

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS–3380–F]

RIN 0938–AU02

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures and increasing competition for open donation service areas (DSAs).

EFFECTIVE DATE: These regulations are effective on February 1, 2021, except for amendment number 3 (further amending § 486.302), which is effective July 31, 2022.

Implementation date: The regulations will be implemented on August 1, 2022.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786–8486; Jesse Roach, (410) 786–1000; Kristin Shifflett, (410) 786–4133; CAPT James Cowher, (410) 786–1948; or Alpha-Banu Wilson, (410) 786–8687.

SUPPLEMENTARY INFORMATION:

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Background

- A. The Importance of Organ Procurement Organizations and the Need To Reform the Organ Procurement System
- B. Statutory and Regulatory Provisions
- C. HHS Initiatives Related to OPO Services and Executive Order (E.O.) 13879

II. Summary of the Proposed Provisions and Responses to Public Comments

- A. General Comments
- B. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318)
 1. General Comments About the Outcome Measures
 2. Donation Rate § 486.318(d)(1)
 3. Donor Definition § 486.302 and the “Zero Organ Donors”
 4. Organ Transplantation Rate § 486.302 and § 486.318(d)(2)

5. Organ Definition § 486.302
6. Donor Potential (§ 486.302 and § 486.318(d)(4))
 - a. Death That Is Consistent With Organ Donation § 486.302
 - i. Death Certificate Data
 - ii. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM)
 - b. Age 75 and Younger
 - c. Inpatient Deaths
 - d. Waiver Hospitals
7. Risk-Adjustments § 486.302 and § 486.318(d)(2)
 - a. Chronic Diseases
 - b. Race
 - c. Gender and Age
 - d. Ventilator Status
8. OPO Performance on Outcome Measures § 486.318(e) and § 486.302
9. Non-Contiguous States, Commonwealths, Territories, or Possessions § 486.318(e)(7)
10. Assessment and Data for the Outcome Measures § 486.318(f)
11. Implementation Timeline
12. Definitions § 486.302
- C. Re-Certification and Competition Processes (§ 486.316)
 1. Re-Certification of OPOs § 486.316(a)
 2. De-Certification and Competition § 486.316(b)
 3. Criteria to Compete § 486.316(c)
 4. Criteria for Selection § 486.316(d)
 5. Extension of the Agreement Cycle for Extraordinary Circumstances § 486.316(f)
- D. Reporting of Data § 486.328
- E. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)
 1. Death Record Review in QAPI
 - F. Response to Solicitation of Comments
 1. Out of Scope
- III. Provisions of the Final Rule
 - A. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318).
 - B. Re-Certification and Competition Processes (§ 486.316)
 - C. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)
 - D. Solicitation of Comments (Including Changes to Re-Certification Cycle)
- IV. Collection of Information Requirements
 - A. ICRs Regarding Re-Certification and Competition Processes (§ 486.316)
 - B. ICRs Regarding Condition: Reporting of Data (§ 486.328)
 - C. ICRs Regarding Quality Assessment and Performance Improvement (§ 486.348)
- V. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Scope of Review
 - C. Effects on OPO Performance
 - D. Anticipated Costs and Benefits
 1. Effects on Medical Costs
 2. Effects on Patients
 3. Implementation and Continuing Costs
 - E. Effects on Medicare, Medicaid, and Private Payers
 - F. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism
 1. Regulatory Flexibility Act
 2. Small Rural Hospitals

3. Unfunded Mandates Reform Act
4. Federalism
- G. Alternatives Considered
 1. Changes to the Denominator
 - a. CALC as the Denominator
 - b. All Deaths, Age <= 75 as the Denominator
 - c. Total Population, Age <75
 2. Changing the Confidence Interval
 3. Changing the Threshold Rates
- H. Accounting Statement and Table
- I. Reducing Regulation and Controlling Regulatory Costs
- J. Conclusion
- Regulations Text

I. Background

A. The Importance of Organ Procurement Organizations and the Need To Reform the Organ Procurement System

Organ procurement organizations (OPOs) are vital partners in the procurement, distribution, and transplantation of human organs in a safe and equitable manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs is available to individuals with organ failure who are on a waiting list for an organ transplant. There are currently 58 OPOs that are responsible for identifying eligible donors and recovering organs from deceased donors in the United States (U.S.), with no current statutory authority to add new OPOs. Therefore, the Centers for Medicare & Medicaid Services (CMS) views OPO performance as a critical element of the organ transplantation system in the United States (U.S.)

As of November 2020, a total of 108,725 people were on the waiting lists for a lifesaving organ transplant.¹ Many people face tremendous quality of life burdens or death while on the waiting list. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive lifesaving organ transplants, which could ultimately save more lives.

Based on public feedback and our own internal analysis of organ donation and transplantation rates, it is the agency’s belief that the current OPO outcome measures are not sufficiently objective and transparent to ensure appropriate accountability in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates.

¹ Organ Procurement and Transplantation Network (OPTN) Data. <https://optn.transplant.hrsa.gov/data/>.

Given OPOs' important role in the organ donation system in the U.S., some stakeholders have stated that underperformers have faced few consequences for poor performance, by noting "Performance varies across the OPO network, with many persistent underperformers failing to improve over the last decade."² They further note that there are serious negative impacts to both organ transplantation and donation when OPOs are underperforming, in that "[w]hen OPOs are inefficient or ineffective, donor hospitals are reluctant to refer potential donors, and transplant programs have fewer organ offers for patients on the waiting list. The end result is a bottleneck within the system that leads to avoidable deaths and increased national health care spending."³

Some stakeholders, including members of the OPO industry, have stated that the current OPO outcome measures should be reformed to incentivize improvements in OPO performance. Some of these stakeholders note that "[e]xisting regulations need dramatic improvement to remove perverse incentives to organ procurement (for example, OPOs are evaluated on the number of organs procured per donor, which leads to older single-organ donors being overlooked) and increase continuous performance accountability."² Reforming the current outcome measures can be achieved, they indicated, through metrics that improve accountability and "by replacing current ineffective metrics for OPO performance with a simplified transparent metric that enables independent performance measurement."²

B. Statutory and Regulatory Provisions

To be an OPO, an entity must meet the applicable requirements of both the Social Security Act (the Act) and the Public Health Service Act (the PHS Act). Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for organ procurement costs to be paid under the Medicare program or the Medicaid program. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified

by the Secretary of the Department of Health and Human Services (the Secretary) as meeting the standards to be a qualified OPO within a certain time period. Section 1138(b)(1)(C) of the Act provides that payment may be made for organ procurement costs "only if" the OPO meets the performance-related standards prescribed by the Secretary. Section 1138(b)(1)(F) of the Act requires that to receive payment under the Medicare program or the Medicaid program for organ procurement costs, the entity must be designated by the Secretary. The requirements for such designation are set forth in 42 CFR 486.304 and include being certified as a qualified OPO by CMS.

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. Section 1138(b)(1)(D) of the Act requires an OPO to be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). OPOs must also comply with the regulations governing the operation of the OPTN (42 CFR part 121). The Department of Health and Human Services (HHS) has explained that only those policies approved by the Secretary will be considered "rules and requirements" of the OPTN for purposes of section 1138 of the Act. The OPTN is a membership organization that links all professionals in the U.S. organ donation and transplantation system. Currently, the United Network for Organ Sharing (UNOS) serves as the contractor for the operation of the OPTN under contract with HHS. OPOs are required under the OPTN final rule (42 CFR 121.11(b)(2)) and 42 CFR 486.328 of the OPO CfCs to report information specified by the Secretary to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d (title VI), section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 and section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116 (section 1557). Title VI and section 1557, protect individuals on the basis of race, color and national origin. Under these laws, OPOs are required to take reasonable steps to ensure meaningful access to their programs by individuals with limited English proficiency. Reasonable steps may include providing language assistance services at no cost, such as

providing interpreters or translated material. Also, section 504 and section 1557 protect qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from discrimination in the administration of organ transplant programs. Under these laws, OPOs must ensure that qualified individuals with a disability are afforded opportunities to participate in or benefit from the organ transplant programs that are equal to opportunities afforded others. Decisions to approve or deny organ transplants must be made based on objective facts related to the individual in question. "Individuals with disabilities are also entitled to reasonable accommodations needed to participate in and benefit from a program, and auxiliary aids and services needed for effective communication. These rights extend in some circumstances to family members of a prospective organ donor or recipient. For example, health care providers and organ donation programs are required to provide auxiliary aids and services (including sign language interpreters) when necessary for effective communication between a relative involved in a prospective donor or recipient's care and a health care provider or donation program." Additionally, if eligibility criteria for being a transplant recipient require an individual to be able to comply with post-transplant regimens, it would be a reasonable accommodation to allow an individual with a developmental or intellectual, or other disability to meet that requirement with the assistance of a relative, attendant, or other individual.

We established CfCs for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements in order to be able to receive payments from the Medicare and Medicaid programs. These regulations set forth the certification and re-certification processes, outcome requirements, and process performance measures for OPOs and became effective on July 31, 2006 (71 FR 30982), which we refer to as the "2006 OPO final rule". The current outcome measures, found under § 486.318, are used to assess OPO performance for re-certification and competition purposes (see § 486.316(a) and (d)).

Section 486.322 requires that an OPO must 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. Meanwhile, 42 CFR 482.45

² The Bridgespan Group. Reforming Organ Donation in America. <https://www.bridgespan.org/bridgespan/images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>.

³ ORGANIZE. Organ Donation Reform Report, 2019.

requires a hospital have written protocols that incorporate an agreement with an OPO under which it must notify, in a timely manner, the OPO or a third party designated by the OPO, of individuals whose death is imminent or who have died in the hospital. Potential organ donors may encounter Medicare- and Medicaid-certified providers prior to an emergency department visit or hospital admission to a critical care unit. Therefore, we expect that each OPO's responsibilities and work begins long before a hospital notifies the OPO of an impending death—through, but not limited to, extensive training and education of all Medicare and Medicaid-certified providers along the continuum of care and by fostering a collaborative relationship among them.

C. HHS Initiatives Related to OPO Services and Executive Order (E.O.) 13879

In 2000, the Secretary's Advisory Committee on Organ Transplantation (ACOT) was established under the general authority of section 222 of the PHS Act, as amended. See 42 CFR 121.12. ACOT is charged to: (1) Advise the Secretary, acting through the Administrator, Health Resources and Services Administration (HRSA) on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines; (2) advise the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; (3) at the request of the Secretary, review significant proposed OPTN policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and (4) provide expert input to the Secretary on the latest advances in the science of transplantation, the OPTN's system of collecting, disseminating and ensuring the validity, accuracy, timeliness and usefulness of data, and additional medical, public health, patient safety, ethical, legal, financial coverage, social science, and socioeconomic issues that are relevant to transplantation.⁴

A 2012 recommendation by ACOT stated: "The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and OPOs and that the current system lacks responsiveness to advances in TCs and OPO performance metrics. The ACOT recommends that

the Secretary direct CMS and HRSA to confer with the OPTN, Scientific Registry of Transplant Recipients (SRTR), the OPO community, and TCs representatives to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on TCs and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for TCs and a statistically sound method for yield measures for OPOs"⁵

On July 10, 2019, President Trump issued Executive Order (E.O.) 13879 titled "Advancing American Kidney Health." The E.O. 13879 states that it is the policy of the U.S. to "prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care; increase patient choice through affordable alternative treatments for end-stage renal disease (ESRD) by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations."

Further, the E.O. 13879 aims to increase the utilization of available organs by ordering that, within 90 days of the date of the order, the Secretary propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising OPO rules and evaluation metrics to establish more transparent, reliable, and enforceable objective outcome measures for evaluating an OPO's performance. In conjunction with the E.O. 13879, HHS set a goal to deliver more organs for transplantation and aims to double the number of kidneys available for transplant by 2030.⁶

In accordance with the E.O. 13879, we published a proposed rule in the **Federal Register** on December 23, 2019 entitled, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" (84 FR 70628 through 70710), (referred to as the "December 2019 OPO proposed rule"), which

proposed to revise the current OPO outcome and process measures to be more transparent, reliable, and provide enforceable objective outcome measures of OPO performance. The December 2019 OPO proposed rule would improve upon the current measures by using objective and reliable data, incentivize OPOs to ensure all viable organs are transplanted, hold OPOs to greater oversight while driving higher performance, and as a result, save more lives.

II. Summary of the Proposed Provisions and Responses to Public Comments

In response to the December 2019 OPO proposed rule (84 FR 70628 through 70710), we received approximately 834 total comments. Commenters included individual OPOs, transplant hospitals, national associations and coalitions, academic researchers, advocacy organizations, health care professionals and corporations, donor families, and numerous individuals from the general public. Most commenters supported the proposed rule's goals to improve organ donation and transplantation in the U.S. and to update the current OPO outcome measures.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and an explanation for changes in the policies that we are finalizing. We note that this final rule is written in order by topic, discussing our primary reason for revising the regulations by revising the outcome measures first, and then discussing some necessary changes and cross-cutting requirements.

A. General Comments

The majority of the comments received on the December 2019 OPO proposed rule were received from the general public and organ donor families.

Comment: The majority of the commenters asked for OPOs to be held accountable for poor performance and for additional oversight of OPOs. Some of the commenters expressed concern that the OPOs are operating as monopolies that are engaged in fraud, waste, and abuse. Many commenters asked CMS to increase the accessibility of organs for transplant and ensure that donated organs reach the many individuals on the organ transplant waitlist.

The comments received from donor families expressed support for the OPO in their service area and expressed concern that the proposed changes

⁴ <https://www.organdonor.gov/about-dot/acot/charter.html>.

⁵ Available at: <https://www.organdonor.gov/about-dot/acot/acotreccs55.html>.

⁶ <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>.

would lead to the decertification of their assigned OPO.

Response: We appreciate the commenters' feedback. The tremendous amount of comments that we received asking for OPOs to be held accountable strongly supports our commitment to reform the organ donation and transplantation system in the U.S. We believe that the changes we are making in assessing OPO performance will ensure positive outcomes and increases in the organ supply. There are other initiatives that HHS and CMS are currently undertaking that will also lead to improvements in organ donation and transplantation, such as the ESRD Treatment Choice (ETC) Kidney Transplant Learning Collaborative.

We also appreciate the time taken by numerous donor families to develop and submit thorough and thoughtful comments on the proposed rule. We understand that the decision to donate a family member's organs is difficult, and we praise these families for their generosity. We acknowledge that the decision to donate their loved one's organs likely saved or improved the recipient's life. The changes that we discuss in this final rule are intended to ensure that donated organs are not wasted and reach those waiting for a lifesaving organ transplant. It is our goal to ensure that OPOs are held to a high level of performance expectations and that all OPOs are pushed to perform better. We acknowledge that through changes to the procurement and transplantation process (such as enacting best practices) we can effect visible changes that can lead to an increase in the number of organs available for transplant and decreases in organ discards. We acknowledge commenters' concerns regarding decertification of OPOs and note that that is a likely potential outcome due to these new measures. However, CMS is committed to ensuring patient access to high quality health care, including access to high performing OPOs. Additionally, we believe the measures will incentivize OPOs to improve result in upward performance across most, if not all, OPOs.

Comment: Several commenters criticized our reference to the Bridgespan study² and objected to our characterization of the failures of OPOs. These commenters also expressed concern about negative stories in the media suggesting that OPOs are poorly performing and do not care about the families they serve. The commenters stated that when media stories share inaccurate or outright false information about the OPO community, these stories

have the strong potential to hurt public perceptions about donation.

Response: We understand that there have been several news articles about the poor performance of some OPOs and some of these articles raise reasons about why the organ donation system needs to be reformed. Our independent assessment of OPO performance on outcome measures is the basis for our belief that more oversight is needed. As of November 2020, a total of 108,591 people were on the waiting lists for lifesaving organ transplants. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive an organ transplant, which could ultimately save more lives. The current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ replacement rates. Given these concerns, as well as those regarding the data quality of self-reported measures, we are finalizing new outcome measures at § 486.318 to hold OPOs accountable as a crucial step in reforming the organ donation system.

B. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318)

In the December 2019 OPO proposed rule, we proposed to revise the outcome measures for re-certification and the corresponding changes in definitions at §§ 486.302 and 486.318 to replace the current outcome measures and definitions. We proposed at § 486.302 the definition of "donation rate" as the number of donors as a percentage of the donor potential. We also proposed to add "donor potential," as the number of inpatient deaths within the donation service area (DSA) among patients 75 years of age and younger with any cause of death that would not be an absolute contraindication to organ donation. We also proposed to define the term "organ transplantation rate," which is discussed in more detail in section II.B.4 of this final rule and changes related to our use of "death that is not an absolute contraindication to organ donation" at § 486.302 of this final rule. We refer readers to section II.B of this final rule for the other definitions we proposed at § 486.302. We proposed to revise the outcome measures for re-certification at § 486.318 to replace the current existing outcome measures with the proposed two new outcome measures that would be used to assess an OPO's performance: "donation rate" and "organ transplantation rate"

effective for calendar year (CY) 2022. We have organized the comments by subject matter.

The comments and our responses are below.

1. General Comments About the Outcome Measures

Comment: Several commenters, supported our proposed new outcome measures while other commenters questioned the need for revising them. Some commenters in support of the proposed new outcome measures recognized that these measures are derived from objective data and would not present an increased burden on OPOs. One commenter was concerned that the proposed new outcome measures would result in the OPOs putting more pressure on families and next-of-kin to authorize organ donations. Other commenters expressed concern that increased pressure from the proposed outcome measures and the threat of de-certification (discussed in section II.C of this final rule) would damage the relationships between the OPOs so that they will no longer cooperate with one another.

Response: We appreciate the comments received on the proposed outcome measures. Under our current regulations, the outcome measures at § 486.318 are used to assess OPO performance for re-certification and to determine the selection of an OPO to take over a DSA as part of the competition for an open DSA. We think the increased transparency and objectivity of the proposed outcome measures will drive improvements in organ donation and transplantation while reducing reporting burdens for OPOs. As discussed in section II.B.1 of this final rule, there are aspects of our current outcome measures that we no longer find adequate; therefore, we believe that revising the current outcome measures would be consistent with the goal of E.O. 13879, which directs CMS to establish more transparent, reliable, and enforceable objective measures for evaluating an OPO's performance. In addition, we believe revising the current outcome measures is a critical step towards achieving the Secretary's goal of doubling kidneys available for transplantation by 2030.

Our proposed outcome measures are based on verifiable and objective data and are designed to increase organ transplantations by comparing an OPO's performance to the top performing OPOs. The top performing OPOs have demonstrated success in their role and responsibilities using practices that do not place inappropriate pressures on

families to consent to an organ donation. We note that studies have shown that giving families sufficient time to make their informed decisions and not putting too much pressure on families results in successful consent.⁷ We also note that by objectively identifying top performing OPOs, poorer performing OPOs can appropriately change and adopt their effective practices that improve their performance in donation and make more organs available for transplantation.

It is clear that our historical approach to measuring OPO performance has resulted in a wide range of performances. This variability is unacceptable to patients and CMS. Thus, CMS intends to hold these entities to revised and higher standards. These revised metrics are necessary in light that over the past 14 years, the sharing of best practices, if it has occurred, has not resulted in consistent improvements throughout the industry. CMS is committed to increasing the availability of organs for transplantation across all DSAs, and continues to believe that this higher standard is necessary to achieve this goal.

Comment: We received multiple comments raising concerns that removing organs for research, other than the pancreata, as part of the outcome measures would hurt research by discouraging OPOs from using organs that are not transplanted for research. A commenter recommended CMS to include organs that are used in organ transplantation research in the outcome measures because the process for obtaining consent and managing these donors is the same as with organ transplantation. Other commenters suggested that we include organs for research as a “third performance metric” or incorporate it in some other way into our conditions. One commenter discussed our history of inclusion of organs for research and stated that OPOs would not pursue marginal organs because they would no longer get credit if the organ was not transplanted, whereas the old outcome measures allowed them to be counted to the organs for research measure.

Response: We appreciate the comments raising concerns about the removal of other organs used for research as part of the outcome measures.

The transplant and research communities commonly described the transplantation of organs into humans

using research protocols (for example, deceased donor intervention research) as both transplants and research. Generally, such research involves the transplantation of organs into transplant candidates that is generally considered clinical care while simultaneously qualifying as human subject research. For the purpose of establishing the performance measures, we contend that organs used for research is meant to apply only to organs procured and used only for research purposes. Organs transplanted into human subjects are counted as part of clinical care. Although organs procured for research may sometimes involve the same procedures and practices of donor management as organs for transplantation, we cannot easily verify the procurement of organs for research unless they are transplanted into a patient on the OPTN waiting list. Furthermore, our concern is that having an outcome measure for organs procured for research may inadvertently incentivize OPOs to direct some organs for research rather than for transplantation. Except for pancreata when procured for research, as noted in the December 2019 OPO proposed rule, we are not adopting the commenters’ suggestion to include organs donated for research in the outcomes measures.

Pancreata procured for islet cell research are included in the outcome measures of this final rule. We carefully considered other options to address pancreata procured for research, such as creating a process measure for these organs, creating a unique outcome measure, and counting these organs in the outcome measures of this final rule as less than the full value of a transplanted organ. However, these alternative policy approaches did not meet the PHS Act, which states that “Pancreata procured by an organ procurement organization (OPO) and used for islet cell transplantation or research shall be counted for purposes of certification or recertification” To meet this statutory requirement, we have chosen to include pancreata for research in the outcome measures in the same way that organs procured for transplantation are included. We think that the impact of pancreata for research on the overall rankings of OPOs will continue to be minimal. From 2014 to 2018 (the most recent year of complete data), the number of pancreata procured for research has been 727, 716, 575, and 579. There is a clear downward trend, and we expect that this trend will continue or level off. Our internal analysis demonstrated little effect on the rankings of OPOs from including or

excluding pancreata for research when calculating performance on both the donor and transplant measures of this final rule. A particular OPO may move up or down 1–3 ranking spots based on the inclusion of this data, but no OPOs moved in such a way that it impacted whether they would be eligible for automatic recertification or would be automatically decertified. We will continue to monitor the trends of pancreata procured for research and will use the survey process to conduct further investigation into any anomalies that such monitoring reveal.

Comment: We solicited comments as to whether we should consider assessing OPO performance based on organ-specific transplant rates and received a comment that broadly supported this approach, but we did not receive details about how we would measure success for the organ-specific transplant rates or how it could be implemented.

Response: We are not including organ-specific transplantation rates in our outcome measures because we do not believe that organ-specific transplantation rates would provide an additive assessment of OPO performance and achieve our goals of increasing organs available for transplantation.

2. Donation Rate §§ 486.302 and 486.318(d)(1)

In the December 2019 OPO proposed rule, we proposed to include at § 486.302 the definition the “donation rate” as the number of donors as a percentage of the donor potential. In current regulations at § 486.318(d)(1), we define the donation rate as being the eligible donors as a percentage of the eligible deaths.

In addition, we proposed that § 486.318(d)(1) specifies that the donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

Comment: The majority of the comments received supported the use of the donation rate to measure OPO performance.

Response: We appreciate the comments received. We consider the donation rate to be an important outcome measure because it assesses the ability of the OPO to obtain consent from the donor family, successfully manage the donor, procure and place at least one organ for transplantation (or pancreas for research), and ensure the safe transport of that organ for transplantation. However, despite all these aspects of the OPO’s role that the donation rate measures, for patients waiting for a life-saving organ

⁷ Siminoff, LA, Agyemang, AA, et al., “Consent to organ donation: a review,” *Prog Transplant*. 2013 Mar; 23(1): 99–104.

transplant, the primary measure of interest is the organ transplantation rate. Therefore, the donation rate can be seen as augmenting the organ transplantation rate. By including the donation rate, we incentivize OPOs to pursue all donors, especially the single organ donors. An OPO is more likely to meet the donation rate measure if they also procure organs from donors after cardiac death (DCD) or marginal donors where relatively fewer organs may be transplantable.

Comment: One commenter suggested CMS measure the OPOs ability to obtain consent in calculating the donation rate. The commenter did not suggest how the consent would be used as an outcome measure.

Response: Although obtaining consent is one part of the donation process, we are not adopting the commenter's suggestion to use obtaining consent as an outcome measure. We recognize the critical role of obtaining consent as the first part of donation, and without it, the rest of the donation process cannot occur. Our regulation at § 486.342 requires OPOs to have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. As with our other CfCs, we survey to ensure compliance with this requirement, and those surveys typically occur every 4 years. However, we cannot verify success in obtaining consent relative to the donor referrals through independent, objective data on an annual basis and instead, rely on surveys. It would be unduly burdensome to OPOs to be routinely surveyed every year for us to identify and verify this information for purposes of the frequent assessment periods in which these outcome measures are calculated to trigger revisions to the Quality Assessment and Performance Improvement (QAPI) plan under the requirements at § 486.348 (also discussed in section II.E of this final rule).

Final Rule Action: We are finalizing as proposed the definition of donation rate at § 486.302, which is defined as the number of donors as a percentage of the donor potential. Furthermore, we are finalizing at § 486.318(d) that an OPO is evaluated by measuring the donation rate in their DSA and at § 486.318(d)(1) the donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

3. Donor Definition (§ 486.302) and the "Zero Organ Donors"

In the December 2019 OPO Proposed rule, we proposed to revise the definition of "donor" at § 486.302 to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured for research or islet cell transplantation. In general, the proposed definition of donor would change the current regulatory definition, requiring that at least one organ be transplanted, rather than being recovered for the purpose of transplantation, in order for the donor to be included in the donation rate. We also included donors who had pancreata procured for islet cell transplantation and research in the definition of donor to respond to the requirements of section 371(c) of the PHS Act.

Comment: Several commenters stated that our proposed new definition of "donor" excluded "zero organ donors." Some commenters had different definitions of "zero organ donors" including: (1) Donors who are taken to the operating room but cannot be a donor for one or more reasons; and (2) are donors in which the transplantable organs are turned down by transplant programs. These commenters claim that excluding "zero organ donors" in the donation rate would discourage OPOs from pursuing extended criteria or marginal and complex donors, which would be inconsistent with our goal of trying to increase donations, particularly of single organ donors.

Response: We acknowledge that the general effect of our proposed definition of donor at § 486.302 would be that, a patient must donate at least one organ that is actually transplanted to qualify as a "donor." We note that the definition also includes a patient who donates a pancreas for research. Although "zero organ donors" would not fall under this definition, we are not persuaded by comments that OPOs will not pursue the extended criteria or marginal, complex donors if we do not include "zero organ donors" in the outcome measures. Not only did we receive comments from some OPOs stating that they are committed to "pursuing every organ every time even if no organs are transplanted," but an OPO that does not pursue these donors will be at risk of being identified as a poorer performer compared to other OPOs and could possibly face the prospect of being de-certified.

Evidence demonstrates that the top performing OPOs are pursuing extended

criteria and single-organ donors, and those OPOs are also successfully placing the organs at programs that transplant them. Some OPOs are relatively successful in recovering organs from more marginal candidates, saving those donors from being "zero organ donors." We accessed the OPTN database on August 12, 2020 and found that from 2018 and 2019, the OPO in Nevada had procured 80 kidneys that were categorized as having the highest Kidney Donor Profile Index (KDPI) scores of 86 through 100. These types of kidneys are primarily from extended criteria or marginal donors that are more likely to end up as "zero organ donors." Meanwhile, the local kidney transplant programs in their DSA transplanted zero kidneys with the highest KDPI scores, meaning that these organs were transplanted by programs outside of their DSA; this example suggests that the local demand was not driving the Nevada OPO's performance. In order for other OPOs to follow this example, they must also pursue the extended criteria and marginal donors, even if the local transplant program does not accept them. Using the comparative performance methodology and holding all OPOs to the performance of these top performing OPOs, we intend to incentivize all OPOs to pursue extended criteria and marginal donors, even if they may become zero organ donors.

Comment: Some commenters recognized that "zero organ donor" counts are self-reported data and are difficult to verify, but suggested that CMS review the charts or use triggers to lead to a chart audit as a means of verifying these donors.

Response: In changing the definition of donor, we are adhering to the principles described in the December 2019 OPO proposed rule that the outcome measures be more transparent, reliable, and objective measures of OPO performance. Part of ensuring reliability is moving away from self-reported data as much as is feasible and using data that can be easily verified. It would require an extraordinary effort for CMS to verify the zero organ donors as frequently as needed to calculate the annual assessments of OPO outcome measures that will be used to trigger revisions of the QAPI program that can spur OPOs to improve their performance, and to rank OPOs for certification purposes.

Comment: We received several comments stating that because it is ultimately the transplant programs that decide whether an organ is transplanted (not the OPO) that redefining "donor" to require that the organ be transplanted would not be appropriate.

Response: Transplant programs decide whether an organ will be transplanted; however, it is the OPO's responsibility to ensure that placement and transport of organs happen in a fast and effective manner. If the OPO engages in best practices for placement, packaging, and transportation of organs, such as using RFID tags to track organs in transit and assure that they are not forgotten or diverted, there should not be significant differences in the frequency of zero organ donors among OPOs because the occurrence of unexpected anatomical issues which contraindicate donation that arise after consent is secured are random and not statistically significant in one DSA compared to another.

Comment: Several commenters stated that OPOs are obligated to the allocation system and that sometimes they run out of time trying to place certain organs. Therefore, the commenters stated that the OPOs should not be punished if they cannot place a transplantable organ.

Response: We respectfully disagree with the commenters' assertion. The OPTN final rule has a section on wastage that explicitly allows transplant programs to transplant an organ into any medically suitable candidate to do otherwise would result in the organ not being used for transplantation (42 CFR 121.7(f)). Therefore, we do not believe the constraints of the allocation system justify not successfully placing a transplantable organ. We believe that this final rule will allow OPOs the opportunity to improve the placement of organs, and drive the transplant community to adopt the technologies necessary to optimize placement.

Comment: We received a comment that there are some events, such as loss of an organ during transport, which OPOs cannot control.

Response: By requiring that the organ be actually transplanted (with the exception of pancreata procured for research) in order to be counted in the donation rate, we are supporting those OPOs that work to successfully complete the final step of the donation process. Unfortunately, we are aware of incidences where organs are lost or damaged during transport.⁸ It is the responsibility of the OPO to arrange the appropriate transport to the transplant program. (See § 486.346 of this final rule.) Therefore, it is important that any measure of OPO performance not stop at the procurement of a transplantable

organ, but also holds OPOs accountable for the subsequent steps for successful placement and transport of organs.

Comment: One commenter suggested that donor families would be disappointed if they consented to the donation, but we did not allow the zero organ donor to be called a donor.

Response: We appreciate every potential donor and are not discouraging OPOs from referring to "zero organ donors" as "organ donors" even if no organs are transplanted when speaking with families. The use of the term "organ donors" has different meanings in different settings. Many families consider their loved ones to be organ donors if they are eye and tissue donors or if the organs are donated for research. Therefore, we do not think our definition, used solely for assessing OPO performance for regulatory purposes, should affect the donor families' perception of the value of their loved one's donation or the terms used by OPOs or other organizations when liaising with families of potential donors.

Comment: One commenter stated that it was important to encourage OPOs to pursue all donors and suggested that we include these "zero organ donors" in the performance measures even if they are not included in the outcome measures.

Response: We will continue to work with OPOs on a more refined reporting process to capture information about zero organ donors and the reason for the organs not being retrieved or transplanted. We intend to continue the dialog with OPOs about the necessary data to collect and how to do so in a verifiable, burden neutral manner, and our CfCs may be revised in the future based on such modifications and further analysis of the data.

Comment: One commenter supported our proposed definition of donor because they agreed that OPOs could "game the system" if we included "zero organ donors."

Response: We appreciate the comment and, as explained above, we are not including "zero organ donors" in the definition of "donor." As we stated in the December 2019 OPO proposed rule, we have concerns with self-reported data. Our internal analysis of the OPTN data found a variation in the frequency of "zero organ donors" as defined as a donor in which an organ was procured for transplantation, but no organ was transplanted. We did not see an association between the OPO's performance and the percentage of these donors, however, we retain the concerns expressed in the December 2019 OPO proposed rule. The OPTN data show

that in 2018, there were 1,255 organs procured from these zero organ donors, but never transplanted. In that same year 31,203 organs were transplanted. Among the top performing OPOs, zero organ donors represented 2.73 percent to 11.86 percent of donors (the range among all OPOs was 0 percent to 17.02 percent) with counts ranging from 3 to 59 zero organ donors.

We do not understand the significance of this variation, but will continue to examine the data about "zero organ donors" and assess whether we can appropriately capture and verify the data for future inclusion in our outcome measures.

Comment: We received a comment raising concerns that the change in the definition of donor could affect reimbursement from Medicare since the previous definition allowed OPOs to be reimbursed for the efforts to procure transplantable organs.

Response: Our revised definition of donor does not impact Medicare reimbursement for organ procurement costs. We did not propose to change our rules for reimbursing OPOs for organ procurement costs. Our payment policies for organ procurement costs do not rely on our definition of donor under § 486.302.

Final Rule Action: We are finalizing as proposed in the December 2019 OPO proposed rule, the definition for donor at § 486.302 to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

4. Organ Transplantation Rate (§ 486.302 and § 486.318(d))

For our second measure, we proposed to assess the OPO's organ transplantation rate, which is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential.

Comment: We received a number of comments supporting our organ transplantation measure because it was a volumetric measure (that is, reflects the volume of organs transplanted). We had one OPO commenter provide an example of how they increased the procurement of lungs for transplantation, but the SRTR method for measuring observed to expected performance in organ transplantation did not capture their improved performance.

Response: We appreciate the comments in support of the volumetric organ transplantation measure. As

⁸ Kaiser Health News, "How Lifesaving Organs for Transplant Go Missing in Transit," February 10, 2020 <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>.

stated earlier, the organ transplantation rate is an important measure as it directly measures the benefit for patients from OPO performance.

Comment: Several commenters opposed the organ transplantation rate because it was too similar to, and not independent of, the donation rate since it shared the same denominator as the donation rate.

Response: In both of our outcome measures, the denominator represents a reasonable effort to estimate of the donor potential and other related factors for the DSA, as required by the OPO Certification Act of 2000.⁹ The numerators measure OPO performance (through the number of donors and organs transplanted) and are somewhat correlated because if there are more donors, there are likely to be more organs transplanted. It is CMS' expectation that high-performing OPOs will likely perform well on both measures and low-performing OPOs will perform poorly on both measures. However, these numerators are not the same and each donor has a range of potential organs that could be transplanted. For example, OPOs that focus primarily on DCD and marginal donors may need to seek more donations in order to have sufficient organs transplanted to mathematically meet the organ transplantation rates. On the other hand, OPOs that are very effective at placing all possible organs from younger, healthier donors may achieve the targeted organ transplantation rate, but not the donation rate, if they choose not to pursue the marginal, complex and DCD donors with only one or two transplantable organs.

Comment: We received a number of comments from the OPO community recommending that we use the SRTR's Donor Yield model, which calculates an observed:expected (O:E) ratio for placing organs for transplantation (also called the SRTR O:E model). These commenters preferred the O:E measures because it includes 34 to 50 risk-adjustments, changes over time, and measures a different part of an OPO's performance from the donation rate (part that involves placement and transport an organ).

Response: While the SRTR's O:E ratio may have value for understanding potential areas for improvement and may be used by the OPTN and OPOs for internal performance assessment, it is derived from the donation rate and is not capable of assessing the number of organ transplants. The SRTR O:E model "uses a series of complex statistical

models" and relies on coefficients from a multinomial regression model.¹⁰ The validity of the model is dependent upon frequent updates to the regression analyses to determine which predictors are in the model (hence range of 34 to 50 risk-adjustments). Because of the complexity of the model and the need for frequent updating, it is not feasible for us to continually update the methodology through notice and comment rulemaking, which is necessary in order to enforce the current version of the model. Use of the SRTR O:E model in regulation has not been practicable. The mathematical complexity of the risk-adjustments creates an opacity that is inconsistent with our goal of increasing transparency in our outcome measures.

Comment: We received comments suggesting we add the SRTR's donor yield model, which measures observed to expected performance in O:E measure with the organ transplantation rate or increase the level of performance on the O:E measure.

Response: We appreciate the commenters recognizing that the O:E measure is based on the average performance of an OPO and suggesting that we retain the measure but increase the level of performance above what was expected so that OPOs would be held to the O:E ratio of the top performing OPOs. As previously discussed, we are not using the O:E measure because it is not capable of measuring volume, is directly correlated to the donation rate, and does not directly capture increases in organs being transplanted. Finally, adding this measure to the organ transplantation rate would introduce additional regulatory complexity and reduce the transparency of these outcome measures. Therefore, we are finalizing the organ transplantation rate as the second measure.

Final Rule Action: We are finalizing the definition of organ transplantation rate with revisions at § 486.302. The revised definition of "Organ transplantation rate" is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. This modification is a clarification that if the organ is transplanted, regardless whether it is part of normal clinical practice or research, it will be counted in the organ transplantation rate. We are also making further modifications to the

definition of "organ transplantation rate," which are discussed in more detail in section II.B.7 of this final rule. We are also finalizing as proposed at § 486.318(d) that the OPO is evaluated by measuring the organ transplantation rate in their DSA.

5. Organ Definition (§ 486.302)

In the December 2019 OPO proposed rule, we specified how we would count the organs that would constitute the numerator for the organ transplantation rate. We proposed to include pancreata procured for islet cell transplantation and research in the definition of "organ" to meet the requirements of the Pancreatic Islet Cell Transplantation Act of 2004, which amended the PHS Act to include section 371(c). (84 FR 70631) Section 371(c) of the PHS Act states that "[p]ancreata procured by an organ procurement organized and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b)."

Comment: Several commenters opposed our inclusion of pancreata for research in our outcome measures since procuring pancreata for research is not a normal function of OPOs and is highly dependent upon the demands of the local researchers. Some commenters supported the inclusion of pancreata procured and placed for research in the organ count. We received comments that including the pancreata for research would lead to artificial inflation of the organ transplantation rate; that we should use a third performance metric to assess performance for pancreata procured for research; and that we did not properly define the scope of "pancreata procured for research."

Response: We agree with the commenters that pancreata for research are specific to the local research demands and may not reflect universal OPO practice. Nonetheless, their inclusion in the outcome measures is consistent with the requirements of the statute, and we are finalizing them as such. We intend to verify the accuracy of the data reported related to pancreata procured for research during the survey process, and believe that this is a sufficient disincentive for inflating the reported data. We considered creating a third outcome measure specifically for pancreata procured for research. However, there is no data source currently available to enable us to analyze performance and establish a meaningful measure. We will continue exploring ways to develop a data source and meaningful measure for consideration in future rulemaking.

¹⁰ <https://www.srtr.org/about-the-data/guide-to-key-opo-metrics/opoguidearticles/donor-yield/>.

⁹ 42 U.S.C. 273(b)(1)(D)(ii)(III).

Comment: Commenters recommended CMS to include vascular composite allografts in the organ count for the organ transplantation rate.

Response: We appreciate this suggestion but are not including vascular composite allografts (VCA) in our definition of organ. VCA transplantation is very localized and rarely performed. In 2019, approximately 15 such transplants occurred, the vast majority being the transplantation of a uterus (12 transplants)¹¹. Inclusion of VCAs as organs would require a separate assessment throughout all CMS policies and regulations that is beyond the scope of this rule.

Final Rule Action: After consideration of public comments, we are finalizing our proposed definition of organ at § 486.302 to mean a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

6. Donor Potential (§§ 486.302 and 486.318(d)(4))

Under § 486.318(d)(4), the donation rate, organ transplantation rate, and kidney transplantation rate use the “Donor potential” as defined under § 486.302 as the denominator. In our December 2019 OPO proposed rule, we proposed to define the donor potential (denominator) as total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that is not an absolute contraindication to organ donation. We proposed to use death certificate information that can currently be obtained from the Center for Disease Control and Prevention’s (CDC), National Center for Health Statistics’ (NCHS’s) Detailed Multiple Cause of Death (MCOd) file as described in our December 2019 OPO proposed rule. The MCOd is published annually and is publicly available upon request. The MCOd comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOd files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data (50 states, New York City, the District of Columbia and the five territories). The jurisdictions use the

U.S. Standard Certificate of Death as a template for their forms.

In order to provide a most robust and detailed discussion, we have divided the comments and responses to our definition of “Donor potential” into separate sections: The use of state death certificates for estimating the donor potential; the specific ICD–10–CM codes used to identify the donor potential; the age threshold for the deaths; the inpatient aspect of the deaths; and the effect of waiver hospitals.

a. Death That Is Consistent With Organ Donation (§ 486.302)

Under § 486.302, within our proposed definition of “Donor potential,” we use a separately defined term, “Death that is not an absolute contraindication to organ donation.” This term is characterized by two major parts: (1) The data source for calculating these deaths (state death certificate data) and (2) the ICD–10–CM codes for identifying these deaths.

We proposed to use state death certificate information that can currently be obtained from the CDC, NCHS’s MCOd file as described in our December 2019 OPO proposed rule to determine the donor potential. The MCOd is published annually and is publicly available upon request. The second part of the definition of “Death that is not an absolute contraindication to organ donation” describes all deaths except those identified by the specific ICD–10–CM codes listed in our definition that would preclude donation under any circumstance. As part of our proposed rule, we also considered the alternative of using the ICD–10–CM codes that are consistent with organ donation in the methodology developed by Goldberg, et al.¹² (84 FR 70662), also known as the “CALC” methodology.

We received numerous comments on both of these components and discuss responses to these comments separately.

i. Death Certificate Data

Comment: We received numerous and varied comments regarding our use of the death certificate information reported to the CDC and currently found in the MCOd files. Many commenters supported the use of data derived from death certificates because it represents the best available option for obtaining objective data at this time to estimate the donor potential. However, several commenters referenced literature that found error rates of the death certificates

ranging from 30 to 60 percent. In addition, numerous commenters from the medical examiner/coroner community questioned the accuracy of the death certificates.

Response: We appreciate the commenters supporting our use of the MCOd file. As discussed in the December 2019 OPO proposed rule, we are aware of the error rates in the death certificate data reported in the literature, but continue to believe this data is the most complete information that is readily and publicly available, that can be used for estimating the donor potential at this time. Every state submits death certificate data to the CDC and the elements collected in the death certificates are standardized to the greatest degree possible. Errors in reporting on the death certificates are primarily from user error, where the individual completing the form makes a mistake. The same user errors likely plague other potential data sources, such as hospital records, and those data sources would come with significant added reporting burdens with limited to no additional benefit. We are not aware of differences in the error rates that would disadvantage one DSA over another DSA (84 FR 70632). In addition, we are not aware of any research that describes such differences. Based on our understanding of which professionals are responsible for completing the death certificates and comments from the public, we do not see a compelling reason why there would be a consistent disparity in the error rates from one DSA to another. Furthermore, no commenters have suggested a source of empirical evidence that could be obtained by reasonable effort of organ donor potential in each designated service area sufficient to meet our needs and expectations. The peer-reviewed research developed by Goldberg, et al. discussed throughout our December 2019 OPO proposed rule and this final rule supports the use of the death certificate data as the best and most comprehensive source for estimating the donor potential at this time.

We appreciate the comments and knowledge from the coroner/medical examiner community about the error rates in the death certificates.

Comment: We received one comment from the OPO in Alabama about errors in the electronic reporting of death certificate data resulting in misreporting inpatient deaths.

Response: We thank the commenter for pointing out the error in reporting inpatient deaths in Alabama. We understand that the reporting error has been resolved for 2019 and was unique to Alabama. We do not have any reason

¹¹ OPTN database accessed on July 11, 2020 and number of transplants for abdominal wall, head & neck (cranial facial), head & neck (scalp), GU: Penile, GU: Uterus, upper limb: Bilateral, upper limb: Unilateral, and VCA were counted for 2018 and 2019. In 2018, there were 11 transplants.

¹² Goldberg D, Karp S, et al., “Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation,” *AmJTransplant*. 2019;00:1–6.

to believe that other states made this error. For purposes of the regulatory impact analysis in this final rule, which uses data from 2018, we have made adjustments to the inpatient deaths in Alabama to be more consistent with historical rates of inpatient deaths prior to the error occurring. If there are future occurrences in which there are similar such errors, we have added an extraordinary circumstances exception (ECE) under § 486.316(f) to allow OPOs to request a 1-year extension to their agreement cycle if there are extraordinary circumstances beyond the control of the OPO that would affect the data being used. This ECE request is discussed in greater detail in section II.C.5 of this final rule, which discusses the data length used for calculating the outcome measures.

Comment: We received a comment describing in detail the process by which the death certificate is completed in their particular state.

Response: We thank the commenter for providing us with this detailed information. States have slightly different processes for completing the death certificates even though all states use the standardized death certificates. The MCOD comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOD files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data (50 states, New York City, the District of Columbia and the five territories). The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms. Although commenters expressed concerns with our use of the MCOD, they did not suggest a different source of empirical evidence that could be obtained without undue reporting burden and was of greater accuracy. Furthermore, this commenter did not provide any information to suggest that this different process for their state would result in less accurate information for that jurisdiction and we do not have reason to believe that a different process would disadvantage one OPO compared to another.

Comment: We received a comment questioning whether our donor potential reflected the DSA because the publicly available CDC data on death certificates has the location of the death based on the individual's home rather than the location of the hospital.

Response: Based upon this comment, we believe that the commenter is referring to the CDC Wide-ranging Online Data for Epidemiologic Research

(WONDER) database, which is available on the CDC public website. This database has the person's residence at the time of death instead of the location of the death. The MCOD file, which we are using to calculate our outcome measures, has information on the location (county) of the inpatient death. The location of the patient's death is more relevant to attributing donor potential for each DSA. A CMS contractor will use information from the MCOD file to attribute deaths to each DSA.

Comment: We received a comment that "death certificate source is limited solely to statistical uses and cannot be used for regulatory purposes" because section 308(d) of the PHS Act (42 U.S.C. 242m) provides that data collected by NCHS "may be used only for the purpose of health statistical reporting and analysis."

Response: We have consulted with the CDC and concluded that our use of the MCOD represents a statistical analysis to characterize OPO performance and is consistent with the PHS Act. We are not using the data from the MCOD file to directly take legal, administrative or other actions against the hospitals and states that submit the data, nor are we taking regulatory action on the inpatient deaths in the DSA. Rather, we are using the data to "normalize" our outcomes of interest: The number of donors and the number of transplants in the DSA. The section of the PHS Act cited by the commenter refers to the confidentiality of the NCHS data and the limitations of the use of the data if "an establishment or person supplying the information or described in it is identifiable." Our calculations use county level data that does not identify the specific hospitals submitting the death certificate data.

Comment: We received comments that the death certificate data does not include information about co-morbidities or other chronic conditions that may make it unlikely for the person to be an organ donor.

Response: Our goal in using the death certificate data was to use the best information available to calculate organ donor potential in each DSA. We are using the death certificate data to adjust the denominator to better reflect the population in the DSA that will more closely resemble individuals likely to become a deceased organ donor (individuals who are 75 and younger and died in the hospital with a cause of death consistent with organ donation). No risk-adjustment method is precise and we do not have evidence that the rate of co-morbidities associated with these causes of deaths is significantly

different from one DSA to another and would be the reason for the differences in performance.

Comment: Several commenters suggested alternative sources for estimating the donor potential: Data from electronic health records, data from hospital chart reviews, insurance billing codes, and hospital reported data of ventilated neurological deaths. Commenters also raised concerns about the burdens of asking donor hospitals to report potential donors and ventilated deaths, a concern that applies to all of the suggested alternatives.

Response: We thank the commenters for the suggestions of alternative data sources. All of the suggested data sources are subject to the same user error inaccuracies as the MCOD files. Furthermore, we note that none of these suggested alternative sources for estimating organ donor potential could be obtained by reasonable efforts and would not be feasible or practical for calculating the outcome measures. Many of the suggested data sources are not feasible to use or sufficiently comprehensive to estimate the donor potential for various reasons. First, not all hospitals have electronic health records that can transmit data or be shared; not all OPOs have the ability to receive electronic health record transmissions. Second, collecting data via hospital chart reviews would likely be burdensome. Third, there is no national or comprehensive database of all insurance claims, and collecting data from insurance claims would inappropriately not count those decedents who did not have insurance. We agree with those comments that raised concerns about the burden on donor hospitals if we asked them to report data on ventilated deaths, and agree that requiring those additional reporting requirements or combining all these disparate data sources to estimate the donor potential could not be obtained by reasonable efforts. CMS will continue to evaluate the benefit and applicability of future data sources as they become available.

Final Rule Action: We are finalizing the death certificate information reported to the CDC and currently found in the MCOD files as the data source for calculating the donor potential of each DSA.

ii. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)

Comment: The vast majority of comments supporting the use of the state death certificate data from the CDC files also preferred using ICD-10-CM codes that represented the causes of

death that is consistent with organ donation rather than our proposed approach based on defining “death that is not an absolute contraindication to organ donation.” Some commenters suggested adding other ICD-10-CM codes to the list of ICD-10-CM codes we would exclude. One commenter stated that the ICD-10-CM codes consistent with organ donation provided a donor potential that was consistent with their own internal calculations. Another commenter provided an estimate of 187,500 donor referrals in the U.S. based on extrapolation of their own data.

Response: Given the overwhelming comments supporting the use of the ICD-10-CM codes from the methodology which is based on the cause, age, and location consistent with organ donation (CALC), we are finalizing the use of ICD-10-CM codes from the CALC methodology, which are inclusion codes, in estimating the donor potential. Our proposed methodology used the ICD-10-CM codes that are exclusion criteria and included significantly more codes. The ICD-10-CM codes that are considered as causes consistent with organ donation were identified in section V.G “Alternatives Considered” of the December 2019 OPO proposed rule, and were confirmed by the developers of the CALC methodology, although they were not specified in the published literature. As discussed in the December 2019 OPO proposed rule, the ICD-10-CM codes in the CALC methodology captures 98–99 percent of all donors. (84 FR 70666). The advantage of this inclusion method over the one we proposed is that given the description of the ICD-10-CM codes chosen, there are unlikely to be new causes of death that would lead to organ donation. However, as we have discovered during the COVID-19 public health emergency (PHE), there is a likelihood of new, unanticipated contraindications for organ donation. If we used exclusion criteria in estimating the donor potential, we could have to update and change our rules much more frequently to adjust for these new contraindications to organ donation. We believe that these unplanned changes could be disruptive to OPO operations and efficiency. Therefore, we agree with commenters that the CALC methodology which identifies ICD-10-CM codes consistent with organ donation is preferable to the methodology we proposed. We discuss this methodology and the calculations that result from using this methodology in greater detail in the discussions of our regulatory

impact analysis under section V of this final rule.

In § 486.302, we have added the definition “Death that is consistent with organ donation” as all deaths from the state death certificates with the primary cause of death listed as the ICD-10-CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V-1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. From our calculations using 2017 data, the CALC methodology resulted in a donor potential of 101,479, which would be a reasonable estimate of the total U.S. donor potential if the donor referral is approximately 187,500 as suggested by a commenter who estimated this donor referral population based on their own referral data.

We also conducted preliminary analyses examining whether there was additive value to excluding the ICD-10-CM codes that were contraindications to organ donation to the causes of death that is consistent with organ donation. We found little difference in the ranking and identification of OPOs at the different thresholds of interest. Therefore, we are not using any ICD-10-CM codes to exclude additional inpatient deaths from the ICD-10-CM codes that are consistent with organ donation.

Comment: We received several comments questioning the donor potential and providing references that cited donor potential varying as low as 10,500 and as high as 272,000 (our estimate).

Response: We know the donor potential cannot be as low as 10,500 because there were 11,870 deceased donors in 2019, according to the OPTN (<https://optn.transplant.hrsa.gov/news/organ-donation-again-sets-record-in-2019/>). Our “donor potential” was not designed to identify an actual donor potential size as we have discovered that the true donor potential changes constantly as technology and demand for organ transplantation changes. Instead, our proposed methodology was designed to estimate the likely donor referral population to normalize the inpatient deaths across the different DSAs. Since the donor potential is part of a rate calculation, identifying the exact, true donor potential is less relevant than providing standardized, reasonable, and objective criteria to estimate it. We know that as public health crises occur, such as the opioid crisis or COVID-19, the donor potential may change. Also, as technology and practices change, the donor potential may change. When the 2006 OPO final rule was published, DCD was so

infrequent that those potential donors were not included in the definition of an eligible death; yet in 2019, almost 23 percent of all deceased donors were DCD donors. Based on public comments, we believe the CALC methodology produces a very close estimate to the current donor potential for each DSA and it also has the flexibility to adjust to changes in the number of these causes of death in the DSA.

Final Rule Action: We are finalizing under § 486.302 that “Death that is consistent with organ donation” means all deaths from state death certificates with the primary cause of death listed as the ICD-10-CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V-1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. We will not include in the final rule a definition of “death that is not an absolute contraindication to organ donation.”

b. Age 75 and Younger

Comment: We received comments that the proposed age cut-off of age 75 in our definition of “donor potential” was too high and suggested that we should use age 65 instead. On the other hand, we also received a comment that the proposed age cut-off of age 75 was too low because OPOs have procured livers from donors older than 75.

Response: We proposed that the denominator for calculating the donation and organ transplant rates will be based on the number of inpatient deaths of someone 75 years old or younger because our previous definition of eligible death uses the age of 75 years old or younger. We do not concur with commenters’ suggestion to lower the age threshold for the donor potential for our new outcome measures. Although we are aware that it is possible to for liver donors to be older than 75 years of age, we also recognize that the practice of using organs from older donors is still relatively new. Data from the OPTN lists the maximum age of liver donors as 65+. The number of living donations from this group between 2014 and 2019 ranged from 571 to 732 with gradual increase over time.¹³ It is, however, a practice we want to encourage in order to increase the number of successful transplants; therefore, we are keeping our age limit at 75 years in order to reward OPOs who are successful with the donation and transplantation of organs from deceased individuals

¹³ <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.

greater than 75. OPOs who are successful in procuring these organs, particularly livers, from older donors may be able to count the donors and organs transplanted in the numerator of our outcome measures without having the death counted in the denominator.

Final Rule Action: We are finalizing that the age cutoff of age 75 for the donor potential definition in § 486.302, as proposed without modification.

c. Inpatient Deaths

We did not receive any comments as to whether the deaths should be limited to inpatient deaths. We are aware of preliminary studies suggesting that potential donors are identified in the emergency department as well as the inpatient setting. However, we believe those individuals are likely to become inpatients and thus, the location where they are identified, may not always correlate with where they die. Our data source is based on the location of death.

Final Rule Action: We are finalizing that the definition of donor potential under § 486.302 be limited to inpatient deaths.

d. Waiver Hospitals

Comment: We received a number of comments inquiring how CMS is addressing the donor potential estimates in DSAs where some donor hospitals sought waivers to work with a different OPO. One commenter raised concerns that we made an error in calculating the donor potential because we assigned the donor potential to the wrong OPO.

Response: Historically, DSAs have been divided based on counties and metropolitan statistical areas. However, donor hospitals can request the ability to work with an OPO outside their DSA through a waiver request (we refer to these donor hospitals as “waiver hospitals” under § 486.308(e)). In estimating the donor potential for each DSA, we relied on the listing of counties found in the SRTR’s OPO-specific reports, which listed both counties to an OPO when more than one OPO was servicing the county because of the waiver hospital. As a result, we erroneously double-counted the donor potential in several DSAs in the December 2019 OPO proposed rule. This inaccurate ranking would not have significantly altered our projections of the number of OPOs that would be automatically certified or decertified in accordance with the measure parameters set forth in the proposed rule.

While there are no data sources which we can use to precisely attribute non-Medicare inpatient deaths to these waiver hospitals, we can apportion the

donor potential to each OPO by calculating the percentage of Medicare inpatient deaths at each acute care and critical care hospital in the county as a proxy, and use that percentage to divide the donor potential and assign the percentage of the donor potential based on the Medicare percentage of inpatient deaths. At this time, the apportionment method we have described is the best solution to addressing donor potential for OPOs that work with waiver hospitals. We intend to explore other options that could improve the data about deaths that should be counted for waiver hospitals.

Final Rule Action: In response to public comments, we are amending the definition of the donor potential at § 486.302 to apportion the donor potential in a county where there is a donor hospital that has received a waiver to work with an OPO out of their DSA. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

7. Risk-Adjustments §§ 486.302 and 486.318(d)(2)

In the December 2019 OPO proposed rule (84 FR 70628), we did not propose other risk-adjustments to the proposed outcome measures, but sought comments as to the accuracy of our assessment and whether additional risk adjustments were necessary. We sought comments on whether risk-adjustments are necessary and which ones, such as donor demographic characteristics (race, gender, age, disease condition) or DSA characteristics (number of ICU beds or level I and II trauma centers) would be significant and clinically appropriate in the context of our proposed approach to identifying OPOs in need of improved performance. Specifically, we requested public comments that provide evidence-based support, such as peer-reviewed literature, that would support those suggestions, as well as data sources that would be necessary to calculate the risk-adjustments recommended.

a. Chronic Diseases

Comment: We received comments from some OPOs about the incidence of certain diseases in their DSA that would make their general population less likely to be organ donors or have more organs available for transplantation. We received comments describing the different incidences of diseases in the different parts of the country.

Response: We appreciate the comments about the different incidences of disease in the different geographic areas and recognize that different DSAs may have different population characteristics. However, these differences are population-based differences, and we did not receive any data that these differences were reflected in the donor potential, resulting in a disadvantage to one OPO compared with other OPOs. As part of our proposed rule, we analyzed whether there was a correlation between the performance of the OPO and the number of patients on the waiting list in the DSA (84 FR 70633). We conducted the analysis to determine whether “demand” in the form of the number of patients on the waiting list for the transplant centers within the OPO’s DSA, is correlated with performance. We did not find any correlation. We reviewed the original analysis to determine whether there was a negative correlation between the waiting list and OPO performance (that is, OPOs flagged were more likely to have a sicker population in its DSA). Here, we treated the waiting list as a surrogate for the magnitude of end-stage organ failure in the DSA. Again, there was no correlation between OPO performance and end-stage organ failure in the DSA. As discussed earlier, we had compared using just the CALC versus the CALC plus our exclusionary criteria. There was no additive value to removing these contraindications to organ donation.

Comment: One commenter suggested that we use data from the U.S. Renal Data System (USRDS) to risk-adjust for chronic kidney disease because people with chronic kidney disease are less likely to be organ donors.

Response: Although we examined the USRDS data, we did not consider using it to risk-adjust for chronic kidney disease because it is population data and does not necessarily reflect the donor potential. Furthermore, the USRDS data does not delineate the different levels of chronic kidney disease. People with early stage chronic kidney disease can donate extra-renal organs for transplantation as well as the kidneys.

b. Race

Comment: We received several comments from OPOs describing the racial/ethnic characteristics of people in their DSA and claiming that if we risk-adjusted for race, their performance would be improved because they serve a smaller percentage of white people than the national average. We also received comments opposing risk-adjustments based on race because of

concern that these risk-adjustments would mask past poor performance in adopting practices that are responsive to the racial/ethnic composition of the DSA served.

Response: As we stated in our December 2019 OPO proposed rule, we decided not to risk-adjust for race because of concerns that it reflects historically poorer performance with certain racial/ethnic populations, and that studies suggest that OPOs can adopt policies and practices responsive to the community they serve and have better results. When we assess OPO performance, as seen in Table 3 in our regulatory impact analysis of this final rule, we see a diversity in the population served by the highest performing OPOs. We also see poor performance among OPOs servicing predominantly white populations. We agree with commenters who raise concerns that risk-adjusting for race could mask poorer performance, and we have concerns that racial risk-adjustments could perpetuate the stereotypes of different racial/ethnic groups and their willingness and ability to be organ donors.

We have reviewed the analysis conducted by the SRTR implying that racial risk-adjustment would ensure that a “correct” decision is made when comparing OPO measures.¹⁴ We do not find these analyses compelling since the risk-adjustments reflect the biases and shortcomings of current OPO organ procurement practices, and we are not aware of a biological reason why race, as an independent factor, would affect the decision to be an organ donor or the number of organs transplanted. We agree with public comments and other literature opposing risk-adjustments for race.¹⁵ We believe OPOs should be adjusting their practices to meet the characteristics of the DSA. Based on the diverse populations serviced by the top performing OPOs, we believe that racial characteristics of the DSA should not be a reason for risk-adjusting OPO performance.

Although one of our previous outcome measure (the O:E measure) includes multiple risk-adjustments, such as for race, we are not including racial risk-adjustments in our final rule. The literature since 2005 (described in

the December 2019 OPO rule), the public comments we received, and our examination of the demographics of the top performing OPOs, suggest that these factors, while they potentially pose hurdles for each OPO in their DSA, they are insufficient justification for additional risk adjustment. Therefore, we expect all OPOs to adjust their practices to overcome these hurdles and best service the populations within their respective DSAs.

c. Gender and Age

Comment: We received comments that we should risk-adjust for identifiable variables in the donor potential data such as gender and age.

Response: We do not know of a biological basis for why gender would be an independent factor in predicting the likelihood for being an organ donor or the number of organs transplanted.

We do, however, agree that there is biological basis for age to predict the likelihood of being a donor and the number of organs transplanted from the donor potential. Our internal analysis found statistically significant differences in the average age of the donor potential when we ranked OPOs based on their outcome measures, suggesting that age has an effect the number of donors and organ that are transplanted.

Since we are already including the age cut-off of 75 years and younger in our donor potential, we do not intend to further risk-adjust the donation rate for age. It is possible that the differences we see in performance based on the average age of the donor potential reflects OPO biases against older potential donors. Further risk-adjustments could mask these biases. Based on our methodology, in the DSAs where the population is older, OPOs have the opportunity to perform better because they have more opportunities for a donor who is older than 75 years of age—and these donors count in the numerator, but not in the denominator.

For the organ transplantation rate, there is no current risk adjustments for the average age of the donor potential. Our own internal analysis found that the average age of the donor potential correlated with performance on the organ transplantation rate, we will risk-adjust the organ transplantation rate based on the average age of the donor potential using the following method, provided here for full transparency and to allow others to replicate our methodology and calculations:

1. The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34,

35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

2. Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as $\Sigma(g=1) Gdg \cdot Rg / \Sigma dg$,¹⁶ where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and Σdg is the OPO's total number individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

3. Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

d. Ventilator Status

Comment: We received comments stating that there were differences in ventilators in ICUs based on geography, and that including ventilator status would be important in deriving the donor potential.

Response: While there are differences in ventilators in ICUs based on geography, we do not have evidence that additional information about ventilator use would improve the CALC methodology. Since publication of our proposed measures, there has been a published study confirming our analysis that additional adjustments on cancers, sepsis and ventilator status to the CALC measure does not alter the ranking of OPO performance.¹⁷

Final Rule Action: We are finalizing with modification the definition of “organ transplantation rate” at § 486.302 to be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as $\Sigma(g=1) Gdg \cdot Rg / \Sigma dg$, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age

¹⁶ Σ is a mathematical symbol indicating summation.

¹⁷ Goldberg DS, Doby B, Lynch R, “Addressing Critiques of the Proposed CMS Metric of Organ Procurement Organ Performance: More Data Isn't Better,” Transplantation; 2019 Nov 26.

¹⁴ Snyder JS, Wey A, et al., “The Centers for Medicare and Medicaid Services’ proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients,” Am J Transplant, 11 Mar 2020.

¹⁵ Goldberg D, Doby B, Siminoff L, et al., “Rejecting bias: The case against race adjustment for OPO performance in communities of color,” Am J Transplant, 2020;00:1–6.

group g, and $\Sigma g d g$ is the OPO's total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO's observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

We are also finalizing at § 486.318(d)(2) that the organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

8. OPO Performance on Outcome Measures § 486.318(e) and § 486.302

In our December 2019 OPO proposed rule, we proposed to use our outcome measures in the context of a comparative donation rate and organ transplantation rate relative to the highest-performing OPOs. Our proposed definition of success would have been based on how OPOs perform on the outcome measures of donation rate and organ transplantation rate compared with the top 25 percent of donation and transplantation rates in DSAs with the goal of driving all OPO performances to cluster with the top performing OPOs. We proposed that OPOs would be assessed annually on these outcome measures and those whose outcome measures were below the top 25 percent would need to revise their QAPI to improve their performance. In the final year of the re-certification cycle, we proposed that OPOs whose outcome measures were below the top 25 percent will have failed their outcome measures for purposes of re-certification. We proposed to generate a one-tailed confidence interval for rates in each DSA to determine whether the OPO's outcome measures were statistically significantly the same or above the threshold rate of the top 25 percent. The top 25 percent rate would be generated using the rates established in the prior assessment period.

It is important to note that the outcome measures requirement does not require an OPO's performance be at or above the lowest rate for the top 25 percent of all of the OPOs. By determining confidence intervals, there is a range of values and the OPOs must not be statistically significantly difference from that range of values. For example, there are currently 58 OPOs. For the 58 current OPOs, twenty-five

percent would be 15 OPOs ($58 \times .25 = 14.5$). However, as discussed below, based on 2018 data, we estimate that 24 OPOs would meeting the criteria in § 486.318 to be designated as a Tier 1 top performing OPO.

We solicited public comments on whether or not comparing OPO performance should be based solely on the performance of the top 25 percent of OPOs within these two outcome measures, whether a different percentile or calculation of OPO performance should be used, or whether additional outcome, structure, or process criteria could be used to inform stakeholders of OPO performance over time (84 FR 70634).

The comments and responses are below.

Comment: We received a diversity of comments in response to our proposed approach of establishing a threshold rate at the top 25 percent performance for OPOs to achieve. Some commenters supported our aggressive threshold rate of performance to drive an increase and improvement in OPO performance.

Response: We thank the commenters who support our aggressive threshold rates. We intend to finalize, as proposed at § 486.318(e)(4) that OPOs whose donation rate and organ transplantation rate in the DSA is statistically significantly at or above the top 25 percent threshold rate will be considered have met the outcome measures for re-certification and their top performance will be recognized with a Tier 1 assignment. As a Tier 1 OPO, they will be rewarded by not being required to revise their QAPI to improve their performance in the outcome measures and their DSAs will not be opened for competition at the end of the re-certification cycle as long as they meet the other Conditions for Coverage during the re-certification survey.

Comment: We received comments suggesting alternative threshold rates such as 50 percent or a tiered approach to ranking OPOs with different changes that must occur based on where the OPO falls in the tier system.

Response: We thank the commenters for these suggestions. As we stated in the discussions of our alternatives in the December 2019 OPO proposed rule, we considered using a threshold rate based on the median or the geometric mean, but were concerned that this lower threshold rate would not incentivize OPOs to be higher performing. Furthermore, we ran the risk of top performing OPOs not being sufficiently incentivized to maintain their current performance level if we did not use an aggressive rate.

However, we also recognized that our aggressive threshold rate could result in too many OPOs being de-certified, particularly in the first re-certification cycle, without enough OPOs with organizational capacity and interest to assume responsibility for those open DSAs. We also recognize that if we set a threshold rate too difficult to attain, we risked incentivizing poorer performing OPOs to not strive to improve while remaining certified for a full 4-year cycle. Therefore, we are modifying our proposal and finalizing a 3-tier system based on public comments whereby OPOs are stratified into different tiers based on their outcome measures. The consequences of being in each tier differ based on whether the performance occurs as part of the annual assessment or if it occurs during the final assessment period. OPOs in Tier 1 are the OPOs that would have reached the goal performance of the top 25 percent threshold rates. We consider these OPOs to be top performing Tier 1. Based on data from 2018, we estimate that 24 OPOs would be in Tier 1.

The next tier will be identified as Tier 2 and will include OPOs in which both measures, donation rate and organ transplantation rate, have reached the median threshold rate or above (but are not in Tier 1). We estimate that there are 12 OPOs that would fall into Tier 2 based on 2018 data. Tier 2 OPOs will be considered to have met the outcome measures under § 486.318, and would not be decertified, but these OPOs will not be automatically re-certified. Since they have not reached the outcome measure requirements for Tier 1 status, their DSAs will be opened for competition and they will have to compete to retain their DSAs. Greater details about the competition process are discussed in section II.C of this final rule.

And finally, the lowest tier will be identified as Tier 3 and will include OPOs who have one or both outcome measures that are statistically significantly below the median threshold rates. We estimate that there are 22 OPOs who fall into Tier 3 based on 2018 data. Tier 3 OPOs will be considered as failing the outcome measures and will be de-certified. Greater details about the competition process are discussed in section II.C of this final rule.

This 3-tier system was designed based on a combination of comments that we use the 50 percent threshold rate instead of the top 25 percent threshold rate and the comments to use a tier system with varying consequences to OPOs based on the tier they were in. Instead of using a 50 percent rate or a mean rate, we chose

the median rate because both the top 25 percent threshold rate and the median rate represent the actual rates performed by one or two OPOs (when there is an even number, the median is calculated by averaging the two rates in the median). The mean rate, on the other hand, is a mathematical rate that may not reflect the performance of an actual OPO. A median, however, is not affected by extremes in performance. By identifying a specific rate of an OPO, other OPOs can directly compare their performance with another OPO.

Our goal in creating these tiers is to reward the top performing OPOs (Tier 1), while giving OPOs in Tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level up and give Tier 2 OPOs the opportunity to demonstrate that they deserve to retain their DSA. These rewards and incentives are described in greater detail in this section and in our discussion about competition in section II.C of the final rule and our regulatory impact analysis (RIA).

Comments: We also received comments that the 25 percent threshold rate was too aggressive and too many OPOs would be de-certified (discussed in detail at section II.C of this final rule), resulting in chaos in the system. Some commenters suggested that if we were to use such an aggressive threshold rate, we should not automatically de-certify OPOs who did not meet the threshold rates. Instead, we should consider a systems improvement agreement (SIA) similar to the ones for transplant program or the substantial changes they have made as part of their QAPI to avoid the disruption from de-certifying the OPO. In contrast, we received a comment that despite our aggressive threshold rate for performance, we should implement outcome measures that continually drive all OPOs to improve their performance.

Response: We agree with some of the comments relating to a tiered approach. OPOs are not automatically decertified the first time that they do not meet the threshold rates. The performance of each OPOs will be assessed annually, this information will be provided to each OPO, and each OPO will then have an opportunity to improve and receive information about its performance following those improvements. Our annual outcome assessment is designed to inform the OPO regularly about their performance. Therefore, OPOs identified as being lower performing at the final assessment period of the agreement cycle would have a history of working with CMS to improve performance, as they would have been provided with their own performance

information and making adjustments to their QAPI to improve their performance in the previous assessment periods. We expect to provide notice to OPOs of their performance and make the results public within 15 months of the end of each assessment period. For instance, performance on data from 2020 will be provided to OPOs and made public by the end of the first quarter in 2022. This period is necessary to accommodate the timeframe for the CDC to process the data and make the MCOD available for public use as well as for CMS calculate the performance measures. Additionally, during this timeframe, CMS will share preliminary results with each OPO to provide the opportunity to review the information and raise any concerns prior to the results being made publicly available and taking any enforcement action. This preliminary review is consistent with past performance updates and while this is an informal process, it does afford each OPO the opportunity to address concerns regarding its results. We acknowledge the time lag in making this information available, however, all data sources have inherent delays in making their information available to the public. Additionally, OPOs should not be relying on any single source of information to conduct self-assessments of their performance and should be employing a variety of information as part of a comprehensive QAPI program for this purpose.

We are not adopting public comments suggesting that poorly performing OPOs should be permitted to continue under an SIA. Allowing poorer performing OPOs the opportunity to continue servicing the DSA through a SIA would not benefit patients if there is a better performing OPO willing and able to service the DSA and provide patients with a higher standard of service.

However, we recognize that there are some OPOs that fall below Tier 1 but have made substantial changes designed to improve performance and have started to improve their performance. It may not be in our or patients' best interest to de-certify those OPOs, unless there is a better OPO prepared and capable of taking over the DSA. Thus, we created Tier 2 in response to the comments that we should lower our threshold rate for performance, and should not automatically de-certify OPOs who cannot reach Tier 1.

The commenter who suggested the tier system proposed that we undertake certain administration actions (like require change in leadership) based on the OPO's tier. While we appreciate the suggestions, we do not believe that there is a one-size fits all approach for all the

OPOs in Tier 2, or that the federal government should dictate the specific steps needed to increase the rates in a particular DSA. Based on our assessment of outcome measures for these OPOs in Table 3, the range of performance is quite varied, with some OPOs very close to Tier 1 and others at the bottom of Tier 2. We are reluctant to follow the comments suggesting that OPOs be given an opportunity to continue as the designated OPO for another cycle subject to an SIA. That suggestion assumes that all OPOs in Tier 2 are capable of improving their performance and that they just need more time to implement best practices and improvements. However, because all OPOs receive interim reports on performance levels, we do not agree that this is always the case. Moreover, we recognize that patients in the DSA well-served by a marginal OPO that is allowed to continue without facing competition from a high performing OPO. Requiring that OPOs in Tier 2 to engage in a competitive process with other interested OPOs, on the other hand, would incentivize continual improvement to the benefit of patients.

Section 1138(b) of the Act and section 371 of the PHS Act required that the Secretary establish performance and outcome measures to be able to evaluate an OPO's performance prior to recertification. Requiring that Tier 2 OPOs compete for their DSA incentivizes best practices and optimizes organ donation and transplant rates. As already discussed and proposed, OPOs whose rates in the DSA fall under Tier 1 are considered to have met the outcome measure requirements and their DSA is protected from competition. OPOs identified as being in Tier 3 are considered to have failed the outcome measures under § 486.318 and will be de-certified, and following any administrative appeals, their DSAs will be open to competition.

Instead of automatically de-certifying OPOs in Tier 2 (those who have a statistically significant donation and organ transplantation rate at or better than the median rate) or implementing an SIA, we will allow these OPOs to compete to retain their DSAs by opening their DSA for competition to all OPOs that have been identified as being in Tier 1 and 2. In summary, all the DSAs for OPOs identified in Tiers 2 and 3 will be open for competition as proposed in our December 2019 OPO proposed rule and all the OPOs who are identified in Tier 1 and 2 will be able to compete for an open DSA. Broadening the number of DSAs open to competition and the number of OPOs eligible to compete will result in greater improvements

among all OPOs. OPOs in Tier 1 will need to maintain or improve their performance if they want to successfully compete to take over a new DSA, and OPOs in Tier 2 will need to improve their performance to retain their DSA or takeover another open DSA. Since OPOs identified under Tier 2 would have been de-certified under our original proposed methodology, this new approach will give mid-performing OPOs, who otherwise would have been de-certified, the opportunity to demonstrate, through the competition process, that they have implemented the requisite changes to progress to becoming a Tier 1 OPO.

Because OPOs have a 4-year exclusive agreement for each DSA with each re-certification cycle (see § 486.308(a)), it is critical that we select the most capable OPO that we can find to service the area, rather than automatically re-certify the incumbent OPO in Tier 2 or trying to “fix” an OPO that has not been able to reach the same performance as the top performing OPO through an SIA. We believe a competition process whereby all OPOs have sufficient incentives to continue to improve will drive all OPOs to cluster near the top.

Comments: We also received many comments suggesting we use a standard deviation from the mean because it was statistically superior.

Response: We disagree with the comments that the standard deviation from the mean methodology is statistically superior for our purposes of calculating OPO performance measures.

Under our methodology, all OPOs have the opportunity to cluster at the top because we generate confidence intervals for their donation and organ transplantation rates. The threshold rate is based on the previous year's rate and represents a specific rate to achieve or exceed. If all the remaining OPOs (below the top 25 percent threshold rate) had rates close to the threshold rate, their confidence interval could have all of them equal or exceed the threshold rate, resulting in clustering near the top. In Table 3, we show that 24 of 58 OPOs meet the top 25 percent threshold rate and this is 41 percent of all OPOs.

The standard deviation from the mean method, on the other hand, generates a list of OPOs that are a certain distance from the mean. As we discussed earlier, the mean is problematic because several lower performing OPOs could skew the calculated mean. The mean and the standard deviations are also generated contemporaneously with the ranking of the OPOs, giving OPOs no notice of their targeted performance. And, by nature of the statistical method of standard deviation, there will always be

an OPO below the targeted standard deviation from the mean, meaning that not all OPOs would have the opportunity to be a top performing OPO unless they all had identical rates.

Comments: We received comments implying that our goal was to reduce the number of OPOs and our methodology would result in an ever increasing threshold rate and ever-shrinking number of OPOs after each cycle.

Response: We understand the concerns expressed by these comments, and want to reassure the public that our goal is to improve oversight of OPOs by reducing the variability in performance among OPOs and in the DSAs, not necessarily reducing the number of OPOs or forcing consolidation. Our methodology allows all OPOs the opportunity to perform as well as the top OPOs. We have proposed to change the outcomes measures because we agree with the public comments that the current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ transplantation rates.

Our methodology may result in increasing the threshold rate without shrinking the number of OPOs or DSAs significantly. Our internal analysis reveals demonstrated improvements in OPO performance from 2017 to 2018 and we anticipate OPO performance will continue to improve when incentivized by more transparent and accountable measures provided under this final rule. But, we recognize that there may be a rate at which OPOs cannot improve anymore and rates may cluster at the top. However, we intend to incentivize increases in the threshold rates for the top 25 percent and median as it would indicate that OPOs are procuring more organs for transplantation. Our methodology does not presume or require an increase in the threshold rates, and accounts for the performance of OPOs under similar circumstances or extraordinary circumstances.

In order for there to be an “ever-increasing threshold rate and ever-shrinking number of OPOs,” the commenter assumed that we would require that DSAs merge when an OPO takes it over. Our methodology for assessing OPO performance is based on the outcome measures for the OPO in each DSA. In our December 2019 OPO proposed rule (84 FR 70636), we stated that our regulations do not require that DSAs merge when a new OPO takes over. It would be our preference to not merge DSAs so that we can properly

assess whether the new OPO is improving performance in each DSA since merging DSAs would result in merging the data on performance. Since DSAs are not required to merge, one OPO could run several DSAs. If an OPO with multiple DSAs cannot reach the outcome measures to be re-certified for one DSA, they will be de-certified for that DSA, but could be re-certified for other DSAs (assuming their performance supports it). Using our estimates from 2018 data, the result after conclusion of the first certification cycle that implements the new measures (2022–2026) could be approximately 36 OPOs servicing 58 DSAs with reductions in OPOs but not in DSAs. With 58 DSAs being served by top performing OPOs each cycle, we would expect the threshold rate to increase until all DSAs have donation and organ transplantation rates that cluster near the top. Even if consolidation were to occur in the industry, we believe that the certification process would retain a sufficiently large number of OPOs to maintain an adequately diversified market in U.S.

Comment: We received some comments that our threshold rate of 25 percent was arbitrary. We also received comments pointing out parts of the country where no OPO was top tier such as the New England area or the Gulf Coast.

Response: We respectfully disagree with the commenter that our proposed threshold rate was arbitrary. It was chosen to mathematically achieve the Secretary's goal of doubling kidney transplants by 2030. It was also chosen because, when we assessed which OPOs were top performing, we found that that threshold rate of 25 percent provided us a diversity of OPOs serving a range of geographic areas and different donor potentials. The 25 percent threshold rate and our inclusion of a confidence interval was chosen to accommodate any uncertainty about what constitutes a top performing OPO.

In our December 2019 OPO proposed rule, we presented maps stratifying OPO performance in quartiles. The purpose of these maps was to show that even though many OPOs did not meet the threshold rate, they were quite close. Our current data analyses in Tables 1 through 3 also show that it is likely achievable for many more OPOs to reach the Tier 1 threshold rates. Additionally, our internal analysis indicates that the number of OPOs historically achieving Tier 1 status increased from 16 in 2017 to 24 in 2018, without any regulatory incentives, demonstrating that OPOs have the ability to improve their performance.

Comment: We received a comment that the 95 percent confidence intervals (CI) were biased against large OPOs because they would likely have a narrow interval.

Response: The purpose of the confidence interval was to ensure that the use of the threshold rate does not bias against small OPOs who may be prone to greater variability of rates due to smaller volumes. We do not concur with the commenters' assertion that our methodology is biased against large OPOs; they have a CI generated, but because they have more data, their CIs are proportionally smaller.

We did not receive any comments on the proposed mathematical methodology which we use to calculate the "Lowest rate among the top 25 percent" or the time period in which the rate will be calculated. Thus, we will be finalizing as proposed that the threshold rates for the donation and organ transplantation rates would be based on the 12-month period immediately prior to the period being evaluated and finalizing the definition of the Lowest rate among the top 25 percent with technical edits to clarify that the rate is based on the donation and organ transplantation rates in the DSAs.

Final Rule Action: Under § 486.302, we are finalizing as proposed the definition that the "Lowest rate among the top 25 percent" will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

We are finalizing § 486.318(e) with revisions, that (1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated: The lowest rate among the top 25 percent in the DSAs (paragraph (e)(1)(i)), and the median rate among the DSAs (paragraph (e)(1)(ii)) and, (2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates (as applicable) during the 12-month period prior to the period being evaluated: The lowest rate among the top 25 percent in DSAs (paragraph (e)(2)(i)), and the median rate among the DSAs (paragraph (e)(2)(ii)).

We are finalizing as proposed at § 486.318(e)(3) that the 95 percent

confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

In response to public comments, we are finalizing § 486.318(e)(4) through (6), the creation of three tiers to identify OPO performance.

Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) will be identified at each assessment period.

Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

9. Non-Contiguous States, Commonwealths, Territories, or Possessions § 486.318(e)(7)

In the December 2019 OPO proposed rule (84 FR 70628), we did not propose different outcome measures for OPOs exclusively serving non-contiguous states, commonwealths, territories, or possessions because we believe that OPOs servicing those areas should perform at the same level as the top 25 percent of OPOs. That being said, we sought comments on the burden and unique challenges that may face OPOs in the noncontiguous states, commonwealths, territories, or possessions, and whether using just the kidney transplantation rate for the Hawaii OPO would be an appropriate measure of performance as discussed in section V.G "Alternatives Considered" of the December 2019 OPO proposed rule.

Comment: We received numerous comments in support of using a different standard for OPOs exclusively serving non-contiguous states, commonwealths, territories, or possessions. Both the Hawaii and Puerto Rico OPOs submitted comments describing the difficulty in placing

extra-renal organs because of the geographic hurdles.

Response: Based on information from the commenters regarding the unique geographical challenges of the OPO servicing the Hawaii DSA, we are persuaded to use one different outcome measure to evaluate the OPO's performance in the Hawaii DSA. Instead of using the organ transplantation rate as one measure, we will use the kidney transplantation rate for only the OPO serving the Hawaii DSA. We agree with the commenters that the OPO for this DSA has a clear geographic hurdle to placing extra-renal organs. We will use the same general methodology as the organ transplantation rate for calculating the kidney transplantation rate. We will not age-adjust the kidney transplantation rates for the same reason that we do not age-adjust the donation rates. The age of 75 cutoff provides sufficient age-adjustments for kidney transplantations.

Although we are not using the organ transplant rate for the Hawaii DSA, we will continue to monitor the development and FDA clearance of organ transport devices and expect the OPO serving the Hawaii DSA to adopt these new technologies when they are available. Moreover, we will also use the same donation rate measure for the Hawaii DSA in assessing the OPO's performance since almost all donors of other organs are also kidney donors. Like all of the other OPOs, the Hawaii DSA will be evaluated based on two outcome measures.

We do not intend to give the OPO servicing Puerto Rico any special consideration for their organ transplantation rates. We made the initial decision to not provide special consideration to the Puerto Rico OPO because of its geographic proximity to parts of the continental U.S. that have significant need for organ transplants. Our analysis of 2018 data confirmed our assessment that the OPO based in Puerto Rico does not need special consideration because that OPO would be assigned as a Tier 1 OPO if the metrics where in effect at that time. We suspected that their performance in 2017 had been significantly hampered by the multiple, strong hurricanes, rather than by sustained geographic disparities that do not change from year to year. This suspicion was confirmed by the significantly higher level of performance that the Puerto Rico OPO attained in 2018 when the island was not as impacted by hurricane activity.

Final Rule Action: We are finalizing in response to comments at § 486.318(e)(7) that for the OPO exclusively serving the Hawaii DSA, the

kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a tier will be the same as in paragraphs (e)(4), (5), and (6) except kidney transplantation rates will be used.

10. Assessment and Data for the Outcome Measures §§ 486.302 and 486.318(f)

In the December 2019 OPO proposed rule, we proposed to assess OPO performance every year, using the most recent 12 months of data from the CDC's MCOF files. Based on the typical timing of the release of the MCOF files, we expect to calculate the outcome measures near the beginning of each calendar year, and the assessment period data will have a 1-year lag. We explained that the reason we were using only 1 year of data is that we did not want to penalize OPOs who have made the effort to improve performance by using their older data in the outcome measure calculations.

Comment: Some commenters stated that 1 year of data was appropriate for the assessment period for purposes of QAPI remediation, but felt that 3 years of data should be used for re-certification. Other commenters supported our use of 1 year of data for re-certification stating that 36 months of data was too long.

Response: In the December 2019 OPO proposed rule, we stated that the reason we are using just 1 year of data is that we want to encourage and reward OPOs who make substantial efforts to improve their performance. If we use all the data from the agreement cycle in our QAPI and re-certification, the older data could mask the current performance of the OPO. It is CMS' belief that using the older data from the agreement cycle to assess OPO performance for re-certification may not accurately reflect the practices of the new OPO.

Comment: We received a comment that OPOs who takeover a DSA should not be held accountable for the performance of the former poorer performing OPO.

Response: Our assessment periods are normally from January 1 to December 31 based on the state death certificate data files that we receive. In our December 2019 OPO proposed rule at § 486.318(f)(3), we proposed that if an OPO takes over another OPO's DSA on a date later than January 1st, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available. This paragraph recognizes that we need 12 months of data to conduct our analysis and that the new

OPO needs the opportunity to be serving the area before they can make changes in response to the outcome measures. Based on the timing of the state death certificate data, it is very likely that most, if not all, of the data at the beginning of a new agreement cycle for a new OPO, will reflect the practices of the prior OPO. However, since we believe it is important that the OPO be aware of the past performance in the DSA and can use that performance as a benchmark for improvement, we will continue to do the evaluation of the assessment period for purposes of ranking and assessing the new OPO and other OPOs. The new OPO would not be required to take actions in its QAPI program in response to the outcome measure, as required at § 486.348(d), until 12 months of data are available. Since we are only using 1 year of data and outcome measures for the final assessment will include data from the middle of the re-certification cycle, the new OPO will not be judged on the performance of the prior OPO and will have had 1–2 years to improve performance in the DSA.

Comment: We received comments that use of only 1 year of data would be problematic for some OPOs servicing smaller DSAs that happened to have a "bad year" during the final assessment period of their agreement cycle. Because these OPOs are smaller, they have less data for analysis and their DSA could have greater variability in the number of deaths.

Response: We recognize that OPOs serving smaller DSAs are mathematically subject to greater variability in their inpatient deaths and number of donors and organ transplants. For this reason, the one-tailed confidence interval that we generate in calculating the donation and organ transplantation rates will account for the potential variability when we are using less data in the smaller OPOs.

As also discussed in section II.C of this final rule, for OPOs receiving an ECE extension, their data will continue to be part of the annual calculations of the outcome measures, and the OPOs' performance will be ranked with the other OPOs; the difference is that they will not be up for re-certification in that particular year. All requests for an ECE extension must occur within 90 days after the end of the extraordinary circumstance but no later than the last day of the final assessment period. To seek an ECE exception, the OPO needs to describe the extraordinary circumstance, the time period in which it occurred, why it was beyond the control of the OPO, and why it affected the OPO's performance in such a way

that the data does not accurately capture the OPO's performance.

The intention of the ECE extension is to allow for those rare exceptions in which a natural disaster (such as a hurricane), a public health emergency or other similar catastrophe would disproportionately affect an OPO. We could also allow situations in which there are errors in the transmission of data to the CDC.

We believe that OPOs will use the option of seeking the extension judiciously because the request to extend their agreement by 1 year is not without risk. Once an OPO is up for recertification off-cycle from the other OPOs, their DSA could potentially be opened for competition at a time when other OPOs are not up for re-certification. While this would not matter for an OPO in Tier 1, a Tier 2 OPO may be more vulnerable to losing its DSA in competition with other OPOs who have more capacity and interest in competing in an off-cycle year.

Comment: We received comments that something could happen with staffing during that final year, such as a loss of a high-performing transplant coordinator, which could adversely affect outcomes during that final assessment period.

Response: Loss of key staff would not be considered an event outside of the OPOs' control and are inevitable in all organizations. Staffing, contingency planning, and other such activities are within the control of an OPO. As such, staffing changes would not constitute an extraordinary event.

Comment: We also received comments raising concerns about the data lag from CDC, with some commenters assuming that we are calculating rates using numerators and denominators from different time periods. We also received comments that the data lag would result in OPOs being re-certified based on data that is more than 2 years old.

Response: While there is a lag in the data from CDC, the numerator and denominator will be based on data from the same time period. We are adding clarifying language in our regulatory text at § 486.318(d)(3) to recognize that "for calculating each measure, the data used is from the same time period as the data for the donor potential." Based on availability of the data from the CDC, the threshold rate determination and the final assessment period will use data from the middle of the agreement cycle. Therefore, OPOs would be notified of their performance on outcome measures for recertification approximately 15 months after the final assessment period just prior to the end of the

recertification cycle. Despite the lags in reporting death certificate data to the CDC, and even the lag in reporting donor and transplant information to the OPTN, the data is the best information available to empirically and transparently evaluate the OPOs' performance.

Final Rule Action: We are finalizing as proposed at § 486.318(f)(1) that an OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.

We are finalizing as proposed at § 486.318(f)(3) that if an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will evaluate the OPO's performance on the outcome measures in the new area once 12 months of data are available.

In response to the comments and to provide additional clarity, we are also adding a new definition, "Assessment period" at § 486.302 to be a 12-month period in which an OPO's outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification. We are finalizing at § 486.318(f)(2) that the assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

We are also finalizing under § 486.318(d) a clarification for calculating each measure. All OPOs will be evaluated based on two measures. For all OPOs, the numerator for the donation rate is the number of donors in the DSA. For most OPOs, the numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. For the OPO servicing the Hawaii DSA only, the donation rate will be the same as for all other OPOs but the kidney transplantation rate will be utilized in lieu of the organ transplantation rate. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors, organs transplanted, and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11. For calculating each measure, the data used

is from the same time period as the data for the donor potential.

11. Implementation Timeline

We requested comments on this proposed change in the December 2019 OPO proposed rule to the applicability of the outcome measure requirements for the cycle beginning in 2022 and ending in 2026. The current OPO certification cycle is due to end on July 31, 2022 however, the OPO agreements for the certification period extend until January 31, 2023. This extra timeframe in the agreement affords the opportunity for any appeals or competition that may occur from any potential enforcement action for non-compliance with the CfCs, including the outcome measures. Normally, absent enforcement action on the part of CMS, the OPO agreements are renewed on August 1 or shortly thereafter to coincide with the start of the next certification period.

Comment: We received a number of comments from the general public and others that encouraged us to implement these new measures as soon as possible and to hold OPOs accountable now. We also received numerous comments from OPOs, supporting a delay of implementation of the new outcome measures to begin in 2022 and end in 2026.

Response: We appreciate the robust comments related to this topic including the desire to drive performance improvements sooner while also being responsive to providing OPOs time to adapt to the new measures and improve performance where needed. We considered the option of extending the current agreements by 2 years and assessing OPOs based on data from 2023 holding OPOs accountable to the new performance measures in 2024. However, the effects of the current COVID-19 PHE are still uncertain in regards to the impact to the organ donation and transplantation system. We note that current data from the OPTN indicate that as of November 7, 2020, there were 28,506 deceased organ transplants conducted compared to 27,658 at this same time the year prior suggesting the impacts may not be as severe as originally anticipated.¹⁸ Therefore, we intend to implement the new measures as proposed, beginning in the 2022 recertification cycle. We believe extending implementation beyond this timeframe will negatively impact our efforts drive improvements to make these critically important life-saving organs sooner.

OPOs will continue to receive performance measures under the current

metrics until the end of the current certification cycle in 2022. However, we intend to also begin providing OPOs an assessment of their performance under the new metrics in each DSA immediately using data from 2019. OPOs will receive results of their performance on the outcome measures from 2019 in the first quarter of 2021 with additional assessments being provided annually. We will rank OPO performance to provide information that may be utilized for purposes of QAPI programs interventions leading up to implementation of the new measures. OPOs will receive performance assessments in the first quarter of the year for their performance 2 years prior. As previously stated, this time lag is inherent the use of objective, reliable, and transparent publically available data sources. It affords the CDC time to collect all information and develop the report for public posting. Additionally, it provides time for CMS to receive and process information, conduct analysis, share preliminary results with OPO, and make the files public. Therefore, for the 2022–2026 certification period, the threshold rate will be established based on data from 2023 and the final assessment period will utilize data from 2024. CMS will conduct activities for recertification in early 2026, including publication of tier ranking in performance measures and conducting onsite surveys of OPO operations. While we acknowledge that OPOs will not know the actual threshold rate that will be utilized for the final assessment period until after it is complete, they will have the results of prior years from which to trend and incorporate into their QAPI program to assist in improving performance. Additionally, we expect that OPOs implement a comprehensive data-driven QAPI program to monitor and evaluate their performance. Therefore, OPOs should already be including a range of data and activities for this purpose that will inform and drive performance toward success in achieving Tier 1 status on the outcome measures and the new QAPI requirement at § 486.348(d) will be one component of that comprehensive plan.

Final Rule Action: This final rule will be effective 60 days after the publication date and the new outcome measures will be implemented on August 1, 2022 to coincide with the start of the next certification period.

12. Definitions § 486.302

In the December 2019 OPO rule, we proposed to remove several definitions from § 486.302, since these terms would no longer apply. Specifically, we proposed to remove the definitions of

¹⁸ <https://unos.org/covid/>.

“eligible death,” “eligible donor,” “expected donation rate,” “observed donation rate”, and “Standard criteria donor (SCD)”. We proposed to revise the definition of “Donor” described in section II.B.3 of this final rule and we will add the terms “Assessment period” described in section II.B.10 of this final rule, “Death that is consistent with organ donation” described in section II.B.6 of this final rule, “Donation rate” described in section II.B.2 of this final rule, “Donor potential” described in section II.B.6 of this final rule, “Kidney transplantation rate” described in section II.B.9 of this final rule, “Lowest rate among the top 25 percent” described in section II.B.8 of this final rule, and “Organ transplantation rate” described in section II.B.4 of this final rule. Public comments related to these definitions and our responses are addressed in sections II.B of this final rule as described above. The addition of “assessment period” and “kidney transplantation rate” were not proposed, and are being added in response to public comments and to provide convenience in understanding the other definitions being defined in the regulation text. The term “Lowest rate among the top 25 percent” was proposed, and we did not receive any comments regarding our methodology for calculating this rate. Therefore, we are finalizing with technical edits. We will define these terms as follows:

- “*Assessment period*” is a 12-month period in which an OPO’s outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

- “*Death that is consistent with organ donation*” means all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

- “*Donor potential*” is the number of inpatient deaths with in the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

- “*Donation rate*” is the number of donors as a percentage of the donor potential.

- “*Kidney transplantation rate*” is the number of kidneys transplanted from donors in the DSA as a percentage of the donor potential.

- “*Lowest rate among the top 25 percent*” will be calculated by taking the number of DSAs in the time period identified for establishing the threshold rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

- *Organ* means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2 ..	2
Liver	1
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, research, islet transplant)	1
Pancreas Segment 1 or Segment 2 ...	1
Pancreas Segment 1 and Segment 2	2

- *Organ transplantation rate* is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

- (1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

- (2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as $\Sigma(g=1)Gdg \cdot Rg / \Sigma gdg$, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific

national transplantation rate in age group g, and Σgdg is the OPO’s total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

- (3) Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO’s observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

Comment: We received several public comments related to the deletion of definitions.

Response: We have addressed all comments related to the deletion of definitions in our discussion about the outcome measures throughout section II.B of this final rule. Comments and responses were addressed in the manner to how they applied to the related new or revised definitions. Eligible death was described in the context of the donor potential in section II.B.6; eligible donor and standard donor criteria in the context of donor definition at section II.B.3; and expected donation rate in the context of risk adjustments at section II.B.7 of this final rule.

Final Rule Action: Under § 486.302, we are finalizing as proposed, the removal of the following definitions: “*Eligible death*,” “*Eligible donor*,” “*Expected donation rate*,” “*Observed donation rate*,” and “*Standard criteria donor (SCD)*.” We are also finalizing as proposed, by adding the definition of “*Donation rate*.” We are finalizing as proposed with modifications, the definitions of “*Donor potential*” and “*Organ transplantation rate*.” And we are finalizing the new definitions: “*Assessment period*,” “*Death that is consistent with organ donation*,” and “*Kidney transplantation rate*.”

C. Re-Certification and Competition Processes (§ 486.316)

1. Re-Certification and Competition Processes § 486.316(a)

In the December 2019 OPO proposed rule, we proposed to revise § 486.316(a) to provide that the OPO must meet the performance requirements of the outcome measures at § 486.318 at the end of the re-certification cycle; and has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

We proposed revisions at § 486.316(a)(1) to correspond to our proposed outcome measures that were

set forth at § 486.318 in the December 2019 OPO proposed rule. To be consistent with the tier system finalized in this rule, we also need revised § 486.316(a)(1), (a)(2) and (a)(3) to reflect that the OPO has been shown by a survey to be in compliance with the conditions for coverage from “§§ 486.320 through 486.360,” so that it is included § 486.360 Conditions for Coverage: Emergency Preparedness, which was effective on November 15, 2016 (81 FR 63859). We are finalizing the inclusion of § 486.360 in § 486.316(a)(1)(i), (a)(2)(i) and (a)(3)(i).

In addition, we proposed to remove § 486.316(a)(3), which provided that for the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle. We intend to relocate paragraphs (a)(3) and (b)(2) to paragraph (g) due to the proposed new outcome measures set forth at § 486.318 becoming effect at the start of the next recertification cycle in 2022.

As described in sections II.B “Proposed Changes to Definitions (§ 486.302)” and “Proposed Changes to Outcome Requirements (§ 486.318)” of this final rule, we are not only finalizing new outcome measures, but we are also finalizing a tier system. The tier system will determine whether the OPO is immediately re-certified, must compete to retain its DSA, or will receive an initial de-certification determination. Thus, we are amending our proposal and finalizing § 486.316(a) to incorporate the tier system.

Final Rule Action: We are finalizing § 486.316(a) by incorporating the language for the tier system to indicate the requirements for each tier. We are also finalizing the inclusion of § 486.360 in the CfCs that all OPOs must meet for re-certification. We are also revising § 486.316(a)(3) as discussed above.

2. De-Certification and Competition Processes § 486.316(b)

In the December 2019 OPO proposed rule, we proposed that if an OPO does not meet the performance requirements or the outcome measures as described in paragraph (b) of this section at the final

assessment prior to the end of the re-certification cycle or the requirements described in paragraph (b)(2) of this section, the OPO would be de-certified. If the OPO does not appeal, or the OPO appeals and the reconsideration official and CMS hearing officer uphold the decertification, the OPO’s service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

As discussed in section II.B of this final rule and based on the comments we received, we are finalizing new outcome measures, for all OPOs, and except for the Hawaii DSA, those measures are the donation and the organ transplantation rates. Based on public comments, we are also establishing a tier system that will be used to classify OPOs for purposes of re-certification, decertification, appeals, and competition. The outcome measures and tier system are discussed in detail in sections II.B.2, II.B.4, and II.B. 6 through 10 of this final rule.

We requested comments on competition, including whether all DSAs should be opened at the end of the re-certification cycle for competition under § 486.316. Only one of the commenters wanted all of the DSAs open for competition each re-certification cycle regardless of the OPO’s performance. Most of the commenters, however, wanted more competition than existed under our prior rules and contended that more competition would improve OPO performance. Some commenters suggested that OPOs that were doing well should not have to compete to retain their DSAs because it would divert resources from their primary mission of procuring organs. This finalized rule does provide for more competition to drive improvements in performance. Prior to this finalized rule, OPOs were either re-certified or de-certified based on their outcome measures. In this final rule, OPOs will be assigned to a tier based on their outcome measures. Only those OPOs that are designated as Tier 1 OPOs will not have their DSAs opened for competition (§ 486.316(a)). Tier 3 OPOs will be decertified and, following any appeals, their DSAs will be opened for competition, unless the de-certification is reversed as a result of the appeals process. With respect to Tier 2 OPOs, those DSAs will also be opened for

competition. The incumbent OPO will have to compete if the OPO wants to retain its DSA and the DSA will also be open for competition from any other OPO that is qualified to compete for open DSAs. If a Tier 2 OPO does not win the competition for its DSA and does not win the competition for any other open DSA it competes for, CMS will not renew its agreement with the OPO. The OPO will not be able to appeal this non-renewal, which is not a de-certification. The change to a tiered approach increases the number of DSAs open for competition and the number of OPOs eligible to compete for open DSAs, which is consistent with the recommendation of most public commenters. Although we proposed to change the criteria for competition at § 486.316(c) to correspond to the new outcome measures in § 486.318, we did not propose any changes to the selection criteria for competition at § 486.316(d). We appreciate all of the commenters that submitted comments on the competition process. Those comments have been reviewed and will be considered in any future rulemaking.

Comment: Some commenters contended that de-certification was too severe of a consequence for OPOs below the lowest rate among the top 25 percent. Those commenters do not believe that this would provide incentive for OPOs to improve their performance.

Response: The establishment of the tier system should provide OPOs with the incentive to improve their performance. We believe that it is realistic that all OPOs, even those that we have estimated would be de-certified based on their past performance, can avoid de-certification by improving their performance. After considering public comments, we have lowered the level of performance that would lead to an OPO being decertified. We do not agree with the commenter that de-certification is too severe of a consequence for Tier 3 OPOs. If an OPO cannot achieve the outcome measures we are finalizing in this rule, or cannot demonstrate compliance with the OPO CfCs through its re-certification survey, we believe that de-certification is the appropriate consequence.

In reviewing our proposal in light of this comment, however, we believe that the language in this section should be clarified. In the December 2019 OPO proposed rule, we said, “the OPO is de-certified.” We believe that statement could be misleading. As set forth in § 486.314(a), when CMS determines that an OPO will be de-certified because of involuntary termination or non-renewal of its agreement with CMS, CMS will

mail the OPO an initial de-certification determination. The OPO then has the appeal rights set forth in § 486.314. Thus, we are revising the language from what we proposed at § 486.316(b) by removing, “the OPO is de-certified” and inserting “CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314”. We have also separated the three requirements after the stem statement to improve clarity and readability.

Comment: Some commenters contended that the OPO CfCs did not need the drastic changes we proposed. Some commenters contended that many OPOs were performing well and the system was not underperforming to the extent that the proposed rule contended.

Response: We agree that some OPOs, as demonstrated by their performance on our assessment of their performances based the new outcome measures, are doing a great job in procuring transplantable organs and working with donor families. This is why we are finalizing the tier system that recognizes those OPO's superior performance. In addition, the estimated number of OPOs that would be de-certified under the proposed rule (refer to Table 3 in the 2019 December OPO proposed rule) was based on the past performance of the OPOs. We believe that OPOs will be incentivized to improve their performance because of the outcome measures and tier system finalized in this rule. At the end of the first re-certification that uses these outcome measures and tier system, we believe that fewer OPOs will be de-certified.

Comment: One commenter was concerned about unintended consequences of the requirements that may come to light if the proposals were finalized.

Response: In any change of regulation, there is always a possibility of unintended consequences. We have taken all of the appropriate steps necessary to consider and develop outcome measures that we believe will improve OPO performance and increase the number of transplantable organs for those individuals on the waiting lists. In addition, OPO performance and patient access impacts will be monitored closely. If any unintended consequences come to our attention, we will appropriately evaluate and address them at that time.

Comment: Some commenters expressed concern that increased pressure from the new outcome measures and the threat of de-certification would damage the relationships between the OPOs so that they will no longer cooperate or share

best practices with each other. The commenter noted that this was especially concerning since the OPTN is moving towards a geographical allocation system, which makes cooperation between OPOs even more important. One commenter contended that the proposal had already damaged some collaboration between OPOs.

Response: While collaboration between OPOs is a worthy goal, such collaboration has not resolved the significant, ongoing disparities that exist in OPO outcomes. Thus, it is CMS' belief that it is necessary to revise the current policies. We believe that the need for additional organs presents such a great need as to outweigh any impacts to OPO collaboration. Thus, in order to achieve such a benefit, it is necessary for incentives for OPOs to improve performance or face competition and decertification.

By finalizing a tiered system, only OPOs that are not in compliance with the outcome measures, or found to be not in compliance with the conditions for coverage at the re-certification survey, will be designated as Tier 3 and receive a notice of de-certification. Many OPOs that would have been de-certified under the proposed outcome measures will be designated in Tier 2 and have the opportunity to compete to retain their DSAs. While this approach may change the nature of recertification, we do not believe it should change the nature of OPO relationships with each other. Cooperation among other OPOs in procuring and placing organs could not only improve an OPO's performance on the outcome measures, but also increase the number of transplantable organs.

Based upon this tiered system, OPOs that fail to meet the outcome measures as specified in § 486.318(e)(6), that is an OPO that fails to meet the median threshold for the donation or transplantation measures, fails to meet the median threshold for the donation and transplantation measures or fails to demonstrate compliance with the OPO CfCs via the re-certification survey, will be the only OPOs that are designated into Tier 3. An OPO that qualifies for Tier 3 designation will receive an initial notice of de-certification determination, has the appeal rights set forth at § 486.314, and, if decertified, cannot compete for either its own or any other open DSA.

Final Rule Action: We are modifying § 486.316(b) to correspond to the tier system we are finalizing for OPOs. In addition, to clarify the requirements associated with this modification, we have also designated three requirements at paragraphs (b)(1) through (b)(3). Paragraph (b)(1) to clarify that the OPO

will receive a notice of initial de-certification determination and the OPO has the right to appeal as established in § 486.314. Paragraph (b)(2) clarifies that the DSA will be open for competition and the OPO cannot compete for its DSA or any other DSA that is open for competition. Paragraph (b)(3) clarifies that the OPO must continue to perform its functions in the DSA until a successor OPO is selected and there has been an orderly transition to the new OPO.

3. Criteria To Compete § 486.316(c)

The current requirements set forth at § 486.316(c) state that for an OPO to compete for an open DSA, it must meet the criteria for re-certification and meeting the following criteria: (1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; (2) The OPO's donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area; and (3) The OPO must compete for the entire service area. We proposed to modify this section by requiring the OPO to meet the performance measures set forth in § 486.318 and the requirements for certification at § 486.303, including the CfCs at §§ 486.320 through 486.360. We also proposed to retain the requirements that the OPO would have to compete for the entire DSA. Except for the last requirement, these proposed changes were necessary to correspond to the proposed outcome measures. We proposed to remove “§ 486.348” and insert “§ 486.360” so that it included § 486.360 Conditions for Coverage: Emergency Preparedness, which was effective on November 15, 2016 (81 FR 63859). This change will be incorporated into § 486.316(a) and § 486.316(c).

Comment: Commenters generally supported the proposed changes, except for the requirement for the competing OPO(s) to compete for the entire open DSA. At least one commenter recommended that there would be more competition if an OPO could compete for a portion, rather than the entire, open DSA.

Response: We respectfully disagree. Since the 2006 OPO final rule, we have required that any OPO that is competing for an open DSA must compete for the entire DSA. OPOs do not have the discretion to decide whether a DSA's boundaries should be adjusted. CMS can adjust or change the boundaries for a DSA consistent with statutory criteria. Moreover, we believe it would be

detrimental to patients and to the system if particular segments were carved out. Under the final rule, all of the OPOs that choose to compete would be competing for the same geographic territory.

Final Rule Action: We are finalizing § 486.316 (c) as proposed, with changes to address the tier system. Specifically, we are adding a reference to “Tier 1 or Tier 2 at § 486.318(e)(4) and (5) instead of the broader reference to § 486.318 as we proposed.

4. Criteria for Selection § 486.316(d)

Section 486.316(d) originally stated that, “CMS will designate an OPO for an open service area based on the following criteria.” In the December 2019 OPO proposed rule, we proposed to modify the stem statement to read, “CMS will consider the following criteria in designating an OPO for an open DSA.” Our original intention was for the criteria listed in this section to be guidelines instead of a strict criteria for selection.

We did not, however, solicit comments on all aspects of § 486.316(d), including the requirements that would be used for competition (84 FR 70635) on selection criteria. We did receive some comments for this requirement. However, we did not solicit comments in a manner that would allow us to receive comments and consider a full range of factors that may impact selections. Those comments have been reviewed and will be considered for future rulemaking.

Final Rule Action: We are finalizing § 486.316(d) as proposed.

5. Extension of the Agreement Cycle for Extraordinary Circumstances § 486.316(f)

We did not propose any exception to the outcome measures requirement if the OPO experienced a disaster or some sort of extraordinary circumstance that was beyond its control and negatively impacted the OPO’s performance during the final assessment period of the re-certification cycle.

Comment: We received comments that there may be natural disasters or events beyond the OPOs control that could happen during that final assessment period.

Response: As discussed above, we recognize that there may be circumstances beyond the OPO’s control that could adversely affect the data in the final assessment period of the agreement cycle. The consequences of these events for the QAPI revision is less significant because re-assessment of performance and making changes to improve performance is a continuous

process. For re-certification, a natural disaster (such as a hurricane) or an infectious disease outbreak (such as an epidemic) that could impact DSAs disproportionately or have a disparate impact between the OPOs. Pursuant to these comments, we are revising the regulations at § 486.316(f), as described in more detail below, to include an extension of the agreement cycle for extraordinary circumstances.

These comments demonstrate that there could be extraordinary circumstances that are beyond an OPO’s control that could negatively impact the OPO’s performance on its outcome measures. This could result in an OPO’s performance not being accurately captured by the outcome measures. It is our intention to set empirical and transparent metrics for performance, and understand that there are extraordinary circumstances that could compromise or skew the underlying data. These extraordinary circumstances could include problems with the data such as data submission or transfer, a natural disaster, or other events with disparate effects. Therefore, we are finalizing that an OPO may apply for an extension of its agreement with CMS for 1-year. This is only for the final assessment period of the re-certification cycle when there has been and extraordinary circumstance beyond the OPO’s control. The OPO must request this extension within 90 days of the end of the occurrence but no later than the last day of the final assessment period.

Final Rule Action: We are finalizing § 486.316(f) that provides for OPOs to 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 that last day of the final assessment period.

D. Reporting of Data § 486.328

In the December 2019 OPO proposed rule, we proposed to eliminate the reporting of the “Number of eligible deaths” and modifying the reporting of the “Number of eligible donors” to “Number of donors” to correlate with the changes of our outcome measures. We also proposed to revise language in this section that incorrectly refers to the “Scientific Registry of Transplant Beneficiaries” and “DHHS.” We did not receive any comments that we should continue to collect eligible death information if it is not being used, nor

did we receive comments about the correction in the other language.

Final Rule Action: We are finalizing at § 486.328(a) by removing the word “Beneficiaries” and adding in its place the word “Recipients” and by removing the acronym “DHHS” and adding in its place the acronym “HHS.” We are finalizing at § 486.328(a)(4) by removing and reserving the reporting of the “Number of eligible deaths,” and revising at § 486.328(a)(7) by removing the word “eligible and revising the language to say “Number of donors.” We are also removing and reserving paragraph (a)(4) of § 486.328.

E. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)

In the December 2019 OPO proposed rule, we proposed at § 486.348(d) to require 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 at each assessment, for each assessment period except the final assessment. Failure to meet the outcome measure in the final assessment period would result in decertification. For all other assessment periods, if the OPO does not meet the outcome measures, the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

As we stated in the December 2019 OPO proposed rule (84 FR 70628), an OPO that was deemed compliant on its QAPI, but did not meet one or both of the proposed outcome measures that would be subject to decertification. We also sought comments as to whether § 486.348(b) should be revised or removed altogether to eliminate death record reviews since we are no longer using eligible deaths.

Comment: Most commenters supported the concept that ongoing performance improvement should be a goal of the organ procurement and transplantation community. However, commenters suggested that we include a process for performance improvement for OPOs which don’t initially meet the metrics before proceeding with decertification. These commenters stated that a systematic approach to decertification provides structure and guidance to lower performing organizations and allows for guidance to improve. They also stated that this improvement will create more stability in the nationwide system and ultimately lead to the end goal of improving performance without disrupting the network of service providers. Commenters stated that using the most

recent 12 months of data gives a more accurate view of the OPOs performance, using the entire 4 years is too long. On the other hand, some commenter's stated that every 12 months is too often and should be only required at least once during the 4-year cycle.

Response: We believe that all OPOs have the potential to improve. Thus, we are finalizing that every 12 months during the 4-year cycle, an OPO will be assessed for its performance on the outcome measures. During that assessment, if the OPO is performing lower than the 25 percent threshold rate, they will have the opportunity to develop a performance improvement plan to improve performance through their QAPI program. The use of annual review allows the OPO to more swiftly identify and address potential problems. We proposed to require that OPOs include a process to evaluate and address their QAPI program if their rates are statistically significantly lower than the top 25 percent at each assessment, for each assessment period, except for the final year. However, public comment supported completing QAPI in all 4 years of the certification period, so we have decided to include the final year in the assessment to allow the OPO to identify opportunities for improvement and implement the changes to improve performance.

Comment: One commenter suggested that the donor hospital CoPs should track organ donation and work to improve the donation process and that this information from donor hospitals should be tracked by CMS. By collecting and reviewing this data from donor hospitals, CMS would be able to use this data to identify "best practices" to share with the donation community. The commenter suggested CMS consider establishing a method to measure and ensure that all three entities (donor hospitals, OPOs, and transplant hospitals) are fulfilling the expectations outlined in federal regulations.

Response: The actions of donor hospitals and their data submission are outside of the scope of this rule. We will consider this suggestion for future rulemaking related to the hospital Conditions of Participation.

Comment: A few commenters questioned whether or not the OPOs are receiving all the information, resources and expertise that they need to be successful in their outcome measures and QAPI programs.

Response: There are many organizations that are available to help OPOs perform the best job possible for organ donors and recipients. The OPTN, through its contract with UNOS, is an organization that provides tools,

resources, and expertise to help OPOs improve the quality of service they provide, in order to achieve our joint goal of placing donated organs equitably and efficiently and saving more lives. This process involves continuously evaluating new advances and discoveries so policies can be adapted to best serve patients waiting for transplants. All transplant programs and organ procurement organizations throughout the country are OPTN members. We have heard from commenters and seen changes since the publication of the December 2019 OPO proposed rule, such that we are confident that through collaboration and the sharing of best practices, the industry is capable of ongoing performance improvement.

Final Rule Action: After consideration of the public comments, we are finalizing our proposal at § 486.348(d) with modification. We will include the review of the QAPI program for all 4 years of the recertification cycle.

1. Death Record Review in QAPI

In the December 2019 OPO proposed rule, we requested comments as to whether the requirement related to monthly death record reviews at § 486.348(b) should be revised or removed altogether.

Comment: We received mixed comments on whether we should eliminate the death record review as part of the QAPI at § 486.348(b). Those who wanted to remove the requirements commented that death record reviews were a tremendous amount of work. Those who suggested that we should retain the requirement found value with the death record reviews.

Response: We are not revising § 486.348(b) to remove the requirement for the death record review. While we appreciate comments related to potential burden from these reviews, commenters also reported important added value from the information. The reviews support verifying accuracy of data reported to the OPTN by the OPO, identify potential missed opportunities for donation, facilitate collaboration with donor hospitals through sharing of results, and facilitate internal QAPI activities. Additionally, data from death record reviews may provide relevant information for judging OPO performance during the survey process.

Final Rule Action: We will not revise § 486.348(b) to remove the requirement for the death record review.

F. Solicitation of Comments

We received many responses to our solicitation of comments in the December 2019 OPO proposed rule. The

comments we received have been addressed in sections II.A, II.B, II.C of this final rule regarding outcome measures, general comments, competition process and recertification.

1. Out of Scope

Comment: We received several comments pertaining to issues that are outside the scope of the proposed rule. Those comments concerned transplant program outcome measures/ harmonizing outcome measures, comments about Medicare and Medicaid spending and FDA approval of drugs relating to organ transplants. In addition, some commenters sought to change instructions to donor hospitals through hospital CoPs, transplant program CoPs, and OPO governance issues.

Response: We thank the commenters for their feedback. However, these issues are outside the scope of the final rule that focused primarily on the outcomes measures for OPOs and the consequences of recertification or decertification of OPOs because of the changes such measures. We will review these comments and consider for potential future rulemaking.

III. Provisions of the Final Rule

In this final rule, we are adopting the provisions of the December 2019 OPO proposed rule (84 FR 70628) with the following revisions:

A. Proposed Changes to Definitions (§ 486.302) and Proposed Changes to Outcome Requirements (§ 486.318).

- We are finalizing as proposed with modifications, the definitions of "Donor potential" and "Organ transplantation rate." And we are finalizing the new definitions: "Assessment period" and "Death that is consistent with organ donation," and "Kidney transplantation rate."

- We are finalizing our proposal at § 486.318(d)(4) in this final rule using the death certificate data to calculate the donor potential.

- We are finalizing a modification to the definition of the "donor potential" under § 486.302 to apportion the donor potential in a county where there is a donor hospital that has sought a waiver to work with an OPO out of their designation service area. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

- We are finalizing under § 486.302 that “death that is consistent with organ donation” means all deaths from state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

- We are finalizing the new definition, “Assessment period” under § 486.302 to be a 12-month period in which an OPO’s outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

- We are finalizing that the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

- We are finalizing as proposed that the age cutoff for the donor potential defined in § 486.302 is 75 and younger.

- We are finalizing the definition of “organ transplantation rate” under § 486.302 to be risk-adjusted for the average age of the donor potential using the following methodology:

(1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

(2) Calculate a national age-specific transplantation rate for each age group. An expected transplantation rate for each OPO is calculated as $\Sigma(g=1)Gdg \cdot Rg / \Sigma gdg$, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and Σgdg is the OPO’s total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

(3) Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO’s observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

- We will be finalizing the implementation this final rule 60 days after publication and the new outcome measures will be implemented on August 1, 2022 to coincide with the start of the next certification period.

- We are finalizing our proposal at § 486.318(d)(1) that the donation rate will be one of the outcome measures for assessing OPO performance, and is

defined as the number of donors as a percentage of the donor potential.

- We are finalizing our proposal at § 486.318(d)(2) that the organ transplantation rate will be an outcome measure for assessing OPO performance, and is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential.

- We are also finalizing under § 486.318(d)(3) a clarification that for calculating each measure. The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from donors in the DSA. The numbers of donors, organs transplanted, and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11. For calculating each measure, the data used would be from the same time period as the data for the donor potential.

- We are finalizing our proposal that we will use the most recent 1 year of data for calculating the outcome measures for each assessment period under § 486.318.

- We are finalizing § 486.318(e)(4) through (6), the creation of three tiers to identify OPO performance.

Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) will be identified at each assessment period.

Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

- We are finalizing under § 486.318(e)(7) that for the OPO exclusively serving the DSA that includes the non-contiguous state of

Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (e)(4), (5), and (6) except kidney transplantation rates will be used.

B. Re-Certification and Competition Processes (§ 486.316)

- We are modifying our proposed changes to § 486.316(a), (b), and (c) to make corresponding changes for the tier system we are finalizing.

- We are modifying the language in § 486.316(b) by removing “the OPO is de-certified” and inserting “CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314”.

- We are finalizing under § 486.316(f) that OPOs can seek a 1-year extension of the agreement cycle if there are extraordinary circumstances beyond the control of the OPO that has affected the data of the final assessment 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 that last day of the final assessment period.

C. Proposed Change to the Quality Assessment and Performance Improvement Requirement (§ 486.348)

- We are finalizing our proposal at § 486.348 with modification. We will include the review of the QAPI program for all 4 years of the re-certification cycle.

- We are not revising § 486.348(b) to remove the requirement for the death record review.

D. Solicitation of Comments (Including Changes to Re-Certification Cycle)

We solicited comments in the December 2019 OPO proposed rule on the following issues:

- Should OPO outcome measures also include an assessment of organ transplantation rates by type of organ transplanted?

- We are proposing to use a performance measure that is based on the OPO’s performance relative to the top 25 percent of donation rates and organ transplantation rates. Should CMS use a static level or a different criterion from what is being proposed? What statistical approach to the data or incentives can we use to encourage all OPOs to strive to be high performers? Can the current performance parameter, which requires that the donation rate be no more than 1.5 standard deviations

below the mean national donation rate, be appropriately applied to achieve this goal? We are requesting that commenters explain and include any evidence or data they have to support their comments.

- What are the benefits, consequences, or unintended consequences, of using these two proposed measures and what are their potential impact on OPOs, transplant programs, organ donation, patient access, and transplant recipients?
- Are there potential additional compliance burdens on OPOs or transplant programs if the two proposed measures were finalized?

We received robust public comments in response to this solicitation that have been summarized and responded to as part of the discussions in sections II.A through C of this final rule.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We received no comments on the need for information collection, the accuracy of our estimates, the quality or utility of the information to be collected, or the information collection burden estimates.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Extension of Agreement Cycle for Extraordinary Circumstances (§ 486.316)

In this final rule at § 486.316(f), we have added a paragraph in response to public comments allowing for an extension of the agreement cycle for extraordinary circumstances. OPOs may

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. In section II.C.5 of this final rule, we state that to seek an ECE exception, the OPO needs to describe the extraordinary circumstance, the time period in 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.

We will need to submit a revised information collection request for the OPO CFC (OMB Control Number 0938–0688, expiring February 2021) information to reflect the opportunity we are providing for OPOs to request an ECE. Since requesting an ECE will place the DSA off-cycle from the other DSAs for re-certification, we expect that OPOs will be judicious in deciding to request the 1-year ECE. It is difficult to predict extraordinary events, however for the purposes of our burden estimate, we anticipate four OPOs requesting an ECE with each 4-year re-certification cycle, resulting in an average of 1 request per year.

We estimate that the OPO director (\$107/hour), and a medical secretary (\$35/hour) will need 1 hour each to collect relevant evidence to support the extraordinary circumstance, describe it in writing, and submit the information to CMS. All wages are adjusted upwards by 100 percent to account for the cost of fringe benefits and overhead. The result would be an annual cost of \$284 (2 hours × \$142).¹⁹

B. ICRs Regarding Re-Certification and Competition Processes (§ 486.316)

At § 486.316(b), we proposed to modify language that refers to the current outcome measure requirements that states that an OPO must meet two out of the three outcome measures at § 486.318. They would instead be required to meet both newly proposed outcome measures, or face de-certification which may then be appealed by the OPO. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-

certification, the OPO's service area would be opened for competition by other OPOs.

In the final rule, we maintain these requirements with some modifications. Most notably, we are creating a three-tier, rather than two-tier, performance system, with OPOs performing below the threshold rate established by the top 25 percent required to update their QAPI program at each assessment period and those OPOs who are in Tier 2 (has at least the donation rate and the organ transplantation rate at or above the median threshold rate) being allowed to compete to retain their DSA rather than automatically being decertified. These changes do not significantly affect the information to be collected or the net effect of the rule on information collection, since all DSAs with outcome measures below the threshold rate of the top 25 percent would remain subject to competition.

The current information collection request for the OPO CFC (OMB Control Number 0938–0688, expiring February 28, 2021) estimates that one OPO would face de-certification per year, but under both the proposed and final rule, revised outcome measures, this number could potentially significantly increase after the first cycle of implementation. The intention for subsequent cycles is that the outcome measures of all DSAs would cluster at the top 25 percent threshold rate. We do not know exactly how many would be de-certified under these new measures. Based on the improvement required to meet the proposed rule measures, we estimated that it would be possible that approximately 7 to 33 OPOs could be de-certified. Given the change in the final rule to the three tier system and the potential for Tier 2 OPOs to retain their certification, we believe that the number would be lower. The range of decertified OPOs would thus vary from zero OPOs that are decertified, to all Tier 3 OPOs being decertified and all Tier 2 OPO DSAs being open for competition. Since there are 22 OPOs in the lowest tier, and all of these will presumably be trying to improve their performance using the assessment period data provided each year and their QAPI, it seems likely that at most about half of the OPOs (11) would be decertified based on their outcome measures in 2024. There would also be 12 OPOs in Tier 2 whose respective service areas would be opened for competition. If the 12 OPOs in Tier 2 were joined by the 22 OPOs in Tier 3, there would be 34 open DSAs subject to potential competition. Of course, with improved performance in response to the annual assessments, the number at

¹⁹ These and subsequent estimated wage costs are based on the Labor Department's Bureau of Labor Statistics annual occupational wage survey at https://www.bls.gov/oes/current/oes_nat.htm. We double the hourly wage estimate to account for the costs of overhead and fringe benefits.

risk could be as low as zero. However, to be conservative we have chosen mid-point estimates to calculate estimated burden and potential impact.

Under § 486.316(d), Criteria for selection, we identify the factors that we will consider in awarding a DSA to an OPO competing for an open service area. In addition to factors that CMS will produce and collect from other aspects of the CfCs, OPO will need to submit information and data that describes the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results. In addition, § 486.316(c) states that to compete for an open service area, an OPO must meet the performance requirements of the outcome measures at § 486.318 and the requirements for certification at § 486.303, including the CfCs at §§ 486.320 through 486.360. The OPO must also compete for the entire service area.

Since much of the information about the outcome measures is already calculated and collected by CMS and performance in the CfCs at §§ 486.320 through 486.360 through the re-certification survey, the burden associated with this requirement is the time it would take to create 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 refer to this documentation as an application.

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. For purposes of estimation, we assume that about half of the DSAs opened for competition based on 2018 calculations would have improved sufficiently that they would not be opened for competition in 2024: 11 DSAs with Tier 3 designation and 6 DSAs with Tier 2 designation. 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 will revise these burden estimates after the first re-certification cycle for accuracy.

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 × 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 compete 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 at 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 × 30 hours × 73 applications) + (\$71 organ procurement coordinator × 30 hours × 73 applications) + (\$107 medical director × 12 hours × 73 applications) + (\$107 OPO director × 30 × 73 applications) + (\$35 medical secretary × 2 hours × 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).

C. ICRs Regarding Condition: Reporting of Data (§ 486.328)

We proposed to revise § 486.318 to eliminate the reporting of the “Number of eligible deaths” and modify the reporting of “Number of eligible donors” to “Number of donors.” Although the current outcome measures include the potentially burdensome OPO self-defined and self-reported “eligible deaths” for evaluation purposes, the current information collection request for the OPO requirements (OMB Control Number 0938–0688, expiring February 28, 2021) does not attribute any burden to this requirement. This is because the type of data and how it is reported to the OPTN is already covered by the information

collection requirements associated with the OPTN final rule (§ 121). The OMB control number for this collection is 0915–0157 (expiring August 31, 2023). Thus, we are not attributing any quantifiable burden reduction to eliminating this requirement in the final rule.

D. ICRs Regarding Quality Assessment and Performance Improvement (§ 486.348)

At § 486.348(d) 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 at each assessment. Assessments would occur at least every 12 months with 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.

As stated in the information collection request for the OPO requirements (OMB Control Number 0938–0688, expiring February 28, 2021), 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. Accordingly, we do not believe this change would impose any additional ongoing quantifiable burden.

V. Regulatory Impact Analysis

A. Statement of Need

All major government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and that they accomplish their goals effectively and efficiently. It has been apparent for a number of years that the current system for organ donation and the rules under which OPO performance is measured do not create the necessary incentives to optimize organ donation and transplantation as evidenced by performance discrepancies among OPOs, the wide geographic and population diversity among both higher- and lower-performing OPOs, and the significant gap between the number of potential organ donors and the number of actual donors (see Tables 1 and 2). As discussed in the December 2019 OPO proposed rule, many anecdotal article titles identify a clear need for action: “Reforms to Organ Donation System Would Save Thousands of Lives,

Millions of Taxpayer Dollars Annually,” “Lives Lost, Organs Wasted,” and “A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives.”²⁰ All three of these articles include, or reference, in-depth studies of the current organ donation system’s problems and discuss reforms that could increase its performance. These articles were written by and published in: Goran Klintman, RealClearHealth, March 4, 2019; Kimberly Kindy, Lenny Bernstein, and Dan Keating, Washington Post, December 20, 2018; and Laura and John Arnold, STAT, July 24, 2019. These problems and the reforms needed to improve organ donation and transplantation have multiple dimensions, including the underperformance of many OPOs to procure and place organs at the levels of the best-performing OPOs. This is the basis for President Trump’s July 10, 2019 Executive Order on Advancing American Kidney Health, to “increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.”

The majority of the public comments agreed that these were major problems and that many lives could be saved if reforms were made. For example, one OPO which had just greatly increased its donor performance stated that “we know that there are many more potential donors in our DSA [and] it is our intent to act on that belief . . . Substantial, not incremental, change is required in our system.”

Relatedly, the Secretary issued a final rule on September 30, 2019, titled “Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” (84 FR 51732), referred to as the “2019 Burden Reduction final rule”, to reduce regulatory burden on several types of health care providers”) that directly addressed the same policy concern. Under that final rule, performance standards for transplant hospitals were revised to reduce the practice of transplanting only the best organs in the healthiest patients. Those performance standards rewarded high 1-year organ and patient survival rates by threatening program closure to hospitals that did not achieve such rates. In so doing, those performance standards gave no weight to maximizing treating the many patients on the waiting lists whose lives

would be saved, even at a higher risk of failure. As discussed in the RIA for 2019 Burden Reduction final rule, lessening or eliminating those standards might reduce the number of “transplant quality” discarded organs, and through transplantation of those organs, save the lives of many patients each year. Because transplant programs had been notified over a year ago that these penalties were likely to be eliminated, the regulatory changes may have led to changes beginning in late 2018 and continuing in 2019 to utilize more organs than in previous years.

Finally, the Executive Order directs the Secretary of HHS as follows: “Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.” That directive applied directly to the proposed rule that preceded this final rule.

B. Scope of Review

We have examined the impacts of both the proposed rule and this final rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Order 13771 states that it is essential to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations and establishes policies and procedures to reduce the costs of both new and existing federal regulations.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order

12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimated and OMB has determined that this rule is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that presented our estimates of the costs and benefits of this rulemaking.

Based on the public comments we received, our review of these comments, our review of new research literature, and the absence of any comments finding errors in our original analysis, we conclude that our estimates on the likely effects of the December 2019 OPO proposed rule may have been reasonable. In this final RIA, we have re-estimated some effects because of the substantive changes made in the final rule, but none of these re-estimates change the main conclusions previously reached on overall costs and benefits of this rule.

C. Effects on OPO Performance

We proposed two new outcome measures that would be used to assess an OPO’s performance: A measure of an OPO’s donation rate and a measure of its organ transplantation rate in the DSA. In the December 2019 OPO proposed rule, these were two independent tiers that each allowed for only “pass or fail” levels of performance. As discussed earlier in the preamble, the final rule now contains a three-tier system for each outcome measure. Table 1 shows current performance using the donation rate outcome measure in this final rule, derived from data spanning January 1, 2018 to December 31, 2018. The final

rule contains a major change in the determination of the donor potential (denominator) for the outcome measures using the CALC methodology for estimating the donor potential as explained in section II.B.6 of the December 2019 OPO proposed rule and in section V.G “Alternatives Considered” of this final rule. The CALC measure is endorsed by much of the peer-reviewed literature as technically superior. For the vast majority of OPOs, using the CALC methodology to estimate the denominator does not change their relative performance substantially from that in the December 2019 OPO proposed rule. For example, in Table 13a of the December 2019 OPO proposed rule, we showed that the top 18 performers on donation using the then-proposed measure were also the top 18 performers using the CALC measure. Seventeen of the 20 lowest donation performers on the then-proposed measures were also in the lowest performing group on the CALC measure.

In both the proposed and final rules, the performance variable for the donation rate is the number of actual donors who had at least one organ transplanted, regardless of the number of organs that each provides. This

measure focuses on the key tasks of obtaining family consent, clinically managing the donor, and arranging for the actual surgical and handling procedures involved in getting at least one organ from the deceased donor to placement in a patient on a waiting list. Hearts, lungs, livers, kidneys, intestines, and pancreas that are transplanted count towards this measure of success. Additionally, a pancreas that is procured and is used for research or islet cell transplantation also counts for this purpose.

In the tables that follow, the first two digits of the letters in parentheses are, in most cases, the primary state of the OPO. Some OPOs serve more than one state, and some states have more than one OPO. The four digits after the OPO’s name represents the digits identifying the DSA and remain unchanged even when the name of the OPO changes. In a few cases in the tables below, we have abbreviated an OPO name to improve simplicity of presentation. For a complete OPO listing and additional information, see the following link: <https://optn.transplant.hrsa.gov/members/member-directory/?memberType=Organ%20Procurement%20Organizations>.²¹ These tables show the performance required of each OPO to reach the performance standard,

including an allowance for statistical “confidence” (one-tailed test), for the OPOs that fell below the standard. Confidence intervals are calculated based on test statistics derived from the assumed binomial and Poisson distribution for the donation rate and transplant rate, respectively. Specifically, the Wilson score interval with continuity correction (Newcombe 1998) is used to calculate the confidence interval for the donation rate of each OPO. The Wilson and Hilferty formula is used to calculate the confidence interval for the transplant rate of each OPO.²² In lay terms, these confidence levels are simply a way to provide for a “margin of error” when calculating the rates for each OPO given the different sizes of the donor potentials.

We are committed to using the best available data to continue our analysis of OPO performance, including, where possible, historical trends in OPO performance; a range of potential outcomes, including a scenario where high performers remain at steady state; and year over year OPO performance and distribution of scores and improvements within the past two certification cycles, using the final rule’s outcome measures.

TABLE 1—OPO DONOR RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS

[OPOs below Top 25 percent in *italics* and below median in ***bold and italics***]

OPO name	Donation rate	Upper bound with 95% confidence interval	Additional donors to reach median	Additional donors to reach top 25%
Midwest Transplant Network (MWOB)	17.85	19.62	0	0
DonorConnect (UTOP)	15.29	17.65	0	0
Nebraska Organ Recovery System (NEOR)	14.04	17.02	0	0
Gift of Life Donor Program (PADV)	15.59	16.63	0	0
OPO at the U. of Wisconsin (WIUW)	14.24	16.26	0	0
Lifesharing—A Donate Life Organization (CASD)	13.42	15.39	0	0
LifeChoice Donor Services (CTOP)	12.03	14.45	0	0
Nevada Donor Network (NVLV)	12.17	14.01	0	0
OurLegacy (FLFH)	12.42	13.97	0	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	12.84	13.84	0	0
Versiti (WIDN)	11.48	13.74	0	0
Donor Network of Arizona (AZOB)	12.41	13.68	0	0
Lifeshare Carolinas (NCCM)	11.78	13.68	0	0
Donor Alliance (CORS)	12.03	13.65	0	0
The Living Legacy Foundation of Maryland (MDPC)	11.98	13.63	0	0
LifeGift Organ Donation Center (TXGC)	11.96	12.96	0	0
Mid-America Transplant Services (MOMA)	11.27	12.64	0	0
Washington Regional Transplant Community (DCTC)	11.01	12.63	0	0
LifeShare of Oklahoma (OKOP)	11.15	12.56	0	0
ConnectLife (NYWN)	9.75	12.32	0	0
LifeCenter Organ Donor Network (OHOV)	10.18	12.29	0	0
Southwest Transplant Alliance (TXSB)	11.20	12.18	0	0
LifeBanc (OHLB)	10.60	12.05	0	0
Louisiana Organ Procurement Agency (LAOP)	10.72	12.04	0	0
New England Organ Bank (MAOB)	10.82	11.85	0	0
LifeCenter Northwest (WALC)	10.74	11.85	0	0

²¹ Some of these OPOs have changed names in recent years, so some other published lists may be

out of date. However, the codes shown in parentheses in our tables have not changed.

²² Wilson and Hilferty 1931, Breslow and Day 1987, Kulkarni and Hemangi 2012.

TABLE 1—OPO DONOR RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS—Continued

[OPOs below Top 25 percent in *italics* and below median in ***bold and italics***]

OPO name	Donation rate	Upper bound with 95% confidence interval	Additional donors to reach median	Additional donors to reach top 25%
LifeLink of Puerto Rico (PRLL)	9.95	11.71	0	0
LifeLink of Florida (FLWC)	10.54	11.68	0	0
Gift of Life Michigan (MIOP)	10.50	11.46	0	0
Tennessee Donor Services (TNDS)	10.24	11.25	0	4
<i>Life Connection of Ohio (OHLC)</i>	<i>9.23</i>	<i>11.18</i>	<i>0</i>	<i>2</i>
<i>LifeLink of Georgia (GALL)</i>	<i>10.16</i>	<i>11.16</i>	<i>0</i>	<i>6</i>
<i>Sharing Hope SC (SCOP)</i>	<i>9.78</i>	<i>11.04</i>	<i>0</i>	<i>6</i>
<i>Donor Network West (CADN)</i>	<i>10.05</i>	<i>10.99</i>	<i>0</i>	<i>12</i>
<i>Legacy of Life (HIOP)</i>	<i>8.35</i>	<i>10.82</i>	<i>0</i>	<i>3</i>
<i>Center for Organ Recovery and Education (PATF)</i>	<i>9.64</i>	<i>10.79</i>	<i>0</i>	<i>12</i>
<i>Lifeline of Ohio (OHLP)</i>	<i>9.34</i>	<i>10.77</i>	<i>0</i>	<i>8</i>
<i>LifeSource—MN (MNOP)</i>	<i>9.50</i>	<i>10.73</i>	<i>0</i>	<i>12</i>
<i>New Mexico Donor Services (NMOP)</i>	<i>8.04</i>	<i>10.23</i>	<i>0</i>	<i>6</i>
<i>Sierra Donor Services (CAGS)</i>	<i>8.31</i>	<i>10.08</i>	<i>0</i>	<i>11</i>
<i>LifeQuest Organ Recovery Services (FLUF)</i>	<i>8.74</i>	<i>9.94</i>	<i>0</i>	<i>24</i>
<i>Pacific Northwest Transplant Bank (ORUO)</i>	<i>8.61</i>	<i>9.93</i>	<i>0</i>	<i>20</i>
<i>New Jersey Sharing Network OPO (NJTO)</i>	<i>8.71</i>	<i>9.89</i>	<i>0</i>	<i>26</i>
<i>Mississippi Organ Recovery Agency (MSOP)</i>	<i>8.29</i>	<i>9.86</i>	<i>0</i>	<i>15</i>
<i>Legacy of Hope—Alabama (ALOB)</i>	<i>8.65</i>	<i>9.84</i>	<i>0</i>	<i>26</i>
<i>Texas Organ Sharing Alliance (TXSA)</i>	<i>8.63</i>	<i>9.77</i>	<i>0</i>	<i>30</i>
<i>Finger Lakes Donor Recovery Network (NYFL)</i>	<i>7.80</i>	<i>9.68</i>	<i>1</i>	<i>12</i>
<i>Iowa Donor Network (IAOP)</i>	<i>7.98</i>	<i>9.66</i>	<i>1</i>	<i>15</i>
<i>Center for Donation and Transplant (NYAP)</i>	<i>7.45</i>	<i>9.33</i>	<i>3</i>	<i>14</i>
<i>LiveOnNY (NYRT)</i>	<i>8.50</i>	<i>9.33</i>	<i>13</i>	<i>68</i>
<i>LifeNet Health (VATB)</i>	<i>7.97</i>	<i>9.07</i>	<i>12</i>	<i>43</i>
<i>OneLegacy (CAOP)</i>	<i>8.31</i>	<i>8.94</i>	<i>43</i>	<i>133</i>
<i>Indiana Donor Network (INOP)</i>	<i>7.79</i>	<i>8.81</i>	<i>19</i>	<i>54</i>
<i>Arkansas Regional Organ Recovery Agency (AROR)</i>	<i>7.06</i>	<i>8.69</i>	<i>9</i>	<i>22</i>
<i>Carolina Donor Services (NCNC)</i>	<i>7.58</i>	<i>8.52</i>	<i>29</i>	<i>69</i>
<i>Kentucky Organ Donor Affiliates (KYDA)</i>	<i>7.15</i>	<i>8.25</i>	<i>26</i>	<i>54</i>
<i>Mid-South Transplant Foundation (TNMS)</i>	<i>6.66</i>	<i>8.19</i>	<i>14</i>	<i>28</i>
<i>Life Alliance Organ Recovery Agency (FLMP)</i>	<i>6.87</i>	<i>7.86</i>	<i>38</i>	<i>71</i>

Note: Cutoffs at 2017 OPO upper bound performance levels of Top 25 percent at 11.37 and median at 9.72.

Table 2 shows the current range of organ transplantation performance, using the new standard of measuring the total number of organs transplanted from deceased donors (including all transplanted organs from each donor) as a percentage of the same donor potential used for the donation rate in the final rule.²³ Table 2 includes both the unadjusted organ transplantation rate and the organ transplantation rate which reflects the rate once it is risk-adjusted for the average age in the donor potential. The organ transplantation rate as defined in § 486.302 will be the basis for re-certification.

According to the NCHS, there are about 2.8 million deaths each year in the U.S., but the potential deceased donor pool is far lower because it only

includes those who die in hospitals, who are age 75 or less, and who have primary causes of death consistent with organ donation. As previously discussed, the December 2019 proposed rule used as its measure of donors those inpatient deaths age 75 or less who have no contraindications to donation. We also proposed as an alternative the CALC methodology that uses the same hospital location and age criteria, but uses ICD-10-CM codes reflecting deaths that are consistent with donation—inclusion rather than exclusion. We believe the CALC measure is more widely accepted in the transplant community and now has a body of literature validating its consistency, thus, we have adopted it in this final rule.

As shown in Table 2, the organ transplantation rates range from 57.90 at the highest levels to 18.94 (using data from calendar year 2018), a range of about three to one from highest to lowest. The top-performing OPOs are geographically and demographically diverse, with potential donor pools ranging from about 463 deaths a year to almost 3,566 a year (using the CALC methodology) as shown in Table 1. We recognize that some OPOs have fewer transplant programs within their service areas than others, but allocation policies are no longer based on the DSA and historically, OPOs had access to the organ match run, which lists all potential recipients for a donated organ in the entire country.

²³ These results would look similar if we used the current estimates of “eligible” deaths but would be

an imperfect comparison since that is not a standardized measure.

TABLE 2—OPO TRANSPLANT RATE FOR 2018 WITH TOP 25% AND MEDIAN CUTOFF LEVELS

[OPOs below top 25 percent in *italics* and below median in ***bold and italics***]

OPO name (primary state)	Organ transplantation rate	Upper bound at 95% CI	Additional organs to reach median	Additional organs to reach top 25%
Nebraska Organ Recovery System (NEOR)	57.90	65.22	0	0
OPO at the U. of Wisconsin (WIUW)	52.92	56.27	0	0
Midwest Transplant Network (MWOB)	52.44	55.29	0	0
Lifesharing—A Donate Life Organization (CASD)	48.49	52.74	0	0
DonorConnect (UTOP)	46.04	49.51	0	0
Nevada Donor Network (NVLV)	45.65	49.28	0	0
LifeLink of Puerto Rico (PRL)	40.31	44.99	0	0
Gift of Life Donor Program (PADV)	42.04	43.63	0	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	40.57	42.44	0	0
LifeShare of Oklahoma (OKOP)	39.29	42.21	0	0
OurLegacy (FLFH)	39.58	42.17	0	0
Gift of Life Michigan (MIOP)	39.43	41.46	0	0
LifeGift Organ Donation Center (TXGC)	39.20	41.03	0	0
Center for Organ Recovery and Education (PATF)	38.24	40.83	0	0
Donor Network of Arizona (AZOB)	38.22	40.09	0	0
The Living Legacy Foundation of Maryland (MDPC)	36.24	38.64	0	0
LifeLink of Florida (FLWC)	36.40	38.63	0	0
Donor Network West (CADN)	36.04	37.90	0	0
Washington Regional Transplant Community (DCTC)	35.39	37.83	0	0
LifeCenter Northwest (WALC)	35.76	37.72	0	0
LiveOnNY (NYRT)	35.49	37.70	0	0
Versiti (WIDN)	33.95	37.45	0	0
LifeBanc (OHLB)	34.74	37.27	0	0
Southwest Transplant Alliance (TXSB)	35.29	37.00	0	0
Lifeshare Carolinas (NCCM)	33.72	36.51	0	0
Mid-America Transplant Services (MOMA)	34.36	36.49	0	0
New England Organ Bank (MAOB)	34.45	36.30	0	0
Tennessee Donor Services (TNDS)	34.18	36.04	0	2
LifeChoice Donor Services (CTOP)	32.17	35.53	0	4
Sierra Donor Services (CAGS)	31.69	35.25	0	7
New Jersey Sharing Network OPO (NJTO)	32.75	35.18	0	15
Louisiana Organ Procurement Agency (LAOP)	32.74	34.86	0	23
ConnectLife (NYWN)	30.17	34.63	0	7
LifeLink of Georgia (GALL)	31.69	33.42	0	75
Pacific Northwest Transplant Bank (ORUO)	30.65	33.31	0	36
Lifeline of Ohio (OHL)	30.14	32.56	0	47
Center for Donation and Transplant (NYAP)	28.06	32.51	0	18
LifeSource—MN (MNOP)	30.23	32.27	0	71
Iowa Donor Network (IAOP)	29.11	32.23	0	32
OneLegacy (CAOP)	30.88	32.18	0	202
Legacy of Hope—Alabama (ALOB)	29.04	31.34	12	75
Mississippi Organ Recovery Agency (MSOP)	28.21	31.22	8	44
Donor Alliance (CORS)	29.26	31.15	15	81
Texas Organ Sharing Alliance (TXSA)	28.57	30.48	31	110
Life Connection of Ohio (OHL)	27.26	30.02	17	50
Sharing Hope SC (SCOP)	28.05	29.89	42	120
LifeNet Health (VATB)	27.65	29.68	44	117
Finger Lakes Donor Recovery Network (NYFL)	26.16	29.30	19	47
LifeCenter Organ Donor Network (OHV)	26.44	29.00	26	60
Arkansas Regional Organ Recovery Agency (AROR)	25.80	28.85	25	56
Carolina Donor Services (NCNC)	26.82	28.62	80	173
LifeQuest Organ Recovery Services (FLUF)	26.55	28.50	63	134
Legacy of Life (HIOP)	22.91	27.01	20	35
New Mexico Donor Services (NMOP)	23.53	26.80	29	51
Indiana Donor Network (INOP)	25.06	26.58	135	236
Kentucky Organ Donor Affiliates (KYDA)	24.17	26.00	110	184
Life Alliance Organ Recovery Agency (FLMP)	23.81	25.59	130	211
Mid-South Transplant Foundation (TNMS)	18.94	21.05	109	149
Totals			915	2,472

Note: Cutoffs at 2017 OPO upper bound performance levels of Top 25% at 36.10 and median at 32.05.

Both outcome measures as originally proposed and in the final rule address multiple goals not met by the current requirements: (1) They can be uniformly

applied across all OPOs; (2) they capture not only success in obtaining donors but also success in placing as many organs as possible; (3) they

capture virtually the entire pool of possible donors (not the pool as determined separately by each OPO); (4) they adjust for the geographic

differences in the number and causes of death; and (5) they meet central necessities for a workable performance standard that exhibits uniformity, timeliness, and stability year-to-year. Of particular importance, these measures, both as proposed and as made final, would replace the subjective and self-reported criteria of eligible donors and eligible deaths. The existing denominator standard allows OPOs to exclude from the calculated potential donor pool those cases where the next-of-kin did not authorize donation, a crucial task we believe all OPOs should be effective and continually improving at. For an extensive discussion of these and related issues, see “Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States.”²⁴ The proposed and final measures do not control for every variable that can affect OPO performance for reasons beyond its control. For example, states without motorcycle helmet laws have higher rates of accidents that create potential donors. Some DSAs have greater transplant hospital competition than others, and more competition for transplantable organs is associated with greater use of organs that might otherwise be discarded.²⁵ Regardless, it is our belief that the untapped donor and organ potential is sufficiently large

in every DSA so that every OPO has both potential donors, organs, and transplant recipients to exceed its current performance level. We received no public comments presenting evidence to the contrary.

One way to understand the potential is to compare current donation rates with the CALC methodology used to calculate potential donors in the final rule, a very important quantitative result: In 2018 there were about 10,000 deceased donors, which is only about 10 percent of the almost 100,000 potential donors in 2018 (https://srtr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx). The highest performing OPOs at present do not quite reach a rate of 20 percent of potential donors becoming actual donors. Importantly, the final rule’s criteria for potential donors already exclude most deaths, and focus on decedents with substantial potential to provide transplantable organs. Hence, all OPOs have a pool of potential donors many times higher than the number of donors and organs needed to meet the final rule’s performance standards. Furthermore, in 2018, there were 1,073,084 death and imminent death referrals reported to the OPTN by OPOs,²⁶ meaning that less than 1 percent of referrals became organ donors.

If the number of donors at the Tier 2 and Tier 3 OPOs were to reach the

threshold rate of the top 25 percent, the number of annual donors would increase by approximately one thousand by the end of the 4-year performance period and increase the number of organ transplantations by about 2,500. As show in Tables 4 and 5, both donors and transplants could be far higher than these thresholds with as little as a 20 percent overall rate of improvement over a 5-year period.

We believe that all OPOs are capable of achieving these higher success rates; our estimates assume improvements at all current levels of performance due to better techniques and methods associated with organ procurement as well as the “incentives” provided to the top performing OPOs (that is, keeping their DSA free from competition and allowing them to compete for an open new DSA). For example, there have been major recent improvements in perfusion techniques used to preserve kidneys and extend the time period allowed between donation and transplantation. This technology rewards focusing efforts on extending the placement of organs beyond local areas for appropriate transplant candidates on waiting lists. These techniques are available to all OPOs, but have not been adopted by all. While there may be future improvements,²⁷ our estimates do not factor in potential future major breakthroughs.

TABLE 3—OPO RATINGS AND TIERS FOR BOTH DONATION AND TRANSPLANT RATES

[OPOs below top 25 percent in *Italics* and below median in ***bold and italics***]

OPO name (primary state)	Donation rate	95% CI	Organ transplant rate	95% CI	Tier
Nebraska Organ Recovery System (NEOR)	14.04	17.02	57.90	65.22	Tier 1.
OPO at the U. of Wisconsin (WIUW)	14.24	16.26	52.32	56.27	
Midwest Transplant Network (MWOB)	17.85	19.62	52.44	55.29	
Lifesharing—A Donate Life Organization (CASD)	13.42	15.39	48.49	52.74	
DonorConnect (UTOP)	15.29	17.65	46.04	49.51	
Nevada Donor Network (NVLV)	12.17	14.01	45.65	49.28	
LifeLink of Puerto Rico (PRLL)	9.95	11.71	40.31	44.99	
Gift of Life Donor Program (PADV)	15.59	16.63	42.04	43.63	
Gift of Hope Organ & Tissue Donor Network (ILIP)	12.84	13.84	40.57	42.44	
LifeShare of Oklahoma (OKOP)	11.15	12.56	39.29	42.21	
OurLegacy (FLFH)	12.42	13.97	39.58	42.17	
Gift of Life Michigan (MIOP)	10.50	11.46	39.43	41.46	
LifeGift Organ Donation Center (TXGC)	11.96	12.96	39.20	41.03	
Donor Network of Arizona (AZOB)	12.41	13.68	38.22	40.09	
The Living Legacy Foundation of Maryland (MDPC)	11.98	13.63	36.24	38.64	
LifeLink of Florida (FLWC)	10.54	11.68	36.40	38.63	
Washington Regional Transplant Community (DCTC)	11.01	12.63	35.39	37.83	
LifeCenter Northwest (WALC)	10.74	11.85	35.76	37.72	
Versiti (WIDN)	11.48	13.74	33.95	37.45	
LifeBanc (OHLB)	10.60	12.05	34.74	37.27	

²⁴ Goldberg D, et al., “Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,” *Am J Transplant* 2017; 17:3183–3192.

²⁵ Adler, et al., “Is Donor Service Area Market Competition Associated with Organ Procurement

Organization Performance?” *Transplantation* 2016; 100; 1349–1355.

²⁶ OPTN 2018 Annual Report, https://srtr.transplant.hrsa.gov/annual_reports/2018/DOD.aspx.

²⁷ <https://www.nih.gov/news-events/news-releases/scientists-triple-storage-time-human-donor-livers>.

TABLE 3—OPO RATINGS AND TIERS FOR BOTH DONATION AND TRANSPLANT RATES—Continued
 [OPOs below top 25 percent in *italics* and below median in **bold and italics**]

OPO name (primary state)	Donation rate	95% CI	Organ transplant rate	95% CI	Tier
Southwest Transplant Alliance (TXSB)	11.20	12.18	35.29	37.00	
Lifeshare of the Carolinas (NCCM)	11.78	13.68	33.72	36.51	
Mid-America Transplant Services (MOMA)	11.27	12.64	34.36	36.49	
New England Organ Bank (MAOB)	10.82	11.85	34.45	36.30	
Center for Organ Recovery and Education (PATF)	<i>9.64</i>	<i>10.79</i>	38.24	40.83	Tier 2.
Donor Network West (CADN)	<i>10.05</i>	<i>10.99</i>	36.04	37.90	
Tennessee Donor Services (TNDS)	<i>10.24</i>	<i>11.25</i>	<i>34.18</i>	<i>36.04</i>	
LifeChoice Donor Services (CTOP)	12.03	14.45	<i>32.17</i>	<i>35.53</i>	
Sierra Donor Services (CAGS)	<i>8.31</i>	<i>10.08</i>	<i>31.69</i>	<i>35.25</i>	
New Jersey Sharing Network OPO (NJTO)	<i>8.71</i>	<i>9.89</i>	<i>32.75</i>	<i>35.18</i>	
Louisiana Organ Procurement Agency (LAOP)	10.72	12.04	<i>32.74</i>	<i>34.86</i>	
ConnectLife (NYWN)	9.75	12.32	<i>30.17</i>	<i>34.63</i>	
LifeLink of Georgia (GALL)	<i>10.16</i>	<i>11.16</i>	<i>31.69</i>	<i>33.42</i>	
Pacific Northwest Transplant Bank (ORUO)	<i>8.61</i>	<i>9.93</i>	<i>30.65</i>	<i>33.31</i>	
Lifeline of Ohio (OHLF)	<i>9.34</i>	<i>10.77</i>	<i>30.14</i>	<i>32.56</i>	
LifeSource—MN (MNOP)	<i>9.50</i>	<i>10.73</i>	<i>30.23</i>	<i>32.27</i>	
LiveOnNY (NYRT)	8.50	9.33	35.49	37.70	Tier 3.
Center for Donation and Transplant (NYAP)	7.45	9.33	28.06	32.51	
Iowa Donor Network (IAOP)	7.98	9.66	29.11	32.23	
OneLegacy (CAOP)	8.31	8.94	30.88	32.18	
Legacy of Hope—Alabama (ALOB)	<i>8.65</i>	<i>9.84</i>	29.04	31.34	
Mississippi Organ Recovery Agency (MSOP)	<i>8.29</i>	<i>9.86</i>	28.21	31.22	
Donor Alliance (CORS)	12.03	13.65	29.26	31.15	
Texas Organ Sharing Alliance (TXSA)	<i>8.63</i>	<i>9.77</i>	28.57	30.48	
Life Connection of Ohio (OHLF)	<i>9.23</i>	<i>11.18</i>	27.26	30.02	
Sharing Hope SC (SCOP)	<i>9.78</i>	<i>11.04</i>	28.05	29.89	
LifeCenter Organ Donor Network (OHOV)	10.18	12.29	26.44	29.00	
LifeQuest Organ Recovery Services (FLUF)	<i>8.74</i>	<i>9.94</i>	26.55	28.50	
Legacy of Life (HIOP)	<i>8.35</i>	<i>10.82</i>	22.91	*27.01	
New Mexico Donor Services (NMOP)	<i>8.04</i>	<i>10.23</i>	23.53	26.80	
LifeNet Health (VATB)	7.97	9.07	27.65	29.68	
Finger Lakes Donor Recovery Network (NYFL)	7.80	9.68	26.16	29.30	
Arkansas Regional Organ Recovery Agency (AROR)	7.06	8.69	25.80	28.85	
Carolina Donor Services (NCNC)	7.58	8.52	26.82	28.62	
Indiana Donor Network (INOP)	7.79	8.81	25.06	26.58	
Kentucky Organ Donor Affiliates (KYDA)	7.15	8.25	24.17	26.00	
Life Alliance Organ Recovery Agency (FLMP)	6.87	7.86	23.81	25.59	
Mid-South Transplant Foundation (TNMS)	6.66	8.19	18.94	21.05	

Note: For donors top 25 percent cutoff level at 11.37 and median at 9.72; for transplants at 36.10 and 32.05.

*Hawaii OPO's kidney transplantation rate will be used instead of the organ transplantation rate. It was in Tier 1 for kidney transplantations.

Table 3 shows the combined results of the donation and organ transplantation rates and the tier assignment for each OPO. As seen by the markings in bold and italics, many OPOs are high or low on both outcome measures. Within the Tier 2 cohort, 8 of the 26 OPOs made it to Tier 2 based on performance on the donation rate only (because their organ transplantation rates were in Tier 3), whereas only 4 OPOs made it to Tier 2 based on their organ transplantation rates (because their donation rates were in Tier 3). This difference suggests that it may be easier for OPOs to reach Tier 2 through the donation rate—possibly by pursuing and successfully placing

organs from the extended criteria donors. There only were only 12 OPOs whose donation and organ/kidney transplantation rates were at or above the median threshold rate, but not in Tier 1. Some OPOs were in Tier 1 on the donation rate, yet Tier 3 in the organ transplantation rate, suggesting that OPOs could do more to strengthen their organ placement practices. Those OPOs with higher performance in their organ transplantation rate than their donation rate could increase their donation rates by increasing their single organ donors.

Our estimates in Tables 4 (donors) and 5 (transplants) show what would be required for all OPOs to achieve either

the median rate, the threshold rate of the top 25 percent, or an increase in performance by 20 percent or to the rate of the top 25 percent, whichever is greater. (While not every OPO would make the same percentage gain, any combination of gains reaching the “greater of” estimate on average would produce the same total gains.) The importance of these estimates is not the exact numbers, but rather that even the currently best-performing OPOs can increase performance over time with concomitant improvements in techniques and technology, and will face strong incentives to do so or risk losing their place in the top 25 percent.

TABLE 4—ADDITIONAL DONORS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%

OPO name (primary state)	Additional donors to reach:				
	Potential donors (2018)	Actual donors (2018)	Median	Top 25%	Higher of top 25% or 20% more
Midwest Transplant Network (MWOB)	1,423	254	0	0	51
DonorConnect (UTOP)	752	115	0	0	23
Nebraska Organ Recovery System (NEOR)	463	65	0	0	13
Gift of Life Donor Program (PADV)	3,566	556	0	0	111
OPO at the U. of Wisconsin (WIUW)	955	136	0	0	27
Lifesharing—A Donate Life Organization (CASD)	954	128	0	0	26
LifeChoice Donor Services (CTOP)	615	74	0	0	15
Nevada Donor Network (NVLV)	1,011	123	0	0	25
OurLegacy (FLFH)	1,417	176	0	0	35
Gift of Hope Organ & Tissue Donor Network (ILIP)	3,302	424	0	0	85
Versiti (WIDN)	671	77	0	0	15
Donor Network of Arizona (AZOB)	2,039	253	0	0	51
Lifeshare Carolinas (NCCM)	934	110	0	0	22
Donor Alliance (CORS)	1,272	153	0	0	31
The Living Legacy Foundation of Maryland (MDPC)	1,219	146	0	0	29
LifeGift Organ Donation Center (TXGC)	3,145	376	0	0	75
Mid-America Transplant Services (MOMA)	1,659	187	0	0	37
Washington Regional Transplant Community (DCTC) ..	1,190	131	0	0	26
LifeShare of Oklahoma (OKOP)	1,561	174	0	0	35
ConnectLife (NYWN)	482	47	0	0	9
LifeCenter Organ Donor Network (OHOV)	707	72	0	0	14
Southwest Transplant Alliance (TXSB)	3,090	346	0	0	69
LifeBanc (OHLB)	1,443	153	0	0	31
Louisiana Organ Procurement Agency (LAOP)	1,717	184	0	0	37
New England Organ Bank (MAOB)	2,790	302	0	0	60
LifeCenter Northwest (WALC)	2,420	260	0	0	52
LifeLink of Puerto Rico (PRL)	955	95	0	0	19
LifeLink of Florida (FLWC)	2,248	237	0	0	47
Gift of Life Michigan (MIOP)	3,057	321	0	0	64
Tennessee Donor Services (TNDS)	2,735	280	0	4	56
Life Connection of Ohio (OHLC)	758	70	0	2	14
LifeLink of Georgia (GALL)	2,795	284	0	6	57
Sharing Hope SC (SCOP)	1,749	171	0	6	34
Donor Network West (CADN)	3,086	310	0	12	62
Legacy of Life (HIOP)	467	39	0	3	8
Center for Organ Recovery and Education (PATF)	2,044	197	0	12	39
Lifeline of Ohio (OHLP)	1,328	124	0	8	25
LifeSource—MN (MNOP)	1,810	172	0	12	34
New Mexico Donor Services (NMOP)	560	45	0	6	9
Sierra Donor Services (CAGS)	842	70	0	11	14
LifeQuest Organ Recovery Services (FLUF)	1,751	153	0	24	31
Pacific Northwest Transplant Bank (ORUO)	1,463	126	0	20	25
New Jersey Sharing Network OPO (NJTO)	1,792	156	0	26	31
Mississippi Organ Recovery Agency (MSOP)	1,037	86	0	15	17
Legacy of Hope—Alabama (ALOB)	1,781	154	0	26	31
Texas Organ Sharing Alliance (TXSA)	1,913	165	0	30	33
Finger Lakes Donor Recovery Network (NYFL)	718	56	1	12	12
Iowa Donor Network (IAOP)	890	71	1	15	15
Center for Donation and Transplant (NYAP)	698	52	3	14	14
LiveOnNY (NYRT)	3,435	292	13	68	68
LifeNet Health (VATB)	1,945	155	12	43	43
OneLegacy (CAOP)	5,634	468	43	133	133
Indiana Donor Network (INOP)	2,183	170	19	54	54
Arkansas Regional Organ Recovery Agency (AROR) ..	864	61	9	22	22
Carolina Donor Services (NCNC)	2,506	190	29	69	69
Kentucky Organ Donor Affiliates (KYDA)	1,803	129	26	54	54
Mid-South Transplant Foundation (TNMS)	931	62	14	28	28
Life Alliance Organ Recovery Agency (FLMP)	2,111	145	38	71	71
Totals	98,686	10,128	208	806	2,238

Nothing guarantees that all OPOs will manage to meet the final rule outcome measures. Nevertheless, the administrative steps we propose to take,

the periodic assessments, and the incentives for an OPO to maintain certification at the end of the 4-year evaluation period provide both means

and incentives for all OPOs to meet or exceed our standards. Moreover, there are three additional reasons to expect performance increases (if any) to occur

in all three tiers. First, Tier 1 OPOs near the Tier 2 boundary will be concerned about maintaining ongoing performance levels high enough to guarantee Tier 1 performance at their final assessment period—since other OPOs may be achieving higher performance levels. Second, only by aiming higher than the minimum needed to gain or remain in Tier 1 earlier in the final assessment period, is it possible to ensure that unexpected decreases at the end of the final assessment period do not result in loss of Tier 1 status. Third, there may be emerging best practices in both areas of performance that can be applied widely by all OPOs. For example, a current Tier 3 OPO could implement a specific management reform or operational innovation that substantially increases performance in increasing consent for donation. If the

effects of this change are observed broadly, then the innovation could be adopted by others. While such an effective best practice could also reduce the likelihood of sharing such best practices, particularly for OPOs on the margins every OPO able to see the published annual performance results of all OPOs, and performance improvements or lack thereof will be readily apparent. Formal and informal communication channels would in any event prevent suppression of information on better practices.

With continuous assessment and public disclosure of the information, OPOs that cannot achieve the outcome measures may decide to voluntarily de-certify and allow a high-performing OPO take over the DSA, even before the end of the 4 year re-certification cycle, or form a partnership with a high-

performing OPO and allow that OPO to take over the management of the DSA, most likely through a merger or friendly takeover. Both our low-end and higher cost and performance calculations assume that this could be avoided through adoption of proven techniques and improved leadership and management by lower-performing OPOs. Careful planning and implementation of OPO de-certifications and OPO DSA competitions could ease such transitions, but each performance level can be reached or exceeded, or maintained, by constant OPO management improvements. The new outcome measures and performance expectations may give each OPO both the opportunity and incentives to assess its performance, innovate, and adopt best practices.

TABLE 5—ADDITIONAL ORGAN TRANSPLANTS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%

OPO name (primary state)	Additional transplants to reach:			
	Actual transplants (2018)	Median	Top 25%	Higher of top 25% or 20% more
Nebraska Organ Recovery System (NEOR)	213	0	0	43
OPO at the U. of Wisconsin (WIUW)	487	0	0	97
Midwest Transplant Network (MWOB)	825	0	0	165
Lifesharing—A Donate Life Organization (CASD)	404	0	0	81
DonorConnect (UTOP)	406	0	0	81
Nevada Donor Network (NVLV)	445	0	0	89
LifeLink of Puerto Rico (PRL)	278	0	0	56
Gift of Life Donor Program (PADV)	1,688	0	0	338
Gift of Hope Organ & Tissue Donor Network (ILIP)	1,305	0	0	261
LifeShare of Oklahoma (OKOP)	548	0	0	110
OurLegacy (FLFH)	597	0	0	119
Gift of Life Michigan (MIOP)	1,106	0	0	221
LifeGift Organ Donation Center (TXGC)	1,240	0	0	248
Center for Organ Recovery and Education (PATF)	680	0	0	136
Donor Network of Arizona (AZOB)	934	0	0	187
The Living Legacy Foundation of Maryland (MDPC)	521	0	0	104
LifeLink of Florida (FLWC)	766	0	0	153
Donor Network West (CADN)	1,062	0	0	212
Washington Regional Transplant Community (DCTC)	490	0	0	98
LifeCenter Northwest (WALC)	883	0	0	177
LiveOnNY (NYRT)	923	0	0	185
Versiti (WIDN)	241	0	0	48
LifeBanc (OHLB)	505	0	0	101
Southwest Transplant Alliance (TXSB)	1,126	0	0	225
Lifeshare Carolinas (NCCM)	354	0	0	71
Mid-America Transplant Services (MOMA)	634	0	0	127
New England Organ Bank (MAOB)	946	0	0	189
Tennessee Donor Services (TNDS)	922	0	2	184
LifeChoice Donor Services (CTOP)	221	0	4	44
Sierra Donor Services (CAGS)	239	0	7	48
New Jersey Sharing Network OPO (NJTO)	538	0	15	108
Louisiana Organ Procurement Agency (LAOP)	604	0	23	121
ConnectLife (NYWN)	134	0	7	27
LifeLink of Georgia (GALL)	898	0	75	180
Pacific Northwest Transplant Bank (ORUO)	401	0	36	80
Lifeline of Ohio (OHLP)	410	0	47	82
Center for Donation and Transplant (NYAP)	145	0	18	29
LifeSource—MN (MNOP)	572	0	71	114
Iowa Donor Network (IAOP)	247	0	32	49
OneLegacy (CAOP)	1,625	0	202	325
Legacy of Hope—Alabama (ALOB)	472	12	75	94
Mississippi Organ Recovery Agency (MSOP)	264	8	44	53
Donor Alliance (CORS)	491	15	81	98

TABLE 5—ADDITIONAL ORGAN TRANSPLANTS TO REACH MEDIAN, TOP 25%, OR GREATER OF TOP 25% OR 20%—
Continued

OPO name (primary state)	Additional transplants to reach:			
	Actual transplants (2018)	Median	Top 25%	Higher of top 25% or 20% more
Texas Organ Sharing Alliance (TXSA)	574	31	110	115
Life Connection of Ohio (OHLC)	233	17	50	50
Sharing Hope SC (SCOP)	555	42	120	120
LifeNet Health (VATB)	521	44	117	117
Finger Lakes Donor Recovery Network (NYFL)	188	19	47	47
LifeCenter Organ Donor Network (OHOV)	232	26	60	60
Arkansas Regional Organ Recovery Agency (AROR)	208	25	56	56
Carolina Donor Services (NCNC)	638	80	173	173
LifeQuest Organ Recovery Services (FLUF)	482	63	134	134
Legacy of Life (HIOP)	95	20	35	35
New Mexico Donor Services (NMOP)	136	29	51	51
Indiana Donor Network (INOP)	636	135	236	236
Kentucky Organ Donor Affiliates (KYDA)	454	110	184	184
Life Alliance Organ Recovery Agency (FLMP)	493	130	211	211
Mid-South Transplant Foundation (TNMS)	196	109	149	149
Subtotal Transplants plus Pancreata Research	33,431	915	2,472	7,296
Total Actual Transplants	32,852	899	2,429	7,169

The characteristics of the organ procurement “market” are unusual because it was established as a system of private monopolies by statute (NOTA). OPOs are part of the supply chain for final goods—organs for transplant—that are not transacted in a market (in the sense of a good’s price being the mechanism whereby the quantity supplied and the quantity demanded achieve equality), and therefore care must be taken in using concepts such as market competition or equilibrium. In another example from the health care sector, which may provide a somewhat more appropriate extrapolation for purposes of this regulatory impact analysis than would results from other contexts with more standard market goods and services, one study found that many hospitals in the English public hospital system faced closure due to potential electoral defeat of their political party protectors in particular geographic areas vulnerable to election swings. To avoid the risk of being the hospital to be closed, hospitals in these situations improved both management practices and medical care performance (measured by reductions in death rates from heart attacks).²⁸ While it is impossible to predict future achievement levels with any certainty from the impact of introducing significantly more competition into any particular monopolistic market (if this

rule indeed avoids bringing about the potential consolidation noted above and the transaction frictions noted below), we have developed a hypothetical scenario for the first 4 years of competition that we believe is consistent with the results from other situations where large numbers of organizations faced potential closure. This scenario would nearly achieve about half of HHS’ 2030 target of doubling kidneys available for transplantation (with 4 years remaining to attain that actual goal); and we can use it in estimating benefits and costs while allowing for either higher or lower results.

From the estimates in Tables 4 and 5, we assume that on average, OPOs may improve their organ procurement and transplantation performances by more than the minimums necessary to retain their DSAs with a margin for error. Striving for organizational survival as well as for professional and life-saving achievements are strong motivations to improve performance not only to the exact level needed for organizational survival, but also to allow for a margin of error. These projections are estimates and subject to change based on future events and decisions, but fall within the improvement ranges seen in recent years in some OPOs, as well as the consistently high performance levels in many OPOs. Additionally, for these projections, we assume CMS monitors OPO performance as frequently as every 12 months, using nationally consistent and timely data in both the numerator and denominator of performance

measures, and intervening with QAPI requests when performance lags. Finally, these projections reflect the direct incentives to both OPOs and transplant hospitals to improve donation and transplantation rates from older donors to older patients, which ultimately facilitate the utilization of the large number of currently discarded, but transplantable, organs. For example, a transplant program that chooses to bypass a transplant quality organ from either its local OPO or some other OPO is also bypassing the revenues from the transplantation of that organ. Since the supply of organs is finite and limited, and many patients die while awaiting transplants, that lost revenue may never be replaced. Furthermore, the recent elimination of the potential for termination of transplant programs that did not achieve the highest possible success rates removes a strong disincentive for accepting and using all transplant quality organs.

Unfortunately, there are many unknowns that impede predicting future outcomes under this final rule. In our most optimistic scenario, about 85 percent of all potential donors would still be potential rather than actual donors. These potential donors are concentrated among those in the age range of 55 to 75, but the vast majority could provide organs of transplant quality if donated. That said, this potential has been obvious for many years, and progress has been inexplicably slow—inexplicably slow except for the now-recently removed threat to survival for transplant

²⁸ Nicholas Bloom et al., *The Impact of Competition on Management Quality: Evidence from Public Hospitals*, Review of Economic Studies, 2015, at <https://nbloom.people.stanford.edu/sites/g/files/sbiybj4746/f/bpsv.pdf>.

programs that did not achieve the highest possible success rates. In this regard, it is important to note that according to OPTN and NCHS mortality data, donation rates are highest among the young and far lower among potential donors in their 50s, 60s, and early 70s.²⁹

More broadly, there were about 10,000 deceased donors in 2018. The highest tenth of OPOs (six of the 58) had an average donation rate of about 14 percent, and the lowest tenth (six of the 58) of about 7 percent. Assuming that this higher level is potentially attainable in any DSA, under ideal circumstances, the total number of donors could increase by about half, to about 15,000—much higher than we project in our high performance scenario. There is no reason to assume that 14 percent is an upper limit for the donation rate, given that there are potentially 100,000 donors every year. That said, it cannot be assumed that all OPOs can match the performance of the top tenth within a 4-year period. Therefore, for purposes of describing a hypothetical level of performance by the end of the second re-certification cycle, in subsequent tables and estimates, we assume that the average donation rate may increase by about 20 percent—from 10,000 to 12,000 donors.

We make a similar set of assumptions for the organ transplantation rate performance measure. In 2018, there were about 33,000 transplants from deceased donors. As shown in Table 2, there is more than a two to one difference between the top tenth (6 out of 58) and the lowest tenth: From an average rate of about 48 percent to about 22 percent. On average, there were about 3.3 organs transplanted per donor. The number of organs transplanted per donor varied widely, from an average of about 3.6 for the top tenth to about 2.8 for the bottom tenth. Assuming a 20 percent increase in number of donors and a 5 percent increase in organs per donor (to an average of 3.45), the number of annual organs transplanted would hypothetically rise from about 33,000 in 2018 to about 41,000 (12,000 × 3.45) by 2026 (Table 5 shows transplant increases not including the 5 percent increase, with the total growing to about 40,000).

While there is no certainty that these or similar levels of performance will be realized, there is additional evidence beyond the known performance levels of the higher-achieving OPOs. As discussed in the December 2019 OPO proposed rule, the discard rate for

kidneys in France has been about half the rate in the U.S., under rules that rewarded rather than penalized using higher risk organs.³⁰ While most European countries use mandatory nation-wide “opt-out” rather than “opt-in” policies and hence more strongly encourage organ donation than in the U.S. (where no states use “opt-out”), a recent study shows that this policy does not explain European success rates and that many American states have organ donation rates higher than many European countries.³¹ One important policy difference that does seem to matter is that in France, as in most other European countries, organs from older donors are systematically matched for use by older patients, without penalizing transplant programs for the lower success rates that inevitably result.³² Performance results such as those achieved in France could be achievable in the U.S. with greater accountability for OPO performance, due to some combination of the removal of the outcome measures that penalized transplant programs that do not achieve their risk-adjusted expected 1-year graft and patient survival outcomes; and payment reform. The October 1, 2020 implementation of a new Medicare Severity-Diagnosis Related Groups (MS-DRGs) for kidney transplants with hemodialysis during the same stay (DRG 019; DRG 650 and DRG 651) raises payments in these cases, such that the increased costs associated with transplanting higher-risk kidneys is less of a financial disincentive.

We also have additional evidence from the U.S. that was not available at the time we proposed this rule. We now know that there were major gains in numbers of kidney transplants from 2017 to 2018. Moreover, there appears to have been another major increase in 2019. According to a recent summary from UNOS, the number of deceased organ donors increased by over 10 percent in 2019; 48 OPOs increased the total number of donors in 2019 over the previous year, and 41 OPOs set their all-time organ donation record in 2019.³³ It will be some time before the various potential reasons for these increases can be determined. However, from what we

are able to ascertain, these data demonstrate that the problem this rule is meant to address has already been lessened, possibly in part due to earlier regulatory interventions.

As discussed earlier in the preamble, we have considered the effects of COVID-19 on the time of the new standards imposed in this rule. The implementation of the rule may be slowed by a year, as a result of COVID-19. In terms of effects on donation and transplantation rates over time, we expect those to be minimal and possibly not even detectable in future data. The numbers of deaths and severe illnesses among younger Americans have been less than from the annual influenza virus. Among the elderly over the age of 75, who are by orders of magnitude the age group most severely affected by morbidity and mortality from COVID-19, both donations and transplants were rare before COVID-19 and will remain so with no particular COVID effect. We are not saying that there will be no effects leading to changes in donation and transplantation practices or results; simply that these will be very small in relation to the number of potential and actual donors and to the number of potential and actual transplant recipients.

D. Anticipated Costs and Benefits

There are intrinsic connections between the costs and benefits examined in this section. Consider, for instance, the relatively low costs for OPOs and other entities in the health care industry (discussed in the subsequent discussion of “Implementation and Continuing Costs”). Such low costs are plausible if OPO de-certifications are rare, which could occur if enforcement is lax; if all or a significant portion of OPOs achieve the threshold rate of the top 25 percent; or if the potential for de-certification results in mergers or voluntary takeovers. Without strong enforcement, OPO behavior change may be minimal, in which case low costs would be accompanied by low longevity benefits and medical expenditure impacts (significantly lower than the estimates appearing in Tables 10 and 13).

On the other end of the spectrum, if the competition and the potential for de-certification motivates substantial improvements, this would make substantial benefits and cost plausible. Foreseeable technological advances that we have not included in our analysis could also lead to substantial volume increases and resulting increases in both costs and benefits.

In any scenario, OPOs undergoing such management change experience

²⁹ Organ donors <50 make up approximately 67 percent of donors, but make up less than 10 percent of deaths.

³⁰ Olivier Aubert et al., “Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased U.S. Acceptance,” *JAMA Intern Med.* Doi:10.1001/jamainternmed.2019.2322.

³¹ Alexandra Glazier and Thomas Mone, “Success in Opt-In Organ Donation Policy in the United States,” August 8, 2019, doi:10.1001/JAMA.2019.9187.

³² See Olivier Aubert, et al.

³³ See the following link at the UNOS website: <https://unos.org/transplant/opos-increasing-organ-donation/>.

difficult to quantify, transition costs including those related to changing a chief executive officer and/or board of directors, as well as cases involving litigation and prolonged management uncertainty, which could pose potentially much larger administrative and management costs in a few cases than those we have projected. Broader societal transition costs could include reduced organ recovery while the de-certification process unfolds, even if improved practices increase transplant activity in the medium- to long-term. It may be the case that some boards of directors of low-performing OPOs, recognizing that major improvement is unlikely under current top management, replace those employees during the period before the de-certification deadline with proven managers from highly effective OPOs. The annual assessments conducted as part of this final rule and the creation of a publicly available tier ranking of OPO performance using objective data will provide OPO Boards the necessary information to make this type of decision. In either case, we would expect that most OPO operations would continue with operational reforms, but with few if any lower-level staff being

replaced and a small number of higher-level managers being replaced.

We expect no costs for disruption of actual organ procurement at any OPOs for two reasons. First, we believe that almost all OPOs will be able to comply with the new tiered standards or will arrange a friendly merger with another OPO. There is no reason to expect performance disruption from a change in top leadership in such cases. In the relative handful of cases where the OPO is actually decertified and replaced, the newly responsible OPO would presumably arrange a smooth continuation of services in the DSA through negotiations with the outgoing Board of Directors and CEO to retain existing staff. No public comments suggested that any more disruptive outcome would ever be likely.

1. *Effects on Medical Costs.* In the estimates that follow, we rely primarily on recent estimates by staff of the actuarial and consulting firm Milliman. Their study, “2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion” compares charges before, during, and after transplantation for all major and minor categories of transplant.³⁴ The advantage of these estimates for our purposes is that they

cover the pre-, intra-, and post-transplant costs on all organs using a consistent cost-estimating methodology. Unfortunately, accurate medical cost estimates are not publicly available from health insurance firms, since the network discounts received by private firms are generally treated as trade secrets, and Medicare’s payments are typically not based directly on costs (with some exceptions, including payments to OPOs). Hence, Milliman uses “charges” for its estimates. As with likely excess of charges over costs, there is a netting off of non-transplantation costs—that is, costs associated with organ failure that are not affected by transplantation itself. For estimating purposes, we assume that these divergences between costs and charges largely cancel each other out, but that the net effect is that actual costs are about 20 percent less than the Milliman charge estimates.

In analyzing the medical costs of the rule, we first estimate the costs per transplant of the three most common organ transplants: Kidneys, livers, and hearts. Between them, they account for about 90 percent of all transplants. Kidneys alone are over 60 percent of all organs transplanted.

TABLE 6—FIRST YEAR COST PER HEART TRANSPLANT (\$)

Heart	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
30 days pre-transplant	43,000	9,000	20,000	0	14,000
Procurement	102,000	0	0	0	102,000
Hospital Transplant Admission	887,000	177,000	0	0	710,000
Physician During Admission	92,000	18,000	0	0	74,000
180 Days Medical Post Discharge	223,000	45,000	60,000	0	118,000
180 Days Drugs Post Discharge	34,000	7,000	10,000	15,000	32,000
Total	1,381,000	256,000	90,000	15,000	1,050,000

As shown in Table 6, the one-time cost of a heart transplant is just over one million dollars after adjusting charges to

costs and reducing the estimates to account for medical and drug costs, both

pre- and post-discharge, that are unlikely to be transplant-related.

TABLE 7—FIRST YEAR COST PER LIVER TRANSPLANT (\$)

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
30 days pre-transplant	41,000	8,000	10,000	0	23,000
Procurement	94,000	0	0	0	94,000
Hospital Transplant Admission	463,000	93,000	0	0	370,000
Physician During Admission	56,000	11,000	0	0	45,000
180 Days Medical Post Discharge	127,000	25,000	60,000	0	42,000
180 Days Drugs Post Discharge	31,000	6,000	10,000	15,000	30,000

³⁴ T. Scott Bentley and Steven J. Phillips, 2017, available to download at [http://www.milliman.com/](http://www.milliman.com/insight/2017/2017-U_S_-organ-and-tissue-transplant-cost-estimates-and-discussion/)

[insight/2017/2017-U_S_-organ-and-tissue-transplant-cost-estimates-and-discussion/](http://www.milliman.com/insight/2017/2017-U_S_-organ-and-tissue-transplant-cost-estimates-and-discussion/).

TABLE 7—FIRST YEAR COST PER LIVER TRANSPLANT (\$)—Continued

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost
Total	812,000	143,000	80,000	15,000	604,000

Table 7 shows the estimated average cost for a liver transplant, estimated on the same basis as heart transplants. Table 8 estimates kidney transplant

costs, with an additional adjustment. In the case of a kidney transplant, there is an off-setting saving for the elimination of ESRD kidney dialysis costs. This is a

substantial saving and in the first year alone, saves about one-third of the estimated transplant cost.

TABLE 8—FIRST YEAR COST PER KIDNEY TRANSPLANT (\$)

Kidney	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (6 months)	Net transplant cost subtotal	Annual dialysis costs avoided	Net first year cost
30 days pre-transplant	30,000	(6,000)	(10,000)	0	14,000	0	14,000
Procurement	97,000	0	0	0	97,000	0	97,000
Hospital Transplant Admission	159,000	(32,000)	0	0	127,000	0	127,000
Physician During Admission	25,000	(5,000)	0	0	20,000	0	20,000
180 Days Medical Post Discharge	75,000	(15,000)	(60,000)	0	0	* (90,000)	(90,000)
180 Days Drugs Post Discharge	29,000	(6,000)	(10,000)	15,000	28,000	0	28,000
Total	415,000	(64,000)	(80,000)	15,000	286,000	(90,000)	196,000

* Estimated annual dialysis costs.

Using these results, it is possible to estimate the extended effects of added and reduced costs over time. In Table 9, we provide a 5-year projection, giving both results for a patient who survives all 5 years with the transplanted organ, and the same estimate adjusted to assume only an 80 to 90 percent patient and organ survival rate for the full 5

years (the higher rate is for kidneys). These estimates do not account for all the varied circumstances that can arise, such as patients whose organs fail and who are then re-transplanted. They include the costs of immunosuppressive drugs. In the case of kidney transplants, the estimates assume a savings of \$90,000 for ending dialysis, offset by a

\$30,000 cost for the immunosuppressive drugs. The weighted results take into account that kidneys account for about 65 percent of transplants for these three organs. As shown in the table, kidney transplants actually reduce costs for the patients who survive the full 5-year period.

TABLE 9—FIVE YEAR COSTS PER WEIGHTED AVERAGE TRANSPLANT (\$)

Annual Percent of Total TX	Heart	Liver	Kidney	All three organs weighted
	11%	24%	65%	100%
First Year	1,050,000	604,000	196,000	387,860
Second Year	20,000	20,000	(60,000)	(32,000)
Third Year	20,000	20,000	(60,000)	(32,000)
Fourth Year	20,000	20,000	(60,000)	(32,000)
Fifth Year	20,000	20,000	(60,000)	(32,000)
Total	1,130,000	684,000	(44,000)	259,860
80 to 90% Survival Total *	1,122,000	676,000	(20,000)	272,660

* Rate is higher for kidneys than for other organs. All deaths are assumed to occur prior to Year 2 (that is, before any dialysis-related savings can accrue).

An annually growing performance increase to about 8,000 additional transplants in the last year of the next 4-year OPO performance period is essential in order to meet the HHS' 2030 goal of doubling the number of kidneys available for transplants. As Table 10 shows, this will require multi-billion dollar increases over current transplant spending levels by the middle of this decade (and far more by 2030). As we

show in our benefit estimates, these levels are exceeded by the life-saving and life-extending benefits of these additional transplants. As discussed later in this analysis, most of the cost increases we estimate in this rule are reimbursed by private payers, rather than by Medicare.

HHS has set a quantitative goal of doubling the number of kidneys available for transplant by 2030. While

there are multiple pathways to achieve this goal, the main approach for achieving this ambitious goal is to increase the number of deceased donors. This will require continuous improvements over time, and we have estimated the approximate numbers that would have to be achieved in the next five years to move about half way towards an annual increase of approximately 16,000 more kidney

transplants by 2030, as shown in Table 10.

In Tables 10 and 13, we show hypothetical projections for annual results for costs and benefits, respectively, as each cohort of new transplants arrives over the OPO performance period from 2021 to 2025—assuming that both donor and transplant rates improve by an average of 20 percent or to the top 25 percent level, whichever is higher, similar to the highest growth rates show in Tables 4 and 5 and using the estimate of 7,283

transplants shown in Table 5. As previously discussed, these are optimistic rates that assume a wide variation in improvements, including improvements by many OPOs in the top 25 percent as well as in the lower performers. These estimates include totals for all organs since one deceased donor normally provides multiple organs. The 7,000 increase shown for 2025 includes about 4,500 kidneys transplanted. These figures assume a 5-year patient and graft survival rate of 90 percent for kidney transplants. As can

be seen, the costs grow substantially with each new cohort. These tables include an extra column that shows the effects of this 5-year cohort in the sixth and future years. While total costs grow over time with each new and larger cohort of new transplants, the savings from reduced kidney dialysis costs from previous kidney transplants grow over time, as do the benefits for those patients whose lives were both extended and improved by transplantation.

TABLE 10—HIGHER COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	1,434	2,868	4,301	5,735	7,169	
Costs for 2021–2 Cohort	\$556	(\$39)	(\$39)	(\$39)	(\$39)	(\$39)
Costs for 2022–3 Cohort		1,112	(78)	(78)	(78)	(78)
Costs for 2023–4 Cohort			1,668	(117)	(117)	(117)
Costs for 2024–5 Cohort				2,224	(156)	(156)
Costs for 2025–6 Cohort					2,781	(195)
Total	556	1,073	1,551	1,990	2,391	(585)

Pancreas research projects do count in our performance measures, as explained earlier in the preamble. However, we do not include pancreatic research in our estimates of either costs or benefits since we have no basis for estimating either under current reporting. Experimental or other research procedures that involve transplantation of islets from an organ donor into a person on the waiting list for a pancreas are counted as transplants and included in our cost and benefit estimates, but the research projects displayed in Table 5 and excluded from Tables 10 to 15 are those specifically categorized under the OPTN's reporting instructions as research not involving a transplant. In 2016 to 2018 the number of such pancreas research projects have been between 500 and 600 a year (579 in 2018). This is 1.73 percent of the number of transplants in 2018, and we project a similar fraction in our estimates for future years. Only bona fide research conducted by a qualified researcher using a pancreas from an organ donor would be counted, and it would be counted as a single research project regardless of the number of research activities performed using that one pancreas and its islets. It is also conceivable that a pancreas might be

used for research when it would otherwise have been used for a transplant. We do not have data to quantify how frequently this may occur and have no basis for subtracting either lives lost or transplant cost savings from any such cases in our estimates of benefits and costs. In addition, any such use would likely raise issues of ethics, payment, and donor family consent. Regardless, we anticipate focusing on pancreatic research performance in both our payment and performance review functions to prevent abuse.

We note that the expenditure data include procurement costs, which average almost \$100,000 per organ transplanted across all three organ types. Accordingly, a cohort of 1,000 patients would involve total procurement costs of about \$100 million, and a cohort of 8,000 patients about \$800 million. These data do not include all organ types, nor all cost savings (notably end-of-life costs), but are a reasonable approximation to the magnitudes involved. The procurement costs are paid to OPOs by transplant centers and finance the costs associated with the actual donation and transportation of the organ to the transplant program as well as the

general operations of the OPO. These costs are, as discussed later in this analysis, largely reimbursed by health insurance.

Our estimates also do not include costs of changes or advances in treatment options for both liver and heart patients, such as new drug treatments for hepatitis C, one of the main causes of liver failure, or heart assist devices that can serve as a bridge while waiting for a heart transplant.

In Table 11, we provide lower cost estimates using the same per-transplant inputs but with aggregates reflecting only the minimum number of new annual transplants required to reach the top 25 percent. As in Table 10, these estimates reflect the timeline changes in the final rule and the need for OPOs to begin immediately to make the reforms needed to raise their performance. As is in Table 10, we exclude pancreas research from our projection. These are hypothetical costs assuming that every OPO could predict future success rates precisely and that all OPOs would act to achieve only the exact minimum level needed to avoid decertification. Compliance starts in 2021 to meet the timelines of this final rule.

TABLE 11—HIGHER COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	180	360	539	719	899	
Costs for 2021–2 Cohort	\$70	(\$5)	(\$5)	(\$5)	(\$5)	(\$5)
Costs for 2022–3 Cohort		139	(10)	(10)	(10)	(10)
Costs for 2023–4 Cohort			209	(15)	(15)	(15)
Costs for 2024–5 Cohort				279	(20)	(20)
Costs for 2025–6 Cohort					349	(24)
Total	70	135	195	250	300	(73)

In Table 12, we describe an intermediate scenario where all lower-performing OPOs (Tiers 2 and 3) achieve the top 25 percent threshold rate (but no more) for organs used in transplantation and the OPOs already in

Tier 1 do not improve their performance. For the ease of analysis, both the lowest and intermediate scenarios assume that OPOs could predict their performance so as to achieve exactly the right level to avoid

any decertification penalty. These scenarios illustrate that there are a range of outcomes that we are unable to predict with any precision since they will depend on OPO by OPO management and other decisions.

TABLE 12—INTERMEDIATE COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH TOP 25% (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	486	972	1,457	1,943	2,429	
Costs for 2021–2 Cohort	\$188	(\$13)	(\$13)	(\$13)	(\$13)	(\$13)
Costs for 2022–3 Cohort		377	(26)	(26)	(26)	(26)
Costs for 2023–4 Cohort			565	(40)	(40)	(40)
Costs for 2024–5 Cohort				754	(53)	(53)
Costs for 2025–6 Cohort					942	(66)
Total	188	364	526	674	810	(198)

2. *Effects on Patients.* On average, organ transplants significantly extend lives. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney transplant patients. A recent literature synthesis found essentially universal agreement that kidney transplants were not only substantially life extending, but also cost reducing.³⁵ The authors performed an extensive literature search and found that from 1968 to 2007, seventeen studies assessed the cost-effectiveness of renal transplantation. The authors concluded that “[r]enal transplantation . . . is the most beneficial treatment option for patients with end-stage renal disease and is highly cost-effective compared to no therapy. In comparison to dialysis, renal transplantation has been found to reduce costs by nontrivial amounts while improving health both in terms of the number of years of life and the quality of those years of life” (page 31). More recent studies and other syntheses have reached similar conclusions. For example, in the article, “Systematic Review: Kidney

Transplantation Compared with Dialysis in Clinically Relevant Outcome,” the authors reviewed 110 studies and concluded that the vast majority of kidney transplant recipients showed major improvement in life quality and reductions in mortality compared to those remaining on dialysis.³⁶ The *Annual Data Report of the United States Renal Data System* utilizes national data on ESRD, and reports that deaths per 1,000 patient years in 2016 were about 134 for dialysis patients but only about 29 for transplant recipients.³⁷ There are similar data on other organs. For example, in the RIA published in the 1998 final rule establishing the governance procedures for the OPTN (63 FR 16296), HHS estimated that “the annual benefits of organ transplantation include about eleven thousand lives vastly improved by kidney transplantation, and another eight thousand lives both vastly improved and prolonged by transplantation of other major organs” (63 FR 16323).

Accordingly, the per-patient potential benefits are substantial. For each new kidney transplant, there would be an average of 10 additional life years per transplant patient compared to those on dialysis.³⁸ Using the more usual metric of survival rates, the 5-year survival rate for kidney transplant patients is 86 percent (Milliman, page 13).

HHS “Guidelines for Regulatory Impact Analysis” explain the concept of Quality-adjusted life years (QALYs).³⁹ QALYs enable estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY amounts used in any estimate of overall benefits, including this one, are not meant to be precise estimates, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars (usually by multiplying QALYs by a

³⁵ Huang, E, et al., “The Cost-Effectiveness of Renal Transplantation,” *When Altruism Isn’t Enough*, edited by Sally Satel (AEI Press, 2008).

³⁶ Tonelli M, et al., *Am J Transplant* 2011; 2093–2109.

³⁷ USRDS 2018 Annual Data Report report, volume 2, Figure 5.1; accessed at <https://www.usrds.org/adr.aspx> and https://www.usrds.org/2018/download/v2_c05_Mortality_18_usrds.pdf.

³⁸ Wolfe RA et al., “Comparisons of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant,” *NEJM*, 1999, 341:1725–30; accessed at <http://www.nejm.org/doi/full/10.1056/NEJM19991203412303#t=article>.

³⁹ <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>.

dollar estimate of the value of a statistical life year).⁴⁰

Table 13 provides estimates of the life-extending and life-improving value of the rule assuming that it succeeds in

improving OPO performance in early years at the magnitudes necessary to meet the 2030 HHS goal (to do so we model achieving the 75th percentile, or a 20 increase, whichever is higher, as

shown in Table 5). The increase of 7,283 transplants in Table 13 is taken from Table 5. For simplicity, we estimate that transplants occur halfway through the year.

TABLE 13—HIGHER BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE TO REACH HIGHER OF 20% OR TOP 25% (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 cohorts
Increase over base year in number of transplants (20% annual increments)	1,434	2,868	4,301	5,735	7,169	
Benefits for 2021–2 Cohort	\$134	\$268	\$268	\$268	\$268	\$268
Benefits for 2022–3 Cohort		268	537	537	537	537
Benefits for 2023–4 Cohort			403	805	805	805
Benefits for 2024–5 Cohort				537	1,073	1,073
Benefits for 2025–6 Cohort					671	1,342
Total	134	537	1,208	2,147	3,355	4,025

Table 13 shows only the first 5 years of increasing transplants, with an extra year added with no new cohort to illustrate how the benefits for each group grow over time. Over a 10-year period, total life extending benefits from about 18,000 additional kidney transplants would be \$23 billion (without discounting) from the five cohorts of additional transplants shown in Table 13 (28,000 organs \times 65 percent of which are kidneys \times $\frac{2}{3}$ patient survival rate \times \$1 million per surviving transplant recipient in life extending benefits = \$23 billion). A similar calculation for all additional transplant recipients reaches a total of \$35 billion over 10 years, with even more years of benefits to most of the same recipients yet to come.⁴¹

We note that these estimates are averages across patients who vary widely in age, medical condition, and life expectancy, as well as type of organ failure. For example, the sickest patients

typically have very low life expectancies without transplant so they stand to gain the most years of life from a transplant. However, these same patients, on average, have slightly lower survival rates post-transplant. Organ and patient survival issues are complex and dealt with by detailed policies and procedures developed and used by the transplant community. These policies are reviewed and revised frequently based on actual experience and changing technology—over time, the success rate from using marginal organs and in transplanting older and sicker patients have both increased substantially. There are additional complexities that we have not used in these broad estimates, such as the ability of kidney transplant recipients to return to dialysis if a transplanted kidney fails, leading to both additional costs and additional benefits. For presentation purposes, we have not discounted future costs and benefits to

“present value” in the preceding tables, but handle discounting in our annualized estimates shown in the Accounting Table that follows. For purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants in the presence of the rule but not in its absence.

Table 14 shows estimates using the same per-transplant life-saving benefits but with aggregates reflecting the lower figure of 1899 new annual transplants shown in Table 5 as an estimate of those number of transplanted need to meet the median threshold rates to avoid decertification based on the outcome measures. These are hypothetical benefits assuming that every OPO could predict future success rates precisely and that all OPOs would be able to act to achieve only the exact minimum level needed to avoid automatic decertification.

TABLE 14—LOWER BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE ONLY TO REACH MEDIAN (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer Term Effect from 2021–2025 Cohorts
Increase over base year in number of transplants (20% annual increments)	180	360	539	719	899	
Benefits for 2021–2 Cohort	\$17	\$34	\$34	\$34	\$34	\$34
Benefits for 2022–3 Cohort		34	67	67	67	67
Benefits for 2023–4 Cohort			50	101	101	101
Benefits for 2024–5 Cohort				67	135	135
Benefits for 2025–6 Cohort					84	168
Total	17	67	151	269	421	505

⁴⁰ Using such a measure to make coverage or reimbursement determinations is prohibited by Section 1182(e) of the Act. That prohibition does not apply to the situation addressed in this proposed rule, where the purpose is not to determine medical coverage for individual patients, but to measure overall success in raising the number of persons who obtain life-saving treatments.

⁴¹ This method of calculating the value of kidney transplantation is similar to but substantially simplified from the method used in P.J. Held et al., “A Cost-Benefit Analysis of Government Compensation of Kidney Donors,” *American Journal of Transplantation*, 2016, pages 877–885 (plus 65 pages of supplementary details explaining all assumptions, data sources, and calculations). Factors for Hearts and Livers come from Elisa F.

Long et al., “Comparative Survival and Cost-Effectiveness of Advance Therapies for End-Stage Heart Failure,” <http://circheartfailure.ahaajournals.org>, April 7, 2017; and Fredrik Aberg et al., “Cost of a Quality-Adjusted Life Year in Liver Transplantation: The Influence of the Indication and the Model for End-Stage Liver Disease Score,” *Liver Transplantation* 17:1333–1343, 2011.

Finally, we have estimates of benefits that correspond to the number of organ transplants needed for all OPOs to reach the level of the Top 25 percent of all OPOs. As shown in Tables 5 and 12, using 2018 data we estimate that 2,429 additional transplants would be needed to reach that level. As is the case for our

other estimates, this is a hypothetical level that in this case corresponds to an Intermediate level of performance. In the real world, it would be unlikely that an OPO would achieve that exact level of performance, and best practice suggests a more prudent approach would be to strive for a higher level if

for no other reason than to avoid some unexpected shortfall. (As before, we estimate no QALY value for research projects that use pancreata, and have no basis for valuing research that does not include an actual transplant.)

TABLE 15—INTERMEDIATE BENEFITS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE ONLY TO REACH MEDIAN (\$ MILLIONS)

Year	2022	2023	2024	2025	2026	Longer term effect from 2021–2025 Cohorts
Increase over base year in number of transplants (20% annual increments)	486	972	1,457	1,943	2,429	
Benefits for 2021–2 Cohort	\$45	\$91	\$91	\$91	\$91	\$91
Benefits for 2022–3 Cohort		91	182	182	182	182
Benefits for 2023–4 Cohort			136	273	273	273
Benefits for 2024–5 Cohort				182	364	364
Benefits for 2025–6 Cohort					227	455
Total	45	182	409	727	1,137	1,364

3. *Implementation and Continuing Costs.* The requirements of this final rule would necessarily have to be read, understood, and implemented by all OPOs. This would create one-time as well as continuing costs. In some cases, these costs would be low, involving understanding the new outcome measures and learning where the OPO stands in relationship to other OPOs in meeting the new outcome measures. In other cases, the OPO may need to significantly change its practices and techniques, increase frontline staffing, and/or change senior leadership.

In all cases, time will have to be spent deciding whether and how to change existing policy and procedures. These effects would be on primarily the 58 OPOs, but secondarily the approximately 750 transplant programs in about 250 transplant hospitals and to a lesser extent the 6,000 donor hospitals. Ultimately, as OPO performance increases, donor hospitals may have more training activities, participate in more organ donation awareness activities, and have increased operating room or ICU activities associated with increased donations. Transplant programs similarly would need to perform more transplants if OPOs improve their performance. Most of the OPO costs are included in the acquisition costs associated with organ procurement and would be paid by Medicare and other health insurers, including the costs that management will incur in learning these new rules. Therefore, our estimates assume that ongoing management operations will continue at current levels and focus on costs needed to understand the new rules and plan changes needed for compliance, such as QAPI and ECE. We

did not receive comments on our estimates as to skills and occupations involved or time likely to be spent.

In total, there are about 400 potentially and directly affected entities or programs. For transplant hospitals (whose business levels will be indirectly affected), we assume that on average there would be 1 hour of time spent by a lawyer, 2 hours of time by an administrator or health services manager, and two hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further assume that for one-tenth of these providers, 2 hours of physician time would be needed to consider changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are \$139 for lawyers (occupation code 23–1011), \$109 for medical and health services managers (occupation code 11–9111), \$89 for statisticians (occupation code 15–2041), \$73 for registered nurses (occupation code 29–1141), \$56 for healthcare social worker (21–1022), and \$203 for physicians (occupation code 29–1060). The medical and health services managers would include such occupations as transplant administrator, organ procurement coordinator, and director of nursing. The statistician might instead be a computer analyst or operations research analyst at a similar wage. The underlying wage numbers are from BLS statistics for 2018.⁴²

We assume that on average, an OPO would involve one person in each

occupation listed in the preceding paragraph, and an average of 8 hours on an interdisciplinary team tasked with learning the new rules, understanding their implications for that OPO, and initiating plans to address performance levels as well as to deal with QAPI and ECE issues. Total costs, on average, would be \$139 plus \$109 plus \$89 plus \$73 plus \$56 plus \$203, for a total of \$669 per hour and \$5,352 (8 × \$669) for eight hours. For the 58 OPOs, the first-year cost would therefore be about \$310,000 (58 × \$5,352).

We also assume that some large fraction of OPOs would either voluntarily, or through decertification and takeover, have a new CEO and perhaps other senior managers, or a new Board of Directors, or both (or, in some cases, the takeover would simply involve an existing Board of Directors assuming an additional DSA responsibility). These costs could involve search costs, potentially higher salary costs for the replacement managers, and legal costs in the cases where the corporation is replaced or merged with the certified OPO newly placed in charge. The extent and magnitude of these types of cost are difficult to predict, as are the numbers of affected OPOs. The costs may be lower, for example, if the low-performing OPO concludes that it cannot meet the new requirements under current management, and voluntarily seeks a merger with another OPO or implements management reforms that do not raise long-term costs. Because we cannot predict the mix of these kinds of alternatives, we assume that these governance and top management-related costs will be \$100,000 a year on average for the

⁴² https://www.bls.gov/oes/2018/may/oes_nat.htm.

bottom-performing half of all OPOs, for a total cost over a 5-year period of \$14.5 million ($29 \times \$100,000 \times 5$).

We also assume that regardless of the precise reform or takeover option involved in a particular DSA, both outgoing and incoming management would undertake careful measures to maintain the integrity and performance of ongoing organ procurement and placement functions with minimal or no disruption. While the analogy is imperfect, and while staff morale problems are common in hospital merger situations, we are unaware of any evidence that patient care was substantially affected adversely by hospital mergers.⁴³ Accordingly, we assume no major or continuing disruption in the provision of actual services related to organ donation or placement during such transitions.

There would also be continuing and far larger costs over time as OPOs and hospitals manage the substantial increases in numbers of donors and number of organs transplanted, while increasing and improving OPO management of current activities, improved procurement and placement techniques, QAPI, and ECE requests if needed. These procurement costs (including reimbursable overhead activities) are included in the cost estimates in Tables 6 to 8, and average approximately \$100,000 per organ. Each additional 1,000 organs would cost about \$100 million, with insurance reimbursement and patient cost-sharing covering essentially all of those costs (see the next section of the analysis). As organ procurement grows, there are two significant effects. First, there are economies of scale as OPOs and hospitals expand their donor-related and transplant services. Second, there are substantial volume increases over time that require additional efforts. For each OPO these are potentially multi-million dollar annual cost (and revenue) increases that reflect additional work performed and donation and transplant increases achieved. For both cost savings and cost increases, effects are primarily from staffing changes; we assume there are relatively few fixed investments beyond rent and equipment. And in both cases, current

reimbursement policies and programs pay for all reasonable costs. We received no comments on these and other workload, cost, and revenue issues and estimates and have left them only moderately changed.

We do not expect substantial costs would be incurred by CMS. The data collection required for enforcement of the standards already exists and can readily be used to assess performance. OPOs are already reviewed and surveyed on a continuing basis. There would be additional costs for technical assistance, processing ECE requests, and reviewing QAPIs, as well as actions regarding any OPOs with major compliance problems. We anticipate increased appeals related activities, however our expectation is that these would be managed through any necessary reallocations of staff time from lower priority activities. The number of affected facilities is also small compared to the number of facilities that CMS works with on a regular basis. CMS estimates that these oversight activities are unlikely to require more than three or four additional person-years of effort, with annual costs of one million dollars or less.

The preceding analysis does not reflect the potentially substantial transition costs associated with the potentially disruptive to top management process of decertification. However, as previously discussed we believe that these costs will fall almost entirely on the very highest levels of OPO governance, not on the ongoing processes of the OPO in procuring organs or arranging transplant placement performed by professional staff.

E. Effects on Medicare, Medicaid, and Private Payers

The preceding cost estimates include all procurement and transplantation costs, regardless of payer. In practice, however, most of the costs are covered by insurance, and the remainder primarily by patients. Typical insurance shares, both public and private, range from 100 percent (Medicaid) to 80–90 percent in private insurance and Medicare, taking into account hospital, physician, ESRD, and drug costs. While overall cost sharing by category of expense is broadly similar among insurance sources and across organ types, both the transplant cost and the shares paid by public and private insurance vary widely by organ type. Specifically, for heart and liver transplants, the vast majority of patients are enrolled in private insurance or in some cases in Medicaid because of the

age restrictions of Medicare (unless disabled). According to the OPTN, in 2018 only 19 percent of heart transplants and 22 percent of liver transplants were performed in recipients 65 and older. In contrast, the vast majority of kidney transplants (about 80 percent) are received by patients who have end-stage renal disease and, as ESRD patients, nearly all are entitled to Medicare regardless of age (about half of ESRD patients are also enrolled in Medicaid, but Medicare is “primary” and pays most costs). This ESRD/kidney transplant group also differs radically in initial transplant cost (much lower than for hearts and livers, as shown in Tables 6 through 8), and in cost over time. For kidney transplant recipients who live 4 years or more after the transplant year, total medical costs over time are lower than for dialysis, resulting in savings to Medicare (see Table 8). For ESRD patients who receive kidney transplants, the public insurance programs would likely save money over time.

We do not have a definitive estimate of costs to each category of payer because those shares will change considerably over time as new cohorts of patients are served, and will also change depending on whether costs are estimated for 1, 5, or 10 years or beyond. For kidney transplant recipients, who account for almost two-thirds of transplants, Medicare cumulatively saves more money than the transplant cost by the fourth or fifth year after transplant. One simple calculation method is to consider the weighted average of costs billed to Medicare for each 1,000 patients transplanted and surviving 5 years. Taking into account all the preceding factors, the weighted average total cost billed by providers to all payers would be about \$270 million (see Table 9). The Medicare share of that would be about \$40 million, largely reflecting the lower initial costs of kidney transplants, the continuing dialysis savings, and the relatively small share of heart and liver transplants paid by Medicare. In the first year for these same 1,000 patients (the year of the actual transplant) the Medicare cost would be about \$150 million of the \$388 million total, reflecting the Medicare coverage of the majority of transplants as well as the lower average cost for those kidney transplants. Across the first 5 years after the final rule takes effect (years in which much of the dialysis savings are not yet realized), total costs shown in Table 10 over this period are about \$10 billion and the average billed to Medicare would be about 25 percent of this, or \$2.5 billion.

⁴³ See Vivian Ho and Barton Hamilton, “Hospital mergers and acquisitions: does market consolidation harm patients?,” *Journal of Health Economics*, September 2000, at <https://www.sciencedirect.com/science/article/abs/pii/S0167629600000527>, and Tim Attebery, A Study to Examine the Relationship Between Hospital Mergers and Patient Experience, Ph.D. Dissertation, University of Alabama, 2018, at <https://search.proquest.com/openview/4653015278eba7781f781fbf0fcb6c8/1?pg-origsite=gscholar&cbl=18750&diss=y>.

Of this, patients would pay on average almost 20 percent, reducing the Medicare costs to about \$2 billion over the 5-year period. Alternatively, if costs only increase by the minimum needed to achieve required standards, total costs and the Medicare share might be only about one fourth as much (see Tables 11 and 12).

F. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

1. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year, varying by type of provider and highest for hospitals). On average, the 58 OPOs have annual revenues of about \$50 million in a market with annual organ acquisition revenues of about \$3 billion annually.⁴⁴ While few of these would meet SBA revenue size standards for “small,” all are, by law, non-profits. Accordingly, almost all of the direct effects on businesses that this rule would create will affect small entities.⁴⁵

The RFA requires that a Regulatory Flexibility Analysis be prepared if a proposed and subsequent final rule would have a “significant economic impact” on a “substantial number” of such entities. The HHS standard for “significant economic impact” is 3 percent or more of annual revenues. Although the HHS position is that this only applies to negative impacts because the RFA requires agencies to “minimize” economic impact, HHS practice in cases involving significant positive effects is to perform the analysis, regardless of the statutory issue. In the case of this rule, we expect

most OPOs to prosper as they reform their practices to meet the new standards, but some may lose their certification and be replaced by existing, high performing OPOs. The HHS standard for “substantial number” is 5 percent or more of those that will be significantly impacted, but never fewer than 20. While there are only 8 OPOs that fall into Tier 3 and we expect that all or most of these will meet our outcome measures within 4 years, there is a possibility that a larger number would not have their agreements renewed because of loss in the competition phase. Hence, we are unable to certify that a Final Regulatory Flexibility Analysis is not required under the RFA. Accordingly, we prepared both Initial and Final Regulatory Flexibility Analyses and this RIA, together with the other preamble sections, meets the requirements for RFAs.

The question arises as to whether transplant programs are affected entities. We believe they are not. They are all medical units within hospitals. Only the hospital itself can be a small entity, and many are, as a consequence of their non-profit status. However, nothing in this rule directly regulates either hospitals or their transplant programs. Moreover, nothing in this rule would have any adverse effects on those programs. They would, instead, likely gain revenues from increases in patients transplanted. The pattern of such increases is impossible to predict since organs are increasingly shared across OPO service area boundaries and, in many cases, across hundreds or thousands of miles. Regardless, in the aggregate, hospital revenues nationwide exceed 1 trillion dollars a year; the estimated costs of this rule assuming higher rather than lower levels of performance over the first 5 years are about \$10 billion, averaging \$2 billion a year, of which only half falls on transplant programs. This would be a fraction of 1 percent of hospital costs or revenues in the hospitals that host transplant programs, which are generally larger hospitals. Since organ acquisition costs are reimbursed by patient health insurance, net costs to hospitals with transplant programs are approximately zero and may actually be negative.⁴⁶ Indeed, if any hospital determined that its transplant program was no longer a profit center, it could simply cease providing that service.

Hence, we conclude that there would be no “significant economic effect” on a “substantial number” of hospitals, and that increases in transplant volume will be neutral or positive.

The potential economic effects on OPOs depend on their ability to meet the thresholds established at the beginning of the 4-year performance period. OPOs who are in Tier 1 should experience positive impacts (a likely increase in organ donors and organ transplants that we estimate to likely be near 20 percent), with revenues from Medicare that reimburses reasonable kidney acquisition costs) and reimbursement from other health insurers. Those OPOs currently at Tier 3 that can achieve the threshold rates over the 4-year period may also benefit from the increased revenue associated with procuring more organs. For OPOs that cannot meet the new outcome measures or improve sufficiently to win the competition for their open DSA, they would incur costs to make the necessary changes to avert a loss of certification. Our final rule methodology is designed to allow all OPOs the opportunity to achieve the threshold rates; however, based on Tables 4 and 5, we believe that there are a range of potential outcomes, assuming high performers remain at steady state or substantially improve over time. Based on 2018 data, these potential outcomes include:

- Eight OPOs in Tier 3 would be subject to de-certification or loss of DSA because they would need to increase their donation and/or transplantation rates by more than 50 percent to meet the Tier 1 threshold rates. These eight are at the most serious risk.

- Approximately 12 DSAs that would be subject to potential takeover because their current OPOs would need to increase their donation and/or transplantation rates by more than 10 to 50 percent to meet the Tier 1 threshold rates.

- Approximately 12 DSAs whose current OPOs would need to achieve relatively little improvement but that would be still subject to potential takeover because they would need to increase their donation and/or transplantation rates by 1 to 10 percent to meet the Tier 1 threshold rates.

In most cases of potential loss of certification for a DSA, we would reasonably expect another OPO to take over that service area, retaining the original staff of the OPO that is being taken over, but changing the leadership and many of the organ procurement practices. Conversely, it is also possible that an OPO taking over a new service area would need to increase its staff or

⁴⁴ Brigitte Sullivan, Executive Director, NYU Langone Transplant Institute, “Maximizing Medicare Cost Report Reimbursement,” 2015, online at http://organdonationalliance.org/wp-content/uploads/2015/08/ATC_BSullivan_CostReport_062016_S5N0001.pdf.

⁴⁵ We appreciate that some OPOs are hospital-based. For purposes of this analysis, we focus on their OPO functions separately from their other functions.

⁴⁶ Patients are not ordinarily accepted on transplant waiting lists if they do not have the insurance or other means to ensure that they can pay not only the hospital and surgical fees, but also for the immunosuppressive drugs that are needed for post-transplant survival.

incur costs related to retraining, or implementation of best practices unfamiliar to the de-certified OPO's staff. We asked for comments on the costs associated with an OPO entering a new DSA after a decertification, including retraining, leadership, relationship building, and implementation of other best practices, but received no comments with which to inform our estimates. As indicated previously in this analysis, we have assumed that disruption costs to OPO organ procurement practices will be mainly related to replacement of Chief Executive Officers and/or Boards and Board members.

Tables 1 to 3 present a list of all affected OPOs and of the gap between their current performance and the final rule standards. These tables use data from 2018 as the baseline year. Based on preliminary 2019 data, which shows substantial overall national improvement in organ transplantations, if the donor potential remained steady in 2019 as it did from 2017 to 2018, these estimates likely overstate the risk for many OPOs (and, by extension, the scope for potential benefits of this rule). These tables show for each OPO what it would have to achieve over a 4-year period to meet the outcome measures. Since the threshold rate using 2019 data would be established prior to the assessment period, each OPO would know from its own workload data and the latest potential donor data exactly where it stands at any point in time over the 4-year re-certification cycle. Since the reasonable and allowed cost of each OPO's increased effort and performance is covered by Medicare for kidney acquisitions, this is not a cost or revenue issue for the OPOs. Instead, our new outcome measures would create a senior leadership and potentially an organizational survival issue. The future of an OPO depends largely on its performance in obtaining donors and on utilization of those organs for transplantation.

Since all OPOs are non-profit organizations and hence "small entities," all of the alternatives and options presented throughout this preamble meet the RFA requirement that effects on these entities be addressed.

Because the measures we have adopted are performance standards, they provide flexibility to the OPOs in meeting the standards. For example, in addition to all the possible internal reforms that an OPO could make, OPOs could merge, or service areas could be merged. These flexibilities are not limited to bilateral agreements and could involve multiple OPOs in

partnership with each other or with transplant hospitals. OPO boards could replace the executive leadership and the new leadership could replace ineffective coordinators. They could work to improve working relationships with donor hospitals within their service areas through programs such as the Workplace Partnership for Life. Should cases arise where an OPO is unable to make the necessary changes or is constrained by circumstances beyond its control so that it cannot reach the performance levels of others, CMS can intervene with technical assistance or to facilitate mergers or other changes. The three tier system put in place by this final rule will facilitate OPO decisions on corrective actions calibrated to their performance tier. We believe that every OPO can meet these standards through good faith reforms to improve both donation and organ placement.

The RFA contains a number of requirements for the content of an Initial or Final Regulatory Flexibility Analysis, including a description of the reasons why action is being considered, a statement of the objectives and legal basis for the rule, a description of any reporting or record-keeping requirements of the rule, and a description of any other Federal rules that duplicate, overlap, or conflict with the proposed or final rule (there are none in this case), among others. This RIA and the preamble taken as a whole meet these requirements. We note that the RFA emphasizes the use of performance rather than design standards, which is precisely what we proposed and are putting in place in this final rule.

2. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule's direct effects do not fall on hospitals and there are no small rural hospitals that operate transplant programs. Accordingly, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before

issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately \$156 million. This rule contains no mandates that directly impose spending costs on state, local, or tribal governments, or by the private sector. Some OPOs would likely find that meeting these standards would require additional spending, but others may find that better performance can be achieved at little or no cost. In either case, reimbursement by both public and private payers would cover all reasonably estimated costs.

4. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule would impose no such requirements.

G. Alternatives Considered

Throughout the preamble sections, the proposed rule presented our proposals and sought comments on potential alternatives. We proposed to implement reform measures that (1) establish empirically-based outcome and process performance measures for OPOs, (2) that can be uniformly applied to all OPOs, (3) that would capture the entire pool of potential deceased-donors, (4) that would use transparent, reliable and objective data that would not require entity-specific judgments, (5) that use data that accounts for geographic differences in the number and causes of death, and (6) that use data that are easily captured and tallied on a continuing annual basis.

In choosing the outcomes measures that we proposed and setting the threshold donation and organ transplantation rate at the top 25 percent of rates as the goal to achieve, but not automatically de-certifying OPOs who had at least one outcome measure at or above the median rate, we sought to strike a balance between the goals set forth by HHS and the potential disruption that could happen if only a few OPOs could comply with our standards. We also analyzed three types of alternatives that could be applied to all the OPOs: Changing the denominator, changing the confidence intervals, and changing the threshold rates. For changes to the denominator, we examined the impact of using the CALC measure as the denominator; using the total unadjusted number of

deaths in the DSA as denominator; and using the total population in the DSA as the denominator. For changes to the confidence interval, we examined the impact of changing the confidence interval (CI) to 90 and 99 percent. For changes to the threshold rates, we examined the impact of setting the threshold at an absolute value based on the geometric mean or the median from the year 2016. For the Hawaii OPO, we analyzed one additional alternative to consider: Using the kidney donation and transplantation rates as a measure of success because of the geographical barriers to transporting the other organs for transplantation outside of Hawaii. We sought comments to these alternatives in addition to our proposed outcome measures.

As explained in both preceding and following sections, we made changes in the final rule dealing with all of these issues.

Changes to the Denominator

CALC as the Denominator

As discussed earlier in the preamble, the CALC method proposed by Goldberg et al., has been published in the literature and presented in various forums. It was endorsed by many commenters. This methodology uses the same NCHS database and also uses inpatient deaths to calculate the denominator. The primary difference between the “cause, age and location” consistent with donation methodology adopted in this final rule and the originally proposed methodology is that it uses the ICD–10–CM codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas the original proposal would exclude ICD–10–CM codes that are an absolute contraindication to organ donation (that is, exclusion criteria). The developers of the CALC methodology believe that the ICD–10 codes used in their inclusion criteria captures nearly 99 percent of all deceased donors according to the OPTN;¹²

- I20–I25 (ischemic heart disease);
- I60–I69 (cerebrovascular disease);
- V–Y89 (external causes of morbidity and mortality): Blunt trauma, gunshot wound, drug overdose, suicide, drowning, and asphyxiation.

We performed a comparative analysis of the CALC methodology and the originally proposed methodology. There was consistency in the OPOs that were flagged for donation and organ transplantation rates that were below the top 25 percent. Notably, the differences were in the total donor potential (denominator) with CALC method resulting in a donor potential of

101,479 inpatient deaths in 2017, whereas our proposed methodology had 272,105 inpatient deaths. Where there were differences in OPOs being flagged for the donation rates (the CALC method flagged more OPOs), the differences were minor (only a small number of donors per OPO). If all OPOs could increase their donation rates to the threshold rate, under the originally proposed methodology, there would be an additional 1,015 donors (approximately 10.43 percent increase), whereas the CALC methodology would yield an additional 1,223 donors (12.57 percent increase).

For organs transplanted, we estimated that if all flagged OPOs were to increase their organs transplanted to the range of the top 25 percent, then using the proposed methodology, there would be an additional 4,903 organs transplanted (15.24 percent increase); using the CALC methodology, there would be 5,590 more organs transplanted (17.37 percent increase). Other than the approximately 2 percent increase in donations and organ transplantation, another difference in the methodologies is the difference in how much of an increase each particular OPO would need to increase in organs transplanted. We sought comments on these differences and whether the CALC method is a more precise and/or accurate assessment of OPO performance. Again, the majority of commenters on the CALC option recommended use of CALC.

All Deaths, Age <= 75 as the Denominator

In addition to analyzing the CALC method for the denominator, we also considered using the total number of deaths of people 75 years and younger, regardless of location or cause of death to define the donor potential. Using total number of deaths as the denominator, the donor potential was estimated at 1,376,541 deaths in 2017 of people 75 years and younger (compared with our donor potential of 272,105 inpatient deaths). Despite this large discrepancy in the denominator, we found very similar results for those OPOs being flagged by our methodology versus an approach that uses total deaths. If all OPOs were able to achieve the threshold 25 percent rate using this methodology, we found that it would have 933 additional donors (compared with the 1,105 with our proposed methodology) and 4,851 more organs transplanted, compared with the 4,903 organs from the originally proposed methodology. Similar to the CALC method, where there were differences in the OPOs being flagged for donation

rates, the additional donors needed were mostly in the single digits. For the organ transplantation rates, the greatest differences were not in which OPOs were flagged, but rather, it was the differences by OPO in the number of additional organs that needed to be transplanted in order to reach the top 25 percent threshold rate. Few commenters regarded this as a preferred methodology, although like CALC, it would have created an objective and known baseline method of calculating performance.

Total Population, Age <75

A third alternative denominator that we analyzed used the U.S. population from the 2010 census of persons less than 75 years old as the denominator.⁴⁷ A population-based approach to recertifying OPOs was used by the Department until the passage of the OPO Certification Act of 2000, which specifically raised concerns about “[a]n exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.” While we considered this approach, no commenters favored it; and for the preceding and following reasons, we rejected it in favor of the CALC alternative. In the population-based approach, using the original two-tiered performance metric, we would have had 1,699 more organ donors and 7,000 more organs transplanted if all flagged OPOs were able to increase their performance to that of the top 25 percent. This increase does not seem realistic given how significantly it differs from the increases utilizing the CALC and total death analysis. A fundamental requirement to achieve these increases is a sufficient number of deaths that could lead to organ donation. A population based approach does not account for the death requirement and is problematic given variance in DSA mortality rates from 3.39 to 7.11. We also found a pattern where OPOs in the geographic areas with lower mortality rates, such as the Pacific Northwest, the Rocky Mountain area, New England, Los Angeles area, New York City area, and Hawaii, had depressed performance rates under this method, as compared to the OPOs in the areas of the country with the highest

⁴⁷ For convenience, we used less than 75 years old rather than 75 and younger because of how the Census data is publicly reported.

rates of deaths consistent with organ donation.⁴⁸ Although we stated that we would not consider a measure that is based solely on population size, we sought comments as to whether there are appropriate risk-adjustments that could be used so that a population measure could be reflective of the organ donation potential. We received no such comments and dropped this option from consideration.

Changing the Confidence Interval

In addition to considering other denominator sources, we considered changing the way in which we measured success. One way in which we measure success is in the confidence that our rate is correctly identifying low performers. Our proposed methodology used a 95 percent CI, so we analyzed the effects of both the 90 percent and 99 percent CIs; that is, we increased and decreased our confidence that we appropriately flagged OPOs based on our donation and organ transplantation threshold rates. By changing to a 99 percent CI, 24 OPOs were flagged for donation rates compared with 33 OPOs (95 percent CI); and, 35 OPOs were flagged for organ transplantation rates compared with 36 OPOs being flagged (95 percent CI). When we examined the effects of the 90 percent CI, the differences were even less noticeable: For donation rates, 35 (90 percent CI) versus 33 (95 percent CI) and for transplantation rates, 38 (90 percent CI) versus 36 (95 percent CI). These changes would, however, have put more OPOs at risk for purely statistical reasons. For this reason and absent any favorable comments we retained the 95 percent CI in the final rule.

Changing the Threshold Rates

An alternative way to measure success would be to change the threshold rate by which OPOs are measured. We examined the impact of using a static, absolute threshold rate based on the geometric mean and the median based on data from 2016 for analyzing data from 2017.

We considered use of a static, absolute threshold based on a geometric mean or median as a viable alternative to use instead of the higher relative performance metric that changes each year, but questioned whether this approach could inadvertently incentivize all OPO performances to move towards a static threshold, thus decreasing total donations and transplantations over time. We sought

robust public comments that would support or refute these concerns and comments that would list the potential impacts, benefits, or consequences of implementing this approach. We specifically requested that commenters present data, studies, or other analysis to support their recommendations. We also sought comments on ways to incentivize continual improvement of all OPOs, including high performers and low performers. Additionally, we sought comments on ways to ensure that the rates for re-certification continue to be based upon current performance and appropriately reflect potential improvements and changes in technology (such as the development of an implantable, artificial kidney or bioengineered pancreatic islet cells). None of these requests led to public comments advocating such changes. Accordingly, we did not adopt such a measure in the final rule.

There were other alternatives that we chose not to propose. We had previously received comment in response to our RFI that we should consider using the deaths referred from donor hospitals as our donor potential. This approach could rely on the regulatory requirement for hospitals to report imminent deaths to OPOs. We declined to propose this on the basis of concerns regarding its potential for inaccuracy. We stated that this approach would incorrectly place the requirement to report an imminent death solely on the donor hospital, although this is a joint responsibility shared with an OPO. We received no comments in favor of using donor referrals as our denominator, but received a number of comments that hospitals should report directly to CMS or the OPTN the ventilated deaths. The final rule does not make such changes because of the potential burden to donor hospitals, as discussed earlier in the preamble.

Another option suggested by some members of the OPO community and commenters in response to the RFI and in comments to our proposed rule was to use ventilated deaths for donor potential. While we appreciated this suggestion, there are no standardized databases that would allow us to determine the ventilator status of deaths, and we were concerned this approach incorrectly assigns “potential donor” status solely based on the fact that the patient is on a ventilator in an ICU. This approach does not consider the role of OPOs in educating donor hospital staff about the range of potential donors, such that resuscitation efforts and inpatient treatment are sufficient and appropriate so that referrals can be made for organ

donation, even for older, single-organ donors. Furthermore, asking hospitals to report the ventilator status of inpatient deaths or expecting OPOs to report that status would create an additional burden for all hospitals (not just transplant hospitals or just OPOs) and is inconsistent with one of our many goals in proposing these new performance measures: To reduce the reporting burdens so that resources can go towards increasing organ donation and transplantation. Therefore, we chose not to adopt this source for estimating the “donor potential” in our final rule.

Also discussed in the preamble, we recognize that the OPO in Hawaii is at a considerable geographic disadvantage for placement of almost all the organs it could procure. As an alternative, we considered measuring the performance of the Hawaii OPO based solely on its kidney donation and transplantation rates, excluding other organs, because Hawaii has a kidney transplant program, yet has greater geographic barriers associated with transporting the extra-renal organs outside of the DSA. As set forth in section II.B, above, we are finalizing a requirement to measure the performance of the Hawaii OPO based on its kidney transplantation rates and its organ donation rate. We did not adopt the kidney donation rate because almost all organ donors are also kidney donors, so the organ donation rate should be an appropriate proxy for the kidney donation rate.

Using solely these measures, we found that the Hawaii OPO would be in the top 25 percent for the kidney transplantation rates and top median for the organ donation rates (but would need only 3 more donors to meet the top 25 percent threshold rate). If we were to use our proposed measure to assess the Hawaii OPO's performance, it would need one additional donor and 38 additional organs transplanted to meet the threshold rate for the top 25 percent of rates. The reason we did not propose this approach for assessing the Hawaii OPO is that we were aware of newer technologies that could significantly reduce the clinical impact of prolonged transport of extra-renal organs and prefer a policy that encourages the innovation and adoption of these types of technologies for the benefit of all potential recipients. We sought comments on this alternative or any other approach that would accurately measure the performance of the Hawaii OPO, such as a phased approach to implementing our new measures. The comments we received generally supported relying on a kidney performance measure alone, and we have adopted that approach in the final

⁴⁸ Cannon RM, Jones CM, et al., “Patterns of geographic variability in mortality and eligible deaths between organ procurement organizations,” *AmJTransplant*. 2019;00:4 (Fig. 2).

rule. We believe that as technology improves, the Hawaii OPO will have both the life-saving incentive and ability to transport more organs across oceanic distances, but that any specific requirement imposed at this time would risk rapid obsolescence.

In analyzing all these different alternatives, we recognized that there were many OPOs whose performance is in the top 25 percent, regardless of which methodology was used. These OPOs are truly high performers and should be the models for the other OPOs. We encourage those OPOs to continue to strive to be top performers and encourage the widespread uptake of their best practices.

In summary, we welcomed comments both on the comparative advantages and disadvantages of alternatives within the scope of the OPO proposed rule, and suggestions for other alternatives that could be addressed in subsequent rule-making or administrative actions to further improve performance of the organ donation and transplantation

system. We received some suggestions for minor improvements in the standards we proposed many recommendations to adopt both CALC; a suggestion to adopt a system with tiers to identify performance and more graduated options that would recognize major progress towards the standards; numerous comments encouraging competition among OPOs; and comments encouraging us to take action more quickly. These last four and a number of more minor changes have been adopted in this final rule.

H. Accounting Statement and Table

As required by OMB Circular A-4 (available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in Table 16 we have prepared an accounting statement showing the classification of the benefits, transfers, and costs that we estimate may arise from the reforms under this final rule.

These reforms' effects are likely to be more substantial in out-years than in the nearer term, and the annualized

estimates provided in this table display the effects that may be expected over the next 5 years, rather than over a longer period of time. The performance uncertainties, technology uncertainties, and future policy uncertainties are so great that we are reluctant to project further into the future. This means, however, that the Accounting Table estimates do not include substantial out-year benefits to patients, additional savings to the ESRD program, and substantial costs to public and private insurance programs that will occur outside the 5-year estimating window. Also, the effects of this rule on organ recovery and transplantation are of unusual uncertainty even in the short run. The factors influencing both upper and lower bounds for benefit and cost reduction estimates are as discussed previously in this RIA.

The rule generates a cluster of interrelated effects, so we are treating the increase in health care expenditures as "negative benefits" for purposes of the Accounting Table.

TABLE 16—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS (\$ MILLIONS)

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (%)	Period covered
Benefits:						
Health Benefits Annualized Monetized (\$million/year)	<0	1,370	2,017	7	2022–2026
		<0	1,430	2017	3	2022–2026
Medical Expenditure Annualized Monetized (\$million/year)	>0	–1,450	2017	7	2022–2026
		>0	–1,450	2017	3	2022–2026

Benefits Notes: Because increased transplant activity imposes costs upfront but yields savings over time, a longer time horizon would show medical expenditure impacts falling in magnitude, potentially (for the portion of the range shown in the "High Estimate" column) to the point of being exceeded by longevity benefits.

Costs:						
Annualized Monetized (\$million/year)	10	10	10	2017	7	2022–2026
	10	10	10	2017	3	2022–2026

Cost Notes: Administrative costs in the event of OPO decertification and for regulatory compliance are believed to be relatively minor compared to the high costs and benefits of increasing donors and transplants.

Transfers	None quantified.					
-----------------	------------------	--	--	--	--	--

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations "to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule has been designated a significant regulatory action as defined by Executive Order 12866, and is expected to be an E.O. 13771 regulatory action.

J. Conclusion

This rule would substantially reform the incentives facing OPOs and as a result, increase organ procurement and transplants over time for all organs, while reducing continuing costs for dialysis and other treatments for patients with severe kidney disease. Organ transplants are life-saving and life-extending events. Predicting future behavior is particularly difficult when major changes in rewards, penalties, and incentives are created, so all

estimates should be regarded as subject to substantial uncertainty.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 486

Definitions, Medicare, Organ procurement.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services amends 42 CFR chapter IV, part 486 as set forth below:

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

- 1. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

- 2. Section 486.302 is amended by adding definitions for “Assessment period”, “Death that is consistent with organ donation”, “Donation rate”, “Donor potential”, “Kidney Transplantation rate”, “Lowest rate among the top 25 percent”, and “Organ transplantation rate” to read as follows:

§ 486.302 Definitions.

* * * * *

Assessment period is a 12-month period in which an OPO’s outcome measures will be evaluated for performance. The final assessment period is the 12-month assessment period used to calculate outcome measures for re-certification.

* * * * *

Death that is consistent with organ donation means all deaths from the state death certificates with the primary cause of death listed as the ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–Y89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

* * * * *

Donation rate is the number of donors as a percentage of the donor potential.

* * * * *

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death that is consistent with organ donation. For OPOs servicing a hospital with a waiver under § 486.308(e), the donor potential of the county for that hospital will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county.

* * * * *

Kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

* * * * *

Lowest rate among the top 25 percent will be calculated by taking the number of total DSAs in the time period identified for establishing the threshold

rate. The total number of DSAs will be multiplied by 0.25 and rounded to the closest integer (0.5 will round to the higher integer). The donation rates and organ transplantation rates in each DSA will be separately ranked and the threshold rate will be the rate that corresponds to that integer when counting down the ranking.

* * * * *

Organ transplantation rate is the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs transplanted into patients on the OPTN waiting list as part of research are included in the organ transplantation rate. The organ transplantation rate will be risk-adjusted for the average age of the donor potential using the following methodology:

- (1) The age groups used for the adjusted transplantation rates are: <1, 1–5, 6–11, 12–17, 18–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64, 65–69, 70–75.

- (2) Calculate a national age-specific transplantation rate for each age group.

An expected transplantation rate for each OPO is calculated as $\Sigma(g=1)Gdg \cdot Rg / \Sigma gdg$, where dg is the number of potential donors in the OPO in age group g, Rg is the age-specific national transplantation rate in age group g, and Σgdg is the OPO’s total number of individuals in the donor potential. This can be interpreted as the overall expected transplantation rate for an OPO if each of its age-specific transplantation rates were equal to the national age-specific.

- (3) Calculate the age-adjusted organ transplantation rate as $(O/E) \cdot P$, where O is the OPO’s observed unadjusted transplantation rate, E is the expected transplantation rate calculated in Step 2, and P is the unadjusted national transplantation rate.

* * * * *

- 3. Effective July 31, 2022, § 486.302 is further amended by—

- a. Revising the definition of “Donor”;
■ b. Removing the definitions of “Eligible death”, “Eligible donor”, “Expected donation rate”, and “Observed donation rate”;
■ c. Revising the definition of “Organ”; and
■ d. Removing the definition of “Standard criteria donor (SCD)”.

The revisions reads as follows:

§ 486.302 Definitions.

* * * * *

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted.

An individual also would be considered a donor if only the pancreas is procured and is used for research or islet cell transplantation.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
(1) Right or Left Kidney	1
(2) Right and Left Kidney	2
(3) Double/En-Bloc Kidney	2
(4) Heart	1
(5) Intestine	1
(6) Intestine Segment 1 or Segment 2	1
(7) Intestine Segment 1 and Segment 2	2
(8) Liver	1
(9) Liver Segment 1 or Segment 2	1
(10) Liver Segments 1 and Segment 2	2
(11) Right or Left Lung	1
(12) Right and Left Lung	2
(13) Double/En-bloc Lung	2
(14) Pancreas (transplanted whole, research, islet transplant)	1
(15) Pancreas Segment 1 or Segment 2	1
(16) Pancreas Segment 1 and Segment 2	2

* * * * *

- 4. Section 486.316 is amended by revising paragraphs (a) through (c) and adding paragraphs (f) and (g) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) *Re-certification of OPOs.* Based upon performance on the outcome measures set forth in § 486.318 and the re-certification survey, each OPO will be designated into either Tier 1, Tier 2, or Tier 3. The tier in which the OPO is designated will determine whether the OPO is re-certified (Tier 1), must compete to retain its DSA (Tier 2), or will receive an initial de-certification determination (Tier 3).

(1) *Tier 1.* An OPO is re-certified for at least an additional 4 years, the OPO’s DSA is not opened for competition, and the OPO can compete for any open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(4) for the final assessment period of the agreement cycle.

(2) *Tier 2.* An OPO’s DSA is open for competition and the OPO is eligible to compete to retain its DSA and for any

open DSA if it meets all of the following:

(i) It has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; and

(ii) It meets the outcome requirements as described in § 486.318(e)(5) at the final assessment period of the agreement cycle.

(3) *Tier 3.* An OPO will receive a notice of de-certification determination under § 486.314 and cannot compete for any open DSA if it meets either of the following:

(i) Has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360; or

(ii) Has outcome requirements as described in § 486.318(e)(6) at the final assessment period of the agreement cycle.

(b) *De-certification and competition.* If an OPO fails to meet the outcome measures set forth in § 486.318(e)(6) at the final assessment period prior to the end of the agreement cycle, or it meets the requirements described in paragraph (a)(3) of this section:

(1) CMS will send the OPO a notice of its initial de-certification determination and the OPO has the right to appeal as established in § 486.314;

(2) If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section. The de-certified OPO is not permitted to compete for its open area or any other open area.

(3) The OPO competing for the open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open DSA, an OPO must meet the performance requirements of the outcome measures for Tier 1 or Tier 2 at § 486.318(e)(4) and (5), and the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

* * *

(f) *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.

(g) *Exception.* For the 2022 recertification cycle only, an OPO is recertified for an additional 4 years and its service area is not opened for competition when the OPO meets one out of the two outcome measure requirements described in § 486.318(a)(1) and (3) for OPOs not operating exclusively in the noncontiguous States, Commonwealths, Territories, or possessions; or § 486.318(b)(1) and (3) for OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, and possessions. An OPO is not required to meet the second outcome measure described in § 486.318(a)(2) or (b)(2) for the 2022 recertification cycle. If an OPO does not meet one of the outcome measures as described in paragraphs § 486.318(a)(1), (a)(3), (b)(1), or (b)(3), or has been shown by survey to not be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

■ 4. Section 486.318 is amended by adding paragraphs (a)(4), (b)(4), (c)(3), (d), (e), and (f) to read as follows:

§ 486.318 Condition: Outcome measures.

(a) * * *

(4) The outcome measures described in § 486.318(a)(1) through (3) are effective until July 31, 2022.

(b) * * *

(4) The outcome measures described in § 486.318(b)(1) through (3) are effective until July 31, 2022.

(c) * * *

(3) An OPO's performance on the outcome measures described in § 486.318(a)(1) through (3) and § 486.318(b)(1) through (3) is based on

the data described in § 486.318(c)(1) and (2) until July 31, 2022.

(d) An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA.

(1) For all OPOs, except as set forth in paragraph (d)(2) of this section, for all OPOs:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The organ transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. The numbers of donors and organs transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent 12-months data from state death certificates.

(2) For the OPO representing the Hawaii DSA:

(i) The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential.

(ii) The kidney transplantation rate is calculated as the number of kidneys transplanted from kidney donors in the DSA as a percentage of the donor potential.

(iii) The numerator for the donation rate is the number of donors in the DSA. The numerator for the kidney transplantation rate is the number of kidneys transplanted from kidney donors in the DSA. The numbers of donors and kidneys transplanted are based on the data submitted to the OPTN as required in § 486.328 and § 121.11 of this title. For calculating each measure, the data used is from the same time period as the data for the donor potential.

(iv) The denominator for the outcome measures is the donor potential and is based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation. The data is obtained from the most recent

12-months data from state death certificates.

(e) An OPO must demonstrate a success rate on the outcome measures in accordance with the following parameters and requirements:

(1) For each assessment period, threshold rates will be established based on donation rates during the 12-month period immediately prior to the period being evaluated:

(i) The lowest rate among the top 25 percent in DSAs, and

(ii) The median rate among the DSAs.

(2) For each assessment period, threshold rates will be established based on the organ transplantation or kidney transplantation rates during the 12-month period prior to the period being evaluated:

(i) The lowest rate among the top 25 percent, and

(ii) The median rate among the DSAs.

(3) The 95 percent confidence interval for each DSA's donation and organ transplantation rates will be calculated using a one-sided test.

(4) Tier 1—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the top 25 percent threshold rate established for their DSA will be identified at each assessment period.

(5) Tier 2—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but is not in Tier 1 as described in paragraph (e)(4) of this section will be identified at each assessment period.

(6) Tier 3—OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation or organ transplantation rates that are below the median threshold rate

established for their DSA will be identified at each assessment period. OPOs that have an upper limit of the one-sided 95 percent confidence interval for their donation and organ transplantation rates that are below the median threshold rate for their DSA are also included in Tier 3.

(7) For the OPO exclusively serving the DSA that includes the non-contiguous state of Hawaii and surrounding territories, the kidney transplantation rate will be used instead of the organ transplantation rate. The comparative performance and designation to a Tier will be the same as in paragraphs (e)(4), (5), and (6) of this section except kidney transplantation rates will be used.

(f)(1) An OPO's performance on the outcome measures is based on an evaluation at least every 12 months, with the most recent 12 months of data available from the OPTN and state death certificates, beginning January 1 of the first year of the agreement cycle and ending December 31, prior to the end of the agreement cycle.

(2) An assessment period is the most recent 12 months prior to the evaluation of the outcome measures in which data is available.

(3) If an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available.

§ 486.328 [Amended]

■ 5. Section 486.328 is amended—

■ a. In paragraph (a) introductory text by removing the word “Beneficiaries” and

adding in its place the word “Recipients” and by removing the acronym “DHHS” and adding in its place the acronym “HHS”;

■ b. By removing and reserving paragraph (a)(4); and

■ c. In paragraph (a)(7), by removing, the word “eligible”.

■ 6. Section 486.348 is amended by adding paragraph (d) to read as follows:

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

* * * * *

(d) *Standard: Review of outcome measures.* (1) An OPO must include a process to review its performance on the outcome measure requirements at § 486.318. The process must be a continuous activity to improve performance.

(2) An OPO must incorporate data on the outcome measures into their QAPI program.

(3) If the outcome measure at each assessment period during the re-certification cycle is statistically significantly lower than the top 25 percent of donation rates or organ or kidney transplantation (Tier 2 and Tier 3 OPOs) rates as described in § 486.318(e)(5) and (6), the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

Dated: November 19, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020-26329 Filed 11-24-20; 4:15 pm]

BILLING CODE 4120-01-P