Supporting Statement for Information Collection Requirements

Contained in BPD-646-FC, Conditions of Coverage

for Organ Procurement Organizations and Supporting Regulations

in 42 CFR, Sections 486.301-.348

A. INTRODUCTION

This information collection package is a request for an extension of the currently approved information collection requirements (ICRs) under CMS-R-13 (0938-0688). This revision is based upon the conditions for coverage (CfCs) contained in the final rule published by CMS on May 31, 2006, Conditions for Coverage for Organ Procurement Organizations (OPOs) (CMS-3064-F).

We are not including a burden analysis for the information collection requirements (ICRs) for 42 CFR 486.306(a), 486.324, 486.344, and 486.346 because we believe these ICRs are exempt from the PRA as usual and customary business practices. We are also not including a burden analysis for the ICRs for 42 CFR 308 (d) and (e), 486.310 (a) (1) and (2), 486.312 (a), and 486.314 because we believe these requirements are exempt from the PRA because less than 10 respondents or entities would be affected by these ICRs. We are also not including a burden analysis for 42 CFR 486.22 because we believe that OPOs should have already satisfied the requirements in that section and should not be currently sustaining any burden from those requirements.

B. BACKGROUND

An organ procurement organization (OPO) is an entity that performs or coordinates the performance of procurement, preservation, and transport of organs for transplantation and maintains a system for locating prospective recipients for those available organs. All OPOs must be certified by the Secretary as meeting the CfCs for OPOs. OPOs can be reimbursed under the Medicare and Medicaid programs for organ procurement costs only if the OPO has been designated by the Secretary for a particular service area.

The nation's 58 OPOs are responsible for all organ recovery from deceased donors in the United States; without OPOs, organs from deceased donors would not be recovered. Each day approximately 78 people receive an organ transplant. However, about 19 people die each day on the waiting list. An OPO that is effective in procuring organs and delivering them safely to transplant centers clearly would save more lives than an ineffective one.

In 2000, the Congress passed the Organ Procurement Organization Certification Act of 2000, Pub. L. 106-505, Section 701. Congress specifically noted the important role that the OPOs played in increasing

organ donation in the United States. The OPO Certification Act required the Secretary of DHHS to promulgate regulations that incorporated certain key requirements. Those requirements have been incorporated in the OPO final rule.

C. JUSTIFICATION

1. Need and Legal Basis

Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509), sets forth the statutory qualifications and requirements that OPOs must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR Part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Conditions of Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its designated service area (DSA), CMS must hold OPOs to high standards. Collection of this information is necessary for CMS to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular service area by the Secretary or replaced by an OPO that can more effectively procure organs within that DSA.

CMS published an Interim Final Rule with Comment (IFC) on December 28, 2001 that re-certified the then 59 existing OPOs through December 31, 2005 and extended their agreements with CMS until July 31, 2006. On February 4, 2005, CMS published a proposed rule that would establish new CfCs for OPOs, including new outcome and process performance measures based on donor potential and other related factors in each service area. On May 31, 2006, CMS published a final rule that finalized the provisions of the proposed rule and re-certified the OPOs from August 1, 2006 through July 31, 2010 and extended their agreements with CMS until January 31, 2011.

2. Information Users

Most of the ICRs contained in this regulation are designed to assure that OPOs are qualified to be certified and designated as OPOs by the Secretary and effective in procuring and distributing organs. The information collected by CMS will be used as a basis for determining whether an OPO is in compliance with the OPO CfCs contained in the final rule.

3. Improved Information Technology

Under this final rule, OPOs are required to establish and use an electronic information management

system to maintain the required medical, social, and identifying information for every donor and transplant recipient. All of the OPOs are currently submitting required data electronically. The OPOs will continue to use this information technology to develop and maintain the remaining ICRs.

4. Duplication/Similar Information

There are no other information collections that duplicate the ICRs in the final rule, except for the data that is required to be reported by the OPOs under Section 486.328. That data is reported directly to the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA) has access to this data. HRSA will be providing any data CMS needs directly to CMS. The OPOs will not be required to duplicate their data submissions by sending the same data to CMS directly, unless requested by the Secretary.

5. Small Business

All OPOs are non-profit organizations and, therefore, considered small entities or businesses. Although all 58 OPOs will be affected by the ICRs in this final rule to a greater or lesser degree, CMS believes that the burden will be minimal. Most of the OPOs have already put many of the practices required by the ICRs into practice. In addition, it is important to note that OPOs are paid by the Medicare program on a cost basis. Thus, any additional costs that exceed an OPO's annual revenues would be fully reimbursed by the Medicare program.

6. Less Frequent Collection

The information required to be provided by the OPOs cannot be collected less frequently than required by the final rule. The ICRs at sections 486.306 and 486.308 are required when an OPO is seeking designation, which would normally be only every four years. The ICR at section 486.310 would be required only if an OPO is contemplating a change in ownership or control. The ICRs at sections 486.312, 486.314, and 486.316 would usually coincide with the four-year re-certification cycle. Section 486.328 requires OPOs to report data monthly. Monthly reporting is necessary for CMS to monitor OPO performance. For the remainder of the ICRs, most of the OPOs have already incorporated them into their usual business practices.

7. Special Circumstances

This collection of information does not require any special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register Notice published May 17, 2013.

9. Payment/Gift to Respondent

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

10. Confidentiality

Confidentiality of this information is assured.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Hours and Wages)

According to CMS, there are 58 OPOs. Therefore, we will use that figure in determining the burden for this rule. In addition to estimating burden hours, we have estimated costs for these burden hours based on average hourly wages for the different healthcare providers. We obtained these average hourly wages from the United States Bureau of Labor Statistics' May 2011 National Occupational Employment and Wage Estimates United States (http://www.bls.gov/oes/current/oes_nat.htm) accessed on May 24, 2012. To compensate for overhead and fringe benefits, we calculated and added in the amount that would ensure that 30 percent of the total compensation was for overhead and fringe benefits.

The sections in the final regulation that contain ICRs are as follows:

Section 486.306 OPO service area size designation and documentation requirements.

Section 486.306(a) requires that an OPO must make available to CMS documentation that verifies that it meets the requirements of paragraphs (b) through (c) of that section at the time of application and throughout the period of its designation. Section 486.306(b) requires that an OPO's defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area. The burden associated with Section 486.306(b) is the time and effort it would take for an OPO to provide such documentation to CMS. We estimate that it would take one OPO 30 minutes or .5 hours to gather the documentation necessary for such verification. For all 58 OPOs, we estimate the annual burden hours for this requirement would be 29 hours. Since OPOs would need to have all of this data readily available to conduct business, the requirement for the retention of this documentation is within an OPO's usual and customary business practice.

Section 486.306(c)(1) through (3) requires an OPO to define and document a proposed service area's location and characteristics through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number of and the names of hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

The burden associated with this requirement is the time and effort necessary for an OPO to gather and document such information. We believe an organ procurement coordinator (OPC) and an administrative staff person would perform this activity. We estimate that it would take a typical OPO an average of 1 hour to comply with this requirement. Thus, for each OPO, it would require 1 burden hour annually at a cost of $35 ($47 an hour for OPC x .5 or about $24 + $22 an hour for a secretary or about $11 for a total of about $35). Therefore, we estimate that it would require a total of 58 hours annually to comply with this requirement at a cost of $2,001.

Annual Burden Hours and Annual Cost Estimates for Complying with Section 486.306 (c) (1) – (3)

Position/Est. Salary/Est. Hours	Annual Burden Hours	Annual Cost Estimates
1 organ procurement coordinator (OPC) (RN) @$47 per hour x .5hr. annually for each OPO x 58 OPOs.	29.00	$1,363
1 secretary @$22 per hr. x .5 hr. annually for 58 OPOs	29.00	$638
Totals	58.00	$2,001

Section 486.308 Designation of one OPO for each service area.

Section 486.308(d) requires that if CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in OPO designation. Section 486.308 (e) states that a hospital may request and CMS might grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital would have to submit data to CMS establishing that (1) the waiver is expected to increase organ donations; and (2) the waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

The burden associated with this section is the time it would take a hospital to request a waiver and to create an agreement with an OPO. Based upon historical data, we estimate that about two hospitals would request a waiver annually and that all of these hospitals would need to enter into an agreement with the designated OPO. Under 5 CFR 1320.3(c), a ``collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements of this section are not subject to the PRA.

Section 486.310 Changes in control or ownership of service area.

Sections 486.310(a)(1) & (2) requires a designated OPO considering a change in ownership or in its service area would have to notify CMS before putting it into effect and would have to obtain prior CMS approval. In the case of a service area change that results from a change of ownership due to merger or consolidation, the OPOs would have to resubmit the information required in an application for

designation. The OPO would have to provide information specific to the board structure of the new organization, as well as operating budgets, financial information, or other written documentation CMS determines to be necessary for designation. The burden associated with this section is the time it takes to gather and submit the information CMS needs. We estimate that two OPOs would be affected annually and that it will require the same amount of time it would take a potential OPO requesting designation. Under 5 CFR 1320.3(c), a ``collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements of this section are not subject to the PRA.

Section 486.312 De-certification.

Sections 486.312(a) requires that if an OPO wishes to terminate its agreement, it would have to send written notice of its intention with the proposed effective date to CMS. In the case of voluntary termination, Section 486.312(e) states that the OPO would have to give prompt public notice of the date of de-certification, and such other information as CMS may require, through publication in local newspapers in the service area. The burden associated with these requirements is the time it would take to send written notice to CMS and to publish pertinent information in the local newspapers. We estimate that one OPO would be affected by these requirements per year. Under 5 CFR 1320.3(c), a ``collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements of this section are not subject to the PRA.

Section 486.314 Appeals.

Section 486.314 requires that if an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds. In its appeal, the OPO may request reconsideration before the Regional Administrator for the OPO's region. If the Regional Administrator upholds the de-certification, the OPO may request a hearing before a CMS Hearing Officer. The burden associated with this provision is the time it will take an OPO to request a reconsideration, and if necessary, a hearing, as well as the time to prepare for both proceedings. However, we do not expect to de-certify more than nine OPOs in a given year. Under 5 CFR 1320.3(c), a ``collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements of this section are not subject to the PRA.

Section 486.316 Re-certification and competition processes.

Section 486.316(a) requires OPOs to meet all three outcome measures requirements in Section 486.318 and to be shown by survey to be in compliance with the requirements for certification at Section 486.303, including the CfCs at Sections 486.320 through 486.348. If an OPO does not meet all of these requirements, it is de-certified. The de-certified OPO can appeal. If the de-certification is overturned on appeal, the OPO is re-certified and its service area is not opened for competition. However, if the de-certification is upheld, the de-certified OPO cannot compete for its service area. Section 486.316(c) states that for an OPO to compete for an open service area, it must have met the criteria for re-certification at Section 486.316(a), donation rate and yield outcome measures at or above 100 percent of the mean national rate averaged over 4 years of the re-certification cycle, and its donation rate must be at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area. Section 486.316(d) states that CMS will determine which OPO to designate for an open service

area based upon (1) performance on the outcome measures at Section 486.318; (2) relative success in meeting the process performance measures and other conditions at Sections 486.320 through 486.348; (3) contiguity to the open service area; and (4) success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. The competing OPO must submit information and data that describe the barriers in its own service area, how those barriers affected organ donation, what steps the OPO took to overcome them, and the results. The burden associated with this requirement is the time it would take to create and submit a document that contains the required information and data related to the OPO's success in identifying and addressing the barriers in its own service area and how they relate to the open service area. We will refer to this documentation as a plan.

We estimate that it will take an average of 104 burden hours to develop the plan needed to meet this requirement to compete for an open service area. Based on our experience with OPOs, we believe that as many as 9 OPOs may be de-certified. We believe that three OPOs of those OPOs will have their de-certifications reversed at some point during the appeal process. Therefore, we estimate that six de-certifications will be upheld and six DSAs would be open for competition.

Based on historical data and our previous experience with the OPOs, we would expect nine OPOs will want to compete for a new DSA and 3 of those OPOs may want to compete for more than one service area. Thus, we believe there will be 12 plans that would need to be developed for the competition process. Based on data and other information provided by CMS Regional Office OPO Coordinators, we believe that developing each plan would require the collective efforts of an OPO's QAPI director (Registered Nurse) (RN), organ procurement coordinator (RN or social worker (SW)), medical director, director, and secretary to develop a plan. We believe that the QAPI director, an OPO coordinator, and the director would each spend about 30 hours in developing the plan. This estimate includes the time it would take for these individuals to collect information and data for the potential new DSA, analyze the data and make an assessment of the incumbent OPO's DSA, identify the factors that affected the incumbent's performance, analyze the existing internal and external barriers to increasing organ donation in the service area, identify the specific activities and interventions the competing OPO will have to perform to increase organ donation, and finally, prepare and submit the required information and data that describe the barriers the competing OPO faced in its own serve area, how those barriers affected organ donation, what steps it took to overcome them, and the results. We believe the OPO medical director would be involved to a lesser extent in this process. Therefore, we estimate that the medical director would spend approximately 12 hours in developing the plan. In addition, we estimate that a secretary would spend approximately 2 hours assisting with the development, preparation, and submission of the plan. Thus, for each plan an OPO develop, it would require 104 burden hours at a cost of $6,368.

Burden Hours and Costs For Each OPO to Prepare a Plan for a DSA Competition

Position	Burden Hours	Hourly Wage	Total
QAPI Director	30	$47	$1,410

OPC	30	$47	$1,410
Director	30	$66	$1,980
Medical Director	12	$127	$1,524
Secretary	2	$22	$44
Totals	104		$6,368

We estimate that each competition would have 9 OPOs developing 12 plans and this would require 1,248 burden hours at a cost of $76,416. For the annual burden, each of these figures needs to be divided by 4, since competition for open DSAs would typically occur every 4 years. Thus, the annual burden hours for all nine OPOs to prepare 12 plans would be 312 (1,248 ÷ 4 = 312) and the annual cost estimate would be $19,104 ($76,416 ÷ 4 = $19,104).

Per Competition and Annual Burden Hours and
Costs Estimates for 9 Competing OPOs Preparing 12 Plans

Position/Est. Salary/Est. Hours x 12 plans	Burden Hours for Each Competition	Cost Estimate for Each Competition.	Annual Burden Hours (Total Burden Hours Divided by 4)	Annual Cost Estimate (Total Cost Estimate Divided by 4)
1 QAPI director (RN) @ $47 per hr. x 30 hr x 12 plans	360	$ 16,920	90	$ 4,230
1 OPO coordinator (RN* $47 per hr. x 30 hrs x 12 plans	360	16,920	90	4,230
1 OPO director @ $66 per hr. x 30 hrs x 12 plans	360	23,760	90	5,940
1 Medical director @127 per hr. x 12 hrs x 12 plans	144	18,288	36	4,572
1 secretary @$22 per hr x 2 hrs x 12 plans	24	528	6	132
Totals	1,248	$ 76,416	312	$19,104

The burden associated with this section is the time it takes to gather the required information and data, evaluate it, and prepare a plan to submit to CMS. However, while this requirement is subject to the PRA, we believe it is exempt since there should be less than 10 respondents.

Section 486.322 Condition: Relationship with hospitals, critical access hospitals, and tissue banks.

Section 486.322 (a) requires an OPO to have a written agreement with 95 percent of the Medicare and Medicaid hospitals in its service area that have both a ventilator and an operating room, that describes the responsibilities of both the OPO and hospital in regard to the requirements for hospitals in Sec.

482.45. The agreement would have to address the requirement in Section 486.326 that the OPO would have to maintain credentialing records for physicians who routinely recover organs in hospitals under contract or arrangement with the OPO and would have to assure those physicians and other practitioners who recover organs in hospitals are qualified and trained.

The burden associated with this requirement is the time it will take an OPO to enter into an agreement with a hospital. Currently, OPOs are likely to have agreements with all hospitals in their DSAs because the hospital CoP for organ, tissue, and eye procurement, which was effective August 21, 1998 (see section 482.45) requires all hospitals to have agreements with their OPOs. However, many OPOs would need to rewrite their standard agreement with hospitals. In addition, some OPOs would have to negotiate and draft specific agreements with some hospitals that would have agree to sign the OPO's standard hospital agreement. However, since the OPO final rule was effective on July 31, 2006, we believe that all OPOs have already drafted agreements that comply with this section. Therefore, OPOs should not be sustaining any current burden from this requirement.

Section 486.324 Condition: Administration and governing body.

Section 486.324 states that the OPO must have bylaws for its board(s) that address conflicts of interest, length of terms, and criteria for selecting and removing members. A governing body or individual would have to have full legal authority and responsibility for the management and provision of all OPO services and would have to develop and implement policies and procedures necessary for the effective administration of the OPO, including services furnished under contract or arrangement, fiscal operations, and continuous quality assessment and performance improvement. The OPO would have to have a procedure to address conflicts of interest for the governing body or individual described above.

The burden associated with the above requirements is the time it would take an OPO to create bylaws and to develop policies and procedures necessary for the effective administration of the OPO. We believe that creating bylaws and developing policies and procedures necessary for effective administration constitutes usual and customary business activities. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to comply with Section 486.324 constitute usual and customary business practices, these activities should be excluded from any burden analysis.

Section 486.326 Condition: Human resources.

Section 486.326(a)(2) requires the OPO to have a written policy that addresses conflicts of interest for the OPO's director, medical director, and senior management, and procurement coordinators. Section 486.326(a)(3) states that an OPO must maintain credentialing records for physicians who routinely recover organs in hospitals with which the OPO has an agreement. We believe that having written policies on conflicts of interest for senior management and staff and maintaining credentialing documents for physicians constitutes usual and customary business practices for health care organizations. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden

analysis. Since the activities that are required to comply with Section 486.326 constitute usual and customary business practices, these activities should be excluded from any burden analysis.

Section 486.328 Condition: Reporting of data.

Section 486.328(a) requires the OPO to provide individually identifiable, hospital-specific organ donation and transplantation data to the OPTN and the SRTR, as directed by the Secretary. The OPO would have to provide hospital-specific data directly to transplant hospitals, annually. In addition, the OPO would be required to provide individually identifiable, hospital-specific organ donation and transplantation and other information to the Secretary, as requested. Such data may include, but are not limited to:

(1) Number of hospital deaths;
(2) Results of death record reviews;
(3) Number and timeliness of referral calls from hospitals;
(4) Potential donor denominator (as defined in 486.302);
(5) Data related to non-recovery of organs,
(6) Data about consents for donation;
(7) Number of donors;
(8) Number of organs recovered (by type of organ); and
(9) Number of organs transplanted (by type of organ).

Sections 486.328(c) & (d) require potential donor data reported to the OPTN to be used for OPO re-certification and it would have to include data for all deaths that occurred in hospitals in the OPO's service area, unless a hospital has a waiver to work with a different OPO. If an OPO determines through death record review or other means that the potential donor denominator data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN.

The burden associated with these requirements is the time it would take the OPOs to report certain information. In this section, we believe it would take 12 hours annually for each OPO or a total of 696 annual burden hours (12 hours each year for each OPO x 58 OPOs = 696 annual burden hours) for all 58 OPOs. We believe that a data entry person would be responsible for submitting this data at a cost of $13,920.

Annual Burden Hours and Annual Cost Estimate for Complying with Section 486.328

Position x Est. Salary x Est. Hrs. x # of OPOs	Annual Burden Hours	Annual Cost Estimate
1 Data Entry Person x $20/hr. x 12 hrs x 58 OPOs	696	$13,920
Totals	696	$13,920

In addition, although it appears this requirement has the potential to add a significant new reporting burden, OPOs are required as a condition of their membership in the OPTN to report a large amount of data to the OPTN (which, in turn, provides the data to the SRTR for analysis). For example, the cadaver donor registration form, (OMB approved 0915-0157), OPOs are required to complete for each

donor contains more than 300 data elements. In addition, 42 CFR 121.11(b)(2) requires OPOs and transplant hospitals to submit information about transplant candidates, transplant recipients, organ donors, transplant program costs and performance, and ``other information that the Secretary deems

appropriate.'' Thus, most information needed by the OPTN, the SRTR, or the Department is already being reported by OPOs.

We believe that almost any OPO data needed by CMS or other agencies within the Department could be obtained from the OPTN or the SRTR. We are including this provision only to give CMS and other agencies the flexibility to request data from OPOs in the event that needed data cannot be obtained expeditiously from the OPTN or the SRTR. We would not request data from OPOs if the data were readily available from other sources.

Section 486.330 Condition: Information management.

Section 486.330 requires OPOs to include specific data elements in their records and to maintain their records in a human readable and reproducible paper or electronic format for 7 years. We do not anticipate any additional burden associated with this requirement since we believe all OPOs are using computer systems due to the OPTN requirements. Additionally, because the final rule governing the operation of the OPTN states that OPOs must maintain donor records for 7 years, OPOs must already meet this requirement. We believe that having records and maintaining these records for a period of years constitutes usual and customary business practices. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to comply with Section 486.330 constitute usual and customary business practices, these activities should be excluded from any burden analysis.

Section 486.342 Condition: Requesting consent.

Section 486.342 (a) and (b) require that an OPO have a written protocol to ensure that the individual(s) responsible for making the donation decision are informed of their options to donate organs and tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

(1) A list of the organs or tissues that may be recovered.

(2) The most likely uses for the donated organs or tissues.

(3) A description of the screening and recovery processes.

(4) Information about organizations that will recover, process, and distribute the tissue.

(5) Information regarding access to and release of the donor's medical records.

(6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.

(7) Contact information for individual(s) with questions or concerns.

(8) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential

donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

We believe that all OPOs currently have policies regarding informed consent, so there would be no additional burden to them as the policies are usual and customary business practice. Some OPOs might have to add some information, which could minimally increase the time it takes to inform the individual(s) making the donation decision. We estimate that 10 percent of the 58 OPOs (that is, rounded to 6 OPOs) may have to add information to adequately meet this requirement. Under 5 CFR 1320.3(c), a ``collection of information'' does not include requirements imposed on fewer than ten entities. Therefore, the requirements of this section are not subject to the PRA.

Section 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

Section 486.344 requires an OPO to have an effective written protocol for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. The OPO must include documentation in the donor's record of all test results, including blood type, prior to organ recovery. The OPO must also establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and transplant program for all activities associated with the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death (DCD). We are requiring that prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended recipient's position on the waiting list in relation to other suitable candidates and the recipient's OPTN identification number and blood type. In addition, if an OPO recovers organs from DCD donors after cardiac death, the OPO must have written DCD protocols.

The burden associated with this requirement is the time it would take to create the protocols. We believe that having written protocols is a usual and customary business practice. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to comply with Section 486.344 constitute usual and customary business practices, these activities should be excluded from any burden analysis.

Section 486.346 Condition Organ preparation and transport.

We have finalized Section 486.346 Condition: Organ Preparation and Transport with minor technical changes to the regulatory language. These changes have resulted in no additional associated burden. The ICR in this section requires that the OPO develop and follow a written protocol for packaging, labeling, handling, and shipping of organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol would have to include procedures to check the accuracy and integrity of labels prior to transport.

The burden associated with this requirement is the time it would take to create the protocols. We believe that having written protocols constitutes a usual and customary business practice. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Since the activities that are required to comply with Section 486.346 constitute usual and customary business practices, these activities should be excluded from any burden analysis.

Section 486.348 Condition: Quality assessment and performance improvement (QAPI).

Section 486.348 requires each OPO to develop, implement, and maintain a comprehensive, data-driven quality assessment and performance improvement (QAPI) program designed to monitor and evaluate ongoing and overall performance of all donation services, including services provided under contract or arrangement.

The burden associated with these requirements would be the time and effort required to develop a QAPI program. We believe that a typical OPO would already have an established QAPI as part of its usual and customary business practices. Under 5 CFR §1320.3 (b) (2), if the activities that are needed to comply with an ICR constitute usual and customary business practices, those activities should be excluded from the burden analysis. Thus, these activities should be excluded from any burden analysis.

Section 486.348 (b) requires that, as part of each OPO's QAPI efforts, that each OPO conduct at least monthly death record reviews in every Medicare and Medicaid participating hospital in every Medicare and Medicaid participating hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals.

The burden associated with these requirements would be the time and effort required to perform and document the death record reviews. Based on our experience, all OPO routinely perform death record reviews in hospitals they consider to have a significant donor potential. We believe that performing and documenting death record reviews as part of a QAPI program constitutes part of its usual and customary business practices for an OPO. However, we also believe that an OPO's definition of "significant donor potential" may not encompass as many hospitals as the requirement in this final rule. To the extent that it does not, the OPO might need to increase staff hours to perform and document the additional death record review. We estimate that approximately 20 percent of OPOs (12 OPOs) may need to add ½ or .5 of an FTE (2,080 annual working hours (40 hours/week x 52 weeks = 2,080 hours) x .5 = 1,040 hours) in order to expend the number of hours needed to perform and document the additional death record reviews that will be required under this final rule. It is likely the death record reviews would be performed by a RN earning about $97,760 annually, thus the cost to an OPO of adding ½ of an RN FTE to perform the additional death record reviews would be approximately $48,880 (97,760 x .5 = $48,880). Thus, for all 12 OPOs this would require 12,480 burden hours (12 OPOs x 1,040 hours = 12,480 hours) at a cost of $586,560 ($48,880 x 12 = $586,560).) . .

Annual Burden Hours and Annual Cost Estimate for Complying with Section 486.348 (b)

Position x Est. Salary x %FTE/Est. Hrs. x # of OPOs	Annual Burden Hours	Annual Cost Estimate
1 RN x $97,760 x .5FTE s x 12 OPOs	12,480	$586,560
Totals	12,480	$586,560

Section 486.348 (c) requires that an OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process. We believe that all OPOs have already developed and established these policies and do not currently sustain a burden from this requirement.

The instructions for this regulation, OPO manual guidance, have been incorporated into the CMS 2567-A, OMB 0938-0391.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The Federal cost is based on the efforts expended by CMS staff to review the data submitted by the respondents. We estimate that this review would require one reviewer at the GS-13 level one hour annually to review this data.

Annual Burden Hours and Annual Cost Estimate for Federal Government

Position x Est. Salary x Est. Hrs. x # of OPOs	Annual Burden Hours	Annual Cost Estimate
1 GS-13 Analyst x $43/hr* x 1 hr./year for all 58 OPOs	1	$43
Totals	1	$$43

*In 2011, a Federal employee at the GS-13, Step 1 level earned $89.303 or an average hourly wage of about $43.

15. Program Changes

The ICRs described herein are needed to implement the OPO final rule, CMS-3064-F, for the current 58 OPOs. The OPO final rule contains new ICRs that have inherently increased the burden in this revised package above the burden noted in the previous burden estimate.

16. Publication and Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

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

18. Certification Statement

We have not identified any exceptions.

C. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

As discussed above in Sections B. 4. Duplication/Similar Information and B.12. Section 486.328 Condition: Reporting Data, the OPOs will be reporting data directly to the OPTN. Once the OPTN collects the required data, the Scientific Registry of Transplant Recipients (SRTR), which is run by the Arbor Research Collaborative For Health, under contract with HRSA, analyzes the OPTN data and creates national and OPO-specific reports, . The SRTR uses statistical methodology in providing the information for the outcome measures at Section 486.318(a), specifically each OPO's donation rate, the mean national donation rate, the expected donation rate for each service area, and the yield measures for each OPO.

Requiring the OPOs to use any type of statistical method would not reduce their burden under this final rule. None of the conditions for coverage contained in this final rule are appropriate for statistical methods. Section 486.328 does require that the OPOs submit specific data to the OPTN. However, this is raw data. As described above, the SRTR handles all of the statistical methodology that is needed to determine the outcome measures used by CMS.

TOTAL BURDEN HOURS AND COST ESTIMATE

Section ICRs	Annual Burden Estimate	Annual Cost Estimate
486.306 (c) (1)-(3)	58	$2,001
486.316 (d)	312	$19,104
486.328 (a)	696	$13,920
486.348 (b)	12,480	$586,560
Totals	**13,546**	**$621,585**