are codified at 42 CFR part 405, Subpart U. Under the Conditions for ESRD coverage, renal transplant centers must meet all appropriate conditions of coverage, which address issues such as compliance with applicable Federal, State, and local laws and regulations; Governing body; Patient long-term program and patient care plan; Patients' rights; Medical records; and Physical environment. In addition, the conditions of coverage include the following criteria specifically for kidney or renal transplant centers:

- *Minimum utilization rates.* The regulations classify renal transplant centers that meet all the other conditions for coverage of ESRD services at 42 CFR 405, Subpart U into the following 4 categories according to the center's minimum utilization rates (annual volume): (1) Unconditional status, (2) conditional status, (3) exception status, and (4) not eligible for reimbursement for that ESRD service. (See 42 CFR 405.2122.) Unconditional status is assigned to a center that performs 15 or more transplants per year. Conditional status is assigned to a center that performs 7 to 14 transplants per year. (See 42 CFR 405.2130.) If a center does not meet the minimum utilization rate for unconditional or conditional status, it may, under certain circumstances, be approved for a time-limited exception status. A center that does not meet the requirements for conditional or unconditional status and is not granted an exception status under § 405.2122(b) is not eligible for reimbursement for that ESRD service. (See 42 CFR 405.2122.)

- *Director of Renal Transplantation.* Renal transplant centers must be under the direction of a qualified transplant surgeon or a physician who is responsible for: (1) Participating in the selection of suitable treatment modalities for each ESRD patient; (2) ensuring adequate training of nurses in the care of transplant patients; (3) ensuring tissue typing and organ procurement services are available either directly or under arrangement; and (4) ensuring transplantation surgery is performed under the direct supervision of a qualified transplant surgeon (See 42 CFR 405.2170).

- *Minimal Service Requirements.* Renal transplant centers must meet the following minimal service requirements: (1) Be part of a Medicare-approved and participating hospital; (2) be under the supervision of the hospital administrator and medical staff; (3)

participate in a patient registry program with an OPO for patients who are awaiting deceased donor transplantation; (4) utilize a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of the patients and identify community resources to assist the patient and family; (5) utilize a qualified dietitian who will, in consultation with the attending physician, assess the nutritional and dietetic needs of each patient, recommend therapeutic diets, provide diet counseling to patients and their families, and monitor adherence and response to a prescribed diet; (6) utilize a laboratory that is approved under 42 CFR Part 493 and that can perform cross-matching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique on a 24-hour emergency basis, and (7) utilize the services of an organ procurement organization (OPO) to obtain deceased donor organs, and have a written agreement covering the services (See 42 CFR 2171).

Even though the ESRD conditions of coverage contained at 42 CFR part 405, subpart U include some kidney transplant center provisions, the proliferation of patient and living donor issues and our desire to standardize requirements for transplant centers necessitate a broader regulatory framework for the oversight of kidney transplant centers. Therefore, we have concluded that it is logical for us to replace the requirements contained in Part 405, Subpart U that pertain solely to renal transplant centers with approval and re-approval requirements for kidney transplant centers in these proposed hospital CoPs for organ transplant centers. Specifically, we propose to delete § 405.2120 through § 405.2134, § 405.2170 through § 405.2171, and the definitions for "histocompatibility testing," "ESRD Network," "Network organization," "organ procurement," "renal transplantation center," "transplantation service," and "transplantation surgeon" contained in § 405.2102. The proposed transplant center CoPs are both outcome and process-based and would collectively ensure that transplantation services furnished in all types of transplant centers are safe and efficient.

Generally, the provisions contained in the proposed transplant center CoPs are applicable to all types of transplant centers. However, kidney transplantation differs from other types of organ transplants in some ways. For example, section 1881(b)(1)(A) of the Act explicitly provides for Medicare

kidney transplants while coverage of most transplant services are provided under the general "reasonable and necessary" authority of section 1862. Also, whereas organ transplantation is the only treatment option for patients with end-stage heart, liver, lung or intestinal failure, dialysis is an alternative treatment for ESRD patients when transplantation is not feasible. To underscore the distinct nature of kidney transplants and kidney transplant centers, we have included some provisions that are specific only to kidney transplant centers in the proposed hospital CoPs for transplant centers. The following proposed CoPs for approval and re-approval of transplant centers contain provisions that are specific only to kidney transplant centers (see Section II. Provisions of the Proposed Regulation for further discussion of the requirements):

- Condition of participation: Patient and living donor selection (proposed § 482.90(a)(1));
- Condition of participation: Patient and living donor management (proposed § 482.94(c)(3)); and
- Condition of participation: Additional requirements for kidney transplant centers (proposed § 482.104).

2. Extra-renal Organ Transplant Centers

Beginning in 1987, we published several notices in the **Federal Register** delineating our coverage policies regarding various organ transplants. On April 6, 1987, the Health Care Financing Administration (HCFA), now known as CMS, published a ruling (52 FR 10935) (HCFAR 87-1) announcing Medicare's national coverage policy on heart transplants. On April 12, 1991, we published a final notice (56 FR 15006) announcing Medicare's national coverage decision on liver transplants in adults. On February 2, 1995, we published a notice with comment (60 FR 6537) announcing Medicare's national coverage decision on lung transplants.

In these notices, we stated that the transplants in adults were medically reasonable and necessary and covered by Medicare under section 1862 (a)(1), 42 U.S.C. 1395y(a)(1), when performed on carefully selected patients in centers that meet certain criteria. As discussed in these notices, we based these policies on research carried out by the Battelle Human Affairs Research Center (heart) and the Public Health Service's Center for Health Care Technology (liver and lung). The specified center criteria for heart, liver, and lung transplant centers included the following:

- *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 phases of treatment.

- *Commitment.* The center must make a sufficient commitment of resources and planning of the transplant center to demonstrate the importance of the center at all levels. Indications of this commitment must be broadly evident throughout the center. The center must use a multidisciplinary team that includes representatives with expertise in the appropriate organ specialty (e.g., hepatology, cardiology, or pulmonology) and the following general areas: Vascular surgery, anesthesiology, immunology, infectious diseases, pathology, radiology, nursing, blood banking, and social services.

- *Facility plans.* The center must have facility plans, commitments, and resources for a program that ensures a reasonable concentration of experience.

- *Maintenance of data.* The 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.

See Section II Provisions of the Proposed Regulations (Proposed Section 482.72) for further discussion of the OPTN rules.

- *Laboratory services.* The center must make available, either directly or under arrangements, laboratory services to meet the needs of patients.

- *Billing.* The center must agree to submit claims to Medicare only for transplants performed on individuals who have Medicare-covered conditions.

- *Experience and survival rates.* The center must demonstrate experience and success with organ transplants. The center staff must have performed a specified volume of transplants for each organ type (12 or more adult heart or liver transplants or 10 or more lung transplants) for covered conditions in each of the two preceding 12-month periods. Additionally, the center must demonstrate a minimum actuarial 1-year and 2-year survival rate. Heart transplant centers must demonstrate actuarial survival rates of 73 percent for 1 year and 65 percent for 2 years. Liver centers must demonstrate a 1-year actuarial survival rate of 77 percent and

a 2-year actuarial survival rate of 60 percent for adult patients. Lung transplant centers must demonstrate a 1-year actuarial survival rate of 69 percent and a 2-year actuarial survival rate of 62 percent.

On July 26, 2000, we issued a national coverage decision (<http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=75>), which was implemented in a program memorandum (See Program Memorandum AB-00-95, http://www.cms.hhs.gov/manuals/pm_trans/2000/memos/comm_date_dsc.asp) with an effective date of October 11, 2000. This decision announced a revision to the volume criterion for transplant centers to require 12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung transplant centers and to eliminate the 2-year minimum experience requirement. The memorandum was issued in response to concerns raised by hospitals that open a new transplant center staffed by an experienced team that has transferred from another Medicare-approved center. The hospitals stated that a new center, staffed with an experienced team, should receive immediate Medicare approval rather than wait at least 2 years until the center was able to demonstrate that it had performed the required volume of transplants. In response to these concerns, we solicited scientific evidence from the transplant community on the relationship between low-volume centers, transplantation team experience, and outcomes. Our analysis of the scientific literature and the information we received indicated that center volume could serve as a proxy for the 2-year minimum experience requirement. In other words, the evidence we reviewed pointed to the fact that volume is a more accurate indicator of outcome than time (see CAG-00061, <http://cms.hhs.gov/ncdr/memo.asp?id=75>, for summary of relevant clinical literature). Thus, new centers staffed with an experienced team that perform a high volume of transplants could be expected to produce satisfactory outcomes.

As of July 1, 1999, Medicare covers whole organ pancreas transplantation for diabetic patients, when it is performed simultaneously with or after a kidney transplant. (See sections 35-82 of Coverage Issues Manual.) Effective for services provided on or after April 1, 2001, Medicare covers isolated intestinal transplant, combined liver-intestinal transplant, and multivisceral transplant. Coverage for all three types of intestinal transplants is limited to

patients who have irreversible intestinal failure and who have failed total parenteral nutrition (TPN). To be Medicare-approved, an intestinal transplant center must have an annual volume of 10 transplants with a 1-year actuarial patient survival rate of 65 percent (See Program Memorandum AB-01-58).

D. Living Donors

Since 1990, living donation has become the fastest growing source of kidneys for kidney transplants and, more recently, of livers for liver transplants. In 2001, the number of living donors exceeded the number of deceased donors for the first time. There were 12,591 organ donors in the U.S. in 2001; 6,510 were living donors and 6,081 were deceased donors. In 2003, the number of living donors continued to exceed the number of deceased donors. In 2003, there were 13,278 organ donors in the U.S.; 6,821 were living donors and 6,457 were deceased donors. Living donor transplantation provides an alternative to deceased donor transplantation for a growing number of waitlist patients. Of the 25,468 transplants performed in the U.S. in 2003, 6,811 were living donor transplants, which is a 3.0 percent increase from the 6,616 living donor transplants performed in 2002. Meanwhile, the number of deceased donor transplants rose by 2.0 percent from 18,292 in 2002 to 18,657 in 2003.

As living donor transplantation increases, there is growing concern over the safety of living donors. Most of the living donor transplant data reported are for kidney and liver transplants. Other types of living donor transplants are rare and data are scarce. For example, among the 6,811 living donor transplants performed in 2003, 6,468 were kidney transplants, 321 liver transplants, 15 lung transplants, 0 pancreas transplant, and 4 intestinal transplant. 3 kidney-pancreas transplants were performed. The risk of donor death for living kidney donors has been very low. In the 46-year history of living donor kidney transplantation, the risk of donor death is estimated to be approximately 0.03 percent.

For example, if we look at the 6,468 living donor kidney transplants performed in 2003 (out of a total of 15,138 living and deceased kidney transplants performed in the U.S. in 2003), we estimate that fewer than 2 of those transplants would result in donor death. Although there is a relatively low risk of donor death for living kidney donors, recent research seems to indicate that living kidney donation may increase the donor's morbidity. For

example, a United Network for Organ Sharing (UNOS) study indicated that a total of 56 previous living donors were identified as having been listed for transplantation. It is unknown if more living kidney donors had suffered from renal failure as well (Ellison MD, McBride MA, Taranto SE, Delmonico FL, Kauffman HM. "Living Kidney Donors in Need of Kidney Transplants: A Report From the Organ Procurement and Transplantation Network. *Transplantation*, 2002 November 15; 74(9): 1349-51). Living renal donation has long-term risks that may not be apparent in the short term, which leads us to believe that potential donors should be informed of these long-term risks.

The risk of donor death for living liver donors is higher than the risk of donor death for living kidney donors. In the 13-year history of living donor liver transplants (LDLTs), the risk of donor death has been estimated to be approximately 1 percent. Living liver donors face a higher risk of morbidity and mortality than living kidney donors due in part to complications from blood clotting, bile duct leakage, and infections. Furthermore, the rapid growth of adult LDLT as an alternative to deceased transplantation has resulted in great variation in surgical techniques, center volumes and recipient and donor selection criteria.

In addition to concerns over donor morbidity and mortality, there is also growing concern about the lack of standard guidelines governing living donor selection and post-operative care. For example, in 2002, a living liver donor death was reported in a transplant hospital in New York. The New York Department of Health launched an investigation into the donor's death and found that the donor's post-operative care was inadequate and fragmented. The New York Department of Health's investigation report concluded that inadequate staffing was a contributing factor in the donor's death ("NY Department of Health charges inadequate staffing a factor in live donor's death at Mt. Sinai Hospital," *Transplant News*, March 15, 2002, at 5.).

Accurate physical and psychosocial assessments of the suitability of prospective donors are imperative to reduce the likelihood of harm to healthy donors. In the absence of national guidelines for donor selection, it is difficult to ensure that living donations are performed safely. Currently, there are few worldwide registries to track living donor outcomes. The OPTN, however, gathers 1-year post-donation

follow-up data on living donors in the US.

Section 1881(d) of the Act entitles any individual who donates a kidney for transplant surgery to Medicare benefits under parts A and B with respect to such donation. Medicare does not have a national coverage determination regarding extra-renal living donor transplants. In the absence of a national coverage determination, however, Medicare contractors may make local coverage determinations either on a claim-by-claim basis or through local medical review policies. We have some concerns about the lack of standardized recipient and donor selection criteria, best practices in living donation procedures, a national outcomes database of donors' long-term follow-up and the variability in surgical expertise, volumes and center resources given the growth in living donor transplants. More systematic data collection and reporting of donor and recipient mortality and morbidity are needed to further assess the risk of death for living donors and the benefit for recipients. Generally, we believe living donation is a very promising medical practice. Therefore, in order to protect the safety of living donors and guarantee the more efficient use of human organs, we have proposed some minimal requirements for transplant centers performing living donor transplants that would apply to all Medicare-approved centers that perform living donor transplants. In accordance with our authority to establish standards necessary for the health and safety of individuals furnished services in hospitals, we believe we possess sufficient authority to prescribe rules for this practice. We invite public comments on these proposed requirements for living donor selection and living donor rights (*see* Section II. Provisions of the Proposed Regulations for a detailed discussion of these proposed requirements). We also request comments on whether we need to establish additional criteria for transplant centers performing living donor transplants.

[If you choose to comment on this issue, please include the caption "CRITERIA FOR CENTERS PERFORMING LIVING DONOR TRANPLANT" at the beginning of your comments.]

E. Why We Are Proposing New CoPs for Transplant Centers

Our current Medicare coverage policies for extra-renal organs are based on the "reasonable and necessary" provision, Section 1862(a)(1)(A) of the Act. ("[N]o payment may be made under part A or part B for any expenses

incurred for items or services—(1)(A) which * * * are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.") Generally a medical procedure will be covered if its safety and efficacy have been adequately demonstrated by scientific evidence and the medical community has generally accepted the procedure. In the **Federal Register** notices announcing the Medicare coverage policies for heart, liver, and lung transplants, we stated that organ transplants in adults were reasonable and necessary when performed on carefully selected patients in facilities that meet certain criteria.

In the past decade, however, the medical community has made remarkable strides in organ transplantation, and data on successful transplant outcomes are compelling. Organ transplantation is generally very effective and successful. Patients who have received transplants benefit substantially from these life-saving procedures in terms of improved quality of life and longer lifetime. Aided by ongoing evolution in pharmacology and transplant technology, organ transplantation is no longer regarded as an experimental procedure by the medical community and most health insurance companies. Instead, transplantation has become the mainstream operation for many patients who are in the end stage of organ failure.

Furthermore, cutting-edge medical technology and pharmacology have raised graft and patient survivals significantly, such that we recognize that the survival standards that we had established previously for heart, liver, and lung centers may be too low. The national mean 1-year patient survival rates for heart, liver, and lung transplants performed in all transplant centers are much higher than the 1-year patient survival thresholds we established in our earlier national coverage decisions for Medicare approval of heart, liver, and lung transplant centers.

Furthermore, the current requirements for heart, liver, and lung centers established threshold requirements for Medicare reimbursement but do not include criteria for re-evaluating the ongoing performance of approved heart, liver and lung centers. Since organ transplantation is a medical procedure that depends completely on organs donated from an appropriate donor, any potential outcome failure should be minimized to minimize organ wastage. Ongoing evaluation of a transplant

center's outcomes would serve as a valuable oversight tool for guaranteeing that donated organs are used efficiently. By establishing criteria for data submission, outcome measures, and process requirements, we can assume that Medicare-approved transplant centers would continue to provide a sufficient quality of transplantation so that organ wastage due to transplant failure would be decreased.

We believe it is important to promulgate regulations that will allow CMS to take advantage of advances in medical technology and establish standards for facilities that will ensure that Medicare beneficiaries receiving care at Medicare-approved transplant centers receive quality transplantation services. We are proposing rules that will encourage centers to seek approval to perform transplants on patients and that will include reasonable requirements necessary to produce a high probability of success. We believe these rules will lead to more efficient usage of donated organs and enhance effective administration of the Medicare program. We are proposing to codify the requirements for the approval and re-approval of transplant centers as an option for hospitals under part 482, Subpart E. These regulations would apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers. For purposes of this regulation, intestine centers are those Medicare-approved liver transplant centers that perform intestinal transplants, combined liver-intestinal transplants, and multivisceral transplants. Pancreas centers are those Medicare-approved kidney transplant centers that perform pancreas transplants, alone or subsequent to a kidney transplant, and that perform kidney-pancreas transplants.

The requirements for Medicare-approved transplant centers have been published over the years in the **Federal Register**, the Coverage Issues Manual, and 42 CFR part 405, subpart U. Locating the Medicare requirements for different organ types has proven difficult for hospitals desiring to become Medicare-approved transplant centers. Therefore, we are proposing to include the criteria for all of the organ transplant types (*i.e.*, heart, heart-lung, intestine, kidney, liver, lung, and pancreas) in the same CFR part: 42 CFR part 482. Although we received some comments during the Town Hall Meeting in December 1999 expressing the view that kidney transplant center criteria should remain with the ESRD facility conditions, we believe it will facilitate ease of reference and understanding if all the transplant center criteria are

consolidated into a specific set of hospital policies.

Entities that request approval as a Medicare transplant center must first meet all of the hospital CoPs in 42 CFR part 482; however, inclusion of the organ transplant center criteria in the hospital CoPs does not imply that every hospital must meet the criteria in order to participate in Medicare. Rather, the transplant criteria represent an optional status based on conditions that are applicable only to hospitals that choose to apply for Medicare approval as a transplant center. Each type of organ transplant center would be approved separately, so only the approval of the individual organ-specific transplant center would be threatened if it were found non-compliant with the CoPs for transplant centers. That is, the hospital would not face the automatic loss of its Medicare approval as a hospital (or the loss of Medicare approval for other transplant centers) if one transplant center in the hospital were found to be noncompliant with the CoPs for that type of transplant center.

II. Provisions of the Proposed Regulations

For the reasons discussed previously, we propose to set forth new hospital CoPs for the approval and re-approval of transplant centers at part 482, subpart E of this chapter. Following is a discussion of the specific requirements contained in the proposed conditions.

Special Requirements for Transplant Centers (Proposed Section 482.68)

The requirements for approval and re-approval of transplant centers contained in this proposed rule represent special requirements that a transplant center must meet in order to receive Medicare approval as an organ-specific transplant center. Therefore, we propose a hospital that has a Medicare provider agreement must meet the CoPs specified in § 482.70 through § 482.104 in order to be granted approval from CMS and to receive reimbursement for providing transplant services. We propose that unless we specify otherwise, the CoPs specified in § 482.70 through § 482.104 apply to all transplant centers addressed in this proposed rule (*i.e.*, heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers).

We also propose that transplant centers seeking Medicare approval meet the hospital conditions of participation specified in § 482.1 through § 482.57. In other words, if the hospital in which a transplant center operates is terminated from Medicare, the transplant center would also lose its Medicare approval. However, loss of a transplant center's

approval status would not automatically lead to termination of the hospital's provider agreement.

Definitions (Proposed § 482.70)

For clarity, we propose standardizing the usage of certain terms by proposing definitions for "transplant hospital," "transplant program," and "transplant center." Sometimes CMS has used the term "transplant center" interchangeably with the term "transplant hospital" and sometimes it has used it interchangeably with the term "transplant program." We propose defining "transplant hospital" as a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients. A transplant hospital may have one or more types of organ transplant programs operating within the same hospital. Based on the definition of "transplant program" set forth at 42 CFR 121.2, we propose defining a "transplant program" as a component within a transplant hospital that provides transplantation of a particular organ type. Under the proposed definitions for "transplant hospital" and "transplant program", we propose to use "transplant center" interchangeably with "transplant program" in this proposed rule.

We propose to delete the definitions for "histocompatibility testing," "ESRD Network," "network organization," "organ procurement," "renal transplantation center," "transplantation service," and "transplantation surgeon" contained in § 405.2102. To emphasize the distinct statutory requirements that kidney transplant centers have to meet and to clarify usage of three terms in the proposed CoPs for transplant centers, we propose to retain in § 482.70 the definitions for "ESRD," "ESRD network," and "network organization" from § 405.2102.

We propose adding a definition for "adverse event" because we propose requiring a center to establish a written policy to address adverse events that occur during any phase of an organ transplantation case. The proposed definition for "adverse event" is derived from the JCAHO definition of an "adverse event" and provides examples of adverse events that may occur in a transplant center.

To reduce confusion, we also propose definitions for the particular types of organ transplant centers addressed in this proposed rule that perform multi-organ transplants. We propose including definitions for "heart-lung transplant center," "pancreas transplant center,"

and "intestinal transplant center" as they are used in this proposed rule.

These definitions, as we propose to include them, are contained in the regulatory text at proposed § 482.70.

Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed section 482.72)

The OPTN was established under section 372 of the Public Health Service (PHS) Act, as enacted by the National Organ Transplant Act of 1984 (Pub. L. 98-507), and amended by Public Law 100-607 and Public Law 101-616. Section 372 of the PHS Act requires the Secretary to provide, by contract, for the establishment and operation of the OPTN to manage the national organ allocation system, to increase the supply of donated organs, and to perform related activities. Since 1986, the Health Resources and Services Administration's (HRSA) Division of Transplantation (DoT) has administered a contract with UNOS to operate the OPTN. On October 20, 1999, HRSA published regulations governing the operation of the OPTN at 42 CFR Part 121 (64 FR 56650).

The primary functions of the OPTN are (1) to ensure that critically-ill and medically-qualified patients have equitable access to organs; (2) to ensure the safe and efficient recovery and use of scarce vital organs; and (3) to collect, maintain, and track information on all transplants and transplant patients from the time of surgery until graft failure or patient death. Although the OPTN regulations referred to above include some provisions that apply to OPTN members, including transplant centers, the OPTN regulations at § 121.4 also require the OPTN to establish policies for its members in order to achieve the goals of the OPTN. As required by the OPTN regulations at § 121.4, policies are established concerning organ procurement and transplantation for OPTN members. These policies established by the OPTN are legally enforceable against OPTN members if the Secretary approves them and they are published in the **Federal Register** in accordance with § 121.4. The Secretary enforces the OPTN policies, or rules, pursuant to the procedure laid out at § 121.10. To date, no OPTN policies have been approved by the Secretary.

Until enactment of the Omnibus Budget Reconciliation Act (OBRA) of 1986 (Pub. L. 99-509), membership in the OPTN was voluntary. However, section 9318 of the OBRA of 1986 added section 1138(a)(1)(B) to the Act to require hospitals that perform organ

transplants to be members of and abide by the rules and requirements of the OPTN as a condition for participation in the Medicare and Medicaid programs. In accordance with section 1138(a)(1)(B) of the Act, the hospital condition of participation for organ, tissue, and eye procurement at § 482.45(b)(1) requires that a hospital in which organ transplants are performed must be a member of the OPTN and abide by the OPTN rules that have been approved by the Secretary. We propose that transplant centers must be located in a transplant hospital that is a member of and abides by the rules and requirements of the OPTN as set forth in § 482.45(b)(1), which are enforceable under § 121.10. We propose that no transplant hospital would be considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the proposed rule, unless the Secretary had given the OPTN formal notice that he or she approved the decision to exclude the transplant hospital from the OPTN and had notified the center in writing.

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

The current requirements for coverage of heart, liver and lung transplants require a Medicare-approved transplant center to report immediately to CMS any events or changes that would affect its approved status. Specifically, a center is required to report to us, within a reasonable period of time, any significant decrease in its experience level (for example, volume) or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of heart, liver or lung transplants at the facility. There are no requirements for kidney transplant centers to report significant changes to CMS. We are proposing to require each transplant center to report immediately to CMS information on any significant changes that would affect its approval, such as an unusually large number of patient deaths during or shortly after transplant that could impact the center's 1-year patient survival rates or a change in key staff members, such as the individual the transplant center designates to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician." This would be a new requirement for kidney, pancreas, heart-lung, and intestine transplant centers. We believe this requirement is necessary for all transplant centers to ensure that each transplant center maintains the resources and commitment needed to safely and efficiently perform

transplants throughout its approval period.

Condition of Participation: Pediatric Transplants (Proposed Section 482.76)

Section 4009(b) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) (Pub. L. 100-203) indicates that pediatric heart transplant centers are Medicare-approved heart transplant centers if they meet certain criteria. Public Law 100-203 specified the following criteria: (1) The hospital's pediatric heart transplant center is operated jointly by the hospital and another facility that is Medicare-approved; (2) the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and (3) the hospital demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients (See Section 35-87 of the Coverage Issues Manual). We currently use criteria for pediatric liver and lung transplant centers similar to the criteria that were specified by Congress for pediatric heart transplant centers. (See Section 35-53.1 of the Coverage Issues Manual for liver transplants and 60 FR 6537 for lung transplants.)

Since many centers that perform pediatric transplants are not jointly operated by another facility that is Medicare-approved, we propose to require all transplant centers, adult and pediatric, that wish to be reimbursed for pediatric transplants performed on Medicare beneficiaries to specifically request Medicare approval to perform pediatric transplants. We would approve and re-approve the center to perform pediatric transplants using the procedures described in proposed § 488.61. A center that wishes to be approved to perform pediatric transplants would have to meet the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients. However, given Congress's intent that pediatric heart centers could participate in Medicare if they meet the requirements described in section 4009(b) of OBRA 1987, we are proposing to retain the statutory criteria as an option for heart transplant centers that wish to become Medicare-approved to perform pediatric heart transplants. In other words, a center that wishes to be approved to perform pediatric heart transplants may be approved by meeting the data submission, outcome, and process requirements proposed in this regulation, or the center may be

approved by meeting the criteria in section 4009(b) of OBRA 1987.

Although all transplant centers that wish to be reimbursed for transplants performed on pediatric Medicare beneficiaries would have to request Medicare approval to perform pediatric transplants, we believe it is necessary to distinguish between two different types of centers that may provide pediatric transplantation services. In some centers, patients are predominantly adults (*i.e.*, 18 years or older) and only a few pediatric transplants are performed. In other centers, pediatric transplant programs are separate from the adult programs and may be operated by departments of pediatrics or children's hospitals where a majority of transplants are performed on pediatric patients (*i.e.*, patients younger than 18).

We propose that in centers where patients are predominantly (≤ 50 percent) adult patients, the center would need to have Medicare approval to perform both adult and pediatric transplants in order to be reimbursed for transplants performed on pediatric Medicare beneficiaries. Since few transplants are performed on children in such centers, we propose that loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, would result in loss of Medicare approval to perform pediatric transplants. However, loss of Medicare approval to perform pediatric transplants would not affect the center's Medicare approval to perform adult transplants.

Likewise, we propose that a center that predominantly (≥ 50 percent) provides transplantation services to pediatric patients (*i.e.*, a pediatric center) would need to have Medicare approval to perform both pediatric and adult transplants in order to be reimbursed for transplants performed on adult Medicare beneficiaries. In this case, however, loss of Medicare approval to perform adult transplants would not impact the center's Medicare approval to perform pediatric transplants while loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would result in loss of Medicare approval to perform adult transplants. Usually, centers that predominantly serve pediatric patients will transplant only a few young adults (18 or 19 years old) who wish to maintain continuity of care but have aged beyond the pediatric patient classification. Because of the occasional adult patients being transplanted at the pediatric centers and the relatively few pediatric transplants in general, we are not requiring a minimum number of

transplants (adult or pediatric) for pediatric centers. We are requesting comments on our proposed methodology for approving and re-approving centers that perform pediatric transplants.

[If you choose to comment on this issue, please include the caption "CENTERS PERFORMING PEDIATRIC TRANSPLANTS" at the beginning of your comments.]

Proposed Transplant Center Data Submission and Outcome Requirements

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

[If you choose to comment on this section, please include the caption "OUTCOME MEASURE REQUIREMENTS" at the beginning of your comments.]

A. Overview

Our intent in promulgating this rule is to establish quality standards for approval and re-approval of transplant centers participating in Medicare. We intend to focus regulations on the actual care being furnished and the outcomes of that care, rather than solely on the underlying policies and procedures.

The Institute of Medicine (IOM) highlighted the importance of focusing on outcomes in its report ("Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule"), published on July 22, 1999. In its recommendation on Federal oversight, the IOM articulated its view that the Department should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

Some representatives from the transplant community that attended the CMS Town Hall Meeting held in December 1999 also voiced a similar opinion that transplant center performance should be assessed using patient-centered outcome measures. However, there was no consensus on how to design an outcome-oriented system for evaluating center performance.

We recognize the fact that transplant outcomes and practices can be assessed from multiple perspectives, and there is no one single criterion that can adequately evaluate the performance of a transplant center. Therefore, we are proposing to evaluate a center's performance by measuring a center's outcomes and experience, in

combination with some specific process requirements we believe will ensure the quality of the transplant center.

In developing a proposed framework for the initial approval of transplant centers, we have included criteria of significance to an outcome-based evaluation system. We are proposing criteria for timely and complete data submission, patient survival, and graft survival.

B. Data Submission Requirements for Initial Approval of Transplant Centers

1. Current Medicare Data Submission Requirements

Under current transplant policies for heart, liver, and lung centers and the current regulations for renal transplant centers, centers applying for Medicare approval are required to supply data to CMS. As appropriate, these applicants must report every heart and liver transplant performed since 1982, every lung transplant performed since January 1, 1990, or every kidney transplant performed during the most recent year of operation and during each of the preceding 2 calendar years. The current criteria for approval of heart, liver, and lung transplant centers require centers to agree to maintain and routinely submit to CMS, in a prescribed standard format, summary data about patients selected, protocols used, and short- and long-term outcomes on Medicare and non-Medicare patients undergoing transplantation.

2. Data Collection and the OPTN

In addition to supplying transplant data to CMS, transplant centers also collect and submit transplant data to the OPTN. Under the Department's Health Information Privacy Rules at 45 CFR 164.512, which implement the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA), covered entities are permitted to use and disclose protected health information to OPOs or other organizations engaged in the procurement, banking, or transplantation of organs, eyes, or tissues from deceased donors. Therefore, data submission to the OPTN is an exception under HIPAA with respect to organ transplants. The OPTN database utilizes electronic submission, review, and modification features through a secure, encrypted web-based system. Under contract with HRSA, the OPTN develops policies concerning data submission as well as policies concerning organ procurement and transplantation.

The OPTN requires its members to submit organ-specific data electronically

to the OPTN through the use of standardized forms. There are a total of 26 different organ-specific forms containing more than 3,500 data fields. Transplant centers are responsible for submitting the appropriate organ-specific forms for each center using six form types. The OPTN also specifies time frames in which each form must be submitted to the OPTN. Below is a description of the six forms for which transplant centers are responsible and the due dates established by the OPTN for each form:

- *Transplant Candidate Registration Form*

includes waitlist data as well as other clinical and organ-specific information collected prior to transplant. There is a form for each organ type: Kidney-pancreas, kidney, pancreas, liver, intestine, heart, lung, and heart-lung. The OPTN requires transplant centers to submit the organ-specific Transplant Candidate Registration Form to the OPTN within 30 days of the form generation date.

- *Transplant Recipient Registration Form*

includes the patient status at discharge, pre- and post-transplant clinical information, as well as treatment data. The form is generated when the patient receives a transplant and is removed from the waitlist. There is a form for each organ type: kidney-pancreas, kidney, pancreas, liver, intestine, and thoracic (*i.e.*, heart, lung, and heart-lung). The OPTN requires transplant centers to complete the organ-specific Transplant Recipient Registration Form when the transplant recipient is discharged from the hospital or six weeks following the transplant date, whichever is first. The OPTN also requires transplant centers to submit the organ-specific Transplant Recipient Registration Form to the OPTN within 60 days of the form generation date.

- *Transplant Recipient Follow-up Form*

is generated six months post-transplant (excluding thoracic) and on the transplant anniversary for every living organ recipient with a functioning graft. It includes patient status, clinical, and treatment information. There is a form for each organ type: Kidney-pancreas, kidney, pancreas, liver, intestine, and thoracic. The OPTN requires transplant centers to submit the organ-specific Transplant Recipient Follow-up Form to the OPTN within 30 days of the form generation date unless the transplant recipient dies or experiences a graft failure. In such circumstances, the OPTN specifies that transplant centers are required to submit the organ-specific Transplant Recipient Follow-up Form to the OPTN within 14 days of the recipient's death or graft failure.

- *Post Transplant Malignancy Form* is generated after a malignancy has been reported on the Transplant Recipient Follow-up Form. The OPTN requires transplant centers to submit the Post Transplant Malignancy Form to the OPTN within 30 days of the form generation date.

- *Living Donor Registration Form* collects data for all living organ donors. The OPTN requires transplant centers to submit the Living Donor Registration Form to the OPTN within 30 days of the form generation date.

- *Living Donor Follow-up Form* includes patient status and clinical information collected on the living donor at intervals of six months and one year post-transplant. The OPTN requires transplant centers to submit the Living Donor Follow-up Form to the OPTN within 30 days of the form generation date.

The OPTN also includes a data submission standard that requires, among other things, 95 percent of the required forms to be completed within 90 days of their due date.

3. The Scientific Registry of Transplant Recipients (SRTR) and the Center-Specific Reports

Once the OPTN collects the required data, the SRTR, which is run by the University Renal Research Education Association (URREA) under contract with HRSA, analyzes the OPTN data and creates national and center-specific reports. Regulations at 42 CFR 121.11 require the SRTR to make center-specific information on the performance of transplant centers available over the Internet and requires the SRTR to update these data at least every 6 months. URREA updates the center-specific reports every January and July, and makes the center-specific reports available over the Internet at <http://www.ustransplant.org>.

The SRTR center-specific reports contain a variety of statistical tables based on the transplants performed at each center in the US. The center-specific reports contain information on each center's performance; including statistics on each center's waitlist activity, deceased and living donor transplant recipient characteristics and outcomes (including patient and graft survival), and donor characteristics. The SRTR also prepares national summary reports of these topics by center. Below, we provide a more detailed description of some of the statistics available in the center-specific reports.

The most important outcome for a lifesaving technology such as transplantation is whether the patient survives the procedure. Currently, the

SRTR center-specific reports provide observed and expected patient survival rates for adult and pediatric patients at the 1-month, 1-year, and 3-year reporting time point for each center. For calculation of the 1-month, 1-year, and 3-year patient survival statistics, the SRTR center-specific reports use transplants that occurred during a 2.5-year interval before a report is published. In order to maximize follow-up of patients that were transplanted towards the end of the 2.5-year interval, there may be a significant lag between the time that the last transplant in the 2.5-year period occurred and the time that patient survival statistics are reported. For example, the July 2003 center-specific reports contain 1-month and 1-year patient survival statistics for abdominal transplants (for example, kidney, kidney-pancreas, intestine, liver, and pancreas transplants) that were performed at a center between January 1, 2000 and June 30, 2002 and for thoracic transplants (for example, heart, heart-lung, and lung transplants) that were performed between January 1, 2000 and June 30, 2002. In the future, the SRTR plans to calculate 1-month and 1-year survival statistics using 2.5-year cohorts for all organs. The 3-year patient survival statistics include transplants performed between January 1, 1998 and December 31, 1999. Additionally, the SRTR center-specific reports include adult patient survival rates and pediatric patient survival rates for deceased and living donor transplants.

A center's observed patient survival rate is an estimate of the fraction of patients in each cohort that would still be alive at the reporting time point had follow-up data been received up to that time. The SRTR uses the Kaplan-Meier method to calculate a center's observed patient survival rate from the OPTN follow-up data and the Social Security Death Master File (SSDMF) data. The Kaplan-Meier method is a standard statistical technique for estimating survival at the reporting time point by assuming that the failure rate would have been the same for those patients lost to follow-up as was observed for patients with complete follow-up data.

Recognizing that some patients are lost to follow-up for reasons beyond a transplant center's control, such as a patient's change of residence, change of providers, or unreported death, the SRTR began augmenting the OPTN data by tracking all transplant patients "lost to follow-up" through the SSDMF. Although there are some flaws in the SSDMF data, it has enhanced the SRTR's ability to determine if patients "lost to follow-up" had died or were

still thought to be alive on a certain date. In addition to enhancing the accuracy of the SRTR's center-specific reports, URREA has determined that the additional data obtained from the SSDMF seems to increase the reported survival rates of some centers.

A center's expected patient survival rate is a risk-adjusted statistic that provides an estimate of the fraction of patients who would be expected to be alive at each reported time point based on the national experience for similar patients. The SRTR uses the Cox proportional hazards regression model to calculate each center's expected patient survival rate.

The Cox model is a statistical modeling technique that is widely used in the analysis of survival data. The Cox model is flexible in the types of data, event rate patterns, and covariates it can handle. It can model dependence of event rates on patient and donor characteristics in a variety of ways including time dependent proportional hazards (covariates), which are extremely useful for modeling the effect of current patient status on mortality and for modeling both short term and long term covariates effects on event rates. Information about the Cox model can be found on the Internet. For example, background on the Cox model can be found at <http://members.aol.com/johnp71/prophaz.html>.

The Cox model is designed to evaluate the outcomes among the recipients at one center, compared to what would be expected, had those same patients received a transplant at an "average" center. One of the most important features of the Cox model is the identification of the adjustment factors that could affect transplant outcomes. These factors are chosen using clinical input supported by statistical analyses. The clinical input comes from the constant review of SRTR models by experts on the OPTN committees and the Secretary's Advisory Committee on Organ Transplantation (ACOT). The Secretary established the ACOT to enhance organ donation, ensure the system of organ transplantation is grounded in the best available medical science, ensure the public that the system is as effective and equitable as possible, and thereby increase public confidence in the integrity and effectiveness of the transplantation system. Some non-statistically significant factors are also included in the Cox models used to calculate expected patient survival in order to improve validity and public acceptance of the models.

Historically, there have been more than 100 models fit for each center-specific report release (e.g., models by organ, by age group, by living/deceased donor, by follow-up time period, by graft/patient survival). Currently, the models used to calculate 1-month and 1-year patient survival are based on the same cohort of patients. The SRTR plans to begin to use a single model to calculate survival, as this would allow for more stable estimation of factors for the 1-month results, which currently are based on relatively few events. This will assure consistency in the expected values for the overall transplant population and the subpopulations of living and deceased donor recipients.

The specific risk adjustment factors that affect transplant outcomes identified in the Cox model and their weights are subject to change with each updated analysis. Semi-annually (every January and July), the SRTR assesses the goodness of fit and stability of a survival model using the index of concordance. The index of concordance is a measure of a model's ability to fit the mortality outcomes for each patient. In order to assess the stability of the models, for each center-specific report release, the models will be fit using the same list of covariates to a series of successive cohorts of transplant recipients. In addition, the values of the coefficients will be reported for each of the models while outcomes are evaluated relative to the norm, or the "average." Significant changes in the index of concordance and the coefficients over a period of time will help to identify the factors that require closer evaluation in order to be sure that the models are as up to date as possible.

In the future, the SRTR plans to complete a table for each of the center-specific report post-transplant models. The table will include the index of concordance, the coefficients, and p-values for the coefficients when the model is fit for transplants during the 2.5-year cohort used for the current center-specific report release as well as that for the two previous releases. This table will be posted publicly on the SRTR Web site (<http://www.ustransplant.org>) at the time of the preview site, which is approximately 1 month before the center-specific report public release date. It is intended to allow users to assess the stability of the models. If the fit of the models or the coefficients of the factors change markedly, one would be careful to evaluate the models to be sure that they are as up to date as possible. If the fit and coefficients do not change markedly, one could be assured that the models are stable.

For purposes of example, the Cox models used in the July 2004 center-specific reports to calculate expected 1-year patient survival rates for deceased donor adult transplants contained the following factors. (Analytic Conventions—Guide to the Center-Specific Reports, <http://www.ustransplant.org/programs-report.html>). Factors for kidney transplants included: diagnosis, donor age, donor history of hypertension, donor meets expanded donor criteria for deceased kidney, donor race, donor serum creatinine, donor cause of death, human lymphocyte antigen (HLA) mismatch, peak panel reactive antibody (PRA), recipient age, recipient ethnicity, recipient medical condition, recipient race, and year of ESRD treatment. Factors for liver transplants included: diagnosis, ABO (i.e., blood types A, B, AB, and O) compatibility, donor Hispanic/Latino, donor age, donor and recipient in the same region but not the same OPO, donor and recipient not in same region or OPO, donor race, donor cause of death, non heart beating donor, recipient portal vein thrombosis, recipient age, recipient any previous transfusions, recipient ascites, recipient creatinine, recipient ethnicity, recipient height, recipient incidental tumor found at time of transplant, recipient insulin dependent diabetes, recipient medical condition, recipient on life support, recipient previous abdominal surgery, recipient race, and split or partial liver. Factors for heart transplants included: diagnosis, donor age, donor cause of death, ischemia time, recipient creatinine, recipient height, recipient medical condition, recipient on extracorporeal membrane oxygenation (ECMO), and recipient on ventilator. Factors for lung transplants included: cardiac index, diagnosis group B, diagnosis group C, diagnosis group D, diagnosis, donor age, donor body surface area, donor history of diabetes, donor race, donor cause of death, percent predicted forced vital capacity (FVC), ischemia time, New York Heart Association (NYHA) class, oxygen required at rest, recipient age, recipient creatinine, recipient female, recipient on ventilator, recipient race, and pulmonary artery (PA) hemodynamics mean by diagnosis interaction.

As in patient survival, the SRTR also calculates observed and expected 1-month, 1-year and 3-year graft survival statistics. Using the Kaplan-Meier method, the SRTR calculates observed graft survival rates for each of the reporting time points (i.e., 1-month, 1-year, and 3-year) from OPTN and SSDMF data. Cox models are used to

calculate expected graft survival statistics for each of the reporting time points. The factors predictive of graft survival models are generally similar to those predictive of patient survival models and generally include an indicator for whether or not this was the first transplant of this type. Again, 1-month, 1-year, and 3-year graft survival statistics in the center-specific reports are stratified by age (i.e. adult or pediatric) and by donor type (i.e. deceased or living) and are calculated using only transplants that occurred during a 2.5-year interval before a report is published.

4. Proposed Data Submission Requirements

Since the SRTR center-specific reports contain a wealth of information about transplant center outcomes and the SRTR prepares its analytical reports from the data that transplant centers are already self-reporting to the OPTN, we propose that the SRTR's center-specific reports could form the foundation for our outcome evaluation system. However, we need to be certain of the completeness of the data used to evaluate each center's outcomes.

In July 2001, an article that appeared in the *Milwaukee Journal Sentinel* ("Transplant Rate Reports Don't Tell Whole Story," <http://www.jsonline.com/alive/column/jul01/marccol30072701.asp>, July 27, 2001) questioned the data used by the SRTR to generate and publish the center-specific reports. The article charged that some centers were getting away with reporting less than half of follow-up data required by the OPTN. Incomplete data can be attributed to several factors, including lost to follow-up. However, the article also alleged that some centers were purposely submitting incomplete data to skew their survival results. In order to ensure that the data used by the SRTR for analysis and compilation of the national and center-specific reports are comprehensive and accurate, we believe that it is important that we establish requirements for timely and complete reporting of data to the OPTN.

As discussed earlier, the OPTN includes a data submission standard that requires, among other things, 95 percent of the required forms to be completed within 90 days of their due date. We propose a similar data submission requirement. We propose, at § 482.80(a) that 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 percent of required data submissions on all transplants

(deceased and living donor) performed at the center. We believe it is important to maintain this 90-day grace period to ensure that transplant data collection and compilation are as complete and accurate as possible.

We propose that required data submissions include, but not be limited to, the submission of the appropriate organ-specific OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up. Requiring timely and complete submission of data will ensure up-to-date and meaningful data.

C. Outcome Measure Requirements for Initial Approval of Transplant Centers

1. Current Medicare Outcome Measure Requirements

Under the current transplant policies, transplant centers applying for Medicare approval of a heart, liver or lung transplant center are required to report their 1-year and 2-year actuarial (unadjusted) patient survival rates using the modified Kaplan-Meier method. The modified Kaplan-Meier method estimates survival at the reporting time point by treating those patients lost to follow-up as dead on the day following the last ascertained survival.

The current actuarial survival standards for heart transplants were developed in 1986. According to those standards, a center is required to demonstrate an actuarial survival rate of 73 percent for 1 year and 65 percent for 2 years for patients who have had heart transplants since January 1, 1982 at that center. Current criteria for approval as a liver transplant center were developed in 1991 and require an actuarial survival rate of 77 percent for 1 year and 60 percent for 2 years for the time period the center is using to calculate survival. The criteria for lung transplants were published in our February 1995 notice of Medicare policy for lung transplants. The criteria require centers to maintain a 1-year actuarial survival rate of 69 percent and a 2-year actuarial survival rate of 62 percent for all transplant cases occurring on or after January 1, 1990.

The Medicare National Coverage Decision that we issued in October 2000 requires intestinal centers to have a 1-year actuarial survival rate of 65 percent for intestinal and multivisceral transplants. The required intestinal threshold is based on a weighted average of the national 1-year patient survival rates for small bowel transplantation, small bowel/liver transplantation, and multivisceral transplantation data from the literature reports on the international intestinal transplant registry. There are no

survival standards in place for kidney, pancreas, and heart-lung transplant centers for Medicare approval.

2. Appropriateness of Current Survival Criteria

At the time the survival criteria for heart, liver and lung transplants were developed, organ transplants were largely viewed as experimental procedures and the survival criteria were designed to be high enough to ensure that Medicare-approved transplant centers were high-quality institutions but low enough to ensure that centers did not exclude high-risk patients. Aided by remarkable advances in medicine and cutting-edge technology, survival rates for heart, liver, and lung transplant patients have steadily increased since our criteria were established. For example, according to the 2003 OPTN/SRTR Annual Report, the unadjusted 1-year patient survival figures for transplants performed between 2000–2001 for deceased donor heart, liver, and lung transplantation were 86 percent, 86 percent, and 78 percent, respectively. The recent national 1-year patient survival rates are considerably higher than the corresponding Medicare 1-year patient survival standards of 73 percent for heart, 77 percent for deceased donor liver, and 69 percent for lung transplantation. It seems clear that the Medicare survival criteria currently used for Medicare approval of heart, liver, and lung centers would not be appropriate under an outcome-oriented set of standards.

We believe it is necessary for us to establish outcome measure requirements for transplant centers to protect patient safety and, given the scarcity of donor organs, to ensure that donor organs, once recovered, are transplanted effectively and are not wasted. In an effort to assure that transplant centers furnish transplantation services efficiently, we believe we need to establish a system for approval and re-approval of transplant centers that focuses on a center's outcomes. A center's outcomes serve as indicators of the center's ability to furnish transplantation services successfully. Since we are proposing a system that focuses heavily on outcomes, it is critical that the outcome standards reflect current conditions. Consequently, we are proposing significant changes in the standards that would be applicable to Medicare approval.

Moreover, we believe our responsibility to ensure that transplantation services are furnished safely and efficiently is no less

important to those beneficiaries in need of kidney transplants than those in need of heart, liver, or lung transplants. Therefore, we are proposing to develop survival criteria for kidney transplant centers.

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

It has been widely acknowledged by the transplant community that a transplant center's performance should be measured on the basis of its outcomes. However, there is no consensus on how to develop an outcome-oriented evaluation system. In developing an outcome-oriented system for evaluating center performance, some issues we considered are what types of measures should be used, how many measures to include, and whether to include both short and long-term outcomes.

The transplant community considers post-transplant outcomes, such as patient and graft survival, to be the "gold standard" for evaluating a transplant center's performance. While post-transplant outcomes, which measure the outcomes of transplant recipients, are widely accepted as meaningful measures of transplant center performance, organ transplantation is both a short and long-term experience.

We currently evaluate a center's performance on the basis of a single outcome measure, patient survival. For the purposes of this proposed rule we considered continuing to evaluate a center's performance on the basis of a single outcome measure. However, this approach could encourage centers to neglect other outcomes. For example, a kidney center might focus its efforts on ensuring that a kidney recipient survives to the detriment of the survival of the graft, since dialysis provides an alternative to death for kidney recipients with a failed graft.

Additionally, we are concerned that use of patient survival rates alone would not paint a complete picture of the quality of transplants performed at a center. While patient survival rates measure patient mortality, patient survival rates do not measure patient morbidity or the success of the actual transplantation procedure. Therefore, we are not proposing to limit outcome criteria for initial approval to patient survival; we are proposing a graft survival criterion as well.

We do not propose to use graft survival exclusively because patient survival is also an important measure for assessing a transplant center's quality. For example, if a transplant

center lost grafts only due to patient deaths, its outcomes may not be poor with respect to graft survival. However, since patient deaths are supposed to occur less frequently than graft loss due to re-transplants and dialysis, this transplant center may have a significantly lower than expected patient survival.

Therefore, we are proposing to use both graft and patient survival as outcome measures that would portray a center's actual performance more accurately. The proposed outcome measure requirements, like the other proposed requirements for initial approval, serve as one of several requirements that transplant centers seeking initial approval would have to meet in order to begin furnishing transplantation services that are covered by Medicare.

We also considered looking at both short-term and long-term outcomes, such as the 2-year statistics we currently require. However, we realize that long-term outcomes are more susceptible to exogenous factors not directly related to the transplantation procedure. After careful analysis of these issues, we propose using 1-year patient survival and 1-year graft survival (and in certain circumstances, 1-month patient survival and 1-month graft survival in lieu of 1-year patient survival and 1-year graft survival) as outcome measures for initial approval. We propose to require centers to meet both the 1-year patient survival and 1-year graft survival requirements separately. We propose to assess a transplant center's 1-year patient and graft survival by comparing a transplant center's expected 1-year patient and graft survival rate to its observed 1-year patient and graft survival rate for all transplants performed in the center, including living donor transplants if applicable. We propose to review a center's observed patient and graft survival against its expected patient and graft survival using a methodology that was developed by the SRTR and used by the OPTN. (This methodology, including its development, is discussed in detail below.) We propose to review a center's outcomes using the patient and graft survival data contained in the most recent SRTR center-specific report.

We also propose to review adult and pediatric outcomes separately if a center other than a lung transplant center requests Medicare approval to perform pediatric transplants. For most organ types, the SRTR has developed separate Cox models for calculating expected patient and graft survival statistics for adult (18 and older) and pediatric (younger than 18) patients. For lung transplants, however, the SRTR

stratifies recipient outcomes using other categories—(1) patients that are 12 and older or (2) patients that are less than 12. Since most lung transplants performed on pediatric patients, which is traditionally defined as patients that are younger than 18 years old, are performed on older children, we propose to use the 1-year patient survival data on patients who are at least 12 years old to assess both adult and pediatric outcomes.

a. Proposed Outcome Evaluation Methodology

Some of the attendees in the CMS Town Hall Meeting expressed the view that transplant centers should be evaluated on the basis of risk-adjusted outcomes because risk adjustment can reduce the impact of patients' diverse risk factors on survival rates. We agree that risk adjustment addresses the potential to inadvertently penalize centers for transplanting high-risk patients or using organs from extended criteria donors. We believe risk adjustment can level the playing field for all transplant centers. As such, we propose an evaluation system that relies on the SRTR's risk-adjusted data.

The SRTR methodology, which was adopted by the OPTN's Board of Directors in June 2003, was designed to update deficiencies in prior OPTN methods. A discussion of prior methods used by the OPTN is available in the OPTN Proposal Archive, March 14, 2003–32 Proposals (Proposed Modifications to OPTN/UNOS Bylaw Appendix B (Criteria for Institutional Membership), Section III (Transplant Programs) at <http://www.optn.org/policiesAndBylaws/publicComment/proposalsArchive.asp>. The current SRTR method, which is being proposed for use by CMS, uses a three-pronged approach that takes into consideration (1) statistical certainty; (2) the value of the finding for allocating resources to perform on-site surveys; and (3) the need for taking action. This three-pronged approach provided the OPTN's Membership and Professional Standards Committee (MPSC) with a balanced tool for assessing transplant center performance without creating excessive demand on the resources of the MPSC.

Specifically, the SRTR methodology compares observed outcomes to expected outcomes using three tests: (1) The p-value to test for statistical significance, (2) the number of observed events (*i.e.*, patient deaths or graft failures) minus the number of expected events ($O - E$), and (3) the number of observed events divided by the number of expected events (O/E). When a transplant center crosses over the

thresholds for all three tests, it is identified for further review by the OPTN.

The first prong of the three-pronged approach of the SRTR methodology is statistical certainty, which is based on assessing whether the difference between the observed number of deaths or graft failures is statistically significantly more than the expected number. Statistical tests often use p-values to distinguish whether chance can or cannot be ruled out or chance is a likely or unlikely explanation for the differences documented between two observations. The p-value measures the statistical significance (or evidence) for testing a hypothesis. Usually, this hypothesis is either that two numbers are equal to each other or that a number is different from zero. A p-value of less than 0.5 (indicating that there is less than a 5 percent chance that any observed difference offered by random chance alone) is often considered "statistically significant". Consequently, the p-value helps to identify centers where chance is an unlikely explanation for the differences between the center's observed events and its expected events.

A low p-value generally indicates that chance is an unlikely explanation for the differences between the actual and expected outcomes. The MPSC determined that a p-value less than 0.05 would be adequate to assure the statistical certainty of the difference between the observed and expected number of deaths or graft failures.

The second prong of the three-pronged approach of the SRTR methodology is the value of the finding for allocating resources to perform on-site surveys. The number of observed events minus the number of expected events (that is, the number of patient deaths or graft failures a transplant center would expect to have based on its patient population) helps to identify centers with relatively large numbers of unexpected events. The OPTN uses the results of this test to determine how to allocate its limited resources available for the review of centers. This avoids allocation of resources to centers with only a small fraction of unexpected deaths. The SRTR proposed a threshold value for each test. The MPSC determined that the number "3" (that is, 3 more patient deaths or graft failures than expected) would be adequate to assure that there was meaningful clinical information to assess for deficiencies in a transplant center ($O - E > 3$). Few smaller centers are expected to show statistical significance (*i.e.*, show a p-value < 0.05) because, from a statistical perspective, it hard to rule out chance when working with

small numbers. Therefore, one could expect that fewer small centers than large centers potentially would be identified using the SRTR methodology.

The OPTN MPSC recognized that it would need to be able to appropriately flag smaller cohorts, especially since the center-specific reports separate adult and pediatric transplants. As such, in 2001, the SRTR presented some analyses that would help the OPTN MPSC decide upon the minimum number of transplants needed in order for the SRTR methodology to flag smaller cohorts. Transplant centers that performed fewer transplants than this minimum number would not be reviewed using the SRTR methodology.

Although a single death has a much greater impact on a center's patient survival rate in a smaller center than in a larger center, the OPTN MPSC felt that the percentage difference when working with smaller cohorts was less useful from a clinical perspective because of the smaller numbers. For example, a transplant center that performs 10 transplants and loses 1 graft has a 90 percent survival rate whereas a center that performs 11 transplants and loses 2 grafts has an 82 percent survival rate. Although the difference between 90 percent and 82 percent may appear to be

significant, when only 10 transplants have been performed, the absolute difference between the loss of 1 graft and 2 grafts is small. The MPSC felt that this type of difference was not sufficient to distinguish small cohorts. Therefore, the MPSC asked the SRTR to help them determine the minimum number of transplants required for the SRTR methodology to flag a transplant center and to have that "flag" be clinically appropriate.

In deciding upon the minimum number of transplants required for use of the SRTR methodology, the OPTN recognized that small transplant centers had to have a minimum excess of graft failures/deaths before there was adequate clinical information to evaluate for deficiencies in the transplant center. Since the minimum number of excess graft failures/deaths was determined to be 3, a transplant center would have to perform at least 4 transplants in order to have an excess of 3 deaths. However, performing 4 transplants and having a 100% graft failure/death rate was not clinically acceptable. Therefore, the SRTR developed a scenario in which a transplant center's expected graft failure/mortality rate was 10 percent, but its actual graft failure/mortality rate

was 50 percent. Using this scenario, the SRTR methodology could flag cohorts as small as 8 transplants. Based on this finding, the OPTN MPSC decided to use the SRTR methodology on cohorts (adult or pediatric) of at least 9 transplants. As the number of transplants increase, the clinical concordance of observed and expected mortality rates should also increase.

The third prong of the approach of the SRTR methodology is the need for taking action. The MPSC determined that it would need to take action when it determined that the observed number of deaths or graft failures was 50 percent more than expected (O/E>1.5).

We applaud the SRTR's effort to strive for better ways to identify under-performing transplant centers. We have carefully reviewed and evaluated the SRTR's methodology for flagging under-performing transplant centers. We believe the SRTR approach to handling small centers is reasonable. To address concerns that the methodology could be perceived as being more lenient towards smaller centers, we analyzed transplant center data from the most recent SRTR center-specific report and found that it flagged centers of all size ranges. Of the 72 small centers (9–25 transplants), 15% were flagged.

ADULT PROGRAMS FLAGGED BASED ON CENTER SIZE

Center size	Number of programs (1)	Number of programs flagged (patient/graft/both) (2)	Flagged/program (2)/(1)
<9	71	0 (0.0%)	0%
9–25	72	11 (20.4%)	15.3%
26–50	98	11 (20.4%)	11.2%
51–100	121	13 (24.1%)	10.7%
101–200	111	15 (27.8%)	13.5%
201–500	60	3 (5.6%)	5.0%
>500	8	1 (1.9%)	12.5%
Total	541	54 (100.0%)	

We believe that the analyses we conducted shows that the p-value test performs very well for centers with at least 9 transplants. Given the fact that an adult center has to have performed 9 transplants in order to enable the SRTR methodology to capture differences during the 2.5 year cohort period, we believe the SRTR methodology can maintain a delicate balance between able to identify the outliers in both large and small centers. We are requesting comments on the appropriateness of proposing this approach.

We propose adapting the general framework of the SRTR methodology to assess a heart, liver, lung, or kidney

transplant center's outcomes for our use. That is, we propose that if a transplant center's observed 1-year patient survival rate and 1-year graft survival rate is lower than the expected 1-year patient survival rate and 1-year graft survival rate, respectively, we would use the three SRTR tests (p-value, O – E, and O/E) to determine whether a center's observed survival rates were unacceptably low and whether thus the center would require CMS follow up.

For each of the outcome measures we proposed for initial approval of heart, liver, lung, and kidney centers, we propose establishing minimum thresholds for the p-value, O – E, and O/E tests. One of the primary concerns

expressed by beneficiaries at our Town Hall Meeting was access to their choice of transplant centers. Therefore, we want to establish a mechanism whereby all transplant centers that perform at or near their expected outcomes are able to obtain initial Medicare approval for transplantation. We recognize that the threshold we establish for each test would affect the quality of care, number and location of centers, and access to centers. It is our goal to establish thresholds to ensure access while ensuring that Medicare beneficiaries receive high quality organ transplantation services. After careful evaluation of SRTR's analysis and OPTN's reasoning, we propose to adopt

thresholds that mirror those adopted by the OPTN.

Specifically, for each outcome measure, we propose considering the center's patient and graft survival rate to be acceptable as long as the center's observed patient and graft survival rate is higher than the center's expected patient and graft survival rate. If a center's observed patient and graft survival is lower than its expected patient or graft survival, we would still consider the center's patient and graft survival rate to be acceptable, unless all three of the following thresholds are crossed over:

- The one-sided p-value is less than 0.05;
- The number of observed events minus the number of expected events ($O - E$) is greater than 3; and
- The number of observed events divided by the number of expected events (O/E) is greater than 1.5.

Our justification for these thresholds is the same as that of the OPTN when it adopted the thresholds in June 2003. A one-sided p-value less than 0.05 can loosely be interpreted to mean that there is a 95 percent probability that the difference between a center's observed patient or graft survival rate cannot be explained by random fluctuations. Therefore, we believe that establishing the threshold for the p-value at 0.05 provides us with reasonable assurance that a transplant center's observed patient or graft survival rate truly cannot be attributed to external factors that may also influence patient or graft survival, as opposed to being the result of a random fluctuation (*i.e.* the difference between the observed and expected is statistically significant). A difference between the observed number of events (*i.e.*, patient deaths or graft failures) and the number of expected events that is greater than 3 indicates that 3 or more of the observed events were unexpected. In establishing the threshold for the $O - E$ test at 3, our goal was to strike a balance between establishing a threshold that is high enough to avoid identifying centers where the absolute number of unexpected events is very small and establishing a threshold that is low enough to reflect that a non-trivial number of patients were affected. When the quotient of the number of observed events divided by the number of expected events is greater than 1.5, this indicates that a substantial fraction (more than 50 percent) of the observed events were unexpected. Therefore, the proposed thresholds for the $O - E$ and O/E tests help to identify centers in which a relatively large portion of the center's transplants resulted in an

unexpected adverse outcome (*i.e.*, patient death or graft failure).

For each outcome measure, we propose that only when a heart, liver, lung, or kidney center crosses over the thresholds established for all three tests, would we consider the center not to be in compliance with the requirements for that particular outcome measure. For example, we would consider a center that demonstrates a p-value of 1.00, $O - E$ of 5.0, and O/E of 2.0 based on the 1-year patient survival data contained in the most recent SRTR center-specific report to meet the patient survival requirement because one of the three thresholds (that for the p-value test) was not crossed over. On the other hand, a center that demonstrates a p-value of 0.01, $O - E$ of 5.0, and O/E of 1.9 for its patient survival data would cross over the thresholds for all three tests; therefore, we would not consider the patient survival requirement to be met.

Transplant centers would have to meet the requirements for each of the outcome measures (*i.e.*, patient survival and graft survival) separately. In other words, a center that meets the requirements for patient survival but not for 1-year graft survival would not meet the proposed outcome measure requirements. By considering centers whose observed outcomes are lower than their expected outcomes to be acceptable unless they cross over the thresholds for all three tests, we believe that we can be reasonably assured that any center identified using this methodology will have both a statistically significant and non-trivial number of unexpected deaths or graft failures. Centers in which the number of unexpected events is relatively large but not statistically significant or in which the number of unexpected events is statistically significant but relatively small would not be inadvertently penalized under this proposed methodology.

We are proposing that an adult transplant center requesting Medicare approval would have to have 1-year patient and 1-year graft survival follow-up data on at least 9 transplants of the appropriate organ type during the 2.5-year period reported in the most recent center-specific report. In other words, centers that perform fewer than 9 transplants generally would not be eligible for Medicare approval under our proposal. We are asking for comments as whether requiring the minimum number of 9 transplants during the 2.5-year period is acceptable for this application of the SRTR methodology.

CMS is cognizant that requiring a minimum number of transplants may appear to limit access to transplantation

for Medicare beneficiaries. However, given that the proposed minimum number of transplants of 9 is lower than the current Medicare requirements (12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung and intestinal transplant centers), we do not believe this requirement would lessen current access to transplant centers. As stated earlier, our analysis of the most recent SRTR center-specific reports indicates that approximately 71 adult transplant centers performed fewer than 9 transplants in the most recent 2.5-year period. It appears that the majority of the smaller cohorts involved pediatric cases, transplant centers at children's hospitals, or centers in transition. After careful analyses, we found that 45 of those centers were the adult component of a pediatric center, which does not have to meet the proposed volume requirement. Of the remaining 26 centers, only 11 are currently active according to the records of the OPTN. Of those 11 centers, there are 5 heart centers, 1 kidney center, 2 liver centers and 3 lung centers. Also, four centers have 7–8 transplants (and could easily reach 9 transplants); 2 centers are affiliated with a large transplant center; one center recently opened; and 2 centers are located in cities with a nearby transplant center.

OPTN requirements are similar to those we propose. The OPTN currently requires that heart, kidney and liver transplant centers perform a minimum of one transplant every 3 months, which equals approximately 9–10 transplants over the course of 2.5 years. Although lung transplant programs are required to perform a transplant only once every 6 months, there were only 3 lung centers that did not perform at least 9 transplants.

Given the very specialized care that needs to be provided to children, as well as the relatively few children who are Medicare beneficiaries, we did not want to restrict access to this group by setting a volume threshold that was inappropriately high. Although we have stated we would review pediatric outcomes separately if a transplant center requests Medicare approval to perform pediatric transplants, we propose not to require such centers to perform a minimum number of pediatric transplants prior to their request for approval. Most centers that would request Medicare approval to perform pediatric outcomes are likely to perform only 2 or 3 transplants per year. Analyses conducted by HRSA's DoT staff indicate that a minimum volume requirement that would still allow the

SRTR's methodology to flag poor-performing centers would preclude most children's hospitals from being able to request Medicare approval. The OPTN, also recognizing the infrequency of pediatric transplantation, requires that only one transplant per year be performed to demonstrate that the pediatric center is functionally active. We request comments on this proposal.

We recognize that there may be some concerns related to our proposed minimum number criterion because the current Medicare volume standards for heart, liver, lung, and intestinal centers are higher. Medicare currently requires heart and liver transplant centers to perform 12 transplants over a 12-month period, and lung and intestinal transplant centers to perform 10 transplants over a 12-month period. Historically, we have used volume as a proxy for outcome. Since we now have risk-adjusted outcome measures, we believe it would be insufficient to propose a volume standard that would be viewed as arbitrary or unscientific. Instead, our volume requirement should only reflect the minimum number of transplants needed for the SRTR to be able to flag a poor-performing center, that is, 9 transplants performed during the reporting period.

If a heart center is requesting Medicare approval in December 2004, we would rely on the 1-year patient and graft survival data contained in the July 2004 SRTR center-specific report. Since the July 2004 report contains 1-year patient and graft survival data on transplants performed between January 1, 2001 and December 31, 2002, we would expect that the July 2004 center-specific report include 1-year patient and graft survival information on at least 9 heart transplants that were performed between January 1, 2001 and December 31, 2002. Meanwhile, a kidney transplant center that requests Medicare approval in December 2004 would be expected to have 1-year patient and graft survival follow-up information on at least 9 kidney transplants that were performed between January 1, 2001 and June 30, 2003, since the SRTR used a 2.5-year cohort in the July 2004 center-specific report to report patient and graft survival statistics for abdominal organs.

This lower volume criterion may also raise the concern that a center could perform 9 transplants quickly and then not perform a transplant for 12 months and yet become or remain Medicare approved. However, we believe this scenario is unlikely to occur because of additional oversight provided through the OPTN. In 1996, the MPSC of the OPTN proposed changes to the bylaws

that would define a functionally inactive transplant center's responsibility to patients on the waiting list. In order to identify such centers, the MPSC set forth criteria that would trigger further investigation of transplant center functional inactivity. Initially, the MPSC considered a transplant center to be functionally inactive if it did not perform a transplant within a 3-month period. As the MPSC has gained greater understanding of the impact of the organ procurement and allocation process on a center's ability to perform transplants, it has revised the initial criteria for determining whether a center is functionally active: for heart, liver and kidney centers—a transplant every 3 months; for lung centers—a transplant every 6 months; for children's hospitals—a transplant once a year. In addition to these frequency standards, the MPSC also reviews organ offers and turndowns at centers that have not performed a transplant recently to determine whether the reason for inactivity is due to lack of suitable organ offers or inadequate resources at the transplant center. If the OPTN determines that a transplant center is functionally inactive, the transplant center is no longer eligible to receive organs for transplantation, and therefore, can no longer perform transplants. These OPTN reviews offer additional oversight to assure the public and Medicare that the organ transplant centers are truly functionally active at the time of Medicare approval and re-approval. We request comments on our proposal to focus more heavily on a center's outcomes by eliminating volume as a separate standard and integrating volume into our outcomes assessment.

b. Evaluation of Alternatives to the SRTR Methodology

Based on our analysis of the July 2004 SRTR center-specific reports, we believe that a majority of the heart, kidney, liver, and lung centers would be able to meet the proposed 1-year patient and 1-year graft survival requirements. Using data from the July 2004 SRTR center-specific reports, approximately 10.0 percent of all heart, kidney, liver, and lung centers that perform adult transplants have observed outcomes that are lower than their expected outcomes and cross over the proposed thresholds for the three tests in terms of both 1-year patient survival and 1-year graft survival. In other words, if all heart, kidney, liver, and lung centers that perform adult transplants were to seek initial Medicare approval simultaneously, approximately 10.0

percent of the 541 heart, kidney, liver, and lung centers that perform adult transplants would not be able to meet the proposed outcome measure requirements. Also, approximately 1.9 percent of the 309 heart, liver, lung, and kidney centers that perform pediatric transplants have observed outcomes that are lower than their expected outcomes and meet the proposed thresholds for all three tests. We invite comments on the proposed outcome measures and their thresholds. We specifically solicit data and evidence that may support alternative thresholds, especially thresholds that may be specific to a particular organ transplant type.

We also welcome comments on the methodology itself. We understand that the OPTN continuously reviews this methodology and may make modifications to the methodology or the thresholds for the three tests in the future. In the event that the OPTN decides to modify the methodology or any of the thresholds currently used, we would consider adopting the modified methodology or thresholds through notice and comment rulemaking.

In addition, we explored two options for applying the SRTR methodology. We would like to take this opportunity to welcome comments on these other options as well. In one option, a heart, kidney, liver, or lung center whose observed outcomes are lower than its expected outcomes would be considered to have unacceptable outcomes if it met the proposed thresholds for just two of the three tests (hereafter referred to as option 1. When we analyzed the data in the July 2004 SRTR center-specific reports, we discovered that option 1 would identify approximately 15.7 percent of the heart, kidney, liver, and lung centers that perform adult transplants and 4.2 percent of the heart, kidney, liver, and lung centers that perform pediatric transplants.

A second option consists of considering a center's outcomes to be unacceptable if its observed outcomes are lower than its expected outcomes and the center met the proposed threshold for just one of the three tests (hereafter referred to as option 2. If option 2 were selected, approximately 41.6 percent of the heart, kidney, liver, and lung centers that perform adult transplants would fail to meet the proposed 1-year patient survival and 1-year graft survival requirements and approximately 67.0 percent of the heart, kidney, liver, and lung centers that perform pediatric transplants would fail to meet the proposed 1-year patient survival and 1-year graft survival requirements.

Considering a transplant center's outcomes to be unacceptable when the center's observed outcomes are lower than its expected outcomes and the center crosses over the proposed threshold for just one or two of the three tests is more stringent than our proposal. However, we are concerned that under this option, we would be conducting inspections on centers where the differences between the observed and expected events are relatively large but not statistically significant, thus diverting resources that should be expended surveying centers

where the differences between the observed and expected events are both large and statistically significant. Therefore, we are proposing to consider a center's outcomes to be unacceptable only when a center's observed outcomes are lower than its expected outcomes and the center crosses over the proposed thresholds for all three tests. We are inviting comments on the merits of our proposed approach.

For comparison, we have summarized the results of our analysis of the effects of our proposal as well as options 1 and 2 in the table below. We used data from

the July 2004 center-specific reports to perform this analysis. We did not, however, screen out centers that performed fewer than 9 adult transplants when we conducted this analysis. Therefore, some of the centers that perform adult transplant that were identified using the proposed methodology or using option 1 or option 2 may not be eligible to request Medicare approval because they did not perform 9 adult transplants during the 2.5-year period reported in the July 2004 center-specific reports.

NUMBER AND PERCENT OF CENTERS IDENTIFIED AS FAILING TO MEET PROPOSED OUTCOME MEASURE REQUIREMENTS UNDER PROPOSAL AND OPTIONS 1 AND 2, BY ORGAN AND TRANSPLANT TYPE (ADULT OR PEDIATRIC)

Organ type	Number (n) and percent (%) of centers identified using:											
	Adult transplants						Pediatric transplants					
	Proposal		Option 1		Option 2		Proposal		Option 1		Option 2	
	n	%	n	%	n	%	n	%	n	%	n	%
Heart	11	8.7	20	15.9	45	35.7	0	0.0	3	4.4	18	26.5
Liver	11	10.3	15	14.0	43	40.2	3	4.2	4	5.6	19	26.8
Lung	7	10.0	8	11.4	25	35.7	0	0.0	0	0.0	10	100.0
Kidney	25	10.5	42	17.6	112	47.1	3	1.9	6	3.8	160	100.0
All Organs	54	10.0	85	15.7	225	41.6	6	1.9	13	4.2	207	67.0

c. Special Circumstances in Which 1-Month Patient and 1-Month Graft Survival May Be Used in Lieu of 1-Year Patient and 1-Year Graft Survival

We are also proposing that, under certain circumstances, we would review a center's outcomes using 1-month post-transplant data in lieu of 1-year post-transplant data. We recognize that transplant teams sometimes move from one hospital to another to open a new transplant center. It is not uncommon for new centers staffed with an experienced team to have good outcomes. These new centers that request Medicare approval may not have 1-year patient and graft survival data (including follow-up data from at least 9 adult transplants performed during the 2.5-year period reported in the SRTR center-specific reports). At a minimum, 1-month post-transplant data can demonstrate the success of the transplantation procedure as well as the skill of the transplantation team. We believe that in the absence of 1-year post-transplant outcomes, 1-month post-transplant outcomes can capture early graft and patient deaths due to poor transplantation skills and poor donor and/or recipient selection. These data are important in the assessment of a new transplant center.

Therefore, we are proposing that a new transplant center may request initial approval using 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 transplant center for a minimum of 1 year prior to the opening of the new center and if the transplant center's team meets the human resources requirements at § 482.98. If these specific conditions are not met, the new center must be reviewed using 1-year post-transplant patient and graft survival follow-up data. A new center with an experienced team requesting initial Medicare approval that does not have 1-year patient and graft survival follow-up data (including 1-year follow-up data on at least 9 adult transplants for centers requesting Medicare approval to perform adult transplants) in the most recent SRTR center-specific report would have to ask the SRTR to generate a customized report of the center's 1-month patient and 1-month graft survival statistics for all transplants performed in the previous 1-year period. The SRTR would generate these customized reports using the same models as those used to generate the center-specific reports.

When 1-month post-transplant outcomes are used, we would review the center's 1-month patient and graft survival rates for all transplants performed at the center during the previous 1-year period using

customized reports. We would evaluate the center's 1-month outcomes using the same SRTR methodology that we propose for evaluating transplant centers' 1-year outcomes. The transplant center would need to have follow-up data on at least 9 transplants of the appropriate organ type. Instead of 1-year follow-up data on at least 9 transplants performed at the center during the 2.5-year period reported in the SRTR center-specific reports, however, the center would need a customized report with 1-month follow-up data on at least 9 transplants performed during the previous 1-year period.

Centers which gain Medicare approval based on 1 month data would be reevaluated based on 1 year data when it became available. We are requesting comments on the frequency with which we should assess these centers after they are approved.

If a center other than a lung transplant center requests Medicare approval to perform pediatric transplants on the basis of its 1-month patient and graft survival data, we would continue to review the adult and pediatric outcomes separately. We do not propose a volume criterion for approving centers to perform pediatric transplants when a center's 1-year patient and graft survival data are used. Therefore, we do not propose a volume criterion for Medicare approval of a center to perform pediatric

transplants when 1-month patient and graft survival data are used.

4. Proposed Outcome Measure Requirements for Heart-Lung, Intestine, and Pancreas Centers

Due to the limited volume of heart-lung, intestinal, and pancreas transplants performed nationwide, the OPTN has not been able to gather enough transplant data on these organ types for the SRTR to develop Cox models for calculating expected survival statistics for these types of transplants. We prefer not to gauge a transplant center's performance on the basis of unadjusted data. Unadjusted data, or a center's observed outcomes, do not take into account variation among transplant centers, such as differences in patient case-mix. We believe evaluating a transplant center on the basis of unadjusted data could potentially discourage centers from performing transplants on severely ill or high-risk patients. Therefore, for heart-lung, intestinal, and pancreas transplant centers, we propose no outcome measure requirements at this time. In the event that the SRTR develops risk-adjustment models for heart-lung, intestinal, or pancreas transplant survival rates in the future, we will consider establishing outcome measure requirements for heart-lung, intestinal, or pancreas transplant centers through rulemaking.

When the Medicare coverage criteria for heart transplants were published in 1987, heart-lung transplants were considered to be experimental and were not covered by Medicare. When the Medicare coverage criteria for lung transplants were published in 1995, we stated that Medicare would cover heart-lung transplants for beneficiaries with progressive end-stage cardiopulmonary disease when they were provided in a facility that was approved by Medicare for both heart and lung transplantation. Although Medicare began covering heart-lung transplants as well as single and double lung transplants, we did not establish separate survival criteria for heart-lung transplants. Instead, lung centers were required to have an aggregate 1-year survival rate of 69 percent and an aggregate 2-year survival rate of 62 percent. In calculating its survival rates, centers were asked to include single and double lung transplants, as well as heart-lung transplants.

When the SRTR calculates statistics for lung transplants, however, the SRTR does not include heart-lung transplants because there is a separate category of data for heart-lung transplants. Even though the SRTR has a separate category

for heart-lung transplant data, the data are not risk-adjusted. We propose that a heart-lung center, as defined in the proposed definition for a "heart-lung transplant center," would need to meet just the proposed data submission requirements to be compliant with the proposed Data Submission and Outcome Requirements for Initial Approval of Transplant Centers CoP. In light of the proposed definition for "heart-lung transplant center," which requires heart-lung centers to be located in a hospital that has Medicare-approval to perform both heart and lung transplants, and the fact that only 33 heart-lung transplants were performed in the U.S. in 2002, we believe that we would have reasonable assurance that the heart-lung center has sufficient expertise to perform heart-lung transplants successfully. We believe skill and expertise in both heart and lung transplantation are sufficient for ensuring that a center is able to perform high quality heart-lung transplants and that separate patient and graft survival rate criteria for heart-lung centers would not be necessary. Again, we request comments on the appropriateness of this approach for evaluating heart-lung transplant centers, as well as alternatives to this approach.

The Medicare coverage decision for multivisceral and intestinal transplants was issued on October 4, 2000 and only covers services provided on or after April 1, 2001. Since only 299 intestinal transplants were performed from 2000 through 2002, it is probable that the current Medicare 1-year patient survival threshold of 65 percent for intestinal transplants continues to be relevant. We are reluctant to establish outcome measure requirements on the basis of unadjusted data. Unlike heart-lung centers, intestinal centers do not have to be affiliated with any other type of center under current Medicare requirements. Historically, however, intestinal centers have evolved as an extension from the liver transplant centers. In 2002, there were 107 intestinal transplants, of which only 44 were intestine alone transplants. Given the historical affiliation of intestinal transplant centers with liver transplant centers and the very small number of intestinal transplants being performed, we are proposing that there not be any outcomes or volume criteria for intestinal transplantation. We believe that the proposed definition for "intestinal transplant center," which requires transplant centers to be located in a hospital that has Medicare approval to perform liver transplants, would be sufficient. Intestinal transplant centers

would need to meet the proposed data submission requirements. We are requesting comment on the appropriateness of the proposal to approving intestinal transplant centers in light of the absence of risk-adjusted outcomes data for intestinal transplantation, the very low frequency of this type of procedure, and potential concerns that setting volume standards would further limit access to a rare procedure.

Of the 1,369 deceased donor pancreas transplants performed in the United States in 2003, 502 were performed alone or subsequent to a kidney transplant and 867 were performed simultaneously with a kidney transplant (*i.e.*, kidney-pancreas transplants). According to the July 2003 SRTR national summary report, the national mean 1-year patient survival rate for adult pancreas transplants performed alone or subsequent to a kidney transplant is 96.01 percent and the national mean 1-year graft survival rate is 78.34 percent. Since the number of pancreas transplants performed alone or subsequent to a kidney transplant is very small, the outcomes are generally very good, and the SRTR has not established a risk-adjustment model for pancreas transplants performed alone or subsequent to a kidney transplant, we do not propose any outcome measure requirements for pancreas transplant centers. We believe that the proposed definition for "pancreas transplant center," which requires transplant centers to be located in a hospital that has Medicare approval to perform kidney transplants, would be sufficient. As with heart-lung and intestinal transplant centers, a pancreas transplant center would still need to meet the data submission requirements to be in compliance with the proposed Data Submission or Outcome Requirements for Initial Approval of Transplant Centers CoP at § 482.80. We request comments on the appropriateness of this approach to evaluating pancreas transplant centers in light of the lack of risk-adjusted data for pancreas transplants that are performed alone or subsequent to a kidney transplant.

We note that these standards would not apply to infusions of pancreatic islet cells, a procedure sometimes termed "islet cell transplantation". Under section 733 of the Medicare Prescription, Drug Improvement, and Modernization Act (MMA) (Pub. L. 108-173), Medicare pays for some investigational islet transplantation procedures. Our pancreas standards would be inappropriate for these islet procedures which do not involve a whole organ or require the same skills

and expertise as surgical transplantation of whole organs.

D. Summary of Proposed Data Submission and Outcome Measure Requirements for Initial Approval, by Organ Type

Since the requirements proposed in § 482.80 vary by organ type, the

following table summarizes the data submission and outcome measure requirements that each type of organ transplant center would have to meet under this proposed CoP.

Type of center	Proposed data submission and outcome measure requirements for initial approval
Heart, Kidney, Liver, or Lung	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all transplants¹ performed to OPTN; and • As long as a center has 1-year post-transplant follow-up on at least 9 transplants that were performed during the 2.5-year period reported in the most recent SRTR center-specific report and the center's observed 1-year patient and graft survival rate is higher than its expected 1-year patient and graft survival rate, the center's outcomes would be acceptable. • If the 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: <ol style="list-style-type: none"> (1) p-value < 0.05, (2) O - E > 3, and (3) O/E > 1.5.
Heart-lung	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all heart-lung transplants performed to OPTN.
Intestine	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all intestinal, combined liver-intestinal, and multivisceral transplants performed to OPTN.
Pancreas	<ul style="list-style-type: none"> • Timely submission to the OPTN of at least 95 percent of required data on all pancreas and kidney-pancreas transplants performed.

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

A. Overview

The current Medicare policies on organ transplants do not have criteria for re-approval of transplant centers. In 2000, 37 percent of Medicare-approved heart transplant centers fell below the Medicare-required volume or survival rate criteria and yet still retained their Medicare-approved status. We believe there is a need to establish criteria for evaluating the ongoing performance of Medicare-approved transplant centers, including post-approval criteria for data submission and outcomes. Without these criteria, we are unable to be assured that once a transplant center becomes Medicare-approved it continues to provide transplantation services in a safe and efficient manner. Given that outcome measures are important indicators of transplantation quality, periodic re-assessment of these indicators, along with the requirement for complete and timely submission of data, would serve as a valuable oversight tool for ensuring that once a transplant center becomes Medicare-approved, it can continually demonstrate a minimum level of commitment to and expertise in transplantation. Therefore, we are proposing specific data submission and outcome requirements for re-approval.

B. Proposed Data Submission Requirements for Re-approval of Transplant Centers

As we proposed for initial approval, we also propose that 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 percent of required data submissions on all transplants (deceased and living donor) performed at the center over the 3-year approval period. As in initial approval, we propose required data submissions include, but not be limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and transplant recipient follow-up for the type of organ(s) transplanted.

C. Proposed Outcome Measure Requirements for Re-approval of Transplant Centers

We propose using the same outcome measures for the re-approval of heart, kidney, liver, and lung centers that we propose for initial approval of these centers. However, while we proposed to give transplant centers the option of using 1-month post-transplant outcomes under certain conditions for initial approval, we are not proposing a similar option for re-approval. Each heart, kidney, liver, and lung center would

have to use 1-year patient and graft survival data contained in the most recent SRTR center-specific report for re-approval. We would also review outcomes for all transplants performed at the center, including living donor transplants, if applicable.

Furthermore, each heart, kidney, liver, and lung center that has Medicare approval to perform adult transplants would need to have 1-year post-transplant follow-up on at least 9 adult transplants of the appropriate organ type performed during the 2.5-year period reported in the most recent SRTR center-specific report. Except for lung transplant centers, we would review outcomes for pediatric and adult patients separately if a center has Medicare approval to perform pediatric transplants. As with initial approval, transplant centers that have Medicare approval to perform pediatric transplants would not need to perform a minimum number of pediatric transplants. As we stated earlier, requiring centers to perform a minimum number of pediatric transplants would preclude many centers from obtaining Medicare approval to perform pediatric transplants. Again we request comments on our proposed approach to evaluating pediatric transplant centers' outcomes.

For the same reasons discussed for the proposed outcome measure requirements for initial approval, we also propose adopting the same methodology for evaluating a heart, kidney, liver, or lung transplant center's outcomes that we propose for initial approval. As long as the center's

¹ Each transplant center must submit data on all transplants performed at the center, including

living donor transplants if applicable, because CMS will review outcomes for all transplants of the appropriate organ type performed at the center.

observed outcomes are higher than the center's expected outcomes, the center's outcomes would be acceptable. If a center's observed outcomes are lower than its expected outcomes, the center's patient and graft survival could still be acceptable, unless all of the following three thresholds are crossed:

- The one-sided p-value is less than 0.05;
- The number of observed events minus the number of expected events (O – E) is greater than 3; and
- The number of observed events divided by the number of expected events (O/E) is greater than 1.5.

Again, we propose that 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, we would not consider the center to be in compliance with the requirements for that particular measure. Centers still would have to meet the outcome requirements for each outcome measure separately. In other words, a heart, kidney, liver, or lung center in which both the observed 1-year patient

survival rate and the observed 1-year graft survival rates are lower than the expected survival rates would have acceptable outcomes unless the center crosses the thresholds for all three tests (*i.e.*, p-value, O – E, and O/E) with respect to its observed and expected 1-year patient survival rates and with respect to its observed and expected 1-year graft survival rates.

We welcome comments on the proposed thresholds for re-approval of heart, kidney, liver, and lung centers and on the methodology itself. Given that failure to meet the outcome measure requirements would not necessarily result in denial of re-approval, as it would for initial approval, we specifically request comments on whether we should consider a heart, kidney, liver, or lung center's outcomes to be unacceptable if the center crosses the thresholds for all three tests as proposed or whether we should consider a heart, kidney, liver, or lung center's outcomes to be unacceptable if the center crosses the thresholds for just one or two of the three tests, as discussed earlier.

For re-approval of heart-lung, intestinal, and pancreas centers, we propose the same requirements as we do for initial approval of heart-lung, intestinal, and pancreas centers. For heart-lung, intestinal and pancreas transplant centers, we do not propose any outcome measure requirements since we feel that at this time skill and expertise in heart and lung transplantation, in liver transplantation, and in kidney transplantation, respectively, are sufficient. We request comments on our proposed approach to evaluating heart-lung, intestine, and pancreas transplant centers' outcomes.

D. Summary of Proposed Data Submission and Outcome Requirements for Re-Approval, by Organ Type

Since the proposed data submission and outcome requirements for re-approval vary by organ type, the following table summarizes the data submission and outcome measure requirements that each type of organ transplant center would have to meet under this CoP.

Type of center	Proposed data submission and outcome measure requirements for re-approval
Heart, Kidney, Liver, or Lung	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all transplants² performed to OPTN; and • As long as a center has 1-year post-transplant follow-up on at least 9 transplants that were performed during the 2.5-year period reported in the most recent SRTR center-specific report and the center's observed 1-year patient and graft survival rate is higher than its expected 1-year patient and graft survival rate, the center's outcomes would be acceptable. • If the 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 would still be acceptable, unless all 3 of the following thresholds were crossed: <ul style="list-style-type: none"> (1) p-value < 0.05, (2) O – E > 3, and (3) O/E > 1.5.
Heart-lung	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all heart-lung transplants performed to OPTN.
Intestine	<ul style="list-style-type: none"> • Timely submission of at least 95 percent of required data on all intestinal, combined liver-intestinal, and multi-visceral transplants performed to OPTN.
Pancreas	<ul style="list-style-type: none"> • Timely submission to the OPTN of at least 95 percent of required data on all pancreas and kidney-pancreas transplants performed.

Proposed Transplant Center Process Requirements

A. Overview

We believe sound policies and processes are keys to ensuring quality care for patients. State agency surveys of hospitals with transplant centers indicate that deficiencies are usually associated with inadequate or poor implementation of patient management policies and procedures, inadequate staffing, and poor or inadequate monitoring of QAPI programs. We believe it is critical to include process-oriented requirements in the regulation

in addition to data submission and outcome requirements. The combination of outcome-oriented and process-oriented requirements will enhance efficient usage of donated organs and thereby decrease organ wastage. The process requirements that we are proposing promote efficiency in the Medicare program and are based heavily on accepted standards of practice in the transplantation field and on continuous quality improvement efforts that have been proven to improve outcomes. To reduce burden on providers, we are revising or eliminating specific requirements that currently apply to

heart, kidney, liver, and lung centers and proposing only requirements that will ensure the overall quality of transplant centers for all transplant types. Proposing that transplant centers meet process requirements is intended to promote the quality of transplant services.

The well-being of living donors is as important as the well-being of transplant recipients. Consequently, based on the Secretary's authority under section 1861(e)(9) of the Act to require hospitals to meet requirements "necessary in the interest of the health and safety of individuals who are

² Each transplant center must submit data on all transplants performed at the center, including

living donor transplants if applicable, because CMS

will review outcomes for all transplants of the appropriate organ type performed at the center.

furnished services in the institution," we have proposed several process requirements we believe are necessary to protect the health and safety of prospective living donors.

B. Current Requirements

Currently, kidney transplant centers are covered under applicable regulations in § 405.2135 through § 405.2160 and specific kidney transplant regulations in § 405.2170 through § 405.2171. The current regulations for kidney transplant centers require, among other things, a kidney transplant center to be under the general supervision of a qualified transplant surgeon or a qualified physician-director, serving as the director of renal transplantation and responsible for the following: (1) Participating in the selection of suitable treatment modalities for each patient; (2) ensuring adequate training of nurses in the care of transplant patients; (3) ensuring tissue typing and organ procurement are available either directly or under arrangement; and (4) ensuring transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon (§ 405.2170).

The regulations also require a kidney transplant center to meet specific minimal service requirements: (1) Be part of a Medicare certified and participating hospital; (2) participate in a patient registry program with an OPO certified or recertified under part 486, subpart G; (3) be under the supervision of the hospital administrator and medical staff; (4) utilize a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of the patients and identify community resources to assist the patient and family; (5) utilize a qualified dietitian who will, in consultation with the attending physician, assess the nutritional and dietetic needs of each patient, prescribe therapeutic diets, provide diet counseling to patients and their families, and monitor adherence and response to a prescribed diet; (6) utilize a laboratory that is approved under 42 CFR Part 493 and that can perform histocompatibility testing on a 24-hour emergency basis, and (7) utilize the services of a designated organ procurement organization (§ 405.2171).

The current Medicare transplant policies for heart, liver, and lung centers have specific process requirements for patient selection, patient management, commitment, facility plans, maintenance of data, organ procurement, laboratory services, and billing.

C. Proposed Process Requirements

Our goals in developing the CoPs are to ensure the quality of care provided in transplant centers and to increase the number of successful transplants. We believe that the OPTN also shares these goals. We believe it will be beneficial for us to adopt certain aspects of the OPTN policies, as they are specific to current practice, in our proposed process requirements. We specifically invite comments on this proposal.

To keep process-oriented requirements to a minimum and to reduce burden on providers, we are proposing only requirements that are directly related to patient outcomes or that are necessary for data collection purposes to ensure the efficient operation of the Medicare program. We propose that our process requirements address the following subjects: (1) Patient and living donor selection, (2) organ recovery and receipt, (3) patient and living donor management, (4) QAPI, (5) human resources, (6) organ procurement, and (7) patients' and living donors' rights, and (8) additional requirements for kidney transplant centers. We want to emphasize that our overall focus is on the continuous, integrated care process that a patient experiences across all aspects of transplantation.

1. Condition of Participation: Patient and Living Donor Selection (Proposed Section 482.90)

[If you choose to comment on this section, please include the caption "PATIENT AND LIVING DONOR SELECTION" at the beginning of your comments.]

We believe transplant centers should have an active role in the management of patients prior to transplantation. We propose to require centers 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 transplantation. When a patient is placed on the center's waitlist or is selected to receive a transplant, we propose that the center must document in the patient's medical record the patient selection criteria that were utilized. We are also asking for comments on whether transplant centers should be required to make the patient selection criteria available to patients, either routinely or upon request.

We have not specifically defined patient selection criteria in the proposed rule because transplant technology is continually changing. We want to preserve centers' flexibility in

identifying organ transplants that are medically reasonable and necessary in light of the most recent transplantation research and the needs of transplant recipients. However, we propose that the patient selection criteria must ensure fair and non-discriminatory distribution of organs.

In general, organ transplants, should be performed only on carefully selected patients whose medical needs cannot be met by other therapies (except for kidney transplants where the dialysis option may continue to exist). We propose that before a transplant center selects a patient for 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 transplantation.

We are proposing an exception to this patient selection requirement for kidney transplant candidates because while kidney transplantation is the preferred treatment for patients with kidney failure, ESRD patients, unlike patients with other types of end-stage organ failure, have an alternative dialysis treatment option available to them, when kidney transplant is not feasible or when the graft has failed. Renal replacement therapy, which is required when kidney functions fall below 10–15 percent, includes either dialysis or kidney transplants.

Studies have shown that dialysis does not seem to yield survival comparable to transplantation. Kidney transplantation has many advantages, such as a lifestyle free from dialysis, a better quality of life and a longer life expectancy. However, kidney transplants have risks, such as surgical complications, rejection, and life-long maintenance medications and associated side effects. Therefore, dialysis continues to be a viable treatment option for an ESRD patient whose kidney transplant was unsuccessful.

We propose that a prospective transplant candidate must receive a psychosocial evaluation prior to placement on the waitlist. Although a person may be medically suitable for transplantation, he or she may have inadequate social support or coping abilities, or may be unable to demonstrate adequate adherence to a therapeutic regimen, which could then put the graft, and ultimately the transplant recipient at risk.

We also propose that before a transplant center places a patient on its waitlist, the candidate's medical record would have to contain documentation that the candidate's blood type has been determined. Requiring documentation

of the candidate's blood type would ensure that transplant centers are verifying the accuracy of vital data necessary to match the transplant candidate to a potential donor. We are specifically requesting comments on this proposal.

Like organ transplant candidates, we believe potential living donors should be carefully selected. Unlike deceased donor transplantation, living donor transplantation presents an ethical quandary in that living donation represents the only area of medicine in which an otherwise healthy individual is subject to surgical risk for somebody else's benefit. Any benefits to the donor are primarily psychological. We propose that transplant centers performing living donor transplants would have to use written living donor selection criteria to determine the suitability of candidates for living donation. We propose that the center must document in the transplant candidate's and living donor's medical records the living donor's suitability for donation. We have not proposed specific living donor selection criteria for transplant centers because there are no established guidelines concerning the selection of living donors at this time. Until living donor standards are established, we propose that the centers' living donor selection criteria must be consistent with the general principles of medical ethics. We propose that prior to donation, a prospective living donor must receive a medical and psychosocial evaluation. We also propose that the transplant center must document that the living donor has given informed consent, as required under § 482.102.

2. Condition of Participation: Organ Recovery and Receipt (Proposed Section 482.92)

As reported in *The Charlotte Observer*, a recent death of a transplant recipient was caused by transplantation of organs from a donor of an incompatible blood type. The incident was attributed to a combination of system errors that occurred during the organ procurement, organ receipt, and transplant processes. Another death was attributed to a miscommunication of blood types between the center's laboratory and the transplant team (Grady, Denise and Lawrence K. Altman, "Suit Says Transplant Error Was Cause in Baby's Death in August," *The New York Times*, 12 March 2003, Section A, Page 23, Column 5). These two events might have been avoided if certain steps were actively taken to validate the ABO (*i.e.* blood type) compatibility and other key data elements.

Under the current policies for heart, liver and lung transplants and the current regulations for renal transplant centers, there are no provisions addressing procedures for transplant centers to ensure that donor organ and transplant recipient data are compared, or to prevent the transplantation of mismatched organs. The OPTN rules specify that an OPO with an organ available for transplantation must obtain a "match run" for that organ type from UNOS. The match run lists potential recipients on the waitlist who are the correct size and blood type to receive the organ that is available. The OPTN also requires the OPO to provide the transplant center with written documentation of the potential donor's age, sex, and race, appropriate laboratory values, blood type, ABO or HLA typing, vital signs, cause of brain death and diagnosis, and current medication and transfusion history. However, these OPTN policies are voluntary. To prevent transplant mishaps caused by blood type mismatch, we propose that transplant centers would need to have written protocols for organ recovery and organ receipt. We propose that the protocols would have to ensure that the transplant center validates the donor's and the recipient's blood type and other vital data. Examples of vital data about the donor and the recipient that a transplant center should validate include, but are not limited to, appropriate laboratory values, vital signs, current medication and transfusion history. We also propose assigning responsibility for ensuring the medical suitability of donor organs for transplantation into the intended recipient to the transplanting surgeon, or the surgeon in the transplant center receiving the organ offer for his or her patient.

We propose that a center's protocols for organ recovery specify that a transplant center's organ recovery team would have to review and compare the recipient and donor data before recovery takes place. We also propose that when an organ arrives at the center, the transplanting surgeon and at least one other individual at the transplant center would have to verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation. These verifications would ensure that transplant centers are actively taking steps to avoid transplantation of mismatched organs throughout the organ distribution process and would also prevent wastage of organs in the event a mismatch was

not discovered until the organ(s) arrived at the transplant hospital.

We also propose that a center's protocols for organ recovery and receipt would have to ensure that the transplanting surgeon and at least one other individual at the transplant center verifies that the living donor's vital data (including blood type) are compatible for transplantation of the intended recipient, immediately before the removal of the living donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

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

Under the current policies for heart, liver and lung transplants, a center is required to have adequate patient management plans and protocols that include therapeutic and evaluative procedures during the waiting, in-hospital, and discharge phases of transplantation. The current conditions for coverage for ESRD services require each ESRD facility, which includes renal transplant centers, to maintain for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. We believe that a patient's care should be managed during every stage of transplantation, starting with the patient's evaluation for placement on a center's waitlist and through the patient's discharge from the hospital following transplant, to ensure that the services provided meet the patient's care needs and that the patient is involved in his or her care. We propose that 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. It is equally important to ensure that living donors receive services that meet their care needs throughout the various stages of donation, starting with donor evaluation and continuing through the donor's immediate discharge from the hospital post-donation. Therefore, we propose that centers performing living donor transplants must have written donor management policies for the donor evaluation, donation, and through the donor's discharge from the hospital following donation. We propose that a transplant center must ensure that each patient or living donor is under the care of a multidisciplinary patient care team coordinated by a physician during all phases of transplantation or living donation.

A center's initial responsibility for a transplant patient begins when he or she is evaluated for placement on that center's waitlist, regardless of whether or not the patient is on another center's waitlist. Effective waitlist management, in our view, means installing and maintaining a reliable administrative system that tracks patient status and provides accurate updated patient data on demand. Inaccurate information on waitlist patients may create a situation where a center may initially agree to accept organs that are offered to them but later decline them at the last minute when they discover that the organs are not suitable for the intended recipients. In order to prevent organs from being wasted once they are recovered, we are proposing a standard specifically for waitlist management.

In 2002, the Clinical Practice Committee of the American Society of Transplantation issued guidelines regarding waitlist maintenance based on a questionnaire sent out to 287 transplant centers, of which 192 responded. The guidelines specifically recommend annual follow-up or assessment of potential transplant recipients as deemed appropriate to ascertain transplant status. Although we do not specifically propose annual follow-up or assessment of transplant candidates, we believe transplant centers need to reassess patients placed on their waitlist to ensure that (1) the center's information on the patient is accurate and (2) the transplant is still medically indicated. We are proposing that transplant centers keep their waitlists up to date, including updating waitlist patients' clinical information on an ongoing basis. We also propose that the transplant center must remove a patient from its waitlist when the patient receives a transplant or dies, or if there is any other reason why the patient should no longer be placed on a center's waitlist (for example, the patient's health could deteriorate or improve to the point that a transplant would no longer be medically suitable or a patient could voluntarily ask to be removed from a center's waitlist). We propose requiring transplant centers to notify the OPTN of the patient's removal from the center's waitlist no later than 24 hours after such removal. This timely notification to the OPTN of a patient's removal from a center's waitlist is crucial. Not only would this notification provide patients with confirmation of their removal from a center's waitlist, but the OPTN would also rely on this information to keep the national waitlist current. Prompt notification of a patient's removal from the waitlist

provides more accurate data to facilitate accurate patient placement on the waitlist. Prompt notification of patient's removal from a center's waitlist would also enhance the accuracy of the SRTR data analyses. Furthermore, OPOs have a very narrow window of opportunity for allocating recovered organs to the appropriate recipient. Some OPOs have complained that transplant centers sometimes agree to accept an organ for a particular individual only to discover later that the individual has already received a transplant or has died prior to receiving a transplant.

We are proposing a requirement at § 482.94(c) that transplant centers maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplant. We believe that accurate patient records are especially crucial in determining a patient's readiness for transplants. Accurate information about a patient's transplant status needs to be readily available to individuals involved in the care of the patient, and to the patients themselves. For example, we have found that in some cases, after a kidney dialysis patient is evaluated for placement on a center's waitlist, the patient's status is not communicated to the dialysis facility or to the patient. The patient, and the dialysis facility, may believe he or she has been placed on a waitlist, only to find months later that the transplant center is waiting for the patient to undergo further clinical testing.

Given that time on the waitlist is often one of the factors that determine which patients ultimately are transplanted, we propose that for each patient who has received an evaluation for placement on a center's waitlist, the transplant center must document in the patient's record that it has notified each patient of his or her placement status. Specifically we propose that the center must notify the patient of: (1) The patient's placement on the center's waitlist; (2) the center's decision not to place the patient on its waitlist; or (3) the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

After a patient is placed on a center's waitlist, we believe it is the transplant center's responsibility to provide waitlisted patients with an annual update of their waitlist status. We propose that once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient has been notified of his or her waitlist status at least once a year,

even if there is no change in the patient's placement status. In addition, we propose that no later than 10 days after a patient's removal from a center's waitlist for reasons other than death or transplantation (such as the patient's voluntary withdrawal from the waitlist or a change in the patient's medical status such that a transplant is no longer indicated), the center must document in the patient's record that the patient has been notified of his or her removal from the waitlist. For dialysis patients, we propose that the transplant center also must document in each patient's record that both the patient and the patient's usual dialysis facility are informed of the patient's transplant status or of changes in the patient's transplant status. In the event there are changes in a dialyzed patient's transplant status, we believe it is imperative for dialysis facilities to have up-to-date and accurate information about kidney transplant candidates to ensure adequate care and coordination between the dialysis facility and the transplant center prior to transplantation. In the case of patients admitted for organ transplants, we propose that the patient records contain written documentation of multidisciplinary care planning during the pre-transplant period and multidisciplinary discharge planning for the patient's post-transplant care.

In addition, we propose requiring transplant centers to make available social and nutritional services, furnished by qualified social workers and dietitians, to patients and living donors. The current kidney transplant center regulations at § 405.2171 require centers to provide a qualified social worker to evaluate transplant patients' psychosocial needs, participate in care planning of patients, and identify community resources to assist the patient and family. Similarly, we believe social services, such as assisting and supporting patients and their families in maximizing the social functioning and adjustment of the patient, are important to all transplant patients and living donors. Therefore, we are proposing that social services, furnished by a qualified social worker, be made available to all transplant patients, living donors and their families. Based on the definition of "qualified social worker" contained in § 405.2102, we propose to define a qualified social worker as an individual who meets licensing requirements in the State in which practicing, and (1) has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the

Council on Social Work Education; or (2) has served for at least 2 years as a social worker, one year of which was in a transplantation program, and has established a consultative relationship with a social worker who has obtained the education described above.

The current kidney transplant center regulations at § 405.2171 also require a qualified dietitian, in consultation with the attending physician, to assess the nutritional and dietetic needs of each patient, recommend therapeutic diets, counsel patients and their families on prescribed diets and monitor adherence and response to diets. All transplant patients and living donors may need dietary modifications, permanently or temporarily, to maintain balances in fluids, electrolytes, and macro or micro-nutrients. We are proposing that nutritional assessments and diet counseling, furnished by qualified dietitians be made available to all transplant patients and living donors. Based on the definition of "qualified dietitian" contained in § 405.2102, we propose to define a qualified dietitian as an individual who (1) is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976 and who has at least 1 year of experience in clinical nutrition; or (2) has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

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

QAPI is the process of using objective data to study and continually make improvements to all aspects of an organization's operations and services. QAPI rests on the assumption that an organization's own quality management system is the key to improved performance. It seeks to increase the amount and quality of information on which to base decisions and improve quality.

We believe that QAPI is regarded by the health care community as the most efficient and effective method for improving the quality and performance of health care providers. Most transplant centers, by virtue of being part of a hospital, already participate in QAPI programs because, in addition to being required by our regulations at § 482.21, QAPI is a process required by JCAHO through its hospital accreditation standards. Although the transplant hospital's QAPI program may not contain elements that are specific to the transplant center, many transplant

centers have voluntarily established strong QAPI programs and utilize them to effect change within the transplantation system. However, transplant centers' QAPI programs vary in their sophistication and scope.

Therefore, we are proposing a requirement that every transplant 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. These requirements are based on our commitment to encouraging continuous quality improvement for all Medicare providers and suppliers. A requirement for transplant centers to have a QAPI program will encourage continuous quality improvement at the center level, as well as the use of best practices, as determined by the individual centers and the transplant community.

We do not intend to stipulate specific activities a transplant center must include in its QAPI program. We propose requiring a transplant center's QAPI program to use objective measures to evaluate improved performance with regard to transplant activities. Areas to be evaluated would include patient and donor selection criteria, accuracy of the waitlist in accordance with the OPTN waitlist, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction and patient rights. We propose that the transplant center would be required to take actions that result in performance improvements and track performance to ensure that improvements are sustained.

As part of the QAPI process, a transplant center would be required to establish and implement a written policy to address adverse events that occur during any phase of the organ transplant process. The policy must address at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. An adverse event for a transplant center could be, for instance, living donor death due to mismanagement of a donor; transplantation of organs of mismatched blood types due to failure to validate donor and recipient's vital information; or transplanting organs to unintended recipients. Examples of situations involving direct patient outcomes that might qualify as adverse events include: (1) Avoidable loss of a healthy living donor; and (2) unintended transmission of infectious disease to a recipient.

In addition, we are proposing that transplant centers would be required to

conduct a thorough analysis of and document any adverse event and to utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents. We believe that the formal analysis is essential to examining a transplant center's existing policies and practices, improving the organ transplantation process, and improving efficiency and outcomes.

5. Condition of Participation: Human Resources (Proposed Section 482.98)

[If you choose to comment on this section, please include the caption "HUMAN RESOURCES" at the beginning of your comments.]

We propose that transplant centers ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services. Currently, the ESRD regulations require a renal transplant center to be under the general supervision of a qualified transplant surgeon or qualified physician-director, who is responsible for planning, organizing, and directing the renal transplant center and devotes sufficient time to carry out certain responsibilities. We believe that all transplant centers should be directed by a qualified transplant surgeon or physician. Therefore, we propose at § 482.98(a) that each transplant center would have to be under the general supervision of a qualified transplant surgeon or a qualified physician-director.

The director of a transplant center would be responsible for planning, organizing, conducting, and directing the transplant center and would have to devote sufficient time to carry out these responsibilities. Specific responsibilities would include, but not be limited to, ensuring adequate training of nursing staff in the care of transplant patients; ensuring tissue typing and organ procurement services are available; and ensuring that transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b). The director of a transplant center would not need to serve in such capacity full-time and may also serve as the center's primary surgeon or physician, as discussed below. Since this would be a new requirement for extra-renal transplant centers, we request comments regarding whether it is necessary to require each transplant center to have a director to oversee the center, in addition to other human resources requirements.

We propose at § 482.98(b) that transplant centers must identify to the OPTN both a primary transplant surgeon and a primary transplant physician with the appropriate training and experience to provide transplantation services. For example, we would consider a transplant surgeon or transplant physician that meets the OPTN's policies regarding the training and experience of transplant surgeons and transplant physicians to have the appropriate training and experience to provide transplantation services. The transplant surgeon would be responsible for providing surgical services related to transplantation while the transplant physician would be responsible for providing and coordinating transplantation care.

In addition, we propose that transplant centers have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. Many transplant centers have clinical transplant coordinators on their teams to ensure coordination and continuity of care before patients are transplanted, while they are hospitalized for the transplant, and following the transplant. We propose that a qualified clinical transplant coordinator would have to be certified by the American Board of Transplant Coordinators (ABTC) which requires at least 12 months of work experience as a transplant professional in vascular organ transplantation and successful completion of the certification examination. We believe ABTC certification ensures that an individual serving in the capacity of a clinical transplant coordinator has met a standard of competency and possesses the necessary knowledge and skills needed to provide quality care for transplant recipients and donors. Clinical transplant coordinators are usually charged with the responsibilities of: (1) Educating patients, living donors, and families about treatment options, and post-operative care or therapies; (2) monitoring patients' and living donors' medical, surgical and psychosocial status; and (3) providing feedback to other team members. We request comments concerning whether an alternative set of training and experience standards should be used for qualified clinical transplant coordinators.

In addition, we propose that a transplant center must identify a multidisciplinary transplant team and

describe the responsibilities of each member of the team. We propose that the team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination and pharmacology. For example, a transplant team in a liver center should be composed of individuals with training and experience to treat and care for patients with end-stage liver disease and not ESRD patients. We have proposed this requirement to ensure that transplant centers have the ability to provide the services necessary to meet all of a transplant patient and a living donor's medical and psychosocial needs. We also believe that a transplant center must make a sufficient commitment of resources and planning to its transplantation program. We propose that a transplant center must demonstrate the availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease, pathology, radiology, and blood banking as related to the provision of transplantation services.

6. Condition of Participation: Organ Procurement (Proposed Section 482.100)

In this proposed rule, we are also proposing to require that transplant centers ensure that the transplant hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary. We propose at § 482.100 that the transplant center would have to ensure that the transplant hospital-OPO agreement identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. In the event that a transplant hospital terminates any agreement with an OPO or an OPO terminates any agreement with the transplant hospital, we propose that the transplant center must notify us in writing no later than 30 days after the termination of the agreement.

7. Condition of Participation: Patients' and Living Donors' Rights (Proposed Section 482.102)

[If you choose to comment on this section, please include the caption "PATIENTS' AND LIVING DONORS' RIGHTS" at the beginning of your comments.]

In addition to meeting the general hospital requirements for patients' rights in 42 CFR 482.13, we propose that a transplant center must protect and promote each transplant patient's and living donor's rights. Prior to

transplantation or living organ donation, transplant centers must inform patients (including living donors) of their rights.

There are some unique aspects of transplantation and living donation that make patient rights, particularly informed consent, critical. Hence, we propose requiring transplant centers to have a written informed consent process that addresses these unique aspects of transplantation and living donation. For example, the critical shortage of donor organs nationwide has caused transplant centers, researchers, and OPOs to investigate the potential of "extended criteria organs" to increase the supply of organs available for transplantation. Only a decade ago, these organs would not have been deemed usable due to the donor's age or health, or the condition of the organ. Such extended criteria organs included livers with excess fat, kidneys with extended cold ischemia time, or organs from donors 70 years of age or older. Although surgeons once rejected such organs, they now may choose to transplant them. Advances in transplant technology and skills, immunosuppressive drugs, improved infection management, and careful donor and recipient selection in combination with our national donor shortage have helped relax the criteria for accepting donor organs. The use of organs from extended criteria donors is now viewed as a viable alternative for patients with medical urgency. Although we agree that extended criteria donors can help to expand the donor pool, we believe it is important that patients be informed that organs from extended criteria donors could affect the success of the graft or the health of the patient.

We propose that the transplant center's written informed consent process notify transplant patients of information about all aspects of and potential outcomes from transplantation, including, but not limited to: (1) The evaluation process; (2) the surgical procedure; (3) alternative treatments; (4) potential medical or psychosocial risks; (5) national and transplant center-specific outcomes, such as graft and patient survival; (6) the fact that future health problems related to the transplantation 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; (7) 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 the disease cannot be detected in an infected donor; and (8) the right to refuse transplantation.

OPOs make every effort to obtain a social/behavioral history for each potential donor from the next-of-kin or other knowledgeable individual. If a potential donor has engaged in a behavior that would have put him or her at high risk of contracting an infectious disease, such as HIV or hepatitis (for example, injecting illegal drugs), donation generally is ruled out, unless the risk to the recipient of not performing a transplant is greater than the risk of contracting an infectious disease. In such case, informed consent regarding the possibility of transmission of infectious disease must be obtained from the transplant recipient.

In 2002, there was a case in Oregon in which hepatitis C was transmitted to transplant recipients that received organs from an individual who tested "negative" for hepatitis C at the time of donation. After further investigation, it was determined that the recipients became infected with hepatitis C because the donor had been infected with the disease but had not built up enough antibodies to test "positive" for the disease at the time of donation. If a donor's social history (e.g., history of drug use, sexual history, etc.) indicates that the donor could potentially be in a "window" period for transmitting HIV, hepatitis C, hepatitis B, or other infectious diseases, we believe that the patient's informed consent should also include this information. In other words, transplant patients should be notified when they are receiving organs from high-risk donors and should be notified that they may be at risk of contracting these diseases by accepting the donated organs. Examples of high-risk donors include, but are not limited to, donors who have tested "negative" for an infectious disease but whose social history indicates that the donor is at high risk for contracting the disease. In notifying transplant patients about a donor's history, we would expect the transplant center to do so in a manner that would keep the identity of the donor confidential. Given that it is difficult to predict whether a high-risk donor could be in a "window" period, and that there is no national standard guiding the use of organs from extended criteria donors, and that some patients can afford to wait for a healthier organ that may become available later, we are soliciting comments on our proposal of the requirements to inform patients of potential risks.

Recently, the ACOT developed a set of recommendations for living donors at

the Secretary's request. ACOT has agreed upon a set of "Ethical Principles of Consent to Being a Live Organ Donor." The principles state that the person who gives consent to becoming a live organ donor must be:

- Competent (possessing decision making capacity),
- Willing to donate,
- Free from coercion,
- Medically and psychosocially suitable,
- Fully informed of the risks and benefits as a donor, and
- Fully informed of the risks, benefits, and alternative treatment available to the recipient.

ACOT also endorsed two other ethical principles:

- Equipose; that is, the benefits to both the donor and the recipient must outweigh the risks associated with the donation and transplantation of the live donor organ; and
- A clear statement that the potential donor's participation must be completely voluntary, and may be withdrawn at any time.

ACOT further recommends that the following "Standards of Disclosure: Elements of Informed Consent" be incorporated into the informed consent document given to the potential live organ donor, with specific descriptions that would ensure the donor's awareness of:

- The purpose of the donation,
- The evaluation process—including interviews, examinations, laboratory tests, and other procedures—and the possibility that the potential donor may be found ineligible to donate,
- The donation surgical procedure,
- The alternative procedures or courses of treatment for potential donor and recipient,
- Any procedures which are or may be considered to be experimental,
- The immediate recovery period and the anticipated post-operative course of care,
- The foreseeable risks or discomforts to the potential donor,
- The potential psychological effects resulting from the process of donation,
- The reported national experience, transplant center and surgeon-specific statistics of donor outcomes, including the possibility that the donor may subsequently experience organ failure, disability and death,
- The foreseeable risks, discomforts, and survival benefit to the potential recipient,
- The reported national experience and transplant center statistics for recipient outcomes, including failure of the donated organ and the frequency of recipient death,

- The fact that the potential donor's participation is voluntary, and may be withdrawn at any time,

- The fact that the potential donor may derive a medical benefit by having a previously undetected health problem diagnosed as a result of the evaluation process,

- The fact that the potential donor undertakes risk and derives no medical benefit from the operative procedure of donation,

- The fact that unforeseen future risks or medical uncertainties may not be identifiable at the time of donation,

- The fact that the potential donor may be reimbursed for the personal expenses of travel, housing, and lost wages related to donation,

- The prohibition against the donor otherwise receiving any valuable consideration (including monetary or material gain) for agreeing to be a donor,

- The fact that the donor's existing health and disability insurance may not cover the potential long-term costs and medical and psychological consequences of donation,

- The fact that the donor's act of donation may adversely affect the donor's future eligibility for health, disability, or life insurance,

- Additional informational resources relating to live organ donation (possibly through the establishment of a separate resources center, as recommended below.

- The fact that by donating, the donor authorizes Government approved agencies and contractors to obtain information regarding the donor's health for life, and

- The principles of confidentiality, clarifying that:

- Communication between the donor and the transplant center will remain confidential;

- A decision by the potential donor not to proceed with the donation will only be disclosed with the consent of the potential donor;

- A transplant center will only share the donor's identity and other medical information with entities involved in the procurement and transplantation of organs, as well as registries that are legally charged to follow donor outcomes; and

- Confidentiality of all patient information will be maintained in accordance with applicable laws and regulations.

We recommend that transplant centers that perform living donor transplants consider the ACOT's recommendations in developing informed consent policies for living donors. Transplant centers may also

wish to review two specific informed consent documents developed by ACOT. The first relates to the potential donor's initial consent for evaluation as a possible donor, "*Living Liver Donor Initial Consent for Evaluation*." The second deals with the potential donor's informed consent for surgery, "*Living Liver Donor Informed Consent for Surgery*." These documents are available on the Department's organ donation Web site at <http://www.organdonor.gov>.

Although the proposed requirements for informed consent incorporate some of the "Standards of Disclosure" recommended by ACOT, we are not proposing to require that transplant centers include all of these standards in their informed consent process for living donors. To serve the best interest of living donors, we are proposing at § 482.102(b) that transplant centers implement a written informed consent process for living donors that inform potential living donors about all aspects of and potential outcomes from living donation. Specific issues on which potential living donors would have to be informed of include, but are not limited to: (1) The fact that communication between the donor and the transplant center will remain confidential in accordance with the Department's Health Information Privacy Rules (45 CFR parts 160 and 164); (2) the evaluation process; (3) the surgical procedure, including post-operative treatment; (4) the availability of alternative treatments for the transplant recipient; (5) the potential medical or psychosocial risks to the donor; (6) the national and transplant center-specific outcomes such as graft and patient survival for both donors and recipients; (7) the possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected; and (8) the donor's right to opt out of donation at any time during the donation process. We request comments regarding our proposed informed consent requirements for living donors, including those requirements we have adopted from the ACOT recommendations, and whether we need to establish additional criteria for transplant centers performing living donor transplants (such as, incorporating other ACOT recommendations).

In addition to requesting assistance in improving the lives of recipients and protecting living organ donors, the Secretary also requested that ACOT consider the desirability of an independent donor advocate (or

advocacy team) to represent and advise the donor so as to ensure that the previously described elements and ethical principles are applied to the practice of all living donor transplantation. ACOT has provided detailed recommendations as to how such an independent donor advocate should be established, as well as the role and qualifications of such an advocate. ACOT recommended that each transplant center identify and provide to each potential donor an independent and trained patient advocate whose primary obligation would be to help donors understand the process, the procedure and risks and benefits of living organ donation; and to protect and promote the interests and well-being of the donor. We believe that a living donor advocate (or advocacy team) would ensure that the informed consent standards meet ethical principles as they are applied to the practice of all living organ transplantation. We are requesting comments on whether we should include a requirement for transplant centers performing living donor transplants to provide the service of an independent donor advocate (or advocacy team) and what the individual or team's credentials should be.

Additionally, we believe that waitlist patients need to be informed of circumstances within a transplant center that may impact their ability to receive a transplant should an organ become available and what procedures are in place to ensure coverage. Thus, we are proposing that a transplant center served by a single transplant surgeon or physician must inform its patients of this fact and of the potential unavailability of the transplant surgeon or physician should an organ become available for the patient. If a transplant center is served by a single transplant surgeon or physician, we also propose that the center inform its patients whether or not the center has a mechanism for providing an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies should the center's transplant surgeon or physician be unavailable.

It is not our intent to disrupt the availability of covered organ transplants for Medicare beneficiaries. Therefore, in the event that termination becomes imminent during the 3-year approval period, we are proposing at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, that the center must inform the patients on the waitlist and must provide assistance to patients who choose to transfer to

another Medicare-approved center without loss of the patient's time accrued on the waitlist. (The OPTN controls the nation's organ transplant waitlist and has rules to ensure that a patient who transfers from one waitlist to another does not lose any accrued time.) Generally speaking, we do not believe transferring patients from the waitlist of a center that is facing loss of its Medicare approval to an open center's waitlist would increase the length of wait for others already on the open center's waitlist because time on the waitlist is just one of several factors that are used to match donor organs to a potential transplant recipient.

We also propose that at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center would have to inform all Medicare beneficiaries added to the waitlist that Medicare will not pay for transplants performed at the center after the effective date of the center's loss of approval. We are proposing these requirements to ensure that patients on the center's waitlist do not lose precious waiting time as a result of a center's loss of approval.

8. Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed Section 482.104)

In addition to meeting the special requirements for transplant centers (proposed § 482.68), we also propose additional requirements for kidney transplant centers. As stated previously, we propose to delete § 405.2120 through § 405.2134, § 405.2170 through § 405.2171, and the definitions for "histocompatibility testing," "ESRD Network," "ESRD network organization," "organ procurement," "renal transplantation center," "transplantation service," and "transplantation surgeon" contained in § 405.2102. We propose to retain some of these requirements at § 482.104.

Specifically, we propose that kidney transplant 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. We propose that the dialysis services furnished by transplant centers would have to be furnished in accordance with part 405, subpart U of this chapter. We propose that 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.

Special Procedures for Approval and Re-Approval of Transplant Centers

Currently, a facility's application to become a Medicare-approved heart, liver, or lung transplant center is evaluated with the aid and advice of non-Federal expert consultants. Generally, the consultants are responsible for reviewing applications at our request, making recommendations to us concerning qualified centers and supporting each recommendation with written documentation. CMS reviews intestinal transplant center applications for Medicare approval. For kidney transplant centers, the CMS Regional Offices review and process requests for Medicare approval.

This proposed rule introduces facility criteria for heart-lung and pancreas transplant centers and changes the process for reviewing applications for approval of heart, intestine, kidney, liver, and lung transplant centers. The current facility criteria for heart, intestine, kidney, liver, and lung centers and the process for reviewing applications for approval of heart, intestine, kidney, liver, and lung transplant centers contained in the Medicare coverage policies and the regulations at 42 CFR part 405, subpart U would continue to be in effect until we announce otherwise. We propose that once this proposed rule is finalized, we, or our designee (*e.g.*, a State survey agency or an accreditation organization with deeming authority for hospitals, such as the JCAHO or AOA), would have responsibility for monitoring and coordinating the procedures for approval or re-approval of a transplant center. For the purpose of approving and re-approving transplant centers, we propose at § 488.61 that we utilize the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A, including the periodic review of compliance and approval contained in § 488.20.

Last year, Congress passed the MMA. Section 901(b) of the MMA, adding new paragraph 1861(d) to the Act, states that "[t]he term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title." Section 936 of the MMA added new section 1866(j) to the Act, which, among other things, gives both providers (as defined at section 1861(u) of the Act) and suppliers (as defined above) the right to seek judicial review of certain adverse agency decisions regarding enrollment and re-enrollment.

We believe that transplant centers are unique entities that do not fit perfectly into either the provider or supplier category. There is no enrollment process involved. A transplant center is an optional status based on conditions that are applicable only to Medicare hospitals that choose to apply for Medicare approval as a transplant center. A Medicare-approved transplant center must first meet all of the hospital CoPs in 42 CFR part 482, which serves as the basis of survey activities for the purpose of determining whether a hospital qualifies for a Medicare provider agreement. Thus, a Medicare-approved transplant center must be operated within a provider as defined in section 1861(u) of the Act (*i.e.*, a Medicare hospital).

However, "transplant center" is not listed in the definition of "provider" under section 1861(u) of the Act. By virtue of the fact that a transplant center is an entity other than a provider (as defined in section 1861(u) of the Act), we could argue that "transplant center" falls under the definition of "supplier" created in section 901 of the MMA. Given the unique nature of transplant centers, we are requesting comments on the appropriate appeals mechanism for transplant centers. Specifically, we are interested in receiving comments regarding whether transplant centers should be regarded as "providers" or as "suppliers" for the purpose of appealing adverse approval and re-approval decisions. We believe that regardless of whether we define a transplant center to be a "provider" or a "supplier," it is necessary to have some type of appeal process in the event that CMS decides to not approve or re-approve a hospital's transplant center.

[If you choose to comment on this issue, please include the caption "PROVIDER VS. SUPPLIER STATUS FOR APPEALS" at the beginning of your comments.]

A. Initial Approval Procedures

We propose at § 488.61(a) that a transplant center can submit a letter of request to CMS for Medicare approval at any time. We are not proposing any particular formal application. The letter, signed by a person authorized to represent the hospital (for example, a chief executive officer), would need to include the hospital's Medicare provider I.D. number, name(s) of the designated primary transplant surgeon and primary transplant physician and a statement from the OPTN that the center has complied with all data submission requirements.

We propose to determine a heart, heart-lung, intestine, kidney, liver, lung,

or pancreas transplant center's compliance with the data submission and outcome requirements proposed at § 482.80 by reviewing the center's data. For compliance with the data submission requirements, we would expect the OPTN to review its statistics on data completeness for the previous calendar year and certify compliance with the data submission requirements. For compliance with the outcome measures requirements, we would review the 1-year patient and graft survival data contained in the most recent SRTR center-specific report unless the center is eligible for initial approval on the basis of its 1-month patient and graft survival. If 1-month patient and graft survival data are used, we would review the customized reports prepared by the SRTR for the previous 1-year period. The center would be responsible for requesting the SRTR to prepare these customized reports.

The SRTR center-specific reports are updated every six months (currently, the reports are updated in January and July of each year). If, for example, we receive a letter from a transplant center requesting Medicare approval on October 1, 2006, we would review the center's 1-year patient and graft survival statistics from the SRTR's July 2006 reports, which includes 1-year graft and patient survival statistics on transplants performed anywhere between 1 to 3.5 years previously. As we have stated previously, we will be reviewing the post-transplant outcomes for all transplants, including living donor transplantation, performed at a center during the 2.5-year period in which the outcomes are reported.

However, a new transplant center may request initial Medicare approval using 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 transplant center for a minimum of 1 year prior to the opening of the new center and if the transplant center's team meets the human resources requirements at § 482.98. We would review the 1-month patient and graft survival data on at least 9 transplants performed during the previous 1-year period captured in the customized reports prepared by the SRTR.

If a center requires Medicare approval to perform pediatric transplants, the center would have to meet the outcome requirements for its pediatric and adult transplant centers separately.

If we determine that a transplant center requesting initial approval is in compliance with the proposed data submission and outcome measure

requirements proposed at § 482.80 (based on our review of the data), then we, or our designee, would conduct a site survey of the center to determine compliance with CoPs proposed at § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A. To maximize efficient utilization of resources, the data and outcome requirements would serve as prerequisites that would need to be met based on a desk review of the data before a survey for compliance with the process requirements would be conducted. We propose that centers that failed to meet the data or outcome requirements, including the requirement to have post-transplant follow-up on at least 9 transplants during the reported cohorts, would be denied approval and no survey would be performed.

B. Effective Dates for Initial Approval

Under the current national coverage decisions for heart, liver, and lung transplant centers, Medicare approval of a facility to perform Medicare-covered transplants is effective as of the date of the letter notifying the center of its approval. Under this proposed rule, Medicare approval of all transplant centers to perform Medicare-covered transplants would be effective as of the date of the letter notifying the center of its approval. However, in order to ensure that Medicare-covered transplants are performed only in centers with continued demonstration of experience and skill in a particular type of transplant, we propose limiting a transplant center's approval to 3 years. A time-limited approval would provide us with a mechanism to re-evaluate a transplant center's ability to maintain the skill and experience necessary to perform transplants safely and efficiently.

C. Re-approval Procedures

We propose at § 488.61(b) that transplant centers would be required to comply with the data submission, outcome and process requirements at all times during the 3-year approval period. We may evaluate whether a transplant center is in compliance with the CoPs for transplant centers at any time during the 3-year approval period. For example, if the OPTN notified us that a center failed to meet the proposed data submission requirements, we would consider this significant information that would warrant conducting a complaint investigation.

At least 180 days before the end of a transplant center's 3-year approval period, we would evaluate each center's data for compliance with the data

submission and outcome requirements for re-approval proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report. For compliance with the data submission requirements, we would review the OPTN's statistics on data completeness for the previous 3 calendar years. For compliance with the outcome measures requirements, we would review the data contained in the most recent SRTR center-specific reports. As stated previously, the SRTR center-specific reports are updated every six months in January and July of each year. If, for example, a transplant center's Medicare approval ends on October 1, 2006, we would review the center's 1-year patient and graft survival statistics from the SRTR's July 2006 reports. As stated previously, the July 2006 SRTR center-specific reports would include patient and graft survival statistics on transplants performed anywhere between 1 to 3.5 years previously.

We propose that if we determine that a transplant center has met the data submission and outcome requirements proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report, the transplant center would be re-approved for 3 years. The re-approval dates would vary from center to center based on their initial approval dates. We propose that if, however, we determine that a center has failed to meet the data submission and outcome measure requirements proposed at § 482.82, including the requirement to have post-transplant follow-up on at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report, a survey for compliance with the CoPs proposed at § 482.68 through § 482.76 and § 482.90 through § 482.104 would be necessary for a transplant center to be re-approved.

Under some circumstances, we believe that a transplant center's inability to meet the data submission or outcome requirements can be influenced by factors that are not necessarily indicative of the quality of transplantation care. It is possible that a transplant center with a large number of transplant recipients that live outside the transplant center's geographical area might have a difficult time tracking these patients to assess the patients' outcomes or that the center-specific model might fail to take into consideration a significant variable

unique to the transplant center. For example, a transplant center may be participating in an institutional review board (IRB) approved immunosuppression withdrawal research protocol that may have resulted in worse than expected graft survival. Therefore, when a center fails to meet the data submission or outcome requirements (including failure to perform at least 9 transplants during the 2.5-year period reported by the SRTR in the most recent center-specific report) based on a desk review of the data, we would also incorporate an onsite survey for compliance with the process requirements. If, based on the survey results, we determine that a center is in compliance with the process requirements, then we would assume that particular center's data submission or outcome data are not necessarily indicative of the quality of transplantation care provided at the center.

As a result, there could be some circumstances under which a center that failed to meet the data submission or outcome requirements would be re-approved. In other words, a successful survey may under certain circumstances make up for a center's failure to meet one or more of the quantitative requirements. We propose that we or our designee would notify the transplant center in writing if it has been re-approved or not. If re-approved, we would also notify the transplant center of the effective date of the re-approval.

D. Alternative Process To Re-Approve Transplant Centers

[If you choose to comment on this issue, please include the caption "ALTERNATIVE PROCESS TO RE-APPROVE TRANSPLANT CENTERS" at the beginning of your comments.]

We have proposed that transplant centers would be re-approved for 3 years if they met the data submission and outcome requirements proposed at § 482.82. We or our designee would conduct a survey for compliance with the process requirements only if we determined that a center failed to meet the data submission and outcome measures requirements. Nonetheless, we are concerned that adherence to the data submission and outcome measures requirements does not necessarily indicate that a transplant center also is in compliance with the process requirements. For example, a transplant center could have good outcomes but be in violation of our proposed requirements for protection of living donors. Therefore, we have developed an alternative approach for re-approval

of transplant centers that would more closely monitor transplant center compliance with the process requirements. We are requesting comments on this alternative process from the public.

First, as put forth in this proposed rule, we would conduct complaint investigations of transplant centers as needed. In addition, we would conduct random surveys of a certain percentage of centers every year to determine their compliance with the process requirements. Finally, before re-approving centers based on their meeting the data submission and outcome measures requirements, we would determine for each center whether a survey for compliance with the process requirements should be conducted prior to re-approval. We would decide whether to conduct a survey based on information provided to us by the OPTN, such as desk and on-site audit findings and actions taken against a transplant center since the last Medicare approval or re-approval of the center.

We are requesting comments on the feasibility and utility of this option, as well as specific comments regarding: (1) How a random sample should be selected (percentage and type of centers); (2) whether all centers should be surveyed every 3 years, regardless of their compliance with the data submission and outcome requirements; and (3) whether it would be appropriate for CMS to base decisions about the need to conduct individual transplant center surveys on information provided by the OPTN.

E. Loss of Medicare Approval

We propose that centers that have lost their Medicare approval may seek re-entry into the program at any time. Although we are not proposing to restrict when a center can re-enter the Medicare program, we propose that the center must request initial Medicare approval as if it were a new center. In other words, the center would have to request approval using the initial approval procedure described in § 488.61(a). Furthermore, the center would have to be in compliance with all requirements for transplant centers, except for the re-approval requirements at § 482.82, at the time of its request. Regardless of whether the loss of Medicare approval was voluntary or involuntary, we propose that a center seeking to re-enter the Medicare program would have to submit a report documenting any changes or corrective actions the center has taken as a result of the loss of its Medicare approval status.

F. Applications From Consortia

A consortium is a group of hospitals with cooperative arrangements to perform organ transplants. The cooperative arrangements can be formed between a variety of hospitals, such as cooperative arrangements between a university hospital and a Veterans Administration hospital or between hospitals in a given city, state, or region. In most consortia, a single transplant surgeon performs transplants throughout all hospitals in the consortium. Currently, we do not approve consortia collectively as organ transplant centers. However, an individual center that is a member of a consortium may submit an individual application at any time.

We are proposing to retain this policy under the revised requirements because we believe that the extent of a facility's skills and experience can be accurately determined only by looking at each facility on an individual basis; attempting to determine a center's experience level on a consortium basis will not provide the same assurances.

G. Effect of New CoPs for Transplant Centers on Centers That Are Currently Medicare-approved

Since this proposed rule introduces a survey component to the approval procedures for transplant centers, we propose that a hospital that is currently Medicare-approved for furnishing organ-specific transplants would need to request approval for each particular type of transplant center. We propose to treat centers that are currently Medicare-approved as new centers. In other words when this proposed rule is published as a final rule, all transplant centers that are currently Medicare-approved would have to submit a letter of request to CMS for initial Medicare approval if they would like to continue operating as Medicare-approved transplant centers. Transplant centers that are currently Medicare-approved would be expected to meet the data submission outcome, and process requirements contained at § 482.68 through § 482.80 and § 482.90 through § 482.104 when they request Medicare approval.

In order to determine whether or not a center that is currently Medicare-approved is in compliance with the requirements in this proposed rule, we will need to conduct surveys of the transplant center. We propose that transplant centers that are currently Medicare-approved have 180 days from the date these regulations become effective to submit a letter requesting Medicare approval. We, or our designee,

would review the center's compliance with the data submission and outcome measure requirements proposed at § 482.80. If we determine that the center that is currently Medicare-approved is in compliance with these quantitative requirements, then we would schedule a survey to determine compliance with the CoPs proposed at §§ 482.68 through 482.76 and §§ 482.90 through 482.104. During the time that the data is reviewed, the survey is conducted and a determination is made, we propose that the transplant centers that are currently Medicare-approved would be able to continue to provide transplant services until we notify them whether or not we have approved them under the new CoPs for transplant centers.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA.

Condition of Participation: Notification to CMS (Section 482.74)

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

We estimate that the burden associated with this rule will be the time required to notify CMS of significant changes. We estimate that there will be 3 occasions annually per center requiring notification. For each occasion, we estimate that it will take 5

minutes to notify us. Therefore, we believe that it should take no more than 15 minutes annually for each center to notify us of any significant changes such as personnel changes. Assuming that all centers may have significant changes each year, we estimate that there will be approximately 900 centers that will need to inform us of these significant changes for a national total of 225 hours.

Condition of Participation: Pediatric Transplants (Section 482.76)

In order to be reimbursed for pediatric transplants provided to Medicare beneficiaries, a hospital that furnishes transplantation services to pediatric patients must seek Medicare approval to provide pediatric transplantation services. The center must submit a written request for Medicare approval.

We believe that the burden associated with this rule would be the time required to prepare and give us the information. In 2002, there were 75 hospitals that reported performing pediatric heart, heart-lung, intestine, liver, lung, and/or pancreas transplants to the OPTN. Assuming that the number of transplant centers performing pediatric transplants does not fluctuate significantly from year to year and assuming that we can expect all eligible hospitals to apply, we anticipate that there will be 75 hospitals requesting approval under this provision and that it will take each hospital 1 hour per center (*i.e.* a pediatric hospital with a lung center and heart center would require 1 hour to request Medicare-approval for its lung center and 1 hour to request Medicare-approval for its heart center). Since the 75 hospitals performing pediatric transplants have an average of 2 centers, we anticipate the total amount of time required for each hospital to request Medicare-approval will be 2 hours for an one-time national total of 150 hours.

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

Except as specified in paragraph (c) of this section, transplant centers must meet all of the data submission requirements in order to be granted approval by CMS. No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants it has performed.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these

requirements is exempt under 5 CFR 1320.3(b)(2).

Under certain circumstances, a center may be eligible for initial approval on the basis of its 1-month patient and graft survival rates. In order for CMS to have 1-month patient and graft survival data on all transplants performed during the previous 1-year period, the center may have to submit follow-up data to the SRTR, in addition to the data it normally would submit to the OPTN. The SRTR would need to prepare customized reports based on the 1-month follow-up data. We anticipate that the burden associated with this requirement would be the time required by the transplant centers to submit the necessary data to the OPTN and the time required by the SRTR to prepare the customized reports and submit them to us. However, we do not believe that more than 9 entities will be eligible to be approved on the basis of its 1-month post-transplant outcomes, making this requirement not subject to the PRA, in accordance with 5 CFR 1320.3(c). Between 1998 and 2002, we received and approved applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. We expect that fewer than 10 centers will apply for and be eligible to apply on the basis of their 1-month post-transplant outcomes each year. Furthermore, out of the 239 heart, liver, lung and intestinal transplant centers that are Medicare-approved as of October 20, 2003, only 5 have voluntarily terminated their Medicare approval. We do not expect this requirement to significantly increase the number of centers that voluntarily terminate their Medicare approval.

Condition of Participation: Data Submission and Outcome Measure Requirements for Re-Approval of Transplant Centers (Section 482.82)

Except as specified in paragraph (c) of this section, transplant centers must meet all the data submission and outcome measure standards in order to be re-approved. No later than 90 days after the due dates established by the OPTN, a transplant center must submit to the OPTN 95 percent of the required data submissions on all transplants it has performed over the last 3 years.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Condition of Participation: Patient and Living Donor Selection (Section 482.90)

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's suitability for transplant. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

Before a transplant center places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined on at least two separate occasions. When a patient is placed on a center's waitlist or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

The facility must document in the transplant candidate's and living donor's medical record the living donor's suitability for donation.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Condition of Participation: Organ Recovery and Receipt (Section 482.92)

Transplant centers must have written protocols for deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital data.

We believe that these requirements reflect usual and customary business practice and would be followed even if there were no Medicare requirements. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

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

Transplant centers must have written patient management policies and patient care planning for the pre-transplant, transplant, and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

The burden associated with these requirements is the time it takes to set forth in writing the required policies and planning. We believe that it is usual

and customary business practice for these entities to write down their policies and planning procedures. Thus, any burden would not be subject to the PRA.

In addition, transplant centers must keep their waitlists up to date, including:

(1) Updating waitlist patients' clinical information, as needed to assess a patient's status if an organ becomes available;

(2) Removing patients from the center's waitlist if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be placed on a center's waitlist; and

(3) Notifying the OPTN within 24 hours of a patient's removal from the center's waitlist.

Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waitlist, the center must document in the patient's record that the patient has been informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waitlist;

(ii) The center's decision not to place the patient on its waitlist; or

(iii) The center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

Once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient is notified of:

(1) His or her placement status at least once a year, even if there is no change in the patient's placement status; and

(2) His or her removal from the waitlist for reasons other than transplantation or death within 10 days of the patient's removal from the center's waitlist.

In the case of dialysis patients, transplant centers must document in the patient's record that both the patient and the dialysis facility has been notified of the patient's transplant status or of changes in the patient's transplant status.

In the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary care planning during the pre-transplant period and multidisciplinary discharge planning for post-transplant care.

The burden associated with this rule is the time required to document all the necessary information. We believe that it will take about 17,971 hours per year for all transplant centers to comply with these documentation requirements.

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

Under this section, a transplant center 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 arrangement.

As part of this condition, a transplant center must establish a written policy to address and document adverse events that occur during any phase of an organ transplantation case and specifies what the policy must address at a minimum.

The burden associated with this rule is the time required to write the improvement program, including the adverse action policy. We anticipate that this will take 8 hours on a one-time basis. Between 1998 and 2002, we received and approved applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. We do not expect that more than 10 centers will apply for and be accepted per year, so the burden subsequent to the implementation of the final rule will be approximately 80 hours.

Condition of Participation: Human Resources (Section 482.98)

The transplant center must identify to CMS and the OPTN a primary transplant surgeon and a transplant physician with appropriate training and experience to provide transplantation services. The burden associated with this requirement is the time it will take to notify CMS. It is information that will be included in the letter requesting initial approval and will not take any additional time.

Condition of Participation: Organ Procurement (Section 482.100)

Under this section, the transplant center must notify CMS in writing no later than 30 days after the termination of any agreement concerning organ procurement between the hospital and the OPO.

The burden associated with this rule is the time required to notify CMS. We estimate that this will not take more than 15 minutes. However, we also do not believe that more than 9 entities will have to comply with this requirement,

making it not subject to the PRA, in accordance with 5 CFR 1320.3(c).

Condition of Participation: Patient and Living Donor Rights (Section 482.102)

Transplant centers must have a written informed transplant patient consent process that informs each patient of:

(1) The evaluation process.

(2) The surgical procedures.

(3) Alternative treatments.

(4) Potential medical or psychosocial risks.

(5) National and transplant center-specific outcomes.

(6) The fact that future health problems related to the transplantation 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.

(7) Organ donor risk factors that could affect the immediate or future success of the graft or the health of the patient, such as the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

(8) His or her right to refuse transplantation.

Transplant centers must also have a written living donor informed consent process that informs the prospective living donor of all aspects of and potential outcomes from living donation. Transplant centers must ensure that the prospective living donor is fully informed about specified subjects.

Transplant centers must notify patients placed on the center's waitlist of information about the center that could impact the patient's ability to receive a transplant should an organ become available:

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waitlist of the potential unavailability of the transplant surgeon or physician and whether or not the center has a mechanism to provide an alternative transplant surgeon or transplant physician that meets the hospital's credentialing policies.

(2) At least 30 days before a center's Medicare approval is terminated, either voluntarily or involuntarily, the center must: (a) Inform patients on the center's waitlist of this fact and assist them in transferring to the waitlist of another Medicare-approved transplant center without loss of time on the waitlist; and (b) inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants

performed at the center after the effective date of the center's loss of approval.

The burden associated with this rule is the time required to give the patient/living donor the required information. For each patient on a center's waitlist, we estimate that there will be an average of no more than 2 instances that will require the center to comply with any one of these requirements. We expect an average of 88,211 (81,604 patients on the waitlist + 6,607 living donors) waitlist patients and living donors per year who will have to be notified. Assuming that each notification would take approximately 5 minutes, the total national annual burden would be 14,701 hours.

Special Procedures for Approval and Re-Approval of Organ Transplant Centers (Section 488.61)

Under this section, transplant centers must submit a letter of request to CMS for Medicare approval. The letter, signed by a person authorized to represent the center (for example, a chief executive officer), must include the hospital's Medicare provider I.D. number; name(s) of the designated primary transplant surgeon and primary transplant physician; and a statement from the OPTN that the center has complied with all data submission requirements.

Once this rule is finalized, all transplant centers that are currently Medicare-approved would be required to submit this letter if they wish to retain their Medicare approval. Since many transplant hospitals have more than one transplant center, we would assume that we would receive one letter from the hospital containing the required information for each of the hospital's transplant centers rather than a letter from each transplant center. Currently, there are approximately 230 hospitals with a Medicare-approved transplant center. We assume that all 230 hospitals with centers that are currently Medicare-approved would request approval under the new CoPs for transplant centers. Assuming that each letter would take approximately 15 minutes, the total national burden upon initial implementation of this rule would be approximately 58 hours (230 hospitals × 15 minutes/hospital).

In addition, we receive and approve applications from an average of approximately 10 heart, intestine, liver, and lung centers each year. Assuming that we continue to receive and approve 10 new transplant centers each year subsequent to the implementation of the final rule and that each letter from a transplant center would take

approximately 10 minutes, we expect the total annual burden subsequent to implementation of the final rule to be approximately 2 hours.

Finally, we propose that any center that has lost its Medicare approval would have to submit a report documenting any changes or corrective actions taken as a result of the center losing its Medicare approval. This report would be submitted to us along with the letter to request Medicare approval. We do not believe that more than 9 entities will be affected by this requirement making this requirement not subject to the PRA, in accordance with 5 CFR 1320.3(c). Out of 239 heart, liver, lung, and intestine centers that are Medicare-approved currently or previously, only 5 centers have voluntarily terminated their Medicare approval. Transplant centers, like other Medicare providers, have rarely had their Medicare approval status revoked involuntarily.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: John Burke, CMS-3835-P Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS-3835-P, christopher_martin@omb.eop.gov Fax (202) 395-6974.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in that document.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibilities of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate the overall economic impact of this rule to be \$300,148; therefore, we do not believe this would be a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, government agencies, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of \$29 million or less in any 1 year (65 FR 69432). Individuals and States are not included in the definition of a small entity. We believe this rule would not have a significant impact on a substantial number of small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We believe this proposed rule would not have a significant impact on small rural hospitals since small rural hospitals do not have the resources to perform organ transplants.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any

rule that may result in expenditure in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector, of \$110 million. We do not believe that this rule will have an effect on State, local or tribal governments, or the private sector, that could create an unfunded mandate greater than \$110 million annually.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose substantial direct requirement costs on State or local governments and does not preempt State law or have other Federalism implications. We have determined that this notice of proposed rulemaking would not significantly affect the rights, roles, and responsibilities of States.

This proposed rule would affect all facilities that perform, or are planning to perform, organ transplants and may have an effect on the ability of those facilities to compete. Although we do not believe this rule will have a significant impact on small rural hospitals or a significant economic impact, to the extent the rule may have significant effects on beneficiaries, or be viewed as controversial, we believe it is desirable to inform the public of our projections of the likely effects of the proposed rule. Thus, we have prepared the following analysis, which, in combination with the other sections of this proposed rule, is intended to conform to the objectives of the RFA and section 1102(b) of the Act.

B. Anticipated Effects

1. Effects on Transplant Hospitals or Centers

Our intent in developing and implementing the proposed conditions of participation for transplant centers is to ensure Medicare-covered transplants are performed in an efficient manner in keeping with the importance of this scarce resource for individuals on organ transplant waitlists. This proposed regulation also serves to keep Medicare requirements current with the state of the art in transplantation. We do not anticipate that changes in the performance standards for transplant centers would affect the number of transplants performed.

This proposed rule would establish conditions of participation for transplant centers that perform organ transplants. The proposed rule would maintain many of the same

requirements that are in the current **Federal Register** notices for heart, lung and liver transplants; National Coverage Policies for pancreas, intestinal and multivisceral transplants, and conditions for coverage for kidney transplant centers. Some of the proposed changes could result in additional costs for some centers. While we do not believe the requirements in this proposed rule would have a substantial economic impact on a significant number of transplant centers, we believe it is desirable to inform the public of our projections of the likely effects of the proposed rule. There are two reasons this proposed rule would have a minimal economic effect.

First, nearly 900 transplant centers may potentially be affected by the requirements in this proposed rule to a greater or lesser degree. However, the majority of the transplant centers probably have already put into practice most of the process requirements we are proposing, because the proposed requirements, for the most part, merely reflect advances in transplantation technology, as well as standard care practices.

Second, although the proposed rule requires a large amount of data to be submitted, transplant centers already submit these data to the OPTN.

a. OPTN Membership

We do not believe there would be any economic impact as a result of our proposal requiring transplant centers to be in a transplant hospital that is member of the OPTN and that abides by OPTN's approved rules and requirements. By statute and under regulations at § 482.45(b)(1) of this chapter, Medicare-approved transplant centers are already required to be in hospitals that are members of the OPTN and that abide by the OPTN's approved rules and requirements.

b. Notice of Significant Changes to CMS

Current Medicare transplant policies require centers to report immediately to CMS any events or changes that would affect their approved status. Specifically, a center is required to report, within a reasonable period of time, any significant decrease in its experience level or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of transplants at the center. The proposed standard for notification of significant changes to CMS is almost identical to the current requirements. We do not anticipate any additional economic impact associated with this requirement.

c. Pediatric Transplants

We have proposed to treat centers that perform pediatric transplants like any other transplant center seeking Medicare approval. In addition, we proposed to give heart centers the option of meeting the current requirements for Medicare approval to perform pediatric heart transplants. Hence, we believe the proposed requirements for pediatric transplant centers will result in the same economic impact that centers requesting Medicare approval to perform adult transplants would face when meeting the requirements of this proposed rule. The requirements for pediatric transplants alone would not be an economic burden.

d. Data Submission

The proposed data submission requirements for initial approval and re-approval require a transplant center to submit to the OPTN, no later than 90 days after the due date established by the OPTN, at least 95 percent of required data submissions on all transplants it has performed. We believe there would be little or no economic impact since the proposed requirements essentially mirror the OPTN's policies on data submission. We anticipate that most transplant centers are already submitting data to the OPTN as part of their membership responsibilities.

e. Outcome Measures

Currently, heart, liver and lung centers are required to calculate and report 1-year and 2-year actuarial survival analysis using the modified Kaplan-Meier technique. We propose shifting all the calculation and analysis responsibilities from the centers to the SRTR, which currently uses the OPTN data to prepare both center-specific and national statistical reports. We have proposed utilizing the SRTR center-specific reports to evaluate transplant center outcomes. Therefore, we believe there would be no or little economic impact on transplant centers as a result of this proposed requirement, unless one of the conditions in which a center may request Medicare approval on the basis of its 1-month post-transplant outcomes applies. In this case, there would be minimal economic burden associated with submitting follow-up data to the SRTR. There will be a cost of approximately \$1,000 to generate a customized report from the SRTR for 1-month post-transplant data. However, transplant centers have the option of waiting until their 1-year post-transplant data is available as part of the

center-specific reports if they do not wish to incur this cost.

f. Patient and Living Donor Selection

Under current policies, centers must have adequate written patient selection criteria and medical criteria for heart, liver and lung transplants, and clinical indications for coverage for pancreas and intestinal transplants. We propose similar patient selection requirements under the proposed condition and we believe there would be little or no economic impact from this condition.

In addition to the proposed patient selection criteria, we are also proposing to require written living donor selection criteria and a psychosocial and medical evaluation for living donors. Given the potential risks to living donors, we believe that every hospital that performs living donor transplants has protocols for the selection of living donors that include procedures for performing a medical and psychosocial evaluation of the donor. Therefore, the condition proposed here would only affect those few transplant centers performing living donor transplants that do not already have written donor selection criteria.

g. Organ Recovery and Receipt

The proposed condition for organ recovery and receipt requires transplant centers to have protocols for organ recovery and receipt that include protocols for validating the donor-recipient match. We believe nearly all transplant centers already have these protocols. We also believe that most transplant centers follow these practices to some degree. The proposed condition for organ recovery and receipt also assigns responsibility for ensuring the medical suitability of donor organs for transplantation into the intended recipient to the transplanting surgeon. We believe that most transplant centers currently follow this practice. Therefore, we foresee only minimal economic impact from the proposed requirements.

h. Patient and Living Donor Management

Some of the requirements proposed in this condition require transplant centers to have patient and living donor management policies during all phases of transplantation or living donation and this would have some economic impact on centers. We are proposing a waitlist management requirement for transplant centers to keep their waitlist current with patients' clinical data and information regarding patients' removal from the waitlist. The requirement also stipulates timely notification of patients' removal to the OPTN. Updating the OPTN of a patient's removal from the

center's waitlist and updating the waitlist patients' clinical information on an ongoing basis are best practices that transplant centers use to assess transplant suitability should an organ become available. We do not anticipate additional economic impact associated with this requirement.

We propose a patient records requirement for transplant centers to maintain current and accurate management records for each patient who is evaluated for placement on the center's waitlist and is admitted for organ transplantation. Specifically, we propose that once a patient has received an evaluation for transplant, a transplant center is required to document that it has notified the patient when: (1) The patient is placed on the center's waitlist; (2) the center decides not to place the patient on its waitlist; or (3) the transplant center requires further clinical testing or documentation before determining whether the patient can be placed on the center's waitlist. We also propose that once a patient is placed on a center's waitlist, the center must notify the patient of his or her removal from the waitlist for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waitlist and document that the patient has been notified in the patient's record. These proposed patient notification and documentation requirements are based on the OPTN requirements.

The currently, the OPTN requires transplant centers to notify patients of their status in writing (1) within 10 business days of the patient's placement on the OPTN Patient Waitlist or if a determination has been made based on evaluation of the patient that the patient will not be placed on the OPTN waitlist at this time and (2) within 10 business days of removal from the OPTN Patient Waitlist for reasons other than transplant. We expect that most transplant centers are currently in compliance with this OPTN requirement. We also believe that our proposed requirements provide transplant centers with more flexibility to determine how to notify patients than the current OPTN requirements. Therefore, we do not believe that transplant centers would incur any additional economic impact as a result of this proposed rule.

We are also proposing to require that once a patient has been placed on a center's waitlist, the center must document in the patient's record that the center has informed the patient of his or her status at least once a year, even if there is no change in status. Furthermore, for patients on dialysis,

the patient's record must also include documentation that the patient's usual dialysis facility is also notified of a patient's transplant status and of changes in the patient's transplant status. We anticipate this requirement would result in some economic impact on transplant centers. As of December 31, 2003, there were 83,731 waitlist registrations on the OPTN waitlist for deceased organs, which was a 5.5 percent increase from 79,387 registrations at the end of 2002 (2003 SRTR Annual Report). Assuming that, on average, the number of registrations on the OPTN waitlist for deceased organs increases by 6 percent each year, we can expect that by the end of 2006, there will be 99,725 registrations on the OPTN waitlist for deceased organs. Since transplant centers vary by size, it is not possible to determine a mean number of patients that each center lists on the OPTN waitlist. Thus, in quantifying the burden of notifying patients of their status annually, we are assuming that every transplant center that is a member of the OPTN either has Medicare approval or applies for Medicare approval as a transplant center as a result of this proposed rule. Consequently, assuming that it will take administrative support personnel, at an average salary of \$12 per hour, no more than 10 minutes to provide each patient on the deceased organ waitlist written notification of their status then the total maximum annual labor hours to all transplant centers is expected to be 16,621 hours (99,725 patient notifications \times 10 minutes for notification) and the total maximum annual labor cost to all transplant centers in the U.S. is expected to be \$199,452 (16,621 hours \times \$12/hour) in 2006. In addition, we estimate the total cost of the paper, envelopes, toner, and postage required to produce and mail each letter would be \$49,863 (99,725 patient notifications \times \$0.50/notification). Therefore, the total estimated cost of notifying patients annually of their waitlist status is \$249,315 (\$199,452 + \$49,863), if we assume that transplant centers choose to notify patients in writing.

We assume that in order to notify a dialysis facility of a patient's status, the transplant center would just send the dialysis facility a copy of the letter notifying the patient of his or her status. We estimate that the 99,725 OPTN waitlist registrations expected by the end of 2006 would include 64,203 registrations on the OPTN kidney waitlist and 3,062 registrations on the OPTN kidney-pancreas waitlist if we assume that the 6 percent annual growth

rate for all transplants applies to kidney transplants and kidney-pancreas transplants. Therefore, transplant centers would need to notify dialysis facilities of the status of 67,265 patients. Since we are assuming that transplant centers would notify patients in writing and just send dialysis facilities a copy of the letter to the patient notifying the patient of his or her status, we estimate that it will take administrative support personnel, at an average salary of \$12 per hour, approximately 1 minute per

letter to print a copy for the dialysis facility. Consequently, the total estimated annual labor burden for all transplant centers to notify dialysis facilities of patient status is approximately 1,121 hours (67,265 dialysis facility notifications × 1 minute/notification) and the total estimated labor costs for all transplant centers to notify dialysis facilities of patient status is approximately \$13,452 (1,121 hours × \$12/hour). The total cost of the paper, toner, and postage required

to produce and mail each letter is estimated to be \$33,633 (67,265 dialysis facility notifications × \$0.50/notification). Therefore, we estimate the total cost of mailing notification letters to the dialysis facility to be \$47,085 and the total cost of notifying both patients and dialysis facilities to be \$296,400 (\$47,085 for notifying dialysis facilities annually + \$249,315 for notifying patients annually).

PROJECTED NUMBER OF WAITING LIST PATIENTS

Calendar year	Number of patients on:		
	OPTN waiting list (all transplants)	Kidney waiting list	Kidney-pancreas waiting list
2003	83,731	53,906	2,571
2004	88,755	57,141	2,725
2005	94,080	60,569	2,888
2006	99,725	64,203	3,062

CALENDAR YEAR 2003 COST ESTIMATES

Requirement	Calculations	Annual burden hours	Annual cost estimate
Annual notification of patient status to patients ...	99,725 patients on OPTN waiting list × 10 min./written notification.	16,621	
	1 admin. support staff × \$12/h × 16,621 h		\$199,452
	99,725 notifications × \$0.50/notification		\$49,863
Total for annual notification to patients		16,621	\$249,315
Annual notification of patient status to dialysis centers.	67,265 patients on OPTN waiting list for kidney or kidney-pancreas transplant × 1 min./written notification.	1,121	
	1 admin. support staff × \$12/h × 1,121		\$13,452
	67,265 dialysis facility notifications × 0.50/notification		\$33,633
Total for annual notification to dialysis facilities.		1,121	\$47,085
Annual Total For Both Requirements		17,742	\$296,400

For patients admitted for organ transplants, we expect that documentation of pre-transplant multidisciplinary patient care planning and post-transplant discharge planning are common practices for most transplant centers. Therefore, there will be little resultant economic impact.

We are proposing to require every center to make available a qualified social worker to provide psychosocial supportive services to transplant patients, living donors, and their families. We are also proposing to require every center to make available a qualified dietitian to provide nutritional assessments and diet counseling to all transplant patients and living donors. Current policies for heart, liver and lung transplants require facility commitment at all levels, including social service resources. We believe nearly all transplant centers already have a qualified social worker and a dietitian to

provide psychosocial, supportive, and nutrition services. Thus, most centers would not need to hire any additional staff to meet this requirement. Therefore, there will be little resultant economic impact.

i. QAPI

The condition for QAPI will have some economic impact on the minority of centers that do not have a data-driven QAPI program. We estimate that a center that does not currently have a QAPI program probably would need one professional position to develop, implement, and coordinate a program that reflects the scope and complexity of the center's transplant program. We imagine a center would likely utilize an experienced individual from its hospital QAPI staff. QAPI coordinators are usually registered nurses (RNs) and sometimes individuals with other backgrounds. In 2002, the mean annual

income of an RN was \$42,730. We request comments addressing whether transplant centers would be able to utilize individuals from the hospital's existing QAPI staff to develop and implement a QAPI program specific to the transplant center or whether transplant centers would need to hire additional staff in order to comply with this proposed requirement.

j. Human Resources

The condition for human resources would require every center to designate a qualified director to provide general supervision over the center and to designate a primary transplant surgeon and physician with the appropriate training and experience to provide transplantation services. The director of the transplant center would not need to serve full time and may also serve as the center's primary transplant physician. Therefore, the primary transplant

surgeon and the physician could be the same individual, if necessary. The kidney transplant regulations require renal transplant centers to be supervised by a qualified transplantation surgeon or qualified physician-director. Current transplant center criteria require a transplant center to be a member of the OPTN and abide by its rules. The OPTN requires its members to have transplant surgeons and physicians with specific qualifications, training and experience. We believe all transplant centers already have designated primary transplant surgeons and transplant physicians. We also believe that in most transplant centers the primary transplant surgeon or transplant physician provides general supervision over the transplant center. Therefore, we do not believe this condition would have a significant economic impact.

We are also proposing to require every center to have a clinical transplant coordinator. Because of the complex medical needs of post-transplant patients and living donors, we believe, it is crucial for every center to have a clinical transplant coordinator. We believe most centers have a clinical transplant coordinator on staff to coordinate all patient care and management activities. Clinical transplant coordinators are usually registered nurses (RNs). According to the Bureau of Labor Statistics, the 2002 mean annual income of an RN was \$42,730.

Like the current policies for heart, liver and lung transplants, the human resources condition also would require centers to have a stable transplant team with delineated responsibilities for its members. The team must be composed of individuals with appropriate qualifications, training, and experience in relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. Since transplant centers and transplant hospitals are usually staffed with such individuals, we believe this requirement would not have a significant economic impact on transplant centers. Also, we propose that transplant centers must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease, pathology, radiology, and blood banking as related to the provision of transplantation services. We expect these are integral parts of transplantation services. Therefore, this requirement would not have resultant economic impact.

k. Organ Procurement

We propose requiring transplant hospitals to have a written agreement

for the receipt of organs with an OPO designated by the Secretary. The transplant hospital-OPO agreement would have to identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation. Under § 482.45, all Medicare participating hospitals already have such written agreements with an OPO in their service areas. There is no additional economic impact associated with this condition.

l. Patients' and Living Donors' Rights

Current kidney transplant regulations require a center to inform patients regarding their suitability for transplantation. The OPTN states that patients must be informed of their rights in advance of transplantation. The proposed condition for patients and living donors' rights would require every transplant center to inform patients and living donors of their rights in advance of transplantation or donation and to provide written informed consent to patients and living donors. The proposed condition requires centers to inform patients of donor history, the use of marginal organs or organs from donors who are at risk for HIV and other infectious diseases. We also propose requiring centers to inform patients of all aspects of and potential outcomes from transplantation, such as the evaluation process, the surgical procedure, alternative treatments for the transplant patient, potential medical and psychosocial risks to the patient, specific transplant outcomes for recipients, and their right to refuse transplantation. Furthermore, the proposed standard requires centers to provide information to prospective living donors regarding all aspects of and potential outcomes from living donation, such as the evaluation process, surgical procedure, alternative treatments for the transplant patient, potential medical and psychosocial risks to the donor, specific transplant outcomes for both donors and recipients, and potential future health and life insurance coverage problems related to living donation. The proposed standard also requires centers to give potential living donors the option to refuse donation at any time during the donation process. We believe all transplant centers have policies for an informed consent process for patients. Under the proposed condition, some centers may have to broaden their informed consent policies to include living donors. However, these provisions would have little resultant economic impact.

Furthermore, the condition also requires centers with a single transplant team to inform patients of the potential unavailability of the transplant team should an organ become available for the patient and whether or not the transplant center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies should the center's transplant surgeon or physician be unavailable. We also propose that at least 30 days before a center's Medicare approval is terminated, the center must inform patients on the center's waitlist of this fact immediately and provide assistance to waitlist patients who choose to transfer to the waitlist of another Medicare-approved center and inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination. We believe that any additional economic impact from this requirement would be minimal because current OPTN requirements require transplant centers that are inactive, either voluntarily or involuntarily, to notify patients and to assist them in transferring to a waitlist of an active center. The OPTN requirements also allow the patient to retain his or her waiting time.

m. Additional Requirements for Kidney Transplant Centers

Current kidney transplant regulations require ESRD facilities such as kidney transplant centers to participate in ESRD network activities for ESRD program administration. Therefore, we do not expect these requirements to have any resultant economic impact.

2. Effects on the Rights of Patients and Living Donors

The patients' and living donors' rights proposed in this rule are designed to increase the focus on patient and living donor transplantation choices. We believe we have strengthened a number of patient protections and have reinforced our mandate to protect the health, safety, and welfare of patients served.

3. Effects on the Medicare Program

Although the number of organ transplants has grown rapidly, donor availability is a significant limitation on the number of transplants that are performed. Because of their age and the presence of other complicating conditions, only a relatively small number of Medicare beneficiaries are presently heart, heart-lung, liver, lung, intestinal, or pancreas transplant

candidates. For example, while Medicare covered 12,721 kidney transplants in 2002, only 515 heart transplants, 779 liver transplants, 209 lung transplants, 6 heart-lung transplants, and 693 pancreas transplants were covered by Medicare. It is difficult to precisely estimate future Medicare costs, largely due to the difficulty of predicting the availability of donor organs over the next few years. All dollar estimates depend on assumptions and estimates related to the number of covered transplants. Based on the Office of the Actuary's 5-year budget projections, we consider future changes in organ transplant cost estimates over time to be negligible, and therefore we believe that this regulation will have no significant dollar impact. If anything, the CoPs could save Medicare dollars by improving patient care (preventing morbidity that would result in re-hospitalization) and preventing some graft failure (which would obviate the need for re-transplantation) or a return to dialysis for kidney patients. In addition, we do not believe this rule will increase the number of Medicare-covered transplants performed since there is nothing in the rule that impacts donation or the allocation of organs.

We propose procedures for approval and re-approval of transplant centers at § 488.61. For initial approval, we propose that all the CoPs proposed at § 482.68 through § 482.104, except for § 482.82 (Re-approval requirements), would have to be met in order for a transplant center to become Medicare-approved. Determinations on whether or not a transplant center is in compliance with these requirements would be made based on a review of a transplant center's data submission and outcome measures data required at § 482.80 and on the results of a survey for compliance with proposed § 482.68 through § 482.76 and § 482.90 through § 482.104, using the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A.

We propose to re-approve transplant centers every 3 years, but transplant centers would need to be in compliance with CoPs at § 482.68 through § 482.76 and § 482.82 through § 482.104 at all times. At least 180 days prior to the end of a transplant center's 3-year approval period, we would review the transplant center's data submission and outcome measures data. We propose that if we, or our designee, determine that a transplant center has met the data submission or outcome requirements proposed at § 482.82, the transplant center would be approved for 3 years. If we, or our designee, determine that the transplant center has failed to meet the

data submission and outcome measure requirements at § 482.82, the transplant center would be surveyed for compliance with § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A. We propose that transplant centers which have lost their Medicare approval would have to apply for initial approval as if they were a new center to re-enter the Medicare program and submit a report documenting any changes and/or corrective actions that have been made as a result of the loss of the center's Medicare approval status. We believe that such documentation would be a customary business practice that would be part of the center and/or hospital's QAPI program.

We believe that the proposed procedures for approval and re-approval will have some economic impact on the Medicare program since transplant centers may need to be surveyed more frequently. We believe most of the economic impact on the Medicare program associated with the proposed approval and re-approval procedures would occur during initial implementation. We propose to treat centers that are currently Medicare-approved as new centers that would need to submit a letter of request to CMS for initial Medicare approval and meet the requirements for initial approval. Therefore, we, or our designee, would need to survey all the centers that are currently Medicare-approved that meet the data submission and outcome measure requirements proposed at § 482.80 when this proposed rule goes into effect. We propose that all transplant centers that are currently Medicare-approved and that wish to continue to be Medicare-approved under the new CoPs for transplant centers would have 180 days from the date these regulations become effective to submit a letter requesting Medicare approval. Based on the number of request letters we receive during these initial 180 days, we would schedule the survey of these transplant centers in a manner that would allow the surveyor(s) to survey all the transplant centers requesting approval within a particular hospital during the same visit. To further minimize burden on the Medicare program, we also propose that during the time the data are reviewed, the survey is conducted, and a determination made, transplant centers that are currently Medicare-approved would be able to continue to provide transplant services until we notify them whether or not we have

approved them under the new CoPs for transplant centers.

Currently, there are approximately 250 transplant hospitals that are members of the OPTN. About 93 percent of these transplant hospitals have at least one Medicare-approved transplant center. Assuming that all the transplant centers that are currently Medicare-approved request approval under the new CoPs and meet the data submission and outcome requirements proposed at § 482.80, we would need to survey approximately 230 hospitals. Since the transplant centers would be able to continue to provide transplantation services until we notify them of their approval status under the new CoPs, we plan to stagger surveys of these hospitals over time. Therefore, we do not believe there would be a significant economic impact as a result of our proposal to treat all centers that are currently Medicare-approved as new centers.

C. Conclusion

We believe that the criteria we have developed are the most effective means available to ensure that organ transplants made available to patients are provided in a safe and effective manner. We estimate the net cost of this proposed rule to be approximately \$300,000. We do not believe that any transplant hospitals are small rural hospitals within the definition of the Social Security Act. Although some transplant hospitals are small entities by virtue of their non-profit status, few if any of them will have any consequential cost. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals or on other small entities.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget (OMB).

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 482

Grant programs—health, Hospitals, Medicare, reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart U—Conditions for Coverage of End-Stage Renal Disease (ESRD) Services

1. The authority citation for Part 405, Subpart U continues to read as follows:

Authority: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

§§ 405.2120 through 405.2134 and 405.2170 through 405.2171 [Removed]

2. Sections 405.2120 through 405.2134 and 405.2170 through 405.2171 are removed.

§ 405.2102 [Amended]

3. Section 405.2102 is amended by—
A. Removing the definitions for “histocompatibility testing,” “Network, ESRD,” “Network organization,” and “organ procurement”.

B. Amending the definition of “ESRD facility” by removing paragraph (a) and by redesignating paragraphs (b) through (e) as paragraphs (a) through (d).

C. Amending the definition of “ESRD service” by removing paragraph (a) and by redesignating paragraphs (b) and (c) as paragraphs (a) and (b).

D. Amending the definition of “Qualified personnel” by removing paragraph (g).

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 is revised to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395RR), unless otherwise noted.

2. Part 482 is amended by revising subpart E to read as follows:

Subpart E—Requirements for Specialty Hospitals

Sec.

482.68 Special Requirements for Transplant Centers.

482.70 Definitions.

General Requirements for Transplant Centers

482.72 Condition of participation: OPTN membership.

482.74 Condition of participation: Notification to CMS.

482.76 Condition of participation: Pediatric Transplants.

Transplant Center Data Submission and Outcome Requirements

482.80 Condition of participation: Data submission and outcome measure requirements for initial approval of transplant centers.

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

Transplant Center Process Requirements

482.90 Condition of participation: Patient and living donor selection.

482.92 Condition of participation: Organ recovery and receipt.

482.94 Condition of participation: Patient and living donor management.

482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

482.98 Condition of participation: Human resources.

482.100 Condition of participation: Organ procurement.

482.102 Condition of participation: Patient and living donor rights.

482.104 Condition of participation: Additional requirements for kidney transplant centers.

Subpart E—Requirements for Specialty Hospitals

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in § 482.70 through § 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at § 482.70 through § 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in § 482.70 through § 482.104, a transplant center must also meet the conditions of participation specified in § 482.1 through § 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include living donor death due to

mismanagement of the donor; transplantation of organs of mismatched blood types due to failure to validate the donor and recipient's vital information; transplantation of organs to unintended recipients; avoidable loss of a healthy living donor; and unintended transmission of infectious disease to a recipient.

End-Stage Renal Disease (ESRD) means that stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestinal transplant center means a Medicare-approved liver transplant center that performs intestinal transplants, combined liver-intestinal transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program within a transplant hospital (*i.e.*, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital that provides transplantation of a particular type of organ.

General Requirements for Transplant Centers

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those

rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No transplant hospital shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that would otherwise alter specific elements in their application for approval or re-approval. Instances in which CMS should be notified include, but are not limited to:

(a) Change in key staff members of the transplant team, such as a change in the individual the transplant center designates to the OPTN as the center's "primary transplant surgeon" or "primary transplant physician;" or

(b) A decrease in the center's volume or survival rates that could result in the center being out of compliance with § 482.82.

§ 482.76 Condition of participation: Pediatric Transplants.

A transplant center that wishes to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described in § 488.61.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will not impact the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants on pediatric

patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will not impact the center's Medicare approval to perform pediatric transplants.

(3) No minimum number of transplants (adult or pediatric) is required prior to approval.

(d) Instead of meeting all of the conditions of participation contained in § 482.68 through § 482.74 and § 482.80 through § 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients, may be approved to perform pediatric heart transplants by meeting the following criteria:

(1) The center's pediatric transplant program must be operated jointly by the center and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) 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.

Transplant Center Data Submission and Outcome Requirements

§ 482.80 Condition of participation: Data submission and outcome requirements for initial approval of transplant centers.

Except as specified in paragraph (c) of this section, transplant centers must meet all of the data submission and outcome measure standards in order to be granted initial approval by CMS. No waivers will be granted to centers that have failed to meet any one of the standards:

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up.

(b) *Standard: Outcome measures.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor

transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report, as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.

(2) The 9 transplants must have been performed during the timeframe reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rate to be acceptable if:

(i) A center's observed patient survival rate and observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05, (B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(4) A center may request that CMS review its 1-month patient and graft survival outcomes for all transplants performed in the previous 1-year period in lieu of 1-year patient and graft survival outcomes if the following conditions are met:

(i) The key members of the center's transplant team performed transplants at a Medicare-approved transplant center for a minimum of 1 year prior to the opening of the new center and the transplant center's team meets the human resources requirements at § 482.98., and

(ii) The most recent SRTR center-specific report does not contain 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type that were performed during the timeframe reported in the most recent SRTR center-specific report

(5) A center that chooses to request initial Medicare approval using its 1-month patient and graft survival outcomes must:

(i) Request the SRTR to calculate the center's observed and expected 1-month

patient and graft survival outcomes for transplants performed during the previous one-year period; and

(ii) Have 1-month post-transplant follow-up on at least 9 transplants of the appropriate organ type that were performed during the previous one-year period.

(6) When assessing a center's 1-month post-transplant outcomes, CMS will compare each transplant center's observed number of patient deaths and graft failures 1-month post-transplant to the center's expected number of patient deaths and graft failures 1-month post-transplant using the methodology described in § 482.80(b)(3).

(c) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the outcome measure requirements at § 482.80(b) for heart-lung transplants performed at the center.

(2) An intestinal transplant center is not required to comply with the outcome performance measure requirements at § 482.80(b) for intestinal, combined liver-intestinal or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the outcome measure requirements at § 482.80(b) for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to perform a minimum number of pediatric transplants prior to its request for approval.

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

Except as specified in paragraph (c) of this section, transplant centers must meet all data submission and outcome measure standards in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN 95 percent of the required data submissions on all transplants (deceased and living donor) it has performed over the 3-year approval period. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration, and recipient follow-up.

(b) *Standard: Outcome measures.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and

pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent SRTR center-specific report, as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.

(2) The 9 transplants must have been performed during the timeframe reported in the most recent SRTR center-specific report.

(3) CMS will not consider a center's patient and graft survival rate to be acceptable if:

(i) A center's observed patient survival rate and observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.5.

(c) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for heart-lung transplants performed at the center.

(2) An intestinal transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for intestinal, combined liver-intestinal and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the outcome measure requirements at § 482.82(b) for pancreas and kidney-pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to perform a minimum number of pediatric transplants to be re-approved.

Transplant Center Process Requirements

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waitlist or a patient's

suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection.* Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Before a patient is selected for transplant, except for kidney transplant patients, the transplant center must employ or consider all other appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation.

(2) Prior to placement on the center's waitlist, a prospective transplant candidate must receive a psychosocial evaluation.

(3) Before a transplant center places a transplant candidate on its waitlist, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(4) When a patient is placed on a center's waitlist or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the transplant candidate's and living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital data. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

(a) *Standard: Organ recovery.* A transplant center's organ recovery team must review and compare the donor-data with the recipient blood type and other vital data before organ recovery takes places.

(b) *Standard: Organ receipt.* When an organ arrives at the center, the

transplanting surgeon and at least one other individual at the transplant center must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient prior to transplantation.

(c) *Standard: Living donor transplantation.* If a center performs living donor transplants, the transplanting surgeon and at least one other individual at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the recipient's organ(s).

§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the pre-transplant, transplant, and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the pre-transplant, transplant, and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waitlist management.* Transplant centers must keep their waitlists up to date, including:

(1) Updating of waitlist patients' clinical information on an ongoing basis;

(2) Removing patients from the center's waitlist if a patient receives a transplant or dies, or if there is any other reason why the patient should no longer be on a center's waitlist; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waitlist.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's waitlist, the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of:

(i) The patient's placement on the center's waitlist;

(ii) The center's decision not to place the patient on its waitlist; or

(iii) The center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed.

(2) Once a patient is placed on a center's waitlist, the center must document in the patient's record that the patient is notified of:

(i) His or her placement status at least once a year, even if there is no change in the patient's placement status; and

(ii) His or her removal from the waitlist for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waitlist.

(3) In the case of dialysis patients, transplant centers must document in the patient's record that both the patient and the patient's usual dialysis facility have been notified of the patient's transplant status and any changes in the patient's transplant status.

(4) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

(i) Multidisciplinary patient care planning during the pre-transplant period; and

(ii) Multidisciplinary discharge planning for post-transplant care.

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

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

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

(e) *Standard: Nutritional services.*

Transplant centers must make nutritional assessments and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors. A qualified dietitian is an individual who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant 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 arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Activities and outcomes may include, but are not limited to, patient and donor selection criteria, accuracy of waitlist in accordance with the OPTN waitlist, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction and patient rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a

qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b).

This director is responsible for planning, organizing, conducting and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

- (1) Ensuring adequate training of nursing staff in the care of transplant patients.
- (2) Ensuring tissue typing and organ procurement services are available.
- (3) Ensuring that transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.

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

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. A qualified clinical transplant coordinator is an individual who is certified by the American Board of Transplant Coordinators.

(d) *Standard: Transplant team.* The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

(e) *Standard: Resource commitment.* The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, and blood banking as related to the provision of transplantation services.

§ 482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary.

(a) The transplant center must ensure that the hospital's agreement with the OPO identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

(b) The transplant center must notify CMS in writing no later than 30 days after the termination of any agreement between the hospital and the OPO.

§ 482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must have a written informed transplant patient consent process that informs each patient of:

- (1) The evaluation process.
- (2) The surgical procedure.
- (3) Alternative treatments.
- (4) Potential medical or psychosocial risks.

(5) National and transplant center-specific outcomes.

(6) The fact that future health problems related to the transplantation 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.

(7) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor.

(8) His or her right to refuse transplantation.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement a written living donor informed consent process that informs the prospective living donor of all aspects of and potential outcomes from living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process.

(3) The surgical procedure, including post-operative treatment.

(4) The availability of alternative treatments for the transplant recipient.

(5) The potential medical or psychosocial risks to the donor.

(6) The national and transplant center-specific outcomes for both donors and recipients.

(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected.

(8) The donor's right to opt out of donation at any time during the donation process.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waitlist of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waitlist of:

(i) The potential unavailability of the transplant surgeon or physician; and

(ii) Whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies.

(2) At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must:

(i) Inform patients on the center's waitlist of this fact and provide assistance to waitlist patients who choose to transfer to the waitlist of another Medicare-approved transplant center without loss of time accrued on the waitlist; and

(ii) Inform Medicare beneficiaries added to the center's waitlist that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of approval.

§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must furnish directly transplantation and other medical and surgical specialty services required for the care of ESRD patients.

(b) *Standard: Dialysis services.* Kidney transplant centers must furnish inpatient dialysis services directly or

under arrangement. Such kidney dialysis centers or units must meet the Conditions for Coverage of Suppliers of ESRD Services contained in part 405 subpart U of this chapter.

(c) *Standard: Participation in network activities.* 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.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh) unless otherwise noted).

Subpart B—Special Requirements

3. Section 488.61 is added to subpart B to read as follows:

§ 488.61 Special procedures for approval and re-approval of organ transplant centers.

For the purposes of this subpart, the survey, certification, and enforcement procedures described at 42 CFR part 488, subpart A apply to transplant centers, including the periodic review of compliance and approval contained in § 488.20.

(a) *Initial approval procedures.* A transplant center can submit a letter of request to CMS for Medicare approval at any time.

(1) The letter, signed by a person authorized to represent the center (for example, a chief executive officer), must include:

(i) The hospital's Medicare provider I.D. number;

(ii) Name(s) of the designated primary transplant surgeon and primary transplant physician; and,

(iii) A statement from the OPTN that the center has complied with all data submission requirements.

(2) To determine compliance with the outcome measure requirements contained at § 482.80(c), CMS or its designee will review the 1-year patient and graft survival data contained in the Scientific Registry of Transplant

Recipient's (SRTR's) most recent center-specific reports.

(3) If both of the conditions in § 482.80(b)(4) apply, the center may request the SRTR to prepare a customized report of the center's 1-month patient and graft survival data for the previous 1-year period. CMS or its designee will determine compliance with the outcome measure requirements contained at § 482.80(b) using the data contained in these customized reports.

(4) If CMS or its designee determines that a transplant center has met the data submission and outcome measure requirements of § 482.80, CMS or its designee will conduct a survey and review the center's compliance with the conditions of participation contained at § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A.

(5) If a transplant center seeking Medicare approval is found to be in compliance with all the conditions of participation contained at § 482.68 through § 482.104, except for § 482.82 (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval.

(6) CMS or its designee will notify the transplant center in writing if it is not Medicare approved.

(7) Initial approval of a transplant center will be for 3 years.

(b) *Re-approval procedures.* Once Medicare-approved, a transplant center must be in compliance with all the conditions of participation for transplant centers contained at § 482.68 through § 482.104, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) At least 180 days before the end of the 3-year approval period, CMS, or its designee, will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements contained at § 482.82(a), CMS or its designee will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the outcome measure requirements at

§ 482.82(c), CMS or its designee will review the data contained in the most recent SRTR center-specific reports.

(2) If CMS or its designee determines that a transplant center has met the data submission and outcome measure requirements contained at § 482.82, the transplant center will be re-approved for 3 years.

(3) If CMS or its designee determines that a transplant center has failed to meet the data submission or outcome measure requirements contained at § 482.82, the transplant center will be surveyed for compliance with § 482.68 through § 482.76 and § 482.90 through § 482.104 using the procedures described at 42 CFR part 488, subpart A.

(4) CMS or its designee will notify the transplant center in writing if it is re-approved or if its approval is being revoked. If re-approved, CMS or its designee will notify the transplant center of the effective date of the re-approval.

(c) *Loss of Medicare Approval.* Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time. A center that has lost its Medicare approval must:

(1) Request initial approval using the procedures described in § 488.61(a);

(2) Be in compliance with §§ 482.68 through 482.104, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

(3) Submit a report to CMS documenting any changes or corrective actions taken by the center as a result of the loss of its Medicare approval status.

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance Program; and No. 13.774, Medicare-Supplementary Medical Insurance Program)

Approved: July 30, 2004.

Tommy G. Thompson,
Secretary.

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