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 transplants 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 lease 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://hrsalarycenter.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://hrsalarycenter.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://hrsalarycenter.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 × 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 × .5 = $40,562 × 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 dieticians. 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 × $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 × $.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://hrsalarycenter.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,

under this final rule, all transplant centers must be re-approved every 3 years, and some centers will be surveyed as part of our re-approval process. Thus, this final rule is likely to increase survey costs.

Nevertheless, to the extent possible, we will minimize costs by prioritizing surveys based on transplant centers performance on the outcome requirements and by conducting surveys in the most efficient way possible. For example, all transplant centers located in the same hospital will be surveyed at the same time.

In addition, since Medicare reimbursement rates are either directly or indirectly influenced by a hospital's costs, we may eventually increase Medicare reimbursement to transplant centers to cover some of the costs of their extra responsibilities. Medicare pays hospitals on a cost basis for certain ''organ acquisition costs''. Costs related to the requirement to have a donor advocate or donor advocate team are organ acquisition costs.

Medicare generally reimburses hospitals for organ transplant costs for beneficiaries using diagnosis related groups (DRGs) in all States, except for Maryland. DRG payments are periodically re-weighted in a budget neutral fashion to increase payments for procedures that have costs that are growing at a faster rate than most other procedures. Therefore, it is possible that DRGs for organ transplants will increase and therefore offset some of the hospitals' costs under the various transplant DRGs.

Conclusion

We believe that the requirements in this final rule will ensure that the organ transplants made available to patients are provided in a safe and effective manner. We also believe that this final rule will ensure that living donors receive the guidance and care that they deserve. We estimate that the first year cost of implementing this final rule is $28,420,256. The cost of implementation in subsequent years is estimated to be $9,566,291 annually.

List of Subjects

42 CFR Part 405

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

42 CFR Part 482

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

42 CFR Part 488

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

42 CFR Part 498

Administrative practice and procedure, Health Facilities, Health professions, Medicare, reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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

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

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

§ 405.2102 [Amended]

■ 2. Section 405.2102 is amended by—

■ A. Removing the definitions for ''histocompatibility testing'' and ''organ procurement''.

■ B. Amending the definition of ''ESRD facility'' by removing paragraph (a) and by re-designating paragraphs (b) through (e) as paragraphs (a) through (d).

■ C. Amending the definition of ''ESRD service'' by removing paragraph (a) and by re-designating paragraphs (b) and (c) as paragraphs (a) and (b).

■ D. Amending the definition of ''Qualified personnel'' by removing paragraph (g).

§§ 405.2120 through 405.2124 [Removed]

■ 3. Sections 405.2120 through 405.2124 are removed.

§ 405.2130 [Removed]

■ 4. Section 405.2130 is removed.

§§ 405.2170 and 405.2171 [Removed]

■ 5. Section 405.2170 and 405.2171 are removed.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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

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

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

Subpart E—Requirements for Specialty Hospitals

Sec.

Subpart E—Requirements for Specialty Hospitals

§ 482.68 Special requirements for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in § 482.72 through § 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at § 482.72 through § 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in § 482.72 through § 482.104, a transplant center must also meet the conditions of participation specified in § 482.1 through § 482.57.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended recipients; and unintended transmission of infectious disease to a recipient.

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

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

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

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

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

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

Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

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

Transplant program means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

General Requirements for Transplant Centers

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

§ 482.74 Condition of participation: Notification to CMS.

(a) 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:

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

(2) 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;

(3) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(4) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

§ 482.76 Condition of participation: Pediatric Transplants.

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 described at § 488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at § 482.72 through § 482.74 and § 482.80 through § 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

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

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

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

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.

(3) 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.

(d) Instead of meeting all conditions of participation at § 482.72 through § 482.74 and § 482.80 through § 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 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 the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

Transplant Center Data Submission, Clinical Experience, and Outcome Requirements

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

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

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

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Recipients (SRTR) center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

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

(i) 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

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

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

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

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

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

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

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

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

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

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the re-approval period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants if applicable. Except for lung transplants, CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTR center-specific report.

(2) The required number of transplants must have been performed during the time frame reported in the most recent SRTR center-specific report.

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

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

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

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome

requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

Transplant Center Process Requirements

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

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

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

(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) 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.

(3) 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.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

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

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

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

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

§ 482.92 Condition of participation: Organ recovery and receipt.

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

(a) *Standard: Organ recovery.* When the identity of an intended transplant recipient is known and the transplant center sends a team to recover the 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.

(b) *Standard: Organ receipt.* 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

(c) *Standard: Living donor transplantation.* 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).

§ 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.

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

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

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

(b) *Standard: Waiting list management.* 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 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.

(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 waiting list and who is admitted for organ transplantation.

(1) 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.

(2) 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.

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

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

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

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

(1) 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) 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 (d)(1) of this paragraph.

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

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

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures 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.

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

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

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

§ 482.98 Condition of participation: Human resources.

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

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b). The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

(1) 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.

(2) Ensuring that tissue typing and organ procurement services are available.

(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

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

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

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a 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. The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, 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.

(d) *Standard: Independent living donor advocate or living donor advocate team.* 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.

(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

(2) The independent living donor advocate or living donor advocate team 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.

(3) The independent living donor advocate or living donor advocate team is responsible for:

(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.

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

(f) *Standard: Resource commitment.* The 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.

§ 482.100 Condition of participation: Organ procurement.

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

responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

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

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

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that 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, 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;

(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 for under Medicare Part B.

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

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

(2) The evaluation process;

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

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

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

(6) The national and transplant center-specific outcomes for 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;

(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 for under Medicare Part B.

(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.

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

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

(ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

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

(i) Inform patients on the center's waiting list 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; and

(ii) 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.

(3) 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.

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

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

(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 their geographic area, in fulfilling the terms of the Network's current statement of work.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Subpart A—General Provisions

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

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

§ 488.6 [Amended]

■ 9. Section 488.6(a) is amended by adding ''transplant centers, except for kidney transplant centers;'' after ''psychiatric hospitals;'' but before ''SNFs.''

Subpart B—Special Requirements

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

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

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

(a) *Initial approval procedures for transplant centers that are not Medicare-approved as of June 28, 2007.* A transplant center, including a kidney transplant center, may submit a request to CMS for Medicare approval at any time.

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

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

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

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

(2) To determine compliance with the clinical experience and outcome requirements at § 482.80(b) and § 482.80(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.

(3) 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.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering initial approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (e.g., natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements, CMS will review the center's compliance with the conditions of participation contained 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. If the transplant center is found to be in compliance with all the conditions of participation at § 482.72 through § 482.104, except for § 482.82 of this chapter (Re-approval Requirements), CMS will notify the transplant center in writing of the effective date of its Medicare-approval. CMS will notify the transplant center in writing if it is not Medicare-approved.

(6) A kidney transplant center may submit a request for initial approval after performing at least 3 transplants over a 12-month period.

(7) Transplant centers will be approved for 3 years.

(b) *Initial approval procedures for transplant centers, including kidney transplant centers, that are Medicare approved as of June 28, 2007.*

(1) A transplant center that wants to continue to be Medicare approved must be in compliance with the conditions of participation at §§ 482.72 through 482.104 as of June 28, 2007 and submit a request to CMS for Medicare approval under the conditions of participation no later than December 26, 2007, using the process described in paragraph (a)(1) of the section.

(2) CMS will determine whether to approve the transplant center, using the procedures described in paragraphs (a)(2) through (a)(5) of this section. Until CMS makes a determination whether to approve the transplant center under the conditions of participation at §§ 482.72 through 482.104, the transplant center will continue to be Medicare approved under the end stage renal disease (ESRD) conditions for coverage (CfCs) in part 405, subpart U of this chapter for kidney transplant centers or the pertinent national coverage decisions (NCDs) for extra-renal organ transplant centers, as applicable, and the transplant center will continue to be reimbursed for services provided to Medicare beneficiaries.

(3) Once CMS approves a kidney transplant center under the conditions of participation, the ESRD CfCs no longer apply to the center as of the date of its approval. Once CMS approves an extra-renal organ transplant center under the conditions of participation, the NCDs no longer apply to the center as of the date of its approval.

(4) If a transplant center that is Medicare approved as of June 28, 2007 submits a request for approval under the CoPs at §§ 482.72 through 482.104 of this chapter but CMS does not approve the transplant center, or if the transplant center does not submit its request to CMS for Medicare approval under the CoPs by December 26, 2007, CMS will revoke the transplant center's approval under the conditions for coverage for kidney transplant centers or the national coverage decisions 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.

(c) *Re-approval procedures.* Once Medicare-approved, transplant centers, including kidney transplant centers, must be in compliance with all the conditions of participation for transplant centers at § 482.72 through § 482.104 of this chapter, except for § 482.80 (initial approval requirements) throughout the 3-year approval period.

(1) Prior to the end of the 3-year approval period, CMS will review the transplant center's data in making re-approval determinations.

(i) To determine compliance with the data submission requirements at § 482.82(a) of this chapter, CMS will request data submission data from the OPTN for the previous 3 calendar years.

(ii) To determine compliance with the clinical experience and outcome requirements at § 482.82(b) and § 482.82(c) of this chapter, 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 SRTR center-specific reports.

(2) If CMS determines 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 § 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.

(3) If CMS determines that a transplant center has met the data submission, clinical experience, and outcome requirements at § 482.82, CMS may choose to review the transplant center for compliance with § 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.

(4) CMS will consider mitigating factors, including (but not limited to) the following in considering re-approval of a transplant center that does not meet the data submission, clinical experience, outcome requirements and other conditions of participation:

(i) The extent to which outcome measures are met or exceeded;

(ii) Availability of Medicare-approved transplant centers in the area; and

(iii) Extenuating circumstances (*e.g.*, natural disaster) that may have a temporary effect on meeting the conditions of participation.

(iv) CMS will not approve any program with a condition-level deficiency. However, CMS may re-approve a program with a standard-level deficiency upon receipt of an acceptable plan of correction.

(5) CMS will notify the transplant center in writing if its approval is being revoked and of the effective date of the revocation.

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

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

(2) Be in compliance with §§ 482.72 through 482.104 of this chapter, except for § 482.82 (Re-approval Requirements), at the time of the request for Medicare approval; and

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

(e) Transplant Center Inactivity. 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. A transplant center must notify CMS upon its voluntary inactivation as required by § 482.74(d) of this chapter.

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

■ 11. The authority citation for part 498 continues to read as follows:

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

Subpart A—General Provisions

§ 498.2 [Amended]

■ 12. In § 498.2, the definition of ''provider'' is amended by adding ''transplant center'' after ''hospital'' the first time it appears.

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

Dated: November 7, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 12, 2006.

Michael O. Leavitt

Secretary.

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