Supporting Statement for Conditions of Participation for Transplant Programs (OMB Control No. 0938-1069/CMS-10266)

A. Background

The purpose of this package is to request approval from the Office of Management and Budget (OMB) to reinstate, with change, the information collection request for OMB Control No. 0938-1069, which expired on November 30, 2022. The information collection request described herein is associated with the Conditions of Participation (CoPs) for Transplant Programs, specified at Title 42 Code for Regulations (CFR) Sections §§ 482.68 to 482.104.[1]

A certified Transplant Program is an approved Medicare provider type that is located within an approved Medicare Hospital provider type. Approved Medicare dialysis facilities also work in conjunction with Transplant Programs, as they support patients before and possibly after kidney transplants. Transplant Programs may receive payment for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplants if, and only if, they are in compliance with the Conditions of Participation (CoPs) specified in 42 CFR §§ 482.68 to 482.104.

The previous iteration of OMB Control Number 0938-1069 was approved on November 29, 2019, with an estimated annual burden of 2,593 hours and an annual cost of $181,130.

For this re-instatement, the total annual hourly burden is revised to **3,340,** with an annual burden cost of **$352,462** (see Table 11). The 29% increase in burden hours (from 2,593 to 3,340) is primarily due to the addition of one missing IC, (IC-3), minor corrections to burden estimates, and updating labor wage data to more recently available data. For a detailed explanation see, **Section 15**.

Note that this PRA package only covers the information collections (ICs) for the CoPs that govern transplant programs embedded in hospitals. Other ICs related to transplant programs can be found in the following PRA packages:

- The ICs associated with a transplant program's emergency preparedness requirements at 42 CFR § 482.78 (which fall within the broader emergency preparedness requirements for hospitals with transplant programs at 42 CFR § 482.15) can be found in the Emergency Preparedness "omnibus" PRA package (OMB Control number 0938-1325).
- The ICs for Hospital CoPs[2] (other than emergency preparedness) can be found under the Hospital PRA package (OMB Control number 0938-0328).

[1] The term "transplant programs" replaced the previous term of "transplant centers" in 2019 to conform to the terminology that is widely used and understood within the transplant community. This change was reflected in all the relevant CoPs and will also be reflected in this reinstatement. In addition, the term for individuals receiving services from transplant programs was revised from "beneficiaries" to "recipients." See 84 FR 51732, 51749 published on September 30, 2019.

[2] 42 CFR §§ 482.1 to 482.57

- The ICs for dialysis facilities' Conditions for Coverage (CfCs)[3] can be found under the End Stage Renal Disease (ESRD) PRA package (OMB Control number 0938-0386).

B. Justification

1. Need and Legal Basis

The regulations containing these information collection requirements are located at 42 CFR §§ 482.68 to 482.104. The statutory authority for these requirements is in sections 1102, 1861(e), 1871(a), and 1881(b)(1) of the Social Security Act (the Act).

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 programs that furnish end stage renal disease (ESRD) as care to beneficiaries.

2. Information Users

CMS uses the ICs to ensure transplant programs comply with Medicare and Medicaid CoPs in order to protect patient health and safety. The ICs are collected by surveyors, employed by state agencies under agreements with Medicare, to determine whether transplant programs meet certification requirements as Medicare providers.
The state surveyors conduct in-person on-site visits and use the ICs to complete the surveys.

3. Improved Information Technology

CMS does not require the use of any specific technology or format so long as the required ICs are readily available for review by State surveyors at the time of the on-site survey. Transplant programs may use any available information technology to collect and maintain the required ICs, as long as they are consistent with existing

[3] 42 CFR at §§ 494.1 to 494.180

confidentiality and record-keeping regulations at 42 CFR § 482.13(d) and standard medical confidentiality practices, such as those required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The use of technology for information collection and retention is encouraged when such methods would reduce burden and are consistent with transplant programs' operations.

4. Duplication of Similar Information

There is no duplication of information collection. The ICs are designed to be sufficiently general, allowing transplant programs flexibility in substance and format within their existing recordkeeping practices. If transplant programs already maintain records that satisfy the ICs, regardless of format (electronic or paper), no additional collection is required.

5. Small Businesses

The ICs do affect small businesses. However, CMS minimizes the impact by allowing small businesses the flexibility to meet the information requirements in ways that are consistent with their existing operations.

6. Less Frequent Collection

Less frequent information collection could limit CMS’s ability to ensure compliance with Medicare Conditions of Participation (CoPs), which could potentially compromise patient health and safety. CMS does not collect the ICs directly from transplant programs but instead relies on surveyors to review the ICs during their on-site surveys, which are conducted every four to six years to recertify transplant programs or in response to complaints. These surveys helps ensure that transplant programs maintain a high level of quality and adhere to established standards for patient care and outcomes.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day *Federal Register* notice was published on January 21, 2026 (91 FR 2536) . CMS received one comment from an individual. See Attachment A for CMS’ Response to Public Comments Received.

The 30-day *Federal Register* notice published on April 16, 2026 (91 FR 20459).

9. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents as part of this information collection.

10. Confidentiality

Transplant programs are subject to standard medical confidentiality practices, such as those outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), codified under 45 CFR §§ 160 and 164. In addition, transplant programs must comply with existing confidentiality in record-keeping regulations at 42 CFR § 482.13(d). These confidentiality requirements help ensure patient privacy and the security of individuals' protected health information.

11. Sensitive Questions

There are no sensitive questions associated with this information collection. Surveyors may ask sensitive questions during the survey process, particularly when reviewing patient records, interviewing staff and patients, and examining quality assessment activities. As indicated in the "confidentiality" section, surveyors must adhere to 45 CFR §§160 and 164, which covers security standards for the protection of electronic protected health information, notification procedures for breaches of unsecured protected health information, and privacy uses and disclosure of individually identifiable health information. Furthermore, surveyors must perform interviews "one-on-one" whenever possible to protect patient privacy.

The survey process follows a structured protocol with clear guidelines about information handling, and surveyors must display their identification badges during on-site surveys, ensuring accountability in the handling of sensitive information.

12. Burden Estimates (Hours & Wages)

This section consists of the following three parts: Part 12-A, Part 12-B, and Part 12-C. Part 12-A explains the general assumptions used to estimate annual hourly burden and costs. Part 12-B explains the Conditions of Participation (CoPs) in detail and describes the methodology used to estimate the annual hourly burden and cost. Part 12-C summarizes the information.

Part 12-A: Assumptions

Below are the global assumptions for the number of new and currently certified facilities (see Table 1) as well as current hourly wages used to estimate the associated burden hours and costs per information collections (ICs) and for the entire industry (see Table 2).

Number of Respondents (Transplant Programs)

A certified transplant program is located within a Medicare-certified hospital that is a member of, and abides by, the rules and requirements of the Organ Procurement and Transplantation Network (OPTN). The burden for the information collections (ICs) described in Part 12-B is based on facility data for hospitals that provide transplants, as reported by CMS' Certification and Survey Provider Enhanced Reporting (CASPER), as shown in Table 1.[4] To estimate the number of transplant programs impacted by these ICs, CMS assumes there will be 237 Medicare-certified transplant programs operating within Medicare-certified hospitals during the next three-year period (2025, 2026, 2027). This estimate is based on the average number of active programs between Calendar Year (CY) 2020 to 2024. In addition, between the same time period, CMS observed an average of two newly certified transplant programs within Medicare-certified hospitals and two terminations annually.

Table 1: Number of Transplant Facilities Impacted[5]

# of Transplant Programs with Hospitals	2020	2021	2022	2023	2024	5-yr. average
Currently Active Programs	237	237	239	239	234	237
New Programs	2	4	3	1	0	2
Terminated Programs	3	1	1	5	0	2

Labor Wages

The burden cost for the ICs described in Part 12-B is based on salary data presented in Error: Reference source not foundbelow. This salary data is derived from the U.S. Department of Labor, Bureau of Labor Statistics (BLS), Occupational Employment and Wage Estimates (OEWS) for Specialty Hospitals (except Psychiatric and Substance Abuse).[6]

To develop the estimates, CMS first identified typical positions employed within transplant programs and then matched those positions with their equivalent labor titles as

[4] Certification and the Survey Provider Enhanced Reporting (CASPER), Last Date Modified: April 13, 2025, https://qcor.cms.gov. Accessed April 16, 2025.
[5] Id.
[6] U.S. Bureau of Labor Statistics May 2024 Industry-Specific Occupational Employment and Wage Estimates for Specialty Hospitals (except Psychiatric and Substance Abuse). *U.S. Department of Labor*, Last Modified Date: June 12, 2025. https://data.bls.gov/oes/#/industry/622300 Accessed on June 12, 2025.

listed in the OEWS. For example, the transplant program "Medical Director" corresponds to the physician or surgeon responsible for the medical care of transplant recipients and living donors. The "Administrator" refers to the transplant program Director, who plans, directs, or coordinates all services provided by the transplant program.

CMS then identified the hourly mean wage for each applicable labor category and applied a 100 percent markup to account for fringe and overhead costs. The resulting wage rates were rounded up to the nearest whole dollar.

Table 2: Hourly Labor Wage Data[7]

Transplant Program Personnel	BLS Labor Title	BLS Labor Code	May 2024 Hourly Mean Wage Cost *(a)*	Wages w/Benefits *(b = a x 2)*
General Counsel	Lawyer	23-1011	$122.86	$246
Medical Director	Physician	29-1210	$129.44	$259
Senior Administrator	Medical and Health Services Manager	11-9111	$71.93	$144
Transplant Coordinator	Registered Nurse	29-1141	$49.76	$100
Administrative Assistant	Medical Secretaries & Administrative Assistants	43-6013	$23.16	$46
Transplant Hospital Administrator	General and Operations Manager	11-2020	$88.80	$178

Part 12-B: Burden Estimates

This section discusses the burden estimates for the ICs embedded in *the general requirements for transplant programs* in Title 42 CFR at §§ 482.72 through 482.78, and the *requirements for transplant programs within specialty hospitals*, located in Title 42 CFR at §§ 482.68 through 482.104. There are also ICs for transplants programs applying for Medicare certification, located at 42 CFR § 488.61 - *Special procedures for approval and re-approval of organ transplant programs*.

Section 482.68 specifies that transplant programs within hospitals holding Medicare provider agreements comply with the CoPs outlined at §§ 482.72 through 482.104 to obtain CMS approval to provide transplant services. The requirements at §§ 482.74(a),

[7] U.S. Bureau of Labor Statistics May 2024 Industry-Specific Occupational Employment and Wage Estimates for Specialty Hospitals (except Psychiatric and Substance Abuse). *U.S. Department of Labor*, Last Modified Date: June 12, 2025. https://data.bls.gov/oes/#/industry/622300 Accessed on June 12, 2025.

482.94(c)(1) and (2), and 482.100 are the only provisions currently associated with burden estimates. These are designated as IC-1 through IC-3, respectively. For completeness, all requirements containing information collections are listed, including those exempt from burden estimation under the Paperwork Reduction Act pursuant to 5 CFR §1320.3(b)(2) for activities that are considered usual and customary business practice and per 5 CFR §1320.3(c)(4) for activities that affect less than 10 entities.

IC-1: § 482.74(a) – Notification of Significant Changes

Section 482.74(a) requires transplant programs to immediately notify CMS of any significant changes that could affect their compliance with the CoPs. Examples of such significant changes include but are not limited to changes to key transplant team staff members, termination of agreements with Organ Procurement Organizations (OPOs) responsible for organ recovery and receipt, and inactivation of transplant programs.

The burden for IC-1 consists of the time required to notify CMS of these significant changes. We assume that each transplant program will notify CMS on average twice (2) per year regarding significant changes, with each notification requiring the following staff and estimated time to complete:

- Medical Director: 0.5 hours (30 minutes)
- Administrator: 0.5 hours (30 minutes)
- Transplant Coordinator: 0.75 hours (45 minutes)[8]
- Administrative Assistant: 0.25 hours (15 minutes)

This results in a total of 2 hours per notification, at a weighted average cost of $289. Assuming each transplant program will submit two (2) notifications per year, the annual burden for each transplant program is 4 hours (2 hours x 2 notifications) at a cost of $578 ($289 x 2). For all 237 existing transplant programs, the total estimated annual burden is 948 hours (4 hours x 237 programs) at a total cost of $136,986 ($578 x 237 programs).

Table 3. IC-1, § 482.74(a) - Notifications of Significant Changes to CMS

Burden to Notify CMS of Significant Changes	**Loaded Hourly Mean Wage** *(a)*	**Burden Hours/ Notification** *(b)*	**Burden Cost/ Notification** *(c = a x b)*
Medical Director (BLS Occ. Code: 29-1210)	$259	0.50	$130
Senior Administrator (BLS Occ. Code: 11-9111)	$144	0.50	$72

[8] Note: In the prior submission of this collection, this staff member's time and cost to prepare each notification was mentioned but inadvertently omitted in the burden calculation for this IC. As a result, the prior estimate of burden hours per notification for IC-1 was incorrectly estimated as 1.25 hours.

Transplant Coordinator (BLS Occ. Code: 29-1141)	$100	0.75	$75
Administrative Assistant (BLS Occ. Code: 43-6013)	$46	0.25	$12
Burden Hours and cost per notification	**-**	**2**	**$289**
Burden Hours and cost per transplant program (2 notifications/year)	**-**	**4**	**$578**

§ 482.76 - Pediatric Transplants

Section 482.76 requires that transplant programs seeking Medicare approval to provide transplantation services to pediatric patients obtain specific approval from CMS by following the approval procedures outlined in §488.61.

We assume the burden associated with this requirement is the time necessary to prepare and submit the required information to CMS. Because transplant programs must comply with the procedures described in section 488.61, the burden for seeking pediatric transplant approval is accounted for under section 488.61, discussed below.

§ 482.78 - Emergency preparedness for transplant programs

Section 482.78 requires transplant programs to develop and maintain an emergency preparedness plan. The burden associated with this requirement is a subset of the overall burden hospitals incur to comply with emergency preparedness requirements at section 482.15. Hospitals that include transplant programs must incorporate those programs into their emergency preparedness response planning. The burden for transplant programs related to emergency preparedness planning is addressed within the "Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" PRA package (OMB Control Number 0938-1325).

§ 482.80 –Data submission, clinical experience, and outcome requirements for initial approval of transplant programs

Section 482.80 requires that, except as specified in section 488.61, transplant programs must meet all data submission, clinical experience, and outcome requirements to obtain initial approval from CMS for Medicare participation.[9] The burden associated with this requirement would be the time necessary for transplant programs to submit the required information. However, under sections 482.72 and 482.45(b), transplant programs located within transplant hospitals must be members of the Organ Procurement and Transplantation Network (OPTN), which requires transplant programs to submit the same

[9] This CoP was revised in 2019 to apply only when transplant programs sought initial approval for Medicare Certification in order to help reduce the burden when seeking re-approval for non-compliance after enforcement actions for example. See e.g., Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction, 83 FR 47686, 47706-07 (September 20, 2018).

data required under §482.80.

Therefore, the requirements under §482.80 do not impose an additional burden on transplant programs, because as members of OPTN, all Medicare-participating transplant programs would need to submit the information specified under §482.80 to the OPTN. Because submission of the required data is a usual and customary business practice, this CoP is exempt from the Paperwork Reduction Act (PRA) under 5 CFR §1320.3(b)(2).

§ 482.90 - Patient and living donor selection

Section 482.90 requires transplant programs to use written patient selection criteria when determining a patient's suitability for placement on the transplant waiting list or for receiving a transplant. If a program performs living donor transplants, it must also use written donor selection criteria to evaluate the suitability of candidates for donation.

Specifically, section 482.90(a) states that before placing a transplant candidate on its waiting list, the transplant program must document the candidate's blood type in the medical record. When a patient is either placed on the waiting list or selected to receive a transplant, the program must document in the patient's medical record the specific selection criteria used. Upon request, the transplant program must provide a copy of its patient selection criteria to the transplant patient or the referring dialysis facility. Section 482.90(b) requires that transplant programs also document the living donor's medical suitability and confirmation of informed consent in their medical record, as required by § 482.102(b). The burden associated with this requirement is the time required for:

- For ***new*** transplant programs to develop written selection criteria for transplant recipients and living donors;
- For ***existing*** transplant programs to document patient and donor information in the medical record in accordance with the selection criteria.

We continue to assume that all transplant programs already maintain written selection criteria for transplant recipients and living donors (where applicable) and that documenting such information in the medical record is standard medical practice. Recording whether patients meet selection criteria prior to surgery is considered a usual and customary business practice for hospitals. Therefore, pursuant to 5 CFR § 1320.3(b)(2), the burden associated with these activities is excluded from PRA consideration.

§ 482.92 - Organ recovery and receipt

Section 482.92 requires new and existing transplant programs to have written protocols to validate donor-recipient matching of blood types and other vital data for deceased donor organ recovery, organ receipt, and the living donor transplantation process. The burden associated with this requirement is the time required for:

- For ***new*** transplant programs to develop written protocols;
- For ***existing*** transplant programs to maintain written protocols.

We continue to assume that it is usual and customary business practice for: a) new transplant programs to develop written protocols for critical functions such as those required by this CoP; and b) existing transplant programs to maintain the written protocols. Therefore, we continue to exclude burden for these requirements pursuant to 5 CFR § 1320.3(b)(2).

§ 482.94(a) - Patient and living donor care

Section 482.94(a) requires transplant programs to have written patient management policies for the transplant and discharge phases of transplantation. In addition, if a transplant program performs living donor transplants, it must also 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 to develop written patient and donor management policies. However, we believe this is a usual and customary business practice for transplant programs, as it would be for any major health care facility. Therefore, in accordance with 5 CFR § 1320.3(b)(2), we do not estimate a burden for these activities.

§ 482.94(b) - Waiting List Management

Section 482.94(b) requires transplant programs to maintain an up-to-date waiting list by:

1. Updating clinical information for patients on the waiting list;
2. Removing patients who have received a transplant, died, or otherwise no longer qualify for the list; and
3. Notifying the OPTN within 24 hours of a patient's removal from the list.

The burden associated with these provisions is the time required to document required information and maintain information. However, transplant programs are subject to similar requirements under OPTN polices, including notification procedures and recordkeeping. Therefore, we believe that most, if not all, programs already follow these practices as part of usual and customary business operations. Consequently, consistent with 5 CFR §1320.3(b)(2), we do not estimate a burden for these activities.

IC-2: § 482.94(c)(1) - (2) – Notification of Transplant Status to Patients and Dialysis Centers

Section 482.94(c)(1) requires kidney transplant programs to notify patients and their dialysis center of the patient’s status on the waiting list, and to document this notification in the patient’s medical record. In addition, section 482.94(c)(2) requires kidney transplant programs to notify patients and their dialysis center within 10 days if a patient is removed from the waiting list for any reason other than death or transplantation.

Although OPTN Policy 3.2.07 already requires transplant programs to notify patients of their waiting list status, OPTN policy does not require kidney transplant programs to notify their patients’ dialysis centers. Therefore, we continue to estimate a burden for this activity

as required under § 482.94(c)(2).

As shown, in Table 4, we estimate that each notification requires the following staff and estimated time to complete:

- 2 hours for a Transplant Coordinator at a weighted hourly wage of $100 to compile patient data and prepare the content for the notification;
- 0.5 hours (30 minutes) for an Administrative Assistant at a weighted hourly wage of $46 to send the notifications.

This results in a total of 2.5 hours per notification, at a weighted average loaded hourly cost of $223 (($100 x 2 hours) + ($46 x 0.5 hours)). Based on four notifications per year, the annual burden per kidney transplant program is ten (10) burden hours (2.5 hours x 4 notifications/year) with an associated cost of $892 ($223 x 4 notifications/year).

Table 4. IC-2, §482.94(c)(1) & (2) -
Notification to Dialysis Facilities of Patients' Status

Burden to Notify Dialysis Facilities	**Loaded Hourly Mean Wage** *(a)*	**Burden Hours/ Notification** *(b)*	**Burden Cost/ Notification** *(c = a x b)*	**Annual Burden Hours per Transplant Program** (for Quarterly Notifications) *(d = b x 4)*	**Annual Cost per Transplant Program** (for Quarterly Notifications) *(e = c x 4)*
Transplant Coordinator (BLS Occ. Code: 29-1141)	$100	2.0	$200	8	$800
Administrative Assistant (BLS Occ. Code: 43-6013)	$46	0.5	$23	2	$92
Burden Hours/Cost	**-**	**2.5**	**$223**	**10**	**$892**

Based on a 5-year average as shown in Table 1, we estimate there will be 237 kidney transplant programs over the next three-year period that must comply with this requirement. Thus, for all kidney transplant programs to provide quarterly notifications of

their patients' waiting list status to dialysis centers every year, the total annual burden for all transplant programs is 2,370 hours (10 hours/program x 237 programs) with an associated annual cost of $211,404 ($892/program x 237 programs).

§482.96 - Quality assessment and performance improvement (QAPI)

Section 482.96 requires transplant programs to develop, implement, and maintain a written, comprehensive, and data-driven Quality Assessment and Performance Improvement (QAPI) Program. The QAPI program must be designed to monitor and evaluate the performance of all transplantation services, including services provided under contract or arrangement.

Specifically, section 482.96(b) requires newly certified transplant programs 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 include, at a minimum, procedures for:

- Identifying adverse events;
- Reporting adverse events;
- Analyzing adverse events; and
- Preventing recurrence of adverse events.

When an adverse event is identified, the transplant program must conduct a thorough analysis and document the findings.
For newly certified transplant programs, the one-time burden under § 482.96(b) is to develop and implement a QAPI program. We continue to believe that such programs would likely rely on an experienced member of the hospital's QAPI staff to assist in developing the transplant program's QAPI system. Hospitals are already required under 42 CFR § 482.21 to maintain a hospital-wide QAPI program that involves all departments. Therefore, the transplant program can draw on the hospital's existing QAPI staff as a substantial resource. As a result, we continue to estimate that any newly certified transplant program would incur only a minimal one-time burden to develop its QAPI program.

For existing transplant programs, the ongoing burden under § 482.96 is to:

- maintain their QAPI programs
- document each adverse event.

We continue to believe that developing and maintaining a QAPI program is standard and customary business practice among transplant programs. Therefore, under 5 CFR § 1320.3(b)(2), the burden associated with the ongoing requirements is exempt from PRA review, as these activities constitute usual and customary business practices.

§ 482.98 – Required notification to OPTN

Section 482.98(b) requires transplant programs to identify to the Organ Procurement and Transplantation Network (OPTN) a primary transplant surgeon and a transplant physician

who possess the appropriate training and experience to provide transplantation services and who are immediately available when an organ is offered for transplantation.

For newly certified transplant programs, the one-time burden associated with this requirement is the time needed to compile and submit this information to the OPTN. Because this is the same information that is already required when a transplant program initially seeks Medicare certification or approval under § 488.61(a), a newly certified transplant program can simply notify the OPTN of the two individuals who were designated as the primary transplant surgeon and transplant physician at the time of Medicare certification. This notification can be completed electronically or through a simple form, depending on OPTN procedures. Therefore, we continue to believe that notifying the OPTN of information already provided for Medicare certification should not result in any additional or appreciable burden to newly certified transplant programs.

IC-3: § 482.100 - Drafting agreement between Transplant Program and OPO

Section 482.100 requires a transplant program to ensure that the hospital in which it operates has a written agreement with an organ procurement organization (OPO) designated by the Secretary of the U.S. Department of Health and Human Services. This agreement must outline the specific responsibilities of both the hospital and the OPO regarding organ recovery and organ allocation.

We assume this requirement represents a ***one-time burden*** for newly certified transplant programs, as they must draft a mutually acceptable agreement with the designated OPO for the receipt of organs.
As shown in Table 5, we continue to estimate that the following staff time is required to negotiate and draft the agreement, which must be signed by both the transplant program and the OPO:

- 4 hours - General Counsel
- 2 hours - Medical Director
- 2 hours - Senior Administrator
- 2 hours - Transplant Coordinator
- 1 hour – Administrative Assistant

This results in a total of eleven (11) burden hours per newly certified transplant program. at a weighted average cost of $2,036 per program.

Based on a 5-year average as shown in Table 1, we expect two (2) newly certified transplant programs over the next three-year period. Therefore, the total one-time burden per year for newly certified program is estimated to be:

- 22 hours annually (11 hours x 2 programs)
- $4,072 in annual cost ($2,036 x 2 programs)

Table 5. IC-3, §482.100 - Draft Agreement between Transplant Program and OPO

Burden to Draft Agreement with OPO	Loaded Hourly Mean Wage *(a)*	Burden Hours/ Program *(b)*	Burden Cost/ Program *(c = a x b)*
General Counsel (BLS Occ. Code 23-1101)	$246	4	$984
Medical Director (BLS Occ. Code 29-1210)	$259	2	$518
Senior Administrator (BLS Occ. Code 11-9111)	$144	2	$288
Transplant Coordinator (BLS Occ. Code 29-1141)	$100	2	$200
Administrative Assistant (BLS Occ. Code 43-6013)	$46	1	$46
One-time Burden Hours/Costs per newly certified transplant program		**11**	**$2,036**

§§ 482.102(a) and (b) - Written Consent Policies

Sections 482.102(a) and (b) require transplant programs to maintain written informed consent policies for both transplant patients and living donors. We continue to expect that nearly all transplant programs already have written policies in place, as these are considered usual and customary business practices. Therefore, the burden associated with these requirements is exempt from the Paperwork Reduction Act (PRA) under 5 CFR §1320.3(b)(2).

§§ 482.102(c)(2) & (c)(3) – Notification of termination of Medicare certification to patients on waiting status

Section 482.102(c)(2) requires transplant programs whose Medicare approval has been voluntarily or involuntarily terminated to notify patients on their waiting list at least 30 days prior to termination. The notice must inform patients that:

a) The program's Medicare approval was terminated;
b) Whether the termination was voluntary or involuntary; and
c) Medicare will no longer cover the cost of transplants performed after the termination date.

Section 482.102(c)(3) also requires transplant programs that voluntarily inactivate to notify patients on the waiting list as soon as possible prior to inactivation. The program must also assist patients transferring to another Medicare-approved transplant program without loss of accrued time on the waiting list.

We continue to believe the burden associated with these requirements is limited to the

time needed to draft and send notification letters – by mail and electronically – to patients on the transplant program's waiting list.

As shown in Table 6, we estimate the following staff time is required to complete these notifications:

- 0.5 hours - Senior Administrator to draft the notification
- 2.5 hours - an Administrative Assistant to prepare and send the required notifications to the affected patients

This results in a total of 3 hours (0.5 + 2.5) per terminated transplant program at a weighted average cost of $187 ($72 + $115) per program.

Table 6. §482.102(c)(2) & (c)(3) - Notifications to Patients on Waiting List of a Transplant Program's Termination of Medicare Certification

Burden for Terminated Programs to Notify Patients	**Loaded Hourly Mean Wage** *(a)*	**Burden Hours/Program** *(b)*	**Burden Cost/Program** *(c = a x b)*
Senior Administrator (BLS Occ. Code 11-9111)	$144	0.5	$72
Administrative Assistant (BLS Occ. Code 43-6013)	$46	2.5	$115
Burden hours and cost per terminated transplant program		**3**	**$187**

Based on five-year historical data (see Table 1), we estimate that two (2) transplant programs per year will lose their Medicare certification over the next three years. Because fewer than ten (10) transplant programs annually may need to comply with the requirements under §§ 482.102(c)(2) and (c)(3) to notify patients on their waiting list of the program's termination of Medicare certification, the burden associated with this activity is exempt from the PRA under 5 CFR §1320.3(c)(4).

§ 482.104 – Additional Requirements for Kidney Transplant Programs

Section 482.104(a) requires kidney transplant programs to have written policies and procedures for ongoing communications with patients' local dialysis facilities. We continue to assume the burden is limited to the time and effort needed to develop written communication policies and procedures. We believe most kidney transplant programs will rely on their clinical Transplant Coordinator to serve as a liaison between the program and dialysis facilities and are therefore exempt under 42 CFR § 482.98(c)(2).

We also believe these policies and procedures will be relatively simple and that the Transplant Coordinator can quickly document existing practices in written form. In addition, many kidney transplant programs may already have such communication

procedures documented. Therefore, we continue to assume that complying with this requirement imposes minimal burden on both new and existing kidney transplant programs.

§§ 488.61(a) & (b) – Request for Initial Medicare Certification Approval

Sections 488.61(a) and (b) specify the requirements for transplant programs that wish to submit a request to CMS for Medicare approval and were not Medicare approved as of June 28, 2007. The burden associated with this requirement is the time needed to prepare and submit a written request to CMS, including a statement from the Organ Procurement and Transplantation Network (OPTN) confirming that the transplant program had complied with all applicable data submission requirements.

As shown in Table 7, we continue to estimate that completing this request will require the following staff time:

- 0.5 hours (30 minutes) - Medical Director
- 0.5 hours (30 minutes) - Senior Administrator
- 0.75 hours (45 minutes) - Transplant Coordinator
- 0.25 hours (15 minutes) - Administrative Assistant

This results in a total of 2 hours (0.5 + 0.5 + 0.75 + 0.25) per transplant program at a weighted average cost of $289 ($130 +$72+$75+$12) per program.

Table 7. §§ 488.61(a) & (b) - Request for Initial Medicare Certification Approval

Burden to Request Initial Medicare Certification Approval	**Loaded Hourly Mean Wage** *(a)*	**Burden Hours/ Program** *(b)*	**Burden Cost/ Program** *(c = a x b)*
Medical Director (BLS Occ. Code 29-1210)	$259	0.5	$130
Senior Administrator (BLS Occ. Code 11-9111)	$144	0.5	$72
Transplant Coordinator (BLS Occ. Code 29-1141)	$100	0.75	$75

Administrative Assistant (BLS Occ. Code 43-6013)	$46	0.25	$12
Burden hours and cost per transplant program		**2**	**$289**

Based on the five-year historical average (see Table 1), we estimate that two (2) transplant programs per year will apply for Medicare certification. Because fewer than ten (10) transplant programs annually will request initial Medicare approval under §§ 488.61(a) and (b), the burden associated with this activity is exempt from the PRA under 5 CFR §1320.3(c)(4).

§488.61(c) - Request re-approval for Medicare Certification

Section 488.61(c) sets forth the requirements for transplant programs that have lost their Medicare approval and wish to request re-entry into the Medicare Program. The burden associated with this requirement is the time needed to prepare and submit the re-approval request to CMS pursuant to §488.61(a), and to prepare and submit a report documenting any changes or corrective actions taken by the transplant program as a result of the loss of its Medicare approval status.

We continue to believe that the same staff who completed the initial approval request under §§488.61(a) and (b) would also prepare and submit the re-approval request under §488.61(c). However, we continue to assume that the re-approval request requires more time than the initial approval because it must include documentation of any changes or corrective action taken following the loss of Medicare approval status.

Therefore, as shown in Table 8, for each transplant program that loses its Medicare certification and seeks to re-approval, we estimate the following staff time is required to prepare and submit the re-approval request:

- 1 hour - Medical Director
- 1 hour - Senior Administrator
- 2.5 hours - Transplant Coordinator
- 0.5 hours - Administrative Assistant

This results in a total of 5 hours (1 + 1 + 2.5 +0.5) per transplant program at a weighted average cost of $676 ($259 + $144 + $250 + $23) per program. See Table 8 below.

Table 8. §488.61(c) – Request re-approval for Medicare Certification

Burden to Request Re-Approval for Medicare Certification	**Loaded Hourly Mean Wage** *(a)*	**Burden Hours/ Program** *(b)*	**Burden Cost/ Program** *(c = a x b)*
Medical Director (BLS Occ. Code 29-1210)	$259	1.0	$259

Senior Administrator (BLS Occ. Code 11-9111)	$144	1.0	$144
Transplant Coordinator (BLS Occ. Code 29-1141)	$100	2.5	$250
Administrative Assistant (BLS Occ. Code 43-6013)	$46	0.5	$23
Burden Hours/Costs per transplant program		**5**	**$676**

Based on five-year historical data (see Table 1), we estimate that two (2) transplant programs per year will lose their Medicare certification over the next three years and may subsequently request re-approval of their certification from CMS per § 488.61(c). Because fewer than ten (10) transplant programs per year may lose their certification and request re-approval, the burden associated with this activity is exempt from the PRA under 5 CFR §1320.3(c)(4).

§ 488.61(e) - Consideration of Mitigating Factors in Initial Approval, Certification, and Enforcement actions for Transplant Programs

Section 488.61(e) allows transplant programs to request reconsideration of mitigating factors if CMS finds at the time of initial approval that a program has condition-level deficiencies due to data submission, clinical experience or outcomes per § 482.80. The transplant program's request for reconsideration must be received by CMS within 14 days of the deficiency notice. Reconsideration of mitigating factors is not permitted if the deficiencies are beyond the requirements under § 482.80 or are related to "situations of immediate jeopardy."

We continue to assume the requirements under § 488.61(e) would involve the transplant program writing and submitting:

- A formal notice of the program's intent to seek re-approval based on mitigating factors, and
- A request for consideration of mitigating factors, including the content required under § 488.61(e)(2).

As shown in Table 9, we estimate this activity would require the following staff time:

- 1 hour - Transplant Hospital's Administrator
- 2 hours - Transplant Program's Medical Director
- 2 hours - Transplant Program's Senior Administrator.

This results in a total of 5 hours (1 + 2 + 2) per transplant hospital and transplant program at a weighted average cost of $984. See Table 9.

Table 9. §488.61(e) – Requesting Reconsideration of Mitigating Factors

Burden to Request Reconsideration of Mitigating Factors	**Loaded Hourly Mean Wage**	**Burden Hours/ Program**	**Burden Cost/ Program**

	(a)	*(b)*	*(c = a x b)*
Transplant Hospital Administrator (BLS Occ. Code 11-1020)	$178	1.0	$178
Medical Director (BLS Occ. Code 29-1210)	$259	2.0	$518
Senior Administrator (BLS Occ. Code 11-9111)	$144	2.0	$288
Burden Hours/Costs per transplant program & transplant hospital		**5**	**$984**

As discussed in Table 1 above, fewer than ten (10) transplant programs per year are expected to be certified. Because fewer than ten transplant programs annually may not meet the requirements at initial approval and may seek reconsideration of mitigating factors under § 488.61(e), the burden for submitting mitigating factors is exempt from the PRA under 5 CFR §1320.3(c)(4).

§ 488.61(g) - Transplant Systems Improvement Agreement

Section 488.61(g) allows a transplant hospital to voluntarily agree enter into a Systems Improvement Agreement ("SIA") with CMS for re-approval. An SIA extends a prospective Medicare termination date and allows the transplant program additional time to comply with the CoPs. We previously assumed that a transplant hospital, in coordination with the transplant program located within it, may annually enter into a SIA as described under §488.61(g). This would involve entering into a binding agreement with CMS to allow the transplant program more time to meet the CoPs.

As shown in Table 10, we continue to estimate that completing all required activities under §488.61(g) would require the following staff time:

- 2 hours - Transplant Hospital's Administrator
- 4 hours - Medical Director
- 4 hours - Senior Administrator
- 4 hours - Administrative Assistant

This results in a total of 14 hours per transplant program and transplant hospital, at a weighted average cost of $2,152.

Table 10. §488.61(g) – Entering into a SIA

Burden to Enter into a SIA	**Loaded Hourly Mean Wage (a)**	**Burden Hours/ Program (b)**	**Burden Cost/ Program (c = a x b)**
Transplant Hospital Administrator (BLS Occ. Code 11-1020)	$178	2.0	$356
Medical Director (BLS Occ. Code 29-1210)	$259	4.0	$1,036

Senior Administrator (BLS Occ. Code 11-9111)	$144	4.0	$576
Administrative Assistant (BLS Occ. Code 43-6013)	$46	4.0	$184
Burden Hours/Costs per transplant program & transplant hospital		**14**	**$2,152**

Based on five-year historical data (see Table 1), we estimate two (2) transplant programs per year will lose their Medicare certification over the next three years and may seek to enter into a SIA per § 488.61(g). Because fewer than ten transplant programs per year are expected to enter into a SIA, the burden associated with this activity is exempt from the PRA under 5 CFR §1320.3(c)(4).

Part 12-C: Burden Summary

As shown in Table 11, we estimate that the total annual burden to the industry for all ICs is **3,340** hours at an annual cost of $**352,462**.

Table 11. Total Annual Burden Hours and Costs for All Transplant Programs

Information Collection No.	CFR Section	Respondents	Responses	Annual Burden Hours	Annual Burden Cost
IC-1: Notification of Significant Changes	§482.74(a)	237	237	948	$136,986
IC-2: Notification to Dialysis centers	§§482.94(c)(1) & (2)	237	237	2,370	$211,404
IC-3: Draft Agreement Between Transplant Program and OPO	§482.100	2	2	22	$4,072
Notification to Patients of Termination of Medicare Certification	§§482.102(c)(2) & (3)	Exempt per 5 CFR §1320.3(c)(4)			
Request Initial Approval for Certification	§§488.61(a) & (b)	Exempt per 5 CFR §1320.3(c)(4)			
Request Re-approval for Medicare Certification	§488.61(c)	Exempt per 5 CFR §1320.3(c)(4)			
Requesting Reconsideration of Mitigating Factor	§488.61(e)	Exempt per 5 CFR §1320.3(c)(4)			
Entering into SIA	§488.61(g)	Exempt per 5 CFR §1320.3(c)(4)			
Burden Hours and Costs for all Impacted Transplant Programs	**-**	**476**	**476**	**3,340**	**$352,462**

13. Capital Costs

There are no capital costs associated with these information collections.

14. Cost to Federal Government

The estimated burden and costs to the federal government for these ICs include the time spent by surveyors, employed by State Survey Agencies under contract with CMS, to complete in-person compliance evaluations for transplant programs. Facilities undergo compliance reviews at the time of initial application for Medicare approval and are surveyed every 3 to 6 years to assess ongoing compliance.

For the initial compliance review, we estimate that it takes 4 hours, resulting in a cost of $284 per facility (4 hours x $71). For ongoing compliance reviews, we estimate that it takes 1 hour, resulting in a cost of $71 per facility (1 hour x $71). The burden for these activities was calculated using a loaded hourly wage of $71 per hour for a surveyor (BLS, Occupation Title: "Survey Researcher," BLS Occupation Code: 19-3022).[10]

As shown in Table 12, the burden to the federal government for each applicable IC is calculated based on those facilities impacted by each IC. The total annual burden for the federal government to conduct the required compliance reviews for IC-1 through IC-3 is 482 hours, at a cost of $34,222.

Table 12. Total Burden and Cost Estimates for Federal Government

Information Collection No.	**CFR Section**	**# of Facilities** *(a)*	**Loaded Hourly Mean Wage[11]** *(b)*	**Burden Hrs./ Task** *(c)*	**Total Burden Hrs.** *(d = a x c)*	**Total Burden Costs** *(e = b x d)*

[10] May 2024 Cross-Industry Occupational Employment and Wage Estimates, *U.S. Bureau of Labor Statistics*, Last Modified Date: June 12, 2025. https://data.bls.gov/oes/#/industry/000000. Accessed on June 12, 2025.
[11] Id.

IC-1: Notification of Significant Changes	§482.74(a)	237	$71	1	237	$16,827
IC-2: Notification to Dialysis centers	§§482.94(c)(1) & (2)	237	$71	1	237	$16,827
IC-3: Draft Agreement Between Transplant Program and OPO	§482.100	2	$71	4	8	$568
Burden Hours and Costs for Federal Government	-	**476**	-	**6**	**482**	**$34,222**

15. Changes to Burden

As shown in Table 11 above, the estimated annual burden hours to the industry increased from 2,593 to 3,340, an increase of 29%. The annual cost increased from $181,130 to $352,462, a 95% increase.

The 29% increase in burden hours is primarily due to:

a) the inclusion of IC-3 (the one-time burden for newly certified transplant programs to draft agreement with designated OPO), which is an existing regulatory requirement but was inadvertently omitted in the previous submission;
b) the addition of Transplant Coordinator's staff time and cost to prepare each notification (0.75 hours). In the prior submission, although this staff member was included among those staff required to prepare each notification, this position's hours and cost were unintentionally omitted in the burden calculation for IC-1.
c) a change in the estimated number of notifications required per year which increased the burden hours for IC-1. Specifically, the burden for submitting two notifications of significant changes per year per transplant program was previously estimated to be a total of 165 per year for all 689 transplant programs certified at that time. In this submission, we applied the original burden assumption for IC-1 that each currently certified transplant program would submit two (2) notifications of significant changes per year which increased the total number of notifications per year for the industry to 474 (237 transplant programs x 2 notifications/program), and thus increased the associated annual burden to the industry from 206 hours to 948 hours.

The 95% increase in annual costs is primarily attributable to the higher number of burden hours and the addition of staff personnel in IC-1 that was unintentionally excluded in the previous submission along with increased hourly wage estimates based on the most recent BLS data for Specialty Hospitals.

16. Publication/Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

CMS will publish a notice in the *Federal Register* to inform the public of both the OMB approval and the expiration date of this information collection request. The public may also view the expiration date by searching for the OMB control number on OMB's website.

18. Certification Statement

There are no exceptions to the certification statement requirements.