Supporting Statement Part A
Conditions for Coverage for Organ Procurement Organizations and Supporting Regulations (CMS-R-13)

A. Introduction

This information collection package is a request for a revision of the currently approved information collection requirements (ICRs) under CMS-R-13 (0938-0688). This revision will address future burden impacts associated with the final rule, Medicare and Medicaid Programs; Organ Procurement Organizations (OPOs) Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization (CMS-3380-F; 85 FR 77898).

We are not including a burden analysis for the information collection requirements (ICRs) for 42 CFR 486.306(a), 486.324, 486.326, 486.330, 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), 486.314, 486.316, and 486.342 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 108 people receive an organ transplant; however, about 17 people die each day on the waiting list (organdonor.gov website accessed October 30, 2020 at https://www.organdonor.gov/statistics-stories/statistics.html. 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.

On May 16, 2012 and May 12, 2014, CMS published burden reduction final rules that included revisions to the OPO CfCs, CMS-9070F 77 FR 29002 (Burden Reduction I) and CMS-3267-F 79 FR 27106 (Burden Reduction II), respectively. Burden Reduction I modified a definition and Burden Reduction II made technical corrections to the OPO CfCs. On November 14, 2016, CMS finalized a rule that modified

definitions, outcome measures, and documentation requirements (CMS-1656-FC and IFC 81 FR 79562) (OPPS CY 2017). CMS published a proposed rule on December 23, 2019 seeking to modify the outcome measures for OPOs (CMS-3380-P) and issued a final rule for this purpose on December 2, 2020 (85 FR 77898). Based upon the rule changes and our experience with OPOs, we have re-assessed the burden associated with certain ICRs, as indicated below.

The major provisions of CMS-3380-F revise the OPO CfCs to increase organ donation rates and organ transplantation rates by replacing the current performance measures with new transparent, reliable, and objective measures. In this rule, we established minimum performance thresholds for both the organ donation and organ transplantation rates based on the lowest rates of the top 25 percent of OPOs. All OPOs will be assessed annually and those with performance rates that are below the top 25 percent will be required to take action to improve their rates through a quality assurance and performance improvement (QAPI) program. Additionally, OPOs will be ranked annually on their performance from the most recent 12-month period used to calculate outcome measures and assigned to a tier based on this performance.

At the end of each re-certification cycle, each OPO will be assigned a final tier ranking based on its performance on the outcome measures and its performance on the re-certification survey. This tier ranking at the end of the recertification cycle will have a direct impact on the OPOs recertification actions. The highest performing OPOs that are ranked in the top 25 percent will be assigned to Tier 1 and automatically recertified for another four years. Tier 2 OPOs are the next highest performing OPOs, where performance on both measures exceed the median rate but do not reach Tier 1. Tier 2 OPOs will not automatically be recertified and will have to compete to retain their DSAs. Tier 3 OPOs are the lowest performing OPOs that have one or both measures below the median. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

We anticipate these changes will hold OPOs to greater standards of oversight, transparency, and accountability while driving higher OPO performance across the board to increase patients' access to needed organ transplants. While we do anticipate significant improvements from OPOs based on application of new robust performance measures, we also anticipate some OPOs will not improve sufficiently which will impact burden associated with this ICR. However, we don't anticipate the burden impacts to be appreciated until 2026 when OPOs will first be held accountable to the new outcome measures for recertification purposes. The new outcome measures will become effective on August 1, 2022 but will not be enforced for recertification purposes until the end of this cycle in 2026. Potential actions related to decertification and appeals, the most impactful for burden estimates, will not occur until this period.

The current outcome measures and recertification processes will remain in effect until July 31, 2022 at which time the new outcome measures from CMS-3380-F will be implemented. Therefore, this PRA submission serves two purposes. First, it describes burden estimate to support a revision of the currently approved ICR through the next three year period (2021 – 2024). Secondly, it describes the burden estimates associated with CMS-3380-F that will go into effect in 2022 but not be realized until the end of the certification period in 2026 and during the subsequent ICR approval during the period of 2024 – 2026.

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.

CMS published a proposed rule CMS-3380-P on December 23, 2019 (84 FR 70628), that would revise the OPO CfCs to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures. This rule was finalized on December 2, 2020 (85 FR 77898).

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. For example, according to §486.306, OPOs must define, and make available to CMS, the names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State; the geographical boundaries of the service area; and the number and names of all of the hospitals and critical access hospitals in the service area that have both a ventilator and an operating room. CMS designates only one OPO for each service area (§486.308(a)). Hence, it is crucial that CMS know the boundaries of the service area. The requirements at 486.318 set minimum performance standards for CMS to assess OPO outcomes in procuring organs. In addition, OPOs are requires by §486.322(a) to have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. Thus, it is essential that CMS know what hospitals are in the OPO's service area that meet that criteria to determine compliance with the CfCs.

3. Improved Information Technology

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, 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.

Under the new performance outcome measures associated with CMS-3380-F, OPOs will continue to report data under 486.328 to the OPTN for purposes of performance monitoring associated with OPTN activities (such as which organs have been successfully placed) and to continue specific reports that assist OPOs in conducting QAPI activities. The OPTN provides a number of different reports that will be important for OPOs to continue to review to assist in understanding their performance from a comprehensive perspective. For calculating the new outcome measures associated with CMS-3380-F, CMS will integrate existing data obtained from the OPTN with data from the CDC National Center for Health Statistics (NCHS) Multiple Cause of Death (MCOD) report. CMS will process this information for developing OPOs specific reports that will be delivered to OPOs and published on the CMS website.

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 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 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. Less frequent information collection would impede efforts to establish compliance with the Medicare CfCs.

7. Special Circumstances

This collection of information does not require any special circumstances.

8. Federal Register Notice/Outside Consultation

The information collection request is associated with the OPO rule which was proposed on December 23, 2019 (84 FR 70628) and finalized on December 2, 2020 (85 FR 77898). We did not receive any comments specific to these ICRs.

9. Payment/Gift to Respondent

There will not be any payment or gifts provided to respondents for the collection of this information. For an OPO to be eligible for reimbursement of qualified OPO expenses by the Medicare and Medicaid programs, the OPO must be certified and designated (§§486. 303 and 486.304) by CMS. To be certified as an OPO by CMS, the OPO must meet the CfCs for OPOs (§486.303(h)).

10. Confidentiality

Information collected will be utilized by CMS and its agents for certification and enforcement actions. This information is publicly disclosable. Any identifiable data subject to the Privacy Act is deleted prior to disclosure.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Hours and Wages)

According to CMS' Certification and the Survey Provider Enhanced Reporting (CASPER), as of September 2020, there are 58 OPOs. 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 2019 National Occupational Employment and Wage Estimates United States (http://www.bls.gov/oes/current/oes_nat.htm) accessed on September 30, 2020. In the previously approved ICRs under CMS-R-13 (0938-0688), we calculated and added in the amount that would ensure that 30 percent of the total compensation was for overhead and fringe benefits. However, according to current policy and to ensure we more accurately account for overhead and fringe benefits, we have increased the amount we add to the average hourly rate for each position to an amount equal to 100 percent of the hourly rate.

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 or medical secretary would perform this activity. We believe that the average OPC is a registered nurse and have used the average hourly wage for a registered nurse in specialty (except psychiatric and substance abuse) hospitals, $74 ($37.24+ $37.24 = $74.48 or $74) (https://www.bls.gov/oes/current/oes291141.htm) accessed on September 30, 2020. For the administrative support person, we used the average hourly wage for a medical secretary, $38 ($19.24+ $19.24 = $38.48 or $38) (https://www.bls.gov/oes/current/oes436013.htm) accessed on September 30, 2020. 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 $56 ($74 an hour for OPC x .5 = $37 and for an administrative assistant x .5 = 18.50) for a total of $56 ($37 + 18.50 = 55.5 or about $56). Therefore, we estimate that it would require a total of 58 hours annually to comply with this requirement at a cost of $3,219.

Table of Service Area Size Designation and Documentation Requirements (486.306)

Position/Estimated Salary/Estimated Hours	Annual Burden Hours	Annual Cost Estimates
OPO Coordinator	29.00	$2,146
Medical Secretary	29.00	$1,102
Totals	**58.00**	**$3,248**

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. We previously estimated that about two hospitals would request a waiver annually and that those hospitals would need to enter into an agreement with the designated OPO. There are currently approximately 80 hospitals with waivers, however, most of these have been established for extended timeframe and CMS has not received more than ten in any three year PRA cycle since prior to 2012. 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) require 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 to process the request. Under 5 CFR 1320.3(c), a "collection of information" does not include requirements imposed on fewer than ten entities. As of November 2020, there have not been any changes of ownerships approved under these regulations since 2006, although we note that one request was recently submitted and is currently being processed. Under provisions of the final rule CMS-3380-F, there is the increased likelihood that a change of ownership could occur and the increased accountability and competition may drive some OPOs to consider this option in the future. However, we don't anticipate that there would be ten or more of these transactions in any one 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 486.312 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 previously estimated that one OPO would be affected by these requirements per year. However, absent urgent need, any de-certification would likely occur at the end of the re-certification cycle, which is every four years. Since the CfCs became effective, July 31, 2006 (71 FR 30982), no OPOs have been de-certified. Therefore, it is unlikely that the minimum threshold of ten entities would be met under the current regulatory framework for the duration of this PRA cycle (2021 – 2024). 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

Under provisions of the final rule CMS-3380-F that utilized data from 2018, we estimate that by the time OPOs are held accountable to the performance measures associated with this rule in 2026, eleven OPOs may be decertified. This estimate is based on 22 OPOs being subject to decertification, using data from 2018, when applied to the new performance outcomes. However, we anticipate the new requirements to incentivize performance so that half of these OPOs would improve to a level where they would not be subject to decertification. This is a mid-point estimate that may actually be higher or lower. It is difficult to predicate or account for costs associated with decertification. The main cost that we can attribute is to the appeals process at 486.314 and an OPO's attempt to have the decertification action overturned. OPOs that are decertified will have their DSA awarded to another OPO after all appeals are exhausted and a competition for the DSA.

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. Since implementing this requirement in 2006, OPOs have only appealed decertification on two occasions; once in 2014 and again in 2018. For the duration of this PRA cycle (2021 – 2024), we don't anticipate a change in the frequency of appeal requests. 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 during this requested approval period.

Under provisions of the final rule CMS-3380-F that utilized data from 2018, we estimate that by the time OPOs are held accountable to the performance measures associated with this rule in 2026, eleven OPOs may be decertified. This estimate is based on 22 OPOs being subject to decertification, using data from 2018, when applied to the new performance outcomes. We anticipate that half of these OPOs would improve performance to a level where they would not be subject to decertification. This is a mid-point estimate that may actually be higher or lower. Of the 11 OPOs that may be decertified, we anticipate that all will appeal the decertification action through the appeals process.

Upon receiving the notice of decertification, the OPO may submit a reconsideration request. The request must be submitted within 15 business days from receipt of the notice of de-certification. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement. We anticipate several key staff would be involved in submitting the reconsideration request including the OPO director, medical director, QAPI director, and medical secretary. We estimate that it would take a coordinated effort among the OPO director, medical director, QAPI director with each contributing approximately 10 hours to review the reason for decertification, evaluate OPO records and practices, and develop the response to be submitted for reconsideration. Additionally, we anticipate a medical secretary would provide approximately 2 hours supporting these efforts by collecting and disseminating information, preparing documents, and processing a response. If the reconsideration is

denied, we anticipate that all OPOs would subsequently request a hearing before a hearing officer. We anticipate that would take the OPO director, medical director, and QAPI director an additional 15 hours each to prepare for the hearing. This includes the time to review the administrative record, prepare responses to address items in the record, attend a pre-hearing conference (if held), and attend the hearing.

For the reconsideration, we estimate the burden for an OPO director ($107/hour x 10 hours), medical director ($107/hour x 10 hours), QAPI director (Registered Nurse, $71/hour x 10 hours), and a medical secretary ($35/hour x 2 hours). The total burden for this activity is 32 hours and $2,920. For the hearing, we estimate the burden for an OPO director ($107/hour x 15 hours), medical director ($107/hour x 15 hours), QAPI director (Registered Nurse, $71/hour x 15 hours), and a medical secretary ($35/hour x 4 hours). The total burden for this activity is 49 hours and $4,415. Total burden for both activities would be 81 hours and $7,335 for each OPO. For all 11 OPOs the burden would be 891 hours and $80,685. The annual burden hours are 297 (891/3 years).

Table of OPO Appeals Burden (486.314)

Action	Burden Hours per OPO	Burden Cost per OPO	Total Burden Hours	Total Burden Cost
Reconsideration	32	$2,920	352	$32,120
Appeal	49	$4,415	539	$48,565
Total	81	$7,335	891	$80,685

Section 486.316 Re-certification and competition processes.

Section 486.316(a) requires OPOs to meet two out of the 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. However, for the 2022 recertification cycle only, an OPO is only required to meet one out of the two outcome measure requirements (84 FR 61492). If an OPO does not meet 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 486.360; (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.

The current certification period for all OPOs will end on July 31, 2022. Since no OPOs have been previously decertified, it is unlikely that the minimum threshold of ten entities would be met under the current regulatory framework for the duration of this PRA cycle (2021 – 2024). Therefore, the requirements of this section are not subject to the PRA during this requested approval period.

Under provisions of the final rule CMS-3380-F that utilized data from 2018, we estimate that by the time OPOs are held accountable to the performance measures associated with this rule in 2026, eleven OPOs may be decertified. This estimate is based on 22 OPOs being subject to decertification, using data from 2018, when applied to the new performance outcomes. We anticipate that half of these OPOs would improve performance to a level where they would not be subject to decertification. This is a mid-point estimate that may actually be higher or lower. Therefore, it is possible that we may conduct competitions for 11 OPO DSAs. Additionally, we anticipate that of the 12 OPOs in Tier 2 based on 2018 data/performance, a total of six would have improved to Tier 1 with six remaining in Tier 2 and subject to competition. Therefore, there would be six Tier 2 and 11 Tier 3 DSAs open for competition absent any successful appeals. Our burden estimates for the competition will be based on competition for these 17 DSAs.

While we have never de-certified an OPO under the current rules, we know from our past experience trying to de-certify an OPO that approximately 10 other OPOs were interested in taking over the open DSA. Since this final rule would expand the number of open DSAs, OPOs are likely to be more strategic in trying to take over an open DSA with more effort being placed to try to take over a DSA being de-certified instead of a DSA designated as Tier 2. For the Tier 3 DSAs, we assume that approximately 5 OPOs will apply for each open DSA, resulting in 55 applications. For the 6 open Tier 2 DSAs, we assume that all incumbent OPOs will try to retain their DSA and an average of 2 other OPOs will try to take over the Tier 2 DSA, resulting in 18 more applications. In total, we estimate approximately 73 applications will be developed to compete for an open DSA at each re-certification cycle.

We believe that developing each application would require the collective efforts of a QAPI director (Registered Nurse, $71/hour), organ procurement coordinator (RN or social worker, $71/hour), medical director ($107/hour), OPO director ($107/hour), and a medical secretary ($35/hour). All wages are adjusted upwards by 100 percent to account for the cost of fringe benefits and overhead. Assuming, consistent with past rulemaking, that it would take these professionals 104 hours to develop such an application, we estimate that a total of 7,592 hours (73 applications x 104 hours) to complete the competition for each re-certification cycle. We further estimate that 47 OPOs are eligible to compete for an open DSA and that all 12 of those OPOs (in Tier 2) will definitely join in the competition to retain their DSA and 4 OPOs (the top third) in Tier 2 will compete for another DSA. Of the remaining 23 OPOs who are in Tier 1, we estimate that most (20) will try to compete for an open DSA.

We estimate that on average, each competition would require 7,592 burden hours for all 43 OPOs to complete 73 applications and would cost all 43 OPOs $644,152 (($71 RN x 30 hours x 73 applications) + ($71 organ procurement coordinator x 30 hours x 73 applications) + ($107 medical director x 12 hours x 73 applications) + ($107 OPO director x 30 x 73 applications) + ($35 medical secretary x 2 hours x 73 applications)). For the annual burden, each of these figures needs to be divided by 4, since competition for open service areas will typically occur every 4 years. Thus, the annual burden hours for all 43 OPOs to prepare 73 plans would be 1,898 (7,592 / 4) and the annual cost estimate would be $161,038 ($644,152 / 4).

Table of OPO Competition Burden (486.316)

Applications	Burden Hours	Burden Cost
One Application	104	$8,824
Tier 2 DSA (3 Applications/DSA)	312	$26,472
Tier 3 DSA (5 Applications/DSA)	520	$44,120
Total Tier 2 & 3 (6 Tier 2 + 11 Tier 3)	7,592	$644,152

Section 486.316(f) Regarding the Extension of Agreement Cycle for Extraordinary Circumstances

Provisions included in CMS-3380-F include a process whereby OPOs can request an emergency exception under certain circumstances when the OPO believes factors outside its control will impact its performance on the outcome measures. The new provision at § 486.316(f) adds a paragraph in response to public comments allowing for an extension of the agreement cycle for extraordinary circumstances. OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPOs that has affected the data of the final assessment period so that it does not accurately capture their performance. OPOs must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period. For OPOs to be granted an ECE exception, it will need to describe the extraordinary circumstance, the time period is which it occurred, why it was beyond the control of the OPO, and why it affected their performance in such a way that the data does not accurately capture.

Since requesting an ECE will place the DSA off-cycle from the other DSAs for re-certification and we anticipate the extraordinary circumstances to be rare, we anticipate that OPOs will be judicious in deciding to request the 1-year ECE. Therefore, we anticipate no more than four OPOs requesting an ECE with each 4-year re-certification cycle, resulting in an average of 1 request 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 486.322 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 ICR burden associated with this requirement is the time it would take each OPO to draft or redraft a standard agreement that complies with the requirements in this section and obtain the hospitals' agreement. Since the effective date of this rule was July 31, 2006, all 58 OPOs should have already drafted a standard agreement for the hospitals in their donation service area. They should have also drafted agreements that contain any specific provision some of the hospitals in their service area may want in their agreements, such as specific sections that pertain to DCD donation. At this time, hospitals should already have these

agreements signed and in place. OPOs should only occasionally need to draft and negotiate new agreements, such as if a new hospital opens up or one of the hospitals in their donation service area wants to negotiate changes. We believe that any further drafting and negotiation of agreements with hospitals constitutes usual and customary business activities. Thus, the ICR burden for written agreements with hospitals as required in §486.322 would have already been sustained. Any additional burden, such as establishing new agreements after a competition, should constitute 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 ICR burden analysis. Since any further activities that are required to comply with § 486.322(a) constitute usual and customary business practices, these activities should be excluded from any ICR burden analysis.

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 eligible 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 within 30 days of the end of the month in which the error is identified.

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. We used the salary for an information or record clerk in a general medical or surgical hospital and added 100 percent to that amount for $34 ($20.39 x 2 = 40.78 or about $41) (https://www.bls.gov/oes/current/oes434199.htm), accessed on September 30, 2020. Thus, the annual cost for all 58 OPOs to submit this data would be $28,536.

Table for Reporting of Data Burden (486.328)

Position	Burden Hours per OPO	Burden Cost per OPO	Annual Burden Hours	Annual Cost Estimate
Data Entry Staff	12	$492	696	$28,536
Totals	12	$492	696	$ 28,536

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.

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 need to periodically need to modify information, which could minimally increase the time it takes to inform the individual(s) making the donation decision. We estimate that over the course of a 3-year PRA approval period, approximately 10 percent of the 58 OPOs (that is, rounded to 6 OPOs) may modify their consent information. 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.

OPOs are required to send paper documentation with the organ(s) regarding blood typing and infectious disease information. This does not restrict the necessary donor information sent to the transplant hospital because all of the other donor information can be assessed electronically by the transplant program. Thus, OPOs must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures arrival without compromise to the quality of the organ. These protocols must also include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

We believe that having written protocols and complying with the requirements for testing, documentation, and packaging when organs are prepared and transported constitute 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, each OPO must conduct at least monthly death record reviews 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.

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.

Under new provisions at § 486.348(d) that will be implemented on August 1, 2022, we are requiring that OPOs include a process to evaluate and address their outcome measures in their QAPI program if their rates are statistically significantly lower than the top 25 percent of OPO at each assessment. Assessments will occur annually based on the most recent prior 12 months of available data, meaning there would be 4 assessments in each 4-year re-certification cycle that might require modifications to these OPOs' QAPI programs.

We believe the information collection requirements associated with maintaining a QAPI program are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by persons in the normal course of their activities. QAPI programs are normal activities that are conducted by most healthcare organizations and the metrics and activities within these programs change periodically as organizations evaluate different data sources and develop action plans. Accordingly, we do not believe this change would impose any additional ongoing quantifiable burden outside of what is normal and customary requirements for these organizations.

Table of Total Burden Hours and Cost Estimate for ICR Revision Request

Section ICRs	Annual Hour Burden	Annual Cost Burden
486.306 (c) (1)-(3)	58	$3,248
486.328 (a)	696	$28,536
486.314(b) & (c)	297	$26,895
486.316(c)	1,898	$214,717
Totals	**2949**	**$273,396**

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are minimal costs associated with these requirements that are accrued at the Federal level and at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to organ procurement compliance.

Table of Annual Burden Hours and Annual Cost Estimate for Federal Government

Position x Estimated Salary x Estimated Hours x Number of OPOs	Annual Burden Hours	Annual Cost Estimate
1 GS-13 Analyst x $48/hour* x 1 hour/year for all 58 OPOs	58	$2748
Totals	58	$2748

* In 2019, a Federal employee at the GS-13, Step 1 level earned $99,172 or an average hourly wage of $47.52 or about $48.

15. Program Changes

In regards to the revision request associated with this ICR, we are removing burden associated with death record reviews at 486.348(b). While this requirement is still in place, it is a usual and customary practice for OPOs that has been in effect since 2006. The previous burden estimate carried over from 2010 when OPOs were still adapting to this requirement and may have needed to increase staffing for this purpose. However, death record review is now considered normal usual and customary practice for OPOs. This reduces the burden by 12,480 hours and $923,520. However, we are adding burden associated with CMS-3380-F resulting a new total of 2,949 hours and $273,396.

The overall change in burden from the previously approved package is 13,234 hours to 2,949.

16. Publication and Tabulation Dates

There is a listing of all of the OPOs at organdonor.gov at: https://organdonor.gov/awareness/organizations/local-opo.html. CMS intends to publish information on OPO outcome measures annually. The information will be posted on the Quality, Certification and Oversight Reports (QCOR) website located at https://qcor.cms.gov/main.jsp.

17. Expiration Date

The expiration date will be posted on the following website: https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/OPOs.html.

18. Certification Statement

We have not identified any exceptions.

D. 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.