# Supporting Statement For Paperwork Reduction Act (PRA) Submissions

Conditions of Participation: Requirements for Approval and Re-approval of Transplant Centers to Perform Organ Transplants (CMS-10266); OMB Control #0938-1069

## A. Background

This information collection package is a request for an extension of a previously approved information collection requirements (ICRs) under CMS-10266. This information collection captures the burden to the transplant centers necessary to comply with the transplant centers CoPs for these 689 transplant centers. This information is used in determining compliance with the transplant centers CoPs.

In recent decades, the number of transplant centers has grown significantly and the complexity of transplantation has evolved substantially. To keep current with transplant practices, CMS published conditions of participation (CoPs) for Approval and Re-approval of Transplant Centers to Perform Organ Transplants on March 30, 2007.

According to CMS, there are currently approximately 689 Medicare-approved transplant centers. Of those 689 centers, there are approximately 233 kidney transplant centers. The ICRs described herein are needed to implement the Medicare CoPs set forth by CMS for these 689 Medicare approved organ transplant centers. These transplant centers must meet the transplant centers CoPs to receive Medicare payment for services provided to Medicare patients.

CMS surveyors visit the transplant centers and evaluate their performance using guidance based upon the transplant center CoPs. Based upon that evaluation (survey), if a transplant center is not in compliance with the CoPs, it can be cited for deficiencies (failures to meet a certain requirement) and face administrative sanctions, up to removal from the Medicare program. However, removal is uncommon and CMS works with the facility to get it back into compliance. The notifications are communications from the transplant center to CMS based upon the requirements in §482.74. Surveys are conducted an average of every 4.5 years, but it varies between 3 and 6 years.

Additionally, CMS published revisions to certain transplant Conditions of Participation on September 30, 2019.

## B. Justification

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR Part 482. These regulatory requirements implement sections 1102, 1861(e), 1871(a), and 1881(b)(1) of the Social Security Act (the Act).

The Secretary may impose additional requirements if the requirements are necessary and in the interest of the health and safety of the individuals who are furnished services by hospitals.

Section 1102 of the Act authorizes the Secretary to publish rules and regulations "necessary for the efficient administration of the functions" with which the Secretary is charged under the Act.

Section 1861(e) of the Act authorizes promulgation of regulations in the interests of the health and safety of individuals who are furnished services by a hospital.

Section 1871(a) of the Act authorizes the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title."

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

2. Information Users

Transplant center surveyors use the CoPs and accompanying requirements specified in the regulations as a basis for determining whether a transplant center qualifies for approval or re-approval under Medicare. CMS and the healthcare industry believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability.

3. Use of Information Technology

Transplant centers may use various information technologies to store and manage patient medical records as long as they are consistent with the existing confidentiality in record- keeping regulations at 42 CFR 485.638. This regulation in no way

prescribes how the facility should prepare or maintain these records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

Transplant centers need the flexibility to use the type of record keeping that is best for them. Thus, we do not specific as long as they are in compliance with regulations.

4. Duplication of Efforts

These requirements do not require a transplant center to duplicate its efforts. If a facility already performs activities or maintains records that satisfy the ICRs for this final rule, regardless of format, they are in compliance with the applicable ICR.

5. Small Businesses

These requirements will not have a significant impact on most hospitals and other providers that are small entities. Most of the requirements in this rule are part of transplant centers' standard practices.

6. Less Frequent Collection

CMS does not collect information directly from transplant centers, with the exception of information collected based on requirements at §§482.74 and 488.61. This information is not collected on a routine basis but only under the circumstances specified in those sections. In most cases, the rule does not prescribe the manner, timing, or frequency of the records or information that must be available. Transplant center records are reviewed at the time of a survey for initial or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs.

7. Special Circumstances

This collection of information does not require any special circumstances.

8. Federal Register/Outside Consultation

This information collection request is associated with Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (0938-AT23) which was proposed on September 20, 2018 (83 FR 47686), and finalized on September 30, 2019 (84 FR 51732). There were no comments received specific to these ICRs.

9. Payments/Gifts to Respondents

There will not be any payment or gifts to respondents for the collection of this information.

10. Confidentiality

Normal medical confidentiality practices assure the confidentiality of this information.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

This package includes the ICRs required for compliance to sections 482.74, (c)(1) and (2), 482.102(c)(2) and (3), and 488.61(d). We are not including burden associated with data submission and most patient-care-related activities such as patient and living donor selection criteria, care plans, patient records, quality assessment and performance improvement, human resources, and patient and living donor rights because these activities would occur in the absence of the Medicare program. These activities are considered usual and customary business practices and as stated in 5 CFR 1320(b)(2) are exempt from the PRA.

We are also not including any burden associated with application for re-entry into the Medicare Program because these activities would affect fewer than 10 transplant centers annually and as stated in 5 CFR 13
20.3(c) are not subject to the PRA.

We obtained the salary data from the May 2016 National Occupational Employment and Wage Estimates United States at the United States Bureau of Labor Statistics (BLS) website at https://www.bls.gov/oes/2016/may/oes_nat.htm.

"Medical director" refers to the physician or surgeon who is responsible for the medical care transplant recipients and living donors, if applicable, receive in the transplant center. Physicians who manage enterprises earn an average hourly wage of $116 ($115.97 or about $116). We added $116 dollars to that amount to allow for fringe benefits and overhead for an average hourly wage of $232.

"Administrator" refers to an individual who plans, directs, or coordinates medical and health services in the transplant center. We used the average hourly wage for a medical and health services managers who work in specialty hospitals, except for psychiatric and substance abuse, which is $58 ($58.30 or about $58). We added $58 to that amount to allow for fringe benefits and overhead for an average hourly wage of $116.

"Transplant coordinator" refers to the registered nurse or clinician who coordinates the continuity of care of transplant patients and, if applicable, living donors. We used the average hourly wage for a registered nurse in a specialty hospital, excluding psychiatric and substance abuse hospitals, which is $37 ($36.80 or about $37). We added $37 to allow for fringe benefits and overhead for an average hourly wage of $74.

"Administrative assistant" (formerly secretary) refers to an individual who performs secretarial duties using specific knowledge of medical terminology and hospital, clinic, or laboratory procedures. We used the average hourly wage of $18 ($18.46 or about $18) for medical secretaries in specialty hospitals, except for psychiatric and substance abuse hospitals. We added $18 for fringe benefits and overhead for an average hourly wage of $36.

"General Counsel" refers to the attorney who provides legal advice and services to the transplant center or the hospital in which the transplant center is located. We used the average hourly wage of $76 ($76.02 or about $76) for attorneys in specialty hospitals, excluding psychiatric and substance abuse hospitals. We added $76 to allow for fringe benefits and overhead for an average hourly wage of $152.

Section 482.68 – Special requirement for transplant centers; and
Section 482.70 – Definitions

We are proposing a nomenclature change at part 482 and the transplant center regulations at §482.68, §482.70, §§482.72 through 482.104, and at §488.61. Because this change would update the terminology used in the regulations to conform to the terminology that is widely used and understood within the transplant community, there are no collection of information requirements associated with these sections.

Section 482.74 – Standard: Notification to CMS

In the original information collection package in 2007, Section 482.74(a) required transplant centers to immediately notify CMS of any significant changes related to the center's transplant program or changes that could affect its compliance with the 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 number of the center's transplants or survival rates that could result in the transplant 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 the 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. On May 12, 2014, CMS published a final rule, "Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction;

Part II," which, among other things, eliminated the requirement for transplant centers to immediately notify CMS of any decrease in the number of the center's transplants or survival rates that could result in the transplant center being out of compliance with §482.82, Condition of Participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers. Based on our experience, we believe this change would result in 40 percent fewer notifications to CMS or 165 annually (275 minus 40 percent or 110 = 165).

In the original information collection package in 2007, we estimated that a transplant center would utilize a medical director, an administrator, a transplant coordinator, and appropriate support or administrative staff to complete and submit a notification report of a change to CMS. We estimated that a transplant center would notify CMS on average two times a year about any significant changes and that each notification would require a medical director, administrator, and administrative assistant for a total of 1.25 hours to prepare and submit each report of notification of change to us. Therefore, it would require an estimated 75 minutes or 1.25 hours annually for each center to notify CMS of any significant changes for a cost of $134.

Annual Burden Hours and Cost Estimates for Each Transplant Center to Make Required Notifications of Significant Changes to CMS

| Position | Hourly Wage for Position | Hours Required for Each Report | Cost Estimate for Each Report |
|---|---|---|---|
| Medical Director | $232 | .25 | $58 |
| Administrator | $116 | .50 | $58 |
| Administrative Assistant | $36 | .50 | $18 |
| Totals | | 1.25 | $134 |

Based upon our experience with transplant centers making these required notifications, we estimate that we would receive an average of 165 notifications annually. Therefore, we estimate that the annual burden to transplant centers for making these notifications would be 206 burden hours (1.25 burden hours x 165 notifications = 206.25 or about 206 burden hours) at a cost of $22,110 ($134 for each notification x 165 notifications = $22,110).

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

Section 482.82 requires that, except as specified in § 488.61, transplant centers must

meet all the data submission, clinical experience, and outcome requirements to be re-approved for Medicare participation. 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. Furthermore, § 482.82(b) requires transplant centers to perform an average of 10 transplants per year during the prior 3 years and § 482.82(c) requires transplant centers to meet the outcome requirements for Medicare re-approval. The burden associated with this requirement would be the time it would take a transplant program to submit the required information. However, as required by §§ 482.72 and 482.45(b), a hospital in which a transplant program is located, must belong to the OPTN, and the OPTN requires that these hospitals submit this data to the OPTN. Therefore, we believe that the requirements under § 482.82 do not impose an additional burden on transplant programs because all Medicare participating transplant programs are already submitting this information to the OPTN.

Section 482.94 (c)(1) and (2) – Standard: Patient and living donor management

Section 482.94(c)(1) requires transplant centers to inform all of the patients who received an evaluation for placement on the center's waiting list of his or her transplant status. These notifications include: 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. For kidney transplant patients, the patient's usual dialysis center must also be notified of the patient's status. The center must also document in the patient's record that those notifications were made. In addition, §482.94(c)(2) requires transplant centers to notify patients, and the usual dialysis center for kidney patients, when a patient is removed from its waiting list for any reason other than death or transplantation no later than 10 days after the patient was removed from the center's waiting list. The center must also document that those notifications were made in the patient's record.

Transplant centers are required 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). OPTN Policies already require transplant centers to notify each patient of his or her status on the waiting list (OPTN Policy 3.2.07). However, the OPTN policy does not require that kidney transplant centers notify the patient's usual dialysis center. Therefore, the notification of the dialysis center does constitute a new burden.

We believe that rather than notifying dialysis facilities on a flow basis for each patient, transplant centers will update dialysis centers quarterly about the status of all patients. We estimate that a kidney transplant center would use one transplant coordinator for two hours and one administrative assistant for half an hour to notify their kidney transplant patients' usual dialysis facilities about each of their patient's

waiting list status or a change in their waiting list status. For each notification, we estimate that it would require each transplant center 2.5 burden hours at a cost of $166.

Annual Burden Hours and 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 | $74 | 2.00 | $148 | 8.0 | $592 |
| Administrative | $36 | .50 | $18 | 2.0 | $72 |
| Totals | | 2.50 | $166 | 10.0 | $664 |

There are approximately 233 kidney transplant centers. Thus, for all of the kidney transplant centers, we estimate it would require 2,330 (10 burden hours for each kidney transplant center x 233 kidney transplant centers = 2,330 burden hours) at a cost of $154,712 ($664 for each kidney transplant center x 233 kidney transplant centers = $154,712).

Section 482.102 (c)(2) and (3) Patient and living donor rights

Section 482.102(c)(2) requires transplant center to inform patients on their waiting list at least 30 days prior to the center's termination of Medicare approval, whether that termination is voluntary or involuntary, of the center's loss of Medicare approval and that Medicare will no longer pay for transplants performed after the effective date of the center's termination of approval. Section 102(c)(3) requires transplant centers that voluntarily inactivate their programs to inform the patients on their waiting list. Generally, centers that voluntarily inactivate do so because they anticipate losing their Medicare approval. Therefore, they are included in the estimate for the center that would lose their Medicare approval. In the original information collection package in 2007, we estimated that 10 transplant centers would lose their Medicare approval each year.
However, based on our experience with transplant centers that lose their Medicare approval, we now estimate that an average of 15 transplant centers lose their Medicare approval annually and that each of these centers has about 136 individuals on their waiting list.

We believe that transplant centers would inform their waiting list patients by mail. We also estimate that it would require an administrator about 30 minutes or .5 hours to draft a letter, and it would take an administrative assistant 2.5 hours to copy and mail these letters to patients. Thus, we estimate that complying with this requirement would require three burden hours at a cost of $148.

Burden Hours and 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 |
|---|---|---|---|
| Administrator | $116 | .50 | $58 |
| Administrative Assistance | $ 36 | 2.50 | $90 |
| Totals | | 3.00 | $148 |

Thus, for the 15 centers, it would require 45 burden hours (3 hours for each instance x 15 transplant centers = 45 burden hours) at a cost of $2,220 ($148 for each instance x 15 transplant centers = $2,220).

Section 488.61(a) and (b) Special procedures for approval and re-approval of organ transplant centers

Section 488.61(a) and (b) requires transplant centers that want to apply for Medicare approval to submit a request to CMS for Medicare approval. The request must be signed by a person authorized to represent the center and the request must include the hospital's Medicare provider identification 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. We estimate that it would take a medical director and an administrator about 30 minutes or .5 hours each to complete this request for a total of one burden hour at a cost of $174.

Annual Burden Hours and Cost for a Transplant Center to Apply for Medicare Approval[2]

| Position | Hourly Wage | Hours Required | Total Cost Estimate |
|---|---|---|---|
| Medical Director | $232 | .50 | $116 |

| | | | |
|---|---|---|---|
| Senior Administrator | $116 | .50 | $58 |
| Totals | | 1 | $174 |

In the original information collection package in 2007, we estimated that only 10 new transplant centers would apply for Medicare approval each year. However, based on our experience with transplant centers, we now estimate that an average of 12 programs will apply for Medicare approval annually. Thus, for those 12 transplant centers to apply for Medicare approval it would require 12 burden hours (1 burden hour for each transplant centers x 12 transplant centers = 12 burden hours) at a cost of $2,088 ($174 for each transplant centers x 12 transplant centers = $2,088).

Section 488.61(d) Application to Re-enter Medicare Program

Section 488.61(d) sets forth the requirements for transplant centers that have lost their Medicare approval to request re-entry into the Medicare Program. In the original information collection in 2007, we estimated that as many as 10 centers would apply for re-entry into the Medicare program annually. However, based on our experience with transplant centers that have lost their Medicare approval since the final rule became effective, we now estimate that only about two centers would apply for re-entry into the Medicare program annually. Under 5 CFR 1320.3(c), a “collection of information” does not include requirements imposed on fewer than ten entities. Therefore, the requirements under $488.61(d) are not subject to the PRA.

Total Annual Burden Hours and Costs for all Transplant Centers

| Section | Responses | Burden Hours | Cost Estimates |
|---|---|---|---|
| §482.74(a) | 165 | 206 | $22,110 |
| §482.94(c)(1) & (2) | 233 | 2,330 | $154,712 |
| §482.102(c)(2) & | 15 | 45 | $2,220 |
| §488.61(a) & (b) | 12 | 12 | $2,088 |
| Totals | 425 | 2,593 | $181,130 |

13. Capital Costs

There are no additional capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, CMS Regional Office staff is responsible for acting on the information collections requirements discussed in this package as it relates to transplant center compliance. Once state survey agencies have completed their surveys and if a decision to terminate a transplant center for noncompliance is to be made, the Central Office and the RO make such decisions.

15. Changes to Burden

The burden has been updated to reflect changes associated with CMS-3346-F. Because there was previously no quantified burden associated with some of the removed requirements, their respective savings due to elimination do not appear in this document. Accordingly, the overall burden in this PRA package remains unchanged at 2,593 hours.

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.