

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 482, 488, and 498

[CMS-3835-F]

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 & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes, for the first time, Medicare conditions of participation for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers. This rule sets forth clear expectations for safe, high quality transplant service delivery in Medicare-participating facilities. In addition, in this rule we respond to public comments on the proposed rule.

EFFECTIVE DATES: These regulations are effective on June 28, 2007.

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SUPPLEMENTARY INFORMATION:

I. Background

A. Key Statutory Provisions

Section 1102 of the Social Security Act (the Act) 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."

Section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with Medicare conditions of participation (CoPs). Responsibilities of the 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. JCAHO, AOA, and 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.) An accreditation organization must apply for and receive approval of deeming authority from CMS.

Section 1865(b)(1) of the Act states that providers of certain services listed in section 1881(b) of the Act cannot be deemed by a national accreditation body to meet the Medicare conditions of participation. Kidney transplant centers are entities listed in 1881(b); thus, they cannot be deemed to be accredited.

Section 1881(b)(1) of the Act contains specific authority for prescribing the health and safety requirements for facilities, including renal transplant centers, that furnish end stage renal disease (ESRD) care to beneficiaries.

B. Past Medicare Policy Regarding Transplantation

Until now, kidney transplant centers have participated in Medicare by meeting requirements set forth at 42 CFR Part 405, subpart U, "Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services." These requirements address issues such as compliance with applicable Federal, State, and local laws and regulations; governing body; patient care plans; patients' rights; medical records; and the physical environment. In addition, the ESRD conditions for coverage (CfCs) delineate minimum utilization rates, requirements for the director of transplantation, and minimum service requirements. (See 405.2170 and 405.2171.) Likewise, we have regulated extra-renal transplant centers under various national coverage decisions (NCDs) published beginning in 1987. The NCDs have been based on the "reasonable and necessary" provision of the Medicare statute (section 1862(a)(1)(A) of the Act). Generally, under section 1862(a)(1)(A), Medicare does not pay for any item or service unless it is medically reasonable and necessary. The NCDs provide that transplantation of extra-renal organs will be considered reasonable and necessary if performed in a center that meets the criteria specified in the applicable NCD.

C. Our Efforts To Improve Oversight of Transplant Centers

In the preamble of the proposed transplant center rule published February 4, 2005 (70 FR 6140), we discussed our efforts that are underway to improve organ donation and transplantation services, including the Secretary's Gift of Life Initiative. Publication of the proposed rule for new CoPs for transplant centers was the first step in moving toward a stronger oversight process. In February 2004, the Office of the Inspector General (OIG) published a report titled "Medicare-approved Heart Transplant Centers" (OEI-01-02-00520), and outlined three recommendations for CMS oversight of heart transplant centers: (1) CMS should expedite the development of continuing criteria for volume and survival rate performance and for periodic recertification; (2) CMS should develop guidelines and procedures for taking actions against centers that do not meet Medicare criteria for volume and survival rate; and (3) CMS should take immediate steps to improve its ability to maintain accurate and timely data on center performance. All of the OIG's recommendations were incorporated into the rule.

Through this final rule, we are codifying requirements for approval and re-approval of transplant centers as CoPs and placing Medicare-approved transplant centers under the survey and certification enforcement process used for all other providers and suppliers of Medicare services.

Since publication of the proposed rule, we have identified quality and service issues that some transplant centers are experiencing. For example, in 2005, we investigated and cited a hospital whose liver transplant center was accused of turning down a large number of organs offered for the patients on its waiting list. As a result, the hospital closed its liver transplant center. In addition, the Government Accountability Office (GAO) is currently reviewing the Department's oversight of the transplantation system in the United States.

Our current oversight of transplant centers relies on self-reporting of significant changes within a transplant center, as well as beneficiary complaints that may lead to a review or survey of a transplant center. The transplant center NCDs do not delineate explicit criteria for de-certifying of organ transplant programs. In this final rule, we are responding to public comments on the proposed rule and recommendations for improvement to this system by setting forth explicit

expectations for outcomes, and high quality transplantation services.

We are codifying the requirements for the approval and re-approval of transplant centers as an option under part 482, subpart E, for hospitals that choose to perform transplants. This final rule applies to hospitals with heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers. For purposes of this final rule, heart-lung transplant centers are those centers that are 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. Intestine centers are those Medicare-approved liver transplant centers that perform intestine transplants, combined liver-intestine 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 also perform kidney-pancreas transplants.

II. Provisions of the Proposed Rule and Response to Comments on the February 4, 2005 Proposed Rule

In the February 4, 2005 **Federal Register** (70 FR 6140), we published the proposed rule entitled, "Hospital Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants" and provided for a 60-day comment period. On March 25, 2005, we published a notice in the **Federal Register** (70 FR 15264) extending the comment period for an additional 60 days, until June 6, 2005, to allow sufficient time for the public to provide comments on the large number of proposed new requirements.

The proposed rule set forth new hospital CoPs for the approval and re-approval of transplant centers at 42 CFR part 482, subpart E. Additionally, following publication of the proposed rule, we conducted an external, independent peer review of several of the technical aspects associated with the proposed outcome measures and options. We contacted five scientists, of which three sent us detailed comments to address the technical questions that we raised. One scientist declined to provide detailed comments but said his views were reflected by the comments provided by the American Society of Transplant Surgeons/American Transplantation Society (ASTS/ATS). Comments provided by the ASTS/ATS partially addressed these technical issues, as well as more general issues of concern to the society. These peer

reviews were received during the public comment period. Below we respond to the comments of the peer reviewers, in addition to the public comments received during the comment period.

We received a total of 91 comments: 48 from individual transplant centers; 10 from professional associations representing those who work in the field of transplantation (including physicians, surgeons, dietitians, nurses, social workers, transplant coordinators, hospitals), 2 from organizations that support transplantation, (that is, the National Kidney Foundation and National Liver Foundation); 9 from individual social workers; 6 from individual transplant coordinators; 5 from individual organ procurement organizations; and 11 from various sources (including the Scientific Registry of Transplant Recipients, United Network for Organ Sharing, the Secretary's Advisory Committee on Organ Transplantation, the New York State Department of Health, the Joint Commission on Accreditation of Healthcare Organizations, individual physicians, a histocompatibility laboratory, a living donor, and a dialysis facility). The comments ranged from general support or opposition to the proposed conditions of participation to very specific questions or comments regarding the proposed criteria. Note that comments made by peer reviewers are identified specifically as peer review comments. All other comments were made by the public.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the economic impact analysis), and our responses to the comments are set forth below. Comments related to the paperwork burden and the impact analysis are addressed in the Collection of Information and Impact Analysis Sections in this preamble.

General Comments

Comment: Many commenters supported and commended our efforts to update Medicare approval and re-approval requirements for transplant centers. Some commenters indicated they were impressed by our recognition of the highly complex issues faced by transplant recipients and living donors. Other commenters stated that the rationales provided in the February 4, 2005 proposed rule were based on sound medical and transplant practices. Some commenters stated that this rule may help to decrease organ wastage and graft failure, which would reduce the

need for kidney dialysis services and re-transplantation of failed organs.

Some of the professional associations and three peer reviewers supported our efforts to update transplantation standards for Medicare-approved centers, codify standards for extra-renal organ transplants, and improve care for Medicare beneficiaries and living donors. One peer reviewer was pleased with the comprehensiveness of the proposed rule, which the peer reviewer said builds upon the work of the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR), and the Health Resources and Services Administration (HRSA). Another peer reviewer supported the re-approval process and stated that a mechanism to re-approve transplant centers is essential.

Response: We thank the commenters and peer reviewers for their assistance in developing this final rule. We are committed to ensuring that Medicare-approved transplant centers consistently maintain the expertise and resources necessary to provide high quality transplantation services to patients.

Comment: A few commenters stated that the proposed rule was too prescriptive and expressed concerns that implementation of the rule would bring extra burden to transplant centers, especially kidney transplant centers, in terms of cost and nursing hours. One commenter suggested a more general approach as opposed to using prescriptive language. One commenter inquired about the source of funding for the extra expenses generated by this rule.

Response: One of our goals in publishing new CoPs for transplant centers is to provide flexibility for transplant centers within the framework of our regulatory authority. As stated in the proposed rule, we have set forth requirements that we believe are absolutely necessary to ensure quality care and protect the health and safety of patients. All of the CoPs are specifically transplant-oriented, and we believe that nearly all requirements in this final rule clarify or strengthen normal business practices for most transplant centers. Centers that have not incorporated the requirements in this final rule into their normal business practices will need to assess their transplantation practices and improve their performance. We believe this rule will strengthen accountability of transplant centers, and we expect centers to maintain compliance with the requirements in this final rule and continuously strive to improve quality of care and patient and

living donor safety in their pursuit of optimal outcomes.

We believe this rule will neither increase nursing workloads nor create significant burdens for centers, including kidney centers. We estimate that on average, the cost for each currently-approved Medicare transplant center to comply will be less than \$56,000 in the first full year following the effective date of the final rule and less than \$21,000 in subsequent years.

Comment: A peer reviewer expressed concern that the level of detail in the proposed rule may hamper the Agency's ability to make needed modifications in the future.

Response: We have included only those requirements that we believe are

absolutely essential for ensuring quality care and protecting the health and safety of Medicare beneficiaries and living donors. From an oversight perspective, we must be specific in our expectations so that providers clearly understand the requirements for Medicare participation.

We will continue to stay abreast of the latest advances in transplantation. If hospitals significantly change how they provide transplant patient care or the SRTR changes its outcome measure methodology, we will review and revise the final rule as necessary.

Comment: One commenter stated that the OPTN oversight process and the CoPs would create inconsistent parallels for review of transplant center performance. Another commenter was

concerned that the OPTN and the proposed CMS review processes were duplicative or inconsistent in some areas. The commenter believed that the OPTN oversight and compliance with the Medicare CoPs should be consistent and work in tandem.

Response: Our intent is that OPTN policies and the requirements in this final rule will complement but not duplicate each other. Nevertheless, in some instances, we have incorporated OPTN policies into our requirements so that they are enforceable under Medicare. Below is a crosswalk chart that shows overlap and differences between OPTN policies and CMS regulations:

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
|--|---|---|
| <p>Main focuses of CMS requirements.</p> <ul style="list-style-type: none"> Regulatory oversight of transplant centers. Patient care & transplant services furnished to beneficiaries. Relationship with transplant centers based on Provider Agreement & Medicare reimbursement. Medicare approval & re-approval based on compliance with Conditions of participation (CoPs). Provider responsibilities. | <p>Part 121 sets forth the governing structure of the OPTN and sets standards for availability of organ transplantation data. Part 121 lays out requirements for transplant program in hospitals at §§ 121.9 and 121.11(b)(1)(C) (defined as OMB-approved OPTN forms). Main focuses of Part 121.</p> <ul style="list-style-type: none"> Govern the operation of the OPTN which is under contract with HRSA. Require OPTN to develop policies for its members. However, as of today, with the exception of "data submission requirements", none of the OPTN policies have been enforceable because they have not been approved and published by the Secretary. | <p>Main focuses of OPTN policies/Bylaws.</p> <ul style="list-style-type: none"> Organ allocation. Credential of transplant surgeons/physicians. Relationship with transplant hospital members is collegial with the goal to help them to improve performance. OPTN Membership application reviewed by peer reviewers. Member obligations. <p>*Additional requirements for non-Medicare approved transplant programs.</p> |
| <p>§ 482.68 Special Requirements for transplant centers. In order to be granted approval from CMS to provide transplant services, a transplant center must:</p> <ul style="list-style-type: none"> Be located within a hospital that has a Medicare provider agreement. Meet the CoPs of this final rule. Meet all hospital CoPs. | <p>Compliance with Part 121 OPTN membership requirements.</p> | <ul style="list-style-type: none"> This rule now makes the data submission requirements of OPTN a Condition of Participation. Transplant centers must comply with CoPs to be reimbursed. |
| <p>§ 482.70 Definitions. CMS has specific definitions for certain types of centers.</p> | <p>Generic definitions in part 121</p> | <p>No comparable OPTN definitions.</p> |
| <p>§ 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 approved rules and requirements of the OPTN established and operated in accordance with § 372 of the Public Health Service (PHS) Act (42 U.S.C. section 274).</p> | <p>§ 121.9 Designated transplant program requirements.</p> <ul style="list-style-type: none"> (a) To receive organs for transplantation, a transplant program must be in a hospital that is a member of the OPTN. | |
| <p>§ 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 alter elements in the approval/re-approval application:</p> <ul style="list-style-type: none"> A change in key staff members of the transplant team. A decrease in the center's volume or survival rates. | <p>OPTN Bylaw Appendix B-3</p> <p>OPTN member programs must notify OPTN immediately when a key person plans to leave.</p> | <p>CMS adopts the OPTN bylaw and adds more requirements.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
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| <ul style="list-style-type: none"> • Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs. • Inactivation of the transplant center. § 482.76 Condition of participation: Pediatric Hospitals. • With the exceptions of heart centers, pediatric centers that wish to provide transplantation services to both adult and pediatric transplants must meet all requirements (except for clinical experience) in this rule and request separate Medical approval. • A center that mostly performs adult transplants cannot be approved to perform pediatric transplants if they lose their approval to perform adult transplants. • A center that mostly performs pediatric transplants cannot be approved to perform adult transplants if they lose their approval to perform pediatric transplants. • Heart centers that want to obtain Medicare approval for pediatric transplants have the option to be approved under the criteria listed under OBRA 1987. § 482.80 Condition of participation: Data submission, clinical experience, and outcome requirements for INITIAL APPROVAL of transplant centers. (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. (b) Standard: Clinical experience. We require an annual volume for the following types of transplant centers: <ul style="list-style-type: none"> • Heart, intestine, liver & lung transplant centers—10 transplants. • Kidney transplant centers—at least 3 transplants. • No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants. | <p>.....</p> <p>§ 121.11(b)(2) Reporting requirements. Member transplant hospitals must submit to the Secretary information as the Secretary prescribes (OPTN forms).</p> <p>§ 121.11(b)(1)(C)</p> <ul style="list-style-type: none"> • The OPTN & the SRTR shall provide to the Secretary any data that the Secretary requests. • Make available to the public timely & accurate program-specific information on the performance of transplant programs. <p>OPTN Policy 7.8 Data Submission Requirements.</p> <ul style="list-style-type: none"> • Each transplant center must collect & submit 95% of expected forms complete within 3 months of the due date and 100% of expected forms complete within 6 months of the due date. <p>No annual volume required by the OPTN. However, it has definitions for "functionally inactive" centers:</p> <ul style="list-style-type: none"> • No transplants performed in 3 months in the case of kidney, liver, & heart transplant programs. • No transplants performed in 6 months in the case of pancreas & lung programs. | <p>No specific OPTN policy/bylaw for pediatric transplant programs.</p> <p>By using the publicly available SRTR data for outcome measures, CMS's outcome complements Part 121. CMS adopts the OPTN policy for the most part.</p> <p>CMS requirements are straighter than OPTN policy for the purpose of monitoring inactivity of centers.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
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| <p>(c) Standard: Outcome measures</p> <ul style="list-style-type: none"> • We 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 pediatric transplants. • A center's (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds: <ul style="list-style-type: none"> • $O - E > 3$. • $O/E > 1.5$. • 1-sided $p < 0.05$. <p>(d) Exceptions. No outcome requirements for:</p> <ul style="list-style-type: none"> • Heart-lung transplant centers. • Intestinal transplant centers. • Pancreas transplant centers. <p>§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for <i>RE-APPROVAL</i> of transplant centers.</p> | <p>OPTN Bylaw Appendix B Attachment Survival Rates.</p> <ul style="list-style-type: none"> • While the precise numerical criteria may be selected by the Membership & Professional service Committee, the initial criteria employed to identify programs with low patient/graft survival rates will include the following findings: <ul style="list-style-type: none"> • $O - E > 3$. • $O/E > 1.5$. • 1-sided $p < 0.05$. | <p>CMS adopts the OPTN bylaws to the extent that the outcome measure standards and the OPTN policies for survival rate criteria & outcome methodology are essentially the same in the assessment of a center's outcomes. However, OPTN uses the survival outcomes as flags for further investigation while CMS uses them as criteria to make approval & re-approval determinations. Compliance with the OPTN's survival rate criteria is not required for initial approval of a new transplant program as an OPTN member. The OPTN grants conditional approval to new transplant programs, which gives the new transplant program 3 years to comply with the OPTN requirements.</p> |
| <p>(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.</p> | <p>See Initial Approval</p> | <p>See Initial Approval.</p> |
| <p>(b) Standard: Clinical experience. We require an annual volume for the following types of transplant centers:</p> <ul style="list-style-type: none"> • Heart, intestine, kidney, liver & lung transplant centers—10 transplants. • No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants. | <p>See Initial Approval</p> | <p>See Initial Approval.</p> |
| <p>(c) Standard: Outcome measures</p> <ul style="list-style-type: none"> • We 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 pediatric transplants. • A center's (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds: <ul style="list-style-type: none"> • $O - E > 3$. • $O/E > 1.5$. • 1-sided $p < 0.05$. <p>(d) Exceptions. No outcome requirements for:</p> <ul style="list-style-type: none"> • Heart-lung transplant centers. • Intestinal transplant centers. • Pancreas transplant centers. | <p>See Initial Approval</p> | <p>See Initial Approval.</p> |
| <p>§ 482.90 Condition of participation: Patient and living donor selection.</p> <p>(a) Standard: Patient selection. Patient selection criteria must:</p> <ul style="list-style-type: none"> • Assure fair and non-discriminatory distribution of organs. • Include a psychosocial evaluation. | <p>§ 121.8 Allocation of Organs</p> <p>The OPTN has wait list policies for the purpose of organ allocation.</p> | <p>CMS requirements complement OPTN policies.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
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| <ul style="list-style-type: none"> • Include documentation in the patient's medical record that the candidate's blood type has been determined on at least two separate occasions. • Include documentation in the patient's medical record of the patient selection criteria used. | | |
| <p>(b) Standard: Living donor selection. The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:</p> | | No comparable OPTN policy/bylaw. |
| <ul style="list-style-type: none"> • Ensure that a prospective living donor receives a medical & Psychosocial evaluation prior to donation. • Document in the living donor's medical records the living donor's suitability for donation. • Document that the living donor has given informed consent, as required. | | |
| <p>§ 482.92 Condition of participation: Organ recovery and receipt.</p> | | |
| <ul style="list-style-type: none"> • Written protocols for—deceased organ recovery, organ receipt, and living donor transplantation to validate donor-recipient matching of blood types and other vital information. • The transplanting surgeon at the transplant center responsible for ensuring medical suitability of donor organs for transplantation into the intended recipient. | | |
| <p>(a) Standard: Organ recovery.</p> | <p>Policy 3.1 Organ Distribution: Definitions.</p> | <p>CMS requirements complement OPTN policies.</p> |
| <p>When an intended transplant recipient is known, the transplant center's organ recovery team must review and compare donor-data with the recipient blood type and other vital information before organ recovery takes place.</p> | <p>3.1.2 Transplant Center—The transplanting surgeon is responsible for ensuring medical suitability of donor organ for transplantation into the potential recipient, including compatibility of donor and candidate by ABO blood type.</p> | |
| <p>(b) Standard: Organ receipt.</p> | <p>Policy 3.1 Organ Distribution: Definitions.</p> | <p>CMS requirements complement OPTN policies.</p> |
| <ul style="list-style-type: none"> • When an organ arrives at the center, the transplanting surgeon and at least one licensed health care professional must verify that the donor's blood type and other vital information is compatible with transplantation of the intended recipient prior to transplantation. | <p>3.1.2 Transplant Center—Upon receipt of an organ, prior to implantation, the transplant center is responsible for verifying the recorded donor ABO with the recorded ABO of the intended recipient.</p> | |
| <p>(c) Standard: Living donor transplantation.</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <ul style="list-style-type: none"> • If a center performs living donor transplants, the transplanting surgeon and at least one licensed health care professional at the transplant center must verify that the donor's blood type and other vital information is 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). | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>§ 482.94 Condition of participation: Patient and living donor management.</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <ul style="list-style-type: none"> • Transplant center must have written patient management policies and patient care planning for the pre-transplant, transplant, and discharge phases of transplantation. • Center must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation if it performs living donor transplants. | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>(a) Standard: Patient and living donor care.</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>Each transplant patient and/or living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout transplantation or donation.</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
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| <p>(b) Standard: Waitlist management. Transplant centers must keep their waitlists up to date, including:</p> <ul style="list-style-type: none"> • Updating waitlist patients' clinical information on an ongoing basis. • 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. • Notifying the OPTN no later than 24 hours after a patient's removal from the center's waitlist. | <p>OPTN Policies 3.2.3.1, 3.6.6</p> <ul style="list-style-type: none"> • Require transplant centers to immediately remove transplant candidates that have received a transplant from a deceased donor, or have died while awaiting a transplant, from the center's waitlist and from the UNOS Patient Waiting List and to notify UNOS within 24 hours of such removal. | <p>CMS Requirements complement OPTN policies.</p> |
| <p>(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. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of:</p> <ul style="list-style-type: none"> • Patient's placement on the center's waitlist; the center's decision not to place the patient on its waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed. • Removal from waitlist for reasons other than transplantation or death within 10 days. • Patient records must contain documentation of: • Multidisciplinary patient care planning during the pre-transplant period. • Multidisciplinary discharge planning for post-transplant care. | <p>OPTN Bylaw Appendix B</p> <p>II.C.10 Transplant Programs: Patient Notification</p> <p>Transplant programs must notify patients in writing:</p> <ul style="list-style-type: none"> (i) within ten business days (a) of the patient's being placed on the UNOS Patient Waiting List including the date the patient was listed, or (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the UNOS Patient Waiting List at this time, whichever is applicable; and (ii) within ten business days of removal from the UNOS Patient Waiting List as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the Waiting List. The transplant program must maintain. | <p>CMS adopts OPTN bylaw for the most part.</p> |
| <p>(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. Definitions for a qualified social worker included.</p> | <p>§ 121.9(a) Designated Transplant Program Requirements</p> <p>OPTN Bylaw Appendix B, Attachment I, III.C.15 Transplant Programs: Social Support—Psychiatric and social support services must be available in transplant programs approved under 121.9(a)(2).</p> | <p>The OPTN bylaw does not define qualification of a qualified social worker. CMS requirement complement OPTN bylaw.</p> |
| <p>(e) Standard: Nutritional services. Nutritional assessments and diet counseling services furnished by a qualified dietitian must be available to all transplant patients and living donors. Definitions for a qualified dietitian included.</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).</p> | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>A transplant center must have a data-driven QAPI programs to monitor & evaluate performance of all transplantation services.</p> | | |
| <p>§ 482.98 Condition of participation: Human resources.</p> | | |
| <p>(a) Standard: Director of a transplant center. Transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director.</p> | | |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
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| <p>(b) Standard: Transplant surgeon and physician.</p> <ul style="list-style-type: none"> • 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, who are immediately available to provide transplantation services when an organ is offered for transplantation. • Transplant surgeon is responsible for providing surgical services related to transplantation. • Transplant physician is responsible for providing and coordinating transplantation care. | <p>OPTN Bylaw Appendix B defines the credential of a qualified transplant surgeon and physician in 15 pages.</p> <p>Each transplant center designated under 42 CFR 121.9(a)(2) must have on-site a qualified transplant surgeon.</p> | <p>The OPTN bylaw for credentials is too detailed for adoption in regulation.</p> <p>CMS requirement for “immediate availability of the primary transplant surgeon & physician” complement OPTN’s “on-site” bylaw.</p> |
| <p>(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 throughout transplantation and donation.</p> | <p>OPTN Bylaw Appendix B: Requirement for a Clinical Transplant Coordinator with defined responsibilities.</p> | <p>CMS requirement complement the OPTN bylaw.</p> |
| <p>(d) Standard: Independent living donor advocate of living donor advocate team. The transplant center that performs living donor transplants must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.</p> | | |
| <p>(e) Standard: Transplant team. The transplant center must identify a multidisciplinary transplant team (composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology) and describe the responsibilities of each member of the team.</p> | <p>§ 121.9(a) Designated Transplant Program Requirements.</p> <p>OPTN Bylaw Appendix B Attachment I.</p> <p>Collaborative Support—Transplant programs approved under 121.9(a)(2) must show evidence of collaborative involvement with experts in the field of hepatology, radiology, pediatrics, infectious disease, nephrology with dialysis capability, pulmonary medicine with respiratory therapy support, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine.</p> | <p>CMS requirements complement Part 121 requirements and OPTN bylaw.</p> |
| <p>(f) 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.</p> | <p>§ 121.9(a) Designated Transplant Program Requirements.</p> <p>Bylaws Appendix B Attachment I.</p> <p>Transplant Programs—Ancillary services—Transplant programs approved under 121.9(a)(2) must have immediate access to sophisticated microbiology, clinical chemistry, tissue typing, bloodbank support, radiology services, as well as the facilities required for monitoring immunosuppressive drugs.</p> | <p>CMS adopts the Part 121 requirements and OPTN bylaw.</p> |
| <p>§ 482.100 Condition of participation: Organ procurement.</p> <ul style="list-style-type: none"> • Transplant center must ensure that transplant hospital has written agreement (with delineated responsibilities for both parties) with an OPO designated by the Secretary. | <p>§ 121.9(a) Designated Transplant Program Requirements.</p> <p>Bylaws Appendix B Attachment I A transplant program approved under 121.9(a)(2) must have letters of agreement or contracts with an OPO.</p> | <p>CMS requirement complement the OPTN bylaw because the OPTN bylaw does not require transplant centers to notify the OPTN or CMS when an agreement with an OPO is terminated.</p> |
| <p>§ 482.102 Condition of participation: Patient and living donor rights.</p> <ul style="list-style-type: none"> • 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. | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |
| <p>(a) Standard: Informed consent for transplant patients.</p> <ul style="list-style-type: none"> • Transplant centers must have written policies for the informed consent process. • Each patient will be informed about: <ul style="list-style-type: none"> —The evaluation process; —The surgical procedure; —Alternative treatments; | <p>.....</p> | <p>No comparable OPTN policy/bylaw.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
|--|---|---|
| <ul style="list-style-type: none"> —Potential medical or psychosocial risks; —National & center-specific outcomes from the most recent SRTR center-specific report, including (but not limited to) the transplant center’s observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center; —Organ donor risk factors that could affect the success of the graft or health of the patient; —His or her right to refuse transplantation; —The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient’s ability to have his or her immunosuppressive drugs paid under Medicare Part B. <p>(b) Standard: Informed consent for living donors.</p> <ul style="list-style-type: none"> • Transplant centers must have written policies for the informed consent process. • Each living donor will be informed about: <ul style="list-style-type: none"> —The fact that communication between the donor & the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 & 164. —The evaluation process. —The surgical procedure, including post-op treatment. —The availability of alternative treatments for the transplant recipient. —The potential medical or psychosocial risks to the donor. —The national & center-specific outcomes for recipients & living donors as data are available. —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. —The donor’s right to opt out of donation at any time during the donation process. —The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient’s ability to have his or her immunosuppressive drugs paid under Medicare Part B. | <p>.....</p> | <p>No comparable OPTN policy/bylaw. CMS adopts many of the informed consent elements contained in the Secretary’s Advisory Committee on Transplantation (ACOT) Recommendations.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
|--|--|---|
| <p>(c) Standard: Notification to patients Transplant centers must notify patients placed on the center's waiting list 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: —The fact the center is served by a single transplant surgeon or physician, 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.</p> <ul style="list-style-type: none"> • At least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must inform: <ul style="list-style-type: none"> —Patients on the waiting list & provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved center without loss of time accrued on the waiting list; and —Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval. • As soon as possible prior to a transplant center's inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. | <p>§ 121.9 Designated Transplant Program Requirements. (a) To receive organs for transplantation, a transplant program approved under 121.9(a)(2) agrees to promptly notify OPTN & patients awaiting transplantation if it becomes inactive. OPTN Bylaws Appendix B Attachment I—Criteria for Institutional Membership. III.C Transplant programs—A transplant program served by a single surgeon or physician shall inform patients of this fact and potential unavailability of 1 or both of these individuals during the year. OPTN Bylaws, Appendix B. VI. Change in Program Status. When a transplant program is voluntarily or involuntarily inactivated, waitlist patients may retain existing waiting time and continue to accrue waiting time. Accrued waiting time may be transferred to the patient's credit when s(he) is listed with a new program.</p> | <p>CMS adopts Part 121 and OPTN bylaws.</p> |
| <p>§ 482.104 Condition of participation: Additional requirements for kidney transplant centers. (a) Standard: End stage renal disease (ESRD). • Kidney transplant centers must furnish directly transplantation & other medical & 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. (c) Standard: Participation in network activities. • Kidney transplant centers must cooperate with the ESRD Network designated for its geographical area, in fulfilling the terms of the Network's current statement of work.</p> | <p>..... Bylaws Appendix B—Criteria for Institutional Membership. III.E Relocation and Transfer of Established Programs.</p> | <p>No comparable Part 121 requirements or OPTN policy/bylaw for kidney transplant centers.</p> |
| <p>No comparable CMS requirements No comparable CMS requirements</p> | <p>Part 121.8 Allocation requirements of Organs. OPTN Policy 3.0 Organ Distribution. 3.3 Acceptance Criteria. 3.4 Organ Procurement, distribution, and alternative systems for organ distribution or allocation. 3.9 Allocation System for Organs Not Specifically Addressed.</p> | <p>Relocation and transfer of established programs is not addressed in CMS requirements. The OPTN policies are all organ allocation/acceptance policies.</p> |

CROSSWALK OF TRANSPLANT CENTER FINAL RULE, PART 121, & OPTN POLICIES AND BYLAWS—Continued

| CMS requirements | 42 CFR Part 121, OPTN policies, and bylaws for transplant centers | Comments |
|--|--|--|
| <p>§ 488.61 Special procedures for approval and re-approval of organ transplant centers.</p> <ul style="list-style-type: none"> • Survey, certification, and enforcement procedures at 42 CFR part 488, subpart A, including the periodic review of compliance and approval contained in § 488.20. • Transplant centers that meet all data submission, clinical experience, outcome, and process requirements will be approved for 3 years. • Current Medicare-approved centers will continue to be Medicare approved after submitting applications and awaiting CMS's decision for approval. • At the end of 3-year approval period, CMS will review transplant center's data to determine compliance with data submission, clinical experience and outcome requirements at § 482.82. • If a center is in compliance with § 482.82, CMS may choose to review its compliance with the rest of the CoPs. • A transplant center may remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle. • Centers that have lost their Medicare approval may seek re-entry into the Medicare program at any time, and the center must: <ol style="list-style-type: none"> (1) Request initial approval; (2) Comply with the initial approval requirements; 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. <p>Part 498 Appeals procedures for determinations that affect participation in the Medicare program and for determinations that affect the participation of ICFs/MR and certain NFs in the Medicaid program.</p> <ul style="list-style-type: none"> • The definition of "provider" is amended by adding "transplant center" after "hospital" the first time it appears. | <p>3.10 Back-up for Inactive Transplant Programs.</p> <p>3.11 Intestinal Organ Allocation. Appendix to Policy 3.0.</p> <p>A. HLA Antigen Values and Split Equivalences.</p> <p>C. Resolving Discrepant Donor and Recipient HLA Typing Results in the OPTN Database.</p> <p>Policy 4.0 Acquired Immune Deficiency Syndrome (AIDS) and Human Pituitary Deceived Growth Hormone (HPDGH) and Human T-Lymphotropic Virus Type I (HTLV-I).</p> <p>Policy 6.0 Transplantation of Non-Resident Aliens.</p> <p>§ 121.10(c)(1)(2) Enforcement of OPTN rules.</p> <p>Sanctions for violations of non-mandatory policies or mandatory policies (w/o approval from the Secretary of DHHS) include:</p> <ul style="list-style-type: none"> • Warning, letter of admonition, or letter of reprimand. • Probation. • Member Not in Good Standing. <p>Additional Sanctions (only for violation of mandatory policies):</p> <ul style="list-style-type: none"> • Suspension of member privileges. • Termination of OPTN membership. • Termination of Status as Designated Transplant Program, Termination of Participation in Medicare/Medicaid, Termination of Reimbursement under Medicare/Medicaid. <p>The 3 additional sanctions can only be imposed by the Secretary.</p> <p>§ 121.10(c) Sanctions can also be imposed for violations of Part 121, including its data submission requirements, and when the Secretary determines that the public health or patient safety is at risk.</p> | <p>OPTN policies and bylaws are voluntary, until approved (i.e., codified) by the Secretary. At this time, the Secretary has not approved or published any OPTN policies and bylaws, except for data submission requirements.</p> <p>For the first time, transplant centers have the same appeal rights as other Medicare providers.</p> |

CMS Oversight and OPTN Policies

Some commenters voiced their opinions about our oversight of transplant centers in comparison to OPTN oversight of its transplant hospital members.

Comment: Some commenters stated their appreciation that the proposed rule is congruent with OPTN policies and bylaws, because OPTN policies and bylaws were developed through a consensus process with broad participation by the transplant community. Commenters pointed out

that the rule sets consistent and unified standards and provides an established infrastructure for performance monitoring and review of transplant centers.

Response: The OPTN's primary responsibilities are to ensure the effectiveness, efficiency, and equity of

organ allocation; increase the supply of transplantable organs; collect and disburse data; and designate transplant programs. We are responsible for establishing minimum standards to protect patient health and safety, and for implementing oversight mechanisms to ensure that transplant centers provide quality transplant and living donor care to Medicare beneficiaries through the development of health and safety requirements. In developing this rule, we worked closely with HRSA, which oversees the OPTN and SRTR, to ensure consistency and minimize the burden on transplant centers where possible.

Comment: A commenter requested that we limit our role to reimbursement of clinical services.

Response: As a health care regulatory agency and a prudent health care purchaser, our responsibility cannot be limited to reimbursement. The Secretary has the statutory authority and responsibility to protect patient health and safety and to ensure that high quality care is provided to patients.

Comment: Many commenters stated that the OPTN oversight process and our approval and re-approval process would create an inconsistent and duplicative mechanism in the oversight of transplant centers. The commenters stated that we should collaborate with the OPTN to streamline the two processes into one unified consistent process, but with more reliance on OPTN oversight. One public commenter stated that CMS should consider termination of a center only if the OPTN Board reports to the Secretary that it has made a final decision to take adverse action against the center. A peer reviewer was concerned that the collegial relationship between OPTN and the transplant centers might be jeopardized by codification of some of the OPTN requirements.

Response: We understand the commenters' concerns. However, for the most part, we and the OPTN have different roles vis-à-vis transplant centers. For example, when surveying transplant centers for compliance with the CoPs in this final rule, we will focus on protections for patient health and safety. When the OPTN surveys (or performs desk audits of) transplant centers, it focuses on compliance with candidate listing and delisting, data submission, and its patient notification policies and verifies that the designated physician and surgeon are the same individuals approved by the OPTN. The degree of authority to act in the event of non-compliance also differs. The OPTN generally takes a collegial approach and assists centers in improving their performance, while we

generally take a regulatory approach which sometimes may lead to termination of the Medicare agreement with providers. However, compliance with the OPTN's policies will facilitate transplant centers' compliance with the requirements in this final rule. Therefore, the OPTN will continue to play a consultative role with transplant centers to assist them in complying with Medicare requirements. We believe the collegial relationship between the OPTN and the transplant centers may be enhanced and strengthened rather than compromised.

Comment: Many commenters stated that the OPTN oversight process is vigorous and effective and that the OPTN should have full oversight of transplant centers to avoid duplicative efforts. The commenters cited 42 CFR part 121 as the regulation governing the operation of the OPTN and stated that the OPTN has legally binding rules enforceable on transplant centers.

Other commenters noted that the OPTN already surveys heart and liver programs once every 3 years. The commenters recommended that the OPTN be recognized as the accrediting body to audit and survey centers periodically based on its expertise in dealing with the complexity of transplantation. A commenter recommended that we review a center for potential termination from the Medicare program only if the Secretary has been notified of a final decision of the OPTN Board to take an adverse action against the center. The commenters stated that reviews or surveys conducted by an inexperienced CMS designee would burden centers and lead to misinterpretation of OPTN policies and CMS regulations, which could cause confusion and loss of Medicare approval.

Response: The commenters are correct that 42 CFR part 121 governs the operation of the OPTN, which establishes policies for transplant hospital members. OPTN policies are enforceable only when they have been incorporated into regulations by the Department. However, with the exception of the OPTN data submission requirements, OPTN policies have not been incorporated by the Department. Therefore, if the OPTN determines that removal of a member's designation as a transplant hospital is warranted for reasons of non-compliance with other OPTN policies, with the final rule governing the operation of the OPTN (42 CFR part 121), or because of a threat to public health and safety, the OPTN will recommend to the Secretary that the member's designation be revoked. The

OPTN has made this recommendation on only two occasions.

We have an obligation to oversee transplant centers serving Medicare beneficiaries, and we do not have the statutory authority to delegate oversight responsibilities to the OPTN. In our view, the OPTN oversight approach is a complement to the Medicare regulatory authority. Once the final rule becomes effective, and before conducting surveys, our surveyors will be trained in applicable OPTN policies for transplant centers.

Comment: A commenter recommended that the Secretary take action to expand the role of the OPTN relative to oversight of living donors.

Response: The commenter's recommendation falls outside the scope of this final rule. We will forward this recommendation to the Secretary for consideration.

Comment: A commenter stated that despite the fact that the OPTN requires transplant programs to abide by OPTN policies and bylaws, we should not codify the OPTN policies and bylaws as regulatory language. One commenter stated that the relatively fluid OPTN policies and bylaws would allow the incorporation of future changes in transplant practice more quickly.

Response: The requirements in this final rule are intended to be broadly applicable to transplant centers over a long period of time. OPTN policies or elements of OPTN policies that we have included in this final rule conform to this intent. We understand that many OPTN policies, particularly organ allocation, transplant surgeon and transplant physician credentials, and criteria for listing and de-listing transplant candidates are subject to rapid changes as transplant medicine advances. Therefore, we did not include such policies in this final rule.

Comment: Some commenters raised confidentiality concerns regarding the sharing of data between the OPTN and CMS under applicable laws and regulations protecting the peer review process. One commenter suggested adding language to state that the regulation is not intended to affect the confidentiality of the process in any manner.

Response: We understand the commenters' concerns about the confidentiality of data shared between the OPTN and CMS. However, under reporting requirements set forth in 42 CFR 121.11(b)(1)(iii), the OPTN and the SRTR are required to provide to CMS any data that we request, as appropriate. Nonetheless, it is not our intention to disrupt the OPTN confidential peer review process. We will obtain only the

OPTN data that is necessary for our oversight of transplant centers.

Comment: One commenter suggested that section 1865 of the Act and regulations at 42 CFR part 488 mean that only CMS's designated national accrediting organizations are eligible for deeming authority for transplant centers. The commenter further stated that organizations that accredit both hospitals and transplant centers are in the best position to ensure consistent quality oversight and avoid fragmented survey arrangements.

Response: We will consider applications from any national accrediting organization for deeming authority for initial approval and re-approval for any of the extra-renal transplant centers. We believe that we have the statutory authority to permit national accrediting organizations to accredit most transplant centers as "facilities," pursuant to paragraph 1865(b)(4) of the Act, with the exception of kidney transplant centers. As discussed previously, section 1864 of the Act authorizes the use of State agencies to determine providers' compliance with the CoPs. A national accreditation program may apply for deeming authority for the providers that are specifically listed in § 488.6. Since "transplant centers" are not specifically identified in § 488.6, this final rule inserts the language "transplant centers, except for kidney transplant centers" in § 488.6(a) with the list of providers eligible for deeming authority. Kidney transplant centers are specifically excluded because they are not eligible for deeming authority by statute. (See sections 1864 and 1865(b)(4) of the Act.)

Special Requirements for Transplant Centers (Proposed § 482.68)

We proposed that a transplant center located within a hospital that has a Medicare provider agreement must meet the CoPs specified in § 482.72 through § 482.104 in order to be granted our approval to provide transplant services.

We proposed that the CoPs specified in § 482.72 through § 482.104 would apply to all heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplant centers, unless specified otherwise.

We also proposed that transplant centers seeking Medicare approval must meet the hospital CoPs specified in § 482.1 through § 482.57.

We received no comments on this section of the proposed regulation and are finalizing it as proposed.

Definitions (Proposed § 482.70)

We proposed definitions for "transplant hospital," "transplant

program," and "transplant center" to clarify the usage of these terms throughout the regulation.

We proposed deleting the definitions for "histocompatibility testing," "ESRD Network," "network organization," "organ procurement," "renal transplantation center," "transplantation service," and "transplantation surgeon" contained in § 405.2102, as these terms are no longer used in the section.

We proposed including the definitions for "ESRD," "ESRD network," and "network organization" from § 405.2102 in this final rule to emphasize the distinct statutory authority and requirements that kidney transplant centers have to meet and to clarify the use of the terms in the proposed CoPs for transplant centers.

We proposed adding definitions for "adverse event," "heart-lung transplant center," "pancreas transplant center," and "intestinal transplant center."

This final rule includes all definitions related to ESRD Network programs from 42 CFR part 405, subpart U, § 405.2102, as well as §§ 405.2110 through 2114. We note that in the proposed rule we incorrectly stated that our proposed definition for "adverse event" was derived from the JCAHO's definition of "adverse event." In fact, JCAHO has a definition for "sentinel event" but not "adverse event." Additionally, we have made a change to the definition of "adverse event" for clarification purposes. The proposed definition listed two examples of adverse events related to living donors: "living donor death due to mismanagement of the donor" and "avoidable loss of a healthy living donor." We have replaced these two examples with "serious medical complications or death caused by living donation" to clarify that the death of any living donor or a living donor's serious medical complications caused by living donation should be investigated as an adverse event. Following are summaries of the comments we received and our responses.

Comment: One commenter applauded our efforts to standardize definitions for transplant hospitals for the purpose of improving communication. The commenter noted that JCAHO developed a Patient Safety Event Taxonomy in response to the lack of agreement on definitions regarding medical errors. The commenter suggested that the adoption of the Patient Safety Event Taxonomy developed by the JCAHO in the quality assessment and performance improvement (QAPI) CoP would

decrease confusion, improve patient safety, and promote quality.

Response: A Patient Safety Event Taxonomy is a system of classifying adverse events at hospitals or other providers of health care. Thus, the Taxonomy is a "language" in which providers can report adverse events. One of the JCAHO's current initiatives is to "promote using health information technology to improve patient safety reporting, data analysis and learning from errors, and to promote a national reporting system for adverse events through the use of standardized patient safety taxonomy and ontology." Although the final rule provides a general definition for an "adverse event" in transplantation, it does not attempt to classify all possible adverse events in health care or transplantation. The Patient Safety Event Taxonomy classifies all health care events, not just those related to transplantation. Incorporation of the Taxonomy into the QAPI CoP would be inappropriate because it falls outside the scope of this rule. Therefore, we have not adopted the commenter's suggestion.

Comment: One commenter noted that the term "transplant center" is commonly used interchangeably with the term "transplant hospital." For this reason, the commenter stated that our proposal to use the term "transplant center" interchangeably with "transplant program" is confusing and the commenter suggested the removal of the term "transplant center" in the final rule.

Response: Although we agree that these terms often are used interchangeably, we believe the transplant community understands our use of the term "transplant center" in this final rule. We do not believe it is necessary to make a change based on this comment.

Proposed General Requirements for Transplant Centers

Condition of Participation: OPTN Membership (Proposed § 482.72)

We proposed that a transplant center must be located in a transplant hospital that is a member of, and abides by the rules and requirements of, the OPTN, as set forth at § 482.45(b)(1), and that are enforceable under 42 CFR 121.10.

We proposed that no transplant hospital would be considered to be out of compliance with section 1138(a)(1)(B) of the Act (which requires participation in the OPTN) unless the Secretary gave the OPTN formal notice that he or she approved the decision to exclude the transplant hospital from the OPTN and notified the center in writing.

We received no comments on this section of the proposed rule. Therefore, we are finalizing it as proposed.

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

We proposed requiring each transplant center to notify us immediately of any significant changes related to the center's transplant program or any change that would otherwise alter specific elements in its application for approval or re-approval.

We proposed that instances in which we should be notified would include, but not be limited to, changes in key staff members of the transplant team (such as the individual who has been designated to the OPTN as the center's primary transplant surgeon or physician) or a decrease in the center's volume or survival rate that could result in the center being out of compliance with § 482.82.

Note that in this final rule, we have added to this section two specific instances that must be reported to us immediately. First, a transplant center must notify us if the hospital in which it is located terminates its agreement with an OPO for recovery and receipt of organs. Further information about this requirement can be found in this preamble in our discussion of the CoP for organ procurement. Second, a transplant center must notify us if it becomes inactive. Further information about our requirements in regard to transplant center inactivity can be found in this preamble in our discussion of clinical experience requirements and special procedures for approval and re-approval of organ transplant centers.

For clarity, we have replaced the language stating that a transplant center must notify us of any change that would otherwise alter specific elements in its application for approval. Section 482.100 of this final rule states that, "a transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation."

Following are summaries of the comments we received and our responses.

Comment: A number of commenters supported the requirement for transplant centers to notify us of significant changes that may affect their approved status. However, some commenters stated that the requirement would be redundant and burdensome because the OPTN already requires such notification.

Response: The OPTN bylaws require transplant hospital members to notify

the OPTN immediately if the hospital learns that its primary surgeon or primary physician plans to leave. The transplant hospital is required to submit to the OPTN the name of the replacement surgeon or physician, curriculum vitae, and documentation of credentials and qualification at least 30 days (if possible) prior to the departure of the individual being replaced.

Although we have avoided duplicating OPTN policies in this final rule (unless we have done so deliberately so that we can enforce a requirement), in this instance, we believe a transplant center should inform us in addition to the OPTN so that we can actively monitor the situation to confirm that the departing surgeon or physician is replaced. We note that the current NCDs require Medicare-approved heart, liver, and lung centers to report such information to us.

Comment: One commenter suggested that transplant centers should not be required to notify us of a significant decrease in volume or survival rates. The commenter stated that an unusually large number of early deaths may not significantly affect 1-year outcomes if the transplant center subsequently has increased volume with successful results. Furthermore, these outcomes will be reflected in the subsequent SRTR 1-year survival reports.

Response: As one component of the active monitoring and oversight of transplant centers, we need to be made aware of any significant changes at transplant centers. However, the outcome requirements in this final rule are based on 1-year patient and graft survival as calculated and reported by the SRTR, meaning that there may be a considerable lapse of time before we have access to data from the SRTR indicating that a transplant center's outcomes have dropped significantly. Although we understand that a decrease in clinical experience (that is, volume) and survival rates within a short period of time does not necessarily signify a problem, we need to be aware of these changes so that we can determine whether they are meaningful, for example, whether a decrease in the number of transplants signals ongoing inactivity and whether a decrease in outcomes signals a significant problem.

When notified by a transplant center of a significant change, we will assess the information to determine how to proceed. We may note the information (such as a change in staff) and take no further action, contact the center for more information, analyze the information in conjunction with HRSA

and the OPTN, and/or conduct an on-site review of the center.

We recognize that it may be challenging for centers to determine whether decreases in the volume and unadjusted survival rates would be significant enough to warrant reporting to CMS. Centers will not be required to independently decide what constitutes a significant change. Centers will receive guidance from CMS through interpretive guidelines and provider notifications as to what constitutes a significant enough decrease in clinical experience or survival rates to necessitate reporting. This guidance is under development.

Interpretive guidelines provide guidance to Medicare surveyors and clarify the intent of regulations. Each provider type is surveyed in accordance with the appropriate protocols based on the substantive requirements in the statute and regulations to determine whether a citation of non-compliance is appropriate. A center will be deemed deficient if it fails to meet the requirements of the statute or regulations, which, in turn, are based on the surveyor's observations of the providers' performance or practices.

The specific process that surveyors use for each type of provider or supplier is outlined in the CMS State Operations Manual. The State Operations Manual is publicly available under the "Manuals" section of the CMS Web site. Included in the appendices of the State Operations Manual are the Interpretive Guidelines (also known as "Guidance to Surveyors") for each type of provider or supplier. The Interpretive Guidelines interpret and clarify the Conditions and Standards that are outlined in statute and regulations. The Interpretive Guidelines merely define or explain the relevant statute and regulations and describe the specific elements that a surveyor will be reviewing and/or observing. The Interpretive Guidelines do not impose any requirements that are not otherwise sets forth in statute or regulation.

Implementation of the survey and certification process for transplant programs will follow this same process. CMS is developing revisions to the State Operations Manual and a separate appendix that will include the Interpretive Guidelines that will be used for surveyors of organ transplant programs. CMS will also be posting informational material on its Web site for providers that would like to request approval for their transplant program. We made no changes based on this comment.

Comment: One commenter noted that there was no definition provided for the term "immediately" for purposes of

describing the time frame within which a transplant center must notify us of changes. Other commenters questioned the term "significant changes" and recommended that the definition should be limited to staff changes and adverse events.

Response: We disagree that the scope of significant changes should be limited to staff changes and adverse events. As we said in our previous response, decreases in the number of transplants performed and in the number of positive outcomes are also significant changes.

We will address the time frame within which a transplant center must notify us of any significant changes and the meaning of "significant changes" in our interpretive guidelines for Medicare surveyors, as that medium permits a more thorough explanation of our expectations. Interpretive guidelines provide guidance to surveyors and serve to clarify and explain the intent of regulations. No changes were made based on this comment.

Comment: One commenter inquired about the consequence of failure to comply with this requirement. The commenter stated that a good faith failure to comply should not constitute grounds for termination.

Response: Notification to us is one of the conditions of participation required for Medicare-approved transplant centers. A center that fails to notify us of any significant changes as delineated in § 482.74 would be considered non-compliant with the transplant conditions of participation and 42 CFR part 488, may be subject to investigation, and could ultimately have its transplant center approval revoked.

Comment: One commenter asked for a CMS contact for notification of changes. A commenter suggested linking transplant centers' notification of changes to the appropriate accrediting organization so that further assessment of the situation can be conducted promptly.

Response: At this time, we do not know whether we or a designee will survey transplant centers. Therefore, under this final rule, a transplant center must report a significant change to us. (See § 482.74.)

Comment: A commenter asked how we will communicate the changes in primary surgeons and physicians to the OPTN, once notified by transplant centers of the change.

Response: The OPTN policies that transplant centers must meet as OPTN members already require transplant centers to inform the OPTN of changes in primary surgeons and physicians immediately; therefore, there is no need

for us to communicate such changes to the OPTN.

Condition of Participation: Pediatric Transplants (Proposed § 482.76)

Children are eligible for Medicare on the basis of ESRD as follows: under section 226A of the Act, an insured worker's dependent child (as defined in regulations) who is medically determined to have ESRD is eligible for Medicare Part A and Part B. According to 42 CFR 408.13, a child is considered "dependent" if he or she is unmarried and is under the age of 22 or is between ages 22 and 26 and has been receiving at least one half of his or her support from the insured worker continuously since before attainment of age 22.

Children are eligible for Medicare on the basis of disability as follows: (1) Under section 223(b) of the Act, individuals who have been entitled to Childhood Disability Benefits (CDB) under section 202(d) of the Act by reason of a disability (as defined in section 223(d) of the Act) for 24 months are entitled to Medicare Part A and Part B the 25th month of disability benefit entitlement. Section 202(d) restricts the first month of CDB entitlement to the month the child attains age 18. Therefore, the earliest month a CDB beneficiary can qualify for Medicare is the month he or she attains age 20; or (2) section 223 of the Act provides that any individual who is under age 65 and has the necessary Social Security work credits, as defined in section 223(c) of the Act, and is under a disability as defined in section 223(d) of the Act, is entitled to Medicare Parts A and B on the 25th month of disability benefit entitlement.

In 2005, Medicare paid for 404 pediatric transplants of different organ types.

We proposed that in order to be reimbursed for transplants performed on pediatric Medicare beneficiaries, a hospital that furnishes transplantation services to both adult and pediatric patients must seek separate Medicare approval to provide pediatric transplantation services.

We also proposed retaining the statutory criteria found at section 4009(b) of the Omnibus Budget Reconciliation Act (OBRA) 1987 (Pub. L. 100-203) as an extra option for heart transplant centers that wish to become Medicare-approved to perform pediatric heart transplants. We did not reference this citation in the proposed rule as an oversight. We proposed that a center that wishes to become Medicare-approved to perform pediatric heart transplants may also be approved by

meeting data submission, outcome, and process requirements in the final rule.

We proposed that 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. For these centers, we proposed that a loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, would result in a loss of the center's approval to perform pediatric transplants. We also proposed that a loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would not impact the center's Medicare approval to perform adult transplants.

We proposed that 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. For these centers, we proposed that loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, would result in a loss of the center's approval to perform adult transplants. We proposed that loss of Medicare approval to perform adult transplants would not impact the center's Medicare approval to perform pediatric transplants.

For a center that performs 50 percent or more of its transplants on pediatric patients, we proposed that there would be no minimum number of adult or pediatric transplants required prior to its request for Medicare approval. Following are summaries of the comments we received and our responses.

Comment: A commenter noted that it is important for pediatric transplant centers to continue to transplant adolescent and young adults beyond the pediatric age range (18-25) to maintain continuity of care of established patients.

Response: We agree. In some situations, a young adult for whom an organ becomes available has received treatment for end stage organ failure from the same pediatric transplant surgeon and pediatric transplant physician for many years and understandably wishes to have the transplant performed at the pediatric center where these physicians practice.

Under the proposed rule and this final rule, which require separate Medicare approvals for performing adult and pediatric transplants, a transplant center performing predominately pediatric transplants will be able to transplant adolescents and young adults age 18 and older. We recognize that pediatric

programs may need to continue transplanting young adults beyond the pediatric age range in order to maintain continuity of care for established patients. The health care needs of these patients are best addressed in a pediatric setting until appropriate transition to adult care can occur. Pediatric centers are required to become certified as both a pediatric and adult transplant center if they intend to provide transplantation services to both populations.

Comment: A few commenters agreed that pediatric centers should meet the transplant center conditions of participation, but they did not agree that adult and pediatric centers should be approved separately. The commenters noted that the low volume of adult transplants performed at pediatric centers does not justify the cost and labor for the centers to seek separate approval to perform adult transplants. Likewise commenters said it would be burdensome to require an adult center to seek separate Medicare approval just to perform a few pediatric transplants.

Response: We understand the commenters' concerns. In our view, a center that performs 50 percent or more of its transplants on adult patients in a 12-month period is considered to be an adult transplant center whereas a center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is considered to be a pediatric transplant center. There are distinct differences between adult centers performing occasional pediatric transplant and pediatric centers performing occasional adult transplants in terms of patient selection criteria, patient management, and the number of transplants performed. Because of these differences, we believe that approving adult and pediatric centers as one unified program is problematic. For example, it would be difficult, if not impossible, for pediatric centers to meet clinical experience requirements that are appropriate for adult transplant centers, which could impair access to pediatric transplants.

However, we will permit a transplant center to submit its request for approval as a pediatric transplant center and its request for approval as an adult transplant center using the same application, which should *minimize the paperwork burden*. We made no changes based on this comment.

Comment: Some commenters stated that in most pediatric centers, the core transplant team performs both adult and pediatric transplants. The commenters said that to be consistent with OPTN requirements for pediatric centers, we should allow the sharing of personnel in

transplant hospitals that have both adult and pediatric transplant programs. Some commenters recommended treating adult and pediatric transplant centers as one unified program or adopting the statutorily-based approval criteria as used in pediatric heart transplant centers.

Response: We recognize that many centers that perform pediatric transplants are operated by, or affiliated with, a Medicare-approved adult transplant center. In some transplant centers, the core transplant team performs both adult and pediatric transplants. We have no objection to such arrangements, provided that a transplant center has committed sufficient resources to both its pediatric and its adult transplant programs. There is nothing in the final rule that precludes a pediatric center and an adult center from operating as one unified program. Nevertheless, we would emphasize that an adult transplant center may not attempt to meet the clinical experience requirement by combining the number of adult transplants it has performed with pediatric transplants that were performed at its pediatric center. The outcomes of pediatric and adult transplant centers are reviewed separately.

Comment: A commenter recommended adopting the OPTN pediatric transplant standards.

Response: OPTN pediatric transplant policies relate primarily to pediatric organ allocation, and transplant surgeon and physician training and experience, and they differ significantly from our proposed CoPs for pediatric centers. We did not make any changes based on the comment.

We received no comments on our proposal to allow a heart transplant center to provide transplantation services to pediatric heart patients to be approved to perform pediatric heart transplants by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100–203). Therefore, the proposal was finalized without change except for the addition of the OBRA 1987 citation.

Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers (Proposed § 482.80)

We proposed that transplant centers must meet all of the data submission and outcome requirements in order to be granted our initial approval. If a center failed to meet any of the requirements, no waiver would be granted. However, we did propose

certain exceptions, which are discussed below.

Proposed Data Submission Requirements

We proposed at § 482.80(a) that 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 submissions on all transplants (deceased and living donor) that the center has performed at the center.

We proposed that required data submissions would include, but not be limited to, the submission of the appropriate organ-specific OPTN forms for transplant candidate registration, transplant recipient registration, and transplant recipient follow up.

We proposed using the same data submission requirements for both initial approval and re-approval.

Proposed Outcome Requirements

We proposed using the same outcome requirements for both initial approval and re-approval.

We proposed using the SRTR's center-specific reports as the foundation of our outcome evaluation system. We proposed reviewing outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. With the exception of lung transplants, we will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants. The OPTN policies for the cutoff for pediatric lung allocation and outcome assessment is under 12 years old, and the number of pediatric (under 12 years old) lung transplants is very small. Therefore, the outcomes of pediatric lung transplants and adult lung transplants are reviewed together. We proposed that we would 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 (or under certain circumstances, 1-month post-transplant patient and graft survival in lieu of 1-year post-transplant patient and graft survival.)

We proposed that under most circumstances, an adult transplant center requesting Medicare approval would need 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 SRTR center-specific report.

We proposed that we would 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 had 1-year post-transplant follow up on at least 9 transplants of the appropriate organ type. We also proposed that if a center's observed patient survival or graft survival rate was lower than the expected patient or graft survival rate and the center crossed over all 3 of the non-compliance thresholds for all 3 tests (p-value less than 0.05, observed—expected greater than 3, and observed/expected greater than 1.5) for either graft or patient survival, we would not consider the center to be in compliance with the outcome requirements.

We proposed that a heart-lung transplant center, an intestine transplant center, and a pancreas transplant center, as defined in the final rule, would not be required to comply with the outcome requirements for re-approval.

We proposed that a center requesting Medicare re-approval to perform pediatric transplants would not be required to perform a minimum number of pediatric transplants prior to its request for Medicare re-approval.

Comment: Some commenters supported the proposed data submission requirements. The commenters were pleased that the provisions would not require additional data beyond the OPTN requirements. The commenters asked us to emphasize that follow-up data are essential for evaluating and reporting of outcomes and the refinement of organ allocation policies.

Response: We appreciate the commenters' understanding of the importance of data submission in the accurate assessment of transplant center performance. We did not propose and are not requiring under this final rule that transplant centers report additional data beyond what they already report to the OPTN. The OPTN's comprehensive data reporting policies provide sufficient data for us to determine whether transplant centers meet the outcome measures in this final rule.

Comment: A commenter stated that we should coordinate our data submission requirements with the OPTN's, so that centers do not have to submit data both to us and to the OPTN.

Response: Under this final rule, we require transplant centers to continue to submit the required data to the OPTN UNetSM system (or any successor system under the OPTN Contract) in accordance with the specified time frame. UNetSM is a secure system for transplant hospitals to communicate

transplant information and data to UNOS. We are not requiring transplant centers to submit data to us separately on a routine basis.

Comment: A commenter stated that compliance with the data submission requirements should not be used as the basis for denial of Medicare approval and re-approval. The commenter said that there is no evidence linking failure to submit OPTN-required data with poor outcomes.

Response: Given that the national and center-specific outcome measures calculated by the OPTN are based largely on data submitted by the transplant centers, it is imperative for centers to report data to the OPTN completely, accurately, and in a timely manner. We cannot provide meaningful oversight of center activities without complete and timely data submission. 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 must have data submission requirements. We made no changes based on this comment.

Comment: Some commenters expressed concern that the expanding scope and complexity of OPTN data submission have significant personnel and financial implications for transplant centers. The commenters urged us to confer with the OPTN to limit the Federal data submission requirements to data needed only to calculate 1-year post-transplant outcomes.

Response: We understand the administrative workload required to achieve compliance with OPTN data submission policies. In 2006, the OPTN engaged in an extensive effort to review all data elements currently submitted by transplant centers to determine whether the number of elements could be reduced to lessen the burden on centers. Based on collaboration with the American Society of Transplant Surgeons and the American Society of Transplantation and input from the public, the OPTN succeeded in reducing the data entry burden on its transplant hospital members. For example, 268 data fields will no longer be required for validation of UNetSM forms, such as the transplant candidate registration form and the transplant recipient registration and follow up forms. Additionally, the requirement to follow transplant recipients for 2 years after graft failure has been eliminated. With significant reduction in data submission elements such as these, the OPTN anticipates that data quality will improve significantly. We continue to support the OPTN's commitment to review its data

collection process annually for opportunities to reduce burden.

However, we believe that the data submitted by transplant centers cannot be limited only to those data needed to calculate 1-year post-transplant outcomes. The more extensive data submitted by transplant centers form the backbone for the research and analyses produced by the SRTR, and the data are necessary for the OPTN, CMS, and transplant centers to develop sound policies. No changes were made based on this comment.

Comment: Some commenters requested that we quantify whether "95 percent compliance" means 95 percent of forms, patients, or data fields. A commenter suggested a data compliance threshold of less than 95 percent.

Response: By 95 percent compliance, we mean that 95 percent of the OPTN-required forms on all transplants (deceased and living donors) must be completed and submitted within 90 days following the OPTN-required time frame. This requirement provides transplant centers with an additional 90 days beyond the OPTN due date to comply. In our view, lowering the threshold to less than 95 percent is unacceptable and inconsistent with OPTN requirements. Therefore, we did not make any changes based on this comment.

Comment: A commenter recommended that if a center produces independent evidence that it has submitted the required data timely or if a center's failure to produce the required data is attributable to unique circumstances that are unlikely to recur, we should consider the center to be compliant with data submission requirements. One commenter stated that the imposition of the "no later than 90 days after the OPTN due date" deadline is unnecessarily harsh and recommended that, as long as a transplant center submits 95 percent of the required 1-year data in time to be included in the SRTR report, we should consider the transplant center to be compliant. Another commenter expressed concern that tying Medicare approval to compliance with the 95 percent data submission requirement would result in centers submitting poor quality data. The commenter suggested that in an effort to comply, centers may resort to marking data elements as "unknown" or "lost to follow up" more often than is currently done.

Response: Data submission policies that differ from those of the OPTN are likely to confuse transplant centers and result in decreased compliance with OPTN policies. When reviewing a center's compliance with the data

submission requirements, we will take into consideration whether circumstances beyond the control of the center prevented it from fully complying with the data submission policies. Nevertheless, any willful falsification of data by a transplant center will be considered a violation of the data submission requirements in this final rule, as well as that of 42 CFR 121.11(b)(2).

Comment: Some commenters asked that we exempt kidney transplant centers from data submission and outcome requirements because kidney transplants are covered under the Act.

Response: The Act provides the authority for Medicare to pay for kidney transplantation. However, it does not preclude us from establishing requirements that kidney transplant centers must meet to participate in the Medicare program. In fact, the statute specifies that payment will be made for kidney transplantation to providers of services that “meet such requirements as the Secretary shall by regulation prescribe * * *” (See section 1881(b)(1)(A) of the Act.)

Further, as noted in the preamble to the proposed rule, we are committed to bringing both the kidney and extra-renal transplant requirements up to date. For consistency across all types of transplant centers, we are requiring Medicare-approved transplant centers, including kidney transplant centers, to submit transplant data per OPTN data submission requirements. No changes were made based on this comment.

Comment: Another commenter recommended that we amend the regulation text to require the submission of 95 percent of a program’s data within 3 months of the due date and 100 percent of the program’s data within 6 months of the due date.

Response: We expect transplant centers to comply with the OPTN policy to submit 100 percent of the required data within 6 months of the due date. However, we are not including the requirement in this final rule because a requirement for 100 percent compliance would be problematic within our framework for Medicare oversight and enforcement. For example, if the OPTN notified us that a transplant center had submitted only 99.9 percent of its data within the required time frame, under such a requirement we would consider the transplant center to be out of compliance, which could subject the transplant center to review and adverse action.

Clinical Experience

We requested comments on: (1) Whether requiring a minimum number

of 9 transplants during a 2.5 year period would be acceptable for the application of the SRTR methodology; and (2) whether our proposal to focus more heavily on a center’s outcomes by eliminating volume as a separate standard and integrating volume into our outcome measures would provide us with the necessary data. In addition, three peer reviewers provided comments on the following specific issues related to volume: (1) Other alternative minimum volume criteria that would ensure that the 3 test criteria can be applied properly; and (2) appropriateness of volume standards for pediatric transplants.

Comment: Only one commenter said that eliminating volume as a separate standard would be a positive change. Overall, commenters said that the proposed methodology-based volume of 9 transplants in a 2.5 year cohort would be unacceptable as a basis for approval or re-approval of transplant centers. Commenters noted that a threshold of 9 transplants in 2.5 years would be much lower than the current Medicare annual thresholds (10 for lungs and intestines, 12 for hearts and livers, and 15 for kidneys). One commenter said that the proposed volume should not be used to assess a center’s performance because it neither serves the best interests of patients nor supports our stated goal to raise transplant standards. Another commenter said that no center performing only 9 transplants in 2.5 years can be considered a legitimate transplant program. Still another commenter said that the proposed volume is so low that it essentially would eliminate a requirement for volume. One commenter suggested that with the exception of isolated geographic locations, we should require 15 transplants as the absolute minimum annual volume, with a higher annual requirement for kidney and liver transplants, such as 30 transplants of each organ per year.

Two peer reviewers voiced concern that the methodology-based volume requirement we proposed may allow Medicare-approved centers to become inactive but retain their Medicare approval.

Response: We proposed requiring only 9 transplants in the 2.5 year cohort used for SRTR center-specific reports because 9 transplants is the minimum number necessary for the SRTR-based methodology to flag a poorly-performing center. In the preamble to the proposed rule, we acknowledged the possibility that a center could perform 9 transplants in a short period of time and remain inactive for a much longer period, while still retaining its Medicare

approval. Nevertheless, we posited that the OPTN’s oversight of transplant center “functional inactivity” would guard against this circumstance.

Additionally, in our move toward an outcome-focused system that reflects the clinical experience, resources, and commitment of a transplant program, we have revised the preamble and the regulations text by removing references to “volume requirements” and instead refer to “clinical experience requirements.” We believe this change reflects our intent to approve transplant centers using an outcome-based methodology under which the number of transplants performed is one of several factors we consider.

However, the comments we received from the public and from peer reviewers, as well as recent findings of prolonged inactivity or sub-optimal clinical experience at some transplant centers, have caused us to re-evaluate our position. In analyzing this issue, we considered several factors, including the possible impact of clinical experience on quality of outcomes and the ability of a patient on a transplant center’s waiting list to obtain a transplant.

Few research studies have been conducted on the link between volume and quality of outcomes in transplantation. A 1994 study found a significantly higher 1-year post-transplant mortality rate among patients transplanted at centers that performed fewer than 9 heart transplants per year when compared to patients transplanted at centers that performed 9 or more heart transplants per year. (Hosenpud JD, Breen TJ, et al. The effect of transplant center volume on cardiac transplant outcomes: a report of the United Network for Organ Sharing Registry. *Journal of the American Medical Association*, 1994; 271: 1844–1849.)

A 1999 study using 1994 through 1997 data showed a similar correlation between liver transplant volumes and outcomes. Specifically, patients transplanted at liver centers that performed 20 or fewer transplants per year had significantly higher 1-year post-transplant mortality than patients transplanted at liver centers that performed more than 20 transplants per year. (Edwards, EB, Roberts JP, et al. The effect of the volume of procedures at transplantation centers on mortality after liver transplantation. *New England Journal of Medicine*, 1999; 341: 2049–2053.)

However, we believe it would be problematic to base clinical experience requirements on research conducted on transplants performed when survival rates, particularly liver transplant

survival rates, were significantly lower than they are today. That is, 1-year risk-adjusted survival after heart transplantation was 83.4 percent in 1994 but had increased to 87.96 percent during the most recent SRTR cohort for which data are available, July 1, 2002 through December 31, 2004. Further, 1-year risk-adjusted survival after liver transplantation was 76.3 percent in 1994 but had increased to 86.59 percent during the most recent time period for which data are available, January 1, 2003 through June 30, 2005. In contrast, 1-year survival from 1994 through 1997 at the high-volume liver centers in the 1999 study was only 80 percent.

A study published in 2004 looked at data for adult patients who received kidney or liver transplants between January 1, 1996 and December 31, 2000. (Axelrod DA, Guidinger MK, et al. Association of center volume with outcome after liver and kidney transplantation. *American Journal of Transplantation*, 2004; 4: 920-927.) The study found a significantly lower rate of 1-year post-transplant kidney graft failure at high volume centers when compared to medium, low, or very low volume centers. The study also found a significantly different rate of 1-year post-transplant patient mortality at high, medium, and low volume liver centers; low volume centers were associated with a significantly higher risk of death. Despite these findings, the study's authors concluded that there is no clear minimal threshold volume.

Additionally, the study's authors identified several potential implications from the results of the study, noting that efforts are underway in other (non-transplant) surgical fields to concentrate procedures at high volume centers when there is a relationship between volumes and outcomes. The study suggested that even with a clear association between volume and outcomes in transplantation, "The adoption of such a policy for liver and kidney transplantation would not be straightforward even if it were desirable, particularly in the case of deceased donor transplantation [because] the benefit of high-volume center performance must be carefully weighed against the increased risk of graft loss associated with the increased cold ischemia time [that] would likely accompany increased regionalization of transplant services." The authors also pointed out that "the frequent follow-up visits necessary after transplantation might prove to be an added hardship if patients were forced to travel great distances. Because patients may be more compliant with follow-up visits if appointments are convenient,

compliance may also be an important determinant of outcome."

Because research on the effect of volume on outcomes in transplantation provides little guidance in establishing the appropriate amount of clinical experience for Medicare approval, we looked at the waiting lists at heart, liver, and kidney centers that have volumes below current Medicare requirements, (12 transplants per year for heart centers and liver centers and 15 transplants per year for kidney centers), and compared them to the waiting lists at higher volume heart, liver, and kidney centers. We found indications that there may be a link between clinical experience and how well patients fare while they are still on the waiting list.

For example, in 2005, there were approximately 117 adult heart transplant centers in the United States. According to the SRTR, 69 centers performed 12 or more transplants, and 48 performed fewer than 12 transplants. Out of the 69 centers that performed 12 or more transplants, 1 had a higher than expected mortality on the waiting list. Of the 48 centers that performed fewer than 12 transplants, 5 had higher than expected mortality on the waiting list.

Nationwide in 2005, there were approximately 106 adult liver transplant centers in the United States. There were 6,122 patients on the liver transplant waiting list. Slightly more than 28 percent (1,745) of these patients died without receiving a transplant. Of the 96 adult liver transplant centers that performed 12 or more transplants in 2005, only one center had more deaths on the waiting list than the number of transplants it performed. However, among the 10 liver centers that performed fewer than 12 transplants in 2005, 5 centers had more deaths on the waiting list than the number of transplants they performed. Of those 5 centers, 2 centers had approximately 3 times the number of deaths on the waiting list as the number of transplants they performed. For example, one liver center performed 7 transplants in 2005 and had 20 waiting list deaths during the same time period.

We also considered whether center clinical experience affects the ability of waiting list patients to obtain a transplant by reviewing transplant rates for kidney centers in 2004/2005. The SRTR calculates whether a center's transplant rate for deceased donor transplants is statistically higher, statistically lower, or not significantly different from other transplant centers. Although we found no definitive link between a kidney center's clinical experience and the transplant rate calculated by the SRTR, we note that the

transplant rate of a small center generally would not be considered statistically lower than expected even if the center performed no transplants during a given year due to the small number of patients on its waiting list. However, in reviewing the data, we found that 7 out of the approximately 231 adult kidney transplant centers in the United States in 2004 and 2005 performed no transplants at all during those 2 years. The number of patients on the waiting lists of the 7 centers numbered between 9 and 47. Although the number of patients affected was small, we are concerned that patients continued to be listed on the waiting lists of centers that performed no transplants in 2 years. We note that, at present, all 7 centers are listed as inactive on the SRTR's Web site.

In summary, public commenters and some peer reviewers recommended a volume standard higher than the proposed 9 transplants in 2.5 years. None of the peer reviewers recommended a specific volume. Studies of the effect of volume on outcomes in transplantation suggest that higher volume centers have better outcomes, although there is no evidence that indicates what the minimum threshold should be. Also, our review of waiting list data raises the concern that waiting list patients at small centers may not fare as well as waiting list patients at larger centers, both in terms of waiting list mortality and the ability to obtain a transplant.

Further, as discussed earlier in this preamble, in the fall of 2005, we found that some centers, although not considered "functionally inactive" by the OPTN, performed few transplants and refused a high percentage of organs that were offered to them for transplantation into their waiting list patients, leading to longer than average waiting times and, possibly, an increased number of deaths among their waiting list patients. These factors must be weighed against the necessity to maintain Medicare beneficiaries' access to transplantation. Also, we must keep in mind the concerns raised by the 2004 study of volume and outcomes in kidney and liver transplantation that centralizing transplants in too few centers could be detrimental to transplant outcomes.

Based on these considerations, we believe transplant centers should be required to perform more than 9 transplants in 2.5 years to become Medicare approved and, once approved, retain their Medicare approval. Without strong statistical evidence supporting a particular threshold for any of the organ types, we believe the most appropriate

solution is to establish a clinical experience requirement that is close to the current volume requirements in our NCDs for heart, intestine, liver, and lung transplant centers and in our CfCs for kidney transplant centers. We believe establishing a clinical experience requirement of 10 transplants per year for all organ types for both approval and re-approval of transplant centers is both sensible and the least disruptive for transplant centers that have current Medicare approval and for the beneficiaries on the waiting lists of these centers.

We are revising § 482.80(b) to state that to be Medicare approved under this final rule, adult transplant centers (with the exception of heart-lung centers, kidney transplant centers, and pancreas centers) generally must perform 10 transplants over a 12 month period. We are revising § 482.82(b) to state that to be re-approved under this final rule, a transplant center must perform an average of 10 transplants per year during the re-approval period. There are no minimum clinical experience requirements for initial approval or re-approval for heart-lung, pancreas, or pediatric centers. (Kidney transplant centers generally must perform 3 transplants over a 12-month period for initial approval and 10 transplants annually for re-approval.) (See §§ 482.80(d)(4) and 482.82(d)(4).) Note that an adult transplant center may not attempt to meet the clinical experience requirement by combining adult transplants with pediatric transplants performed at an affiliated pediatric center.

As stated previously, the main intent of the clinical experience requirement for re-approval is to ensure that Medicare-approved centers stay active. We recognize that a center's transplant numbers may fluctuate at times. Nonetheless, we believe that a transplant center must perform an average of 10 or more transplants per year to demonstrate commitment to its transplant program and gain adequate clinical experience.

To determine a center's compliance with the clinical experience requirement, we will review the data contained in the most recent OPTN Data Report and SRTR center-specific reports. (See § 488.61(a)(2) and § 488.61(c)(1)(ii).)

Comment: Some commenters said that all kidney transplant centers should be exempt from initial approval requirements (such as the requirement to perform 9 transplants) because a lengthy initial approval process would delay access to the new kidney center's transplantation services for Medicare

beneficiaries. That is, until a new kidney transplant center receives Medicare approval, Medicare will not pay for beneficiaries to receive transplants at the facility.

Response: We share the commenters' concern that a lengthy approval process for kidney centers, particularly a requirement to perform 10 transplants prior to approval, may prevent kidney transplant centers from opening in areas of the country where access to kidney transplant services is already limited.¹ Meeting a clinical experience requirement of 10 transplants would be particularly difficult for new kidney transplant centers, because Medicare is either primary payer or secondary payer for 69 percent of kidney transplants performed in the United States, while the other 31 percent of kidney transplants are paid for by private insurance, Medicaid, and the Department of Veterans Affairs (unlike extra-renal transplants for which Medicare pays between approximately 20 percent and 40 percent, depending upon organ type). Thus, a new kidney transplant center would have considerable difficulty finding 10 non-Medicare patients to transplant.

Under the current ESRD CfCs for kidney transplant centers, a new center may be approved without performing any transplants if it has a written plan detailing how it will achieve conditional status (7–14 transplants) within 2 years and unconditional status (15 or more transplants) within 4 years. Currently, there are no outcome requirements for kidney transplant centers. However, this final rule contains outcome requirements for initial approval of kidney transplant centers, and in order for us to assess a new kidney transplant center's performance, the center must perform some transplants. Taking this information into consideration, we have determined that requiring new kidney transplant programs to complete 10 transplants before applying for approval could prevent new centers from entering the Medicare program.

We believe that completing 3 consecutive, successful transplants, as determined by 1-year post-transplant graft and patient survival outcomes, is necessary for a new kidney center to demonstrate sufficient experience in transplantation and enhances the new

¹ Although nearly half of all transplant centers in the United States are kidney transplant centers, there are barriers to access to kidney transplantation services in some areas of the country where there are large dialysis populations but few kidney transplant centers, and in some largely rural States that have no in-State kidney transplant centers and few centers in neighboring States.

transplant center's ability to recruit transplant candidates from the limited pool of the non-Medicare-eligible kidney transplant candidate population.

We are sensitive to the difficulty a new kidney transplant center will have in finding non-Medicare patients to transplant. We are committed to maintaining and improving access to kidney transplantation services for Medicare beneficiaries, but we also believe it is essential to assess a kidney transplant center's performance prior to approving it for the Medicare program. Therefore, this final rule establishes a clinical experience requirement of 3 transplants for initial Medicare approval for kidney transplant centers that had not been approved by Medicare under § 405.2122 as of this rule's effective date at § 482.80(d)(5). We believe this requirement will allow new kidney transplant centers to obtain Medicare approval expeditiously, while ensuring that some data are available to demonstrate whether the center's outcomes are acceptable.

Like extra-renal transplant centers, kidney transplant centers will be approved for 3 years and will be required to perform an average of 10 transplants per year for re-approval. However, because a kidney center will be required to perform only 3 transplants before obtaining initial approval, we will scrutinize the center's clinical experiences and outcomes closely, particularly in the year following its initial approval. CMS will monitor the clinical experience and outcomes statistics of the center in the year following its initial approval. We are requesting center-specific data already collected through the OPTN, and expect to review the data at least quarterly. If the center's clinical experience and outcomes highlight a need for additional investigation, CMS will follow up through its survey and certification process.

We note that in the past, new transplant centers interested in applying for Medicare approval have offered to perform transplants for Medicare beneficiaries free of charge so that the center could meet the clinical experience requirement for initial Medicare approval quickly. This practice has serious implications for a Medicare beneficiary who accepts a transplant center's offer of a free transplant. Medicare pays for prescription drugs used in immunosuppressive therapy under Medicare Part B only if the transplant was performed in a Medicare approved facility. Although an individual may be eligible for payment for his or her immunosuppressive drugs under

Medicare Part D, the beneficiary may pay several thousand dollars more out of pocket every year.

Therefore, we have added a requirement under the CoP for Patients' and Living Donor Rights at § 482.102(a)(8) and (b)(9) that a transplant center must inform Medicare beneficiaries who are prospective transplant recipients and their prospective living donors that receiving a transplant that is not provided in a Medicare-approved transplant center could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B. See further discussion of this requirement in this preamble under "Patients and Living Donor Rights" and "Centers With Current Medicare Approval."

Comment: A commenter stated that OPTN policies do not specify that transplant centers must perform a minimum number of transplants per year and said that our requirements and those of the OPTN should be consistent. A commenter also asked us to clarify in more detail what the OPTN means when it terms a transplant center "functionally inactive," as well as how this status may impact a center's eligibility to receive organs.

Response: As discussed in the proposed rule, although the OPTN does not require a transplant center to perform a minimum number of transplants, programs (centers) are reviewed and may be classified as "functionally inactive" if they have not performed a single transplant within a specified period of time. The specific time frame that the OPTN Membership and Professional Standards Committee (MPSC) uses to determine "functional inactivity" is 3 months for kidney, liver, and heart programs, 6 months for pancreas and lung programs, and 1 year for stand-alone pediatric programs. Under OPTN Bylaws, Appendix B(II), an OPTN member transplant hospital that fails to remain functionally active with respect to any designated transplant program may be encouraged to voluntarily deactivate its transplant program until such time as the circumstances affecting the status of the program have been resolved (up to 12 months) or relinquish designated transplant status for the program. If the member fails to take either action voluntarily, the MPSC may recommend that the Board of Directors notify the Secretary of this inactivity (if the transplant program is Medicare approved or located within a Federal hospital) and take appropriate action in accordance with the OPTN bylaws.

The OPTN's determination that a transplant program is "functionally inactive" does not, by itself, prohibit a center from receiving organs. However, hospitals with transplant centers usually follow the recommendation of the MPSC by voluntarily inactivating the transplant center in question.

Although we want to ensure that transplant centers remain active, we do not want a transplant center that is experiencing problems to continue to perform transplants just to avoid losing its Medicare approval. Therefore, we have added a provision to this final rule that a transplant center may inactivate its program for a period not to exceed 12 months during the 3-year approval cycle without losing its Medicare approval (see § 488.61(e)), but the center must notify us immediately of significant changes in the number of transplants performed, as required at § 482.74(a)(4). The transplant center also must notify the patients on its waiting list and, as requested by the Secretary, assist patients in transferring to the waiting list at another transplant center, without loss of time accrued on the waiting list. (See § 482.102(c)(3).) We will confer with HRSA and the OPTN on a case-by-case basis to determine whether to instruct an inactive center to notify its waiting list patients and assist them in transferring to another transplant center's waiting list.

We proposed that a center that was requesting initial Medicare approval to perform pediatric transplants would not be required to perform a minimum number of pediatric transplants prior to its request for Medicare approval.

Comment: Most commenters agreed that volume requirements are not relevant for pediatric centers and they strongly supported having no volume requirements for centers performing pediatric transplants. Two peer reviewers said that a volume requirement would be inappropriate for pediatric centers. One peer reviewer agreed that volume standards are not appropriate for pediatric transplant programs, but also expressed concerns about the ability of pediatric centers to maintain their expertise because many centers perform so few pediatric transplants. Another peer reviewer stated that since setting a volume requirement for small pediatric centers is challenging, Medicare approval for pediatric centers that are affiliated with Medicare-approved adult transplant programs is recommended. Like the other peer reviewer, this peer reviewer also had concerns about small, stand-alone pediatric transplant programs' ability to maintain resources and expertise in transplantation.

However, two commenters stated that a minimum volume requirement is necessary to ascertain the commitment and investment a hospital has made in its pediatric transplant center. One commenter recommended ten pediatric transplants a year for liver and kidney programs and a lower volume for heart programs. The commenter suggested counting open and closed congenital heart surgeries toward the volume requirement for pediatric heart transplants. One commenter expressed a strong belief that having no volume requirement for pediatric transplant centers would allow small programs with limited resources to perform transplants, with potential poor outcomes.

Response: Given the nature of the pediatric transplants performed and the low numbers of pediatric transplants in general, it would be impossible for most pediatric transplant centers to obtain Medicare approval if we required them to meet clinical experience requirements, limiting access for pediatric Medicare beneficiaries who need transplants. As stated earlier, we will monitor pediatric centers' outcomes to ensure they provide high quality transplantation services to Medicare pediatric patients. We made no changes based on this comment.

Comment: Some commenters stated that in most pediatric centers, the core transplant team performs both adult and pediatric transplants. The commenters said that to be consistent with OPTN requirements for pediatric centers, we should allow the sharing of personnel in transplant hospitals that have both adult and pediatric transplant programs. Some commenters recommended treating adult and pediatric transplant centers as one unified program or adopting the pediatric heart transplant center statutory approval criteria.

Response: We recognize that many centers that perform pediatric transplants are operated by or affiliated with a Medicare-approved adult transplant center. In some transplant centers, the core transplant team performs both adult and pediatric transplants. We have no objection to such arrangements, provided that a transplant center has committed sufficient resources to both its pediatric and its adult transplant programs. There is nothing in the final rule that precludes a pediatric center and an adult center from operating as one unified program. Nonetheless, approval of the pediatric center is not automatic. The pediatric center and adult center must apply for separate approval.

We invited comments from the public on the proposed outcome requirements.

In addition, we conducted independent peer reviews of the following specific issues related to the outcome requirements:

(1) Appropriateness and usefulness of using 1-year post-transplant graft and patient survival rates to assess transplant center performance;

(2) Alternative outcome measures;

(3) Appropriateness of using 1-month post-transplant data for initial approval of new centers;

(4) Outcome measures for heart-lung, intestine and pancreas transplant centers;

(5) Use of the Cox model to explain the risk-adjusted expected 1-year post-transplant graft and patient survival rates;

(6) Appropriateness of using the 3 proposed thresholds to determine center performance; and

(7) Use of the proposed p-value to assess centers with ≥ 9 transplants during a 2.5-year period. None of the peer reviewers suggested alternative outcome measures. All reviewers agreed that the Cox model is the most widely used, flexible, and reliable tool to measure transplant outcomes because it allows adjustments, additions, or deletions of co-variables to reflect clinical changes in transplantation over time.

Following are summaries of the comments we received and our responses.

Use of 1-Year Post-Transplant Graft and Patient Survival Rates as Outcome Measure Standards

In our discussion of outcome measures in the preamble to the proposed rule, we said that we would 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 most recent SRTR center-specific reports. We also stated that we would not consider a center's patient and graft survival rates to be acceptable if 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.

Comment: Many commenters agreed that risk-adjusted graft and patient survival rates are appropriate measures of transplant center performance. Some commenters stated that the proposed comparison of 1-year observed graft/patient survival rates with 1-year expected graft/patient survival rates is reasonable and achievable. The commenters noted that the proposed risk-adjusted survival data with a 1-year

follow-up period has more statistical validity than the evaluation of a survival curve at a particular time point, such as when the Kaplan Meier model is used. The commenters appreciated our effort to strive for consistency with OPTN standards and in establishing meaningful outcome standards. One commenter believed that outcome measure reviews should be based on trends and not just on one single snapshot in the SRTR reports.

All three peer reviewers agreed with the public commenters that it is appropriate to use 1-year graft and patient survival rates to assess transplant center performance. Three peer reviewers added that a survival time frame longer than 1 year, such as 3 years or 5 years, may provide a more accurate assessment of center performance and minimize statistical deviations for small centers. However, they pointed out that the drawback of a longer time frame is that more patients would be lost to follow up, and a longer time frame may not be applicable to smaller programs.

Response: Although we agree that a time frame for the outcome measures longer than 1-year post-transplant would provide some additional information, the drawbacks include increased mortality from patients' comorbidities and more patients lost to follow up. We believe that utilizing 1-year survival data for approvals and re-approvals is sufficient. We have made no changes based on these comments.

Alternatives to the OPTN Outcome Thresholds

We solicited comments on different options to apply the SRTR methodology. Following are summaries of the comments we received and our responses.

Comment: A commenter stated that graft and patient survival rates alone do not give a complete picture of transplant center performance. The commenter encouraged us to continue to identify or develop measures to capture the full scope of a transplant center's performance.

Response: We agree with the commenter that graft and patient survival rates alone do not provide a complete picture of transplant center performance. To provide a broader view, we will assess each center's compliance with the other CoPs, which focus on other measures of quality, such as direct patient care. If the OPTN and SRTR develop additional measures, we will consider whether those measures should be incorporated into our CoPs through the rulemaking process. We

made no changes based on this comment.

Comment: A commenter suggested including waiting list mortality, the number of organ donors, and the size of the waiting list in the outcome measure analysis.

Response: We considered using waiting list mortality as one of the outcome measures, but after careful deliberation, we determined that using this criterion would be problematic because transplant centers do not provide direct patient care for all of the patients on their waiting lists. Some waiting list patients routinely receive their primary care from other providers, particularly patients awaiting kidney transplants who are likely to receive their care through a dialysis facility. In addition, some waiting list patients are listed at more than one center. We would have considerable difficulty determining which transplant center should be accountable for the death of a patient listed on more than one waiting list. Finally, waiting list patients may die for reasons unrelated to their end-stage organ failure. We believe it would be unfair to hold a transplant center responsible for the death of a waiting list patient if the cause of death were unrelated to the patient's transplant.

Although the commenter suggests using the number of organ donors as one of the outcome measures in the final rule, we would point out that cooperating with organ procurement organizations (OPOs) in the organ donation process would be a function of the hospital in which a transplant center is located, not of the transplant center itself. Furthermore, the hospital CoP at § 482.45 "Organ, tissue, and eye procurement" lists specific requirements all hospitals must meet related to their performance as donor hospitals. We made no changes based on this comment.

Comment: A commenter also suggested using the size of a transplant center's waiting list as an outcome measure.

Response: We disagree. There are many different variables affecting the size of a transplant center's waiting list, such as geographic location, patient selection criteria, cultural factors, and transplant resources, among others. Thus, we do not believe the size of a transplant center's waiting list is an appropriate outcome measure. We did not make any changes based on these comments.

The 3 Thresholds ($p < 0.05$, Observed—Expected > 3 , and Observed/Expected > 1.5)

We requested comments on the three proposed non-compliance thresholds for the outcome measures and solicited data and evidence that would support alternative thresholds, especially thresholds specific to a particular organ type.

We proposed that a transplant center's performance would not be acceptable if its observed patient survival rate and observed graft survival rate were lower than its expected patient survival rate and expected graft survival rate and if all three of the following thresholds were crossed over:

(1) One-sided p-value is less than 0.05;

(2) Number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3; and

(3) Number of observed events divided by the number of expected events is greater than 1.5.

Comment: Although some commenters expressed support for the three proposed thresholds, a few commenters stated that these thresholds would be too lenient. Other commenters suggested making the thresholds more rigorous but only if the outcome measures were used solely as a trigger for further investigation. Three peer reviewers supported using all 3 proposed non-compliance thresholds ($p < 0.05$, $O-E > 3$, and $O/E > 1.5$) to determine transplant center performance. However, one peer reviewer recommended changing the threshold for $O/E > 1.5$ to $O/E > 1.3$ in order to narrow the variations among centers. One commenter stated that the three thresholds for outcome measures are arbitrary since the outcome measure methodology may change in the future.

Response: We disagree that the proposed thresholds are too lenient. The OPTN uses the same thresholds currently to flag centers for further review, and the SRTR uses the thresholds to report observed and expected patient and graft survival.

Changing the threshold of $O/E > 1.5$ to $O/E > 1.3$, as one peer reviewer suggested, would be inconsistent with the OPTN O/E threshold for flagging centers for further review. If the OPTN changes the criteria to narrow the variation in the future or we determine that the threshold is insufficiently rigorous for our purposes, we will re-assess it.

We will not use these thresholds simply to flag centers for further review as suggested by some of the

commenters. Although failure to meet the outcome requirements does not mean that a transplant center will be denied Medicare approval automatically or lose Medicare approval automatically, a transplant center's performance on the outcome requirements is the single most important factor we will consider in making these determinations because these measures are designed to reflect the importance of the need for a transplant center to have sufficient expertise in all phases of transplantation, such as conducting pre-transplant evaluations, performing the surgical procedure, and regulating post-transplant immunosuppression and other medications to prevent graft failure. Since we will be using outcomes data, along with other data and information on transplant center performance, to make decisions on initial approvals and re-approvals of transplant centers, we believe the thresholds are sufficiently rigorous to ensure we can identify transplant centers whose performance is unacceptable.

We do not agree that simply because we or the OPTN may change the proposed outcome requirements in the future, they are definitionally arbitrary. We are establishing thresholds at a level that is optimal to identify transplant centers whose performance is not adequate for delivery of transplantation services to Medicare beneficiaries. If we determine in the future that any of the three thresholds is too low or too high, we will propose changes in the threshold through the rulemaking process. We made no changes based on these comments.

Comment: A few commenters suggested that we should establish the criteria for unacceptable performance at crossing over 2 out of the 3 (instead of all 3) non-compliance thresholds.

Response: Throughout the final rule, we have been careful to conform our requirements to OPTN policies in almost all cases, so that our requirements for and our oversight of transplant centers does not conflict with the OPTN's. Currently, the OPTN requires that a transplant center has crossed over all three thresholds to be flagged for further review. We do not believe it would make sense to adopt the SRTR methodology and most of the OPTN's outcome measures policies in this final rule but establish a different criterion for the thresholds. In addition, we are mindful that the existing OPTN thresholds were established with the support of the transplant community. If the OPTN changes its thresholds in the future, we will determine at that time

whether we should change the thresholds in our regulations. We made no changes based on this comment.

Comment: A commenter pointed out that the OPTN uses a 2-year cohort, but we proposed using a 2.5-year cohort. Commenters said that use of different cohort lengths would lead to different results when centers are reviewed.

Response: As of 2005, the SRTR changed the OPTN cohort from 2 years to 2.5 years to be consistent with the public SRTR center-specific reports.

Appropriateness of Using the Proposed Outcome Requirements, the 3 Thresholds, and the SRTR Methodology as the Basis To Approve and Re-Approve Transplant Centers

Comment: A few commenters supported the basis for the outcome measure methodology designed by the SRTR and tested within the transplant community. Commenters said they believed that the proposal meets the principles of equity and fairness, and the outcome measures can be applied equitably to all types of transplant centers, both large and small. However, one commenter stated that the OPTN outcome data were never designed as a test for Medicare approval and re-approval. The commenter recommended that we defer any approval or re-approval decisions regarding data submission or outcome requirements to the OPTN Board, which makes the final decision about transplant center performance.

Response: We have been using patient survival outcome measures as approval criteria for transplant centers since Medicare began paying for heart transplants in 1987. Over the years, we have established outcome requirements for approval of liver, lung, and intestine transplant centers, as well. The sophisticated SRTR methodology described in this final rule allows us to improve upon the current outcome requirements by incorporating risk adjustment and ensuring statistical validity. Clearly, the outcome requirements that we are establishing in this final rule also can be utilized as indicators for potential problems, which is how we will use them in the approval and re-approval processes. Non-compliance with data submission, clinical experience, or outcome measure requirements may trigger a review for compliance with the CoPs, similar to the OPTN process, which also uses transplant outcomes data to flag centers for further review and investigation. However, as stated previously, the OPTN does not have the oversight authority to approve or re-approve transplant centers for Medicare. We

must conduct the review and investigation of a transplant center that does not meet the outcome measures. We have made no changes in this final rule based on this comment.

Comment: A few commenters stated that the SRTR center-specific report that we cited for review and approval/re-approval of transplant centers is 1 to 3 years behind current data and does not reflect a transplant center's current outcomes. Therefore, centers that have improved recently may be sanctioned unnecessarily. The commenters recommended that we review more recent data or data in at least two previous SRTR reports to evaluate a transplant center's outcome trends.

A peer reviewer stated that the outcome measure review should be based on outcome trends over a longer period of time and not on a single snapshot in the SRTR report. Another reviewer recommended a review of graft and patient survival rates in two consecutive SRTR reports.

Response: We agree that some transplant centers' outcome trends may be best understood by reviewing two SRTR reports. However, since our approach to approving centers is multi-dimensional (data, clinical experience, outcomes, and process), and the OPTN review of transplant centers is ongoing, we believe that review of one SRTR report is sufficient to assess a transplant center's performance. If we consistently use the SRTR center-specific reports for outcome review, the trend of a center's performance or a clinically significant pattern should be reasonably apparent over an extended period of time. The SRTR updates its center-specific reports every 6 months. However, since the outcome requirements in this rule include 1-year post-transplant data, the delay in compiling and reporting the data by the SRTR is unavoidable. Thus, the age of the data that we review will vary from 1.5 to 3 years old.

Nevertheless, the SRTR reports provide the most cost-effective, transparent, and objective measures currently available. Since we will use the SRTR center-specific reports consistently to review outcomes, the trend of a center's performance or a clinically significant pattern should be reasonably apparent over an extended period of time. An on-site survey will counterbalance the outcomes data if the outcome trend is negative but is not reflective of the center's performance. On the other hand, the reporting of significant (negative) changes and inactivity to CMS will counterbalance the outcomes data if the center's performance trend appears to be

positive but is, in fact, not reflective of the center's performance.

Comment: Some commenters were concerned that the proposed outcomes requirement may not be able to accommodate future changes in the OPTN's policies for application of the SRTR methodology or the methodology itself. A commenter suggested that we should include provisions to assure automatic adoption of future changes in the OPTN/SRTR data submission and outcome measure policies through issuance of Program Notices.

Response: The SRTR refines their methodology on an ongoing basis. For example, the SRTR reassesses the methodology's risk adjustment factors periodically and makes changes based on research and changes in the field of transplantation. The SRTR also adds or changes data sources, as appropriate. Periodically, the OPTN asks the SRTR to look into statistical techniques to improve data analysis. Such changes will not require us to engage in rulemaking. If the OPTN makes a substantive change to its policies regarding the methodology or chooses a different methodology for calculation of outcomes, we will assess the change to determine whether we should adopt it. For example, if the OPTN were to change the threshold for the p-value, and we determined that the change to the threshold would be appropriate for our outcome requirements, we likely would be required to engage in rulemaking so that the public would have the opportunity to comment. Based on our knowledge of the OPTN's past practices, we do not expect substantive changes to occur frequently. In fact, since the OPTN published the first annual report containing transplant center-specific outcomes data and transplant survival rates in 1992, there has been only one major change in the methodology used to measure outcomes—the change from the OPTN methodology to the SRTR methodology, which took place in 2002. We have made no changes based on these comments.

Risk-Adjustment Factors

Comment: Many commenters expressed concern that the SRTR model does not include all the risk-adjustment factors impacting outcomes, for example, new immunosuppression protocols, organs from extended criteria donors (ECDs) and donors after cardiac death (DCDs), steatosis, and centers' participation in research. The commenters were concerned that: (1) Transplant centers may be penalized for using organs from ECDs and DCDs if using such organs leads to poorer

outcomes; (2) centers may refuse to use such organs because they fear their outcomes will be affected; (3) centers may be penalized for participating in research studies that yield negative outcomes; and (4) some centers may deny access to high-risk patients in order to meet the outcome measures.

One peer reviewer also expressed concern that the SRTR model does not risk adjust for organs from DCD or ECD donors, which the reviewer said may need to be incorporated into the model to meet the needs of an increasingly aging recipient population.

Response: We understand the commenters' and the peer reviewers' concerns. However, the SRTR methodology is not simply a list of covariates or values for parameter estimates. The SRTR revises risk-adjustment factors periodically in response to trends in organ donation and transplantation. For example, it has already included ECD organs as one of the risk-adjustment factors in its outcome methodology model so that centers using ECD organs frequently are not disadvantaged. We are confident that the OPTN/SRTR will be able to develop appropriate risk-adjusted outcome measures for DCD donor organs in the future. We made no changes based on these comments.

Appropriateness of Allowing a New Center to Use 1-Month Post-Transplant Data and Frequency of Subsequent Review of the Center's Post-Transplant Data

We proposed that if a new transplant center hired an experienced team from another transplant center, we would permit the new center to request that we review its 1-month post-transplant patient and graft survival for all transplants performed in the previous 1-year period, if the following conditions were met: (1) 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; (2) the transplant team met the human resources requirement at § 482.98; and (3) the most recent SRTR report on the center did not contain 1-year post-transplant follow-up data on at least 9 transplants of the appropriate organ type for the reported time frame.

We proposed that if we approved a transplant center based on 1-month post-transplant outcomes data, we would re-evaluate the center when 1-year post-transplant data became available.

We asked for comments on our proposal, as well as comments regarding the frequency with which we should re-

assess these new centers after they receive initial Medicare approval.

Comment: Some commenters supported the idea of approving new centers based on 1-month post-transplant data. The three peer reviewers did not object to the proposal to review a new center's 1-month post-transplant graft and patient survival outcome; however, they believed that reviewing a new center's 3-month or 6-month post-transplant data would provide more relevant information. One peer reviewer recommended an interim approval of new centers based on a 1-month post-transplant data review, pending a subsequent review of 3-month post-transplant data. Another peer reviewer recommended the comparison of projected 1-year post-transplant graft and patient survival rates with the expected 1-year post-transplant graft and patient survival rates, in addition to review of 1-month post-transplant data.

Some commenters stated that 1-month post-transplant data may be more reflective of the transplant team's surgical outcomes than the quality of the transplant center. One peer reviewer suggested that 1-month post-transplant data is too close to the date of the transplant and, thus, patient outcomes may not truly reflect the impact of the transplantation itself. The peer reviewer recommended that a 3-month post-transplant data review, in conjunction with three consecutive annual reviews, is a better marker for new center approval.

Another peer reviewer stated that approval of new centers based on review of 1-month post-transplant data for approval of new centers would be ill-advised. The peer reviewer said that 1-month post transplant data likely reflect primarily surgical expertise and the quality and the thoroughness of pre-transplant evaluation, rather than the skill of the multi-disciplinary transplant team. The peer reviewer stated that the use of 1-month post-transplant data for approval of new centers should be allowed only when the new center has demonstrated acceptable 1-year post-transplant graft and patient survival rates in other established organ transplant programs. The peer reviewer said that having acceptable 1-year post-transplant graft and patient survival rates for a minimum of 9 transplants should be mandatory for a new center that has no other organ transplant experience. Some commenters stated that simply having an experienced surgeon or transplant team should not be sufficient to qualify a new center. One commenter said that there are other factors besides surgical or

transplantation experience that we should use to assess a new transplant center's performance. Another commenter expressed concern that Medicare approval of new centers based on review of 1-month post-transplant data would:

(1) Create an incentive for transplant teams to move from center to center, thus causing disruption to transplant patient services, negatively impacting patient follow up, significantly undermining the financial and human resource investment of transplant centers, and increasing costs to the health care system; and

(2) Raise patient safety issues, because experience indicates that it takes more than a year for a transplant center to develop and maintain a comprehensive transplant program.

Response: The comments from peer reviewers and the public, as well as the recent, abrupt closure of a new kidney transplant center following an investigation by the California Department of Managed Health Care, have led us to the conclusion that approving new transplant centers based on a review of 1-month post-transplant outcomes data and the experience of the transplant surgeon and transplant physician would not serve the best interests of Medicare beneficiaries who need transplants.

We share the commenter's concern that approving transplant centers based on 1-month post-transplant data has the potential to harm patient care. Most important, we have been unable to identify a need for centers to be approved quickly using abbreviated data.

Establishing a new transplant center is not an easy task. Clearly, a transplant center must provide non-surgical support services for transplant patients and perform many functions in addition to the transplant surgery itself, including, but not limited to, nursing, nutrition counseling, social services, pharmacology, immunology, pathology, and radiology. In fact, the president of the managed care organization that recently shut down its new kidney center was quoted as saying that establishing a transplant program was much more difficult than anticipated and that the organization was naïve to think the program could be established quickly.

Furthermore, we believe it would be inadvisable to approve a new center based on the fact that the hospital in which the center is located has a successful center that transplants another type of organ, as one commenter recommended (unless there is a direct relationship between organ types, such

as a kidney center that seeks approval as a pancreas center). The SRTR center-specific reports indicate that the performance of organ transplant centers is not always consistent within a multi-center transplant hospital. Within the same transplant hospital, some centers may have outstanding outcomes while some centers may have marginal or sub-optimal outcomes.

Taking these factors into consideration, we believe it would be inappropriate for us to use the expertise of the key members of a transplant center's team as a proxy for the quality of a transplant center's overall operations.

Consequently, we have eliminated proposed § 482.80(b)(4) through (6). Under this final rule, we will use 1-year post-transplant patient and graft survival data to assess the performance of all transplant centers seeking initial Medicare approval.

Outcome Requirements for Heart-Lung, Intestine, and Pancreas Centers

We requested comments on the appropriateness of having no outcome requirements for heart-lung, intestine, and pancreas centers. We also asked for recommendations for alternative methods to evaluate centers that transplant these types of organs.

We proposed defining a heart-lung transplant center as a center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung transplant center that performs combined heart-lung transplants. We proposed defining an intestine transplant center as a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants. We proposed defining a pancreas transplant center as a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant, as well as kidney-pancreas transplants. That is, we proposed that a Medicare-approved kidney transplant center would be permitted to perform all types of pancreas transplants.

Comment: Some public commenters supported having no outcome measure requirements for heart-lung, intestine, and pancreas transplant centers since there are no risk-adjusted outcome measure models for these types of transplants. Three peer reviewers agreed with our proposal for heart-lung, intestine, and pancreas centers but added that once a risk-adjusted outcome measure model becomes available in the

future, it should be applied to these centers.

Response: Once the SRTR has developed risk-adjusted models for heart-lung transplants, intestine transplants, and pancreas transplants, we will consider establishing outcome measure criteria for the approval and re-approval of centers that perform these transplants.

In the absence of risk-adjusted outcome measure models for these types of organ transplants, we believe the approach we proposed and have made final in this rule without change is most appropriate at this time.

Outcome Measures for Pediatric Transplants

We requested comments on our proposed approach to evaluating pediatric transplant centers' outcomes and approving centers performing pediatric transplants.

Comment: Some peer reviewers were concerned about pediatric centers' ability to maintain resources due to infrequent transplantation activities. A reviewer stated that the OPTN routinely peer reviews pediatric program case logs, and the peer reviewer recommended that the OPTN notify us about under-performing programs using pre-established thresholds.

One commenter agreed with our proposal to apply outcome requirements for adult centers to centers performing pediatric transplants. However, one commenter voiced concern that the inability of pediatric centers to perform 9 transplants in a 2.5-year period (as required for the SRTR methodology to be valid) may prevent them from participating in Medicare. Nonetheless, the commenter urged the SRTR to continue analyzing pediatric 1-year post-transplant outcomes. The commenter encouraged the SRTR to develop evidence-based outcome guidelines by analyzing center-specific 1-year outcomes of pediatric patients transplanted over a 2.5-year period.

Response: We intend to confer with the OPTN, as appropriate, about both pediatric and adult centers to ensure that we can effectively monitor the quality of transplant programs.

Proposed Process Requirements for Transplant Centers

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

We proposed requiring centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list for transplantation. We proposed that

patient selection criteria must ensure fair and non-discriminatory distribution of organs.

We proposed that before a patient is selected for a non-renal transplant, the transplant center must 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 proposed that before a center places a patient on its waiting list, the center must ensure that the prospective transplant candidate receives a psychosocial evaluation and that the potential transplant candidate's medical record contains documentation of the candidate's blood type. (A psychosocial evaluation conducted by transplant centers of potential transplant recipients screens for issues that could affect the patient's compliance with the post-transplant treatment that is necessary to maximize the chances of a successful transplant, such as substance abuse or behavioral or psychiatric issues.) We also proposed that when a patient is placed on a center's waiting list, the center must document in the patient's medical record the patient selection criteria used.

We proposed that if a center performs living donor transplants, the center must use written donor selection criteria in determining the suitability of living donors for donation. We proposed that the living donor selection criteria must be consistent with the general principles of medical ethics. We proposed that the transplant center 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. The psychosocial evaluation conducted by a transplant center of a potential living donor assesses the donor's motivation and his or her understanding of the donation process and post-donation treatment. A center assesses whether the potential living donor has any behavioral or psychiatric issues that could influence the decision to donate and whether he or she is being pressured to donate.

Following are summaries of the comments we received and our responses.

Comment: Many commenters supported the proposed written patient and living donor selection requirements. Commenters stated that the requirements are reasonable and that many centers already have these

selection criteria in place. One commenter applauded us for giving transplant centers the flexibility to develop their own criteria. The commenter commended us for refraining from defining patient selection criteria. However, some commenters opposed the requirement for transplant centers to have written patient and living donor selection criteria. Commenters stated that the requirements are too prescriptive and would be burdensome.

Response: We disagree that these requirements are too prescriptive. In fact, current Medicare requirements for heart, liver, and lung transplant centers have specific patient selection criteria guidelines for centers to use to select patients for transplantation. Conversely, this final rule permits transplant centers to develop the criteria that best fit the needs of their patients and gives centers the flexibility to change their criteria as transplant medicine changes over time. We will no longer require transplant centers to use the existing patient selection criteria. As long as their patient selection criteria are fair and non-discriminatory, transplant centers are free to develop their criteria based on the medical judgment of their transplant physicians and surgeons.

Comment: Some commenters said they believe that written patient selection criteria may pose undue risk to centers when the criteria used to select a transplant patient deviate from the transplant center's written criteria. Another commenter stated that the disclosure of deviations from patient selection criteria will pose legal risks for transplant centers.

Response: We disagree with the commenters that written patient and living donor selection criteria will pose undue legal risk to centers. Instead, we believe that well-written patient and living donor selection criteria can reduce the legal risk for a transplant center, as long as the center adheres to its criteria or documents the reason why it has deviated from its criteria. Given the scarcity of organs, we believe established written patient selection criteria, at a minimum, will ensure equity and consistency when transplant risk-benefit decisions are made. No change was made based on these comments.

Comment: Some commenters stated that patient selection is a medical judgment and that there are gray areas, subtleties, and subjectivities involved in selecting patients for transplants.

Response: We acknowledge that selecting patients for transplantation is the responsibility of the transplant surgeon and that transplant surgeons

must exercise their medical judgment when weighing the risks and benefits of transplantation. This final rule does not dictate how transplant candidates should be selected for placement on the waiting list and transplantation. Although we require transplant centers to have written patient selection criteria, transplant centers are free to include a process for justifying exceptions to the selection criteria.

Comment: A few commenters stated that the proposed requirement for written patient criteria is duplicative of the OPTN patient listing policies. The commenters said that a center's adherence to the OPTN policies should satisfy our patient selection criteria.

Response: The OPTN policies for patient placement on the waiting list focus mainly on the criteria for organ allocation and not on the criteria for placement on or exclusion from a center's waiting list. We believe that if transplant centers adhere to OPTN policies and comply with the patient selection criteria requirement in this final rule, they will place patients on their waiting lists appropriately. Therefore, we have finalized the patient selection criteria requirement as proposed.

Comment: A commenter stated that patient selection for transplants is usually a medical judgment based on guidelines developed by professionals. Guidelines change from time to time. A commenter recommended the Patient Care and Education Guidelines developed by the American Society of Transplantation as a helpful resource for transplant decisions.

Response: We support the concept of incorporating professional guidelines into a transplant center's transplant candidate selection policies, as the center deems appropriate. We expect that transplant centers will revise their policies periodically as needed. We have made no changes based on this comment.

Comment: A commenter stated that we should encourage patients to take some responsibility for their own care. The commenter suggested that in the transplant candidate evaluation process provision, we should include some patient self-management provisions.

Response: We agree with the commenter that transplant candidates should share responsibility for their own care. Transplant centers are free to incorporate this concept in their patient evaluation policies. However, including such a requirement in regulations would be unnecessarily prescriptive.

Comment: Some commenters opposed the requirement that a transplant center must employ or consider all other

appropriate medical and surgical therapies that might be expected to yield both short and long-term survival comparable to transplantation before a patient is selected for placement on the waiting list. The commenters said this practice interferes with medical judgment and may place transplant centers at legal risk. A few commenters requested an exemption for kidney, heart, and pancreas transplant centers from this requirement because transplant decisions for these organ types are sometimes based on quality of life considerations, rather than survival alone. Commenters pointed out that medical and surgical therapy changes constantly, and it is difficult for transplant centers to set the upper and lower parameters in exhausting all available therapies before placing patients on the waiting list. Some commenters asked us to define "all other appropriate medical and surgical therapies" and questioned how compliance with this requirement would be determined.

Response: We understand the commenters' concerns that some transplant risk-benefit decisions are not based on survival alone and that it may be difficult for transplant centers to establish parameters for alternative medical and surgical therapies. Therefore, we are not finalizing our proposed requirement at § 482.90(a)(1).

Comment: Some commenters supported our proposal to require a psychosocial evaluation for prospective transplant candidates and suggested that a transplant center should designate qualified staff to perform the evaluation. One commenter suggested that prospective transplant candidates who have a history of psychiatric illness and substance abuse should be further evaluated by a psychologist or psychiatrist.

Response: We agree that a psychosocial evaluation should be performed by qualified staff. For good patient care, we expect that the individual who performs a psychosocial evaluation of a transplant candidate or prospective living donor will make a referral for further evaluation if a patient shows symptoms of, or has a history of, psychiatric illness or substance abuse. However, we have made no changes based on this comment.

Comment: Many commenters recommended changing our proposed language to state that a prospective transplant candidate or prospective living donor must receive a "qualified social worker evaluation" because the proposed language "psychosocial evaluation" is too ambiguous and does not indicate who conducts the

evaluation. Other commenters recommended that a qualified social worker should be designated to perform the evaluation using the Standards for Social Work Services in ESRD Facilities developed by the ESRD Network of Texas, Inc. as the standardized assessment tool.

Response: We appreciate the commenters' recommendations. However, since there is more than one category of qualified professional who can conduct a psychosocial evaluation of a prospective transplant candidate, we have chosen to give transplant centers the flexibility to designate the type of qualified individual who will conduct the psychosocial evaluation. This individual may be a qualified social worker or another qualified individual.

In our view, there is no standardized psychosocial evaluation tool that would be applicable to all prospective organ transplant candidates. Therefore, this final rule, as proposed, provides a transplant center with the flexibility to select a standardized psychosocial evaluation tool or to devise its own psychosocial evaluation tool. We have made no changes based on this comment.

Comment: One commenter stated that it is impractical and inappropriate to require transplant centers to conduct a psychosocial evaluation of some prospective transplant candidates, such as infants and very small children, as well as patients who are acutely ill with fulminate hepatic failure or acute cardiomyopathy.

Response: In nearly all cases, a transplant center should ensure that patients receive a psychosocial evaluation prior to placement on the center's waiting list. However, we agree with the commenters that conducting a psychosocial evaluation is not always possible, for example, in emergency situations or when the patient is very young. Therefore, we have revised the regulation text at § 482.90(a)(1) to state that "prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible." We expect transplant centers to perform psychosocial evaluations in every situation in which it is possible to do so.

Comment: A few commenters supported the requirement for determining and documenting a transplant candidate's blood type in medical records prior to being placed on the waiting list. However, one commenter suggested that we should refer to the UNetSM system to determine a candidate's ABO blood type, instead

of establishing a new blood type documentation requirement.

Response: We are not establishing a new blood type documentation requirement. We require only that before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation of the candidate's blood type. Similarly, OPTN policies require a transplant program to be responsible for ensuring the accuracy of candidate ABO data on the waiting list. OPTN policies also include on-line verification of a candidate's ABO data against the source document by an individual other than the person initially entering the candidate's ABO data in UNetSM. The OPTN expects a transplant program to maintain records documenting that such separate verification of the source document against the entered ABO has taken place and make such documentation available for audit. Our requirements complement these OPTN policies. The individual who verifies the source document (which could be the determination of blood type in the candidate's medical record against the UNetSM) may simply annotate the verification in the medical record.

Comment: A commenter questioned the rationale for requiring documentation of the patient selection criteria used. One commenter stated that documenting patient selection criteria would be time-consuming and a departure from current practice. Another commenter suggested that adherence to some written basic patient selection criteria or cross-referencing the patient selection criteria should be adequate evidence of compliance. A few commenters stated that the documentation of patient selection criteria, including the evaluation process and analysis of extensive medical work-up, would add administrative burden to transplant centers and increase Medicare expenses.

Response: The rationale for requiring documentation of the patient selection criteria used is to ensure that the transplant center's written patient selection policies and procedures are consistently implemented and that this is reflected in medical records. We agree that repeating a written narrative of all previous pre-transplant evaluation processes and medical work-ups would be burdensome. However, in documenting the patient selection criteria used, a transplant center may choose to use electronic formats, forms, or checklists to indicate the applicable criteria, as set forth in the center's own policies and procedures manual. We believe that any administrative burden

associated with the patient selection criteria documents will be minimal and will not raise Medicare expenses appreciably.

Comment: A few commenters supported the requirement that living donor selection criteria must be consistent with general medical ethics. Commenters stated that selection criteria are important in bringing some standardization to the living donor evaluation and selection processes. A commenter recommended giving flexibility to transplant centers to evaluate medical ethics issues on a case-by-case basis. However, one commenter stated that there is no consensus on what constitutes medical ethics. Another commenter requested more explicit clarification of the meaning of general medical ethics.

Response: We expect a transplant center to assess the prospective living donor carefully to ensure, insofar as possible, that donation will not cause long-term harm to the individual's health. Furthermore, we expect transplant centers to apply the ethical principle of " equipoise " to assess whether the benefits to both the donor and the recipient outweigh the risks associated with the donation and the transplantation. We believe the provisions set forth in this final rule provide flexibility for transplant centers to evaluate every prospective living donor individually, using the same medical ethics they would use in providing health care to any patient. No changes were made based on these comments.

Comment: A commenter questioned if Internet donor matching is ethical.

Response: The commenter is correct that the transplant community has not reached consensus on the ethics of certain donation practices, such as Internet donor matching. However, such issues are beyond the scope of this final rule.

Comment: Some commenters suggested adopting the OPTN Ad Hoc Living Donor Committee Living Liver and Kidney Donor Evaluation Guidelines or the Living Donor Evaluation Criteria developed by the American Society of Transplantation.

Response: We support the concept of incorporating professional guidelines into a transplant center's living donor selection policies. However, we believe incorporating the suggested guidelines or evaluation criteria into this final rule would be too prescriptive and would not provide centers with sufficient flexibility. We made no changes based on this comment.

Comment: Although some commenters supported medical and

psychosocial evaluation of living donors, one commenter did not support the requirement for a living donor to receive a psychosocial evaluation, as it might delay transplantation and would add to the cost of the transplantation. The commenter noted that, in the case of parent to child donation, the psychosocial evaluation would not be warranted.

Response: Transplant centers are free to include a process in their policies and procedures to respond to emergency situations when it may not be possible to conduct a psychosocial evaluation prior to donation. However, in the absence of such a situation, we expect transplant centers to conduct psychosocial evaluations of all prospective living donors. An evaluation can assist the prospective living donor in evaluating the pros and cons of donating and the potential psychological impact of donating and thus aid the individual in making an appropriate donation decision. Even a parent donating to a child may feel conflicted; for example, a parent may worry about the possible impact of the parent's donation on other children in the family.

Comment: One commenter supported the documentation of living donor suitability in medical records. However, some commenters had concerns that such documentation in the transplant candidate's medical records would compromise the privacy of the donor's individually identifiable health information and violate the HIPAA regulations, putting transplant centers at legal risk. Another commenter stated that this requirement deprives the potential living donor of an exit out of the donation process if the individual is reluctant to donate but prefers the transplant candidate to think he or she cannot donate for medical reasons.

Response: We believe the commenters have valid concerns, and we agree that documentation of a living donor's suitability for donation in the transplant recipient's medical records would be inappropriate. Therefore, we have eliminated the proposed requirement at § 482.90(b)(2) to document the transplant recipient's medical record with the living donor's suitability for donation. However, we have finalized our proposal to require documentation of the living donor's suitability for donation in the living donor's medical record. (See § 482.90(b)(2).)

Availability of Patient Selection Criteria

In the proposed rule, we requested comments on whether transplant centers should be required to make the

patient selection criteria available to patients routinely or upon request.

Comment: One commenter stated that providing transplant patients with patient selection criteria would restore public trust in the transplant system and ensure fairness in organ allocation. However, another commenter stated that providing candidates with patient selection criteria may set unrealistic expectations in the complex organ allocation and transplantation process. A few commenters recommended that a copy of the patient selection criteria should be given to patients only if requested.

Response: We agree that the knowledge of a transplant center's patient selection criteria would help a patient to better understand his or her treatment options. However, given that transplantation is not a straightforward decision, we agree with the commenter who expressed concern that providing the patient selection criteria to patients may lead to misunderstanding or give some patients unrealistic expectations of their likelihood of receiving a transplant. Some patients may want to rely on their surgeons and physicians to give them advice and recommendations about transplantation. Therefore, this final rule requires a transplant center to provide a copy of its patient selection criteria to a patient only upon the patient's request.

We are sympathetic to the view of the commenter who said that providing copies of patient selection criteria to patients would ensure fairness in organ allocation. We believe that additional transparency in the selection process can further the goal of equity in transplantation and give dialysis facilities a tool to ensure that referral of dialysis patients to kidney transplant centers for evaluation is fair and non-discriminatory. That is, once a dialysis facility knows the specific patient selection criteria used by each kidney transplant center in its vicinity, it can better ensure that it refers all patients who may be eligible for transplantation. Therefore, we have added a requirement to this final rule specifying that a kidney transplant center must provide a copy of its transplant patient selection criteria to a transplant candidate or a dialysis facility, at the request of the patient or the facility. (See § 482.90(a)(4).)

We note that a patient who believes that a transplant center's patient selection criteria are unfair or discriminatory or that a transplant center has not followed its patient selection criteria may find a remedy in the grievance process of the hospital in which the transplant center is located. Section 482.13, Patient Rights, requires

hospitals to protect and promote each patient's rights. Section 482.13(a)(2) further requires that hospitals establish a grievance process for the prompt resolution of patient grievances and that the hospital's grievance procedures are clearly explained to the patient.

Condition of Participation: Organ Recovery and Receipt (Proposed § 482.92)

We proposed that transplant centers must have written protocols to validate donor-recipient matches and other vital data for deceased organ recovery, organ receipt, and living donor transplantation. We proposed assigning responsibility to the transplanting surgeon for ensuring the medical suitability of donor organs for transplantation into the intended recipient.

We proposed that a transplant center's organ recovery team would have to review and compare the recipient and donor data with the recipient blood type and other vital data before recovery took place. We also proposed requiring that, when an organ arrives at a transplant center, the transplanting surgeon and at least one other individual at the transplant center must verify prior to transplantation that the donor's blood type and other vital data indicate that the donor's organ is compatible with transplantation of the intended recipient.

We proposed that if a center performed living donor transplants, the transplanting surgeon and at least one other individual at the transplant center would be required to verify that the living donor's blood type and other vital data indicated that the donor's organ is 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).

Following are summaries of the comments we received and our responses.

Comment: Some commenters supported the proposed requirement for transplant centers to have written protocols to validate donor-recipient compatibility in organ recovery, receipt, and transplantation to prevent unintended transplantation of organs mismatched by blood type. However, a commenter stated that protocols for validation of data may pose a legal risk for transplant centers.

Response: A crosscheck verification of the donor's blood type with the blood type of the intended recipient is a critical step in organ allocation and transplantation. Therefore, in this final rule, as we proposed, we require

transplant centers to have written protocols to ensure that this essential process takes place. We believe that consistent application of such sound protocols ultimately will reduce legal risks for transplant centers.

Comment: A commenter stated that it is impossible to be inclusive of all possible scenarios encountered in organ recovery; therefore, the use of a written protocol for organ recovery would be limited.

Response: We recognize that the unexpected may happen during organ recovery. However, a well-written organ recovery protocol should anticipate as many of these scenarios as possible.

Comment: Some commenters disagreed that the transplant surgeon should be fully responsible for suitability of donor organs during organ recovery because:

(1) Information provided by an OPO may not be accurate;

(2) At the time of organ recovery, the identity of the intended recipient may not be known; and

(3) At the time of organ recovery, information about the organ donor may not be complete.

Response: The requirement does not mean that the transplant surgeon is responsible for the suitability of donor organs prior to or during recovery. The transplant surgeon is responsible for ensuring the medical suitability of a donor organ for transplantation into the intended recipient only after the organ has arrived at the transplant center. If the transplant surgeon makes the determination of medical suitability based on inaccurate information provided by the OPO about the donor organ (for example, the paperwork that accompanies the organ to the transplant center is marked with the wrong blood type), the transplant surgeon will not be held responsible for his or her determination of medical suitability.

Comment: A commenter suggested that the transplant coordinator should be responsible for blood type verification.

Response: Transplant centers may delegate this responsibility to transplant staff or the transplant coordinator. No change was made based on this comment.

Comment: Some commenters stated that the proposed blood type validation is duplicative of OPTN policies; therefore, additional requirements would not be necessary. Some commenters suggested that the OPTN policies and Medicare requirements should be consistent.

Response: The commenters are correct that our requirement is similar to the OPTN policy, which requires a

transplant center, upon receipt of an organ and prior to transplantation, to perform and document crosscheck verification of the donor's blood type with the blood type of the intended recipient. As we have stated previously in this preamble, with the exception of OPTN data submission requirements, OPTN policies are not enforceable unless they are approved by the Secretary under 42 CFR 121.4.

Comment: Some commenters suggested that our proposals for organ recovery were unnecessary. For example, a commenter stated that organ procurement procedures start before the recipient is identified or the transplant center is notified. Another commenter stated that many large OPOs already have developed protocols for organ recovery teams that recover organs for the OPO or for transplant centers, which means that transplant centers would have minimal involvement in the organ recovery process. However, another commenter agreed with our proposal and said that a transplant center's recovery team should validate donor and recipient blood type and other vital data before organ recovery takes place.

Response: We recognize that in many cases, transplant centers may have little involvement in the process of organ recovery. Therefore, we have revised the regulation text at § 482.92(a) to reflect that when the intended recipient is known, and the transplant center sends a team to recover organ(s), the transplant center's recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

Comment: A commenter suggested that instead of requiring at least one other individual to verify donor-recipient blood type and vital information, we should specify that the individual must be a licensed health care professional.

Response: We agree with the commenter. We have changed the regulatory text at § 482.92(b) to require that after an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended recipient. In addition, we have changed the regulatory text at § 482.92(c) to say that if a center performs living donor transplants, the transplanting surgeon and another licensed health care professional 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). Since cross checking donor and recipient information generally is performed in the operating room just prior to transplantation, nurses and other licensed health care professionals should be readily available.

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

We proposed that transplant centers must have written patient management policies for the pre-transplant, transplant, and discharge phases of transplantation. We proposed that if a center performs living donor transplants, it must have written donor management policies for the donor evaluation, donation, and discharge phases of the living organ donation. We proposed that a transplant center must ensure that each transplant patient and living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout all phases of the transplantation or living donation.

We proposed that transplant centers must keep their waiting lists current, including updating waiting list patients' clinical information on an ongoing basis. We also proposed that a transplant center must remove a patient from its waiting list if the patient receives a transplant, if the patient dies, or if there is any other reason that the patient should no longer be on a center's waiting list.

We proposed requiring transplant centers to notify the OPTN of a patient's removal from the center's waiting list no later than 24 hours after the removal.

We proposed that 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 waiting list and who is admitted for organ transplantation. For each patient who receives an evaluation for placement on a center's waiting list, we proposed that the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of: (1) The patient's placement on the center's waiting list; (2) the center's decision not to place the patient on its waiting list; or (3) the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

We proposed that once a patient is placed on a center's waiting list, the center must document in the patient's record that the patient has been notified

of: (1) His or her placement status (at least once a year, even if there was no change in the patient's placement status); and (2) his or her removal from the waiting list for reasons other than transplantation or death no later than 10 days after removal.

We proposed that kidney 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 of any changes in the patient's transplant status.

We proposed that when a patient is admitted for transplantation, the patient's record must contain written documentation of multidisciplinary patient care planning during the pre-transplant period and multidisciplinary discharge planning for the patient's post-transplant care.

We proposed that transplant centers must make social services, furnished by qualified social workers available to transplant patients, living donors, and their families. We proposed that a qualified social worker is an individual who meets licensing requirements in the State in which he or she is practicing and: (1) Has completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker.

We proposed that transplant centers must make nutritional assessment and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors.

We proposed that 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.

We also are responding to comments we received on the ESRD proposed rule from dialysis facilities relating to transplant referral tracking of dialysis patients and the grandfather requirement for social workers. Although these comments were submitted along with comments on the ESRD proposed rule (February 4, 2005, 70 FR 6184), we are responding to them in the preamble to this final rule because they are relevant to our

proposed requirements for notification of waiting list patients and our proposed requirements for social workers.

Following are summaries of the comments we received and our responses to the comments.

Comment: Commenters agreed that transplant centers should play an active role in the care and management of transplant patients. Some commenters suggested that transplant centers should be required to provide pre-transplant and post-transplant care to transplant recipients in conjunction with the recipient's local provider team. However, many commenters stated that transplant centers should not be held accountable for transplant patients' pre- and post-transplant care because many waiting list patients do not live near the transplant center and are cared for by their local providers, particularly in the case of dialysis patients. Kidney transplant patients usually receive their pre- and post-transplant care from their local nephrologists and dialysis facilities. Commenters stated that pre-transplant care planning for kidney patients is the responsibility of the dialysis facilities where the patients receive care.

Response: As stated previously, we agree with the commenters that the care of transplant patients is best coordinated by local health care providers and transplant centers. Transplant patients require clinical evaluation before being placed on the waiting list, clinical care while they are on the waiting list, and follow-up monitoring after transplantation. In most cases, while transplant candidates are waiting for suitable organs, they continue to receive non-transplant-related routine medical care from their local health care providers and (for kidney patients) dialysis facilities, rather than from the transplant center where they are listed. Therefore, based on public comments, we have not finalized our proposed requirement at § 482.94 that transplant centers must have written patient management policies for the pre-transplant phase of transplantation or our proposed requirement that they must provide pre-transplant care to transplant patients.

We agree with the commenters that transplant patient management is better coordinated with the transplant patient's local providers, and we expect that for the most part, this is already a standard practice. However, we see no reason to prescribe explicitly how transplant centers should work with other providers, with the exception of dialysis facilities.

The relationship between dialysis facilities and kidney transplant centers

is unique because dialysis facilities treat and monitor their patients more frequently than other health care providers. Any changes in a dialysis patient's clinical status may affect his or her transplant suitability. Thus, it is important for kidney transplant centers to have open and frequent communication with dialysis facilities to ensure that all transplant-related issues are communicated clearly to the patient and to the patient's provider(s) of care. Based on these comments, we have added a requirement at § 482.104(a) that a kidney transplant center must have written policies and procedures for ongoing communication with dialysis patients' local dialysis facilities.

Coordination also ensures that the transplant center has the information about the patient's status that it needs to keep its waiting list and the OPTN's waiting list current. For example, a patient may have to be removed from the waiting list because he or she has become too ill to receive a transplant. Therefore, we are finalizing the proposed requirement at § 482.94(c) as follows. Section 482.94(c)(1) specifies that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient's placement on the center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed. Section 482.94(c)(2) requires that if a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

For post-transplant care, we expect a transplant center to use the discharge planning process to coordinate transplant-related follow-up care. (See § 482.94(c)(3)(ii).) As a general rule, patients receive several months of post-transplant care from the transplant center that performed the transplant, even if they do not live near the transplant center. After that, patients often continue to receive care from the transplant center for an extended period of time in conjunction with their local

physician or dialysis center.

Coordination of care ensures that the transplant center will have access to the patient follow-up data it needs to abide by the OPTN data collection and submission policies.

Comment: One commenter stated that the provision for multidisciplinary patient care planning is overly detailed and would place a burden on centers.

Response: We disagree with the commenters. We believe the multidisciplinary patient care planning provision proposed at § 482.94(c)(4) is flexible and general in nature. We believe the requirements will allow a transplant center to assemble a multidisciplinary patient care team using in-house hospital staff, which should create little or no extra burden. Therefore, we are finalizing this requirement as proposed.

Comment: One commenter stated that the proposed patient care requirements are duplicative of the JCAHO survey standards for inpatient care planning and discharge planning. Another commenter noted that the OPTN policies already address transplant care and patient management guidelines.

Response: We agree that there are similarities between the JCAHO survey standards for inpatient care planning and discharge planning and our requirements for patient care in this final rule. However, some requirements in this final rule (such as living donor care, management of the waiting list, and patient records) are absent from JCAHO's survey standards for acute care hospitals. Furthermore, even if Medicare requirements were identical to JCAHO standards and OPTN policies, this fact would not eliminate the need to incorporate the requirements into our regulations because JCAHO standards and the OPTN's policies are not legally enforceable by CMS.

Comment: Many commenters stated that kidney transplant centers should be exempt from the requirement for a written long-term care plan because kidney transplant candidates are usually cared for by their referring physicians, nephrologists, social workers, dietitians, and dialysis facilities while awaiting transplants. Some commenters suggested that instead of developing a care plan, kidney transplant centers should be required only to obtain a copy of the patient's long-term care plan from the dialysis facility and keep it with the transplant candidate's medical records.

Response: The commenters may have misunderstood the proposed patient management requirement. We are not requiring transplant centers to develop long-term care plans for transplant patients. We agree that this is the

responsibility of each patient's local health care providers and dialysis facility, as appropriate. As stated earlier, we strongly encourage transplant centers to collaborate with local providers and dialysis facilities to tailor patient management policies to their patients' needs. Given that it is a standard practice for health care providers to request medical records from other providers who are actively treating their patients, we do not believe we need to require a transplant center to obtain a copy of the patient's long-term care plan from the dialysis facility, nor do we need to exempt kidney transplant centers from these requirements. No changes have been made to this final rule based on these comments.

Comment: One commenter supported the proposal that living donors should be under the care of a multidisciplinary team to safeguard their interests and well-being. The commenter suggested that we should require centers to be responsible for living donors' post-discharge issues or complications and provide specialists to follow living donors.

Response: Since some living donors may receive immediate post-donation care in hospital units outside the transplant center, we want to ensure that living donor care is well coordinated.

We expect transplant centers to coordinate follow-up care for living donors upon discharge as well. Although this final rule does not specifically delineate transplant centers' responsibilities for living donors' post-discharge care, we expect a transplant center to provide care, as needed, if a living donor experiences donation-related problems or complications post-discharge.

Comment: Many commenters commended us for our clarity in describing the waiting list management requirements that would positively impact the organ allocation system. The commenters stated that it is important for transplant centers to update the status of waiting list patients continuously to increase the efficiency of organ allocation and ultimately reduce organ wastage and organ discard rates. However, a few commenters stated that the waiting list management requirements are overly detailed and may put centers at legal risk.

Response: We disagree that the waiting list management standard is overly detailed. The waiting list management requirements in this final rule are steps transplant centers must take to help the OPTN keep the waiting list current, so that: (1) Organ allocation

is prioritized based on medical urgency and other relevant factors; (2) OPOs do not waste valuable time contacting centers about patients who should no longer be on the waiting list; and (3) organ wastage is minimized.

We have no evidence that keeping its waiting list current will create a legal risk for a transplant center.

Comment: One commenter suggested that we should specify how frequently transplant centers must update their waiting lists (that is, daily, weekly, or monthly).

Response: We are not imposing an arbitrary timeframe for transplant centers to keep their waiting lists up to date. The availability of waiting list patients' clinical information varies from patient to patient, and clinical information may change frequently or infrequently. We expect transplant centers to update their waiting lists, including updates of clinical information and removal of patients from waiting lists on an ongoing basis as the information becomes available. For clarity we have added "on an ongoing basis" at § 482.94(b) to emphasize that transplant centers must keep their waiting lists up to date.

Comment: Some commenters expressed appreciation that we did not propose to mandate an annual evaluation of all patients on the waiting list. One commenter suggested that waiting list management should be clinically driven. That is, we should require centers to identify "high risk" transplant candidates and evaluate them annually. A commenter suggested requiring centers to conduct periodic clinical re-evaluations of transplant candidates to enhance updating of clinical information in those patients' medical records and their information on the waiting list.

Response: We developed the requirement for transplant centers to update clinical information for their waiting list patients on an ongoing basis based on the assumption that updating of patients' clinical information is clinically driven. We understand that some patients are in critical condition, requiring more intense evaluation and monitoring, and other patients remain stable for longer periods of time. We expect transplant centers to keep their waiting lists updated accordingly. We expect that transplant centers will determine how often waiting list patients should be evaluated, based on the acuity of the individual patient. No changes were made in this final rule based on these comments.

Comment: A commenter stated that it is unreasonable to expect large centers with long waiting lists to update all

patients' clinical information on an ongoing basis because the requirement would be too burdensome.

Response: We believe it is essential for a transplant center to stay abreast of its waiting list patients' clinical status and keep its waiting list updated on an ongoing basis so that when an organ offer is made, the transplant center knows the clinical status of the potential recipient. If a long waiting list is the reason for a center's failure to update waiting list patients' clinical status, the transplant center may need to re-evaluate its policies to determine if the number of patients on its waiting list is beyond its capacity to manage.

Comment: Some commenters stated that managing a transplant center's waiting list is a very complex task and is already subject to OPTN oversight. Some commenters suggested that the OPTN should be the entity to set guidelines for waiting list management, and one commenter recommended that we should ask the OPTN to develop guidelines for transplant centers. Another commenter suggested that the OPTN should incorporate and publish the transplant waiting list management guidelines developed by the American Society of Transplant Surgeons (ASTS). Commenters said that our regulations should require only that transplant centers comply with OPTN waiting list policies.

Response: As appropriate, we have included OPTN patient waiting list policies in this final rule for oversight and enforcement purposes. The OPTN has waiting list management policies that go beyond our requirements, including patient screening and listing criteria, waiting time modifications, multiple listings, and removal of transplant candidates from waiting lists. As we proposed at § 482.94(c), we have included some OPTN patient waiting list policies in this final rule for oversight and enforcement purposes. Suggestions regarding the OPTN's incorporation of specific guidelines, such as those developed by ASTS, fall outside the purview of this final rule and should be addressed to the OPTN.

Comment: Some commenters stated that dialysis facilities do not always inform kidney transplant centers about changes in the clinical status of their dialysis patients. The commenters suggested that transplant centers, referring nephrologists, and dialysis facilities all should be held accountable for collaboration and communication regarding the clinical and listing status of patients on the waiting list. The commenter said that the collaboration process would help the transplant

center to keep patients' clinical information current.

Response: We agree. Based on public comments, we have added a requirement for kidney transplant centers to have written policies and procedures for ongoing communication with dialysis patients' local dialysis facilities. (See § 482.104(a).) We believe this requirement will resolve the commenters' concern about insufficient communication or lack of communication between transplant centers and dialysis facilities.

Comment: A commenter stated that the requirement to notify the United Network of Organ Sharing (UNOS) (i.e., the OPTN Contractor) within 24 hours after a patient's removal from the center's waiting list does not take into consideration the inaccessibility of the UNetSM over the weekend for on-call staff.

Response: UNetSM is available 24 hours a day, 7 days a week to the transplant community. Transplant centers need to provide access for on-call or weekend staff so that they can notify the OPTN timely outside of normal business hours.

Comment: A commenter stated that timely notification to the OPTN about patients' removal from the waiting list is affected by data provided by dialysis facilities and local clinicians. One commenter suggested that we purchase software to help centers interface with dialysis facilities timely.

Response: As we developed the proposed ESRD rule, we recognized the need for dialysis facilities to inform transplant centers about changes in the status of kidney transplant candidates.

Although currently there is no software available to provide an interface between transplant centers and dialysis facilities, we do not expect transplant centers to have difficulty communicating with dialysis facilities.

Comment: Some commenters supported the requirement for centers to notify each patient who is evaluated for transplant of his or her transplant status. However, some commenters stated that our patient notification requirements would be duplicative of OPTN policies.

Response: Current OPTN bylaws for transplant hospitals include notification of patients in writing within 10 business days of: (1) A patient's placement on the waiting list, including the date the patient was listed; (2) completion of a patient's evaluation as a candidate for transplantation, if the evaluation has been completed and the patient will not be placed on the waiting list; or (3) removal from the waiting list as a transplant candidate for reasons other than transplantation or death. Further,

transplant hospitals are expected to maintain documentation of these notifications and make the documentation available to the OPTN. As we proposed at § 482.94(c)(2), we have incorporated similar notification policies into this final rule for purposes of oversight and enforcement. In addition, as proposed at § 482.94(c)(3), this final rule requires a transplant center to document that it has notified the patient and dialysis facility, if applicable, if the transplant center is unable to make a decision whether to place the patient on the waiting list because further clinical testing or documentation is needed, as required by § 482.94(c)(1)(iii).

Comment: A commenter stated that communicating waiting list status to patients via mail is too labor-intensive. A few commenters stated that our impact analysis in the proposed rule underestimated the cost of notifying patients and dialysis facilities. One commenter stated that the cost quoted to notify patients and dialysis facilities does not include management oversight time and expenses. Another commenter suggested that centers should use a letter to notify patients whether they will be placed on the waiting list and use phone calls for other types of communication.

Response: As we proposed, the patient notification requirements in this final rule do not mandate how transplant centers will notify patients and dialysis facilities about patients' waiting list status. Transplant centers have the flexibility to determine how they will communicate such information to patients and dialysis facilities. Further discussion of the paperwork and the economic impact of these requirements are found in the Collection of Information and Impact Analysis sections of this preamble.

Comment: Some commenters stated that the yearly requirement to notify transplant patients goes beyond the OPTN requirement and is unreasonable, costly, prescriptive, burdensome, and impractical.

Response: We have carefully evaluated all the public comments we received on this issue and concluded that annual notification to patients would be unduly burdensome for transplant centers and is not necessary, as long as transplant centers can document that they notified transplant candidates, as appropriate, about the transplant candidate's placement status in accordance with § 482.94(c) in this final rule. Therefore, we are not adopting the yearly notification requirement we proposed at § 482.94(c)(2)(i).

However, as we proposed at § 482.94(c), we are requiring that if a transplant center evaluates a patient for placement on the waiting list, the center must document in the patient's record that the patient is informed of his or her transplant status, including notification of: (1) The patient's placement on the center's waiting list; or (2) the center's decision not to place the patient on its waiting list. Furthermore, as we proposed, once a patient is placed on a center's waiting list, the center must document in the patient's record that the patient is notified of his or her removal from the waiting list for reasons other than transplantation or death no later than 10 days after the patient's removal from the center's waiting list.

To clarify that the requirement for notifying patients of their status after they have been evaluated for transplantation is the same for all patients but that a kidney patient's usual dialysis facility also must be notified, we have removed proposed section 482.94(c)(3) and added language to sections 482.94(c)(1) and (2). Section 482.94(c)(1) now reads in part, "For each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of * * *." Section 482.94(c)(2) now reads in part, "If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified * * *."

Comment: A commenter stated that patients should take some responsibility for waiting list accuracy. Another commenter suggested that transplant patients should be given the "Patient Bill of Rights and Responsibilities" package in which the patient acknowledges in writing that he or she has the responsibility to keep the transplant center informed of his/her whereabouts.

Response: We agree that waiting list patients should keep the center or centers where they are listed informed of their whereabouts and informed of any other relevant information. We encourage transplant centers to educate potential transplant candidates about their responsibilities. However, we have made no changes based on this comment.

Comment: A commenter suggested that a center should be found in

compliance if it documents that it made a reasonable attempt to notify a patient without actually succeeding.

Response: When notification of a waiting list patient or a prospective waiting list patient is required under this final rule, we expect the transplant center to make a concerted effort to locate and notify the patient. Nevertheless, we understand there may be circumstances in which the patient cannot be found. At a minimum, a transplant center should maintain documentation in the medical record that it made several attempts to contact the patient.

Comment: Some individuals who commented on the ESRD proposed rule stated that dialysis facilities should relinquish transplantation referral tracking responsibility once the referral has been made. Commenters expressed concerns that some transplant centers do not communicate with dialysis facilities regularly. One commenter stated that transplant centers should provide dialysis facilities with the information they need to monitor transplantation status.

Response: As we proposed, and as adopted in this final rule, a kidney transplant center bears considerable responsibility for patient tracking once a dialysis facility has referred a patient for evaluation. Section 482.94(c)(1) requires documentation of notification of the patient of his or her placement on the center's waiting list, the center's decision not to place the patient on its waiting list, or the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed. Under § 482.94(c)(3), transplant centers must document in the patient's medical record that both the patient and the patient's local dialysis facility have been notified of the patient's transplant status and of any changes in the patient's transplant status (in accordance with § 482.94(c)(1)).

Comment: Many commenters supported the requirement that transplant centers must make social services furnished by qualified social workers available to transplant patients, living donors, and their families. Some commenters recommended that transplant centers should be required to provide transplant patients and living donors with ongoing access to qualified transplant social workers for continuity of care after discharge. One commenter inquired about the time frame for post-transplant social services provided by transplant centers and the potential for Medicare reimbursement for the services.

Response: Under the final rule and as we proposed, transplant centers are responsible for making social services furnished by a qualified social worker available to all transplant patients, living donors, and their families while a transplant patient or living donor is hospitalized. For Medicare beneficiaries (and their living donors), the services are often reimbursed. We did not propose requiring, nor does this final rule require, transplant centers to provide post-discharge social services to all transplant recipients or living donors. Nonetheless, we expect any social services needed post-discharge would be arranged through the discharge planning process. Some centers may choose to continue to provide such services to patients and living donors even though they may not be Medicare reimbursable. Medicare reimbursement for post-transplant social services outside the hospital setting falls outside the purview of this rule.

Comment: Many commenters supported the proposed definition of a qualified social worker as an individual with a master's degree in social work (MSW). Commenters noted that the MSW degree requires an additional 900 hours of specialized training beyond a baccalaureate degree in social work, which prepares the individual with an MSW to work independently in the transplant setting where supervision and peer support is not always readily available.

Many commenters recommended that we not allow social work experience to substitute for an MSW, as we proposed. We proposed permitting social workers to qualify if they served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and had established a consultative relationship with a social worker who qualified under our requirements for social workers with a master's degree. (See proposed § 482.94(d)(2).) Conversely, in the ESRD proposed rule (70 FR 6184), we proposed eliminating a provision found in the current ESRD regulations at § 405.2102 (which applies both to dialysis facilities and to kidney transplant centers), which defines a social worker, in part, as an individual who, “* * * Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976 * * *”

Many who commented on the ESRD proposed rule said that we should retain this “grandfather clause” for non-MSWs so that currently employed non-MSWs working as social workers do not lose their jobs. Some commenters said that experienced non-MSW social workers

are competent and have a lot to offer, and they recommended that we continue the grandfather clause.

Response: In general, we agree with commenters who stated that a social worker with an MSW degree is the best qualified individual to evaluate and assess transplant candidates, recipients, families, and living donors who are facing multiple psychosocial stressors. However, we also agree with commenters who said that non-MSW social workers who were employed as such prior to September 1, 1976 have much to offer patients and families. We also believe that there should be one standard for all transplant centers.

To reconcile the conflicting viewpoints of commenters opposed to non-MSW social workers providing social services in transplant centers and commenters who urged us to retain the grandfather clause in the ESRD final rule, we have finalized the requirements for an individual to be a qualified social worker in any transplant center (not just a kidney transplant center) as follows. This final rule states that a qualified social worker is an individual who meets licensing requirements in the State in which he or she practices 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) is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 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).

This grandfather clause applies only to individuals who are currently employed as social workers in a transplant center as of the effective date of this final rule. Although we believe the number of these individuals to be small, we do not intend that these employees should lose their jobs because of the deletion of the “grandfather clause.”

Comment: A commenter suggested that we adopt the OPTN policies for the psychosocial services that transplant centers should offer without defining the required qualifications for a social worker.

Response: We do not agree that adopting OPTN policies without establishing requirements for social worker qualifications would serve the best interests of patients and living donors. As commenters overwhelmingly agreed, master's degree-prepared social workers are best qualified to provide

social services to transplant candidates and recipients, as well as living donors. Social workers often perform psychosocial evaluations of prospective transplant candidates and prospective living donors, and social workers provide critical services to transplant recipients and living donors during the inpatient and discharge phases of donation and transplantation. For example, prior to discharge, social workers provide counseling services to transplant recipients to assist them in maintaining the resolve they need to remain compliant with their immunosuppressive and other medications, which are necessary to prevent graft failure. We made no changes based on this comment.

Comment: A commenter recommended that a qualified social worker should have training in, and knowledge of, pediatric transplant issues.

Response: We agree that qualified social workers should have transplant training and knowledge of pediatric transplant issues, which can be achieved through on-the-job training or continuing education, if they are providing services in a pediatric center. We expect transplant centers to ensure that qualified social workers working in pediatric transplant programs receive ongoing staff development training to better handle issues that are unique to pediatric transplantation. We made no changes based on this comment.

Comment: Some commenters supported the requirement for transplant centers to have nutritional assessments and diet counseling services furnished by a qualified dietitian available to all transplant patients and living donors. One commenter stated that medical nutrition therapy is important for patients and living donors. However, some commenters stated that transplant centers should not be responsible for transplant candidates' pre-transplant nutritional care or care during the evaluation phase for transplant, which is usually provided by candidates' local providers. A few commenters stated that transplant centers should not be required to provide ongoing post-transplant nutritional services to patients and living donors. The commenters requested clarification of the time frame for nutritional services provided to post-transplant patients, and stated that Medicare should reimburse for such services.

Response: We agree that pre- and post-transplant nutritional care is usually provided by transplant patients' and living donors' local health care providers. This final rule requires

transplant centers to provide nutrition services to transplant recipients and living donors only during their inpatient stay. For example, a transplant recipient may need to be counseled on the modification of his or her dietary regimen after organ transplant or a living donor may need to be counseled for his or her temporary adjustment in nutritional intake after living organ donation. These services are part of the hospital inpatient services reimbursed by Medicare for beneficiaries and often for their living donors.

Comment: Some commenters suggested that living donors, particularly living kidney donors, should be exempt from nutritional services since they are healthy individuals.

Response: Although living donors are usually healthy individuals, we believe they should receive the same care provided to transplant recipients. Under the final rule and as proposed, transplant centers are responsible for making nutritional assessment and dietary counseling services furnished by a qualified dietitian available to all living donors while they are hospitalized for organ donation.

Comment: A commenter suggested that we should adopt the OPTN policy for nutritional services without defining the qualifications for a qualified dietitian.

Response: Currently, the OPTN does not have a policy for nutritional services furnished by transplant centers.

Comment: One commenter suggested adopting the Medical Nutrition Therapy (MNT) regulation definition of "qualified dietitian." A few commenters suggested that the definition of a qualified dietitian in the transplant center rule and the ESRD rule should be consistent.

Response: We have not used the MNT definition for registered dietitian in this final rule because it includes both registered dietitians and other nutritional professionals, and we believe this may cause confusion. However, we have revised the proposed requirements at § 482.94(e).

In this final rule, we require that a qualified dietitian must be a registered dietitian with the Commission on Dietetic Registration (CDR), who meets the practice requirements in the State in which he or she is employed. (See § 482.94(e).) For the most part, these requirements are similar to those included in the proposed rule for new conditions for coverage for ESRD facilities published February 4, 2005 (70 FR 6184). To date, the ESRD facility final rule has not yet been published.

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

We proposed that every transplant center must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate the performance of all transplantation services, including services provided under contract or arrangement.

We proposed requiring a transplant center's QAPI program to use objective measures to evaluate the center's performance with regard to transplant activities and outcomes. We proposed that these activities and outcomes may include, but would not be limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list, accuracy of donor-recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient satisfaction, and patient rights. We proposed that the transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

We proposed that transplant centers must establish and implement written policies to address and document any adverse events that occur during any phase of an organ transplantation case. We proposed that a transplant center must have policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. We also proposed that a 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. Following are summaries of the comments we received and our responses.

Comment: Some commenters supported the proposed requirement for a transplant center to have a defined QAPI process. Commenters said the proposed objective measures and adverse events standards were reasonable and would provide impetus for transplant centers to scrutinize and improve performance. A commenter stated that QAPI programs should be quality-driven and not complaint-driven.

Response: We appreciate the commenters' support of the proposed QAPI requirements. We anticipate that transplant centers will take advantage of their own transplant data as well as the wealth of transplant data available

through the OPTN and the SRTR and utilize them effectively to evaluate their own performance and effect positive changes.

Comment: Some commenters stated that the proposed requirement for a transplant center to develop, implement, and maintain a QAPI program would not contribute to improving patient outcomes.

Response: We disagree with the commenters. The effectiveness of QAPI programs in improving the delivery of health care is widely accepted throughout the health care community. An effective QAPI program uses objective data to study and make improvements to all patient care processes on a continuing basis. We expect transplant centers to focus on areas of sub-optimal performance and prioritize outcome measures for improvement. Using this approach, a transplant center can: (1) Identify areas where outcomes indicate a need for improvement; (2) define systematic changes needed to improve outcomes; (3) review implementation of improvement actions; and (4) determine the success of the actions to improve performance.

Comment: Some commenters stated that the QAPI program of a JCAHO accredited hospital and the OPTN oversight of transplant centers should eliminate the need for a separate transplant center-based QAPI program. Some commenters were concerned about the extra resources needed for a transplant center to have a separate QAPI program. Commenters suggested using the OPTN and SRTR as surrogates for transplant centers' QAPI programs. Some commenters recommended that transplant centers should be given the choice of using the hospital QAPI program or establishing a transplant-center-based QAPI program. A few commenters suggested using a formal QAPI program as part of a remediation process for centers that failed to comply with outcome measures.

Response: It is a common practice to use QAPI programs to improve the delivery of health care to patients. The intent of the QAPI requirement in this final rule is to develop a structured process for transplant centers to analyze and evaluate transplant patient outcomes data and transplant center processes continuously and effect changes accordingly. Hospitals have the flexibility to incorporate a transplant center's QAPI program into the hospital QAPI process. However, given the complexity and the uniqueness of some transplant issues, we disagree that a general hospital QAPI program or OPTN oversight alone could adequately

substitute for a transplant center-based QAPI program. Further, we disagree that the OPTN and the SRTR should serve as surrogates for transplant centers' QAPI programs. Every transplant center should tailor its QAPI program to meet its needs and its patient population to better serve the best interests of its patients.

Comment: A commenter recommended expanding the components of the QAPI program to include adverse events, electronic prescribing, clinical decision support, bar coding, and provider and patient education.

Response: We thank the commenter for the suggestions. We agree that it is appropriate to include patient education as part of the QAPI components, and we have included this requirement in the regulation text at § 482.96(a) in this final rule.

As we proposed, this final rule includes a separate QAPI standard at § 486.92(b) that requires transplant centers to establish and implement written policies to address and document adverse events. Therefore, we do not believe it is necessary to list adverse events as one of the specific components of a QAPI program at § 482.96(a).

We believe the other components suggested by the commenter belong in the hospital's overall QAPI program because they affect patient care and other functions throughout the organization. Therefore, no other changes have been made based on this comment.

Comment: A few commenters supported the proposed standard for transplant centers to address transplant-related adverse events. A commenter noted that we should specify the frequency of internal and external audits of the adverse events reporting and analysis.

Response: We expect transplant centers to analyze adverse events as they occur and to make systemic and other changes promptly, as necessary, based on their analysis. However, this final rule does not specify the frequency of internal audits or external audits of adverse events. The frequency of adverse events reporting and analysis should be contained in a transplant center's QAPI adverse events policies.

Comment: Some commenters stated that JCAHO survey standards require hospitals to have QAPI policies and sentinel events reporting and investigation. The commenters were concerned that the proposed adverse event standard is redundant and resource-intensive.

Response: As stated earlier, to reduce redundancy, a transplant-oriented QAPI program can be integrated into a hospital's QAPI program for accreditation purposes. Therefore, we do not believe the adverse events requirement, which is one of the QAPI standards in this final rule, will be excessively resource-intensive.

Comment: A few commenters requested the exclusion of non-transplantation-related end-stage organ disease in the adverse events definition.

Response: We did not propose including non-transplantation-related end-stage organ disease in the definition of "adverse events." The examples of adverse events provided in the definition of adverse events in both the proposed rule and this final rule relate only to donation by living donors and to transplantation.

Condition of Participation: Human Resources (Proposed § 482.98)

We proposed that transplant centers 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.

We proposed that each transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director with designated responsibilities. We proposed that 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).

We proposed that the director would be responsible for planning, organizing, conducting and directing the transplant center and must devote sufficient time to carrying out these responsibilities, which include, but are not limited to, ensuring:

(1) Adequate training of nursing staff in the care of transplant patients;

(2) That tissue typing and organ procurement services are available;

(3) That transplantation surgery is performed under the direct supervision of a qualified transplant surgeon in accordance with § 482.98(b).

We proposed 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. We proposed that the transplant surgeon is responsible for providing surgical services related to transplantation, and the transplant physician is responsible

for providing and coordinating transplantation care.

We proposed that transplant centers must have a qualified clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. We proposed requiring that a qualified clinical transplant coordinator must be certified by the American Board of Transplant Coordinators (ABTC).

We proposed that a transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. We also proposed 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.

We proposed that a transplant center must demonstrate the 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. Following are summaries of the comments we received and our responses.

Comment: Although some commenters supported the proposal that transplant centers must ensure that all individuals providing transplant services are qualified, one commenter stated that transplant centers should have the flexibility to determine their own personnel needs. The commenter voiced concern that the cost of meeting the proposed staffing requirements would increase costs to such an extent that facilities would no longer be able to contract with managed care companies because managed care reimbursement would be insufficient to cover costs.

Response: We believe the staffing requirements in this final rule are critical for the protection of the health and safety of living donors and transplant recipients. Based on public comments, we have eliminated our proposed requirement for ABTC certification for clinical transplant coordinators, and we have added a requirement in this final rule for a living donor advocate or advocate team, which may increase overhead costs for some transplant centers. However, as we discuss in more detail in the Impact Analysis Section of this preamble, we do not expect the donor advocate or donor advocate team requirement in this final rule to increase costs substantially. In fact, we expect an average increase of

less than \$18,500 per transplant center annually.

Comment: Some commenters stated that the OPTN policies for transplant personnel are industry gold standards and that they should be adopted by us and monitored by the OPTN. One commenter stated that the OPTN and CMS human resources requirements should be consistent.

Response: We believe our requirements are consistent with OPTN policies and bylaws. Section 482.72 of this final rule requires transplant centers to be OPTN members. While the final rule governing the operation of the OPTN does not require transplant programs within OPTN member hospitals that receive their designation by virtue of their Medicare approval to meet the OPTN's on-site primary transplant surgeon and transplant physician requirements, such programs are reviewed by the OPTN, on a voluntary basis, for compliance with such requirements. We expect that transplant centers, as members of the OPTN, will have no difficulty meeting these regulatory requirements, as the OPTN requirements are more extensive than our requirements.

Comment: One commenter suggested that we should add a "grandfather clause" for transplant staff to § 482.98, Human resources, as a transition to the new human resources requirements. That is, transplant centers should be permitted to continue to employ their current staff, even if some staff do not meet specific education, training, or licensure requirements in the final rule.

Response: As we stated in our previous response, we expect that transplant centers who are OPTN members will have no difficulty meeting our requirements. Our requirements for transplant surgeons and physicians are congruent with OPTN requirements. Furthermore, we have eliminated the proposed requirement for ABTC certification for transplant coordinators based on public comments, and we replaced it with a requirement for a clinical transplant coordinator to be an RN or clinician licensed in the State in which the coordinator practices and to have specific job-related skills. We expect that all or nearly all currently-employed clinical transplant coordinators already have these qualifications. We are requiring a donor advocate or donor advocate team to have certain knowledge and abilities but not specialized education or training.

Comment: A commenter recommended that we require transplant centers to have a transplant pharmacist on the transplant team.

Response: Section 482.98(e) of this final rule states that the multidisciplinary transplant 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. Therefore, we expect that the team will include an individual with expertise in transplant pharmacotherapy. We have not made any changes in this final rule based on this comment.

Director of a Transplant Center

Comment: Some commenters supported the proposal that a transplant center be under the general supervision of a qualified transplant surgeon or a qualified transplant physician director. However, one commenter suggested that we clarify the requirements for a qualified director of a transplant center. The commenter suggested that we permit a surgeon or a physician who meets the OPTN requirements for a designated surgeon or physician to be a transplant center director. Other commenters suggested that we cross-reference the OPTN definition for transplant surgeon or transplant physician qualification in the final rule. Some commenters recommended that we require the qualified transplant center director to be a certified surgeon or physician who has completed an approved American Society of Transplant Surgeons (ASTS) training/fellowship and who has been certified for all transplant programs.

Response: We did not define the qualifications for a transplant center director, so that transplant centers will have the flexibility to recruit an OPTN-qualified transplant surgeon or physician for the position. The ASTS training/fellowship is one of the options for transplant surgeons to meet the OPTN training program requirement. However, there are other options surgeons can choose to meet the OPTN training requirement. We do not believe it is necessary to require transplant surgeons to participate in a specific organization's training program to be qualified to provide transplantation services in a Medicare-approved transplant center.

As we have stated in some of our previous responses, we are not incorporating OPTN policies and bylaws into regulations by cross reference because we would be required to go through notice and comment rulemaking every time the policies and bylaws changed. OPTN policies for transplant surgeons and physicians are very detailed and subject to frequent

changes. We believe that such changes will occur too often for us to incorporate them expeditiously into our regulations. We will provide guidance regarding the definitions of qualified transplant center directors, surgeons, and transplant physicians in the Interpretive Guidelines. However, we can assure transplant centers that transplant surgeons and physicians who meet current OPTN requirements will meet the requirements in this final rule.

Comment: One commenter pointed out that nurses do not routinely report to physicians in hospital settings. The commenter suggested that instead of holding the director of a transplant center responsible for ensuring adequate training of nursing staff in the care of transplant patients, we should require the hospital in which the transplant center is located to be responsible for the training of nursing staff.

Response: The commenter was correct in stating that nursing staff do not usually report to physicians in a hospital setting. Therefore, we have modified our proposed language at § 482.98(a)(1) in this final rule, to state that the director of a transplant center must collaborate with the transplant hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

Transplant Surgeon and Physician

Comment: Some commenters recommended grandfathering all currently active transplant surgeons who have not completed an ASTS fellowship. They also recommended that we require an ASTS fellowship for all new transplant surgeons.

Response: Given that the OPTN gives transplant surgeons different options toward meeting the OPTN qualification requirements, we do not believe a grandfather clause is advisable. As stated previously, the ASTS training/fellowship is just one of the options for transplant surgeons to fulfill the OPTN training program requirements. Requiring all new transplant surgeons to complete an ASTS fellowship would be far too prescriptive and would be inconsistent with the OPTN bylaws.

Availability of Primary Transplant Surgeon and Physician

We received many comments urging us to conform our requirements to the OPTN policies and bylaws for transplant surgeons and physicians, and we believe that we should be consistent with the OPTN rules in this regard. Under OPTN bylaws, a transplant center designated under 42 CFR 121.9(a)(2)

must have a primary transplant surgeon and a primary transplant physician onsite at all times. The immediate availability of a transplant surgeon is imperative to minimize time on the waiting list and mortality of transplant candidates. Recently, our surveyors discovered that the inability of a liver transplant center in California to retain a full-time transplant surgeon was a contributing factor to the center's high organ refusal rate, low numbers of transplants, and prolonged waiting time for transplant candidates.

Therefore, under the final rule, we require not only that a 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 as proposed at § 482.98(b), but also that these individuals are immediately available to provide transplantation services when an organ is offered for transplantation. By "immediately available," we mean that the transplant surgeon and transplant physician must be available to provide transplantation services within a time frame that ensures there is no compromise to the viability of the organ or the health of the organ transplant recipient.

Clinical Transplant Coordinator

Comment: Most commenters supported the proposed requirement for a transplant center to have a clinical transplant coordinator.

Response: Clinical transplant coordinators are important links for transplant patients and living donors to transplant centers and dialysis facilities. We believe that clinical transplant coordinators are essential in coordinating the continuity of care of patients and living donors. They provide guidance to transplant recipients during the pre-transplant, transplant, and post-transplant phases and to living donors during the pre-donation, donation and post-donation phases.

Comment: Many commenters supported the proposed requirement for American Board of Transplant Coordinators (ABTC) certification for a qualified clinical transplant coordinator and stated that the ABTC certification would minimize medical errors associated with donation and transplantation. A commenter stated that the ABTC certification is the "gold standard".

However, many commenters strongly objected to our proposed requirement for ABTC certification. The commenters said that a requirement for ABTC certification would be arbitrary, given

that there are other agencies that certify coordinators. Many transplant center commenters attested that their clinical transplant coordinators are Advance Practice Nurses, have received in-house training, have received continuing education training, or are ABTC-qualified but not ABTC certified, yet they perform their responsibilities well and provide excellent patient care. The commenters suggested accepting subspecialty certifications, such as critical care or case management, to qualify clinical transplant coordinators.

Some commenters stated that the ABTC requirement would create recruitment hardship, especially for pediatric centers, and eventually raise overhead expenses for transplant centers. A few commenters requested an extension for pediatric centers to meet the ABTC requirement. The commenters noted that pediatric transplant programs usually hire Pediatric Advanced Practice Nurses who then acquire pediatric transplant experience through on-the-job training. Some commenters estimated that it takes about 18 months for a clinical transplant coordinator to become ABTC certified. To ease the difficulty of recruiting ABTC certified transplant coordinators, especially pediatric clinical transplant coordinators, some commenters suggested that we should allow 2 years for a newly-hired transplant coordinator to obtain ABTC certification while he or she continues to work under the supervision of an ABTC-certified coordinator. One commenter suggested requiring ABTC certification for non-RN clinical transplant coordinators while allowing RNs to be certified by credentialing bodies other than the ABTC. Some commenters recommended grandfathering all clinical transplant coordinators with at least 5 years of work experience.

Some commenters did not believe that ABTC certification would improve the care of transplant patients. Other commenters suggested requiring the transplant director to be responsible for ensuring that clinical transplant coordinators receive adequate education and training. Several commenters recommended eliminating the ABTC certification requirement in the final rule.

Response: Since the publication of the proposed rule, we have further examined the education, training, and experience of individuals who serve as clinical transplant coordinators. Although the ABTC certification examination is a valuable avenue to demonstrate transplant knowledge and skill, we found that many clinical transplant coordinators are RNs, clinical

nurse specialists, and nurse practitioners who have acquired transplant knowledge and practice experience in a variety of roles and settings. In recent decades, alternative health care practice models have provided the opportunity for nurses and clinicians to take on an expanded role in transplantation. Therefore, we have concluded that commenters were correct that there is more than one way to acquire the necessary knowledge and skill to be a clinical transplant coordinator. Furthermore, we agree with the commenters that limiting certification to a single organization is not appropriate. Therefore, we have not included a requirement for ABTC certification for transplant coordinators, as we proposed at § 482.98(c).

However, we believe that clinical transplant coordinators should be registered nurses or have clinical experience, and we note that OPTN policies require the clinical transplant coordinator to be either a registered nurse or other licensed clinician. Therefore, in this final rule, we have added a requirement that the clinical transplant coordinator must be either a registered nurse or a clinician licensed by the State in which the clinical transplant coordinator practices, who has experience in and knowledge of, transplantation and living donation issues. (See § 482.98(c).) In addition, this final rule requires that the director of the transplant center must ensure that clinical transplant coordinators have adequate training in the care of transplant patients and living donors. (See § 482.98(a)(1).) Also, we have added language that describes the responsibilities of the clinical transplant coordinator, which include, but are not limited to: (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and (2) acting as a liaison between a kidney transplant center and dialysis facilities, where applicable. (See § 482.98(c).)

Comment: Some commenters asked how many ABTC-certified coordinators are required, that is, whether one coordinator per transplant hospital or organ-specific transplant center is sufficient or whether all coordinators would need to be ABTC certified. A commenter suggested requiring only one ABTC-certified coordinator on site to provide overall supervision to other non-ABTC certified coordinators. A commenter recommended requiring a transplant center to have either an ABTC-certified clinical transplant coordinator or a State-licensed nurse with proficiency in complex professional and administrative transplant skills.

Response: Although this final rule does not require ABTC certification, each organ-specific transplant center must have at least one clinical transplant coordinator who meets the requirements at § 482.98(c) of this final rule. Small transplant centers may share one clinical transplant coordinator.

Donor Advocate or Donor Advocate Team

Comment: The majority of commenters supported our proposed requirement for an independent living donor advocate or a multidisciplinary advocate team. The commenters stated that a living donor advocate or multidisciplinary advocate team can ensure continuity of care of living donors during the pre-donation, donation and post-donation phases.

Only one commenter said that the services of a donor advocate or donor advocate team would not add value to the process of living donation. A few commenters stated that the requirement for a living donor advocacy team would cause hardship for small transplant programs.

Response: We agree with the commenters who said that this requirement will serve the best interests of living donors. We expect that donor advocates and donor advocate teams will educate potential living donors about living donation, ensure that living donors have comprehensive medical and psychosocial evaluations, and make recommendations to the transplant team regarding prospective donors' suitability for donation. The presence of either a living donor advocate or an advocate team will encourage accountability for the protection of living donors' health and safety and ensure that principles of medical ethics and informed consent standards are applied to the practice of living donation.

Under this final rule at § 482.98, we state that a transplant center may choose to have either a living donor advocate or a donor advocate team. These individuals may be in-house hospital staff members who perform other duties in addition to their living donor advocate responsibilities. We believe this flexible approach will minimize the burden of providing donor advocacy services.

Comment: Some commenters stated that transplant centers should be given the flexibility to define their own policies for a living donor advocate program. A few commenters stated that it is unnecessary to require a transplant center to designate a living donor advocate or an advocate team as long as there is an independent process to assess a living donor's risks and the

benefits of donation. One commenter suggested that transplant centers should be required only to offer the consulting services of an in-house transplant-educated health care worker not directly involved in transplant procedures.

Response: This final rule provides transplant centers with great flexibility in providing either a living donor advocate or donor advocate team. We do not specify requirements for a donor advocate's background, education, or training or the donor advocate team's composition. Instead, we specify their duties and the skills they must be able to demonstrate, specifically: (1) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and (2) understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor. The independent living donor advocate or living donor advocate team is responsible for: (1) Representing and advising the donor; (2) protecting and promoting the interests of the donor; and (3) respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion. A transplant center must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors. The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

Comment: Many commenters suggested that the donor advocate team should include a qualified social worker as described in the proposed rule or a medical social worker (a social worker working in a medical setting). One commenter suggested that a multidisciplinary advocate team should include an internal medicine physician, a transplant coordinator/nurse clinician, a licensed social worker with a master's degree, a psychiatrist, and an ethicist. Some commenters suggested that either the living donor advocate or advocate team members should be educated in organ transplants.

Response: We appreciate the commenters' suggestions for the composition of the multidisciplinary donor advocate team, and we agree that all the named professionals would be an asset to a donor advocate team. Transplant centers that choose to have a multidisciplinary donor advocate team may want to consider these suggestions in selecting appropriate team members to meet their needs. However, we believe it would be unnecessarily

prescriptive to require that donor advocate teams be composed of individuals from specific professions.

Comment: Many commenters stated that the living donor advocate or the advocate team should be independent from the transplant team. That is, transplant centers should use different physicians and social workers to work with transplant patients and living donors. A commenter stated that it is difficult for a hospital-employed living donor advocate to stay independent.

Response: We agree that the living donor advocate or donor advocate team should function independently from the transplant team to avoid conflicts of interest. Therefore, as stated earlier, this final rule at § 482.98 (d)(1) requires that the living donor advocate or living donor advocate team not be involved routinely in transplantation.

Comment: A commenter suggested that we designate the United Network for Organ Sharing (UNOS) as the gatekeeper for living donor rights and establish an Ombudsman as a resource for all donors nationwide.

Response: UNOS functions as a contractor for the OPTN to collect and track all transplant data, including living donor transplants. CMS does not have the authority to designate UNOS as the gatekeeper for living donor rights. Such suggestions should be referred to UNOS and HRSA. The suggestion that we establish an Ombudsman as a resource for all donors nationwide falls outside the purview of this regulation. Therefore, no changes have been made based on this comment.

Multidisciplinary Transplant Team and Resource Commitment

Comment: A few commenters stated that the OPTN policies already stipulate personnel requirements for transplant centers and that our proposed requirements either duplicated or were inconsistent with OPTN policies.

Response: We proposed that a 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. The OPTN has personnel requirements for certain personnel, such as a clinical transplant coordinator, transplant pharmacist, and financial coordinator. However, the OPTN does not have the transplant team requirements that we proposed and that we have finalized in this rule.

Comment: Many commenters suggested changing the term “social services” to “social work” (because there is ambiguity about who provides such services), and the term “pharmacology” to “pharmacist” because not all centers have pharmacologists but all centers have pharmacists.

Response: This final rule requires transplant centers to employ individuals with expertise in different relevant areas. We do not believe the terms “social services” or “pharmacology” need to be changed or clarified because this standard addresses the expertise of the individual transplant team members, and not the profession of these individuals. We made no changes based on this comment.

Comment: A commenter recommended changing “immunology” to “immunology and immunosuppression management”.

Response: One facet of immunology as a science is the study of organ transplantation and immunosuppression. We expect that to comply with the requirement in this final rule to demonstrate resource commitment in immunology, a transplant center will demonstrate resource commitment and availability of expertise in both immunology and immunosuppression. We have made no changes based on this comment.

Comment: A commenter requested that we require pediatric transplant centers to demonstrate availability of expertise in “pediatric medicine, pediatric surgery, pediatric urology, pediatric nursing, pediatric dialysis and pediatric intensive care.”

Response: To be in compliance with the requirements in this final rule, a transplant center must provide services appropriate to its patient population. For example, § 482.98(e) requires a transplant center to identify a multidisciplinary transplant team composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology. This means that the individuals who are part of a transplant team at a pediatric transplant center must have the qualifications, training, and experience to provide transplantation services to pediatric patients. Section 482.98(f) requires a transplant center to demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services. To

meet this requirement, a pediatric transplant center must ensure that the expertise is commensurate with the needs of pediatric patients. Furthermore, the Department’s OPTN regulations at 42 CFR 121.9 require transplant programs in OPTN member hospitals designated under OPTN criteria in § 121.9(a)(2)(v) to show evidence of collaborative involvement with experts in the fields of, among other disciplines, pediatrics as appropriate.

Comment: One commenter anticipated the rule will increase demand for nursing staff and suggested that we should recognize that Advanced Practice Registered Nurses (APRN) can play a role in transplant patient care.

Response: We agree with the commenter that APRNs play an important role in health care. Transplant centers certainly have the discretion to recruit APRNs for their transplant teams as they believe necessary.

Comment: One commenter said that the proposed resource commitment requirements would enhance patient’s self-care management and positive patient outcomes. The commenter suggested that we add patient education.

Response: We agree that patient education enhances patient’s self-care management and positive patient outcomes. In fact, most transplant centers provide ongoing patient education, which is provided by the transplant center staff, including transplant surgeons, physicians, nurses, transplant coordinators, dietitians, pharmacists, and social workers. We have adopted the comment to include patient education in this final rule as a required resource commitment for transplant centers at § 482.98(f).

Condition of Participation: Organ Procurement (Proposed § 482.100)

We proposed requiring transplant centers to ensure that the hospital in which the center operates has a written agreement for the receipt of organs with an OPO designated by the Secretary.

We proposed that the transplant center would be required to ensure that the transplant hospital’s agreement with the OPO identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

We proposed that the transplant center must notify us in writing no later than 30 days after the termination of any agreement between the hospital and the OPO. Following is a summary of the comments we received on our proposed

provisions and our responses to the comments.

Comment: A commenter stated that the proposed organ procurement provision is duplicative of 42 CFR 121.9(a)(2)(i).

Response: The commenter was correct in identifying similarities between this provision and the designated transplant program requirements in the Department's regulations for the OPTN at 42 CFR 121.9(a)(2)(i). Including the organ procurement requirements in this final rule provides us with oversight and enforcement authority and imposes the requirements on transplant programs that received their designation by virtue of their approval for reimbursement for Medicare.

Comment: A few commenters suggested requiring a center to notify the OPTN if its hospital's agreement with an OPO has been terminated.

Response: We do not believe terminating an agreement with an OPO is a step a hospital would take without the knowledge of the OPTN. Thus, we do not believe it is necessary for us to require a transplant center to notify the OPTN if the hospital in which it is located terminates its agreement with an OPO. We have made no change in this final rule based on this comment.

Note that for the sake of consistency and to facilitate transplant centers' use of the regulations, we have moved the requirement to notify us if the hospital in which a transplant center is located terminates its agreement with an OPO for organ recovery and receipt from § 482.100 to § 482.74(a)(3), Notification to CMS. This change locates all events that must be reported to us within the same condition of participation and results in consistent time frames for notification. The requirement for notifying us if the hospital in which a transplant center is located terminates its agreement with an OPO for organ recovery and receipt is changed from 30 days to "immediately," to facilitate monitoring of waiting list patients' access to organs.

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

In our discussion of patient rights in the preamble to the proposed rule, we said that we believed a living donor advocate or advocate team would ensure that the informed consent standards meet ethical principles as applied to the practice of living donor organ transplantation. Thus, we requested comments on whether we should include a requirement in the final rule for transplant centers performing living donor transplants to provide the

services of an independent living donor advocate or advocate team, as well as recommendations for individual or team credentials. Based on public comments, we have added a requirement in this final rule, at § 482.98(d) CoP: Human resources, for an independent living donor advocate or living donor advocate team. The preamble discussion of an independent living donor advocate or living donor advocate team is located under the Human resources section of this final rule.

We proposed that in addition to meeting the general hospital requirements for patients' rights in the hospital CoPs at § 482.13, a transplant center must protect and promote each transplant patient's and living donor's rights.

We proposed that the transplant center 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 and 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; and (8) his or her right to refuse transplantation.

We proposed that transplant centers must implement a written living donor informed consent process that informs prospective living donors of all aspects of living donation and potential outcomes from living donation. We proposed that transplant centers must ensure that prospective living donors are 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) availability of alternative treatments for the transplant recipient; (5) potential medical and psychosocial risks to the donor; (6) 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; and (8) the donor's right to opt out of donation at any time during the donation process.

We proposed that a transplant center must notify its waiting list patients of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and the procedures that are in place to ensure the availability of a transplant team.

We proposed that a transplant center served by a single transplant surgeon or physician would be required to inform its waiting list patients of the potential unavailability of the transplant surgeon or physician and whether the center had a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies.

We proposed that at least 30 days before a center's Medicare approval was terminated, whether voluntarily or involuntarily, the center would have to inform the patients on the waiting list of this fact, 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 waiting list.

We also proposed that if a transplant center were terminated, such transplant center would have to inform Medicare beneficiaries on the center's waiting list that Medicare would no longer pay for transplants performed at the center after the effective date of the center's loss of approval.

We requested comments on the proposed requirement for a transplant center to inform patients of potential 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 could not be detected in an infected donor. We also solicited comments regarding our proposed informed consent requirements for living donors, including those requirements we proposed adopting from the Secretary's Advisory Committee on Transplantation (ACOT) recommendations, and whether we would need to establish additional criteria for transplant centers performing living donor transplants.

Following are summaries of the comments we received and our responses.

Comment: Some commenters said that all kidney transplant centers should be

exempt from initial approval requirements (such as the requirement to perform 9 transplants) because a lengthy initial approval process would delay access to the new kidney center's transplantation services for Medicare beneficiaries.

Response: We share the commenters' concern that a lengthy approval process for kidney centers, particularly a requirement to perform 10 transplants prior to approval, may disadvantage Medicare beneficiaries who need kidney transplants by limiting their access to transplantation services at new kidney transplant centers. Under section 1861(s)(2)(J) of the Act, almost all ESRD transplant candidates must have their transplant surgery and follow-up care provided by a center that is already Medicare-certified in order for their immunosuppressant drugs to be paid for under Part B of Medicare as part of the Medicare transplantation services. Therefore, we are concerned that some new kidney centers may offer to provide free kidney transplants to Medicare beneficiaries in order to meet the Medicare clinical experience requirements and thus obtain Medicare approval expeditiously. These prospective kidney transplant candidates may not be aware of the implications for such free transplants that Medicare only pays for prescription drugs used in immunosuppressive therapy under Medicare Part B if the transplant was performed in a Medicare-approved facility.

Therefore, we have added a requirement under the CoP for Patient and Living Donor Rights at §§ 482.102(a)(8) and 482.102(b)(9) that a transplant center must inform Medicare beneficiaries who are prospective transplant recipients and their living donors that receiving a transplant that is not provided in a Medicare-approved transplant center could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B. See further discussion of this requirement in this preamble under "Centers With Current Medicare Approval."

Comment: A commenter recommended that the OPTN incorporate ACOT recommendations on transplant patient and living donor rights into its policies and monitor transplant center compliance. Another commenter suggested that we or the OPTN should provide transplant centers with sample education materials to educate donors about their rights.

Response: The OPTN has published a variety of transplant education brochures for centers to distribute to patients and living donors; the list of

resources is available at www.transplantliving.org. Although the OPTN does not have any publications specific to living donation (with the exception of some limited information published in the booklet titled "What Every Patient Needs to Know") it has posted extensive living donation information on its Web site. Suggestions that the OPTN adopt ACOT recommendations are beyond the scope of this rule.

Informed Consent

We are removing the proposed requirement that transplant centers inform transplant candidates of "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." This language was included in the proposed rule in the standard for informed consent for transplant patients at § 482.102(a)(6); similar language was included in the standard for informed consent for living donors at § 482.102(b)(7). It was intended to apply only to living donors. Thus, it has been removed at § 482.102(a)(6).

Comment: Many commenters supported the requirement for informed consent to protect patient rights. However, some commenters supported the adoption of the ACOT recommendations in their entirety, rather than the limited number of specific informed consent elements that we proposed. One commenter recommended that we require a standardized informed consent process for all transplant centers.

Response: We have chosen not to adopt the ACOT recommendations in their entirety because they are extensively detailed and go beyond what we perceive as necessary for Medicare approval. Instead, we have adopted the ACOT recommendations that are directly related to transplant patient and living donor rights. We have not included other recommendations that address organ donation, organ allocation, and organ procurement organizations. This final rule does not require a standardized informed consent process because such a requirement would deprive transplant centers of the flexibility we believe they need to develop informed consent policies that best serve their needs.

Comment: A few commenters stated that the proposed informed consent provisions for transplant patients and living donors are too prescriptive and not a standard practice in medicine. The commenters said that a transplant center's only legal obligation is to

provide patients and living donors with sufficient information to make an informed decision. A few commenters said that the requirement for a written informed consent process is burdensome and unnecessary since hospitals already have informed consent policies that may be applicable to transplants.

Response: As a standard practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make informed decisions. We believe the elements of informed consent that we proposed and that we require under this final rule are the minimum necessary to ensure transplant patients and living donors can make an informed decision. (See § 482.102(a).) We believe this basic information should be provided to patients and living donors by all transplant centers.

We recognize that a transplant center's informed consent process may overlap with the hospital's informed consent process. A transplant center may choose to integrate the required elements for the transplant center informed consent process into the hospital informed consent process. We note, however, that transplant patients and living donors are uniquely vulnerable patients. Prospective transplant recipients desperately need scarce, life-saving organs, and many of them will die waiting. Prospective living donors are healthy individuals who are contemplating undergoing surgery, at some risk to themselves, to provide a life-saving transplant to another individual. These patients and prospective living donors must absorb a great deal of information in order to provide a truly informed consent.

In their recommendation, ACOT endorsed two ethical principles: (1) Equipose; that is, the benefits to both the donor and the recipient outweigh the risks associated with the donation and transplantation of the live donor organ; and (2) that the potential donor's participation is completely voluntary and may be withdrawn at any time. We believe transplant centers should base their informed consent policies and procedures on these principles and implement them scrupulously. We made no changes based on these comments.

Comment: A commenter stated that once a transplant center documents in medical records that a patient's informed consent was obtained (including the specifics that were discussed), it should be sufficient evidence that an informed consent policy exists.

Response: We disagree. We expect a transplant center to have informed consent policies that include a written informed consent process and documentation that informed consent was given. Therefore, the documentation of informed consent alone would not be sufficient to substitute for a written informed consent policy.

Comment: Some commenters suggested eliminating the prescriptive informed consent language. One commenter stated that the requirement for a transplant center to inform patients about the patient evaluation process is too prescriptive.

Response: We believe the information in the elements of informed consent that we proposed and that are set forth in this final rule are necessary for patients to make an informed decision about transplantation. We also believe it is important for transplant candidates to understand how they will be evaluated for placement on the waiting list, how their readiness for transplant will be ascertained while they are awaiting transplantation (for example, through periodic blood tests), and what factors could require their removal from the waiting list.

Comment: Some commenters said that a transplant center should be required to use a patient education checklist to educate patients about transplant risks. One commenter asked how patient informed consent should be documented to comply with this requirement.

Response: A transplant center may use any patient education tools, such as a patient education checklist, to educate patients about transplant risks, as long as the center includes the required elements. A transplant center may choose to document the discussion of informed consent in any format as long as the discussion is documented in the patient's medical record.

Comment: One commenter stated that a last-minute discussion of potential donor risk with a transplant recipient would be extremely difficult because the window of time between organ procurement and transplantation is very short. The commenter said that it is unrealistic to require centers to repeat the extensive informed consent process at the time of transplantation and suggested that the discussion with transplant candidates about potential risks should be done well before an actual organ offer takes place. The commenter recommended that the informed consent process be limited to the point in time when a patient is placed on a transplant waiting list.

Response: We agree with the commenter. Our expectation is that discussion of potential donor risk factors should occur well before an organ is offered, for example, when the patient is first placed on the waiting list, and the information should be reviewed with the patient from time to time. We agree with the commenters that the time period between organ procurement and the offer of an organ may be too short for a thorough discussion of informed consent with patients. We do not expect a transplant center to rush through a detailed discussion of potential donor risk factors with transplant candidates just prior to transplantation.

Comment: Some commenters expressed concern that it could be impossible for transplant centers to discuss all potential organ donor risk factors with transplant candidates. Another commenter stated that requiring a transplant center to provide a written explanation of organ-specific risk factors to patients would be burdensome.

Response: Although it may not be possible for transplant centers to discuss every single potential organ donor risk factor with patients on their waiting lists, we expect centers to cover, at a minimum, the factors listed in the text of this final rule, that is, donor history; condition or age of the organs used; and the patient's risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor. Providing this information should ensure that patients understand before they make transplant decisions that certain factors may affect the success of their transplant. Transplant centers certainly have the flexibility to discuss other risk factors beyond those we have delineated in this final rule.

The requirement for transplant centers to have a written informed consent process does not mean that centers must provide a written explanation of organ-specific risk factors to transplant patients. As proposed, this final rule requires only that a transplant center inform patients of organ and organ donor risk factors.

Comment: A commenter recommended that we require transplant centers to provide some minimal information for patients contemplating acceptance of an extended criteria donor (ECD) kidney as follows: (1) The increased likelihood of delayed graft function; (2) decreased graft survival compared to a non-ECD kidney; (3) increased longevity compared to remaining on dialysis; (4) the potential for decreased waiting time for a donated kidney; and (5) the benefit

of receiving a transplant prior to beginning dialysis, which may cause related morbidity and mortality.

Response: We agree with the commenter that these factors should be discussed with patients contemplating acceptance of an ECD kidney. As discussed in our previous comment, the fact that transplantation of certain types of organs (such as ECD or DCD organs) may have an effect on patient or graft survival must be discussed with transplant candidates, as appropriate. Thus, if a kidney transplant center transplants organs from ECDs, they should include all relevant facts about ECD organs in their discussion of organ donor risk factors with patients who are candidates for transplantation with an ECD organ, especially information about patient morbidity and mortality on dialysis versus transplantation with an ECD organ.

Comment: A commenter suggested letting the transplant surgeon decide based on OPTN guidelines whether the organ donor risk factors are significant enough to warrant a discussion with a patient.

Response: We agree with the commenter that the transplant surgeon should be responsible for taking the lead in discussing potential organ donor risk factors with the patient. At a minimum, we expect the transplant surgeon to discuss the potential organ donor risk factors described at § 482.102(a). The transplant surgeon also should decide whether other factors should be discussed. Although currently, there are no universal guidelines for organ donor risk factors, we believe surgeons should be able to reference current practices in their discussions with patients.

Comment: Some commenters objected to the proposed requirement to inform patients of national and center-specific transplantation outcomes, as indicated in the SRTR reports. The commenters stated that expected survival rates indicated in the SRTR do not reflect the potential compromise of outcomes resulting from the use of ECD/DCD organs by some centers.

In addition, the commenters were concerned that some patients may not have adequate knowledge to interpret the expected survival data properly.

Response: The national and center-specific outcomes as indicated in the SRTR reports are already publicly available at <http://www.ustransplant.org>. The SRTR has added ECD as one of the risk-adjustment factors used in calculating expected survival rates. The OPTN may consider including DCD organs as one of the risk-adjustment factors when more data are available.

Some patients may not be able to fully comprehend the SRTR reports. Nonetheless, we expect a transplant center to provide guidance to patients and families in finding and interpreting the SRTR reports in relation to the center's own patient outcomes. At a minimum, we expect a transplant center to provide prospective transplant recipients, their families, and prospective living donors with information from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

Comment: Many commenters supported establishing requirements for an informed consent process for living donors. Some commenters noted that informed consent for living donors protects the donor and reduces legal liability for the transplant team. Many commenters said that they specifically supported incorporating the ACOT recommendations into Medicare requirements. In fact, one commenter was concerned that we had not adopted all of ACOT's initial recommendations related to living donation.

Response: We agree that protections for living donors are essential. Therefore, as proposed, we are adopting the ACOT recommendations that address the health and safety of living donors.

Although we have not adopted the ACOT recommendations for living donors in this final rule in their entirety, because some of them fall outside the purview of this rule, we recommend that transplant centers that perform living donor transplants consider them when developing informed consent policies for living donors.

Comment: A commenter stated that there is no compelling reason why the proposed informed consent process for living donors should go beyond the OPTN requirements.

Response: Currently, the OPTN Living Donor Committee workgroup has identified living donor safety promotion as a major focus of the OPTN. However, standardized OPTN informed consent language for living donors has yet to be developed. In light of the fact that living donation is becoming more common, there is an increasing need to protect the health and safety of living donors. Further, as we have stated in our responses to previous comments including these requirements in regulations provides us with the authority for oversight and enforcement.

Comment: A commenter stated that the requirement for transplant centers to model the ACOT recommendations for informed consent for living liver donors is overbearing and noted that it should not apply to living kidney donors as living kidney donation is a more simplified procedure requiring fewer informed consent details.

Response: We did not propose requiring hospitals to adopt the ACOT recommendations for informed consent for living liver or kidney donors. We cited the documents in the preamble to the proposed rule only to provide guidance for transplant centers developing informed consent policies for living donors. However, all living donors deserve the same level of protection. Although individuals contemplating living donation of different organ types may need different information, all living donors should be provided with sufficient information on which to make a fully informed decision.

Comment: A commenter requested clarification on the requirement for documentation of informed consent for living donors, and the commenter asked if separate informed consent forms are needed for living donors.

Response: A transplant center may choose to document the discussion of informed consent with living donors in any manner it chooses. The center may document every discussion in detail or use a checklist or any other tool of its choice to indicate that all the core components were covered. We expect that transplant centers will use different informed consent forms for living donors since the informed consent components are slightly different than for transplant recipients.

Comment: A commenter noted that the presentation of the elements of informed consent to potential recipients and living donors should be easy to understand and consistent with each patient's native language and educational level. The commenter said that adequate time should be given to donors to make a donation decision that is free from coercion and noted that New York State law gives living donors 2 weeks to make a decision.

Response: We agree with the commenter's observations. Nevertheless, we have not specified requirements in this final rule for educational level or language for informed consent documents, nor have we specified a standard period of time prospective living donors be given to make a donation decision. We have avoided such prescriptive requirements throughout this final rule to provide transplant centers with the maximum

flexibility to implement the rule's requirements according to their needs and the needs of their patient populations. Although we have not incorporated the commenter's suggestions into this final rule, we would urge transplant centers to consider the suggestions as they develop their informed consent process.

Comment: Some commenters supported the concept of informing living donors of short and long-term risks but suggested eliminating the requirement because providing this information would require the availability of a living donor registry that tracks these risks. A commenter recommended that the Secretary pursue action to establish a living donor registry.

Response: Currently, there is no official living donor registry. However, collection of living donor outcome metrics by the OPTN is ongoing, and the follow-up data period for live donors has been extended from 1 year to 2 years post-transplant. The OPTN is re-evaluating living donor follow-up forms, developing strategies to improve their completeness, and considering the development of a living donor registry. Once data for national and transplant center-specific outcomes for living donors are readily available to transplant centers, centers must begin providing the data to living donors to assist them in making a decision whether to donate. In the interim, each center must provide whatever data are available on its own living donor outcomes to prospective living donors. Should national living donor data become available in the future, transplant centers must provide this information to prospective living donors. Thus, we have added language at § 482.102(b)(6) that specifies living donors must be informed about national and center-specific outcomes for living donors, as data are available.

Notification to Patients

Note that we have removed the phrase "that meets the hospital's credentialing policies" from the end of the sentence "whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician that meets the hospital's credentialing policies" in § 482.102(c)(1)(ii) of the proposed rule. A hospital where a transplant center is located should have a process for credentialing of its staff as required by § 482.22. Therefore, a requirement for an alternate transplant surgeon or transplant physician "that meets the hospital's credentialing policies" is unnecessary.

Comment: Some commenters supported the requirement for a transplant center to notify patients of information that could impact the patients' ability to receive an organ. Such information would include informing patients of the possibility that a center's sole transplant team might be unavailable when an organ becomes available and whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician. However, other commenters said that the requirement would be burdensome. They stated that a requirement to notify patients about short-term absences (for example, sickness, vacation, and conferences) would be unrealistic. The commenters suggested that a requirement to notify waiting list patients of the unavailability of the transplant surgeon or physician for more than 30 days would be realistic.

Response: We did not propose nor do we require in this final rule that transplant centers notify waiting list patients about specific absences as they occur. Instead, we are requiring a transplant center served by a single transplant surgeon or physician to inform each waiting list patient of the possibility that the center's transplant surgeon(s) or physician(s) may not be available at the time an organ becomes available. We also require a transplant center to tell each waiting list patient whether the center has a mechanism to provide an alternate transplant surgeon or physician.

Comment: A commenter suggested that in the context of termination under § 482.102(c)(2), which requires a transplant center whose Medicare approval is terminated to inform waiting list patients at least 30 days prior to the termination, we should modify the 30-day requirement by adding "and following the exhaustion of all appeals provided pursuant to [part] 498 * * *."

Response: The general provisions under 42 CFR part 498 provide for an administrative judicial review of administrative determinations, for providers facing termination of Medicare approval. Thus, if a transplant center appeals a termination of Medicare approval under 42 CFR, part 498, the termination will not occur until the appeals process, if any, is completed. Therefore, there is no need to incorporate the commenter's suggested language.

Comment: A commenter stated that the proposed rule does not address how care would be provided for patients on the waiting list of a transplant center whose Medicare approval was terminated.

Response: We disagree. Sections 482.102(c)(2)(i) and (ii) of both the proposed rule and this final rule provide that at least 30 days before a center's Medicare approval is terminated, whether voluntarily or involuntarily, the center must inform patients on the center's waiting list. The transplant center also must provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. Further, the transplant center must inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval.

This final rule adds a requirement at § 482.102(c)(3) for patient notification if a transplant center voluntarily inactivates. We require that as soon as possible, prior to a transplant center's inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. As we stated earlier, we intend to monitor transplant center inactivity closely.

Condition of Participation: Additional Requirements for Kidney Transplant Centers (Proposed § 482.104)

We proposed to delete some sections from part 405, subpart U and move some of the sections in subpart U to this final rule.

We proposed that kidney transplant centers be required to furnish: (a) Transplantation and other medical and surgical specialty services required for the care of ESRD patients; and (b) inpatient dialysis services, directly or under arrangement. We proposed that such kidney dialysis centers or units must meet the conditions for coverage of suppliers of ESRD services contained in part 405, subpart U.

We proposed that kidney transplant centers would be required to cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the network's current statement of work.

Following are summaries of the comments we received and our responses. Note that based on public comments summarized earlier in this preamble, we have added a requirement at § 482.104(a) that a kidney transplant center must have written policies and procedures for ongoing communication

with dialysis patients' local dialysis facilities.

Comment: A commenter requested clarification about the extent to which a dialysis facility providing acute services to transplant recipients must meet the requirements of a chronic dialysis facility under the ESRD rule. Another commenter suggested deleting the proposed requirement for transplant centers that furnish inpatient dialysis services to meet the conditions for coverage for suppliers of ESRD Services contained in part 405 Subpart U. A commenter recommended that we add a new condition of participation for inpatient dialysis units to provide regulatory guidance for providers of inpatient dialysis services in acute care settings.

Response: Based on these comments and further analysis of our proposal, we have concluded that it is unnecessary to require transplant centers that provide inpatient dialysis services to kidney transplant patients to comply with the Conditions for Coverage for Suppliers of ESRD Services in part 405 subpart U. Kidney transplant centers are located inside hospitals that must comply with the Medicare hospital CoPs, which include quality standards that apply to all services provided by hospitals. Since inpatient dialysis services furnished either directly by kidney transplant centers or under arrangement are subject to the requirements in the hospital CoPs, we see no need to regulate inpatient dialysis services separately.

Therefore, we have removed the proposed requirement at § 482.104(b) that inpatient kidney dialysis centers or units must meet the Conditions for Coverage, part 405, subpart U for suppliers of ESRD services. We have retained in this final rule only the requirement that kidney transplant centers must furnish inpatient dialysis services directly or under arrangement. However, a kidney transplant center that furnishes outpatient dialysis services directly or under arrangement in dialysis centers or units is required to meet the Conditions for Coverage for Suppliers of ESRD Services contained in part 405, subpart U.

Comment: A commenter suggested requiring transplant centers performing pediatric kidney transplants to provide inpatient pediatric dialysis services with appropriate pediatric equipment and nursing expertise.

Response: We expect both pediatric and adult transplant centers to provide staffing, equipment, and other resources appropriate to the needs of their specific patient population. Since providing inpatient dialysis services to pediatric patients may require specialized

pediatric equipment and specific pediatric nursing expertise, we believe transplant centers should have the flexibility to determine how they will provide these services. We have made no changes in this final rule based on this comment.

Comment: A few commenters supported the requirement for kidney transplant centers to remain associated with the ESRD Network. However, one commenter stated that the proposed requirement for participation in network activities is duplicative of 42 CFR part 405, subpart U and requested clarification.

Response: Existing §§ 405.2110 through 405.2112 contain provisions that relate to the designation and functions of the ESRD networks. These provisions focus primarily on the role and responsibilities of the ESRD networks. Although we do not believe the role and responsibilities of the networks need to be included in this final rule, we believe that kidney transplant centers must continue to share information and collaborate with the networks. Thus, under § 482.104(c), we are finalizing our proposal that kidney transplant centers must cooperate with the ESRD network designated for their geographical area in fulfilling the terms of the network's current statement of work.

Deeming Authority (§ 488.6)

Under § 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 the State survey agencies for compliance with the CoPs. Instead, they are deemed to meet the requirements based on either their JCAHO or AOA accreditation. In order to receive this deemed status, hospitals as well as other providers and suppliers, which are accredited by JCAHO, AOA, or other national accreditation programs with deeming authority under § 488.6 of the regulations (see part 488, Survey and Certification Procedures), must meet requirements that are at least as stringent as the Medicare CoPs. Therefore, an accreditation organization could apply for and receive approval of deeming authority for the transplant center CoPs if the accreditation organization demonstrates that its requirements for transplant centers are at least as stringent as those in this final rule. In this final rule, we are amending § 488.6, as described at 42 CFR part 488, subpart A, to include transplant centers, except for kidney transplant centers, among those providers and suppliers

that are eligible to receive deemed status based on such an accreditation. A transplant center can choose to meet the requirements through the accreditation process or through a State survey. As a designee of CMS, an accrediting organization or a State survey agency must survey each transplant center's compliance with the clinical experience, outcome, data submission, and process requirements. In either case, the special procedures for transplant centers, as described under § 488.61, will ultimately guide the survey process.

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

We proposed utilizing 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. We would retain § 488.60 to apply exclusively to ESRD facilities. Following are summaries of the comments we received and our responses.

(a) Initial Approval Procedures

We proposed that a transplant center would be permitted to submit a letter of request to us for Medicare approval at any time. We proposed that the letter, signed by a person authorized to represent the center, would have to include the hospital's Medicare provider I.D. number, name(s) of the designated primary transplant surgeon and primary physician, and a statement from the OPTN that the center had complied with all data submission requirements.

We proposed that we or our designee would determine a transplant center's compliance with the data submission and outcome requirements proposed at § 482.80(b) and (c). We or our designee would review the 1-year patient and graft survival data contained in the SRTR's most recent center-specific reports.

We proposed that, if both of the conditions in § 482.80(b)(4) applied, the center could ask the SRTR to prepare a customized report of the center's 1-month patient and graft survival data for the previous 1-year period. We or our designee would determine compliance with the outcome requirements contained at § 482.80(b) using the data contained in these customized reports.

We proposed that if we or our designee determined that a transplant center met the data submission and outcome requirements of § 482.80, we or our designee would 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.

We proposed that if a transplant center seeking Medicare approval was found to be in compliance with all conditions of participation at § 482.68 through § 482.104, except for § 482.82 (Re-approval requirements), we would notify the transplant center in writing of the effective date of its Medicare approval or notify the transplant center in writing if it were not approved. We proposed that we would grant initial approval to a transplant center for 3 years.

(b) Re-Approval Procedures

We proposed that once Medicare-approved, a transplant center would have to be in compliance with all conditions of participation for transplant centers at § 482.68 through § 482.104, except for § 482.80 (Initial approval requirements) throughout the 3-year approval period.

We proposed that at least 180 days before the end of the 3-year approval period, we or our designee would review the transplant center's data in making re-approval determinations.

We proposed that: (1) To determine compliance with the data submission requirements at § 482.82(a), we or our designee would request data submission data from the OPTN for the previous 3 calendar years; and (2) to determine compliance with the outcome requirements at § 482.82(c), we or our designee would review the data contained in the most recent SRTR center-specific reports.

We proposed that if we or our designee determined that a transplant center met the data submission and outcome requirements at § 482.82, the transplant center would be re-approved for 3 years.

We proposed that if we or our designee determined that a transplant center failed to meet the data submission or outcome requirements contained 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 proposed that we or our designee would notify the transplant center in writing if it were re-approved or if its approval were being revoked. If re-approved, we or our designee would notify the transplant center of the effective date of the re-approval.

(c) Loss of Medicare Approval

We proposed that centers that lost their Medicare approval would be permitted to seek re-entry into the program at any time, using the procedures described at § 488.61(a). We proposed that a center that lost its Medicare approval would be required to be in compliance with §§ 482.68 through 482.104, except for § 482.82 (Re-approval procedures), at the time of the request for Medicare approval. We proposed that a center seeking to re-enter the Medicare program would be required to submit a report documenting any changes or corrective actions the center took as a result of the loss of its Medicare approval status.

We proposed that transplant centers with current Medicare approval would be permitted to continue to provide transplant services until we notified them whether they were approved under the new CoPs for transplant centers. For clarity we are adding the words "OPTN Data Report" to the regulation text for this section to describe the source of the data we will review to determine compliance with the clinical experience requirements. Following are summaries of the comments we received and our responses.

Initial Approval Procedures for New Transplant Centers

Comment: Some commenters disagreed with the proposed process for initial approval of transplant centers, specifically, that if a center did not meet the data submission and/or outcome requirements, the center would not be considered for approval. Some commenters stated that data submission and outcome measures should be used only as indicators and not as pass/fail tests to approve centers. Other commenters suggested that the initial approval procedures should be similar to the proposed re-approval procedures, so that centers failing to meet the data and outcome requirements would not be denied Medicare approval automatically but would be surveyed to determine whether they should be approved.

Response: In view of the public comments, as well as the potential disruption for Medicare beneficiaries if a large number of currently approved centers are denied initial approval under the requirements of this final rule, we will not deny initial approval to a transplant center automatically as we proposed at § 488.61, if it fails to meet the data, clinical experience, or outcome requirements at § 482.80. Instead, we will take a flexible approach to our initial approval of transplant

centers, as described at § 488.61 in this final rule. For the initial approval process, we will conduct a follow-up survey in all instances at currently Medicare-approved transplant centers if the center has not met the clinical experience and/or outcome requirements. We will exercise our discretion for new applications to the Medicare program. CMS will prioritize the scheduling of follow-up surveys based on the center's volume and outcome measurements and the program's history. CMS will survey these centers for the remaining conditions of participation and develop plans of correction for any condition or standard that is not met. If a center has "failed" the outcome measures, we will expect the plans of correction to include steps to improve these outcomes within a reasonable time frame (for example, by the next release of outcomes in the center-specific report).

Thus, under this final rule at 488.61(a)(3), if we determine that a transplant center, including a kidney transplant center, applying for initial approval has not met the data submission, clinical experience, or outcome requirements, we may deny the request for approval or we may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request should be approved. Our review may include a survey of the transplant center. We will notify the transplant center in writing whether its request has been approved and, if approved, the effective date of its approval.

However, we will not grant initial approval unless: (1) The center has met or has come very close to meeting the data, clinical experience, and outcome requirements; and (2) the center is in compliance with all other conditions of participation. In the initial approval process, we will give the center an opportunity to correct any areas that do not meet the Conditions of Participation in a reasonable time period through a Plan of Correction that is developed by the Center, and approved and monitored by CMS.

Following are examples of situations in which a transplant center applying for initial approval fails to meet the data submission, clinical experience, or outcome requirements and, for each example, an explanation of why we would or would not approve the center.

Example 1: A large heart transplant center that is currently Medicare approved under the NCDs applies for initial approval under the new CoPs. The center consistently

performs a large number of heart transplants annually and demonstrates superior performance on the outcome requirements. However, the transplant center has not met the data submission requirement by submitting 95 percent of the required data to the OPTN within 90 days of the due date. In fact, in the preceding 12 months, the transplant center submitted less than 90 percent of its transplant data within 90 days of the due date.

Because of the transplant center's extensive clinical experience and superior outcomes, we perform a review of the center and determine that the center meets all conditions of participation other than the standard for data submission. The transplant center submits a plan of correction to us, demonstrating how it plans to come into compliance with the data submission requirement by hiring additional staff to collect transplant data and report it to the OPTN. We review and accept the plan of correction and approve the center.

Example 2: A small, currently-approved liver transplant center applies for initial approval under the new CoPs. The center is the only liver center in a large western state that is primarily rural. The center meets the data submission requirement and its outcomes are acceptable. However, the center performed only 7 transplants in the preceding 12 months. Because the transplant center meets the data submission and outcome requirements and because it is the only liver transplant center in a largely rural state, we perform a review of the center and determine that it meets all the standards other than the clinical experience requirement. The center submits a plan of correction, detailing how it will attempt to meet the clinical experience requirement in the future (for example, by accepting more extended criteria organs for its patients). We accept the plan of correction and approve the center.

Example 3: A small kidney center that is currently approved under the ESRD CfCs applies for approval under the new CoPs. The kidney center meets the data submission requirement. The center performed 2 of the 10 transplants in the preceding 12 months and its outcomes are slightly below what is required under the CoPs. Although the center failed to meet both the clinical experience and the outcome requirements, we will review the transplant center's compliance with the other conditions of participation before making a decision on its request for approval. However, it is unlikely that we will grant approval under such conditions.

Example 4: A lung center located in a large city in the northeastern United States applies for Medicare approval under the requirements in the final rule. The lung center is currently Medicare approved. The center meets the data submission and clinical experience requirements. However, the center's 1-year observed patient and 1-year observed graft survival has been considerably below its expected 1-year expected patient and 1-year expected graft survival for the entire 2.5 year cohort. The center's outcomes show no sign of trending upward. We deny the center's request for approval. The center is free to re-apply at any time.

In summary, the flexibility of the initial approval process in this final rule will permit us to survey and possibly approve transplant centers that fail to meet the data submission, clinical experience, or outcome requirements when there are mitigating circumstances or when a transplant center's reported outcomes do not reflect the general high quality of its transplantation services. Based on the comments we received, § 488.61(a)(3) has been revised to read "If CMS determines that a transplant center has not met the data submission, clinical experience, and outcome requirements, CMS may deny the request for approval or may review the center's compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center's request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, the effective date of its approval."

Initial Approval Procedures For Centers With Current Medicare Approval

Comment: Commenters objected to the proposed requirement that all transplant centers with current Medicare approval must apply for initial approval under the CoPs.

Response: We do not believe it would be in the best interests of Medicare beneficiaries awaiting organ transplants to automatically approve centers with current Medicare approval because these centers were approved under NCDs for heart, liver, lung, and intestine centers or the ESRD CfCs for kidney transplant centers, which are different in many aspects from the CoPs in this final rule. For example, there are no outcome requirements for kidney transplant centers in the ESRD CfCs. Further, we know that some extra-renal transplant centers that were approved based on NCD criteria no longer meet those criteria. Therefore, automatically approving centers with current Medicare approval has the potential to permit a number of poor or marginal performers to continue to participate in Medicare. Based on these considerations, prior to approving currently approved transplant centers under our new requirements, we must first verify that they meet the CoPs in this final rule. The requirement for all currently-approved transplant centers to re-apply for initial approval under these new standards is consistent with our goals to increase transparency in the approval process and strengthen our oversight authority.

We expect all transplant centers, including kidney transplant centers, that are Medicare approved as of the effective date of this final rule that wish to continue to provide services to Medicare beneficiaries to be in compliance with the CoPs at §§ 482.72 through 482.104, as of the effective date of this final rule. Such transplant centers have 180 days from the effective date of this final rule to submit a request for Medicare approval under the CoPs at §§ 482.72 through 482.104, using the process described at § 488.61(b).

CMS will consider mitigating factors, including (but not limited to) the following in considering approval of a transplant center that does not meet the conditions of participation: the extent to which outcome measures are met or exceeded, availability of Medicare-approved transplant centers in the area, and extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation. In addition, the transplant center must submit to CMS and implement a plan of correction to meet the conditions of participation.

We will determine whether to approve the transplant center using the procedures described in paragraphs § 488.61(a)(2) through (a)(5). Until we make a determination whether to approve the transplant center's request for approval, the transplant center will continue to be approved under the ESRD CfCs (for kidney transplant centers) or the pertinent NCDs (for extra-renal transplant centers), as applicable. The transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

Once we approve a kidney transplant center under the CoPs, the ESRD CfCs will no longer apply to the transplant center as of the date of its approval. Once we approve an extra-renal transplant center under the conditions of participation, the NCDs will no longer apply to the transplant center as of the date of its approval. (See § 488.61(b).) Until we approve a currently approved transplant center under the CoPs in this final rule, the transplant center must continue to comply with the requirements in the NCDs or the ESRD CfCs, as applicable.

If a transplant center that is Medicare approved as of the effective date of this final rule does not submit a request to us for Medicare approval under the CoPs at §§ 482.72 through 482.104 within 180 days after the effective date of the final rule, or if the transplant center applies timely, but we do not approve the transplant center under the CoPs in this final rule, we will revoke

the transplant center's approval under the CfCs for kidney transplant centers or the NCDs for extra-renal transplant centers, as applicable, and the transplant center will no longer be reimbursed for services provided to Medicare beneficiaries. CMS will notify the transplant center in writing of the effective date of its loss of Medicare approval.

Re-Approval Procedures

We asked the public and the five peer reviewers to comment on the following re-approval issues: (1) The feasibility and utility of the alternative approach to re-approve transplant centers based on random surveys; (2) methodology for selecting a random sample for surveys; (3) the necessity of surveying all centers every 3 years, regardless of their compliance with data submission and outcome measure requirements; and (4) the appropriateness of making re-approval survey decisions based on OPTN information (that is desk review, on-site audits and action(s) taken since last Medicare approval).

Following are the comments we received and our responses.

(1) The Feasibility and Utility of the Alternative Approach To Re-Approve Transplant Centers Based on Random Surveys

Comment: A peer reviewer agreed that a transplant center's compliance with data submission and outcome measure requirements by itself is not sufficient evidence for CMS to grant Medicare re-approval. However, two peer reviewers did not agree with using random surveys to identify transplant programs with deficiencies and stated that random surveys would miss many programs whose performance may warrant a survey. One peer reviewer supported using random surveys to re-approve transplant centers and believed it to be a systematic approach to assess transplant centers. One peer reviewer stated that Medicare's re-approval process should rely on the OPTN's monitoring and oversight process for transplant centers.

Many public commenters also agreed with our concern that a center's compliance with data submission and outcome requirements may not necessarily indicate a center is also in compliance with the process requirements. These commenters supported targeted or random surveys to determine re-approval decisions. However, one commenter said that random surveys for re-approval are unnecessary if a center has demonstrated consistent compliance with the requirements.

Response: We recognize that transplant center performance varies greatly and random surveys of centers may not be able to identify all poor performers. After carefully evaluating all the comments and taking into consideration the results of our recent survey of transplant centers, we believe finite resources are best used to survey the poorest performers and centers with significant deficiencies. Therefore, we will not perform random surveys as part of the re-approval process for transplant centers. Instead, we will review centers that do not meet the data submission, clinical experience, and outcome requirements for compliance with the CoPs before making our re-approval decision. The review may include an on-site visit. Under the final rule at § 488.61(c)(2), if we determine that a transplant center has not met the data submission, clinical experience, or outcome requirements at § 482.82, the transplant center will be reviewed for compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A. Under the final rule at § 488.61(c)(3), if we determine that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, we may choose to review the transplant center for compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104, using the procedures described at 42 CFR part 488, subpart A.

CMS will consider mitigating factors, including (but not limited to) the following in considering approval of a transplant center that does not meet the conditions of participation: The extent to which outcome measures are met or exceeded, availability of Medicare-approved transplant centers in the area, and extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation. In addition, the transplant center must submit to CMS and implement a plan of correction to meet the conditions of participation.

During the Medicare approval cycle, a transplant center will be reviewed at some point to ensure it is in compliance with the CoPs. The existing complaint investigation process and the use of relevant data, including the OPTN data, are good tools to identify centers with deficiencies.

As stated earlier, the OPTN and CMS oversight have a different focus, and they compliment each other. Therefore, we disagree with the commenter that OPTN oversight can substitute for CMS

oversight. Further, we do not have the statutory authority to delegate regulatory authority to the OPTN to regulate transplant centers. No changes have been made in this final rule based on this comment.

(2) Methodology To Select a Random Sample for Surveys

Comment: Most peer reviewers had no comments on this issue. One peer reviewer suggested that 5–10% of small and large organ-specific centers should be selected for random surveys.

Response: We thank the peer reviewer for his suggestions. However, as stated in our responses earlier, we are not using random surveys to make re-approval decisions in this final rule. No changes have been made based on this comment.

(3) Whether Centers Should Be Surveyed Once Every 3 Years, Regardless of Their Compliance With Data Submission and Outcome Measure Requirements

Comment: A few commenters recommended surveying only centers that fail to comply with data submission and outcome measure requirements every 3 years. A commenter stated that all centers should be surveyed for compliance with the process requirements every 3 years, regardless of whether they are in compliance with data and outcome requirements. The commenter suggested allowing a plan of correction if a center is out of compliance with one or more conditions for coverage. Another commenter recommended that re-approval surveys be conducted only when a center has become an OPTN “member not in good standing” and only after exhaustion of all OPTN appeals processes and remedies. A commenter recommended that transplant centers be subject to only one survey every 3 years by either the OPTN or CMS but not both because surveys are burdensome, bureaucratic, and costly.

Two peer reviewers supported routine periodic survey of transplant centers for the purposes of: (1) Validating the timeliness and accuracy of data submission, (2) enhancing transplant centers’ self-assessment process, and (3) sharing best practices to improve performance. A peer reviewer recommended surveying only centers that fail to comply with data submission and outcome measure requirements every 3 years. One peer reviewer stated that routine surveys are burdensome for centers that are performing well.

Response: We agree with the commenters and peer reviewers that transplant centers’ data submission and

outcome performance should be reviewed regularly to ensure they are in compliance with all of our requirements, even if they are consistently in compliance with data submission and clinical experience requirements. Nonetheless, we are also mindful of the potential burden on centers that are in compliance with the CoPs. Therefore, we will minimize the burden for transplant centers by conducting targeted re-approval surveys. For example, a center that barely meets the outcome requirements may be surveyed every 3 years, while a center that consistently has superior outcomes may be surveyed less often.

As stated previously, transplant centers will be subject to the same remediation process, including plans of correction, used for nearly all other Medicare providers and suppliers.

Also, we disagree with the commenter’s suggestion to use the OPTN membership status of “not in good standing” as a trigger for surveys because the OPTN may designate a member as “not in good standing” for reasons that have nothing to do with the center’s compliance with CMS’s regulatory requirements (for example, OPTN organ allocation policies). If a transplant center were to become an OPTN “member not in good standing,” we most likely would treat the member’s status with the OPTN as a complaint and conduct a survey of the center to determine its compliance with our regulatory requirements. If a Medicare provider is substantially out of compliance with our conditions of participation, we must take independent action promptly to oversee the provider’s development and implementation of a plan of correction. We must base our decision whether to review or survey a center on issues that directly relate to the requirements in this final rule. Therefore, no changes have been made based on this comment.

Comment: Some commenters supported the re-approval procedures for Medicare-approved transplant centers and the 3-year re-approval cycle. However, some commenters suggested extending the approval cycle to 5 or 6 years.

Response: We agree with the commenters that centers should be monitored and re-approved every 3 years. Ongoing evaluation is critical to ensure that after Medicare approval, a center continues to meet Medicare requirements. Frequent, active oversight of transplant centers helps to ensure that Medicare beneficiaries continue to receive high quality transplantation services. We disagree that 5 or 6 years is an appropriate time period for re-

approval. Given rapid changes in the field of transplantation, a center's performance may change radically in 5 or 6 years from its initial Medicare approval.

Comment: A peer reviewer requested clarification on whether CMS will rely on the OPTN's Membership and Professional Standards Committee's (MPSC) extensive method to flag centers for further review or develop a similar method for this scrutiny.

Response: We plan to convene a technical expert panel to develop a similar methodology for targeting transplant centers for survey. However, we expect to minimize burden for transplant centers by conducting targeted re-approval surveys.

Comment: A peer reviewer favored a periodic "self-study" report by all programs regarding the state of their compliance with process requirements. A robust self-study process could potentially eliminate the need for, or reduce the frequency of, on-site surveys.

Response: We welcome the idea of transplant centers performing periodic "self-study" to assess their compliance with the process requirements. We urge transplant centers to consider incorporating a robust self-study process to enhance their preparedness for surveys. No changes have been made based on this comment.

(4) Use of OPTN Information To Identify Centers That Need To Be Surveyed

Comment: Many commenters agreed that it would be appropriate to make survey decisions based on OPTN information since it is widely accepted by U.S. health care payers. Nonetheless, a peer reviewer cautioned that routine use of OPTN information may alter the generally collegial responses that the OPTN receives from transplant programs. Transplant centers may become less open, less responsive, and more guarded. The peer reviewer said that this possibility should be carefully considered if the OPTN information-based survey approach is taken. The peer reviewer also recommended that we clearly define the thresholds for passing OPTN information to CMS.

Another peer reviewer was concerned that the sharing of OPTN data with CMS jeopardizes the confidentiality of transplant centers' data submissions to the OPTN under applicable laws and regulations protecting peer review processes employed by the OPTN committees. The reviewer recommended adding language to note that nothing in the final rule changes existing OPTN rules and policies with respect to confidentiality of data

obtained from centers, as part of its oversight and compliance obligations.

Response: We agree that the use of OPTN information for survey decisions is appropriate since it is transparent, acceptable to the transplant community, and is publicly available. We will use relevant information such as OPTN data to prioritize survey decisions.

We do not believe the sharing of OPTN data with us jeopardizes the confidentiality of transplant centers' data under applicable laws and regulations because the OPTN final rule at 42 CFR part 121, states in § 121.11(b)(1)(iii) that the OPTN and the SRTR, as appropriate, shall provide to the Secretary any data that the Secretary requests. Because of the language in part 121, we do not see a need to add clarifying language with respect to confidentiality of data obtained from centers. We expect the OPTN/MPSC to continue its review process to flag centers for further review and we expect that centers will continue to maintain their collegial relationships with the OPTN.

Comment: A public commenter asked whether CMS or some other agency or organization will monitor transplant center's compliance with the outcome requirements. One commenter recommended that CMS consult with the OPTN.

A peer reviewer stated that we need to delineate the methodology we will use to survey transplant centers, identify the designated organization that will perform the surveys, and provide assurance that the organization has the experience and expertise to perform transplant center surveys.

Response: Although we have not yet determined which entity will monitor extra-renal transplant centers, we will inform them as soon as possible. Kidney transplant centers will not be monitored by any of the national accrediting bodies. Pursuant to sections 1865(b)(1) and 1881(b) of the Act, kidney transplant centers cannot be deemed by a national accreditation body to meet the Medicare conditions of participation. If a national accrediting organization applies for deeming authority for any of the extra-renal transplant centers, we will assess its expertise and review its application. If an accrediting organization is approved for deeming authority the transplant centers will be routinely reviewed (which could include surveys) by the accrediting organization. We will continue to have oversight responsibility for complaint surveys and validation surveys and will work closely with the accrediting organization on an ongoing basis. Most transplant centers

are located in accredited hospitals and surveys of the transplant center may be combined with the routine survey of the hospital which may allow for a more efficient review since some of the transplant center documentation and records will be combined with the hospital records. We will include information about how transplant center surveys will be performed in the Interpretive Guidelines that we will develop following publication of the final rule. Under this final rule, we will monitor transplant center compliance with the clinical experience and outcome requirements. We will continue to work with the OPTN through HRSA on transplant center issues.

Accreditation, Corrective Actions, Appeal Process and Loss of Medicare Approval

We requested comments on whether transplant centers should be regarded as providers or as suppliers for the purpose of appealing adverse approval and re-approval decisions.

Comment: A commenter suggested that transplant centers should be identified as a provider in the regulations for accreditation and appeals purposes. One commenter suggested that the part 498 appeals process is an appropriate mechanism for transplant center appeals. Another commenter requested that we state clearly that the denial of initial approval and re-approval is a determination that triggers appeal rights under part 498.

Response: We agree with the commenter that transplant centers should have provider status for accreditation and appeals purposes because transplant centers are located within hospitals, which are considered providers under the Medicare program. Therefore, we have added transplant centers to the list of providers in 42 CFR 498.2 that have the right to appeal decisions that affect their participation in the Medicare program. Additionally, we have added transplant centers to the list of providers and suppliers in 42 CFR 488.6 that can receive deemed status through an accrediting organization. Transplant centers that apply for and are denied Medicare approval, as well as Medicare-approved transplant centers that are terminated from the Medicare program may appeal these decisions under part 498.

Comment: A few commenters recommended that a center should be allowed to continue Medicare participation pending exhaustion of any appeals, provided that its treatment of Medicare beneficiaries does not jeopardize their health and safety.

Response: In most cases, Medicare providers and suppliers are permitted to continue to participate in Medicare while an appeal is pending, unless the deficiency is such that the health and safety of patients is in immediate jeopardy.

Comment: Many commenters asked us to clarify whether transplant centers that do not meet the data and outcome requirements in the initial approval and re-approval process will have an opportunity for corrective action. A commenter suggested that we should provide a process of remediation and corrective actions for centers that fail to comply with the data submission and outcome requirements that is like the process for hospitals that face termination from the Medicare program. A commenter recommended 180 days for centers to submit acceptable plans of correction and correct deficiencies through the use of an acceptable QAPI program. Another commenter stated that we should consult with the OPTN before denying re-approval of Medicare-approved centers. A commenter suggested that we should review a center for potential termination of Medicare approval only when the Secretary has been notified of an OPTN decision to take adverse action against the center. A commenter recommended that we adopt the OPTN remediation process for centers failing to meet outcome requirements.

Response: Once approved under the requirements of this final rule, transplant centers will be subject to the same remediation process used for nearly all other Medicare providers and suppliers. Under the process for re-approval, a transplant center found to be out of compliance with one or more CoPs, including the CoP for data submission, clinical experience, and outcome requirements, will have an opportunity to come back into compliance once it has submitted an acceptable plan of correction. Generally, the transplant center will be permitted to continue to provide services to Medicare beneficiaries while we monitor implementation of the plan of correction. We also will use this process if we find, during a complaint investigation, that a transplant center is out of compliance with one or more conditions of participation. We do not have a remediation or corrective action process for entities that apply for initial Medicare certification or approval under this final rule and fail to meet the requirements. However, a transplant center that is not approved may re-apply for initial approval at any time.

We will include additional details about the processes for initial approval

and re-approval, plans of correction, and other matters related to survey and certification of transplant centers in Interpretive Guidelines for surveyors and manual instructions that will be published following the effective date of this final rule.

III. Provisions of the Final Rule

In the final rule, we are adopting the provisions as set forth in the February 4, 2005 proposed rule with the following revisions:

Amend § 482.70, "Definitions," by—

- Revising the term "adverse event." The proposed definition listed two examples of adverse events related to living donors: "living donor death due to mismanagement of the donor" and "avoidable loss of a healthy living donor." We have replaced these two examples with "serious medical complications or death caused by living donation" to clarify that the death or serious medical complications due to living donation of any living donor should be investigated as an adverse event. The proposed definition also listed another example of an adverse event as "transplantation of organs of mismatched blood types due to failure to validate the donor and recipient's vital information." We have revised this example to now read "unintentional transplantation of organs of mismatched blood types" in order to further clarify this term.

- Removing the term "intestinal" wherever it appears, when referring to such transplants and transplant centers, and adding in its place the term "intestine."

Amend § 482.72, "Condition of participation: OPTN membership," by—

- Revising the beginning of the last sentence in the condition statement by changing it from "No transplant hospital * * *" to "No hospital that provides transplantation services * * *"

Amend § 482.74, "Condition of participation: Notification to CMS," by—

- Redesignating the proposed introductory text as paragraph (a) and proposed paragraphs (a) and (b) as paragraphs (a)(1) and (a)(2) respectively.

- Revising the newly redesignated paragraph (a) to read "A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to: * * *"

- Redesignating § 482.100(b) as § 482.74(a)(3) and revising newly designated paragraph (a)(3).

- Adding a new paragraph (a)(4) to clarify that a transplant center must notify CMS immediately of its inactivation.

- Adding a new paragraph (b) to specify the actions CMS will take to follow-up with a transplant center that notifies us of significant changes in their program.

Amend § 482.76, "Condition of participation: Pediatric transplants," by—

- Removing the word "wishes" and adding in its place "seeks Medicare approval" in the condition statement to clarify that it is only those centers seeking Medicare approval to perform pediatric transplants that must submit a request for this specific purpose.

- Adding the phrase "in a 12-month period" after "A center that performs 50 percent or more of its transplants," at proposed § 482.76(b) to clarify that a center that performs predominately adult transplants must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

- Adding the phrase "in a 12-month period" after "A center that performs 50 percent or more of its transplants" at proposed § 482.76(c) to clarify that a center that performs predominately pediatric transplants must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

- Revising proposed § 482.76(c)(3) to read "A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center."

- Adding the citation of "Omnibus Budget and Reconciliation Act (OBRA) 1987 criteria in section 4009(b) (Pub. L. 100-203)" at paragraph (d) to clarify that the alternate criteria for Medicare approval of heart transplant centers providing transplantation services to pediatric heart patients are mandated by statute, and in paragraph (d)(1) changing the word "center" to "hospital" to conform with the language in OBRA 1987.

Amend § 482.80, "Condition of participation: Data submission and outcome requirements for initial approval of transplant centers," by—

- Adding the phrase "clinical experience" to the CoP section heading and to the condition statement to clarify that there is a clinical experience requirement, and so that the heading now reads "Data submission, clinical experience, and outcome requirements for initial approval of transplant

centers.” (The appropriate revisions regarding the clinical experience requirements for approval and re-approval, including the special procedures for approval and re-approval described at § 488.61, have been made throughout the final rule.)

- Revising the condition statement. Throughout the proposed rule the terms “outcome measure” and “outcome measure standards” are used. We have replaced both terms with “outcome requirements” here and throughout the final rule in order to clarify, through the use of a uniform term throughout, that these are requirements and not measures or standards. We have done this, along with our removal of the reference to waivers in the proposed rule, in order to further clarify that centers not meeting the data submission, clinical experience, and outcome requirements may be reviewed to augment CMS’s approval decisions.

- Removing in paragraph (a) “transplant recipient registration, and recipient follow-up” and adding in its place the words “transplant recipient registration and follow-up.” In addition, adding at the end of paragraph (a) “and living donor registration and follow-up” to clarify that they are part of the required data submissions.

- Adding a new paragraph (b), Standard: Clinical Experience requirements. An organ-specific transplant center generally must perform 10 transplants over a 12-month period.

- Re-designating proposed § 482.80 paragraph (b) as paragraph (c) and revising the paragraph heading to now read “(c) Standard: Outcome requirements.” All references to this paragraph have been amended accordingly.

- Revising proposed § 482.80 paragraph (b)(1) (now (c)(1)) by removing the words “as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.”

- Revising proposed § 482.80 paragraph (b)(2) (now (c)(2)) by removing the words “The 9” and adding in its place the words “The required number of” so that the paragraph now reads: “The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.”

- Removing proposed § 482.80 paragraphs (b)(4), (b)(5), and (b)(6) to clarify that a center may not request CMS to 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 certain conditions are met. We are not finalizing the proposed review of 1-month post-transplant data of new centers seeking Medicare approval.

- Re-designating proposed § 482.80 paragraph (c) as paragraph (d) with the heading continuing to read “Exceptions.” All references to this paragraph have been amended accordingly.

- Revising newly re-designated paragraph (d)(1) to clarify that heart-lung transplant centers are not required to meet the clinical experience requirements or the outcome requirements for heart-lung transplants performed at the center.

- Revising newly re-designated paragraph (d)(2) to clarify that intestine transplant centers are not required to meet the outcome requirements for intestine, combined liver-intestine, or multivisceral transplants performed at the center.

- Revising newly re-designated paragraph (d)(3) to clarify that pancreas transplant centers are not required to meet the clinical experience requirements or the outcome requirements for pancreas and kidney-pancreas transplants performed at the center.

- Removing in newly re-designated paragraph (d)(4) the words “perform a minimum number of pediatric transplants” and adding in its place the words “comply with the clinical experience requirements in paragraph (b)” to clarify that a center requesting initial Medicare approval to perform pediatric transplants does not have to comply with the clinical experience requirements prior to its request for approval as a pediatric transplant center.

- Adding paragraph (d)(5) to state that “a kidney transplant center that is not Medicare-approved on the effective date of this final rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.”

Amend § 482.82 “Condition of participation: Data submission and outcome requirements for re-approval of transplant centers” by—

- Adding the phrase “clinical experience” to the CoP section heading and to the condition statement to clarify that there is a clinical experience requirement, and so that the heading now reads “Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.”

- In paragraph (a), revising “transplant recipient registration, and recipient follow-up” to read “transplant recipient registration and follow-up.” In

addition, adding the words “and living donor registration and follow-up” at the end of paragraph (a) to clarify that they are part of the required data submission.

- Adding a new paragraph (b), Standard: Clinical experience requirements. An organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

- Re-designating proposed paragraph (b) as paragraph (c) and revising the paragraph heading to now read “(c) Standard: Outcome requirements.” All references to this paragraph have been amended accordingly.

- Revising proposed paragraph (b)(1) (now (c)(1)) by removing the phrase “as long as the center has 1-year post-transplant follow-up on at least 9 transplants of the appropriate organ type.”

- Revising proposed § 482.82 paragraph (b)(2) (now (c)(2)) by removing the words “The 9” and adding in its place the words “The required number of” so that it now reads: “The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.”

- Re-designating proposed § 482.82 paragraph (c) as paragraph (d) with the paragraph heading continuing to read “Exceptions.” All references to this paragraph have been amended accordingly.

- Revising newly re-designated paragraph (d)(1) to clarify that heart-lung transplant centers are not required to meet the clinical experience requirements or the outcome requirements for heart-lung transplants performed at the center.

- Revising newly re-designated paragraph (d)(2) to clarify that intestine transplant centers are not required to meet the outcome requirements for intestine, combined liver-intestine, or multivisceral transplants performed at the center.

- Revising newly re-designated paragraph (d)(3) to clarify that pancreas transplant centers are not required to meet the clinical experience requirements or the outcome requirements for pancreas and kidney-pancreas transplants performed at the center.

- Revising newly re-designated paragraph (d)(4) by removing the phrase “perform a minimum number of pediatric transplants” and adding in its place the words “comply with the clinical experience requirements in paragraph (b)” in order to clarify that a center does not have to comply with the clinical experience requirements to be re-approved.

Amend § 482.90 “Condition of participation: Patient and living donor selection” by—

- Removing the word “waitlist” and adding in its place the words “waiting list” in the condition statement and throughout the requirements where applicable.

- Removing proposed paragraph (a)(1) and re-designating paragraphs (a)(2), (a)(3), and (a)(4) as paragraphs (a)(1), (a)(2), and (a)(3).

- Revising newly re-designated paragraph (a)(1) by adding the words, “if possible” at the end of the sentence to allow transplant centers the discretion to give psychosocial evaluation to prospective transplant candidates.

- Adding the words “transplant patient” to paragraph (a)(4) which reads “A transplant center must provide a copy of its patient selection criteria to a transplant patient or dialysis facility, if requested by such transplant patient or facility.”

- Removing the words “transplant candidate’s” in proposed paragraph (b)(2) so that the transplant center is only required to document the living donor’s suitability for donation in the living donor’s medical record.

Revise § 482.92 “Condition of participation: Organ recovery and receipt” by—

- Revising the first line of the condition statement to read “Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation process.”

- Adding the phrase “When the identity of an intended transplant recipient is known and the transplant center sends a team to recover organ(s),” at the beginning of paragraph (a) to clarify that if the intended recipient for the organ being recovered is known, the transplant center’s recovery team must review and compare the donor data with the recipient blood type and other vital data before organ recovery takes place.

- Adding the phrase “a licensed health care professional” to paragraph (b) to clarify that this individual must be present for the verification of donor’s blood type and vital data when an organ arrives at the transplant center.

Amend § 482.94 “Condition of participation: Patient and living donor management” by—

- Removing the word “pre-transplant” in the condition statement and in paragraph (a)(1) to clarify that a transplant center is not required to provide the care of a multidisciplinary patient care team coordinated by a

physician in the pre-transplant phase of transplantation.

- Removing the words “on an ongoing basis” in paragraph (b)(1) and adding them to paragraph (b) introductory text to clarify that transplant centers must keep their waiting lists up to date on an ongoing basis.

- Adding the phrase “(and in the case of a kidney patient, the patient’s usual dialysis facility)” in paragraph (c)(1) to clarify that the dialysis facility of the kidney transplant patients must also be notified of the patient’s transplant status”.

- Adding the phrase “(and in the case of a kidney patient, the patient’s usual dialysis facility)” in paragraph (c)(2) to clarify that the dialysis facility of the kidney transplant patients must also be notified of the kidney patient’s removal from the waiting list for any reason other than death or transplantation no later than 10 days after the date the patient was removed from the waiting list.

- Removing the requirement in proposed (c)(2)(i) that once a patient is placed on a center’s waiting list, the center must document in the patient’s record that the patient is notified of his or her placement status at least once a year, even if there is no change in the patient’s placement status. We are not finalizing this proposed requirement.

- Re-designating the proposed paragraph (c)(2)(ii) as paragraph (c)(2).

- Removing proposed paragraph (c)(3).

- Revising proposed paragraph (c)(4)(i) to replace the word “pre-transplant” with “transplant.”

- Re-designating proposed paragraph (c)(4) as paragraph (c)(3).

- Revising proposed paragraph (d) to now define a qualified social worker as “an individual who meets licensing requirements in the State in which he or she practices; 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) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 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) of this paragraph.

- Revising proposed paragraph (e) by removing paragraphs (e)(1) and (e)(2), and now defining a qualified dietitian as an individual who meets practice requirements in the State in which he/she practices and who is a registered

dietitian with the Commission on Dietetic Registration.

Amend § 482.96 “Condition of participation: Quality assessment and performance improvement (QAPI)” by—

- Adding in paragraph (a) the word “requirements” after the words “OPTN waitlist (now waiting list)” in order to further clarify this example of a QAPI program activity.

- Adding in paragraph (a) the words “patient education” to clarify that this is one of the included QAPI activities and outcomes.

Amend § 482.98 “Condition of participation: Human resources” by—

- Revising proposed paragraph (a)(1) to read: “Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors” to further clarify the responsibilities of the Director of a transplant center.

- Revising paragraph (a)(3), to clarify that the director of the transplant center is responsible for ensuring that surgery is performed “by, or under the direct supervision of, a qualified transplant surgeon.”

- Adding the phrase “and who are immediately available to provide transplantation services when an organ is offered for transplantation” at the end of the sentence at paragraph (b) to clarify that a transplant surgeon and physician must be immediately available to perform a transplant when an organ is offered.

- Removing in paragraph (c), the portion of the definition of a qualified clinical transplant coordinator, which requires an individual to be certified by the American Board of Transplant Coordinators, and adding in its place an expanded one that states “The clinical transplant coordinator must be a registered nurse or other licensed clinician who has experience and knowledge of transplantation and living donation issues. The clinical transplant coordinator’s responsibilities must include, but are not limited to, the following: (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and (2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.”

- Adding a new standard at paragraph (d) titled “Independent living donor advocate or living donor advocate team.” This new requirement states “The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure

protection of the rights of living donors and prospective living donors.” As noted below, this new standard also has three new provisions contained within it.

- Requiring under the new paragraph (d)(1) that the living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

- Requiring under the new paragraph (d)(2) that these independent advocates or advocate teams must demonstrate: (i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and (ii) understanding of the potential impact of family and other external pressures on the prospective living donor’s decision whether to donate and the ability to discuss these issues with the donor.

- Requiring under the new paragraph (d)(3) that the independent living donor advocate’s or living donor advocate team’s responsibilities include: (i) Representing and advising the donor; (ii) protecting and promoting the interests of the donor; and (iii) respecting the donor’s decision and ensuring that the donor’s decision is informed and free from coercion.

- Re-designating proposed § 482.98 paragraph (d) as paragraph (e) with heading continuing to read “Standard: Transplant team.” All references to this paragraph have been amended accordingly.

- Re-designating proposed § 482.98 paragraph (e) as paragraph (f) with heading continuing to read “Standard: Resource commitment.” All references to this paragraph have been amended accordingly.

- Adding the words “patient education” in newly re-designated paragraph (f) to clarify that this is one of the areas of expertise that a transplant center is required to have available under its resources.

Amend § 482.100 “Condition of Participation: Organ procurement” by—

- Removing the paragraph designation “(a)” and combining the text with the condition statement.

- Re-designating proposed paragraph (b) as § 482.74(a)(3) and revising newly designated § 482.74(a)(3) to read “Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs;”.

Amend § 482.102 “Condition of participation: Patient and living donor rights” by—

- Adding the words “Patient rights” to the condition statement to clarify that § 482.13 is the Patients rights CoP.

- Revising proposed § 482.102 paragraph (a) to read “Transplant

centers must implement written transplant patient informed consent policies that inform each patient of:
* * *

- Amending paragraph (a)(5) to specify that information provided to patients includes (but is not limited to) information from the most recent SRTR center-specific report, including (but not limited to) the transplant center’s observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center.

- Removing the text of proposed paragraph (a)(6);

- Re-designating the proposed (a)(7) as (a)(6).

- Re-designating the proposed (a)(8) as (a)(7).

- Adding a new paragraph (a)(8) to read “The fact that if his or her transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient’s ability to have his or her immunosuppressive drugs paid for under Medicare Part B.”

- Revising proposed § 482.102 paragraph (b) to read “Transplant centers must implement written living donor informed consent policies that inform * * * .”

- Adding paragraph (b)(9) to read “The fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient’s ability to have his or her immunosuppressive drugs paid under Medicare Part B.”

- Deleting the phrase “that meets the hospital’s credentialing policies” from proposed § 482.102 paragraph (c)(1)(ii) in order to clarify this provision.

- Revising proposed § 482.102 paragraph (c)(2)(ii) to read: “Inform Medicare beneficiaries on the center’s waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center’s termination of approval.”

- Adding a new provision at § 482.102(c)(3) that reads “As soon as possible prior to a transplant center’s voluntary inactivation, the center must inform patients on the center’s waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.”

Amend § 482.104 “Condition of participation: Additional requirements for kidney transplant centers” by—

- Revising proposed § 482.104 paragraph (a) by adding a new line that

reads “A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients’ local dialysis facilities.”

- Removing the requirement at proposed § 482.104 paragraph (b) that kidney dialysis centers or units in kidney transplant centers providing dialysis services to inpatients directly or under arrangement must meet the Conditions of Coverage of Suppliers of ESRD Services contained in part 405 subpart U of this chapter. We are not finalizing this proposed requirement in the final rule.

Amend § 488.6 “Other national accreditation programs for hospitals” by—

- Revising paragraph (a), first sentence, by inserting the words “transplant centers except for kidney transplant centers;” after the words “psychiatric hospitals;”.

Amend § 488.61 “Special procedures for approval and re-approval of organ transplant centers” by—

- Revising the heading to paragraph (a) to read “Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.”

- Revising paragraph (a) to clarify that a transplant center, including kidney transplant centers, may submit a request to CMS for Medicare approval at any time.

- Revising proposed § 488.61 paragraph (a)(2) to include provisions from proposed paragraph (a)(3) to read “To determine compliance with the clinical experience and outcome requirements at § 482.80(b) and (c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.”

- Deleting proposed paragraph (a)(3) and redesignating proposed paragraph (a)(4) as (a)(3). We revised proposed paragraph (a)(4), now (a)(3) to read: If CMS determines that a transplant center has not met the data submission, clinical experience, or outcome requirements, CMS may deny the request for approval or may review the center’s compliance with the conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104 of this chapter, using the procedures described at 42 CFR part 488, subpart A, to determine whether the center’s request will be approved. CMS will notify the transplant center in writing whether it is approved and, if approved, of the effective date of its approval.

- Adding a new paragraph (a)(4) to describe mitigating factors CMS will consider in determining initial approval

or re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation.

- Revising paragraph (a)(5) to outline the initial Medicare approval review process and approval period, and to specify how transplant centers will be notified of approval.
- Deleting proposed paragraph (a)(6) and including its content in proposed paragraph (a)(4) (now (a)(3)).
- Adding a new paragraph (a)(6) to state that a kidney center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.
- Revising proposed paragraph (a)(7) for clarity.

All references to these paragraphs have been amended accordingly.

- Redesignating proposed paragraph (b) as paragraph (c).
- Adding a new paragraph (b) to clarify that all transplant centers, including kidney transplant centers, approved as of the effective date of this final rule that want to continue to be Medicare approved must submit a request to CMS for Medicare approval under the conditions of participation by December 26, 2007, using the process described in paragraph (a)(1) of the section. CMS will determine whether to approve a transplant center using the procedures described in paragraphs (a)(2) through (a)(5) of the section.
- Revising proposed paragraph (b) (now (c)), for clarity.
- Revising proposed § 488.61 paragraph (b)(1)(ii) (now (c)(1)(ii)) to read “To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and (c), CMS will review the data contained in the most recent OPTN Data Report and 1-year patient and graft survival data contained in the most recent Scientific Registry of Transplant Recipient (SRTR) center-specific report.”
- Revising proposed 488.61 paragraph (b)(4) (now (c)(1)) to read “Prior to the end of the 3-year approval period, CMS will review the transplant center’s data in making re-approval determinations.”
- Adding a new paragraph (c)(4) to describe mitigating factors CMS will consider in determining re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation.
- Revising proposed § 488.61 paragraph (b)(4) (now (c)(5)) to read: “CMS will notify the transplant center in writing if its approval is being

revoked and of the effective date of the revocation.”

- Adding the phrase “including kidney transplant centers” to paragraph (c) to clarify that all transplant centers must be in compliance with all the CoPs for transplant center at § 482.72 through § 482.104, except for § 482.80 (Initial approval requirements) throughout the 3 year approval period.
- Adding a new transplant center inactivity requirement at paragraph (e) to state that a transplant center may inactivate its program for a period not to exceed 12 months during the 3-year approval cycle. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(a)(4).

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-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 comments 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.

We solicited public comments on each of these issues for the sections of this document that contain information collection requirements (ICRs).

General Comments

Comment: Some commenters said they were concerned that CMS generally underestimated the total burden hours and/or total estimated costs that this regulation would impose on transplant centers. Other commenters felt that some of the data used in the proposed rule were inaccurate.

Response: After further analysis of the tasks needed for the paperwork requirements in this final rule and review of more recent financial data, we agree with the commenters that for certain requirements, we underestimated the total burden hours (and in the economic impact analysis, the total estimated costs) associated

with the paperwork requirements in the proposed rule. Therefore, we have increased our estimate of total burden hours and/or total costs for some of the conditions of participation. These changes are discussed below for each relevant condition of participation.

Comment: Some commenters said that many of the requirements in the proposed rule would be unnecessary because some of the proposed requirements are similar or identical to either current OPTN or JCAHO requirements.

Response: The commenters are correct; however, we disagree that these requirements are unnecessary. For these requirements to be enforceable by us through our oversight and survey and certification process, they must be promulgated as regulations.

Also, some commenters stated that the regulation would increase post-transplant health care costs. However, this final rule regulates only inpatient transplant services and will not increase the cost of providing post-transplant care once patients are discharged from the hospital.

Section 482.74 Condition of Participation: Notification to CMS

Section 482.74 requires a transplant center to notify us immediately of any significant changes related to the center’s transplant program or changes that could affect its compliance with the CoPs. The instances in which a transplant center must notify us include, but are not limited to: any change in key staff members of the transplant team; a decrease in the number of the center’s transplants or survival rates that could result in the center being out of compliance with § 482.82, Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers; termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs; and inactivation of the transplant center.

In the proposed rule, we estimated that the burden associated with this section would be the time required to notify us of significant changes. We estimated that there would be three occasions annually per center requiring notification. For each occasion, we estimated that it would take 5 minutes to notify us. Therefore, we estimated that it would take no more than 15 minutes annually for each center to notify us of any significant changes. We said that since there were approximately 900 transplant centers, we estimated that the total burden hours for

complying with this section would be a total of 225 hours. The estimate of 900 transplant centers included non-Medicare approved transplant centers. However, our analysis will only concern Medicare-approved centers.

Comment: One commenter said that we significantly underestimated the burden required for transplant centers to comply with this requirement. The commenter noted that notifying us of

these changes required the involvement of the program's medical director, an administrator, and appropriate clerical/support staff. The commenter opined that large centers would have a significant number of changes per year, perhaps as many as 6–12, and that each change would require 15–30 minutes of time for each of the individuals involved or approximately one and one-half to two hours per change.

Response: We agree that we underestimated the burden of this requirement. We agree that reporting a significant change to us would require more than 5 minutes and would involve senior staff and management. After further analysis of the tasks involved in complying with this section and the personnel that generally would be involved.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE FOR SUBMITTING SIGNIFICANT CHANGES TO CMS

| Position | Hourly wage | Hours required per report | Total cost estimate for each report | Total annual burden hours per center (for 3 reports) | Total annual cost estimate per center (for 3 reports per year per center) |
|------------------------------|-------------|---------------------------|-------------------------------------|--|---|
| Medical Director | \$116.60 | .50 | \$58.30 | 1.5 | \$174.90 |
| Senior Administrator | 92.31 | .50 | 46.16 | 1.5 | 138.46 |
| Transplant Coordinator | 43.87 | .75 | 32.90 | 2.25 | 98.71 |
| Secretary | 21.81 | .25 | 5.45 | .75 | 16.36 |
| Totals | | 2.00 | 142.81 | 6.0 | 428.43 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>.

Section 482.76 Condition of Participation: Pediatric Transplants

Section 482.76 states that a transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures at § 488.61, Special procedures for approval and re-approval of organ transplant centers. The center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation in §§ 482.72 through 482.74 and §§ 482.80 through 482.104, with respect to its pediatric patients.

The burden associated with this requirement would be the time required to prepare and submit the required information and data to us. Since pediatric centers must comply with the procedures at § 488.61, the burden for pediatric centers to request Medicare approval will be analyzed under that section.

In lieu of meeting all of the requirements in those sections noted above, § 482.76(d) provides that a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplant by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100–203) as follows:

(1) The center's pediatric transplant program must be operated jointly by the

hospital 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 must demonstrate 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.

The burden associated with this requirement is the time required for heart transplant centers that choose to use the alternative criteria under § 482.76(d) to prepare and submit the required information to us. We believe that it would require additional time to apply using the alternative criteria in this section. However, we also believe that the additional burden would be minimal.

In addition, we believe that fewer than 10 entities would choose to apply for Medicare approval using the alternative criteria in this section in any given year. There are currently seven Medicare-approved pediatric heart transplant centers. Even if we should receive requests for Medicare approval from the equivalent of 50 percent of the currently approved centers, we would receive only about 4 requests. Under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than ten entities. Therefore, the requirements under § 482.76(d) are not subject to the PRA.

Section 482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Initial Approval of Transplant Centers

Section 482.80 requires that, except as specified in paragraph (d) of that section and at 488.61, transplant centers must generally meet all data submission, clinical experience, and outcome requirements to be granted initial approval by us. Section 482.80(a) requires transplant centers to submit to the OPTN at least 95 percent of the required data on all transplants (deceased and living donors) no later than 90 days after the date established by the OPTN. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

The burden associated with this requirement is the amount of time it would take the transplant center to submit the required data. In the proposed rule, we stated that we believed that these requirements reflected usual and customary business practice and would be followed even if there were no Medicare requirements. Thus, we said that the burden for these requirements would be exempt under 5 CFR 1320.3(b)(2).

Comment: A national organization that represents professionals in the transplant community commented that the data submission requirements

necessary for OPTN compliance have had a huge financial impact on transplant centers. The commenter noted that multiple forms are required for each patient, from the time of registration on the OPTN waiting list to several years post-transplant. They noted that the analysis did not account for the additional resources needed to complete and submit these forms.

Response: Although we appreciate that the data submission requirements necessitate significant resources from the transplant centers, we would point out that OPTN policies require transplant hospitals as a condition of membership to submit these required data to the OPTN. The final rule governing the operation of the OPTN (42 CFR 121.11) also imposes this requirement by Federal regulation. Further, existing Medicare regulations require that if a hospital performs transplants, it must be a member of the OPTN and provide organ-transplant-related data, as requested, to the OPTN, SRTR, and the OPOs. (See 42 CFR 482.45(b).) Therefore, complying with this section imposes little additional burden on the transplant centers and constitutes usual and customary business practice.

Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Thus, these activities will not be included in the burden analysis for this final rule.

Section 482.82 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Re-Approval of Transplant Centers

Section 482.82 provides that, except as specified in paragraph (d) of this section and at 488.61, transplant centers must meet all the data submission, clinical experience, and outcome requirements to be re-approved. Section 482.82(a) requires that 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 the required data submissions on all transplants (deceased and living donors) it has performed over the 3-year approval period. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow up, and living donor registration and follow up.

The burden associated with this requirement is the time it would take the transplant center to submit the

required data. As discussed above under § 482.80, we already require hospitals in which transplant centers are located to belong to the OPTN, and the OPTN requires that these hospitals submit data to the OPTN. (See § 482.45(b).)

Thus, complying with this section imposes little additional burden on the transplant centers and constitutes usual and customary business practice. Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Therefore, these activities will not be included in this final rule's burden analysis.

Section 482.90 Condition of Participation: Patient and Living Donor Selection

Section 482.90 requires transplant centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplant. If a center performs living donor transplants, the center must also use written donor selection criteria in determining the suitability of candidates for donation.

Section 482.90(a) states that before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined. When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria that were used. Section 482.90(b) states that a transplant center also must document in the living donor's medical records the living donor's suitability for donation and that the living donor has given informed consent, as required under § 482.102(b).

Comment: Some commenters said that the patient selection criteria requirements would be burdensome. For example, one commenter said that it would take at least 30 minutes of staff time to document the patient selection criteria in the file of each patient or living donor.

Response: We disagree. Each center has the flexibility to determine the most expedient way to satisfy this requirement. Centers should be able to reduce the resources needed to document individual potential transplant recipient and living donor medical records significantly by using electronic formats, forms, or checklists. Therefore, complying with this requirement constitutes a minimal burden to the transplant centers.

Comment: One commenter said that we did not address the recordkeeping burden for this requirement.

Response: For the reasons discussed immediately below, we do not believe a burden analysis of this requirement should be included in this PRA analysis.

The burden associated with complying with this section is the time to develop the transplant recipient and living donor selection criteria and document each potential transplant recipient's and living donor's medical record. We expect that all transplant centers have policies regarding selection criteria for potential transplant recipients and living donors (if they perform living donor transplants). In addition, it is standard medical practice to document in the medical record of a hospital patient undergoing surgery whether the patient meets the hospital's criteria for surgery. Thus, we believe that the activities required by this section constitute usual and customary business practices for transplant centers. Therefore, pursuant to 5 CFR 1320.3(b)(2), we will not include these activities in the burden analysis for this final rule.

Section 482.92 Condition of Participation: Organ Recovery and Receipt

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

The burden associated with this section is the time required to develop these written protocols. We believe that developing written protocols for critical functions such as those required by this section reflect usual and customary business practice for transplant centers. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2).

Section 482.94 Condition of Participation: Patient and Living Donor Management

Transplant centers must have written patient management policies for the 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 develop written patient management policies. We believe that it is usual and customary business practice for

transplant centers, as it would be for any major health care facility, to have written patient management policies. Thus, under 5 CFR 1320.3(b)(2), these activities should be excluded from any burden analysis.

In addition, § 482.94(b) requires that transplant centers must keep their waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

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

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

Section 482.94(c) requires transplant centers to maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

Section 482.94(c)(1) states that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of: (i) The patient's placement on the center's waiting list; (ii) The center's decision not to place the patient on its waiting list; or (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

Section 482.94(c)(2) states that if a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified of his or her removal from the waiting list no later than 10 days after

the date the patient was removed from the center's waiting list.

Section 482.94(c)(3) states that in the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary patient care planning during the transplant period and multidisciplinary discharge planning for post-transplant care.

The burden associated with this section, except for notifying dialysis facilities, is the time required for a transplant center to document all the necessary information and maintain the waiting list. As described above, all transplant centers must already follow OPTN requirements for notification of patients and maintenance of their waiting lists. We believe that most, if not all, transplant centers have business practices that already comply with this section. For the remainder of centers, compliance should require only a minimal burden.

Under 5 CFR 1320.3(b)(2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to satisfy this section constitute usual and customary business practices, the burden associated with them will not be included in our PRA analysis for this final rule.

Section 482.94(c)(1) and (2) require kidney transplant centers, in the case of dialysis patients, to 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 all changes in the patient's transplant status as required under § 482.94(c)(1). Since this is not a requirement for OPTN members, we do not believe that all kidney transplant centers are currently notifying dialysis facilities.

The burden associated with this requirement is the time it would take for the transplant center to notify the various dialysis facilities of the status of their patients on the transplant center's waiting list. Rather than notifying

dialysis facilities on an individual basis, we believe that transplant centers would chose to periodically notify the dialysis centers about their patients' status. Thus, for the purposes of determining the burden for this requirement, we will assume quarterly notifications by the transplant centers to the dialysis facilities. Note that this final rule does not establish a time frame transplant centers must use to notify dialysis centers about patient status. We are using quarterly notification only to estimate an economic impact for this notification requirement.

According to UNOS, as of December 31, 2005, there were 64,848 individuals awaiting kidney transplants. Currently, there are approximately 4,649 dialysis facilities and approximately 243 Medicare-approved kidney transplant centers. Therefore, the average transplant center will have to notify 19 dialysis clinics about the waiting list status of their patients (4,649 dialysis facilities divided by 243 Medicare-approved kidney transplant centers = 19.13 dialysis centers). Since there are 64,848 patients waiting for kidney transplants and 4,649 dialysis facilities, there are an average of 14 patients on the waiting list for kidneys at each dialysis facility (64,848 patients divided by 4,649 dialysis facilities = 13.9). Thus, for each of the 243 kidney transplant centers, there are about 267 waiting list patients (64,848 patients divided by 243 transplant centers = 266.86 or 14 patients per dialysis facility \times 19 dialysis facilities = 266). Therefore, on average, each transplant center would have to determine the status of about 267 patients and notify an average of 19 dialysis facilities about the status of these patients 4 times a year.

Based upon our past experience, we believe that this notification would require the involvement of the transplant coordinator and appropriate support/clerical staff. We would anticipate that the transplant centers would utilize modern technology to minimize the burden of satisfying this requirement.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS

| Position | Hourly wage | Burden hours per event* | Cost estimate per event* | Total annual hours required (for 4 events) | Total annual cost estimate (for 4 events) |
|------------------------------|-------------|-------------------------|--------------------------|--|---|
| Transplant Coordinator | \$ 43.87 | 2.00 | \$87.74 | 8.0 | \$350.96 |
| Secretary | 21.81 | .50 | 10.90 | 2.0 | 43.62 |
| Totals | | 2.50 | 98.64 | 10.0 | 394.58 |

All salary information is from the salary.com Web site at <http://hrs.salarycenter.salary.com>.

*Each notification is an "event."

Thus, we anticipate that the burden hours for each time a transplant center notifies the relevant dialysis centers of the status of their patients on the center's waiting list would require 2.5 burden hours and the cost estimate would be \$98.64. With the transplant centers conducting these notifications on a quarterly basis, that is, 4 notifications per year for each kidney center, the total annual burden hours for each center would be 10 and the total annual cost estimate would be \$394.58. Since there are currently 243 current Medicare-approved kidney transplant centers, their total burden hours would be 2,430 (243 centers × 10 hours = 2,430) and the total cost complying with this ICR is \$95,882.94 (243 centers × \$394.58 = \$95,882.94).

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

Section 482.96 requires transplant centers to 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.

Section 482.96(b) requires transplant centers to establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. These policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events. When an adverse event is identified, the transplant center must conduct a thorough analysis of and document any adverse event.

The burden associated with this rule is the time required to develop these policies and document each adverse event. In the proposed rule, we estimated that it would take 8 hours on a 1-time basis to comply with this requirement.

Comment: Some commenters disagreed with our analysis and said that we underestimated the time and

staff hours required to comply with this section. One commenter stated that a large center would require one full-time equivalent (FTE) to comply with this requirement. Another commenter indicated that it took 160 staff hours to develop and establish the QAPI program at his or her hospital and 1.25 FTEs to maintain the program. This commenter indicated that eight hours would only be a "start" in complying with this requirement.

Response: We agree with the commenters that 8 hours is insufficient to develop the policies necessary to comply with this section. However, since all transplant centers are located in Medicare hospitals and Medicare hospitals are required to have a QAPI program (see 42 CFR 482.21), we believe that each center will have sufficient resources available to develop its own QAPI program in considerably fewer than 160 burden hours.

We believe that the typical transplant center would already have established a QAPI program as part of its usual and customary business practices and, thus, would not incur any additional associated burden. Therefore, since the activities required to comply with this section constitute usual and customary business practices, any burden associated with this requirement is exempt from the burden analysis under 5 CFR 1320.3(b)(2).

Section 482.98 Condition of Participation: Human Resources

Section 482.98(b) requires transplant centers to identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services who are immediately available to provide transplantation services when an organ is offered for transplantation.

The burden associated with this requirement is the time it will take to compile this information and forward it to the OPTN. Since this same information is required for the letter requesting initial approval for the transplant center at § 488.61(a), each

transplant center will only need to notify the OPTN of the two individuals it has designed as its primary transplant surgeon and transplant physician. This could be done electronically or by a simple form, depending upon OPTN requirements. Thus, notifying the OPTN of the same information should not result in any additional appreciable burden to the transplant centers.

Section 482.100 Condition of Participation: Organ Procurement

Section 482.100 requires a transplant center to ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

The burden associated with this rule is the time required to draft a mutually acceptable agreement between the transplant center and the designated OPO for the receipt of organs. Section 121.9 of the Department's regulations governing the OPTN requires transplant centers to have letters of agreement or contracts with an OPO. However, such a letter of agreement or contract will not satisfy the requirements of this section if it does not identify specific responsibilities for the hospital and the OPO with respect to organ recovery and organ allocation. Thus, we believe that approximately 50 percent, or 252, transplant centers will need to re-draft the letters of agreement or contracts between themselves and their designated OPOs that identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Based upon our experience with transplant centers, as well as other health care organizations, agreements of this type would require the involvement of the transplant center's attorney, medical director, administrator, transplant coordinator, and appropriate clerical/support staff. We believe that it would require a total of approximately

11 hours to negotiate and draft a mutually acceptable agreement that

would be signed by both the transplant center and OPO.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO DEVELOP AN AGREEMENT BETWEEN A TRANSPLANT CENTER AND AN OPO CONCERNING ORGAN RECOVERY AND ORGAN ALLOCATION

| Position | Hourly wage | Total annual hours required | Total annual cost estimate |
|-----------------------------------|-------------|-----------------------------|----------------------------|
| General Counsel or Attorney | \$176.86 | 4.0 | \$707.44 |
| Medical Director | 116.60 | 2.0 | 233.20 |
| Senior Administrator | 92.31 | 2.0 | 184.62 |
| Transplant Coordinator | 43.87 | 2.0 | 87.74 |
| Secretary | 21.81 | 1.0 | 21.81 |
| Totals | | 11.00 | 1,234.81 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>.

Thus, for each transplant center to negotiate and draft an agreement with its designated OPO concerning organ recovery and organ allocation, the total annual burden hours would be 11 and the total cost estimate would be \$1,234.81. For 252 transplant centers to negotiate and draft these agreements, the total burden hours would be 2772 (11 annual burden hours × 252 transplant centers = 2,268) and the total cost estimate would be \$311,172.12 (252 transplant centers × \$1,073.30).

Section 482.102 Condition of Participation: Patient and Living Donor Rights

Section 482.102 requires transplant centers to implement written transplant patient informed consent policies. The policies must inform 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) 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; (7) his or her right to refuse transplantation; and (8) the fact that if his or her transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

Section 482.102(b) also requires transplant centers to implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Each transplant center 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; (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 risk to the donor; (6) the national and transplant center-specific outcomes for recipients; and national and center-specific outcomes for living donors, as data are available; (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; and (9) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

We expect that nearly all transplant centers currently have written policies regarding informed consent. Therefore, there would be no additional burden on them, as these policies are usual and customary business practices. Therefore, the burden of these requirements is exempt under 5 CFR 1320.3(b)(2) and will not be included in our PRA analysis for this final rule.

Section 482.102(c) requires each transplant center to notify patients placed on its waiting list 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. Section 482.102(c)(1) specifically requires a transplant center served by a single transplant surgeon or physician to inform patients placed on the center's waiting list of the potential

unavailability of the transplant surgeon or physician and whether the center has a mechanism to provide an alternative transplant surgeon or transplant physician.

Comment: One commenter pointed out that complying with this requirement would entail the drafting of a letter by an administrator, approval by the surgeon, searching a database to identify appropriate patients, clerical or support resources to prepare and mail the letters, and the expense associated with actually mailing the letters. The commenter pointed out that this would be an extensive and unrealistic use of resources for short-term unavailability issues, such as the absence of the transplant surgeon.

Response: As discussed earlier in this preamble, this provision does not require transplant centers to inform waiting list patients on an ongoing basis about the short-term unavailability of a transplant surgeon, for example, when a transplant surgeon is on vacation. The provision simply requires that, at the time a patient is placed on the waiting list, the patient is informed about circumstances that could impact the patient's ability to receive a transplant should an organ become available and what procedures the transplant center has in place to address these circumstances. Clearly, this requirement is particularly important when a transplant center is served by a single transplant surgeon or transplant physician. We expect that most transplant centers already provide this information to patients when they are placed on the waiting list.

Therefore, the burden associated with this requirement is exempt under 5 CFR 1320.3(b)(2). The burden of these activities will not be included in our PRA analysis for this final rule.

Section 482.102(c)(2) states that at least 30 days before a transplant center's Medicare approval is terminated, whether voluntarily or involuntarily,

the center must inform patients on the center's waiting list of this fact and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. The transplant center must also inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval at least 30 days before their Medicare

approval is terminated. In addition, § 482.102(c)(3) requires that as soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without the loss of time accrued on the waiting list. The burden associated with this section would be the time required of a transplant center to draft a letter notifying patients on its waiting list of

the loss of the program's Medicare approval status and, by mail or otherwise, provide the letter to all patients on the center's waiting list. We estimate that it would require an administrator approximately 30 minutes to draft the letter. It would then require a secretary or other support staff person 2.5 hours to copy and/or mail these letters to the individuals on the center's waiting list(s). Based on our estimate, complying with this section would require three burden hours and the total cost would be \$100.69.

TOTAL BURDEN HOURS AND TOTAL COST ESTIMATE FOR NOTIFYING PATIENTS ON A CENTER'S WAITING LIST OF A TRANSPLANT CENTER'S LOSS OF MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|----------------------------|-------------|----------------|---------------------|
| Senior Administrator | \$92.31 | .50 | \$46.16 |
| Secretary | 21.81 | 2.50 | 54.53 |
| Totals | | 3.00 | 100.69 |

All salary information is from the salary.com Web site at <http://hrs.salarycenter.salary.com>.

As discussed in more detail below under section § 488.61, we believe that, based upon the requirements contained in this final rule, up to two percent of transplant centers or approximately 10 centers may lose their Medicare-approved status annually. If 10 centers annually lost their Medicare-approved status, either voluntarily or involuntarily, then the total annual burden hours would be 30 (10 transplant centers × 3 burden hours = 30 total burden hours) and the total annual cost estimate would be \$1,006.90 (\$100.69 cost estimate × 10 transplant centers = \$1,006.90).

Section 482.104 Condition of Participation: Additional Requirements for Kidney Transplant Services

Section 482.104(a) states that a kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

The burden associated with this requirement is the time and effort it would take for a kidney transplant center to develop the written policies and procedures for such communication. Under this final rule, one of the responsibilities of the clinical transplant coordinator is to act as a liaison between a kidney transplant center and dialysis facilities. (See § 482.98(c)(2).) We believe that most centers currently use their clinical transport coordinators in this role. Most centers will be able to meet this requirement by putting their current

practice into writing. This will probably be done by the clinical transplant coordinators. Since they are memorializing their current practices, we believe it can be accomplished in a very short time. We believe that this communication policy and procedures will be straightforward and can be accomplished quickly by the coordinators. In addition, many centers may already have such policies and procedures in writing. Thus, complying with this requirement will constitute a minimal burden to the centers.

Section 488.61 Special Procedures for Approval And Re-Approval of Organ Transplant Centers

Section 488.61(a) requires transplant centers that are not Medicare-approved as of June 28, 2007 to submit a request to CMS for Medicare approval. Section 488.61(b) requires transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007 to submit a request for Medicare approval no later than December 26, 2007. The process for making the request for Medicare approval is the same for both types of transplant centers. (See § 488.61(b)(1).) The request for Medicare approval must be signed by a person authorized to represent the center (for example, a chief executive officer). The request must include the hospital's Medicare provider identification (I.D.) number; the 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.

The burden associated with this section would be the time required to prepare and submit this letter to us. In addition, the center would have to obtain a statement from the OPTN that the center had complied with all data submission requirements to submit with the letter.

In the proposed rule, we estimated that each hospital would spend approximately 15 minutes to prepare and submit the letter requesting Medicare approval to us. We did note that a hospital may have multiple transplant centers and, therefore, could be submitting more than one request for approval.

Comment: We received public comments on the proposed rule that said we had underestimated the time required for a transplant center to apply for Medicare approval. One commenter emphasized that transplantation centers take applying for Medicare approval very seriously. The commenter also indicated that the preparation, approval, and submission of the request for Medicare approval could take days at many large institutions.

Response: After further analysis of the tasks and the personnel that would be involved in applying for Medicare approval, we agree with the commenters that 15 minutes significantly underestimates the time required to prepare, obtain the required center approval(s), obtain the statement from

the OPTN, and submit the request for Medicare approval to us. However, we disagree with the commenter that said it could take "days" to accomplish all of the required tasks. Our analysis of the total burden hours and total cost estimate are discussed in detail below.

We now believe that accomplishing all of the tasks necessary for complying with § 488.61(a) would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff. We estimate that it

would take these individuals approximately the same amount of time as it would take the transplant center to notify us of a significant change in their program or approximately 2 burden hours.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR A TRANSPLANT CENTER TO APPLY FOR MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|------------------------------|-------------|----------------|---------------------|
| Medical Director | \$116.60 | .50 | \$58.30 |
| Senior Administrator | 92.31 | .50 | 46.16 |
| Transplant Coordinator | 43.87 | .75 | 32.90 |
| Secretary | 21.81 | .25 | 5.45 |
| Totals | | 2.00 | 142.81 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>.

This final rule requires all transplant centers that are currently Medicare-approved to apply for initial approval under the requirements in this final rule. There are currently approximately 504 Medicare-approved transplant centers. We believe that all 504 transplant centers will submit requests to us to retain their Medicare approval. In addition, based on our previous experience, we believe that approximately 10 new centers a year may apply for Medicare approval. Thus, we anticipate 514 transplant centers will be applying for Medicare approval of their transplant programs in the first year following the effective date of this final rule.

For the first year after the effective date of this final rule, the total burden hours would be 1,028 (514 transplant centers × 2 burden hours = 1,028 total burden hours), and the total cost estimate would be \$73,404.34 (514 transplant centers × \$142.81 = \$73,404.34). For subsequent years, we anticipate that about 10 transplant centers will request initial Medicare approval. For those subsequent years, the total burden hours are 20 (10 transplant centers × 2 burden hours = 20 total burden hours) and the total cost estimate would be \$1,428.10 (10 transplant centers × \$142.81 = \$1,428.10).

Section 488.61(d) allows transplant centers that have lost their Medicare approval to 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 at § 488.61(a);

(2) Be in compliance with §§ 482.72 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 us documenting any changes or corrective action(s) taken by the center as a result of the loss of its Medicare approval status.

The burden associated with this section would be the time required to prepare and submit the request for approval to us pursuant to § 488.61(a) and the time to prepare and 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. After further analysis of the tasks that would be involved and the personnel that would be needed, we believe that developing and submitting the required plan would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff.

In the proposed rule, we said that we believed no more than 9 entities would be affected by this requirement which made it exempt from the PRA, in accordance with 5 CFR 1320.3(c). This was based on our previous experience with transplant centers. Previously, only five centers had voluntarily terminated their Medicare approval.

However, this final rule has minimum clinical experience, outcome, and process requirements that transplant centers must meet to obtain initial

Medicare approval and to stay in the program. Considering these requirements, we anticipate that more centers may voluntarily terminate their Medicare approval status in order to give themselves time to correct any problems they may have in meeting these requirements. In addition, it may become more common for transplant centers to be involuntarily terminated. Therefore, we estimate that up to two percent or approximately 10 of the currently Medicare-approved centers may lose their status at some point in any given year and later seek to re-enter the program.

We believe that accomplishing all of the tasks necessary for complying with § 488.61(d) would require the same staff as needed for § 488.61(a) and (b). However, we also believe that the center requesting re-entry into the Medicare program will spend more time preparing the request due to the preparation of the report documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status. Thus, we believe that a transplant center complying with this sub-section's requirements would require a total of 5 burden hours and have a total cost estimate of \$329.50. In any given year, we anticipate as many as 10 centers may seek to re-enter the Medicare program. For these 10 centers, the total burden hours would be 50 (10 centers × 5 burden hours to re-apply = 50 total burden hours) and the total cost estimate would be \$3,295.00 (\$329.50 per center to re-apply × 10 centers = \$3,295.00).

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR TRANSPLANT CENTERS SEEKING RE-ENTRY INTO THE MEDICARE PROGRAM AFTER LOSS OF MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|------------------------------|-------------|----------------|---------------------|
| Medical Director | \$116.60 | 1.00 | \$116.60 |
| Senior Administrator | 92.31 | 1.00 | 92.31 |
| Transplant Coordinator | 43.87 | 2.50 | 109.68 |
| Secretary | 21.81 | .50 | 10.91 |
| Totals | | 5.00 | 329.50 |

All salary information is from the salary.com Web site at <http://hrs.salarycenter.salary.com>.

Thus, for all of the PRA requirements in this rule, the total burden hours for the first year are 8,830, and the total cost estimate is \$659,989.50. For subsequent years the total burden hours are 5,554 and the total cost estimate is \$317,541.66. The burden hours and cost estimate are detailed in the chart below. All of the PRA requirements noted in this chart constitute new collections of information.

SUMMARY OF PRA REQUIREMENTS FOR TRANSPLANT CENTERS (TCs) IN THE FIRST YEAR OF THIS FINAL RULE

| PRA requirement | Total annual cost estimate per TC | Total annual burden hours (BHs) per TC | Total annual cost estimate for "X" TCs | Total annual burden hours (BHs) for "X" TCs |
|--|-----------------------------------|--|--|--|
| § 482.74—Notification to CMS of Significant Changes. | \$428.43 | 6.0 | \$215,928.72 for 504 TCs (currently there are 504 Medicare approved TCs). | 3,024 BHs for 504 TCs (currently there are 504 Medicare approved TCs). |
| § 482.94(c)(3)—Notification to Dialysis Facilities of Patients' Waiting List Status. | 394.58 | 10.0 | \$95,882.94 for 243 TCs (currently there are 243 Medicare-approved kidney TCs). | 2,430 BHs for 243 TCs (currently there are 243 Medicare-approved kidney TCs). |
| § 482.100—Development of Agreement Between T.C. and Each OPO on Organ Recovery and Allocation ¹ . | 1,234.81 | 11.0 | \$311,172.12 for 252 TCs (we estimate that about 50 percent, or 252, TCs will need to re-draft letters of agreements of contracts between themselves and their designated OPOs). | 2,772 BHs for 252 TCs (we estimate that about 50 percent, or 252, TCs will need to re-draft letters of agreements of contracts between themselves and their designated OPOs). |
| § 482.102(c)(2)—Notification of Patients on Waiting List of Loss of Medicare Approval. | 100.69 | 3.0 | \$1,006.90 for 10 TCs (we estimate that about 10 TCs would lose their Medicare Approval each year). | 30 BHs for 10 TCs (we estimate that about 10 TCs would lose their Medicare Approval each year). |
| § 488.61(a)—Application for Medicare Approval ² . | 142.81 | 2.0 | \$73,404.34 for 514 TCs (first year—all 504 currently Medicare-approved TCs would need to apply and we estimate that 10 new TCs would also apply for a total of 514 TCs applying for Medicare approval in the first year). | 1,028 BHs for 514 TCs (first year—all 504 currently Medicare-approved TCs would need to apply and we estimate that 10 new TCs would also apply for a total of 514 TCs applying for Medicare approval in the first year). |
| § 488.61(d)—Application to Re-Enter Medicare Program. | 329.50 | 5.0 | \$3,295.00 for 10 TCs (we estimate that 10 TCs who had lost their Medicare approved status would seek to re-enter the Medicare Program each year).. | 50 BHs for 10 TCs (we estimate that 10 TCs who had lost their Medicare approved status would seek to re-enter the Medicare Program each year). |
| Totals | 2,630.82 | 37.0 | 700,690.02 | 9,334 BHs. |

¹ These estimates are for the first year of implementation only. After the first year, we estimate that fewer than 10 transplant centers will need to comply with this requirement. Therefore, in subsequent years, this requirement would not be subject to the PRA.

² This estimate is for the first year only. In subsequent years, we estimate that only 10 new transplant centers will apply for Medicare approval each year. Thus, for subsequent years, the estimated burden hours will be 20 (2 BHs × 10 TCs) and the cost estimate will be \$1,428.10 (\$142.81 × 10 TCs).

If you comment on 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, Division of Regulations Development, Attn.: Melissa Musotto, CMS-3835-F,

Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS-3835-F,

carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the

Regulatory Flexibility Act (RFA) (September 16, 1980 Public Law 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 new 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 final rule to be a cost of \$28,420,259 and a benefit of \$1,257,516 in the first year. The social benefits that should result from implementation of this final rule are significant. However, we have no reasonably accurate method of quantifying those social benefits. Thus, we do not believe that this final rule is economically significant.

The RFA requires agencies to analyze options for regulatory relief of small entities. 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 will not have a significant impact on a substantial number of small businesses because most of the requirements in this final rule are already part of the transplant centers' standard practices.

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 604 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 (superseded by Core Based Statistical Areas) and has fewer than 100 beds. We believe this final rule will 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 or more. 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 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 final rule will not significantly affect the rights, roles, and responsibilities of states.

This final rule will 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. Thus, while we do not believe the requirements will have a significant economic impact on these facilities, we believe it is desirable to inform the public of the likely effect of this final rule on those facilities. Thus, we have prepared the following analysis, which in combination with the other sections of this final rule, is intended to conform to the objectives of the RFA and section 1102(b) of the Act.

B. Anticipated Effects

Our intent in developing and implementing these CoPs for transplant centers is to ensure Medicare-covered transplants are performed in an effective, efficient manner and that high quality transplantation services are provided to Medicare beneficiaries. This is critical due to the scarcity of transplantable organs for the individuals on organ transplant waiting lists. This final rule also serves to keep Medicare requirements current with the best practices in transplantation. We believe that adherence to these outcomes and process requirements will result in reduced organ wastage and, as a consequence, fewer graft failures and re-transplantations. We do not anticipate that the changes in our requirements for transplant centers will affect the number of organ transplants performed because this final rule will have no effect on the number of organs available for transplantation.

This final rule will establish CoPs for transplant centers that perform organ transplants. The final rule will maintain many of the same requirements that are in the current National Coverage Decisions (NCDs) for heart, liver, lung, and intestine transplants, and conditions for coverage (CfCs) for kidney transplant centers in 42 CFR, Part 405, subpart U. Some of the requirements in this final rule could result in additional costs for some centers. Although we do not believe the requirements in this final rule will 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 this final rule. There are two reasons this final rule will have a minimal economic effect.

As of October 1, 2006, 504 Medicare-approved transplant centers potentially will be affected by the requirements in this final rule to a greater or lesser degree. However, we believe the majority of the transplant centers have already put into practice most of the process requirements contained in this final rule. Since these requirements, for the most part, reflect advances in transplantation technology, we believe they are routine or standard practices for most transplant centers. Furthermore, although this final rule requires a large amount of data to be submitted, transplant centers are already submitting these data to the OPTN.

General Comments

In the public comments to the proposed rule, some commenters said that CMS had underestimated the impact the requirements in the proposed rule would have on transplant centers. They stated that the number of hours and the costs associated with some requirements were either inaccurate or were underestimated.

We agree with the commenters that in certain instances the economic impact was underestimated in the proposed rule. We have performed further analysis of the tasks and resources required to satisfy the CoPs in this final rule, and we have reviewed more recent economic data. Based on this further analysis, we have adjusted our estimate of the economic impact for the final rule. These adjustments are discussed below for each relevant condition of participation.

Some commenters said that some of the CoPs in the proposed rule were unnecessary because some of the requirements are similar or even identical to either current OPTN or JCAHO requirements. We agree that

some of the CoPs are similar or perhaps even identical to OPTN or JCAHO requirements. However, for these requirements to be mandatory and enforceable by CMS through our survey and certification process, they must be promulgated as regulations.

Some commenters expressed concern that these new requirements would increase costs. One commenter noted that increased costs could result in increased organ acquisition fees and subsequent increased expenses to the Medicare program and could also reduce access to transplantation services for some individuals. The commenter speculated that hospitals could have difficulty contracting with managed care organizations due to the increased costs.

As we stated above, we do not believe this rule will have a significant economic impact on most transplant centers because most of the requirements are routine practice in the majority of centers. In addition, all transplant centers are located in hospitals and thus, already have access to resources that should minimize the additional costs needed to satisfy the requirements in this final rule. Only the costs associated with the donor advocate or donor advocate team requirements will affect organ acquisition fees. We estimate that in the first year of its implementation, the requirements in this final rule will increase the cost of a transplant by approximately \$1,071 per transplant (\$28,420,256 total first year costs divided by 26,539 total transplants in 2004 = \$1,070.88 or about \$1,071). However, in subsequent years, the increase will drop to approximately \$360 per transplant (about 9,566,291 implementation costs in subsequent years divided by 26,539 total transplants in 2004 = \$360.46 or approximately \$360). In light of the fact that the total first-year cost of an organ transplant (including both hospital and physician charges) varies from about \$175,000 for a kidney transplant to nearly \$400,000 for a heart transplant, the impact of this rule will be negligible. Thus, hospitals should have no difficulty contracting with managed care organizations due to the requirements in this final rule.

Section 482.72 Condition of Participation: OPTN Membership

Section 482.72 requires each transplant center to be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). Under § 482.45(b)(1) of the hospital CoPs, all transplant centers that are currently Medicare-approved are

required to be located in hospitals that are members of the OPTN and that abide by the OPTN's rules. Thus, there is no additional burden or economic impact associated with this condition to centers that currently have Medicare approval. Since this final rule requires centers to perform a certain number of transplants prior to applying for Medicare approval, new centers also will be members of the OPTN. Thus, there is no economic impact from this requirement to centers that will be applying for Medicare approval after the effective date of this rule.

Section 482.74 Condition of Participation: Notification to CMS

Section 482.74 requires a transplant center to notify us immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the applicable CoPs. Instances in which CMS should be notified include, but are not limited to, changes in key staff members of the transplant team; a decrease in the center's number of transplants or survival rates that could result in the center being out of compliance with § 482.82; termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs; and inactivation of the transplant center.

We believe that satisfying this requirement would require the involvement of the program's medical director, an administrator, a transplant coordinator, and appropriate support or administrative staff. Based upon our previous experience with transplant centers, we believe that three significant changes per year per center is an appropriate estimate. We also believe that it would take the above described personnel approximately 2 hours to comply with this section.

Thus, each time a transplant center is required to report a significant change to us, the total economic impact or cost estimate is \$142.81. For the estimated three significant changes per transplant center per year, the total cost estimate would be \$428.43. Since there are currently approximately 504 Medicare-approved transplant centers, the total annual cost estimate for complying with this section is \$215,928.72 (\$428.43 annual cost estimate per center × 504 transplant centers = \$215,928.72).

Section 482.76 Condition of Participation: Pediatric Transplants

Section 482.76 requires transplant centers that want Medicare approval to provide transplant services to pediatric patients to submit to us a request

specifically for Medicare approval to perform pediatric transplants using the procedures described in § 488.61, Special procedures for approval and re-approval of organ transplant centers. Section 482.76(d) allows heart transplant centers that want to provide transplantation services to pediatric heart patients to be approved to perform pediatric heart transplants by meeting the OBRA 1987 criteria in section 4009(b) (Pub. L. 100-203) as follows: (1) The center's pediatric transplant program must be operated jointly by the hospital 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.

We believe that most transplant centers that want to obtain Medicare approval to do pediatric transplants will use the procedures at § 488.61. Therefore, the economic impact for centers requesting approval to do pediatric transplants will be discussed under that section. For those centers that want to request approval using the alternative criteria, we believe there will be some impact, but it will be minimal and should affect very few centers. Currently, there are approximately 13 pediatric heart centers; 6 of these centers are Medicare approved. Based on these figures, we expect that no more than one pediatric heart center will apply for Medicare approval per year.

Section 482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant Centers

Section 482.80 requires that transplant centers must generally meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS. Section 482.80(a) states that 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 the required data on all transplants, (deceased and living donors) it has performed. The required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up. However, transplant centers already

submit these data to the OPTN, using the time frame specified by the OPTN, as required by 42 CFR 121.11, which regulates transplant hospitals' submission of data to the OPTN. Therefore, there is no additional cost to transplant centers from the data submission requirement in this final rule. Section 482.80(b) establishes a clinical experience requirement of 10 transplants in a 12-month period for initial Medicare approval for heart, intestine, kidney, liver, and lung transplant centers. The clinical experience requirement for initial approval for kidney centers is 3 transplants in a 12-month period. (See § 482.80(d)(5).)

Current national coverage decisions require 10 transplants for intestine and lung centers and 12 transplants for liver and heart centers. Current conditions for coverage for kidney transplant centers require 15 or more kidney transplants annually for a center to have unconditional status. Thus, all currently approved transplant centers should be performing the minimum number of transplants required.

Furthermore, even if a center does not meet the clinical experience requirements, we may grant the center initial Medicare approval based on a review of the center's compliance with the relevant conditions of participation at § 482.72 through § 482.76 and § 482.90 through § 482.104. (See § 488.61(a)(3).)

Nevertheless, some centers may not be granted Medicare approval due to their failure to satisfy the clinical experience requirements. Loss of Medicare approval is likely to result in the center losing patients. If a center with current Medicare approval applies for and is denied Medicare approval under this final rule, it has the option to leave the Medicare program voluntarily until it can satisfy the requirements.

Although we believe the economic impact of the clinical experience requirements will be minimal, we are not aware of any research that quantifies the cost or benefit to a hospital of having a transplant center. Anecdotal information indicates that some hospitals with a transplant center lose money or break even but that some hospitals experience a financial benefit. Whether a transplant center is a benefit or a cost to a hospital may depend at least in part on the type of organ transplanted, the volume of transplants performed, and the center's operational efficiency.

We also recognize that there may be benefits and/or costs to Medicare beneficiaries and other patients on the

waiting lists of centers that lose Medicare approval, although we do not believe it is possible to quantify the benefits or costs. Benefits would include improved patient safety and better outcomes for patients who transfer to the waiting lists of transplant centers that furnish higher quality transplantation services. Costs could include increased cost for transportation to a center that is farther from a waiting list patient's home and an increase in the time until an organ becomes available, with the potential for increased morbidity and mortality.

Section 482.80(c) states that 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. Outcome data must be available for review. 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 reports. (See § 488.61(d)(1).) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report. (See § 488.61(c)(2).) CMS will not consider a center's patient and graft survival rates to be acceptable if: (1) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and (2) 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. (See § 488.61(c)(3).)

Current national coverage decisions for heart, liver, lung, and intestine transplants already contain outcome requirements. However, those outcome requirements only concern patient (not graft) survival rates. The outcome requirements associated with § 482.80(c) are more comprehensive because they include graft survival. We believe that more centers may have difficulty in meeting these new standards. However, under § 488.61(a)(3), CMS, as an option, may approve a center that does not meet the patient and graft survival if a survey of the center demonstrates that the center was in compliance with § 482.72

through § 482.76 and § 482.90 through § 482.104. In addition, a center also may choose to withdraw voluntarily from the Medicare program and seek re-entry after it has corrected any problems. (See 42 CFR § 488.61(d).) Thus, we believe the economic impact from the new outcome measures will be minimal.

Section 482.82 Condition of Participation: Data Submission, Clinical Experience, and Outcome Measure Requirements for Re-Approval of Transplant Centers

Section 482.82 provides that transplant centers must generally meet all data submission, clinical experience, and outcome requirements in order to be re-approved. The data submission, clinical experience, and outcome requirements and exceptions to those requirements generally are identical to those in § 482.80, which contains the requirements for initial approval. However, in this section, the review will cover the 3-year approval period.

The economic impact of this section is the same as the economic impact of § 482.80, except that transplant centers will have to comply with these requirements for the entire time they have Medicare approval. Thus, the economic impact associated with this section constitutes an annual economic impact for all of the centers with Medicare approval. However, we believe the economic impact will be minimal.

Section 482.90 Condition of Participation: Patient and Living Donor Selection

Section 482.90 requires transplant centers to use written patient selection criteria in determining a patient's suitability for placement on the waiting list 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.

Section 482.90(a) requires that before a prospective transplant candidate is placed on a center's waiting list, each prospective transplant candidate shall receive a psychosocial evaluation, if possible. In addition, the candidate's medical record must contain documentation that the candidate's blood type has been determined. When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used. A transplant center must provide a copy of its patient selection criteria to a transplant patient,

or a dialysis facility, as requested by the patient or the dialysis facility.

In our experience, all or nearly all transplant centers conduct psychosocial evaluations of transplant candidates. Such evaluations are performed routinely so that centers can evaluate how well a prospective candidate will do after transplantation (for example, whether the patient is likely to be compliant with the immunosuppressive medications needed to prevent graft failure). Thus, we expect no economic impact from this requirement for most transplant centers.

In the public comments we received on the proposed rule, some commenters said that the patient selection criteria requirements would be burdensome. For example, one commenter said that it would take at least 30 minutes of staff time to document the patient selection criteria in the file of each patient or living donor. Some commenters indicated that the patient selection criteria would need constant updating. They also noted that the proposed rule did not contain an analysis of the economic impact for this requirement.

We disagree that the requirement to have written patient selection criteria would have a significant impact on transplant centers. We expect that heart, liver, and lung transplant centers already have patient selection criteria because current NCDs require these centers to have such criteria. Further, Medicare coverage of pancreas and intestine transplants is based on specific clinical indicators. Although there are no current requirements for kidney transplant centers to have patient selection criteria, based on our experience, we expect that all or nearly all centers already have such criteria because many kidney transplant centers provide their patient selection criteria to local dialysis facilities. Therefore, complying with this requirement should have no additional impact on heart, liver, and lung centers and only a minimal impact on other transplant centers.

We believe that transplant centers should be able to document the patient selection criteria in a patient's medical record in considerably less than 30 minutes. Generally, documenting the patient selection criteria in a patient's medical record should involve no more than tracking the patient's primary diagnosis and any co-morbid conditions to the appropriate patient selection criteria. Under this final rule, each center has the flexibility to determine the most expedient way to satisfy this requirement. Centers should be able to significantly reduce the resources needed to document the required

information in the potential transplant recipient and living donor medical records by using electronic formats, forms, or checklists.

In addition, it is standard medical practice to document in the medical record of a hospital patient undergoing surgery whether the patient meets the hospital's criteria for surgery. Although we do not know how many prospective transplant candidates would be interested in requesting a copy of a transplant center's patient selection criteria, we believe that the activities required by this section would have a minimal economic impact on transplant centers. Supplying a copy of patient selection criteria to a dialysis facility at its request can be done electronically and should require only minimal effort. Thus, we believe that the activities required by this section would require no additional staff and have only a minimal economic impact on transplant centers.

Section 482.90(b) provides that transplant centers performing living donor transplants must ensure that each prospective living donor receives a medical and psychosocial evaluation prior to donation and must document in the living donor's medical records both the living donor's suitability for donation and that the living donor has given informed consent, as required under § 482.102.

We expect the economic impact of these living donor requirements to be minimal, as they are similar to the requirements for transplant patients discussed previously. Due to the potential risks associated with donation, we expect that every transplant center that performs living donor transplants already has criteria for the selection of living donors, as well as protocols that require a medical and psychosocial evaluation of the donor. In addition, as with any other surgical procedure, documenting a living donor's informed consent should be standard practice for any transplant center. Thus, we believe that these activities would constitute a minimal economic burden to centers that perform living donor transplants.

Section 482.92 Condition of Participation: Organ Recovery and Receipt

Transplant centers must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. There are also specific requirements related to each of these processes, such as a requirement that the transplanting surgeon and another licensed health care

professional 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. (See § 482.90(b).)

We expect that all transplant centers already have written protocols for critical functions addressed within this section. Although some centers' protocols may need to be reviewed and revised so that they satisfy the requirements in this section, the economic impact will be negligible.

Section 482.94 Condition of Participation: Patient and Living Donor Management

Transplant centers must have written patient management policies for the 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.

We expect that it is standard practice for transplant centers to have written policies for the evaluation, transplant, and discharge phases of transplantation. Thus, developing written policies for these areas should have no economic impact on most transplant centers. However, we acknowledge that some of the centers' written policies may need to be revised to satisfy the individual standards in this section. Thus, the economic impact of individual standards will be discussed below.

Section 482.94(a) states that a transplant center's patient and donor management policies must ensure that each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation. If the center performs living donor transplants, the same patient care requirement applies for living donors throughout the donor evaluation, donation, and discharge phases of donation.

We believe that it is a standard practice for hospitals to have patient management policies that cover both the in-patient stay and discharge planning. Thus, we expect that transplant centers already have patient and donor management policies for the transplant and the discharge phases of transplantation. Due to the potential risks to living donors, we expect that every transplant center that performs living donor transplants already has written policies that cover the evaluation of living donors. We acknowledge that publication of this final rule may cause some centers to

review or revise their policies to ensure that they are in compliance. However, the economic impact on these transplant centers will be minimal.

Section 482.94(b) requires that transplant centers must keep their waiting lists up to date on an ongoing basis, including: (1) Updating of waiting list patients' clinical information; (2) removing patients from the center's waiting list 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 waiting list; and (3) notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

We believe these activities are standard practice for most transplant centers. Transplant centers must keep their patients' clinical information updated to ensure that organ offers are made for patients appropriately, based on their clinical status. Further, the OPTN requires transplant centers to: (1) Remove a patient from the waiting list if the patient receives a transplant or dies; and (2) notify the OPTN within 24 hours of the patient's transplantation or death. Thus, there should be no economic impact on transplant centers from this requirement.

Section 482.94(c) requires transplant centers to maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

Section 482.94(c)(1) states that for each patient who receives an evaluation for placement on a center's waiting list, the center must document in the patient's record that the patient has been informed of his or her transplant status, including notification of the patient's placement on the center's waiting list, the center's decision not to place the patient on its waiting list, or the center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

Section 482.94(c)(2) states that if a patient on the center's waiting list is removed for any reason other than death

or transplantation, the center must document in the patient's record that the patient was notified no later than 10 days after the date the patient was removed from the center's waiting list.

Section 482.94(c)(4) states that in the case of patients admitted for organ transplants, transplant centers must maintain written records of multidisciplinary patient care planning during the transplant period and multidisciplinary discharge planning for post-transplant care.

All transplant centers must follow OPTN requirements regarding notification of patients and maintenance of their waiting lists. If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, § 482.94(c)(2) requires the transplant center to document in the patient's record that the patient was notified not later than 10 days after the date the patient was removed from the waiting list. The OPTN already requires this notification, and documentation of the patient's record would be usual and customary business practice. Since we expect that all transplant centers are already complying with this requirement, there should be no economic impact on transplant centers from this requirement of the final rule. Thus, we believe that transplant centers already comply with the requirements in § 482.94(c), with the exception of the requirement for notification of dialysis facilities. Therefore, there is no economic impact on transplant centers from these requirements.

Sections 482.94(c)(1) and (2) require kidney transplant centers, in the case of dialysis patients, to notify the patients' usual dialysis facility. Since this is not an OPTN requirement, we do not believe that all transplant centers currently notify dialysis facilities about this information. When a kidney transplant center must notify a patient within 10 days about a change in status, the transplant center could choose to inform the dialysis facility at the same time it notifies the patient. If it did, we believe the burden of complying with this requirement would be minimal. However, the transplant center also could choose to notify the dialysis

facilities periodically about other changes in status.

For the purpose of estimating the economic impact, we will assume that rather than notifying dialysis facilities on a flow basis for each patient, transplant centers will update dialysis centers periodically about the status of all patients. Thus, for the purposes of determining the burden for this requirement, we will assume quarterly notifications by transplant centers to dialysis facilities.

According to the OPTN, as of December 31, 2005, there were 64,848 individuals awaiting kidney transplants. Currently, there are 4,649 dialysis facilities in the United States. Since the number of patients at these facilities varies greatly, the following analysis will use the average number of dialysis patients at a facility. There are currently approximately 243 Medicare-approved kidney transplant centers. Therefore, each transplant center has patients on its kidney transplant waiting list from an average of 19 (4,649 dialysis facilities divided by 243 Medicare-approved kidney transplant centers = 19.13) dialysis centers. Since there are 64,848 patients waiting for kidney transplants and 4,649 dialysis facilities, each transplant center has an average of 14 kidney waiting list patients at each dialysis facility (64,848 patients divided by 4,649 dialysis facilities = 13.9). For each of the 243 kidney transplant centers, there are about 267 patients (64,848 patients divided by 243 transplant centers = 266.86 or 14 patients per dialysis facility × 19 dialysis facilities = 266). Thus, on average, each transplant center will have to determine the status of about 267 patients and notify an average of 19 dialysis facilities about the status of these patients 4 times per year.

Based upon our past experience, we believe that this notification will require the involvement of the transplant coordinator and appropriate support/clerical staff. We anticipate that transplant centers will utilize modern technology to minimize the burden of satisfying this requirement.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS

| Position | Hourly wage | Burden hours per event | Cost estimate per event | Total annual hours required (for 4 events) | Total annual cost estimate for 4 events) |
|------------------------------|-------------|------------------------|-------------------------|--|--|
| Transplant coordinator | \$43.87 | 2.00 | \$87.74 | 8.0 | \$350.96 |
| Secretary | 21.81 | .50 | 10.90 | 2.0 | 43.62 |

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO NOTIFY DIALYSIS FACILITIES OF THEIR PATIENTS' WAITING LIST STATUS—Continued

| Position | Hourly wage | Burden hours per event | Cost estimate per event | Total annual hours required (for 4 events) | Total annual cost estimate for 4 events) |
|-------------|-------------|------------------------|-------------------------|--|--|
| Total | | 2.50 | 98.64 | 10.00 | 394.58 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>.

Thus, we anticipate that each quarterly notification will cost about \$98.64. With the transplant centers conducting these notifications on a quarterly basis (that is, 4 notifications per year for each kidney center), the total annual economic impact to each kidney transplant center would be \$394.58. Since there are currently about 243 Medicare-approved kidney transplant centers, the total economic impact from this requirement will be \$95,882.94 annually (243 transplant centers × \$394.58 = \$95,882.94).

Section 482.94(d) states that a transplant center must make social services, furnished by qualified social workers, available to transplant patients, living donors, and their families. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices 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) is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 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).

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 to provide social services. Further, we have been careful to retain an exception for bachelor's-prepared social workers so that transplant centers that employ these social workers do not have to replace them with master's-prepared social workers, if they were employed as social workers in the transplant center as of the effective date of this final rule and served for at least 2 years as a social worker, 1 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). Thus, satisfying this requirement would constitute a

minimal economic impact for most, if not all, centers.

Section 482.94(e) states that transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietician, available to all transplant patients and living donors. A qualified dietician is an individual who meets practice requirements in the State in which he or she practices, and is a registered dietician with the Commission on Dietetic Registration.

Some commenters said that this requirement was too expensive and burdensome. We disagree. Kidney transplant centers are required by ESRD CfCs at § 405.2171(c) to ensure patients receive nutritional services from a qualified dietician. Thus, all kidney centers currently should be providing these services to transplant patients and living donors. We expect that most extra-renal transplant centers provide nutritional services to transplant patients, because these patients have very specific nutritional needs. Some liver, lung, and intestine centers that transplant organs from living donors may need to obtain a dietician's services for their living donors if they do not already provide these services. However, since the number of living liver, lung, and intestine donors in 2004 totaled fewer than 400, we believe liver, lung, and intestine centers can obtain nutritional services for their living donors from dieticians already employed by the hospitals in which the centers are located at little cost to the center. Thus, we expect the economic impact to be minimal.

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

Section 482.96 requires transplant centers to 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.

Section 482.96(a) states that the transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to

transplantation activities and outcomes. Outcomes may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, 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.

Section 482.96(b) requires transplant centers to establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case. These policies must address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events. When an adverse event is identified, the transplant center must conduct a thorough analysis of and document any adverse event. The center must then use this analysis to effect changes in its policies and practices in order to prevent repeat incidents.

In the proposed rule, we estimated that only a minority of centers did not already have a data-driven QAPI program. For those centers that would need to develop a QAPI program that would satisfy this requirement, we estimated that a center would likely utilize an experienced individual from its hospital QAPI staff. We used the salary of a registered nurse (RN) to estimate the economic impact, since many QAPI coordinators are RNs. We noted that the 2002 mean annual income of an RN was \$42,730 and requested 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. We did not make a specific estimate of the economic burden; however, we estimated the PRA burden to be 8 hours

on a one-time basis to comply with this requirement.

Comment: Some commenters disagreed with the resources we believed would be required to satisfy this requirement. One commenter stated that a large center would require one FTE to comply with this requirement. Another commenter indicated that it took 160 staff hours to develop and establish the QAPI program at their hospital and 1.25 FTEs to maintain the program. This commenter indicated that 8 hours would be only a "start" in complying with this requirement. Others noted that the establishment, implementation, and maintenance of such a QAPI program would be much more complex and would require more resources.

Other commenters disagreed with our use of the 2002 mean annual RN salary of \$42,730. One commenter noted that a budget of \$42,000 would not cover their projected expenses to satisfy this requirement. Another commenter also noted that this was insufficient. They noted the nursing shortage and that most of the clinical coordinators who would be doing this work were generally both highly experienced and trained, and held either a bachelor's or master's degree. One commenter explicitly said that the average annual national RN salary was not the appropriate salary to use in estimating the burden associated with the QAPI requirement.

Another commenter cautioned us about assuming that the hospital's QAPI program would satisfy this requirement. The commenter stated that although a hospital QAPI program may be able to support a single transplant center, the scope and complexity of multiple transplant centers would require more resources.

Response: We acknowledge that we underestimated the economic impact of the QAPI requirement in the proposed rule. It clearly will take more than 8 hours to develop and implement the policies necessary to comply with this section. We also agree that the use of the 2002 mean annual national RN salary is inadequate. However, while we agree that a hospital QAPI program may be inadequate to fully support its transplant center, particularly if a hospital has multiple transplant centers, we believe that the hospital's QAPI program would be a substantial resource for the staff responsible for the transplant center's QAPI program.

We believe that many centers have already established and implemented a QAPI program that satisfies this final rule's QAPI requirement. However, some of the centers may need to review

and revise their programs. We believe this will constitute only a minimal economic impact to those centers.

Some centers may need to develop and implement a QAPI program. Beginning in 2003, hospitals are required to have hospital-wide QAPI programs that involve all hospital departments. (See 42 CFR 482.20.) Therefore, we believe that no more than 20 percent of the 504 currently Medicare-approved centers (101 centers) will need either to develop and implement a QAPI program or substantially revise an existing program. We also believe that no more than 40 percent of the centers (202 centers) will need to perform moderate revisions to their programs so that they will satisfy the QAPI requirements in this final rule. However, since each center is located in a hospital, we believe that centers will have substantial resources to draw upon in developing their QAPI programs.

Based on our past experience, we believe it is likely that centers will utilize an experienced staff person, possibly an experienced RN with some knowledge of the transplant program. An individual with this experience would likely be paid approximately the same as a transplant nurse coordinator or about \$91,456 annually. We have considerable experience providing guidance to OPOs in developing comprehensive QAPI programs, which has provided us with knowledge of how many staff resources are needed to implement or modify a data-driven QAPI program. We believe it will require 1 FTE for each one of the 101 centers that will need either to develop a QAPI program or perform substantial revision to an existing QAPI program. We believe it will require half of an FTE for each one of the 202 centers that will need to perform at least moderate revisions to their programs. The cost to the 101 centers that need 1 FTE would be \$9,237,056 ($\$91,456 \times 101 = \$9,237,056$), and the cost to the 202 centers that need a half FTE would be \$9,237,056 ($\$91,456$ divided by 2 = \$45,728 and $\$45,728 \times 202$ centers = \$9,237,056). The total economic impact of this requirement on the transplant centers would be \$18,474,112 ($\$9,237,056 + \$9,237,056 = \$18,474,112$).

This section also requires the centers to maintain their QAPI programs. We believe that having and maintaining a QAPI program should be considered standard practice by the transplant centers. Once the center's QAPI program is developed and implemented, we believe that maintaining it would have a minimal economic impact on the transplant centers.

Section 482.98 Condition of Participation: Human Resources

Section 482.98 states that transplant centers 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. Section 482.98(a) requires each transplant center to be under the general supervision of a qualified transplant surgeon or qualified physician-director. This director need not serve full time and may also serve as the center's primary transplant surgeon or transplant physician. Section 482.98(b) requires transplant centers to identify to the OPTN a primary transplant surgeon and a transplant physician with appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

Any economic impact associated with these requirements should be minimal. The current regulations for kidney transplant centers already require renal transplant centers to be supervised by a qualified transplantation surgeon or qualified physician-director, and we expect most extra-renal transplant centers have a director who would be considered qualified under this final rule. The OPTN requires transplant centers to have transplant surgeons and physicians with specific qualifications, training, and experience, and we believe that in most transplant centers, the primary transplant surgeon and transplant physician are immediately available to provide transplantation services when an organ is offered for a patient.

Section 482.98(c) requires transplant centers to have a clinical transplant coordinator who is either a registered nurse or other licensed clinician who has experience and knowledge of transplantation and living donation issues. Based on our experience with transplant centers, we believe that all or nearly all centers already have a clinical transplant coordinator on staff to coordinate all patient care and management activities. Therefore, we do not believe that this requirement will constitute any additional burden for transplant centers.

Section 482.98(d) states that transplant centers that perform living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure the protection of the rights of living donors and prospective living donors. This

individual(s) must not be involved in transplantation activities on a routine basis.

Due to the potential risks living donors face, we believe it is crucial that living donors have an independent living donor advocate or advocate team. In addition, due to their growing numbers, there is an urgent need to provide this type of service for these living donors. According to the 2005 OPTN/SRTR Annual Report, in 2003, there were a total of 6,820 living donors. In 2004, there were a total of 7,002 living donors, of which 6,645 were living kidney donors, 323 were living liver donors, 28 were living lung donors, and 6 were living intestine donors.

In determining an economic impact for this requirement, it is important to note that the number of living donors at a particular transplant center varies greatly. In order to estimate the economic impact, we have determined the annual average number of living donors per center, based on the annual number of living kidney and living liver donors. Since there are so few living lung and intestine donors, we have not estimated the impact of this requirement on lung or intestine transplant centers.

There are currently about 243 Medicare-approved kidney transplant programs. However, 31 of those centers perform only pediatric kidney transplants. Based on our review of data from the SRTR, pediatric kidney centers transplant very few kidneys from living donors. However, nearly all of the 212 adult kidney transplant centers perform living kidney transplants. There are currently 90 Medicare-approved liver transplant centers. However, in 2005 only about 36 percent or about 32 of those centers performed living liver transplants. We expect that at least half of the kidney and liver centers that perform living donor transplants already have a donor advocate or donor advocate team that fulfills the requirements of this final rule. Thus, we will determine an estimate of the economic impact for this requirement

based on 106 kidney transplant centers (half the number of currently Medicare-approved kidney transplant centers) and 16 liver transplant centers (half the number of currently Medicare-approved liver transplant centers that perform living transplants).

Although some centers may choose to develop an independent living donor advocate team, we believe that most centers will choose to have an independent living donor advocate. Most centers will probably choose either an RN or a social worker to fill this position. We believe that the total annual compensation for this position would be approximately \$81,124, which is the median annual total compensation for a renal dialysis staff nurse. Due to the number of living kidney donors, we believe that on average each center will need to have 1 FTE for the independent living donor advocate position. Thus, the total annual economic impact to kidney transplant centers would be \$8,599,144 ($\$81,124 \times 106$ transplant centers = \$8,599,144). However, there are far fewer living liver transplants performed per transplant center. Although each center will vary in the number of transplants performed, we estimate that on average each center will need about half FTE for an independent living donor advocate. Thus, the total annual economic impact to the liver transplant centers will be \$648,992 ($\$81,124 \times .5 = \$40,562 \times 16$ centers = \$648,992). Thus, the total economic impact for this requirement is \$9,248,136 ($\$8,599,144 + \$648,992 = \$9,248,136$).

Section 482.98(e) states that transplant centers 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.

Current NCDs for heart, liver, and lung transplant centers require them to

have multi-disciplinary transplant teams, and current CfCs for kidney transplant centers require them to have both social workers and dietitians. We believe that all transplant centers have identified their multidisciplinary transplant teams and described the responsibilities of each member of that team. Thus, we do not anticipate that this requirement will have any economic impact on centers.

Section 482.98(f) states that each transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services. Current NCDs for heart, liver, and lung transplant centers have similar requirements. Since every transplant center is part of a larger hospital, we expect that all transplant centers already have access to expertise in all of these areas. Therefore, this requirement will result in no additional economic impact.

Section 482.100 Condition of Participation: Organ Procurement

Section 482.100 requires a transplant center to ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Therefore, we expect that all centers have some type of written agreement or contract with an OPO. However, these agreements may not satisfy the requirements of this section. Thus, we believe that approximately 50 percent of the 504 centers or 252 centers would need to revise the agreements between themselves and their designated OPOs for the receipt of organs that identify specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST ESTIMATE TO DEVELOP AN AGREEMENT BETWEEN A TRANSPLANT CENTER AND AN OPO CONCERNING ORGAN RECOVERY AND ORGAN ALLOCATION

| Position | Hourly wage | Total annual hours required | Total annual cost estimate |
|-----------------------------------|-------------|-----------------------------|----------------------------|
| General Counsel or Attorney | \$176.86 | 4.0 | \$707.44 |
| Medical Director | 116.60 | 2.0 | 233.20 |
| Senior Administrator | 92.31 | 2.0 | 184.62 |
| Transplant Coordinator | 43.87 | 2.0 | 87.74 |
| Secretary | 21.81 | 1.0 | 21.81 |
| Totals | | 11.00 | 1,234.81 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>

Based on our experience with health care organizations, agreements of this type would require the involvement of the hospital's attorney and an administrator. It would also involve the transplant center's director, transplant coordinator, and appropriate clerical/support staff. We believe that it would require a total of approximately 11 hours to negotiate and draft a mutually acceptable agreement that would be signed by both the transplant center and the OPO.

For each hospital in which one of the 252 transplant centers is located, the total cost estimate to negotiate and draft an organ recovery and organ allocation agreement with its designated OPO is \$1,234.81. The total cost estimate is \$311,172.12 (252 transplant centers \times \$1,234.81 = \$311,172.12).

Section 482.102 Condition of Participation: Patient and Living Donor Rights

Section 482.102 requires transplant centers to implement written transplant patient informed consent policies that inform each patient about: (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) 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; (7) his or her right to refuse transplantation; and (8) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

Section 482.102(b) also requires transplant centers to implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. The centers must ensure that the prospective living donor is fully informed about: (1) The fact that communication between the donor and the transplant center will remain confidential; (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 risk to the donor; (6) the national and transplant center-specific outcomes for recipients; and the national and center-specific outcomes for living donors, as data are available; (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; and (9) the fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid under Medicare Part B.

We believe that all transplant centers currently have policies regarding informed consent. Although we acknowledge that some centers may need to review and revise their informed consent policies to satisfy the requirements for this section, we believe that the economic impact will be minimal.

Section 482.102(c) requires a transplant center to notify patients placed on the center's waiting list 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. Section 482.102(c)(1) specifically requires a transplant center served by a single transplant surgeon or physician to inform patients placed on the center's waiting list of the potential unavailability of the transplant surgeon or physician and to indicate whether or not the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

In the public comments we received to the proposed rule, one commenter pointed out that complying with this requirement would entail the drafting of a letter by an administrator, approval by the surgeon, searching a database to identify appropriate patients, clerical or support resources to prepare and mail the letters, and the expense associated with actually mailing the letters. The commenter pointed out that this would be an extensive and unrealistic use of resources for short-term unavailability issues, such as the absence of the transplant surgeon.

As discussed earlier in this preamble, this provision does not require that transplant centers inform waiting list patients on an ongoing basis about the short-term unavailability of a transplant surgeon, such as, when a transplant surgeon is on vacation. The provision simply requires that at the time a patient is placed on the waiting list, the patient must be informed about circumstances that could impact the patient's ability to receive a transplant and what procedures the transplant center has in place to address these circumstances. Clearly, this requirement is particularly important when a transplant center is served by a single surgeon. We expect that most transplant centers already provide this information to patients when they are placed on the waiting list. Thus, the economic impact for this requirement is minimal.

Section 482.102(c)(2) requires that, at least 30 days before a transplant center's Medicare approval is terminated, either voluntarily or involuntarily, the center must inform patients on its waiting list of this fact and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list. The transplant center must also inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's loss of Medicare approval.

Section 482.102(c)(3) requires that as soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on its waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list as soon as possible.

We expect that transplant centers would inform waiting list patients by mail. We estimate that it would require an administrator approximately 30 minutes to draft a letter. A secretary or other support staff person would copy and mail these letters to the individuals on the center's waiting list. Based on our estimate, the economic impact of performing these tasks would be \$100.69 for each center.

TOTAL BURDEN HOURS AND TOTAL COST ESTIMATE FOR NOTIFYING PATIENTS ON A CENTER'S WAITING LIST OF A TRANSPLANT CENTER'S LOSS OF MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|----------------------------|-------------|----------------|---------------------|
| Senior Administrator | \$ 92.31 | .50 | \$ 46.16 |
| Secretary | 21.81 | 2.50 | 54.53 |
| Totals | | 3.00 | 100.69 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>

In addition, the transplant center would incur costs for paper, envelopes, and postage. We estimate these costs to total \$.55 per mailing. On average, each transplant center has 112 patients, so the total cost of mailing the letter to each waiting list patient would be approximately \$61.60 (112 patients x \$.55 = \$61.60).

As discussed in more detail below under § 488.61, we believe that based upon the requirements contained in this final rule, up to two percent of transplant centers or approximately 10 centers may lose their Medicare approved status annually. If 10 centers annually lost their Medicare approved status, either voluntarily or involuntarily, the total cost estimate would be \$1,622.90 (\$100.69 salary cost estimate + \$61.60 materials/postage cost estimate x 10 transplant centers = \$1,622.90).

Section 482.104 Condition of Participation: Additional Requirements for Kidney Transplant Centers

Section 482.104(a) requires kidney transplant centers to directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. The centers must have written policies and procedures for ongoing communications with the dialysis patients' local dialysis facilities. Section 482.104(b) states that the kidney transplant centers must also furnish inpatient dialysis services directly or under arrangement. In addition, Section 482.104(c) states that the centers must cooperate with the ESRD network designated for their

geographic area, in fulfilling the terms of the Network's current statement of work.

We believe that these requirements constitute standard practice for transplant centers. Thus, the activities required to comply with this section constitute a minimal economic impact.

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

Section 488.61(a) requires transplant centers that are not Medicare-approved as of June 28, 2007 to submit a request to CMS for Medicare approval. Section 488.61(b) requires transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007 to submit a request for Medicare approval no later than December 26, 2007. The process for making the request for Medicare approval is the same for both types of transplant centers. (See § 488.61(b)(1).) The request for Medicare approval must be signed by a person authorized to represent the center (for example, a chief executive officer). The request must include the hospital's Medicare provider identification (I.D.) number; the 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.

In the proposed rule, we estimated that each hospital would spend approximately 15 minutes to prepare and submit the request for Medicare approval to CMS. We did note that a

hospital may have multiple transplant centers and, therefore, could be submitting more than one request for approval.

We received public comments on the proposed rule that said we had underestimated the time required for a transplant center to apply for Medicare approval. One commenter emphasized that transplant centers regard applying for Medicare approval very seriously. The commenter also indicated that the preparation, approval, and submission of the request for Medicare approval could take days at many large institutions. After further analysis of the tasks and the personnel that would be involved in applying for Medicare approval, we agree with the commenters that 15 minutes significantly underestimates the time required to prepare the request, obtain the required center approval(s), and submit the request for Medicare approval to CMS. However, we disagree with the commenter that said it could take "days" to accomplish all of the required tasks. Our analysis of the total cost estimate is discussed in detail below.

We believe that accomplishing all of the tasks necessary for complying with Section 488.61(a) would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support/administrative staff. We estimate that it would take these individuals approximately the same amount of time as it would take the transplant center to notify CMS of a significant change in their program or approximately 2 burden hours.

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR A TRANSPLANT CENTER TO APPLY FOR MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|------------------------------|-------------|----------------|---------------------|
| Medical Director | \$116.60 | .50 | \$58.30 |
| Senior Administrator | 92.31 | .50 | 46.16 |
| Transplant Coordinator | 43.87 | .75 | 32.90 |
| Secretary | \$21.81 | .25 | \$5.45 |
| Totals | | 2.00 | 142.81 |

All salary information is from the salary.com Web site at <http://hrsalarycenter.salary.com>

This final rule requires all currently-approved transplant centers that want to continue to provide services to Medicare beneficiaries to apply for initial approval. There are currently approximately 504 Medicare-approved transplant centers. We believe that all 504 transplant centers will submit letters requesting initial approval under the requirements of this final rule. In addition, based on our experience, we believe that approximately 10 new centers a year may apply for Medicare approval. Thus, we anticipate that 514 transplant centers will apply for Medicare in the first year following the effective date of this final rule.

For the first year after the effective date of this final rule, the total cost estimate would be \$73,404.34 (514 transplant centers × \$142.81 = \$73,404.34). For subsequent years, we anticipate that about 10 transplant centers will request initial Medicare approval. For those subsequent years, the total cost estimate would be \$1,428.10 (10 transplant centers × \$142.81 = \$1,428.10).

Section 488.61(d) allows transplant centers that have lost their Medicare approval to seek re-entry into the Medicare program at any time. If a center chooses to seek Medicare approval after losing it, the center must: (1) request initial approval using the

procedures at § 488.61(a); (2) be in compliance with §§ 482.72 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 action taken by the center as a result of the loss of its Medicare approval status.

A transplant center would utilize resources to prepare and submit a request for approval to CMS pursuant to § 488.61(a) and to prepare and submit a report to CMS documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status. After further analysis of the tasks that would be involved and the personnel that would be needed, developing and submitting the requests and the report would involve the transplant program's medical director, an administrator, a transplant coordinator, and appropriate support or administrative staff. We also believe that it will require more time to request re-entry into the Medicare program due to the development of the report documenting any changes or corrective action taken by the center as a result of the loss of its Medicare approval status.

During 2005 and 2006, only six centers voluntarily terminated their Medicare approval. Transplant centers have rarely had their Medicare approval

status revoked involuntarily. However, this final rule has outcome requirements, clinical experience requirements, and process requirements that transplant centers must generally meet to obtain initial Medicare approval and to retain their approval. Considering these requirements, we anticipate that more centers may voluntarily terminate their Medicare approval status in order to give themselves time to correct any problems they may have in meeting these requirements. In addition, it may become more common for transplant centers to be involuntarily terminated from the Medicare program. Therefore, we estimate that, in any given year, up to two percent, or approximately 10, of the currently 504 Medicare-approved centers may lose their status annually and later seek to re-enter the program.

Based on the above, we estimate that a transplant center complying with the requirements to apply for initial approval would incur a total cost of \$329.50. In any given year, we anticipate that as many as 10 centers may seek to re-enter the Medicare program. For these 10 centers, the total cost estimate would be \$ 3,295.00 (\$329.50 per center to re-apply × 10 centers = \$ 3,295.00).

TOTAL ANNUAL BURDEN HOURS AND TOTAL ANNUAL COST FOR TRANSPLANT CENTERS SEEKING RE-ENTRY INTO THE MEDICARE PROGRAM AFTER LOSS OF MEDICARE APPROVAL

| Position | Hourly wage | Hours required | Total cost estimate |
|------------------------------|-------------|----------------|---------------------|
| Medical Director | \$116.60 | 1.00 | \$116.60 |
| Senior Administrator | 92.31 | 1.00 | 92.31 |
| Transplant Coordinator | 43.87 | 2.50 | 109.68 |
| Secretary | 21.81 | .50 | 10.91 |
| Totals | | 5.00 | 329.50 |

All salary information is from the salary.com Web site at <http://hrs.salarycenter.salary.com>

Thus, the estimated total economic impact for this section in the first year after this final rule becomes effective is \$73,404.34 (514 transplant centers × \$142.81 = \$73,404.34). For subsequent years, the estimated annual total economic impact is \$4,723.10 (\$1,428.10 + \$3,295.00 = \$4,723.10).

Our estimate of the first-year economic impact on transplant centers to meet the requirements in this final rule are as follows:

- \$215,928 for notification to CMS of significant changes to the center's transplant program.
- \$95,882 annually for kidney transplant centers to notify dialysis facilities' of their patients' waiting list status.

- \$311,172 to revise agreements with OPOs.
- \$18,474,112 to develop and implement a QAPI program.
- \$9,248,136 to provide a living donor advocate in those centers that perform living donor transplantations.
- \$1,622 for centers that have lost their Medicare approval status to notify the patients on their waiting list.
- \$73,404 in the first year of implementation of this final rule to apply for Medicare approval.

Summary of Direct Cost

The overall first year economic impact of implementing the requirements in this final rule will be approximately \$28,420,256, and the first

year cost to each of the transplant centers will be an average of about \$56,389 per transplant center. This figure includes the total compensation for all of the staff hours that were calculated.

Benefits and Effects of This Final Rule

The primary economic benefit of this final rule lies with its potential to improve Medicare-approved transplant centers' effectiveness and efficiency and thus reduce the number of patient deaths and graft failures for patients who receive transplants at Medicare-approved facilities. We believe that implementing the requirements in this final rule will result in a decrease in patient deaths and graft failures.

However, it is difficult to estimate the percentage of that decrease. For some transplant centers, most of the requirements in this final rule are already standard practice. Other centers will need to make only minor improvements to their current processes and practices. And, some transplant centers will need to make substantial modifications to their processes and practices to be in compliance. In addition, while some requirements will probably have only a minor, if any, effect on patient outcomes, there are certain requirements that we believe have the potential to substantially improve patient outcomes. For example, § 482.72(a) requires transplant centers to submit to the OPTN at least 95 percent of the required data on all transplants it has performed no later than 90 days after the due date established by the OPTN. Since this is already a requirement of the OPTN and the hospitals in which transplant centers are located must already belong to the OPTN, we do not anticipate that this requirement in the final rule will have any effect on patient outcomes. However, other requirements could have a substantial effect. Section 482.96 requires that transplant centers must develop, implement, and maintain a written, comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate performance of all transplantation services. These types of QAPI programs have the potential to substantially improve patient outcomes. Centers that do not have such QAPI programs currently could experience substantial improvements in their patient outcomes. However, since some centers are already complying with the QAPI requirement, as well as the other requirements in the final rule, we do not believe that the increase in improvement for all transplant centers will be substantial. Due to the current diversity in processes and procedures existing in transplant centers, we cannot calculate any percentage of decrease in patient deaths or graft failures to any degree of reasonable certainty. Thus, we will not be able to quantify the social benefits we believe will result from implementation of this final rule.

The social benefits from the implementation of this regulation will result from both the lives saved and the decrease in graft failures. Organ failure is usually fatal within a short period of time. Patients with ESRD are an exception. Some ESRD patients can survive for many years on dialysis and many of those patients can do quite well. However, dialysis is quite

demanding and requires a substantial commitment on the part of these patients and their families. Therefore, kidney transplantation offers these patients a substantially increased quality of life. In addition, graft failures for very seriously ill patients often require re-transplantation for the patient to survive for more than a short length of time. And, considering the significant shortage of transplantable organs, it is crucial for transplant centers to operate efficiently and provide the best quality of care to transplant recipients to optimize the use of the transplantable organs that are available.

In addition to a decrease in patient deaths and graft failures, many of the requirements in this regulation should contribute to a higher quality of care for both transplant recipients and living donors. This increase in the quality of care will result in substantial social benefits. For example, the requirements for informed consent, donor management, a living donor advocate or living donor advocate team, and psychosocial evaluations of both potential transplant recipients and living donors should all lead to an improvement in the quality of care received by both transplant recipients and living donors. Based upon the above, we believe that the social benefits from the implementation of this final rule include:

- Increase in years of life gained.
- Improvements in quality of life, particularly for chronic kidney disease patients who can terminate dialysis.
- Resumption of work/volunteerism/productivity for some patients.
- An increase in the number of taxpayers (patients who return to work).
- An increase in family stability due to the life saved and improved health of a family member.
- An increase in access to dialysis as more patients receive kidney transplants.
- An increase in the number of patients who are transplanted due to the reduction in patients who need to be re-transplanted due to graft failures.
- Improved quality of care for both potential and actual transplant recipients and living donors.

Effects on the Medicare Program

In addition to the social benefits discussed above, we can estimate a monetary benefit from a reduction in the number of kidney graft failures, which forces kidney transplant patients to return to dialysis for treatment. Medicare pays for kidney dialysis for the vast majority of dialysis patients in the United States.

In 2003 (the most recent year for which complete data are available), there were 15,722 kidney (deceased or living donor) and kidney-pancreas transplants. Of the approximately 15,722 patients who received these transplants, 1-year graft survival data show that 1288 (less than 10 percent) of kidney grafts failed. We do not have data to show how many of the transplants were performed at Medicare-approved facilities, but since all or nearly all kidney transplant centers are Medicare approved, we will assume that all 2003 kidney and kidney-pancreas transplants were performed at Medicare-approved transplant centers. As stated above, we believe that the improvement in the number of graft failures will be modest. We estimate that the improvement could be from 1 to 3 percent. A 1 to 3 percent decrease in kidney graft failures would result in approximately 13 to 39 fewer graft failures in the first year after implementation of this regulation. Based on the median decrease of 2 percent, we can estimate that there could be as many as 26 fewer kidney graft failures.

The 2003 average per person per year primary payer cost for dialysis patients was \$63,723, while the cost for end-stage renal disease patients with a functioning kidney graft was \$15,357 (United States Renal Data System (USRDS): 2005 Annual Data Report: Atlas of End-Stage Renal Disease in the United States pages 674 and 680). Therefore, net health care cost savings would be \$48,366 annually per patient and the cost savings for 26 patients would be \$1,257,516 (26 patients × \$48,366 cost savings per patient = \$1,257,516).

It is important to note that re-transplantation of a kidney patient who experiences graft failure prevents a patient on the kidney waiting list from receiving a kidney and, thus, ending dialysis treatment. It is also important to note that while fewer graft failures will result in more patients receiving a first transplant (rather than a re-transplant), we estimate that the number of organs available for transplantation will remain the same. Thus, we do not anticipate that Medicare will face increased costs because the number of transplants should remain approximately the same.

We expect that the procedures for approval and re-approval contained in this final rule will have some economic impact on the Medicare program because CMS will need to survey all 504 transplant centers that are currently approved by Medicare if they wish to continue to provide services to Medicare beneficiaries. Furthermore,