

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

This information collection package is a request for new information collection requirements. With this submission, we are creating a new PRA package for transplant centers.

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 new conditions of participation for Approval and Re-approval of Transplant Centers to Perform Organ Transplants on March 30, 2007.

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.

The information collection captures information necessary to support the implementation of the implement the Medicare CoPs for 504 transplant centers. Salary data is based on the salary website at <http://hrsalarycenter.salary.com> The salary estimates contained in this package are based on the following personnel:

“Medical director” refers to the <http://hrsalarycenter.salary.com> median salary for a medical director. The estimated median annual salary of \$242,528 for all medical directors at <http://hrsalarycenter.salary.com> was used to calculate an estimated hourly rate of \$116.60 per hour (i.e., \$242,528 divided by 52 weeks per year divided by 40 hour per week).

“Senior administrator” refers to the administrator who runs the day to day operation of a transplant hospital, who, according to <http://hrsalarycenter.salary.com>, has a median annual income of \$192,005. Thus, the hourly rate used in this report is \$92.31 (i.e., \$192,005 divided by 52 weeks per year divided by 40 hours per week).

“Transplant coordinator” refers to the registered nurse or clinician who coordinates the continuity of care of transplant patients and living donors, who, according to <http://hrsalarycenter.salary.com>, has a national median salary of \$91,249. Thus, the hourly rate used in this report is \$43.87 (i.e., \$91,249 divided by 52 weeks per year divided by 40 hours per week).

“The “Secretary” salary is based on the median hourly wage of the secretary who does paperwork, mailing or faxing, who, according to <http://hrsalarycenter.salary.com>, has a median annual salary of \$45,365. Thus, the hourly rate used in this report is \$21.81 (i.e., \$45,365 divided by 52 weeks per year divided by 40 hours per week).

“General Counsel” refers to the attorney who provides legal counseling on transplant matters, who, according to <http://hrs.salarycenter.salary.com>, has a median annual salary of \$367,869. Thus, the hourly rate used in this report is \$176.86 per hour (i.e., \$367,869 divided by 52 weeks per year divided by 40 hours per week).

This document represents all transplant center CoPs currently effective.

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.

The information collection requirements described herein are needed to implement the Medicare CoPs for 514 Medicare-approved organ transplant centers: 504 currently approved centers and an estimated 10 centers that apply for approval every year.

There are 504 current Medicare-approved transplant centers that must meet the transplant centers CoPs and about 10 new transplant centers requesting Medicare-approval a year must meet the hospital CoPs in order to receive program payment for services provided to Medicare patients. The total number of transplant centers for purposes of this information collection request will be 514 (504 existing + 10 annually).

We believe many of the requirements applied to these transplant centers will impose no burden since a prudent institution would self-impose them in the course of doing business. Regardless, we have made an attempt to estimate the associated burden for a transplant center to engage in these standard industry practices. Statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating transplant centers require the inclusion of these requirements in standards for care provided in transplant centers.

2. Information Users

The CoPs and accompanying requirements specified in the regulations are used by our surveyors 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.

4. Duplication of Efforts

These requirements are specified in a way that do not require a transplant center to duplicate its efforts. If a facility already maintains these general records, regardless of format, they are in compliance with this requirement. The general nature of these requirements makes variations in the substance and format of these records from one facility to another acceptable.

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 specific circumstances. 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

Absent a legislative amendment, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 30, 2008.

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Normal medical confidentiality practices are observed.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

482.74 – Standard: Notification to CMS

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 CoPs. The instances in which a transplant center must notify CMS include, but are not limited to: any 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. We estimate that a transplant center will 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 estimate that a transplant center will notify CMS three times a year about its significant changes. We estimate that transplant center will utilize a medical director, senior administrator, a transplant coordinator, and a secretary for a total of 2 hours to prepare and submit each report of notification of change to us. Therefore, we estimated that it would take 6 hours annually for each center to notify us of any significant changes.

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	Total Annual Cost Estimate Per Center
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				3 reports)	(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 website at <http://hrsalarycenter.salary.com>.

482.94 (c)(1)(2) – Standard: Patient and living donor management – Notification to patients and dialysis facilities of patient’s waiting list status

A kidney transplant center must document in the patient’s record that both the patient and, in the case of a dialysis patient, the patient’s usual dialysis facility have been notified about a patient’s waiting list status, including his or her removal from the waiting list for any reason other than death or transplantation. We assume 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 will utilize one transplant coordinator for two hours and one secretary for half an hour to notify all its kidney transplant patients and their usual dialysis facilities about the waiting list status or a change in their waiting list status.

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 website at <http://hrsalarycenter.salary.com>.

482.100 – Standard: Organ procurement

A 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. We estimate that a transplant center will utilize a general counsel or attorney for four hours, a medical director for two hours, a senior administrator for two hours, a transplant coordinator for two hours, to develop an agreement with an OPO and one hour for a secretary to put it into a final form.

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 Allocation¹

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 website at

[HTTP://HRSALARYCENTER.SALARY.COM](http://HRSALARYCENTER.SALARY.COM)

¹These 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.

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

Prior to a transplant center's termination of Medicare approval or voluntary inactivation, a transplant center must inform its waiting list patients and, as directed by the Secretary, provide

assistance to waiting list patients who choose to transfer to the waiting list of another transplant center without loss of time accrued on the waiting list as soon as possible. We estimate that transplant centers would inform waiting list patients by mail. We also estimate that it would require an administrator about 30 minutes to draft a letter, and it would take a secretary or other support staff 2.5 hours to copy and mail these letters to patients. (We estimate that up to two percent of transplant centers or approximately 10 centers may lose their Medicare approval.)

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 website at <http://hrsalarycenter.salary.com>

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

A transplant center, whether it is currently Medicare-approved or non-Medicare-approved, must 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, a senior administrator, a transplant coordinator, and a secretary for a total of 2 hours to compile and submit a request for approval or re-approval.

Total Annual Burden Hours and Total Annual Cost for a Transplant Center to Apply for Medicare Approval²

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 website at <http://hrsalarycenter.salary.com>

²This 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 x 10 TCs) and the cost estimate will be \$1,428.10 (\$142.81 x 10 TCs).

488.61(d) Application to Re-enter Medicare Program

Transplant centers that have lost their Medicare approval can seek re-entry into the Medicare Program at any time. A center is required to request initial approval using the procedures at §482.61 (a) and be in compliance with §482.72 through 482.104, at the time of the request. The transplant center is also required to submit a report to CMS documenting any changes or corrective actions taken as a result of the loss of its Medicare approval status. We estimate that a transplant center would involve the transplant program's medical director, an

administrator, a transplant coordinator, and appropriate support/administrative staff to do the tasks. We believe that the tasks are similar to the ones necessary for complying with §482.61(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. Therefore, we estimate that it would take a transplant center 5 burden hours and a total cost of \$329.50 to comply with this sub-section requirement. Also, in any given year, we anticipate that as many as 10 centers may seek re-entry into the Medicare Program. For these 10 centers, the total burden hours to re-apply would be 50 (10 centers x 5 burden hours = 50), and the total cost estimate to re-apply would be \$3,295.00 (\$329.50 per center x 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 website at <http://hrsalarycenter.salary.com>

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, RO 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 final decision to terminate a transplant center for noncompliance is to be made, such decisions are made by the Central Office and the RO.

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

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

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This section does not apply because statistical methods were not used in developing this collection.