

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS-3380-P]

RIN 0938-AU02

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on February 21, 2020.

ADDRESSES: In commenting, please refer to file code CMS-3380-P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3380-P, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3380-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Diane Corning (410) 786-8486, Eric Laib (410) 786-9759, Jesse Roach (410) 786-1000, Alpha-Banu Wilson (410) 786-8687, or CAPT Hui-Hsing Wong (410) 786-9007.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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 seriously ill people 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.). Therefore, OPO performance is a critical element of the organ transplantation system in the U.S.

As of September 2019, a total of 112,846 people were on the waiting lists for a lifesaving organ transplant.¹ Many people face tremendous quality of life burdens or even 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.

Given OPOs’ important role in the organ donation system in the U.S., some stakeholders have argued that underperformers have faced few consequences for poor performance. These stakeholders, mainly from advocacy organizations, have noted that “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 centers 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, agree that the OPO outcome measures should be reformed. 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.”⁴ Reforming the 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.”⁵

Based on public feedback and our own internal analysis of organ donation and transplantation rates, we agree 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

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.

⁴ 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>.

⁵ 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>.

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

best practices and optimization of donation and organ placement rates.

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 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 OPTN under contract. OPOs are required under the OPTN final rule (42 CFR 121.11(b)(2)) and 42 CFR 486.328 of the OPO Conditions for Coverage (CfCs) to report specific information to the OPTN,

including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with 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, which protects qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from unlawful 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 program 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.”

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).

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 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 began long before a hospital notified 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 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, and implementing regulations under 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.⁶

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

⁶ <https://www.organdonor.gov/about-dot/acot/charter.html>.

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—. . . .”⁷

On July 10, 2019, President Trump issued Executive Order 13879 titled *Advancing American Kidney Health*. The Executive Order 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 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 Executive Order 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 measures for evaluating an OPO’s performance. In conjunction with the Executive Order, the Department set a goal to deliver more organs for transplantation and aims to double the number of kidneys available for transplant by 2030.⁸

In accordance with the Executive Order and in response to ACOT’s recommendations and stakeholder feedback, we are proposing to revise the OPO outcome and process measures so that they are more transparent, reliable, and objective measures of OPO performance. We believe that these changes will lead to increased procurement opportunities for transplantation, increased organ utilization, and as a result, more lives saved.

⁷ Available at: <https://www.organdonor.gov/about-dot/acot/acotrecs55.html>.

⁸ <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>.

II. Provisions of the Proposed Regulations

A. Proposed Changes to Outcome Requirements (§ 486.318)

On May 31, 2006, CMS published the final rule, “Medicare and Medicaid Programs: Conditions for Coverage for Organ Procurement Organizations (OPOs)” in the *Federal Register* (71 FR 30982). That final rule established the CfCs that OPOs must comply with in order to receive Medicare and Medicaid reimbursement for organ procurement costs. It also set forth outcome measures at 42 CFR 486.318 and specifies the condition for reporting of data, 42 CFR 486.328. OPOs must report data to the OPTN in accordance with 42 CFR 121.11(b)(2) (describing data specified by the Secretary) and 42 CFR 486.328 (describing data required by the Secretary) for the operations of the OPTN and for CMS’s assessment of OPO performance. Under these authorities, OPOs must report data to the OPTN or the SRTR specified by the Secretary (including on OMB-approved forms pursuant to the Paperwork Reduction Act of 1995). The CfCs for OPOs at 42 CFR 486.318(a) and (b) have required that an OPO must meet two of the three following outcome measures:

- The OPO’s donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO’s donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by SRTR;

- The OPO data reports, averaged over the 4 years of the re-certification cycle, must meet the rules and requirements of the most current OPTN aggregate donor yield measure.

For the 2022 re-certification cycle only however, under 42 CFR 486.316(a)(3), OPOs are not required to meet the second outcome measure (the observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by SRTR). OPOs must instead meet 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 (84 FR 61434 through 61436).

We have heard concerns from some stakeholders within the organ donation and transplantation community about these outcome measures since finalization in 2006. Some stakeholders contend that the current outcome measures are not reliable and transparent indicators of OPO performance. Most comments have centered on the self-defined and self-reported nature of the data on “eligible deaths” that are used for the evaluation of the outcome measures. Stakeholders increasingly have brought to our attention that the interpretation of “eligible deaths” appears to be inconsistent across donation service areas (DSAs), and that “all OPO data is unaudited and self-reported” and therefore, “the accuracy and consistency of that data cannot be assured.”⁹

In addition, there were concerns about the donor yield outcome measure. According to stakeholders, there are “pressures from donor yield reporting” that “drives OPOs to walk away from cases in which the donor only has one organ viable for transplant (such as for older patients, where it is common that only the liver is medically viable), even in cases where next of kin consents to donation.”¹⁰ As a result, some commenters have suggested that “the regulations may be causing OPOs to ‘game’ the process of meeting [this] standard by only targeting ‘high-yield’ organ candidates.”¹¹ Given these comments, we are concerned that potentially transplantable organs may be wasted, exacerbating the organ shortage problem.

To address some of these stakeholder concerns, we made several changes to these outcome measures since we finalized the CfCs for OPOs in 2006. In 2012, we modified the definition of “donor document” (that is, the document that an individual can sign to authorize the procurement of their own

⁹ Letter from Helen Irving, President and CEO, New York Organ Donor Network, to Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Oct. 2013. Available at: https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf

¹⁰ ORGANIZE. Organ Donation Reform Report. 2019.

¹¹ Letter from Helen Irving, President and CEO, New York Organ Donor Network, to Howard Shelanski, Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget. Oct. 2013. Available at: https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.

organs after their death) (77 FR 29020). In 2013, we changed the requirement that an OPO had to meet three outcome measures to requiring that the OPO had to meet only two out of the three outcome measures (78 FR 75141). In 2016, we modified our definition of “eligible death” to be consistent with the OPTN definition, modified current requirements for documentation of donor information that is sent to the transplant center with the organ, and modified the yield measure to the most current OPTN aggregate donor yield measure (81 FR 79830).

In addition, in November 2019, we finalized a proposal to reconcile the definition of “expected donation rate” in the OPO CfCs with the definition currently used by the SRTR. The rule also finalized a policy that requires OPOs to meet one out of the two outcome measures for the 2022 re-certification cycle only. OPOs therefore are not required to meet the second outcome measure (the observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by SRTR) for the 2022 re-certification cycle. Absent additional regulatory changes, an OPO would be required to meet 2 of the 3 regulatory requirements for future evaluation cycles (84 FR 61434 through 61436). We also published a Request for Information (RFI) in the CY 2020 OPPS/ASC proposed rule that solicited comments regarding what revisions may be appropriate for the current CfCs for OPOs that are set forth at 42 CFR 486.301 through 486.360 and the current Conditions of Participation (CoPs) for TCs that are set forth at 42 CFR 482.68 through 482.104 (84 FR 39595 through 39598). That RFI also requested comments on two potential outcome measures, which we now describe in more detail in this proposed rule.

In a continued effort to respond to these concerns and as required by Executive Order 13879 and controlling statutes, we are proposing to revise the outcome measures for re-certification at § 486.318 to replace the existing outcome measures with two new outcome measures that would be used to assess an OPO’s performance: “donation rate” and “organ transplantation rate” effective for CY 2022. The “donation rate” would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ

donation; and the “organ transplantation rate” would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation.

The first measure, “donation rate”, would demonstrate the OPO’s percentage of possible deceased donors who become actual donors and the second measure, “organ transplantation rate”, would demonstrate the percentage of organs transplanted after procurement. We have chosen this combination of measures to reflect our view that OPOs should be expanding their efforts on both converting potential donors into actual donors and successfully placing all possible organs for transplantation. We chose to include actual organ donors who had at least one organ transplanted in our measure to encourage the pursuit of single-organ donors because we believe that these donors are the greatest opportunity for growth; it is our understanding that transplant centers have recently been willing to expand the definition of traditional organ donors and accept organs from these donors. We also chose the total number of organs transplanted to emphasize the role of the OPO in successful organ placement. We acknowledge concerns that donation rate and transplant rate measures may seem redundant and highly correlated; however, we believe that evidence of the high level of correlation is due to our current outcome measures that include both donation rates and organ transplant yield. We selected both donation rates and transplantation rates in order to reduce the risk that resources would be diverted to focus on one measure rather than increasing overall efforts to address both types of measures, which we believe could result in more single-organ donors and minimize discarding of transplantable organs. We are cautious in creating outcome measures that inadvertently decrease one or the other type of measure. For example, if we choose measures based only on donation rates, we are concerned whether there would be sufficient incentives to place as many as possible organs from each donor, which can be time-consuming. Conversely, if we chose measures based solely on organ transplantation rates, we would be concerned that there would be fewer incentives to procure single organs from older donors or donors after cardiac death, as there would be to

procure multiple organs from the younger, healthier donor after brain death.

For the first measure, donation rate, the numerator is defined as the number of actual deceased donors in the DSA who had at least one organ transplanted based on data reported to the OPTN. In the current § 486.302 Definitions, we define “Donor” to mean a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation. We are proposing to change this definition to require that the organ be transplanted, not just recovered. There are three primary reasons for requiring that the organ be actually transplanted: (1) To discourage the discarding of procured organs, (2) to encourage transplantation of every organ, including those from single-organ donors, and (3) because it is easier to verify the existence of a donor who had at least one organ transplanted compared with donors who did not have an organ transplanted. We are seeking comments on the change in definition of “donor.”

For the second measure, organ transplantation rate, we are not changing the definition of “Organ,” but propose to provide clarification as to how the organs are counted (see Table 1) for purposes of determining the organ transplantation rate (as our current regulations do not provide the specificity that we now propose to more accurately track donations). We are excluding organs procured for research, but not transplanted, from our definition, except for pancreata that are procured for islet cell transplantation or research (transplanted or not transplanted), as this is required by section 371(c) of the PHS Act. The numerator is defined as the number of actual organs transplanted based on data obtained from the OPTN. We are seeking comments on this proposed change and clarification.

TABLE 1—ORGANS TRANSPLANTED COUNT

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

TABLE 1—ORGANS TRANSPLANTED COUNT—Continued

Organ type	Number of organs transplanted
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

Some members of the OPO community have stated that the proposed measure, organ transplantation rate, reflects the transplant hospitals' acceptance practices and that OPOs should not be held accountable for the transplant hospitals' decisions. We understand the role of transplant hospitals in the organ transplantation rate measure; however, we also recognize the influence OPOs have on transplant hospital practice through OPO advisory boards (§ 486.324(a)(5)), which include a transplant surgeon from every transplant hospital in the DSA. Although the historical basis of this requirement was so that transplant hospitals could advise OPOs about transplant practices and have input into their policies,¹² we believe the relationship has evolved bilaterally, such that OPOs can educate transplant hospitals in the DSA about the performance of organs that were turned down by one hospital, but accepted by another. By serving on the OPO advisory board, transplant surgeons can learn more about the practices of the other transplant surgeons on the board, as well as about acceptance practices at transplant hospitals outside the DSA, and share that information with their own transplant hospitals. We also note that OPOs are often expected to place their organs outside of their DSA; our understanding of organ transplant practice is that there are numerous transplant hospitals throughout the country that successfully transplant "less than perfect" organs. It is our belief that given the unacceptable number of patients dying on the waiting list or on dialysis waiting for a transplant, there are transplant hospitals

in the U.S. that will accept "less than perfect," but still transplantable organs. As such, we believe it is the OPO's responsibility to ensure that those organs are transplanted, instead of discarded. Our goal for this rule and the organ transplantation rate measure is to incentivize the "system" to establish efficiencies that will result in substantial improvement of organ placement and transplantation.

The numerators for these measures will be based on the actual donors who had at least one organ transplanted and the number of organs procured and transplanted from those donors in the DSA. Since the data for the numerators for both of these measures are already being submitted by the OPOs and verified by the transplant hospitals when they perform the transplant, we do not believe that these proposed changes create additional reporting burdens for the OPOs or the transplant hospitals.¹³ Also, we are confident in the veracity of the information as it can be corroborated by the OPTN, which has a record of all organs in which a match is run for allocation, and requires reporting of the transplantation by the OPO, as well as the transplant program, and requires documentation of the disposition of the organ.

For both measures, the denominator (that is, donor potential) is defined as the number of total inpatient deaths within the DSA among patients 75 years of age or younger with a cause of death that would not be an absolute contraindication to organ donation. For calculating the denominator, we would use data obtained from state death certificates. Currently, this information can be obtained from the Center for Disease Controls' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCO) as described in more detail in this section. The MCO is published annually and is publicly available upon request. The MCO meets NCHS data privacy and security requirements.

The MCO comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCO 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.¹⁴

Within the standard certificate of death are key variables relevant to our measures such as where the death occurred: Hospital (inpatient, emergency room/outpatient, and dead on arrival) or somewhere other than a hospital (hospice facility, nursing home/long-term care facility, decedent's home, other). In addition, there is information on the cause of death. The information on the cause of death is based on free text entered by the certifier, usually a physician, medical examiner, or coroner. Based on the causes of death on the certificate, NCHS assigns a code from the International Classification of Diseases, Tenth Revision (ICD-10) to each cause of death reported. This coding is done centrally at NCHS with software designed for this purpose or manually using expert coders; they have been using ICD-10 codes since 1999. In addition to the underlying cause of death, each record has space for up to 20 multiple cause codes. The ICD-10 codes that could be assigned are found in CDC's Instruction Manual, Part 2e, Volume 1: *ICD-10, International Statistical Classification of Diseases and Related Health Statistical Classification of Diseases and Related Health Problems. Tabular List, 2017*; modified by the National Center for Health Statistics for use in the classification and analysis of medical mortality data in the U.S.¹⁵ Although there may be inaccuracies in the description of the causes of deaths in these death certificates, we have no evidence that there are differences in the rate of errors on inpatient death certificates based on the DSA and that any particular DSA would be disproportionately affected.

Deaths that are not an absolute contraindication to organ donation are calculated from those ICD-10 codes and would exclude clinical causes of death in which organs would never be used for transplantation. Our definition of "a death that is not an absolute contraindication to organ donation" means all deaths except those identified by the specific ICD-10 codes that would preclude donation under any circumstance. This information would be obtained from the state death certificates, and include both immediate cause of death and contributing causes of death. We have listed the three character categories of ICD-10 codes in Table 2 to be absolute contraindications to organ donation which was generated

¹² Senate Report 104-256—Organ and Bone Marrow Transplant Program Reauthorization Act of 1995 and § 486.324.

¹³ The data submitted to the OPTN has already been accounted for in the OPTN final rule's Paperwork Reduction Act analysis.

¹⁴ <https://www.cdc.gov/nchs/data/dvs/DEATH11-03final-acc.pdf>.

¹⁵ https://www.cdc.gov/nchs/data/dvs/2e_volume1_2017.pdf.

from and reviewed by several sources (the current list of eligible deaths, public stakeholder input, and HHS

medical advisors). We are interested in comments on whether all appropriate subcategories are included and whether

other ICD–10 codes should also be excluded from the denominator.

TABLE 2—ICD–10 CODES EXCLUDED FROM THE DENOMINATOR

Tuberculosis	All.
Other bacterial diseases	A39 Meningococcal infection. A40 Streptococcal septicaemia. A41 Other septicaemia.
Viral infections of the central nervous system	A82 Rabies.
Viral infections characterized by skin and mucous membrane lesions ...	B03 Smallpox.
Human immunodeficiency virus [HIV] disease	B20 Human immunodeficiency virus [HIV] disease with infectious and parasitic diseases. B21 Human immunodeficiency virus [HIV] disease with malignant neoplasms. B90 Sequelae of tuberculosis.
Sequelae of infectious and parasitic diseases	All.
Malignant neoplasms of lip, oral cavity and pharynx	All.
Malignant neoplasms of digestive organs	All.
Malignant neoplasms of respiratory and intrathoracic organs	All.
Melanoma and other malignant neoplasms of skin	C43 Malignant melanoma of skin.
Malignant neoplasms of bone and articular cartilage	All.
Melanoma and other malignant neoplasms of skin	All.
Malignant neoplasms of methothelial and soft tissue	All.
Malignant neoplasm of breast	All.
Malignant neoplasms of female genital organs	All.
Malignant neoplasms of male genital organs	All.
Malignant neoplasms of thyroid and other endocrine glands	All.
Malignant neoplasms of ill-defined, secondary and unspecified sites	All.
Malignant neoplasms of lymphoid, haematopoietic and related tissue ...	All.
Malignant neoplasms of independent (primary) multiple sites	All.
Neoplasms of uncertain or unknown behavior	D44 Neoplasm of uncertain or unknown behaviour of endocrine glands. D46 Meylodyplastic syndromes. D47 Other neoplasms of uncertain or unknown behavior of lymphoid, haematopietic and related tissue. D48 Neoplasms of uncertain or unknown behavior of other and unspecified sites.
Coagulation defects, purpura and other haemorrhagic conditions	D65 Disseminated intravascular coagulation [defibrination syndrome]. D69 Purpura and other haemorrhagic conditions.
Metabolic disorders	E84 Cystic fibrosis.
Infections specific to the perinatal period	P36 Bacterial sepsis of newborn.

One of our current measures used to measure OPO performance relies upon measuring the donation rate based on eligible deaths. While the “eligible death” definition allows for a more narrow and definitive estimation of the organ donation potential, it also limits the pool of potential organ donors by which OPOs are evaluated and does not take into account the advances in medicine that could expand the pool of potential donors (such as, very effective treatments for hepatitis C allowing hepatitis C positive donors to donate to patients who do not have hepatitis C);¹⁶ further, it is subject to bias in interpretation and reporting. By using inpatient deaths from this objective data source and eliminating causes of death that are absolute contraindications to organ donation, we are targeting a specific population that is more likely to be organ donors and mitigating concerns that the data could be manipulated

based upon varying interpretations of an eligible death.

The denominator will be the number of inpatient deaths of someone 75 years old or younger identified using the most recent prior 12 months of available data from the state death certificates from the DSA, and the numerators will be based on the number of donors and organs transplanted during the same corresponding time period. We chose to calculate our measures based on the most recent prior 12 months of available data from the DSA because we do not want to penalize OPOs that have improved their performance by using older data. Also, since the purpose of our performing this assessment is to recertify an OPO for another 4 years, historical performance from more than two years prior may be less reflective of current performance or less predictive of future performance. Finally, we are interested in comments on whether there are alternative or additional data sources or types we should consider, including those already being collected, when assessing OPO performance. As

stated earlier, we acknowledge that there are certain limitations of the CDC Multiple Cause of Death File. We are therefore interested in whether there are additional data sources, such as those collected by the OPTN, which could supplement the precision of outcome measures. We are also interested in the availability and utility of additional types of data, such as donor enrollment practices, discarded organs, or referral management.

In the regulatory impact analysis (RIA) section of this proposed rule, we present tables reflecting the results of our proposed measures using data from January 1, 2017 to December 31, 2017. We found a wide range of donation rates (1.65 to 6.45 donors/100 inpatient deaths) and organ transplantation rates (4.47 to 21.14 transplants/100 inpatient deaths). We did not find a correlation between the performance of OPOs and the number of deaths (reflecting experience with larger volumes of potential donors) or the number of patients on the waiting list (reflecting the demand for organs) in the DSA.

¹⁶ Woolley, AE, et al, “Heart and Lung Transplants from HCV-Infected Donors to Uninfected Recipients,” *NEJM*, 2019; 390:1606–1617.

Although Cannon et al. found statistically significant clustering of the top 5 causes of death in organ donors (blunt trauma, gunshot wounds, drug overdose, cerebrovascular accidents, and cardiovascular disease), we compared the donation rates and organ transplantation rates using these proposed measures to the geographic variability in those top five causes of death and found no correlation between high OPO performance and distribution or incidence of those causes of death.¹⁷ We examined the characteristics of the DSAs among the top 25 percent performing OPOs and found that they include geographic areas representative of all parts of the U.S. and diverse racial and ethnic populations. Despite this seemingly broader definition of potential organ donors, we did not notice any particular geographic patterns (including urban vs. rural) distinguishing the top performing OPOs from the rest of the cohort, leading us to conclude that our broad definition, inpatient deaths among those 75 and younger within the DSA, excluding causes of deaths that are an absolute contraindication for organ donation, appropriately describes the donor potential in a DSA and that the primary factors for differences in OPO performance using these measures are within the control of the OPOs to change. We are seeking comments as to the accuracy of our assessment and whether additional research is necessary to ensure that all DSAs will be impacted equally under the new measures. Specifically, we are requesting public comments that provide evidence-based support, such as peer-reviewed literature, that we should consider to inform our conclusion that our proposed definitions would not disadvantage any particular OPO as a result of population demographics or incidence of disease within a DSA.

Since our criteria for the denominator takes into consideration many of the clinical characteristics associated with possible organ donation (the age of the potential donor, the inpatient hospitalization, and contraindication to donation), we believe all appropriate risk-adjustments to the clinical characteristics of the donor potential have been made. We are aware of literature identifying racial disparities among organ donors, specifically that African Americans were less willing to donate their own organs compared with

whites (72.6% v. 88.3%).¹⁸ However, we are concerned regarding the applicability of that study, given it was from 2000, and more recent evidence suggesting that the racial concordance of the OPO requester plays a role in the rate of authorization for organ donation.¹⁹ Further, we are not aware of any validated coefficients that reflect the likelihood of a particular racial/ethnic group to donate organs and we are concerned that any current risk-adjustments factors being used include the historical poorer performances. Based on the most recent literature and our internal analyses, we have decided not to risk-adjust for race. We seek comments as to whether there is other literature or data regarding race or other demographics or other public health factors that warrant the consideration of further risk adjustment.

Similarly, we are not proposing any additional risk-adjustments to our measures other than the exclusion of the ICD-10 codes that are absolute contraindications to organ donation, the age of 75 and younger, and the requirement that the death occurred as an inpatient in the hospital. However, we are seeking comments on whether other 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. If risk adjustment were to be implemented, it would likely be done retrospectively by identifying risk factors that have a statistically significant impact on transplantation rates using regression analysis. We are interested in comments on specific risk adjustment public health emergencies or other local activities (for example, legislative changes on presumed consent). We are also requesting that commenters provide evidence and data sources that would be necessary to calculate the risk-adjustments recommended. Finally, we are seeking comments about any potential unintended consequence of using risk-adjustments to our measures. Depending on the substance of the public comments received, we could establish

a risk adjustment methodology in the final rule.

In order to ensure that our measures adjust to changes in medical technology and causes of death and in order to achieve the goal of doubling the number of kidneys available for transplantation by 2030, we are proposing to use our measures in the context of a comparative donation rate and organ transplantation rate relative to the highest-performing OPOs. By using comparative rates, we assume that the highest performing OPOs are adjusting their practices to reflect medical technology and other factors that may impact the number of donors and organs transplanted. Our ultimate definition of success, however, is to encourage the performance of all OPOs to cluster around the highest performers. Therefore, our proposed definition of success will be 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 for OPOs. We acknowledge that there may be other success factors for assessing performance of OPOs outside of the two outcome measures of donation rate and organ transplantation rate. Thus, we are soliciting 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.

In determining our calculations, we will establish a threshold donation rate and organ transplantation rate based on the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated. For example, if we are doing an assessment on December 31, 2024 and using data from January 1, 2023 to December 31, 2023, the threshold rates would be based on the lowest donation rate and organ transplantation rate of the top 25 percent donation and organ transplantation rates for the time period of January 1, 2022 to December 31, 2022. Since there are currently 58 OPOs, there are 15 OPO rates (rounded to the closest integer) in the top 25 percent. There are two primary benefits for using this separate cohort to establish the threshold rates: (1) The predetermined threshold rate obtained from an external source would be known to OPOs before their evaluation cycle and (2) from a

¹⁷ 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).

¹⁸ Siminoff, LA, et al. "Racial Disparities in Preferences and Perceptions Regarding Organ Donation," *JGIM*, 2006; 21:995-100.

¹⁹ Bodenheimer, HC, et al. "The Impact of Race on Organ Donation Authorization Discussed in the Context of Liver Transplantation," *Transactions of the American Clinical and Climatological Association*, Vol. 123, 2012.

statistical standpoint, such a predetermined threshold rate would be considered a known constant, not subject to random variation. If we were to use a threshold rate based on the same time period being evaluated, then the threshold rate would not be known to OPOs before their evaluation cycle. From a statistical standpoint, such a threshold rate would not be considered a constant; in that case, its uncertainty would need to be accounted for in the testing procedure, resulting in lower statistical power. To avoid this problem, we instead use a predetermined threshold rate obtained from an external source.

Then, we will determine whether the donation rates and organ transplantation rates for each of the OPOs are statistically significantly lower than the predetermined threshold rate by calculating the 95 percent confidence interval (CI) for each OPO and flagging those OPOs whose upper limit of the one-sided 95 percent CI is lower than the threshold rate. By using this approach, we allow all OPOs the opportunity to re-certify as long as their performance is not statistically significantly different from the top 25 percent.

Importantly, Executive Order 13879 recognizes the problem of organ discards. In choosing the 25 percent cutoff, we hope to encourage OPOs to successfully place every organ they procure and to improve their donation rates. We analyzed the impact of these new outcome measures on data from January 1, 2017 to December 31, 2017 and determined that if all underperforming OPOs reached the threshold rate for that time period, we would have approximately 4,900 more organs transplanted. According to the OPTN data, from that same time period, there were a total of 4,905 organs discarded, of which 3,542 were kidneys.²⁰ A recent study showed that if U.S. transplant centers expanded the type of deceased donor kidneys that they transplanted to include the lower quality kidneys, similar to those transplanted in France, there would be 17,435 more kidneys transplanted, resulting in 132,445 allograft years over an 11-year period.²¹

However, eliminating all inappropriate organ discards alone will

not be enough to achieve the 4,900 more organs transplanted that we hope to achieve in setting the top 25 percent threshold. The reason we believe a top 25 percent threshold rate is appropriate is that we also found a wide variation in donation rates among OPOs, suggesting that there is significant opportunity, especially among the lower-performing OPOs, to increase their donation rates and subsequently, their organ transplantation rates. If we had not seen such a wide variation in donation rates, we would have aligned our expected increase in organs transplanted with the number of organs discarded that we believed could be transplantable and set a lower threshold rate, such as 30 percent or 40 percent. We are seeking comments on the threshold rate cutoffs for determining success and our methodology for calculating the threshold rates.

Our proposed measures are similar to the measures presented in the study, “Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation.”²² This study describes a similar approach using the NCHS data, but uses a cause, age, and location consistent (CALC) donation measure. We are actively considering this approach as well as other alternatives and have described them in greater detail in the RIA, Section G: Alternatives Considered.

We believe that the consistency and quality of these proposed measures would be a significant improvement over the current measures because they would rely on independent data to measure donor potential. Stakeholders have increasingly brought to CMS’ and HHS’ attention that the self-reporting of data could inadvertently reward poor performance, suggesting that OPOs who are less proficient at identifying eligible deaths in their donation service area could have lower denominators, resulting in higher rates of donations. The current outcome measures also include potentially burdensome OPO self-defined and self-reported “eligible deaths” for evaluation purposes. We believe that using CDC data on inpatient deaths from the state death certificates as the denominator would greatly reduce reporting burdens on OPOs and allow them to more efficiently utilize their resources to improving donation rates and organ transplantation rates.

By establishing a definition of success that is compared with the top performing OPOs, we hope to increase the number of organs, particularly kidneys, to achieve the goal of doubling kidney transplantations by 2030. Therefore, we do not think it is appropriate for us to include a measure that assesses the OPO’s actual donation or transplantation rates based on their expected donation or transplantation rates since that measure relies on average performances to assess OPOs. Our new measures are designed to drive OPOs to perform optimally by motivating them to pursue every organ, every time, rather than setting standards at or near the current average performance. For all the reasons stated above, we believe that the proposed changes to our outcome measures would standardize the assessment of OPO performance, reduce reporting burdens on OPOs, and increase the number of transplantable organs. We would expect OPOs to continue their quality improvement efforts through their Quality Assurance and Performance Improvement (QAPI) program, as required by our rules at § 486.348, and they would continue to seek and implement best practices for organ procurement. We note that OPOs are already required to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, and we expect them to use the data provided as part of their QAPI program.

In the current regulations, we have specifically separated OPOs operating exclusively in noncontiguous States, Commonwealths, Territories, or possessions from the other OPOs. In this proposed rule, we are not proposing different outcome measures for these OPOs because we believe the residents of those areas deserve every opportunity for organ transplantation and that OPOs servicing those areas should perform at the same level as the top 25 percent of OPOs. Although these OPOs may not be in a DSA with transplant hospitals capable of transplanting all organs that possibly could be procured, organs are frequently offered to hospitals outside of the DSAs in which they are procured. Further, we believe that geographical distances may not be as much of a hurdle as previously believed. For example, the OPO in Puerto Rico is geographically proximal to the continental U.S. where there are numerous transplant hospitals. The OPO in Hawaii may have more difficulty placing all organs given how long it takes to reach the continental

²⁰ OPTN databased accessed on August 28, 2019 (<https://optn.transplant.hrsa.gov/data/view-data-reports/build-advanced/>).

²¹ Aubert, Reese, et al, “Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance,” *JAMA Intern Med.* Published online August 26, 2019. Doi:10.1001/jamainternmed.2019.2322.

²² Goldberg D, Karp S, et al, “Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation,” *Am J Transplant.* 2019;00:1–6.

U.S. from there; however, we understand that there are new technologies that could be employed to allow for transport for organs that cannot tolerate longer transport time (such as for kidneys, livers, and lungs) and that the geographic distance may be less of a barrier to placement of these organs. We are seeking comments on this proposed change, particularly 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 the RIA, Section G: Alternatives Considered.

B. Proposed Changes to Definitions (§ 486.302) and Re-Certification and Competition Processes (§ 486.316)

In line with our proposal to change the outcome measures at § 486.318, as discussed in section II.A. of this document, we are proposing to modify language in § 486.316(a)(1) that an OPO must meet two out of the three outcome measures at § 486.318 and at § 486.316(a)(3) that for the 2022 re-certification cycle only that an OPO must meet one out of the two outcome measures described in § 486.318 (a)(1) and (3) and (b)(1) and (3). We are also proposing to remove several definitions from § 486.302, since these terms would no longer apply. Specifically, we are proposing to remove the definitions of “eligible death,” “eligible donor,” “expected donation rate,” “observed donation rate”, and “Standard criteria donor (SCD)”. Finally, we are proposing to modify the definition of “donor” as described in section II.A of this rule and are proposing to add the terms “death that is not an absolute contraindication to organ donation,” “donation rate,” “donor potential,” and “organ transplantation rate.” We are proposing to define these terms as follows:

- “Death that is not an absolute contraindication to organ donation”: All deaths from the state death certificates except those with any cause of death identified by the specific ICD-10 codes that would preclude donation under any circumstance.
- “Donor potential”: Is the number of inpatient deaths with in the DSA among patients 75 and younger with any cause of death that is not an absolute contraindication to organ donation.
- “Donation rate”: Is the number of donors as a percentage of the donor potential.
- “Organ transplantation rate”: The number of organs transplanted as a percentage of the donor potential.

Accordingly, we are proposing to modify the reporting requirements in § 486.328 to eliminate the reporting of the “Number of eligible deaths” and modifying the reporting of “Number of eligible donors” to “Number of donors.” In addition, we are proposing to revise the language that incorrectly refers to the “Scientific Registry of Transplant Beneficiaries” and “DHHS” in this section. We would instead include the terms “Scientific Registry of Transplant Recipients” and “HHS.” We are requesting comments on these proposals.

Sections 486.316 (c) and (d) describe the criteria that an OPO must meet in order to compete for an open service area and the criteria for selection of an OPO for an open service area, respectively. Once an OPO is decertified and their agreement is terminated, either voluntarily or involuntarily as described in § 486.312, the OPO’s service area is open to competition from other OPOs. Under § 486.316(b), the OPO that has been decertified is not permitted to compete for its service area or any other service area. If an OPO is interested in competing for an open service area, the OPO 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. These current requirements for competition once an OPO is de-certified will continue to apply if we finalize the changes to the outcome measures described in this proposed rule. If no OPO applies to compete for a de-certified OPO’s open area, § 486.316 (e) allows for CMS to select a single OPO to take over the entire open area or adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS would select the new OPO to take over the entire open area based on the criteria set out at § 486.316(d); however, our regulations do not require that the DSAs merge when a new OPO takes over. However, we acknowledge that decertification of multiple OPOs could require changes to OPTN policies. We are soliciting comments on our current regulations related to assigning an open DSA in the case where no OPO applies to compete for that open area or in the case where CMS selects an OPO to take over the entire open DSA, but the OPO refuses to do so.

Our goal is to ensure continuous coverage of an OPO service area in the event an OPO is decertified. Although we would attempt to minimize disruptions to organ procurement services in an open service area as much

as possible, we acknowledge that there is the potential for disruption when one or multiple OPOs are decertified. We are therefore seeking comments on ways that we can reduce any potential disruptions when an OPO is decertified and their service area is open to competition. We are particularly interested in comments on such potential options including ways that we could improve or ease the process of transitioning an open service area from the decertified OPO to another OPO and other related factors that may impact organ donation or the OPO’s ability to meet the outcome measures.

OPOs are also required to meet certain criteria in order to compete for an open service area. In general, OPOs must meet two out of the three outcome measures requirements at § 486.318 (with the exception of the 2022 re-certification cycle where OPOs are required to meet one out of two outcome measures) and the OPO must be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360. The OPO that is applying to compete for the open service area must also meet additional criteria, including that 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; and
- Donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area.
- The OPO must also compete for the entire service area.

These existing requirements, however, are not consistent with our proposed method of assessing an OPO’s performance, which would compare OPOs to an established threshold rate (using the lowest rate among the top 25 percent of donation rates and organ transplantation rates during the 12-month period prior to the time period that is being evaluated). We therefore are proposing to remove the additional requirement for an 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) and the requirement that an OPO’s donation rate be at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area. We believe that OPOs will be held to a high standard of performance under the new proposed outcome measures. This would ensure that any OPO that is seeking to compete for an open service

area performs significantly better than the de-certified OPO. By meeting the outcome measure requirements, an OPO would also demonstrate its ability to perform well in its own DSA. We are soliciting comments on whether there should be additional criteria beyond what we are proposing to include here to demonstrate that an OPO is performing significantly better than the de-certified OPO. We are not proposing to eliminate the requirement that OPOs compete for the entire service area. Maintaining this requirement will prevent competition of partial service areas, which may lead to OPOs attempting to obtain certain neighboring service areas purely for business reasons, with no regard to whether the OPO can increase organ donation in those areas.

Finally, the current requirements list certain criteria for selection of an OPO for designation of an open service area including:

- Performance on the outcome measures at § 486.318;
- Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360;
- Contiguity to the open service area; and
- Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. 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.

We are proposing to make a clarifying change to these requirements to emphasize that CMS will consider the current criteria when determining which OPO to designate for an open service area. Our original intent was to list these criteria as guidelines as opposed to requirements that an OPO must meet in order to be selected. For example, we could select a high performing OPO that meets the outcome measures and other CfC requirements, but may not be contiguous to the open service area. This change would provide clarity to the circumstances under which CMS would select an OPO to take over an open service area.

We are soliciting comments on all of our proposed changes to § 486.316. We are especially interested in comments on whether the contiguity of an OPO to the open service area is still an important factor to consider when selecting an OPO to take over an open service area. Since we implemented the OPO CfCs in 2006, there have been

advances in technology that have improved organ procurement and transplantation and that have changed the way and the speed, in which OPOs and transplant centers communicate with each other. It may be the case that an OPO that is taking over an open service area may no longer need to be contiguous to the open service, especially if that OPO is a high performer that could increase the number of organs procured and eventually transplanted in an open service area. We are seeking comments on whether this specific criterion is still applicable.

We are also soliciting comments on whether we should reconsider opening the service area of every OPO for competition at the conclusion of every re-certification cycle, regardless of whether the OPO met the outcome performance standards for the prior re-certification cycle. Under our current regulations, OPOs that successfully pass the outcome and process performance measures and comply with our CfCs are automatically renewed. Only OPOs that are unsuccessful in meeting these regulatory requirements could be de-certified. We are seeking comments on an alternative approach where all OPO service areas would be open for competition at the end of each agreement cycle. Any OPO seeking to renew the agreement could face competition from another OPO that wanted to take over that DSA.

In 2005, we proposed opening every OPO's service area for competition at the end of every re-certification cycle. Specifically, we proposed that once we determined that an OPO met the outcome measures at proposed § 486.318 for the previous re-certification cycle and was found to be in compliance with the process performance measures at §§ 486.320 through 486.360, that we would open the OPO's service area for competition from other OPOs. Some of the comments we received at the time included concerns that such a proposal would threaten cooperation and collaboration between OPOs, and would impact the sharing of best practices and change strategies between OPOs (71 FR 30996). In response to this feedback, we finalized a modified version of this proposal whereby this process would only occur in the service areas of OPOs that have been de-certified. We are seeking comments as to whether circumstances in the past 15 years have changed that would warrant our reconsidering our policy of limiting the competition to just open service areas. If we were to consider a policy to open the service areas of all OPOs, we seek

comment on how much effort it would take to prepare a bid for the open service area, how this type of competition may affect organ donation, and how it would affect cooperation when transplant centers are receiving organs from outside the service area.

C. Proposed Changes to the Re-Certification Cycle (§ 486.302 and § 486.318)

In accordance with our rules at § 486.308(b)(1), OPOs are re-certified on a four-year cycle. Currently, OPOs are assessed based on 36 months of data analysis. This data period begins six months after the certification period starts and ends six months prior to the end of the certification cycle. CMS analyzes these data and determines if the OPO is out of compliance with outcomes prior to the end of the current cycle and prior to the start of the next cycle. OPOs are given interim reports every six months during the certification period to gauge performance. The survey and certification administrative enforcement actions begin six months before the end of the certification period. For instance, the data collection period for the previous re-certification cycle ended on December 31, 2017. Re-certification surveys were conducted January 1, 2018 through July 31, 2018 and outcomes measures were assessed for the 36 month period beginning January 1, 2015 through December 31, 2017, with the next certification cycle beginning on August 1, 2018. We recognize that waiting a full 36 months to assess and take actions to improve OPO performance would result in numerous lost opportunities to procure and transplant potentially viable organs. Therefore, we propose that the outcome measures assessment occur at least every year and be based on data from the most recent 12 months of data from the state death certificates. OPOs that are flagged as having donation rates or organ transplantation rates that are statistically significantly less than the threshold rates established by the top 25 percent of OPOs are expected to take actions to improve their performance and include the specific actions that they will undertake to improve their outcome measures in their QAPI program. Currently, OPOs receive data on their performance from the SRTR every six months, so our proposed methodology would not provide assessments as frequently. But, this approach could provide for a continuous assessment of OPO performance and allow for more responsive performance improvement actions from low performers because of

the role of the QAPI program. In the spirit of transparency, we intend make these outcome measures public at each assessment.

Although the assessments would occur at least once every 12 months, no OPO may be de-certified until the end of the re-certification cycle, except in cases of urgent need.²³ We are proposing to use the most recent prior 12 months of data at the last assessment cycle before re-certification to be the basis for de-certification. The reason we are proposing to use only the prior 12 months of data is that we do not want to penalize an OPO who has made legitimate and successful efforts to improve their performance by including the older data, nor do we want to reward an OPO whose recent performance has fallen to be able to rely on past performance as the basis for a subsequent four-year re-certification. In the past, we have used 36 months of data to determine re-certification, so we are seeking comments on the use of the shorter length of data as opposed to all the data during the re-certification cycle. Although using the longer period of time would include data that does not reflect the OPO's current status, it would allow OPOs who had been performing adequately through most of the four-year cycle to remain certified even if they had a lapse in performance at the last cycle. We are also seeking comments on other approaches to use the data to identify high-performing OPOs for re-certification.

After considering public comments and finalizing this rule, we expect to begin calculations of the outcomes measures before the beginning of the next re-certification cycle in 2022. We are requesting comments on this proposed change to the applicability of the outcome measure requirements for the cycle beginning in 2022 and ending in 2026.

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

QAPI requirements for OPOs were first established in 2006 (71 FR 31054). OPOs are required to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation

services, including services provided under contract or arrangement under § 486.348. In addition, an OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to certain OPO activities, and the OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

A QAPI program is an important, data driven process that allows health care entities to assess their functioning continuously and make changes to improve their quality and efficiency over time. Since we are proposing to revise the outcome measure requirements at § 486.318 and the re-certification process at § 486.316, we believe that OPOs should also be required to include a process to address and improve poor performance on their outcome measures as part of their QAPI program. We currently do not have such a requirement for an OPO's QAPI program, but because OPOs are re-certified every 4 years, it is important that OPOs continuously strive to improve outcomes over the course of the re-certification cycle. An OPO's QAPI program provides a process to achieve these improvements. We, therefore, are proposing 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 de-certification. 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 have previously described in this proposed rule, we are proposing that an OPO's performance on the outcome measures be assessed at least every 12 months, based on the most recent prior 12 months of data. We would expect OPOs to use the data that are obtained from each assessment to drive changes to their QAPI program in order to improve their performance on the outcome measures. If proactive changes are made early in the re-certification cycle, an OPO would be able to begin to address poor performance on the outcome measures early in the re-certification cycle and prior to the re-certification determination. We are additionally interested in whether the QAPI process is sufficiently robust to capture year

over year improvements, as well as other quantitative factors that may not be captured in our proposed outcome metrics. As such, we encourage commenters to consider ways the QAPI process may be modified or enhanced to better assess OPO performance relative to past performance and to other OPOs. As proposed in this rule, an OPO that was deemed compliant on its QAPI, but did not meet one or both of the proposed outcome measures would be subject to decertification.

E. Solicitation of Comments

In addition to our requests for comments throughout the preamble, we are specifically seeking the public's input on the following questions:

- 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 centers, organ donation, patient access, and transplant recipients?

- Are there potential additional compliance burdens on OPOs or transplant centers if the two proposed measures were finalized? Please explain.

In § 486.316(c)(3), we require an OPO to compete for an entire service area as a criterion to compete for an open service area. At this time, we are not proposing to change this requirement but would like comments as to whether we should consider revising this subsection and redefining the open service area for competition. Although we have proposed eliminating the definition of "eligible deaths," we have not proposed to remove the requirement that OPOs conduct monthly death record reviews. We are seeking comments as to whether § 486.348(b)

²³ The Organ Procurement Organization Certification Act of 2000 changed the re-certification cycle from every 2 years to every 4 years; § 486.312(d) and § 486.302 states that CMS can give written notice of de-certification in cases of urgent need and defines urgent need as occurring when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ beneficiary.

should be revised or removed altogether to eliminate such reviews. Please include justifications and explanations in your comments.

We encourage detailed comments that answer all of the aforementioned questions. Additionally, in the RIA, Section G: Alternatives considered, we discuss a number of different alternatives that we are actively considering. These alternatives examine different type of denominators, different statistical confidence intervals for calculations, and different threshold rates for assessment. We are actively considering these policy alternatives and are seeking comments on them.

III. 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 are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

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

At § 486.316(b), we are proposing 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.

The current information collection request for the OPO CfC (OMB Control Number 0938–0688, Exp. February 2021) estimates that one OPO would face de-certification per year, and under the proposed outcome measures, this number would have potential to increase. We do not know exactly how many would be de-certified under these new measures; however, based on the improvement required to meet the proposed measures it is possible that approximately 7 to 33 OPOs could be de-certified. Assuming some number of these de-certifications are upheld, their respective service areas would be opened for competition.

Under § 486.316(b), 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. 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 conditions for coverage at §§ 486.320 through 486.348. The OPO must also compete for the entire service area.

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 will refer to this documentation as a plan.

Based on historical data and our previous experience with the OPOs, we would expect a total of nine OPOs will want to compete for a new service area and three of those OPOs may want to compete for more than one service area. Thus, we believe there will be a total of 12 plans that will need to be developed for the competition process.

We believe that developing each plan 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 a plan, we estimate each competition would require 1,248 burden hours for all 9 OPOs to complete 12 plans and would cost all 9 OPOs \$79,416 ((\$71 RN × 30 hours × 9 OPOs)

+ (\$71 organ procurement coordinator × 30 hours × 9 OPOs) + (\$107 medical director × 12 hours × 9 OPOs) + (\$107 OPO director × 30 × 9 OPOs) + (\$35 medical secretary × 2 hours × 9 OPOs)). 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 9 OPOs to prepare 12 plans would be 312 (1,248/4) and the annual cost estimate would be \$19,854 (\$79,416/4).

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

We are proposing 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, Exp. February 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 (42 CFR 121). Thus, we are not attributing any quantifiable burden reduction to this proposed change.

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

At § 486.348(d) we are proposing 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. Assessments would occur at least every 12 months with the most recent prior 12 months of available data, meaning there would be 3 assessments in each 4 year re-certification cycle that might require modifications to an OPO's QAPI program.

As stated in the information collection request for the OPO requirements (OMB Control Number 0938–0688, Exp. February 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 proposed change would

impose any additional ongoing quantifiable burden.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by February 21, 2020.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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 the following Tables 3 and 4). Recent article titles tell the story as well: “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.”²⁴ 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 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 and 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.”

We note that the Secretary recently issued a final rule to reduce regulatory burden on several types of health care providers (“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, September 30, 2019) that directly addresses 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 and allowing transplantable organs to be discarded and sicker patients to die without a transplant. Those performance standards rewarded very high one-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 regulatory impact analysis (RIA) for CMS–3346–F, there is the potential for regulatory reform to reduce the number of “transplant quality” discarded organs, and through transplantation of those organs, save the lives of many patients each year.

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 applies directly to this proposed rule.

B. Scope of Review

We have examined the impacts of this proposed 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), E.O. 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

E.O. 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 E.O. 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 E.O.

An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any one year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of this rulemaking.

C. Effects on OPO Performance

We are proposing two new outcome measures that would be used to assess an OPO’s performance: A measure of an OPO’s donation rate and organ

²⁴ 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.

transplantation rate. Table 3 shows current performance using the donation rate outcome measure that we propose derived from data spanning January 1, 2017 to December 31, 2017. The number of potential donors is similar to the measure used in the current regulatory provisions (on numbers of deceased persons that potentially qualify as organ donors, but the proposed measure would be nationally standardized, using an objective data source); however, the performance variable 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 task 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, kidneys, intestine, and pancreata (those transplanted or sent for research) count towards this measure of success.

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. We are also including, in the Appendix, a map for each proposed measure that depicts geographic trends in performance. 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>.²⁵ These tables show the performance required of each OPO to reach the proposed performance standard, including an allowance for statistical “confidence” (one-tailed test), for the OPOs that fell below the standard. Confidence intervals are

²⁵ 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.

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 (Wilson and Hilferty 1931, Breslow and Day 1987, Kulkarni and Hemangi 2012) is used to calculate the confidence interval for the transplant rate of each OPO.

We are committed to using all 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 proposed metrics.

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Table 3. OPO Donor Rate for Calendar 2017 with Top 25 Percent Cutoff (4.11 incl. Confidence Interval) (OPOs below Threshold in Bold and Italics)

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	149	5.65	6.45	0	0.00%
Lifesharing - A Donate Life Organization (CASD)	1,986	109	5.49	6.42	0	0.00%
DonorConnect (UTOP)	2,048	107	5.22	6.12	0	0.00%
Midwest Transplant Network (MWOB)	4,297	230	5.35	5.96	0	0.00%
Versiti (WIDN)	1,844	92	4.99	5.92	0	0.00%
Nevada Donor Network (NVLV)	2,367	118	4.99	5.80	0	0.00%
Gift of Life Donor Program (PADV)	9,771	509	5.21	5.60	0	0.00%
Donor Network of Arizona (AZOB)	4,991	241	4.83	5.36	0	0.00%
Nebraska Organ Recovery (NEOR)	1,519	66	4.34	5.33	0	0.00%
The Living Legacy Foundation of Maryland (MDPC)	3,171	143	4.51	5.17	0	0.00%
ConnectLife (NYWN)	1,239	50	4.04	5.10	0	0.00%
LifeShare of Oklahoma (OKOP)	3,954	177	4.48	5.06	0	0.00%
Washington Regional Transplant Community (DCTC)	3,158	138	4.37	5.03	0	0.00%
OurLegacy - FL (FLFH)	3,541	153	4.32	4.93	0	0.00%
Southwest Transplant Alliance (TXSB)	8,727	373	4.27	4.65	0	0.00%
Mid-America Transplant Services (MOMA)	5,266	217	4.12	4.61	0	0.00%
Donor Alliance (CORS)	3,469	137	3.95	4.55	0	0.00%
LifeGift (TXGC)	8,579	356	4.15	4.52	0	0.00%
Sierra Donor Services (CAGS)	2,092	78	3.73	4.50	0	0.00%
Lifeshare Carolinas (NCCM)	2,599	98	3.77	4.46	0	0.00%
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	372	4.08	4.45	0	0.00%
Tennessee Donor Services (TNDS)	7,189	283	3.94	4.34	0	0.00%

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
Center for Organ Recovery and Education (PATF)	5,500	212	3.85	4.31	0	0.00%
LifeSource - MN (MNOP)	4,707	173	3.68	4.17	0	0.00%
New Mexico Donor Services (NMOP)	1,628	54	3.32	4.16	0	0.00%
<i>Legacy of Life - Hawaii (HIOP)</i>	<i>1,077</i>	<i>33</i>	<i>3.06</i>	<i>4.11</i>	<i>1</i>	<i>0.00%</i>
<i>LifeCenter Organ Donor Network (OHOV)</i>	<i>2,029</i>	<i>68</i>	<i>3.35</i>	<i>4.10</i>	<i>1</i>	<i>0.24%</i>
<i>LifeCenter Northwest (WALC)</i>	<i>6,408</i>	<i>236</i>	<i>3.68</i>	<i>4.10</i>	<i>1</i>	<i>0.24%</i>
<i>New Jersey Sharing Network (NJTO)</i>	<i>5,093</i>	<i>184</i>	<i>3.61</i>	<i>4.08</i>	<i>2</i>	<i>0.74%</i>
<i>LifeBanc (OHLB)</i>	<i>4,149</i>	<i>147</i>	<i>3.54</i>	<i>4.06</i>	<i>2</i>	<i>1.23%</i>
<i>LifeLink of Florida (FLWC)</i>	<i>5,665</i>	<i>205</i>	<i>3.62</i>	<i>4.06</i>	<i>3</i>	<i>1.23%</i>
<i>Louisiana Organ Procurement Agency (LAOP)</i>	<i>5,072</i>	<i>182</i>	<i>3.59</i>	<i>4.05</i>	<i>3</i>	<i>1.48%</i>
<i>Life Alliance Organ Recovery Agency (FLMP)</i>	<i>4,931</i>	<i>175</i>	<i>3.55</i>	<i>4.02</i>	<i>5</i>	<i>2.24%</i>
<i>Lifeline of Ohio (OHLP)</i>	<i>3,587</i>	<i>122</i>	<i>3.40</i>	<i>3.95</i>	<i>6</i>	<i>4.05%</i>
<i>Sharing Hope SC (SCOP)</i>	<i>4,598</i>	<i>156</i>	<i>3.39</i>	<i>3.87</i>	<i>11</i>	<i>6.20%</i>
<i>Donor Network West (CADN)</i>	<i>8,699</i>	<i>298</i>	<i>3.43</i>	<i>3.77</i>	<i>29</i>	<i>9.02%</i>
<i>OneLegacy (CAOP)</i>	<i>12,725</i>	<i>442</i>	<i>3.47</i>	<i>3.75</i>	<i>44</i>	<i>9.60%</i>
<i>Pacific Northwest Transplant Bank (ORUO)</i>	<i>3,791</i>	<i>119</i>	<i>3.14</i>	<i>3.65</i>	<i>17</i>	<i>12.60%</i>
<i>Life Connection of Ohio (OHLC)</i>	<i>2,072</i>	<i>61</i>	<i>2.94</i>	<i>3.65</i>	<i>9</i>	<i>12.60%</i>
<i>Gift of Life Michigan (MIOP)</i>	<i>8,736</i>	<i>289</i>	<i>3.31</i>	<i>3.64</i>	<i>39</i>	<i>12.91%</i>
<i>Texas Organ Sharing Alliance (TXSA)</i>	<i>5,079</i>	<i>162</i>	<i>3.19</i>	<i>3.63</i>	<i>23</i>	<i>13.22%</i>
<i>LifeLink of Georgia (GALL)</i>	<i>8,573</i>	<i>280</i>	<i>3.27</i>	<i>3.60</i>	<i>42</i>	<i>14.17%</i>
<i>LifeQuest Organ Recovery Services (FLUF)</i>	<i>4,234</i>	<i>132</i>	<i>3.12</i>	<i>3.60</i>	<i>21</i>	<i>14.17%</i>
<i>New England Organ Bank (MAOB)</i>	<i>8,712</i>	<i>284</i>	<i>3.26</i>	<i>3.59</i>	<i>43</i>	<i>14.48%</i>
<i>Mid-South Transplant Foundation (TNMS)</i>	<i>2,305</i>	<i>67</i>	<i>2.91</i>	<i>3.56</i>	<i>12</i>	<i>15.45%</i>

OPO Name (Primary State)	Potential Donors (Denominator)	Total Donors	Donation Rate	Upper Bound with Confidence Interval	Additional Donors Needed to Reach 25% Cutoff	Estimated Improvement Required
<i>Carolina Donor Services (NCNC)</i>	6,781	199	2.93	3.30	53	24.55%
<i>LiveOnNY (NYRT)</i>	9,385	278	2.96	3.27	76	25.69%
<i>Indiana Donor Network (INOP)</i>	5,783	161	2.78	3.17	52	29.65%
<i>Iowa Donor Network (IAOP)</i>	2,136	52	2.43	3.07	21	33.88%
<i>Mississippi Organ Recovery Agency (MSOP)</i>	2,927	74	2.53	3.07	29	33.88%
<i>LifeNet Health (VATB)</i>	5,449	144	2.64	3.03	56	35.64%
<i>LifeLink of Puerto Rico (PRL)</i>	3,205	78	2.43	2.94	35	39.80%
<i>LifeChoice Donor Services (CTOP)</i>	2,561	60	2.34	2.91	29	41.24%
<i>Center for Donation and Transplant (NYAP)</i>	2,451	55	2.24	2.81	30	46.26%
<i>Kentucky Organ Donor Affiliates (KYDA)</i>	5,389	107	1.99	2.33	90	76.39%
<i>Arkansas Regional Organ Recovery Agency (AROR)</i>	2,604	46	1.77	2.27	44	81.06%
<i>Legacy of Hope - Alabama (ALOB)</i>	8,025	159	1.98	2.26	141	81.86%
<i>Finger Lakes Donor Recovery Network (NYFL)</i>	2,486	41	1.65	2.15	45	91.16%
Totals	272,105	9,731			1,015	

Table 4 shows the current range of organ transplantation performance, using the new proposed 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.²⁶ According to the NCHS, there are about 2.8 million deaths each year in

²⁶These 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.

the U.S., but the potential donor pool is far lower because it only includes those who die in hospitals, who are age 75 or less, and who have no contraindications to donation (such as metastatic cancers). Table 4 shows that organ transplantation rates range from 19.44 at the highest levels to 4.47 (using data from calendar year 2017), a range of about four to one from highest to lowest. The top one-fourth of OPOs achieve rates above 12 donors/100 inpatient deaths, more than double the rates of many lower performing OPOs. The top-performing OPOs are geographically and

demographically diverse, with potential donor pools ranging from about 2,000 deaths a year to almost 10,000 a year. We recognize that some OPOs have fewer transplant programs within their service areas than others, but allocation policies allow OPOs to place organs outside their DSA. The organ match run, which lists all potential recipients for a donated organ, includes eligible patients on the waiting list for that particular organ and organs are often offered to hospitals outside of the DSAs in which the organs were procured.

Table 4. OPO Transplant (TX) Rates for Calendar 2017 with Top 25 Percent Cutoff**(13.73 incl. Confidence Interval)** (OPOs below Threshold in Bold and Italics)

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
Lifesharing - A Donate Life Organization (CASD)	1,986	386	19.44	21.14	0	0.00%
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	499	18.92	20.37	0	0.00%
Midwest Transplant Network (MWOB)	4,297	821	19.11	20.24	0	0.00%
DonorConnect (UTOP)	2,048	353	17.24	18.82	0	0.00%
Versiti (WIDN)	1,844	314	17.03	18.70	0	0.00%
Donor Network of Arizona (AZOB)	4,991	847	16.97	17.96	0	0.00%
Nebraska Organ Recovery (NEOR)	1,519	245	16.13	17.93	0	0.00%
The Living Legacy Foundation of Maryland (MDPC)	3,171	500	15.77	16.98	0	0.00%
Nevada Donor Network (NVLV)	2,367	367	15.50	16.90	0	0.00%
Gift of Life Donor Program (PADV)	9,771	1,575	16.12	16.80	0	0.00%
Washington Regional Transplant Community (DCTC)	3,158	462	14.63	15.80	0	0.00%
OurLegacy - FL (FLFH)	3,541	506	14.29	15.38	0	0.00%
Southwest Transplant Alliance (TXSB)	8,727	1,275	14.61	15.30	0	0.00%
LifeGift (TXGC)	8,579	1,244	14.50	15.20	0	0.00%
Lifeshare Carolinas (NCCM)	2,599	349	13.43	14.67	0	0.00%
Mid-America Transplant Services (MOMA)	5,266	719	13.65	14.52	0	0.00%
ConnectLife (NYWN)	1,239	156	12.59	14.38	0	0.00%
LifeShare of Oklahoma (OKOP)	3,954	528	13.35	14.35	0	0.00%
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	1,243	13.65	14.30	0	0.00%

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
Louisiana Organ Procurement Agency (LAOP)	5,072	667	13.15	14.02	0	0.00%
Tennessee Donor Services (TNDS)	7,189	944	13.13	13.86	0	0.00%
Sierra Donor Services (CAGS)	2,092	260	12.43	13.77	0	0.00%
<i>LifeSource - MN (MNOP)</i>	<i>4,707</i>	<i>589</i>	<i>12.51</i>	<i>13.40</i>	<i>16</i>	<i>2.46%</i>
<i>Sharing Hope SC (SCOP)</i>	<i>4,598</i>	<i>564</i>	<i>12.27</i>	<i>13.15</i>	<i>26</i>	<i>4.41%</i>
<i>Donor Alliance (CORS)</i>	<i>3,469</i>	<i>410</i>	<i>11.82</i>	<i>12.83</i>	<i>31</i>	<i>7.01%</i>
<i>Donor Network West (CADN)</i>	<i>8,699</i>	<i>1,058</i>	<i>12.16</i>	<i>12.80</i>	<i>80</i>	<i>7.27%</i>
<i>LifeBanc (OHLB)</i>	<i>4,149</i>	<i>479</i>	<i>11.54</i>	<i>12.45</i>	<i>52</i>	<i>10.28%</i>
<i>Lifeline of Ohio (OHLP)</i>	<i>3,587</i>	<i>410</i>	<i>11.43</i>	<i>12.40</i>	<i>46</i>	<i>10.73%</i>
<i>Center for Organ Recovery and Education (PATF)</i>	<i>5,500</i>	<i>637</i>	<i>11.58</i>	<i>12.37</i>	<i>73</i>	<i>10.99%</i>
<i>LifeCenter Northwest (WALC)</i>	<i>6,408</i>	<i>743</i>	<i>11.59</i>	<i>12.32</i>	<i>88</i>	<i>11.44%</i>
<i>Texas Organ Sharing Alliance (TXSA)</i>	<i>5,079</i>	<i>581</i>	<i>11.44</i>	<i>12.25</i>	<i>73</i>	<i>12.08%</i>
<i>LifeLink of Florida (FLWC)</i>	<i>5,665</i>	<i>650</i>	<i>11.47</i>	<i>12.24</i>	<i>82</i>	<i>12.17%</i>
<i>OneLegacy (CAOP)</i>	<i>12,725</i>	<i>1,468</i>	<i>11.54</i>	<i>12.04</i>	<i>210</i>	<i>14.04%</i>
<i>New Mexico Donor Services (NMOP)</i>	<i>1,628</i>	<i>171</i>	<i>10.50</i>	<i>11.92</i>	<i>28</i>	<i>15.18%</i>
<i>New Jersey Sharing Network (NJTO)</i>	<i>5,093</i>	<i>565</i>	<i>11.09</i>	<i>11.89</i>	<i>91</i>	<i>15.48%</i>
<i>LifeCenter Organ Donor Network (OHOV)</i>	<i>2,029</i>	<i>215</i>	<i>10.60</i>	<i>11.86</i>	<i>36</i>	<i>15.77%</i>
<i>Indiana Donor Network (INOP)</i>	<i>5,783</i>	<i>627</i>	<i>10.84</i>	<i>11.58</i>	<i>121</i>	<i>18.57%</i>
<i>Life Alliance Organ Recovery Agency (FLMP)</i>	<i>4,931</i>	<i>515</i>	<i>10.44</i>	<i>11.23</i>	<i>119</i>	<i>22.26%</i>
<i>New England Organ Bank (MAOB)</i>	<i>8,712</i>	<i>920</i>	<i>10.56</i>	<i>11.15</i>	<i>219</i>	<i>23.14%</i>
<i>Carolina Donor Services (NCNC)</i>	<i>6,781</i>	<i>710</i>	<i>10.47</i>	<i>11.14</i>	<i>171</i>	<i>23.25%</i>
<i>LifeQuest Organ Recovery Services (FLUF)</i>	<i>4,234</i>	<i>430</i>	<i>10.16</i>	<i>11.00</i>	<i>112</i>	<i>24.82%</i>
<i>LifeLink of Georgia (GALL)</i>	<i>8,573</i>	<i>883</i>	<i>10.30</i>	<i>10.89</i>	<i>238</i>	<i>26.08%</i>

OPO Name (Primary State)	Potential Donors (Denominator)	Number TX	TX Rate	Upper Bound with Confidence Interval	Additional Organs Needed to Reach 25% Cutoff	Estimated Improvement Required
<i>Pacific Northwest Transplant Bank (ORUO)</i>	3,791	376	9.92	10.80	107	27.13%
<i>Gift of Life Michigan (MIOP)</i>	8,736	888	10.16	10.74	255	27.84%
<i>Mid-South Transplant Foundation (TNMS)</i>	2,305	214	9.28	10.40	73	32.02%
<i>LiveOnNY (NYRT)</i>	9,385	907	9.66	10.21	323	34.48%
<i>Legacy of Life - Hawaii (HIOP)</i>	1,077	90	8.36	9.96	38	37.85%
<i>Life Connection of Ohio (OHLIC)</i>	2,072	180	8.69	9.83	77	39.67%
<i>LifeNet Health (VATB)</i>	5,449	493	9.05	9.75	210	40.82%
<i>Mississippi Organ Recovery Agency (MSOP)</i>	2,927	255	8.71	9.66	114	42.13%
<i>Iowa Donor Network (IAOP)</i>	2,136	165	7.72	8.79	100	56.20%
<i>LifeChoice Donor Services (CTOP)</i>	2,561	190	7.42	8.37	131	64.04%
<i>Kentucky Organ Donor Affiliates (KYDA)</i>	5,389	395	7.33	7.97	300	72.27%
<i>LifeLink of Puerto Rico (PRL)</i>	3,205	217	6.77	7.58	189	81.13%
<i>Center for Donation and Transplant (NYAP)</i>	2,451	162	6.61	7.53	145	82.34%
<i>Legacy of Hope - Alabama (ALOB)</i>	8,025	496	6.18	6.66	551	106.16%
<i>Arkansas Regional Organ Recovery Agency (AROR)</i>	2,604	149	5.72	6.56	178	109.30%
<i>Finger Lakes Donor Recovery Network (NYFL)</i>	2,486	111	4.47	5.23	200	162.52%
Totals	272,105	32,173			4,903	

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Both proposed outcome measures 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 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 would replace the non-standardized criteria for

“eligible” donors as determined by each OPO. 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.”²⁷ The proposed measures do not control

²⁷ Goldberg D, et al, “Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States,” *AmJTransplant* 2017; 17:3183–3192.

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.²⁸ Regardless, it is our belief that the untapped donor and organ potential is sufficiently large in every DSA so that every OPO has

²⁸ Adler, et al “Is Donor Service Area Market Competition Associated with Organ Procurement Organization Performance?” *Transplantation* 2016; 100; 1349–1355.

both potential donors, organs, and transplant recipients to exceed its current performance level.

Tables 3 and 4 also show a very important quantitative result: At present, there are about 10,000 deceased donors a year, which is only about three percent of the 272,000 potential donors in 2017. Importantly, the proposed criteria for potential donors already exclude many deaths, and focus on decedents with greater potential to provide transplantable organs. Hence, all OPOs will have a pool of potential donors many times higher than the number of donors and organs needed to meet the proposed performance standards.

If the number of donors at the lower-performing OPOs were to reach what is now the 75th percentile of achievement, the number of donors would increase by over one thousand by the end of the four-year performance period. Both through this increase, and greater success in maximizing the number of organs actually transplanted from each donor, achieving the 75th percentile for the transplant rate would increase the number of such transplants from about 32,000 by as many as 6,000 by 2024, and by as many as 10,000 by 2026, for a total of about 42,000 in that year (see Table 12). Achieving higher success rates would be unlikely to occur in just the lower performers, and these estimates assume improvements at all current levels of performance as better techniques and methods are identified and widely adopted. 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 OPOs. There may be future improvements as well, but our estimates do not assume any major breakthroughs will be routinely available in the near term. In September 2019, the National Institutes of Health reported that a new method of

preserving livers for transplantation would potentially increase the viability of livers from nine to 27 hours, but this is still in a development stage.²⁹ Our estimates in Tables 5 and 6 assume that all OPOs would achieve either the 75th percentile targets, or increase performance on both measures by 20 percent, whichever is greater.

Nothing guarantees that all OPOs will manage to meet the standards if finalized as proposed. But, the administrative steps we propose to take, the periodic assessments, and the incentives for an OPO to maintain certification at the end of the four-year evaluation period will provide both means and incentives for all OPOs to meet or exceed our proposed standards. Furthermore, there is no need to wait until the end of the four-year period to take action regarding any OPOs that are underperforming. With continuous assessment and public disclosure of the information, OPOs who cannot achieve the outcome measures may decide to voluntarily de-certify and allow a high-performing OPO to take over the DSA, even before the end of the re-certification cycle or form a partnership with a high-performing OPO and allow that OPO to take over the management of the DSA. Our low-end cost and performance calculations assume that this could be avoided through adoption of proven techniques and improved leadership and management by lower-performing OPOs, because careful planning and implementation of de-certification and OPO replacement actions could ease such transitions. The new proposed outcome measures and performance expectations will give each OPO both the opportunity and market incentives to assess its performance and motivate the widespread adoption of best practices.

While we cannot predict future achievement levels, we have developed a hypothetical scenario that we believe is likely to nearly achieve HHS' 2030 target in 2026 (with 4 years remaining to attain that goal) and that we can use

²⁹ <https://www.nih.gov/news-events/news-releases/scientists-triple-storage-time-human-donor-livers>.

in estimating benefits and costs while allowing for either higher or lower results. In Tables 5 and 6, we show the results of all OPOs achieving the minimum performance requirements, or improving by 20 percent, whichever is greater, by 2026. These projections are estimates and are 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 when the 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 will ultimately facilitate the utilization of the large number of discarded, but transplantable, organs. In assessing this 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 74, but the vast majority of them could provide organs of transplant quality if donated. 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.³⁰ With advances in successful utilization of organs from older donors, we believe the upward potential for both donation and transplantation is higher than shown in tables 5 and 6.

Table 5 shows all OPOs achieving the minimum standard, or a 20 percent increase, whichever is greater. With these parameters, the number of annual donors would rise from about 10,000 in 2017 to over 12,000 by 2026.

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³⁰ Organ donors <50 make up approximately 67 percent of donors, but make up less than 10 percent of deaths.

Table 5. OPO Donor Rates Assuming All OPOs Attain Donor Rate of 4.11, or an increase of 20 Percent, whichever is greater, by 2026

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	179	6.78
Lifesharing - A Donate Life Organization (CASD)	1,986	131	6.59
DonorConnect (UTOP)	2,048	128	6.27
Midwest Transplant Network (MWOB)	4,297	276	6.42
Versiti (WIDN)	1,844	110	5.99
Nevada Donor Network (NVLV)	2,367	142	5.98
Gift of Life Donor Program (PADV)	9,771	611	6.25
Donor Network of Arizona (AZOB)	4,991	289	5.79
Nebraska Organ Recovery (NEOR)	1,519	79	5.21
The Living Legacy Foundation of Maryland (MDPC)	3,171	172	5.41
ConnectLife (NYWN)	1,239	60	4.84
LifeShare of Oklahoma (OKOP)	3,954	212	5.37
Washington Regional Transplant Community (DCTC)	3,158	166	5.24
OurLegacy - FL (FLFH)	3,541	184	5.18
Southwest Transplant Alliance (TXSB)	8,727	448	5.13
Mid-America Transplant Services (MOMA)	5,266	260	4.94
Donor Alliance (CORS)	3,469	164	4.74
LifeGift (TXGC)	8,579	427	4.98
Sierra Donor Services (CAGS)	2,092	94	4.47
Lifeshare Carolinas (NCCM)	2,599	118	4.52

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	446	4.90
Tennessee Donor Services (TNDS)	7,189	340	4.72
Center for Organ Recovery and Education (PATF)	5,500	254	4.63
LifeSource - MN (MNOP)	4,707	208	4.41
New Mexico Donor Services (NMOP)	1,628	67	4.11
<i>Legacy of Life - Hawaii (HIOP)</i>	<i>1,077</i>	<i>44</i>	<i>4.11</i>
<i>LifeCenter Organ Donor Network (OHOV)</i>	<i>2,029</i>	<i>83</i>	<i>4.11</i>
<i>LifeCenter Northwest (WALC)</i>	<i>6,408</i>	<i>283</i>	<i>4.42</i>
<i>New Jersey Sharing Network (NJTO)</i>	<i>5,093</i>	<i>221</i>	<i>4.34</i>
<i>LifeBanc (OHLB)</i>	<i>4,149</i>	<i>176</i>	<i>4.25</i>
<i>LifeLink of Florida (FLWC)</i>	<i>5,665</i>	<i>246</i>	<i>4.34</i>
<i>Louisiana Organ Procurement Agency (LAOP)</i>	<i>5,072</i>	<i>218</i>	<i>4.31</i>
<i>Life Alliance Organ Recovery Agency (FLMP)</i>	<i>4,931</i>	<i>210</i>	<i>4.26</i>
<i>Lifeline of Ohio (OHLP)</i>	<i>3,587</i>	<i>147</i>	<i>4.11</i>
<i>Sharing Hope SC (SCOP)</i>	<i>4,598</i>	<i>189</i>	<i>4.11</i>
<i>Donor Network West (CADN)</i>	<i>8,699</i>	<i>358</i>	<i>4.11</i>
<i>OneLegacy (CAOP)</i>	<i>12,725</i>	<i>530</i>	<i>4.17</i>
<i>Pacific Northwest Transplant Bank (ORUO)</i>	<i>3,791</i>	<i>156</i>	<i>4.11</i>
<i>Life Connection of Ohio (OHLC)</i>	<i>2,072</i>	<i>85</i>	<i>4.11</i>
<i>Gift of Life Michigan (MIOP)</i>	<i>8,736</i>	<i>359</i>	<i>4.11</i>
<i>Texas Organ Sharing Alliance (TXSA)</i>	<i>5,079</i>	<i>209</i>	<i>4.11</i>
<i>LifeLink of Georgia (GALL)</i>	<i>8,573</i>	<i>352</i>	<i>4.11</i>
<i>LifeQuest Organ Recovery Services (FLUF)</i>	<i>4,234</i>	<i>174</i>	<i>4.11</i>
<i>New England Organ Bank (MAOB)</i>	<i>8,712</i>	<i>358</i>	<i>4.11</i>

OPO Name (Primary State)	New Potential Donors (Denominator)	New Total Donors	New Donation Rate
<i>Mid-South Transplant Foundation (TNMS)</i>	2,305	95	4.11
<i>Carolina Donor Services (NCNC)</i>	6,781	279	4.11
<i>LiveOnNY (NYRT)</i>	9,385	386	4.11
<i>Indiana Donor Network (INOP)</i>	5,783	238	4.11
<i>Iowa Donor Network (IAOP)</i>	2,136	88	4.11
<i>Mississippi Organ Recovery Agency (MSOP)</i>	2,927	120	4.11
<i>LifeNet Health (VATB)</i>	5,449	224	4.11
<i>LifeLink of Puerto Rico (PRL)</i>	3,205	132	4.11
<i>LifeChoice Donor Services (CTOP)</i>	2,561	105	4.11
<i>Center for Donation and Transplant (NYAP)</i>	2,451	101	4.11
<i>Kentucky Organ Donor Affiliates (KYDA)</i>	5,389	221	4.11
<i>Arkansas Regional Organ Recovery Agency (AROR)</i>	2,604	107	4.11
<i>Legacy of Hope - Alabama (ALOB)</i>	8,025	330	4.11
<i>Finger Lakes Donor Recovery Network (NYFL)</i>	2,486	102	4.11
Totals	272,105	12,491	

Table 6 shows a similar magnitude of change for rates of transplantation. It shows an increase in the number of transplants, and a performance of achieving the minimum standard, or a

20 percent increase, whichever is greater. With these parameters, the number of annual transplants would rise from about 32,000 in 2017 to almost 42,000 by 2026. (By contrast, Table 4

shows that, in isolation, achievement of the proposed minimum standard would yield 4,903 additional transplants per year, roughly half the 9,474 [= 41,647 – 32,173] implied by Table 6.)

Table 6. OPO Transplant Rates Assuming All OPOs Attain TX Rate of 13.73, or an increase of 20 Percent, whichever is greater, by 2026

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
Lifesharing - A Donate Life Organization (CASD)	1,986	463	23.32
Organ Procurement Organization at U. of Wisconsin (WIUW)	2,638	599	22.70
Midwest Transplant Network (MWOB)	4,297	985	22.93
DonorConnect (UTOP)	2,048	424	20.68
Versiti (WIDN)	1,844	377	20.43
Donor Network of Arizona (AZOB)	4,991	1,016	20.36
Nebraska Organ Recovery (NEOR)	1,519	294	19.35
The Living Legacy Foundation of Maryland (MDPC)	3,171	600	18.92
Nevada Donor Network (NVLV)	2,367	440	18.61
Gift of Life Donor Program (PADV)	9,771	1,890	19.34
Washington Regional Transplant Community (DCTC)	3,158	554	17.56
OurLegacy - FL (FLFH)	3,541	607	17.15
Southwest Transplant Alliance (TXSB)	8,727	1,530	17.53
LifeGift (TXGC)	8,579	1,493	17.40
Lifeshare Carolinas (NCCM)	2,599	419	16.11
Mid-America Transplant Services (MOMA)	5,266	863	16.38
ConnectLife (NYWN)	1,239	187	15.11
LifeShare of Oklahoma (OKOP)	3,954	634	16.02
Gift of Hope Organ & Tissue Donor Network (ILIP)	9,108	1,492	16.38

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
Louisiana Organ Procurement Agency (LAOP)	5,072	800	15.78
Tennessee Donor Services (TNDS)	7,189	1,133	15.76
Sierra Donor Services (CAGS)	2,092	312	14.91
<i>LifeSource - MN (MNOP)</i>	<i>4,707</i>	<i>707</i>	<i>15.02</i>
<i>Sharing Hope SC (SCOP)</i>	<i>4,598</i>	<i>677</i>	<i>14.72</i>
<i>Donor Alliance (CORS)</i>	<i>3,469</i>	<i>492</i>	<i>14.18</i>
<i>Donor Network West (CADN)</i>	<i>8,699</i>	<i>1,270</i>	<i>14.59</i>
<i>LifeBanc (OHLB)</i>	<i>4,149</i>	<i>575</i>	<i>13.85</i>
<i>Lifeline of Ohio (OHLP)</i>	<i>3,587</i>	<i>492</i>	<i>13.73</i>
<i>Center for Organ Recovery and Education (PATF)</i>	<i>5,500</i>	<i>764</i>	<i>13.90</i>
<i>LifeCenter Northwest (WALC)</i>	<i>6,408</i>	<i>892</i>	<i>13.91</i>
<i>Texas Organ Sharing Alliance (TXSA)</i>	<i>5,079</i>	<i>697</i>	<i>13.73</i>
<i>LifeLink of Florida (FLWC)</i>	<i>5,665</i>	<i>780</i>	<i>13.77</i>
<i>OneLegacy (CAOP)</i>	<i>12,725</i>	<i>1,762</i>	<i>13.84</i>
<i>New Mexico Donor Services (NMOP)</i>	<i>1,628</i>	<i>224</i>	<i>13.73</i>
<i>New Jersey Sharing Network (NJTO)</i>	<i>5,093</i>	<i>699</i>	<i>13.73</i>
<i>LifeCenter Organ Donor Network (OHOV)</i>	<i>2,029</i>	<i>279</i>	<i>13.73</i>
<i>Indiana Donor Network (INOP)</i>	<i>5,783</i>	<i>794</i>	<i>13.73</i>
<i>Life Alliance Organ Recovery Agency (FLMP)</i>	<i>4,931</i>	<i>677</i>	<i>13.73</i>
<i>New England Organ Bank (MAOB)</i>	<i>8,712</i>	<i>1,196</i>	<i>13.73</i>
<i>Carolina Donor Services (NCNC)</i>	<i>6,781</i>	<i>931</i>	<i>13.73</i>
<i>LifeQuest Organ Recovery Services (FLUF)</i>	<i>4,234</i>	<i>581</i>	<i>13.73</i>
<i>LifeLink of Georgia (GALL)</i>	<i>8,573</i>	<i>1,177</i>	<i>13.73</i>

OPO Name (Primary State)	Potential Donors (Denominator)	New Number Transplants	New Transplant Rate
<i>Pacific Northwest Transplant Bank (ORUO)</i>	<i>3,791</i>	<i>521</i>	<i>13.73</i>
<i>Gift of Life Michigan (MIOP)</i>	<i>8,736</i>	<i>1,199</i>	<i>13.73</i>
<i>Mid-South Transplant Foundation (TNMS)</i>	<i>2,305</i>	<i>316</i>	<i>13.73</i>
<i>LiveOnNY (NYRT)</i>	<i>9,385</i>	<i>1,289</i>	<i>13.73</i>
<i>Legacy of Life - Hawaii (HIOP)</i>	<i>1,077</i>	<i>148</i>	<i>13.73</i>
<i>Life Connection of Ohio (OHLC)</i>	<i>2,072</i>	<i>284</i>	<i>13.73</i>
<i>LifeNet Health (VATB)</i>	<i>5,449</i>	<i>748</i>	<i>13.73</i>
<i>Mississippi Organ Recovery Agency (MSOP)</i>	<i>2,927</i>	<i>402</i>	<i>13.73</i>
<i>Iowa Donor Network (IAOP)</i>	<i>2,136</i>	<i>293</i>	<i>13.73</i>
<i>LifeChoice Donor Services (CTOP)</i>	<i>2,561</i>	<i>352</i>	<i>13.73</i>
<i>Kentucky Organ Donor Affiliates (KYDA)</i>	<i>5,389</i>	<i>740</i>	<i>13.73</i>
<i>LifeLink of Puerto Rico (PRL)</i>	<i>3,205</i>	<i>440</i>	<i>13.73</i>
<i>Center for Donation and Transplant (NYAP)</i>	<i>2,451</i>	<i>337</i>	<i>13.73</i>
<i>Legacy of Hope - Alabama (ALOB)</i>	<i>8,025</i>	<i>1,102</i>	<i>13.73</i>
<i>Arkansas Regional Organ Recovery Agency (AROR)</i>	<i>2,604</i>	<i>358</i>	<i>13.73</i>
<i>Finger Lakes Donor Recovery Network (NYFL)</i>	<i>2,486</i>	<i>341</i>	<i>13.73</i>
Totals	272,105	41,647	

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While there is no certainty that these or higher levels of performance will be realized, there is additional evidence beyond the known performance levels of the higher-achieving OPOs. A recent study compared French and American organ utilization in the period from 2004 to 2014.³¹ This study showed that the discard rate for kidneys from deceased donors was about nine percent

³¹ 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.

in France and 18 percent in the U.S. The lower discard rate reflected a far greater use in France of kidneys from older donors that had inferior "kidney donor risk index" (KDRI) scores. The mean age of donor kidneys in France was 51 years and in the U.S., 37 years. Despite the higher use of seemingly less desirable organs, the study estimates that had the U.S. used French practices, there would have been about 132,000 additional years of graft (and patient) survival in the U.S. 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.³² 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,

³² 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.

without penalizing transplant programs for the lower success rates that inevitably result.³³ These results strongly suggest that with the regulatory penalties removed on transplant centers that do not achieve the highest possible one-year graft and patient survival outcomes (as discussed in the proposed rule, “Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction” 83 FR 47686) and with the greater accountability for OPO performance proposed in this rule, performance results such as those achieved in France could be achievable in the U.S.

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 set forth in the “Implementation and Continuing Costs” subsection; such low magnitudes are plausible primarily if OPO decertification is very rare. Without a credible threat of decertification, 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 below in Tables 11R and 12R).

An opposite case is one in which decertification is common, thus motivating OPO behavior change and making non-negligible benefits plausible. OPOs undergoing management change would experience transition costs that are substantial (although difficult to quantify). Broader societal transition costs could include reduced organ recovery while the decertification process unfolds, even if improved practices increase transplant activity in the medium- to long-term.

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’s 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 proposed 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 7 shows the data for hearts:

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

Heart	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six 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 7, 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 8—FIRST YEAR COST PER LIVER TRANSPLANT (\$)

Liver	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six 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
Total	812,000	143,000	80,000	15,000	604,000

³³ See Olivier Aubert, et al.

³⁴ T. Scott Bentley and Steven J. Phillips, 2017, available to download at 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/.

Table 8 shows the estimated average cost for a liver transplant, estimated on the same basis. Table 9 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 9—FIRST YEAR COST PER KIDNEY TRANSPLANT (\$)

Kidney	Milliman charge estimate	Likely excess of charges over costs	Assumed non-TX costs	Immuno-suppressive drugs (six 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 10 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 save money for the patients who survive the full 5-year period.

TABLE 10—FIVE YEAR COSTS PER WEIGHTED AVERAGE TRANSPLANT (\$)

	Heart	Liver	Kidney	All three organs weighted
Annual Percent of Total TX	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 four-year OPO performance period would be essential in order to have enough growth in the second half of the decade to meet the HHS' 2030 goal of doubling the number of kidneys available for transplants. As Table 11 shows, that will require multi-billion dollar increases over current transplant spending levels by the middle of the next 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 proposed rule are reimbursed by private payers, not 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, such as increasing the number of living donors, avoiding penalizing transplant programs for using kidneys with lower likelihood to transplantation success, and improving techniques for

maintaining organs during the time before transplantation to reduce discards of organs shared outside the DSA, the main approach for achieving this ambitious goal is to increase the number of deceased donors. This will require continuing improvements over time, and we have estimated the approximate numbers that would have to be achieved in the next four-year OPO performance period to move about half way towards an annual increase of approximately 20,000 more kidneys available and (assuming a reduction in discard rates) approximately 16,000

more kidney transplants by 2030, as shown in Table 11.

In Tables 11 and 12 we show the annual results as each cohort of new transplants arrives over the OPO performance period from 2021 to 2025. These estimates include totals for all organs since one deceased donor normally provides multiple organs. The

10,000 increase shown for 2025 includes about 6,500 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 for 2026 that shows the effects of these same cohorts

alone in the sixth year. 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 11—COSTS OVER TIME AS ORGAN TRANSPLANTS HYPOTHETICALLY INCREASE
[\$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	1,000	3,000	6,000	8,000	10,000	Same Cohorts
Costs for 2021–2 Cohort	\$388	(\$29)	(\$29)	(\$29)	(\$29)	(\$29)
Costs for 2022–3 Cohort		\$1,164	(\$86)	(\$86)	(\$86)	(\$86)
Costs for 2023–4 Cohort			\$2,327	(\$173)	(\$173)	(\$173)
Costs for 2024–5 Cohort				\$3,103	(\$230)	(\$230)
Costs for 2025–6 Cohort					\$3,879	(\$288)
Total	\$388	\$1,135	\$2,212	\$2,815	\$3,360	(\$806)

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 great bulk of the procurement costs are paid to OPOs and finance not only direct involvement with donor families and donations, but

also management and direction of the OPO.

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

Table 11R shows estimates using the same per-transplant inputs but with aggregates reflecting the 4,903 new annual transplants shown in Table 4; impacts are assumed to begin in 2023 because existing OPO contracts run

through 2022, thus preventing any decertification before then. (We note that a steady new transplant level may be an oversimplification because the proposed policy, setting a threshold at the 75th percentile performance amongst OPOs, could lead to a continual ratcheting of the performance necessary for compliance, and we request comment that would allow for such year-to-year changes to be reflected in our analysis.) These estimates feed into the upper bound estimates that appear in the accounting statement (Table 19), below.

TABLE 11R—COSTS OVER TIME AS ORGAN TRANSPLANTS INCREASE
[\$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	0	0	4,903	4,903	4,903	Same Cohorts
Costs for 2023–4 Cohort			\$1,902	(\$142)	(\$142)	(\$142)
Costs for 2024–5 Cohort				\$1,902	(\$142)	(\$142)
Costs for 2025–6 Cohort					\$1,902	(\$142)
Total	\$0	\$0	\$1,902	\$1,760	\$1,618	(\$427)

2. *Effects on Patients.* Every organ that is used for transplantation has a very high probability of substantially extending the life of the recipient. There is extensive literature on life expectancy before and after transplant, quality of life, and cost savings for kidney 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 have reached similar conclusions, as have other syntheses. For example, in the article, “Systematic Review: Kidney Transplantation Compared with Dialysis in Clinically Relevant Outcome,” the authors reviewed 110 studies and

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

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 and about 29 for transplant recipients (see 2018 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). There are similar data on other organs. For example, in 1998, HHS published a final rule with comment period that established governance procedures for the OPTN (63 FR 16296). In the RIA for that rule, 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.³⁷ Using the more usual metric of survival rates, the five-year survival rate for kidney transplant patients is 86 percent (Milliman, page 13).

HHS “Guidelines for Regulatory Impact Analysis” explain in some detail the concept of QALYs.³⁸ QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are 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 and VSLY amounts used in any estimate of overall benefits, including this one, is not meant to be precise estimates, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.³⁹

Table 12 provides estimates of the life-extending and life-improving value of the proposed rule assuming that it succeeds in improving OPO performance in early years at the magnitudes necessary to meet the 2030 HHS goal. For simplicity, we estimate that transplants occur halfway through the year.

TABLE 12—LIFE-EXTENDING AND IMPROVING BENEFITS OVER FIRST 5 YEARS AS TRANSPLANTS HYPOTHETICALLY INCREASE
[\$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	1,000	3,000	6,000	8,000	10,000	Same Cohorts.
2021–2 Cohort	\$94	\$187	\$187	\$187	\$187	\$187.
2022–3 Cohort		\$281	\$562	\$562	\$562	\$562.
2023–4 Cohort			\$562	\$1,123	\$1,123	\$1,123.
2024–5 Cohort				\$749	\$1,497	\$1,497.
2025–6 Cohort					\$936	\$1,872.
Total	\$94	\$468	\$1,310	\$2620	\$4,305	\$5,241.

This table 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 ten year period, total life extending benefits from about 18,000 additional kidney transplants would be \$23 billion (without discounting) from the 2021 to 2025 cohorts of additional transplants shown in Table 12 (28,000 organs times 65 percent of which are kidneys times 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 ten years, with even

more years of benefits to most of the same recipients yet to come.⁴⁰

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, and hence stand to gain the most years of life from a transplant. Offsetting this, 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 previously marginal organs, and in 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

³⁶ Tonelli M, et al, *AmJTransplant* 2011; 2093–2109.

³⁷ 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/NEJM199912023412303#t=article>.

³⁸ <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>.

³⁹ 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.

⁴⁰ 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.ahajournals.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.

purposes of this analysis, the proper measure is the average gain across all patients who would receive transplants in the presence of the proposed rule but not in its absence.

Table 12R shows estimates using the same per-transplant inputs but with aggregates reflecting the 4,903 new annual transplants shown in Table 4;

increases are assumed to begin in 2023 because existing OPO contracts run through 2022, thus preventing any decertification before then. (We note that a steady new transplant level may be an oversimplification because the proposed policy, setting a threshold at the 75th percentile performance amongst OPOs, could lead to a

continual ratcheting of the performance necessary for compliance, and we request comment that would allow for such year-to-year changes to be reflected in our analysis.) These estimates feed into the upper bound estimates that appear in the accounting statement (Table 19), below.

TABLE 12R—LIFE-EXTENDING AND IMPROVING BENEFITS OVER FIRST 5 YEARS AS TRANSPLANTS INCREASE
[\$ millions]

Year	2021	2022	2023	2024	2025	2026
Increase Over Base Year in Number Transplants.	0	0	4,903	4,903	4,903	Same Cohorts.
Costs for 2023–4 Cohort	\$461	\$917	\$917	\$917.
Costs for 2024–5 Cohort	\$461	\$917	\$917.
Costs for 2025–6 Cohort	\$461	\$917.
Total	\$0	\$0	\$461	\$1,378	\$2,295	\$2,751.

3. *Implementation and Continuing Costs.* The requirements of the final rule, if issued, would necessarily have to be read, understood, and implemented by all OPOs. This would create one-time costs even though the proposed requirements would not directly create unreimbursed cost burdens. In many cases, these costs would be very low, and may be as simple as learning where the OPO stands in relationship to other facilities in meeting the new performance standards. In some cases, the OPO would need to significantly adjust its procedures and techniques. In still other cases, time would have to be spent deciding how to change existing policy and procedures. These effects would be felt primarily by the 58 OPOs, but secondarily by the approximately 750 transplant programs in about 250 transplant hospitals. Many of these hospitals would need to respond if OPOs implement new technologies or procedures to optimize their performance. These costs, however, are part of the acquisition costs associated with organ procurement and would be paid by Medicare and other health insurers. 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. We welcome comments on our estimates as to skills and occupations involved, and time likely to be spent.

In total, there are about 800 affected entities or programs. We assume that on average there would be one hour of time spent by a lawyer, two 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, two 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, at https://www.bls.gov/oes/current/oes_nat.htm#23-0000.

We assume that on average, an OPO would involve one person in each occupation and an average of eight hours on an interdisciplinary team tasked with learning the new rules, understanding their implications for that OPO, and initiating plans to address performance levels. 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). A somewhat different mix of occupations would lead to a similar total cost. For transplant programs, we assume that only half as many hours would be needed, using a similar mix of occupations, for a total of \$669 per hour and \$2,676 (\$669 × 4) for four hours. For 750 transplant programs the total first year cost would therefore be about \$2,007,000 (\$2,676 × 750).

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. These procurement costs are included in the cost estimates shown in Tables 7 to 9 and summarized in Tables 10 and 11, 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 procurement grows, there would be two significant effects. First, there are economies of scale as OPOs and hospitals expand their donor-related and transplant services. Second, and more than offsetting such gains, substantial improvements over time would require additional efforts. Some OPOs would also likely incur additional costs as they consider and in some cases prepare for such actions as mergers or replacements. For both cost savings and cost increases, effects are primarily from staffing changes; we assume there are relatively few fixed investments in plant and equipment. And in both cases, current reimbursement policies and programs pay for all reasonable costs. We welcome comments and if possible, data on these and other workload, cost, and revenue issues and estimates.

We do not expect substantial costs would be incurred by CMS. The data collection required for enforcement of the proposed standards already exists and can readily be used to assess performance. OPOs are already reviewed and assessed on a continuing basis. There would be additional costs for technical assistance and possibly more severe actions regarding any OPOs with major compliance problems, or increased appeals related activities, but 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. Regardless, 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 disruptive process of decertification. We request comment that would inform estimates of this category of costs.

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. Relatively few are Medicare patients. This is because these patients are overwhelmingly below age 65 and ineligible for Medicare unless disabled. The age 65 and older percentage is only 17 percent for hearts, and 18 percent for livers. In sharp contrast, the vast majority of kidney transplants (about 80 percent) are received by patients who have end-stage renal disease and, as ESRD patients, are nearly all 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 7 through 10), and in cost over time. For kidney transplant patients 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 10). For ESRD patients who receive kidney transplants, the public insurance programs would 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 more. For kidney patients, 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 10). 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 would not yet be realized), total costs shown in Table 11 over this period are about \$10 billion and the average billed to Medicare would be about 25 percent of this, or \$2.5 billion. Of this, patients would pay on average almost 20 percent, reducing the Medicare costs to about \$2 billion over the five year period.

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 proposed rule would have a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all 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 \$7.5 million to \$38.5 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.⁴¹ 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 proposed rule would create will affect small entities.

The RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be prepared if a proposed 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 some OPOs to prosper as they reform their practices to meet the standards under the proposed rule, but some may lose their certification and be replaced by more effective OPOs. The HHS standard for “substantial number” is 5 percent or more of those that will be significantly impacted, but never fewer than 20. There is a possibility that as many as 20 OPOs would lose certification and hence we are unable to certify that an Initial Regulatory Flexibility Analysis is not required under the RFA. Accordingly, we are preparing an IRFA.

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 proposed rule directly

⁴¹ Brigitte Sullivan, Executive Director, NYU Langone Transplant Institute, “Maximizing Medicare Cost Report Reimbursement,” 2015, online at http://organdonationalalliance.org/wp-content/uploads/2015/08/ATC_BSullivan_CostReport_062016_S5N0001.pdf.

regulates either hospitals or their transplant programs. Moreover, nothing in this proposed 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 one trillion dollars a year; the estimated costs of this proposed rule 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 one 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.⁴² 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 (however, see the further discussion of payment issues in the Alternatives section).

The potential economic effects on OPOs depend on their ability to meet the thresholds established at the beginning of the four-year performance period. OPOs who are at or above this threshold by the end of this period should face relatively small effects (a likely increase in organ donors and organs transplanted that we estimate to be likely to be near 20 percent, with revenues from Medicare that reimburse their incurred reasonable costs) and other health insurers. Those currently below the threshold that can achieve the threshold rate over the four-year period will benefit from the increased revenue associated with procuring more organs. For OPOs that cannot meet the new performance standards, the issue would be making the necessary changes to avert a loss of certification. Our methodology was designed to allow all OPOs the opportunity to achieve the threshold rates; however, based on Tables 3 and 4, we believe that there are a range of potential outcomes, assuming

the high performers remain at steady state. These include:

- Eight OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 50 percent to meet the threshold rates.
- Eighteen OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 25 percent to meet the threshold rates.
- Thirty-three OPOs who would be subject to de-certification because they would need to increase their donation and/or transplantation rates by more than 10 percent to meet the threshold rates.

In most cases of potential decertification, we would reasonably expect another OPO to take over that service area, retaining the original staff, 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 incur costs related to retraining, or implementation of best practices unfamiliar to the de-certified OPO's staff. We solicit comment 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.

Tables 3 and 4 present a list of all affected OPOs and of the gap between their current performance and the proposed standards. These tables use as a base year 2017 data but for most OPOs, the potential donor data from the state death certificates are not likely to change substantially from updates between the proposed and final rule and between the final rule and first performance year. These tables show for each OPO what it would have to achieve over a four-year period to meet the proposed performance standards. Since the threshold rate 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 four-year performance period. Since the cost of each OPO's increased effort and performance is covered by Medicare, this is not primarily a cost or revenue issue for the OPOs. Instead, our new performance measures would create 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 “small entities,” all of the alternatives and options presented throughout this preamble meet the RFA requirement that effects on these entities be addressed. We emphasize, however, that we already know that many OPOs already meet or in many cases far exceed our proposed standards without any regulatory relief, and we know that the HHS goal for increasing kidney donation and transplantation can not be met without a substantial increase in performance. We also know that the current performance requirements permit most OPOs to perform far below the levels of their peers in serving the long waiting lists of patients in need of organ donation and transplantation.

Because our proposals 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 leadership could replace any 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 any case arise where an OPO is unable to make the changes necessary to or constrained by circumstances beyond its control that it cannot reach the performance levels of others, CMS can intervene with technical assistance or to facilitate mergers or other changes. We believe that every OPO can meet the proposed 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 Regulatory Flexibility Analysis, including a description of the reasons why action is being considered, a statement of the objectives and legal basis for the proposed rule, a description of any reporting or record-keeping requirements of the proposed rule, and a description of any other Federal rules that duplicate, overlap, or conflict with the proposed rule (there are none in this case), among others. This RIA and the preamble taken as a whole meet these requirements. We welcome comments about effects on small entities and on alternatives that might improve the rule in meeting its stated objectives. We note that the RFA emphasizes the use of performance

⁴² 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.

rather than design standards, which is precisely what we propose.

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 603 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 proposed 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 proposed 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 one year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This proposed rule contains no mandates that directly impose spending costs on State, local, or tribal governments, or by the private sector. Some OPOs would undoubtedly find that meeting the proposed 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.* E.O. 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 proposed rule would impose no such requirements.

G. Alternatives Considered

Throughout the preamble sections, we present our proposals and seek comments on potential alternatives. We seek 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 are proposing and setting the threshold donation and organ transplantation rate at the top 25 percent of rates, 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 are seeking comments to these alternatives in addition to our proposed outcome measures.

Changes to the Denominator

CALC as the Denominator

The following table shows the likely effects of using the CALC to define the donor potential:

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Table 13a. OPO Donation Rates Using CALC Measures

(Threshold donation rates are 4.11 for proposed, and 11.36 for CALC measure. OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			CALC Measure		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	14.87	16.87	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	12.49	14.50	0
DonorConnect (UTOP)	5.22	6.12	0	13.72	15.94	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	15.31	16.94	0
Versiti (WIDN)	4.99	5.92	0	13.29	15.64	0
Nevada Donor Network (NVLV)	4.99	5.80	0	11.37	13.14	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	14.00	14.99	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	11.42	12.64	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	13.15	15.93	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	11.81	13.46	0
ConnectLife (NYWN)	4.04	5.10	0	11.19	14.00	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	11.33	12.75	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	11.69	13.36	0
OurLegacy - FL (FLFH)	4.32	4.93	0	10.74	12.20	0

OPO Name	Proposed Measure			CALC Measure		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	11.70	12.68	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	12.12	13.48	0
Donor Alliance (CORS)	3.95	4.55	0	10.59	12.12	0
LifeGift (TXGC)	4.15	4.52	0	11.42	12.41	0
Sierra Donor Services (CAGS)	3.73	4.50	0	8.65	10.37	9
Lifeshare Carolinas (NCCM)	3.77	4.46	0	10.47	12.29	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	11.36	12.32	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	10.25	11.26	3
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	10.10	11.26	2
LifeSource - MN (MNOP)	3.68	4.17	0	9.89	11.16	4
New Mexico Donor Services (NMOP)	3.32	4.16	0	8.77	10.91	3
Legacy of Life - Hawaii (HIOP)	3.06	4.11	1	7.24	9.62	8
LifeCenter Organ Donor Network (OHOV)	3.35	4.10	1	9.30	11.30	1
LifeCenter Northwest (WALC)	3.68	4.10	1	9.54	10.58	19
New Jersey Sharing Network (NJTO)	3.61	4.08	2	9.37	10.53	16
LifeBanc (OHLB)	3.54	4.06	2	9.91	11.29	1
LifeLink of Florida (FLWC)	3.62	4.06	3	9.47	10.58	17

OPO Name	Proposed Measure			CALC Measure		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Louisiana Organ Procurement Agency (LAOP)	3.59	4.05	3	9.86	11.09	5
Life Alliance Organ Recovery Agency (FLMP)	3.55	4.02	5	8.25	9.31	42
Lifeline of Ohio (OHLP)	3.40	3.95	6	9.71	11.22	2
Sharing Hope SC (SCOP)	3.39	3.87	11	8.97	10.19	20
Donor Network West (CADN)	3.43	3.77	29	9.17	10.06	41
OneLegacy (CAOP)	3.47	3.75	44	8.11	8.75	139
Pacific Northwest Transplant Bank (ORUO)	3.14	3.65	17	8.65	10.02	18
Life Connection of Ohio (OHLC)	2.94	3.65	9	7.20	8.87	20
Gift of Life Michigan (MIOP)	3.31	3.64	39	9.21	10.11	38
Texas Organ Sharing Alliance (TXSA)	3.19	3.63	23	8.14	9.23	41
LifeLink of Georgia (GALL)	3.27	3.60	42	10.26	11.27	3
LifeQuest Organ Recovery Services (FLUF)	3.12	3.60	21	7.41	8.53	48
New England Organ Bank (MAOB)	3.26	3.59	43	9.52	10.46	26
Mid-South Transplant Foundation (TNMS)	2.91	3.56	12	7.37	8.99	20
Carolina Donor Services (NCNC)	2.93	3.30	53	8.25	9.24	49
LiveOnNY (NYRT)	2.96	3.27	76	8.18	9.00	78
Indiana Donor Network (INOP)	2.78	3.17	52	7.29	8.28	65

OPO Name	Proposed Measure			CALC Measure		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Iowa Donor Network (IAOP)	2.43	3.07	21	6.27	7.86	27
Mississippi Organ Recovery Agency (MSOP)	2.53	3.07	29	7.13	8.61	27
LifeNet Health (VATB)	2.64	3.03	56	7.38	8.44	55
LifeLink of Puerto Rico (PRL)	2.43	2.94	35	7.30	8.77	26
LifeChoice Donor Services (CTOP)	2.34	2.91	29	7.07	8.72	21
Center for Donation and Transplant (NYAP)	2.24	2.81	30	6.49	8.09	26
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.33	90	5.50	6.44	91
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.27	44	4.83	6.16	46
Legacy of Hope - Alabama (ALOB)	1.98	2.26	141	5.76	6.55	127
Finger Lakes Donor Recovery Network (NYFL)	1.65	2.15	45	4.89	6.34	39
Totals			1,015			1,223

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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. This methodology uses the same NCHS database and also uses inpatient deaths to calculate the denominator. The primary difference between the CALC methodology and our proposed methodology is that it uses the ICD-10 codes to identify deaths that are consistent with donation (that is, inclusion criteria) whereas we exclude ICD-10 codes that are an absolute contraindications to organ donation (that is, exclusion criteria). The developers of the CALC methodology believe that the ICD-10 codes used in

their inclusion criteria capture 98-99 percent of all donors:

- I20-I25 (ischemic heart disease);
- I60-I69 (cerebrovascular disease)
- V-1-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 our proposed methodology. There is 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 at the threshold rate, under our 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).

We also compared the CALC methodology on organs transplanted, as shown in the following table:

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Table 13b. OPO Transplantation Rates Using CALC Measures

(Threshold organ transplantation rates are 13.73 for proposed, and 37.85 for CALC measure.

OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			CALC Measure		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	44.22	48.10	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	49.80	53.63	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	54.66	57.90	0
DonorConnect (UTOP)	17.24	18.82	0	45.26	49.42	0
Versiti (WIDN)	17.03	18.70	0	45.38	49.82	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	40.14	42.49	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	48.80	54.25	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	41.29	44.46	0
Nevada Donor Network (NVLV)	15.50	16.90	0	35.36	38.55	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	43.33	45.17	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	39.12	42.25	0
OurLegacy - FL (FLFH)	14.29	15.38	0	35.51	38.22	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	39.98	41.87	0
LifeGift (TXGC)	14.50	15.20	0	39.92	41.84	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	37.29	40.74	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	40.17	42.72	0

OPO Name	Proposed Measure			CALC Measure		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
ConnectLife (NYWN)	12.59	14.38	0	34.90	39.86	0
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	33.80	36.32	24
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	37.94	39.76	0
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	36.15	38.54	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	34.20	36.09	48
Sierra Donor Services (CAGS)	12.43	13.77	0	28.82	31.94	51
LifeSource - MN (MNOP)	12.51	13.40	16	33.68	36.05	31
Sharing Hope SC (SCOP)	12.27	13.15	26	32.43	34.77	52
Donor Alliance (CORS)	11.82	12.83	31	31.68	34.38	44
Donor Network West (CADN)	12.16	12.80	80	32.56	34.26	114
LifeBanc (OHLB)	11.54	12.45	52	32.28	34.81	44
Lifeline of Ohio (OHLP)	11.43	12.40	46	32.64	35.42	30
Center for Organ Recovery and Education (PATF)	11.58	12.37	73	30.35	32.40	111
LifeCenter Northwest (WALC)	11.59	12.32	88	30.04	31.92	143
Texas Organ Sharing Alliance (TXSA)	11.44	12.25	73	29.18	31.25	128
LifeLink of Florida (FLWC)	11.47	12.24	82	30.02	32.03	123
OneLegacy (CAOP)	11.54	12.04	210	26.93	28.11	521
New Mexico Donor Services (NMOP)	10.50	11.92	28	27.76	31.51	37
New Jersey Sharing Network (NJTO)	11.09	11.89	91	28.77	30.84	134

OPO Name	Proposed Measure			CALC Measure		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
LifeCenter Organ Donor Network (OHOV)	10.60	11.86	36	29.41	32.93	35
Indiana Donor Network (INOP)	10.84	11.58	121	28.40	30.33	162
Life Alliance Organ Recovery Agency (FLMP)	10.44	11.23	119	24.27	26.10	242
New England Organ Bank (MAOB)	10.56	11.15	219	30.85	32.58	154
Carolina Donor Services (NCNC)	10.47	11.14	171	29.45	31.33	153
LifeQuest Organ Recovery Services (FLUF)	10.16	11.00	112	24.14	26.15	202
LifeLink of Georgia (GALL)	10.30	10.89	238	32.34	34.19	98
Pacific Northwest Transplant Bank (ORUO)	9.92	10.80	107	27.35	29.78	107
Gift of Life Michigan (MIOP)	10.16	10.74	255	28.30	29.91	243
Mid-South Transplant Foundation (TNMS)	9.28	10.40	73	23.54	26.37	100
LiveOnNY (NYRT)	9.66	10.21	323	26.68	28.19	321
Legacy of Life - Hawaii (HIOP)	8.36	9.96	38	19.74	23.52	61
Life Connection of Ohio (OHLC)	8.69	9.83	77	21.25	24.05	111
LifeNet Health (VATB)	9.05	9.75	210	25.26	27.21	201
Mississippi Organ Recovery Agency (MSOP)	8.71	9.66	114	24.57	27.25	106
Iowa Donor Network (IAOP)	7.72	8.79	100	19.88	22.62	120
LifeChoice Donor Services (CTOP)	7.42	8.37	131	22.38	25.24	102

OPO Name	Proposed Measure			CALC Measure		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.97	300	20.29	22.05	298
LifeLink of Puerto Rico (PRLL)	6.77	7.58	189	20.30	22.72	155
Center for Donation and Transplant (NYAP)	6.61	7.53	145	19.13	21.79	129
Legacy of Hope - Alabama (ALOB)	6.18	6.66	551	17.96	19.34	497
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.56	178	15.63	17.91	181
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.23	200	13.25	15.51	177
Totals			4,903			5,590

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For organs transplanted, if all flagged OPOs were to increase their organs transplanted to the range of the top 25 percent, then using the CMS 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 are seeking comments on these differences and whether the CALC method is a more precise and/or accurate assessment of OPO performance.

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. The following tables show the effects of measure the donor potential based on the total deaths:

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Table 14a: OPO Donation Rates Using Deaths (Age <=75) Measure

(Threshold donation rates are 4.11 for proposed, and 8.11 for Deaths (Age <=75) measure. OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			Deaths (Age<=75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	9.91	11.37	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	10.77	12.64	0
DonorConnect (UTOP)	5.22	6.12	0	9.34	10.99	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	9.39	10.48	0
Versiti (WIDN)	4.99	5.92	0	9.31	11.10	0
Nevada Donor Network (NVLV)	4.99	5.80	0	10.81	12.61	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	9.99	10.75	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	8.49	9.45	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	8.74	10.76	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	7.77	8.94	0
ConnectLife (NYWN)	4.04	5.10	0	7.35	9.34	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	8.68	9.84	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	8.98	10.35	0
OurLegacy - FL (FLFH)	4.32	4.93	0	8.15	9.33	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	9.12	9.93	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	8.76	9.81	0
Donor Alliance (CORS)	3.95	4.55	0	6.57	7.58	11

OPO Name	Proposed Measure			Deaths (Age<=75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
LifeGift (TXGC)	4.15	4.52	0	8.70	9.50	0
Sierra Donor Services (CAGS)	3.73	4.50	0	6.60	7.99	2
Lifeshare Carolinas (NCCM)	3.77	4.46	0	7.69	9.11	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	8.00	8.72	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	8.28	9.15	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	6.98	7.83	9
LifeSource - MN (MNOP)	3.68	4.17	0	6.92	7.86	6
New Mexico Donor Services (NMOP)	3.32	4.16	0	5.82	7.33	7
Legacy of Life - Hawaii (HIOP)	3.06	4.11	1	6.47	8.71	0
LifeCenter Organ Donor Network (OHOV)	3.35	4.10	1	6.07	7.45	7
LifeCenter Northwest (WALC)	3.68	4.10	1	7.22	8.05	2
New Jersey Sharing Network (NJTO)	3.61	4.08	2	7.18	8.12	0
LifeBanc (OHLB)	3.54	4.06	2	6.61	7.59	11
LifeLink of Florida (FLWC)	3.62	4.06	3	7.15	8.03	3
Louisiana Organ Procurement Agency (LAOP)	3.59	4.05	3	7.23	8.18	0
Life Alliance Organ Recovery Agency (FLMP)	3.55	4.02	5	7.00	7.95	4
Lifeline of Ohio (OHLP)	3.40	3.95	6	7.03	8.18	0
Sharing Hope SC (SCOP)	3.39	3.87	11	6.28	7.18	22

OPO Name	Proposed Measure			Deaths (Age<=75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Donor Network West (CADN)	3.43	3.77	29	6.71	7.39	31
OneLegacy (CAOP)	3.47	3.75	44	7.26	7.86	15
Pacific Northwest Transplant Bank (ORUO)	3.14	3.65	17	5.50	6.41	35
Life Connection of Ohio (OHLC)	2.94	3.65	9	4.89	6.08	24
Gift of Life Michigan (MIOP)	3.31	3.64	39	6.42	7.09	45
Texas Organ Sharing Alliance (TXSA)	3.19	3.63	23	6.80	7.76	8
LifeLink of Georgia (GALL)	3.27	3.60	42	6.05	6.68	64
LifeQuest Organ Recovery Services (FLUF)	3.12	3.60	21	5.88	6.81	28
New England Organ Bank (MAOB)	3.26	3.59	43	5.93	6.55	72
Mid-South Transplant Foundation (TNMS)	2.91	3.56	12	6.03	7.42	8
Carolina Donor Services (NCNC)	2.93	3.30	53	5.60	6.30	61
LiveOnNY (NYRT)	2.96	3.27	76	6.87	7.59	21
Indiana Donor Network (INOP)	2.78	3.17	52	5.79	6.61	40
Iowa Donor Network (IAOP)	2.43	3.07	21	4.28	5.42	30
Mississippi Organ Recovery Agency (MSOP)	2.53	3.07	29	5.26	6.40	23
LifeNet Health (VATB)	2.64	3.03	56	5.54	6.37	43
LifeLink of Puerto Rico (PRLI)	2.43	2.94	35	5.30	6.42	23
LifeChoice Donor Services (CTOP)	2.34	2.91	29	4.68	5.82	27

OPO Name	Proposed Measure			Deaths (Age<=75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Center for Donation and Transplant (NYAP)	2.24	2.81	30	4.21	5.30	34
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.33	90	3.98	4.69	87
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.27	44	3.18	4.09	54
Legacy of Hope - Alabama (ALOB)	1.98	2.26	141	5.72	6.53	42
Finger Lakes Donor Recovery Network (NYFL)	1.65	2.15	45	3.69	4.81	34
Totals			1,015			933

Table 14b: OPO Transplantation Rate Using Deaths (Age <=75) Measure

(Threshold organ transplantation rates are 13.73, and 27.16 for Deaths (Age <=75 measure). OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			Deaths (Age <= 75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	38.13	41.48	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	33.20	35.75	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	33.52	35.51	0
DonorConnect (UTOP)	17.24	18.82	0	30.83	33.67	0
Versiti (WIDN)	17.03	18.70	0	31.79	34.90	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	29.84	31.58	0

OPO Name	Proposed Measure			Deaths (Age <= 75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	32.45	36.07	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	27.17	29.26	0
Nevada Donor Network (NVLV)	15.50	16.90	0	33.61	36.64	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	30.92	32.24	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	30.05	32.45	0
OurLegacy - FL (FLFH)	14.29	15.38	0	26.96	29.01	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	31.16	32.63	0
LifeGift (TXGC)	14.50	15.20	0	30.39	31.84	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	27.38	29.92	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	29.03	30.88	0
ConnectLife (NYWN)	12.59	14.38	0	22.93	26.19	7
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	25.88	27.81	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	26.72	28.00	0
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	26.49	28.24	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	27.63	29.16	0
Sierra Donor Services (CAGS)	12.43	13.77	0	22.01	24.39	32
LifeSource - MN (MNOP)	12.51	13.40	16	23.58	25.24	47
Sharing Hope SC (SCOP)	12.27	13.15	26	22.71	24.34	68
Donor Alliance (CORS)	11.82	12.83	31	19.65	21.32	118
Donor Network West (CADN)	12.16	12.80	80	23.82	25.06	92

OPO Name	Proposed Measure			Deaths (Age <= 75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
LifeBanc (OHLB)	<i>11.54</i>	<i>12.45</i>	<i>52</i>	<i>21.53</i>	<i>23.22</i>	<i>85</i>
Lifeline of Ohio (OHLP)	<i>11.43</i>	<i>12.40</i>	<i>46</i>	<i>23.63</i>	<i>25.64</i>	<i>26</i>
Center for Organ Recovery and Education (PATF)	<i>11.58</i>	<i>12.37</i>	<i>73</i>	<i>20.98</i>	<i>22.40</i>	<i>141</i>
LifeCenter Northwest (WALC)	<i>11.59</i>	<i>12.32</i>	<i>88</i>	<i>22.73</i>	<i>24.15</i>	<i>96</i>
Texas Organ Sharing Alliance (TXSA)	<i>11.44</i>	<i>12.25</i>	<i>73</i>	<i>24.40</i>	<i>26.14</i>	<i>24</i>
LifeLink of Florida (FLWC)	<i>11.47</i>	<i>12.24</i>	<i>82</i>	<i>22.67</i>	<i>24.19</i>	<i>83</i>
OneLegacy (CAOP)	<i>11.54</i>	<i>12.04</i>	<i>210</i>	<i>24.12</i>	<i>25.19</i>	<i>118</i>
New Mexico Donor Services (NMOP)	<i>10.50</i>	<i>11.92</i>	<i>28</i>	<i>18.44</i>	<i>20.93</i>	<i>55</i>
New Jersey Sharing Network (NJTO)	<i>11.09</i>	<i>11.89</i>	<i>91</i>	<i>22.05</i>	<i>23.64</i>	<i>88</i>
LifeCenter Organ Donor Network (OHOV)	<i>10.60</i>	<i>11.86</i>	<i>36</i>	<i>19.20</i>	<i>21.49</i>	<i>61</i>
Indiana Donor Network (INOP)	<i>10.84</i>	<i>11.58</i>	<i>121</i>	<i>22.55</i>	<i>24.09</i>	<i>83</i>
Life Alliance Organ Recovery Agency (FLMP)	<i>10.44</i>	<i>11.23</i>	<i>119</i>	<i>20.61</i>	<i>22.17</i>	<i>121</i>
New England Organ Bank (MAOB)	<i>10.56</i>	<i>11.15</i>	<i>219</i>	<i>19.21</i>	<i>20.29</i>	<i>322</i>
Carolina Donor Services (NCNC)	<i>10.47</i>	<i>11.14</i>	<i>171</i>	<i>19.98</i>	<i>21.26</i>	<i>205</i>
LifeQuest Organ Recovery Services (FLUF)	<i>10.16</i>	<i>11.00</i>	<i>112</i>	<i>19.17</i>	<i>20.76</i>	<i>139</i>
LifeLink of Georgia (GALL)	<i>10.30</i>	<i>10.89</i>	<i>238</i>	<i>19.07</i>	<i>20.16</i>	<i>317</i>
Pacific Northwest Transplant Bank (ORUO)	<i>9.92</i>	<i>10.80</i>	<i>107</i>	<i>17.37</i>	<i>18.92</i>	<i>172</i>
Gift of Life Michigan (MIOP)	<i>10.16</i>	<i>10.74</i>	<i>255</i>	<i>19.74</i>	<i>20.86</i>	<i>277</i>
Mid-South Transplant Foundation (TNMS)	<i>9.28</i>	<i>10.40</i>	<i>73</i>	<i>19.27</i>	<i>21.58</i>	<i>59</i>
LiveOnNY (NYRT)	<i>9.66</i>	<i>10.21</i>	<i>323</i>	<i>22.41</i>	<i>23.67</i>	<i>138</i>
Legacy of Life - Hawaii (HIOP)	<i>8.36</i>	<i>9.96</i>	<i>38</i>	<i>17.65</i>	<i>21.04</i>	<i>29</i>

OPO Name	Proposed Measure			Deaths (Age <= 75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 1,000 deaths)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Life Connection of Ohio (OHLC)	8.69	9.83	77	14.44	16.34	129
LifeNet Health (VATB)	9.05	9.75	210	18.98	20.44	169
Mississippi Organ Recovery Agency (MSOP)	8.71	9.66	114	18.12	20.10	95
Iowa Donor Network (IAOP)	7.72	8.79	100	13.59	15.47	135
LifeChoice Donor Services (CTOP)	7.42	8.37	131	14.82	16.71	128
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.97	300	14.71	15.99	290
LifeLink of Puerto Rico (PRL)	6.77	7.58	189	14.74	16.50	150
Center for Donation and Transplant (NYAP)	6.61	7.53	145	12.41	14.14	162
Legacy of Hope - Alabama (ALOB)	6.18	6.66	551	17.83	19.20	215
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.56	178	10.30	11.80	212
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.23	200	9.98	11.68	163
Totals			4,903			4,851

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Using total number of deaths as the denominator, the donor potential was 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 find 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 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 our 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.

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.⁴³ A population-based approach to re-

⁴³ For convenience, we used less than 75 years old rather than 75 and younger because of how the Census data is publicly reported.

certifying 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, for this reason, and others that we discuss in further detail, we chose not to propose it. The following tables show the effects of using an eligible population as the donor potential:

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Table 15a: OPO Donation Rates Using Census Population (Age < 75) Measure
 (Threshold donation rates are 4.11, and 4.31 for Census Population (Age <75) measure. OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			Census Population (Age <75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	4.73	5.42	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	3.76	4.42	0
DonorConnect (UTOP)	5.22	6.12	0	3.39	3.99	10
Midwest Transplant Network (MWOB)	5.35	5.96	0	4.85	5.41	0
Versiti (WIDN)	4.99	5.92	0	4.27	5.10	0
Nevada Donor Network (NVLV)	4.99	5.80	0	6.31	7.37	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	5.27	5.67	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	4.37	4.87	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	4.02	4.96	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	4.33	4.99	0
ConnectLife (NYWN)	4.04	5.10	0	3.84	4.88	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	5.46	6.19	0
Washington Regional Transplant	4.37	5.03	0	3.04	3.51	34

OPO Name	Proposed Measure			Census Population (Age <75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Community (DCTC)						
OurLegacy - FL (FLFH)	4.32	4.93	0	5.18	5.94	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	4.51	4.92	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	5.40	6.06	0
Donor Alliance (CORS)	3.95	4.55	0	2.80	3.23	50
LifeGift (TXGC)	4.15	4.52	0	4.09	4.47	0
Sierra Donor Services (CAGS)	3.73	4.50	0	2.97	3.60	17
Lifeshare Carolinas (NCCM)	3.77	4.46	0	4.43	5.26	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	3.48	3.79	53
Tennessee Donor Services (TNDS)	3.94	4.34	0	5.95	6.57	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	4.55	5.11	0
LifeSource - MN (MNOP)	3.68	4.17	0	2.87	3.26	60
New Mexico Donor Services (NMOP)	3.32	4.16	0	3.02	3.81	9
Legacy of Life - Hawaii (HIOP)	3.06	4.11	1	2.83	3.82	6
LifeCenter Organ Donor Network (OHOV)	3.35	4.10	1	3.50	4.30	1

OPO Name	Proposed Measure			Census Population (Age <75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
LifeCenter Northwest (WALC)	3.68	4.10	1	3.31	3.69	42
New Jersey Sharing Network (NJTO)	3.61	4.08	2	2.85	3.22	67
LifeBanc (OHLB)	3.54	4.06	2	4.04	4.65	0
LifeLink of Florida (FLWC)	3.62	4.06	3	4.93	5.55	0
Louisiana Organ Procurement Agency (LAOP)	3.59	4.05	3	4.58	5.18	0
Life Alliance Organ Recovery Agency (FLMP)	3.55	4.02	5	3.37	3.82	24
Lifeline of Ohio (OHLP)	3.40	3.95	6	4.13	4.81	0
Sharing Hope SC (SCOP)	3.39	3.87	11	4.07	4.65	0
Donor Network West (CADN)	3.43	3.77	29	2.64	2.90	153
OneLegacy (CAOP)	3.47	3.75	44	2.59	2.80	248
Pacific Northwest Transplant Bank (ORUO)	3.14	3.65	17	2.71	3.16	48
Life Connection of Ohio (OHLC)	2.94	3.65	9	3.01	3.74	11
Gift of Life Michigan (MIOP)	3.31	3.64	39	3.42	3.77	44
Texas Organ Sharing Alliance (TXSA)	3.19	3.63	23	2.88	3.29	55
LifeLink of Georgia (GALL)	3.27	3.60	42	3.21	3.54	64
LifeQuest Organ Recovery Services (FLUF)	3.12	3.60	21	4.08	4.72	0

OPO Name	Proposed Measure			Census Population (Age <75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
New England Organ Bank (MAOB)	3.26	3.59	43	2.67	2.95	139
Mid-South Transplant Foundation (TNMS)	2.91	3.56	12	3.77	4.64	0
Carolina Donor Services (NCNC)	2.93	3.30	53	3.23	3.64	40
LiveOnNY (NYRT)	2.96	3.27	76	2.44	2.69	177
Indiana Donor Network (INOP)	2.78	3.17	52	3.25	3.71	28
Iowa Donor Network (IAOP)	2.43	3.07	21	1.99	2.52	43
Mississippi Organ Recovery Agency (MSOP)	2.53	3.07	29	3.59	4.37	0
LifeNet Health (VATB)	2.64	3.03	56	3.10	3.56	33
LifeLink of Puerto Rico (PRL)	2.43	2.94	35	2.37	2.88	44
LifeChoice Donor Services (CTOP)	2.34	2.91	29	2.09	2.60	45
Center for Donation and Transplant (NYAP)	2.24	2.81	30	2.00	2.52	45
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.33	90	2.83	3.34	35
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.27	44	2.13	2.74	31
Legacy of Hope - Alabama (ALOB)	1.98	2.26	141	3.85	4.40	0

OPO Name	Proposed Measure			Census Population (Age <75)		
	Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Donors Needed to Reach 25% Cutoff
Finger Lakes Donor Recovery Network (NYFL)	<i>1.65</i>	<i>2.15</i>	<i>45</i>	<i>1.76</i>	<i>2.30</i>	<i>43</i>
Totals			1,015			1,699

Table 15b: OPO Organ Transplantation Rates Using Census Population (Age < 75) Measure

(Threshold donation rates are 13.73, and 14.26 for Census Population (Age <75) measure. OPOs flagged are in bolded italics.)

OPO Name	Proposed Measure			Census Population (Age <75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	13.31	14.48	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	15.83	17.04	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	17.30	18.32	0
DonorConnect (UTOP)	17.24	18.82	0	<i>11.19</i>	<i>12.22</i>	<i>62</i>
Versiti (WIDN)	17.03	18.70	0	14.58	16.01	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	15.37	16.27	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	14.93	16.60	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	15.15	16.32	0
Nevada Donor Network (NVLV)	15.50	16.90	0	19.61	21.38	0

OPO Name	Proposed Measure			Census Population (Age <75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Gift of Life Donor Program (PADV)	16.12	16.80	0	16.30	16.99	0
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	10.18	11.00	144
OurLegacy - FL (FLFH)	14.29	15.38	0	17.13	18.44	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	15.43	16.16	0
LifeGift (TXGC)	14.50	15.20	0	14.31	14.99	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	15.79	17.26	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	17.91	19.04	0
ConnectLife (NYWN)	12.59	14.38	0	11.98	13.68	8
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	16.27	17.49	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	11.62	12.18	219
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	16.78	17.89	0
Tennessee Donor Services (TNDS)	13.13	13.86	0	19.84	20.94	0
Sierra Donor Services (CAGS)	12.43	13.77	0	9.92	10.99	82
LifeSource - MN (MNOP)	12.51	13.40	16	9.77	10.46	223
Sharing Hope SC (SCOP)	12.27	13.15	26	14.71	15.77	0
Donor Alliance (CORS)	11.82	12.83	31	8.37	9.08	245
Donor Network West (CADN)	12.16	12.80	80	9.36	9.85	488
LifeBanc (OHLB)	11.54	12.45	52	13.18	14.21	2

OPO Name	Proposed Measure			Census Population (Age <75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Lifeline of Ohio (OHLP)	11.43	12.40	46	13.87	15.06	0
Center for Organ Recovery and Education (PATF)	11.58	12.37	73	13.68	14.60	0
LifeCenter Northwest (WALC)	11.59	12.32	88	10.42	11.07	222
Texas Organ Sharing Alliance (TXSA)	11.44	12.25	73	10.33	11.06	175
LifeLink of Florida (FLWC)	11.47	12.24	82	15.64	16.69	0
OneLegacy (CAOP)	11.54	12.04	210	8.61	8.98	884
New Mexico Donor Services (NMOP)	10.50	11.92	28	9.57	10.86	58
New Jersey Sharing Network (NJTO)	11.09	11.89	91	8.74	9.37	307
LifeCenter Organ Donor Network (OHOV)	10.60	11.86	36	11.08	12.41	35
Indiana Donor Network (INOP)	10.84	11.58	121	12.67	13.54	35
Life Alliance Organ Recovery Agency (FLMP)	10.44	11.23	119	9.91	10.66	182
New England Organ Bank (MAOB)	10.56	11.15	219	8.64	9.13	534
Carolina Donor Services (NCNC)	10.47	11.14	171	11.53	12.27	120
LifeQuest Organ Recovery Services (FLUF)	10.16	11.00	112	13.29	14.40	0
LifeLink of Georgia (GALL)	10.30	10.89	238	10.11	10.69	304
Pacific Northwest Transplant Bank (ORUO)	9.92	10.80	107	8.55	9.31	210
Gift of Life Michigan (MIOP)	10.16	10.74	255	10.50	11.10	262

OPO Name	Proposed Measure			Census Population (Age <75)		
	TX Rate	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff	Rate (per 100,000 pop.)	Upper Bound of CI	Additional Organs Needed to Reach 25% Cutoff
Mid-South Transplant Foundation (TNMS)	9.28	10.40	73	12.05	13.50	13
LiveOnNY (NYRT)	9.66	10.21	323	7.95	8.40	655
Legacy of Life - Hawaii (HIOP)	8.36	9.96	38	7.72	9.20	55
Life Connection of Ohio (OHLIC)	8.69	9.83	77	8.88	10.05	81
LifeNet Health (VATB)	9.05	9.75	210	10.60	11.42	128
Mississippi Organ Recovery Agency (MSOP)	8.71	9.66	114	12.37	13.72	11
Iowa Donor Network (IAOP)	7.72	8.79	100	6.32	7.19	176
LifeChoice Donor Services (CTOP)	7.42	8.37	131	6.62	7.46	186
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.97	300	10.46	11.37	106
LifeLink of Puerto Rico (PRLI)	6.77	7.58	189	6.61	7.39	216
Center for Donation and Transplant (NYAP)	6.61	7.53	145	5.90	6.73	197
Legacy of Hope - Alabama (ALOB)	6.18	6.66	551	12.00	12.93	54
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.56	178	6.91	7.91	130
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.23	200	4.77	5.58	191
Totals			4,903			7,000

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In the population-based approach, we would have 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 rates of deaths consistent with organ

donation.⁴⁴ Although we would not consider a measure which is based solely on population size, we are seeking comments as to whether there are appropriate risk-adjustments that could be used so that a population

⁴⁴ 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).

measure could be reflective of the organ donation potential.

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 flagging correctly. Our

methodology uses 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. The following tables show the effects of these different CIs:

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Table 16a. OPO Donor Rates Compared at 90 Percent, 95 Percent and 99 Percent Confidence Levels

(Threshold donation rate is 4.11.)

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.27	6.45	6.81
Lifesharing - A Donate Life Organization (CASD)	5.49	6.21	6.42	6.83
DonorConnect (UTOP)	5.22	5.92	6.12	6.52
Midwest Transplant Network (MWOB)	5.35	5.82	5.96	6.22
Versiti (WIDN)	4.99	5.71	5.92	6.34
Nevada Donor Network (NVLV)	4.99	5.61	5.80	6.16
Gift of Life Donor Program (PADV)	5.21	5.51	5.60	5.76
Donor Network of Arizona (AZOB)	4.83	5.24	5.36	5.60
Nebraska Organ Recovery (NEOR)	4.34	5.10	5.33	5.77
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.02	5.17	5.46
ConnectLife (NYWN)	4.04	4.86	5.10	5.59
LifeShare of Oklahoma (OKOP)	4.48	4.93	5.06	5.32
Washington Regional Transplant Community (DCTC)	4.37	4.88	5.03	5.31
OurLegacy - FL (FLFH)	4.32	4.80	4.93	5.20
Southwest Transplant Alliance (TXSB)	4.27	4.57	4.65	4.81
Mid-America Transplant Services (MOMA)	4.12	4.50	4.61	4.82
Donor Alliance (CORS)	3.95	4.41	4.55	4.81
LifeGift (TXGC)	4.15	4.44	4.52	4.69
Sierra Donor Services (CAGS)	3.73	4.32	4.50	4.84
Lifeshare Carolinas (NCCM)	3.77	4.30	4.46	4.76
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.36	4.45	4.60
Tennessee Donor Services (TNDS)	3.94	4.25	4.34	4.51

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Center for Organ Recovery and Education (PATF)	3.85	4.21	4.31	4.51
LifeSource - MN (MNOP)	3.68	4.05	4.17	4.38
New Mexico Donor Services (NMOP)	3.32	3.97	4.16	4.55
Legacy of Life - Hawaii (HIOP)	3.06	3.86	4.11	4.59
LifeCenter Organ Donor Network (OHOV)	3.35	3.93	4.10	4.44
LifeCenter Northwest (WALC)	3.68	4.00	4.10	4.28
New Jersey Sharing Network (NJTO)	3.61	3.97	4.08	4.28
LifeBanc (OHLB)	3.54	3.94	4.06	4.29
LifeLink of Florida (FLWC)	3.62	3.96	4.06	4.25
Louisiana Organ Procurement Agency (LAOP)	3.59	3.95	4.05	4.26
Life Alliance Organ Recovery Agency (FLMP)	3.55	3.91	4.02	4.23
Lifeline of Ohio (OHLP)	3.40	3.83	3.95	4.19
Sharing Hope SC (SCOP)	3.39	3.76	3.87	4.08
Donor Network West (CADN)	3.43	3.69	3.77	3.92
OneLegacy (CAOP)	3.47	3.69	3.75	3.88
Pacific Northwest Transplant Bank (ORUO)	3.14	3.54	3.65	3.88
Life Connection of Ohio (OHLC)	2.94	3.48	3.65	3.97
Gift of Life Michigan (MIOP)	3.31	3.57	3.64	3.79
Texas Organ Sharing Alliance (TXSA)	3.19	3.53	3.63	3.83
LifeLink of Georgia (GALL)	3.27	3.53	3.60	3.75
LifeQuest Organ Recovery Services (FLUF)	3.12	3.49	3.60	3.81
New England Organ Bank (MAOB)	3.26	3.52	3.59	3.74
Mid-South Transplant Foundation (TNMS)	2.91	3.41	3.56	3.86
Carolina Donor Services (NCNC)	2.93	3.22	3.30	3.46
LiveOnNY (NYRT)	2.96	3.20	3.27	3.40

OPO Name	All Organ Donation Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Indiana Donor Network (INOP)	2.78	3.08	3.17	3.34
Iowa Donor Network (IAOP)	2.43	2.93	3.07	3.37
Mississippi Organ Recovery Agency (MSOP)	2.53	2.95	3.07	3.31
LifeNet Health (VATB)	2.64	2.95	3.03	3.21
LifeLink of Puerto Rico (PRL)	2.43	2.82	2.94	3.17
LifeChoice Donor Services (CTOP)	2.34	2.78	2.91	3.17
Center for Donation and Transplant (NYAP)	2.24	2.68	2.81	3.08
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.25	2.33	2.49
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.15	2.27	2.50
Legacy of Hope - Alabama (ALOB)	1.98	2.20	2.26	2.38
Finger Lakes Donor Recovery Network (NYFL)	1.65	2.03	2.15	2.38

Table 16b. OPO Organ Transplantation Rates Compared at 90 Percent, 95 Percent and 99 Percent Confidence Levels

(Threshold organ transplantation rate is 13.73)

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Lifesharing - A Donate Life Organization (CASD)	19.44	20.77	21.14	21.86
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.05	20.37	20.98
Midwest Transplant Network (MWOB)	19.11	19.99	20.24	20.72
DonorConnect (UTOP)	17.24	18.47	18.82	19.49
Versiti (WIDN)	17.03	18.33	18.70	19.40
Donor Network of Arizona (AZOB)	16.97	17.74	17.96	18.38

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
Nebraska Organ Recovery (NEOR)	16.13	17.53	17.93	18.69
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.71	16.98	17.49
Nevada Donor Network (NVLV)	15.50	16.59	16.90	17.49
Gift of Life Donor Program (PADV)	16.12	16.65	16.80	17.09
Washington Regional Transplant Community (DCTC)	14.63	15.54	15.80	16.29
OurLegacy - FL (FLFH)	14.29	15.14	15.38	15.84
Southwest Transplant Alliance (TXSB)	14.61	15.15	15.30	15.59
LifeGift (TXGC)	14.50	15.04	15.20	15.49
Lifeshare Carolinas (NCCM)	13.43	14.40	14.67	15.20
Mid-America Transplant Services (MOMA)	13.65	14.33	14.52	14.89
ConnectLife (NYWN)	12.59	13.98	14.38	15.14
LifeShare of Oklahoma (OKOP)	13.35	14.13	14.35	14.77
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.16	14.30	14.58
Louisiana Organ Procurement Agency (LAOP)	13.15	13.83	14.02	14.38
Tennessee Donor Services (TNDS)	13.13	13.70	13.86	14.16
Sierra Donor Services (CAGS)	12.43	13.48	13.77	14.34
LifeSource - MN (MNOP)	12.51	13.20	13.40	13.77
Sharing Hope SC (SCOP)	12.27	12.96	13.15	13.52
Donor Alliance (CORS)	11.82	12.60	12.83	13.25
Donor Network West (CADN)	12.16	12.66	12.80	13.06
LifeBanc (OHLB)	11.54	12.25	12.45	12.83
Lifeline of Ohio (OHLP)	11.43	12.19	12.40	12.81
Center for Organ Recovery and Education (PATF)	11.58	12.19	12.37	12.69
LifeCenter Northwest (WALC)	11.59	12.16	12.32	12.62
Texas Organ Sharing Alliance (TXSA)	11.44	12.07	12.25	12.59
LifeLink of Florida (FLWC)	11.47	12.07	12.24	12.57
OneLegacy (CAOP)	11.54	11.93	12.04	12.26
New Mexico Donor Services (NMOP)	10.50	11.61	11.92	12.53

OPO Name	TX Rate	Upper Bound of Confidence Interval 90%	Upper Bound of Confidence Interval 95%	Upper Bound of Confidence Interval 99%
New Jersey Sharing Network (NJTO)	11.09	11.72	11.89	12.23
LifeCenter Organ Donor Network (OHOV)	10.60	11.58	11.86	12.40
Indiana Donor Network (INOP)	10.84	11.42	11.58	11.89
Life Alliance Organ Recovery Agency (FLMP)	10.44	11.06	11.23	11.57
New England Organ Bank (MAOB)	10.56	11.02	11.15	11.40
Carolina Donor Services (NCNC)	10.47	10.99	11.14	11.42
LifeQuest Organ Recovery Services (FLUF)	10.16	10.81	11.00	11.35
LifeLink of Georgia (GALL)	10.30	10.76	10.89	11.14
Pacific Northwest Transplant Bank (ORUO)	9.92	10.61	10.80	11.17
Gift of Life Michigan (MIOP)	10.16	10.62	10.74	10.99
Mid-South Transplant Foundation (TNMS)	9.28	10.15	10.40	10.87
LiveOnNY (NYRT)	9.66	10.09	10.21	10.44
Legacy of Life - Hawaii (HIOP)	8.36	9.60	9.96	10.65
Life Connection of Ohio (OHLC)	8.69	9.58	9.83	10.32
LifeNet Health (VATB)	9.05	9.59	9.75	10.04
Mississippi Organ Recovery Agency (MSOP)	8.71	9.45	9.66	10.07
Iowa Donor Network (IAOP)	7.72	8.55	8.79	9.24
LifeChoice Donor Services (CTOP)	7.42	8.16	8.37	8.77
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.83	7.97	8.23
LifeLink of Puerto Rico (PRLI)	6.77	7.40	7.58	7.92
Center for Donation and Transplant (NYAP)	6.61	7.33	7.53	7.92
Legacy of Hope - Alabama (ALOB)	6.18	6.55	6.66	6.86
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.37	6.56	6.91
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.06	5.23	5.55

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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).

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.

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Table 17a. OPO Donation Rates Using Geometric Mean or Median Measures

(Threshold donation rates are 4.11 for the proposed measure, 3.54 for the median measure, and 3.40 for the geometric mean measure. OPOs flagged are in bolded italics.)

OPO Name	Donation Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	6.45	6.45
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	6.42	6.42
DonorConnect (UTOP)	5.22	6.12	6.12	6.12
Midwest Transplant Network (MWOB)	5.35	5.96	5.96	5.96
Versiti (WIDN)	4.99	5.92	5.92	5.92
Nevada Donor Network (NVLV)	4.99	5.80	5.80	5.80
Gift of Life Donor Program (PADV)	5.21	5.60	5.60	5.60
Donor Network of Arizona (AZOB)	4.83	5.36	5.36	5.36
Nebraska Organ Recovery (NEOR)	4.34	5.33	5.33	5.33
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	5.17	5.17
ConnectLife (NYWN)	4.04	5.10	5.10	5.10
LifeShare of Oklahoma (OKOP)	4.48	5.06	5.06	5.06
Washington Regional Transplant Community (DCTC)	4.37	5.03	5.03	5.03
OurLegacy - FL (FLFH)	4.32	4.93	4.93	4.93
Southwest Transplant Alliance (TXSB)	4.27	4.65	4.65	4.65
Mid-America Transplant Services (MOMA)	4.12	4.61	4.61	4.61
Donor Alliance (CORS)	3.95	4.55	4.55	4.55
LifeGift (TXGC)	4.15	4.52	4.52	4.52
Sierra Donor Services (CAGS)	3.73	4.50	4.50	4.50
Lifeshare Carolinas (NCCM)	3.77	4.46	4.46	4.46
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	4.45	4.45
Tennessee Donor Services (TNDS)	3.94	4.34	4.34	4.34
Center for Organ Recovery and Education (PATF)	3.85	4.31	4.31	4.31

OPO Name	Donation Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
LifeSource - MN (MNOP)	3.68	4.17	4.17	4.17
New Mexico Donor Services (NMOP)	3.32	4.16	4.16	4.16
Legacy of Life - Hawaii (HIOP)	3.06	4.11	4.11	4.11
LifeCenter Organ Donor Network (OHOV)	3.35	4.10	4.10	4.10
LifeCenter Northwest (WALC)	3.68	4.10	4.10	4.10
New Jersey Sharing Network (NJTO)	3.61	4.08	4.08	4.08
LifeBanc (OHLB)	3.54	4.06	4.06	4.06
LifeLink of Florida (FLWC)	3.62	4.06	4.06	4.06
Louisiana Organ Procurement Agency (LAOP)	3.59	4.05	4.05	4.05
Life Alliance Organ Recovery Agency (FLMP)	3.55	4.02	4.02	4.02
Lifeline of Ohio (OHLP)	3.40	3.95	3.95	3.95
Sharing Hope SC (SCOP)	3.39	3.87	3.87	3.87
Donor Network West (CADN)	3.43	3.77	3.77	3.77
OneLegacy (CAOP)	3.47	3.75	3.75	3.75
Pacific Northwest Transplant Bank (ORUO)	3.14	3.65	3.65	3.65
Life Connection of Ohio (OHLC)	2.94	3.65	3.65	3.65
Gift of Life Michigan (MIOP)	3.31	3.64	3.64	3.64
Texas Organ Sharing Alliance (TXSA)	3.19	3.63	3.63	3.63
LifeLink of Georgia (GALL)	3.27	3.60	3.60	3.60
LifeQuest Organ Recovery Services (FLUF)	3.12	3.60	3.60	3.60
New England Organ Bank (MAOB)	3.26	3.59	3.59	3.59
Mid-South Transplant Foundation (TNMS)	2.91	3.56	3.56	3.56
Carolina Donor Services (NCNC)	2.93	3.30	3.30	3.30
LiveOnNY (NYRT)	2.96	3.27	3.27	3.27
Indiana Donor Network (INOP)	2.78	3.17	3.17	3.17
Iowa Donor Network (IAOP)	2.43	3.07	3.07	3.07
Mississippi Organ Recovery Agency (MSOP)	2.53	3.07	3.07	3.07
LifeNet Health (VATB)	2.64	3.03	3.03	3.03
LifeLink of Puerto Rico (PRLI)	2.43	2.94	2.94	2.94

OPO Name	Donation Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
LifeChoice Donor Services (CTOP)	2.34	2.91	2.91	2.91
Center for Donation and Transplant (NYAP)	2.24	2.81	2.81	2.81
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.33	2.33	2.33
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.27	2.27	2.27
Legacy of Hope - Alabama (ALOB)	1.98	2.26	2.26	2.26
Finger Lakes Donor Recovery Network (NYFL)	1.65	2.15	2.15	2.15

Table 17b. OPO Transplant Rates Using Geometric Mean or Median Measures

(Threshold transplant rates are 13.73 for the proposed measure, 11.61 for the median measure, and 11.25 for the geometric mean measure. OPOs flagged are in bolded italics.)

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	21.14	21.14
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	20.37	20.37
Midwest Transplant Network (MWOB)	19.11	20.24	20.24	20.24
DonorConnect (UTOP)	17.24	18.82	18.82	18.82
Versiti (WIDN)	17.03	18.70	18.70	18.70
Donor Network of Arizona (AZOB)	16.97	17.96	17.96	17.96
Nebraska Organ Recovery (NEOR)	16.13	17.93	17.93	17.93
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	16.98	16.98
Nevada Donor Network (NVLV)	15.50	16.90	16.90	16.90
Gift of Life Donor Program (PADV)	16.12	16.80	16.80	16.80
Washington Regional Transplant Community (DCTC)	14.63	15.80	15.80	15.80
OurLegacy - FL (FLFH)	14.29	15.38	15.38	15.38
Southwest Transplant Alliance (TXSB)	14.61	15.30	15.30	15.30

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
LifeGift (TXGC)	14.50	15.20	15.20	15.20
Lifeshare Carolinas (NCCM)	13.43	14.67	14.67	14.67
Mid-America Transplant Services (MOMA)	13.65	14.52	14.52	14.52
ConnectLife (NYWN)	12.59	14.38	14.38	14.38
LifeShare of Oklahoma (OKOP)	13.35	14.35	14.35	14.35
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	14.30	14.30
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	14.02	14.02
Tennessee Donor Services (TNDS)	13.13	13.86	13.86	13.86
Sierra Donor Services (CAGS)	12.43	13.77	13.77	13.77
LifeSource - MN (MNOP)	12.51	13.40	13.40	13.40
Sharing Hope SC (SCOP)	12.27	13.15	13.15	13.15
Donor Alliance (CORS)	11.82	12.83	12.83	12.83
Donor Network West (CADN)	12.16	12.80	12.80	12.80
LifeBanc (OHLB)	11.54	12.45	12.45	12.45
Lifeline of Ohio (OHLP)	11.43	12.40	12.40	12.40
Center for Organ Recovery and Education (PATF)	11.58	12.37	12.37	12.37
LifeCenter Northwest (WALC)	11.59	12.32	12.32	12.32
Texas Organ Sharing Alliance (TXSA)	11.44	12.25	12.25	12.25
LifeLink of Florida (FLWC)	11.47	12.24	12.24	12.24
OneLegacy (CAOP)	11.54	12.04	12.04	12.04
New Mexico Donor Services (NMOP)	10.50	11.92	11.92	11.92
New Jersey Sharing Network (NJTO)	11.09	11.89	11.89	11.89
LifeCenter Organ Donor Network (OHOV)	10.60	11.86	11.86	11.86
Indiana Donor Network (INOP)	10.84	11.58	11.58	11.58
Life Alliance Organ Recovery Agency (FLMP)	10.44	11.23	11.23	11.23
New England Organ Bank (MAOB)	10.56	11.15	11.15	11.15
Carolina Donor Services (NCNC)	10.47	11.14	11.14	11.14
LifeQuest Organ Recovery Services (FLUF)	10.16	11.00	11.00	11.00
LifeLink of Georgia (GALL)	10.30	10.89	10.89	10.89

OPO Name	Transplant Rate	Upper Bound of CI		
		Proposed	Median	Geometric Mean
Pacific Northwest Transplant Bank (ORUO)	9.92	10.80	10.80	10.80
Gift of Life Michigan (MIOP)	10.16	10.74	10.74	10.74
Mid-South Transplant Foundation (TNMS)	9.28	10.40	10.40	10.40
LiveOnNY (NYRT)	9.66	10.21	10.21	10.21
Legacy of Life - Hawaii (HIOP)	8.36	9.96	9.96	9.96
Life Connection of Ohio (OHLC)	8.69	9.83	9.83	9.83
LifeNet Health (VATB)	9.05	9.75	9.75	9.75
Mississippi Organ Recovery Agency (MSOP)	8.71	9.66	9.66	9.66
Iowa Donor Network (IAOP)	7.72	8.79	8.79	8.79
LifeChoice Donor Services (CTOP)	7.42	8.37	8.37	8.37
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.97	7.97	7.97
LifeLink of Puerto Rico (PRL)	6.77	7.58	7.58	7.58
Center for Donation and Transplant (NYAP)	6.61	7.53	7.53	7.53
Legacy of Hope - Alabama (ALOB)	6.18	6.66	6.66	6.66
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.56	6.56	6.56
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.23	5.23	5.23

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We are actively considering use of a static, absolute threshold as a viable alternative to use of a relative performance metric, but question whether this approach could inadvertently incentivize all OPO performances to move towards a static threshold, thus decreasing total donations and transplantations. We are interested in robust public comments that support or refute these concerns and comments that list the potential impacts, benefits, or consequences of implementing this approach. We specifically request that commenters present data, studies, or other analysis to support their recommendations. We also seek comments on ways to incentivize continual improvement of all OPOs, including high performers and low performers. Additionally, we are interested in 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).

There were other alternatives that we chose not to propose. We 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 believe that this approach incorrectly places the requirement to report an imminent death solely on the donor hospital, rather we believe this is a joint responsibility shared with an OPO.

Another option suggested by some members of the OPO community and commenters in response to the RFI is using donor/ventilated deaths for donor potential. While we appreciate this suggestion, there are no standardized databases that would allow us to determine the ventilator status of

deaths, and we are 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 are sufficient and appropriate referrals are 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 our goals in proposing these new performance measures: To reduce the reporting burdens so that resources can go towards increasing organ donation and transplantation.

Also discussed in the preamble, we recognize that the OPO in Hawaii is at a considerable geographic disadvantage for placement of 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. These

tables show the effects of the kidney donation and transplantation rates:

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Table 18a. OPO Donation Rates for All Organs Compared to Kidneys Only with Top 25 Percent Cutoff

(Threshold donation rate for all donors is 4.11 and for kidney donors is 3.45.)

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Organ Procurement Organization at the University of Wisconsin (WIUW)	5.65	6.45	0	120	4.55	5.28	0
Lifesharing - A Donate Life Organization (CASD)	5.49	6.42	0	96	4.83	5.72	0
DonorConnect (UTOP)	5.22	6.12	0	94	4.59	5.44	0
Midwest Transplant Network (MWOB)	5.35	5.96	0	200	4.65	5.22	0
Versiti (WIDN)	4.99	5.92	0	70	3.80	4.63	0
Nevada Donor Network (NVLV)	4.99	5.80	0	89	3.76	4.48	0
Gift of Life Donor Program (PADV)	5.21	5.60	0	408	4.18	4.53	0
Donor Network of Arizona (AZOB)	4.83	5.36	0	215	4.31	4.82	0
Nebraska Organ Recovery (NEOR)	4.34	5.33	0	60	3.95	4.89	0
The Living Legacy Foundation of Maryland (MDPC)	4.51	5.17	0	107	3.37	3.96	0
ConnectLife (NYWN)	4.04	5.10	0	44	3.55	4.57	0
LifeShare of Oklahoma (OKOP)	4.48	5.06	0	153	3.87	4.42	0
Washington Regional Transplant Community (DCTC)	4.37	5.03	0	127	3.66	4.24	0
OurLegacy - FL (FLFH)	4.32	4.93	0	137	3.87	4.45	0
Southwest Transplant Alliance (TXSB)	4.27	4.65	0	300	3.44	3.78	0
Mid-America Transplant Services (MOMA)	4.12	4.61	0	165	3.13	3.56	0
Donor Alliance (CORS)	3.95	4.55	0	50	1.95	2.48	23
LifeGift (TXGC)	4.15	4.52	0	293	3.42	3.76	0

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Sierra Donor Services (CAGS)	3.73	4.50	0	67	3.20	3.92	0
Lifeshare Carolinas (NCCM)	3.77	4.46	0	85	3.27	3.92	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	4.08	4.45	0	287	3.15	3.47	0
Tennessee Donor Services (TNDS)	3.94	4.34	0	227	3.16	3.52	0
Center for Organ Recovery and Education (PATF)	3.85	4.31	0	173	3.15	3.57	0
LifeSource - MN (MNOP)	3.68	4.17	0	149	3.17	3.62	0
New Mexico Donor Services (NMOP)	3.32	4.16	0	48	2.95	3.75	0
Legacy of Life - Hawaii (HIOP)	3.06	4.11	1	31	2.88	3.89	0
LifeCenter Organ Donor Network (OHOV)	3.35	4.10	1	55	2.71	3.40	1
LifeCenter Northwest (WALC)	3.68	4.10	1	213	3.32	3.72	0
New Jersey Sharing Network (NJTO)	3.61	4.08	2	150	2.95	3.37	4
LifeBanc (OHLB)	3.54	4.06	2	107	2.58	3.03	17
LifeLink of Florida (FLWC)	3.62	4.06	3	167	2.95	3.35	6
Louisiana Organ Procurement Agency (LAOP)	3.59	4.05	3	143	2.82	3.24	10
Life Alliance Organ Recovery Agency (FLMP)	3.55	4.02	5	142	2.88	3.31	7
Lifeline of Ohio (OHLP)	3.40	3.95	6	99	2.76	3.26	7
Sharing Hope SC (SCOP)	3.39	3.87	11	131	2.85	3.29	7
Donor Network West (CADN)	3.43	3.77	29	256	2.94	3.26	16
OneLegacy (CAOP)	3.47	3.75	44	353	2.77	3.03	52
Pacific Northwest Transplant Bank (ORUO)	3.14	3.65	17	110	2.90	3.40	2
Life Connection of Ohio (OHLIC)	2.94	3.65	9	46	2.22	2.85	12

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff	Kidney Only Donors	Kidney Donation Rate	Upper Bound of CI	Additional Donors Needed to Reach Cutoff
Gift of Life Michigan (MIOP)	3.31	3.64	39	232	2.66	2.96	41
Texas Organ Sharing Alliance (TXSA)	3.19	3.63	23	153	3.01	3.44	1
LifeLink of Georgia (GALL)	3.27	3.60	42	206	2.40	2.70	62
LifeQuest Organ Recovery Services (FLUF)	3.12	3.60	21	110	2.60	3.04	16
New England Organ Bank (MAOB)	3.26	3.59	43	248	2.85	3.16	24
Mid-South Transplant Foundation (TNMS)	2.91	3.56	12	54	2.34	2.94	11
Carolina Donor Services (NCNC)	2.93	3.30	53	174	2.57	2.91	35
LiveOnNY (NYRT)	2.96	3.27	76	225	2.40	2.68	69
Indiana Donor Network (INOP)	2.78	3.17	52	138	2.39	2.75	38
Iowa Donor Network (IAOP)	2.43	3.07	21	46	2.15	2.76	14
Mississippi Organ Recovery Agency (MSOP)	2.53	3.07	29	62	2.12	2.62	23
LifeNet Health (VATB)	2.64	3.03	56	124	2.28	2.64	42
LifeLink of Puerto Rico (PRL)	2.43	2.94	35	56	1.75	2.19	37
LifeChoice Donor Services (CTOP)	2.34	2.91	29	115	3.64	4.25	0
Center for Donation and Transplant (NYAP)	2.24	2.81	30	44	1.80	2.32	26
Kentucky Organ Donor Affiliates (KYDA)	1.99	2.33	90	87	1.61	1.93	77
Arkansas Regional Organ Recovery Agency (AROR)	1.77	2.27	44	39	1.50	1.96	35
Legacy of Hope - Alabama (ALOB)	1.98	2.26	141	117	1.46	1.70	133
Finger Lakes Donor Recovery Network (NYFL)	1.65	2.15	45	33	1.33	1.78	38
Totals			1,015	8,030			886

Table 18b. OPO Organ Transplantation Rates for All Organs Compared to Kidneys Only with Top 25 Percent Cutoff

(Threshold organ transplantation rate for all organs is 13.73 and for kidneys is 6.67)

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Lifesharing - A Donate Life Organization (CASD)	19.44	21.14	0	186	9.37	10.58	0
Organ Procurement Organization at the University of Wisconsin (WIUW)	18.92	20.37	0	232	8.79	9.81	0
Midwest Transplant Network (MWOB)	19.11	20.24	0	380	8.84	9.63	0
DonorConnect (UTOP)	17.24	18.82	0	181	8.84	10.00	0
Versiti (WIDN)	17.03	18.70	0	134	7.27	8.39	0
Donor Network of Arizona (AZOB)	16.97	17.96	0	411	8.23	8.94	0
Nebraska Organ Recovery (NEOR)	16.13	17.93	0	114	7.50	8.77	0
The Living Legacy Foundation of Maryland (MDPC)	15.77	16.98	0	200	6.31	7.09	0
Nevada Donor Network (NVLV)	15.50	16.90	0	167	7.06	8.02	0
Gift of Life Donor Program (PADV)	16.12	16.80	0	778	7.96	8.45	0

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Washington Regional Transplant Community (DCTC)	14.63	15.80	0	223	7.06	7.89	0
OurLegacy - FL (FLFH)	14.29	15.38	0	252	7.12	7.90	0
Southwest Transplant Alliance (TXSB)	14.61	15.30	0	570	6.53	7.00	0
LifeGift (TXGC)	14.50	15.20	0	548	6.39	6.86	0
Lifeshare Carolinas (NCCM)	13.43	14.67	0	160	6.16	7.02	0
Mid-America Transplant Services (MOMA)	13.65	14.52	0	312	5.92	6.51	9
ConnectLife (NYWN)	12.59	14.38	0	85	6.86	8.22	0
LifeShare of Oklahoma (OKOP)	13.35	14.35	0	284	7.18	7.92	0
Gift of Hope Organ & Tissue Donor Network (ILIP)	13.65	14.30	0	535	5.87	6.31	32
Louisiana Organ Procurement Agency (LAOP)	13.15	14.02	0	271	5.34	5.91	37
Tennessee Donor Services (TNDS)	13.13	13.86	0	426	5.93	6.42	18

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Sierra Donor Services (CAGS)	12.43	13.77	0	128	6.12	7.09	0
LifeSource - MN (MNOP)	12.51	13.40	16	286	6.08	6.70	0
Sharing Hope SC (SCOP)	12.27	13.15	26	253	5.50	6.11	25
Donor Alliance (CORS)	11.82	12.83	31	246	7.09	7.88	0
Donor Network West (CADN)	12.16	12.80	80	487	5.60	6.03	54
LifeBanc (OHLB)	11.54	12.45	52	199	4.80	5.39	51
Lifeline of Ohio (OHLP)	11.43	12.40	46	186	5.19	5.86	28
Center for Organ Recovery and Education (PATF)	11.58	12.37	73	324	5.89	6.46	12
LifeCenter Northwest (WALC)	11.59	12.32	88	393	6.13	6.67	1
Texas Organ Sharing Alliance (TXSA)	11.44	12.25	73	287	5.65	6.23	22
LifeLink of Florida (FLWC)	11.47	12.24	82	312	5.51	6.05	34
OneLegacy (CAOP)	11.54	12.04	210	668	5.25	5.60	133
New Mexico Donor Services (NMOP)	10.50	11.92	28	91	5.59	6.65	1
New Jersey Sharing	11.09	11.89	91	286	5.62	6.19	24

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Network (NJTO)							
LifeCenter Organ Donor Network (OHOV)	10.60	11.86	36	98	4.83	5.71	18
Indiana Donor Network (INOP)	10.84	11.58	121	254	4.39	4.87	100
Life Alliance Organ Recovery Agency (FLMP)	10.44	11.23	119	268	5.44	6.01	31
New England Organ Bank (MAOB)	10.56	11.15	219	460	5.28	5.70	82
Carolina Donor Services (NCNC)	10.47	11.14	171	331	4.88	5.35	86
LifeQuest Organ Recovery Services (FLUF)	10.16	11.00	112	205	4.84	5.44	50
LifeLink of Georgia (GALL)	10.30	10.89	238	383	4.47	4.86	150
Pacific Northwest Transplant Bank (ORUO)	9.92	10.80	107	209	5.51	6.18	18
Gift of Life Michigan (MIOP)	10.16	10.74	255	421	4.82	5.22	122
Mid-South Transplant	9.28	10.40	73	103	4.47	5.26	31

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Foundation (TNMS)							
LiveOnNY (NYRT)	9.66	10.21	323	431	4.59	4.97	154
Legacy of Life - Hawaii (HIOP)	8.36	9.96	38	61	5.66	7.01	0
Life Connection of Ohio (OHLC)	8.69	9.83	77	84	4.05	4.86	35
LifeNet Health (VATB)	9.05	9.75	210	235	4.31	4.81	97
Mississippi Organ Recovery Agency (MSOP)	8.71	9.66	114	119	4.07	4.73	53
Iowa Donor Network (IAOP)	7.72	8.79	100	87	4.07	4.87	36
LifeChoice Donor Services (CTOP)	7.42	8.37	131	90	3.51	4.19	60
Kentucky Organ Donor Affiliates (KYDA)	7.33	7.97	300	171	3.17	3.60	157
LifeLink of Puerto Rico (PRLI)	6.77	7.58	189	101	3.15	3.72	89
Center for Donation and Transplant (NYAP)	6.61	7.53	145	83	3.39	4.06	60
Legacy of Hope - Alabama (ALOB)	6.18	6.66	551	221	2.75	3.08	276

OPO Name	Donors for Any Organs			Donors of Only Kidneys			
	All Organ Transplant Rate	Upper Bound of CI	Additional Organs Needed to Reach Cutoff	Number of Kidneys Transplanted	Kidney Transplant Rate	Upper Bound of CI	Additional Kidneys Needed to Reach Cutoff
Arkansas Regional Organ Recovery Agency (AROR)	5.72	6.56	178	73	2.80	3.41	79
Finger Lakes Donor Recovery Network (NYFL)	4.47	5.23	200	61	2.45	3.04	84
Totals			4,903	15,144			2,349

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Using just these measures, the Hawaii OPO would be in the top 25 percent for both kidney donation rates and kidney transplantation rates. 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 are aware of newer technologies that could significantly reduce the clinical impact of prolonged transport of extra-renal organs and would prefer a policy that encourages the innovation and adoption of these types of technologies for the benefit of all potential recipients. We are seeking 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.

In analyzing all these different alternatives, we recognize 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 best practices. In summary, we welcome comments both on the comparative advantages and disadvantages of alternatives within the scope of this proposed rule, and suggestions for other alternatives that could be addressed in subsequent rule-makings or administrative actions to further improve performance of the organ donation and transplantation system.

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 18, we have prepared an accounting statement showing the classification of the benefits, transfers, and costs that we estimate will arise from the reforms if this proposed rule is adopted.

These reforms will create substantial out-year effects, and the annualized

estimates provided in this table display the effects that are 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 farther into the future. This means, however, that the Accounting Table estimates do not include very substantial out-year benefits to patients and savings to the ESRD program that will occur outside the five-year estimating window. Also, the effects of this proposed rule on organ recovery and transplantation are of unusual uncertainty even in the short run. The upper bound for benefit and cost reduction estimates are as discussed elsewhere in this regulatory impact analysis. We welcome comments on the estimates made in this proposed rule and on ways to improve their calculation or presentation.

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 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS
[\$ millions]

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (percent)	Period covered
Benefits:						
Health Benefits Annualized Monetized (\$million/year)	<0	698	2017	7	2021–2025
	<0	769	2017	3	2021–2025

TABLE 19—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED BENEFITS, TRANSFERS, AND COSTS—Continued
[\$ millions]

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (percent)	Period covered
Medical Expenditure Annualized Monetized (\$million/year)	>0	– 923	2017	7	2021–2025
.....	>0	– 996	2017	3	2021–2025

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 to the point of being exceeded by longevity benefits.

Costs:						
Annualized Monetized (\$million/year)	0.477	2017	7	2021–2025
.....	0.445	2017	3	2021–2025

Cost Notes: Transition costs in the event of OPO decertification have not been estimated.

Transfers	None quantified					
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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 proposed rule has been designated a significant regulatory action as defined by Executive Order 12866, and, if finalized as proposed, is expected to be an E.O. 13771 regulatory action.

J. Conclusion

This proposed rule would substantially reform the incentives facing OPOs and as a result, substantially 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. Because organ transplants are life-saving and life-extending events, we believe that these benefits to patients will be far more consequential than the effects on medical treatments and costs. Our

expectation is that the numbers of lives saved or extended will be many thousands each year, as estimated in the preceding analysis.

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

Medicare, Organ procurement, and Definitions.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 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. 1302 and 1395hh.

■ 2. Section 486.302 is amended by—
■ a. Adding definitions for “Death that is not an absolute contraindication to organ donation” and “Donation rate”;

- b. Revising the definition of “Donor”;
- c. Adding a definition for “Donor potential”;
- d. Removing the definitions of “Eligible death”, “Eligible donor”, and “Expected donation rate”;
- e. Adding a definition for “Lowest rate among the top 25 percent”;
- f. Removing the definition of “Observed donation rate”;
- g. Revising the definition of “Organ”;
- h. Adding a definition for “Organ transplantation rate” and
- i. Removing the definition of “Standard criteria donor (SCD)”.

The additions and revisions read as follows:

§ 486.302 Definitions.

* * * * *

Death that is not an absolute contraindication to organ donation means all deaths from the state death certificates except those with any cause of death identified by the specific ICD–10 codes that would preclude donation under any circumstance.

Tuberculosis	all.
Other bacterial diseases	A39 Meningococcal infection. A40 Streptococcal septicaemia. A41 Other septicaemia.
Viral infections of the central nervous system	A82 Rabies.
Viral infections characterized by skin and mucous membrane lesions	B03 Smallpox.
Human immunodeficiency virus [HIV] disease	B20 Human immunodeficiency virus [HIV] disease with infectious and parasitic diseases. B21 Human immunodeficiency virus [HIV] disease with malignant neoplasms.
Sequelae of infectious and parasitic diseases	B90 Sequelae of tuberculosis.
Malignant neoplasms of lip, oral cavity and pharynx	all.
Malignant neoplasms of digestive organs	all.
Malignant neoplasms of respiratory and intrathoracic organs	all.
Melanoma and other malignant neoplasms of skin	C43 Malignant melanoma of skin.
Malignant neoplasms of bone and articular cartilage	all.

Melanoma and other malignant neoplasms of skin	all.
Malignant neoplasms of methothelial and soft tissue	all.
Malignant neoplasm of breast	all.
Malignant neoplasms of female genital organs	all.
Malignant neoplasms of male genital organs	all.
Malignant neoplasms of thyroid and other endocrine glands	all.
Malignant neoplasms of ill-defined, secondary and unspecified sites	all.
Malignant neoplasms of lymphoid, haematopoietic and related tissue	all.
Malignant neoplasms of independent (primary) multiple sites	all.
Neoplasms of uncertain or unknown behavior	D44 Neoplasm of uncertain or unknown behaviour of endocrine glands. D46 Meylodyplastic syndromes. D47 Other neoplasms of uncertain or unknown behavior of lymphoid, haematopietic and related tissue. D48 Neoplasms of uncertain or unknown behavior of other and unspecified sites.
Coagulation defects, purpura and other haemorrhagic conditions	D65 Disseminated intravascular coagulation [defibrination syndrome]. D69 Purpura and other haemorrhagic conditions.
Metabolic disorders	E84 Cystic fibrosis.
Infections specific to the perinatal period	P36 Bacterial sepsis of newborn.

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

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.
 * * * * *

Donor potential is the number of inpatient deaths within the DSA among patients 75 and younger with any cause of death that is not an absolute contraindication to organ donation.
 * * * * *

Lowest rate among the top 25 percent will be calculated by taking the number of total OPOs in the time period identified for establishing the threshold rate. That number 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 will be separately ranked and the threshold rate will be the rate that corresponds to the 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 even if it is used for research or islet cell transplantation.

Organ type	Number of organs transplanted
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, re-search, 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.
 * * * * *

■ 3. Section 486.316 is amended by revising paragraphs (a)(1) and (2), (b), (c), and (d) introductory text to read as follows:

§ 486.316 Re-certification and competition processes.

- (a) * * *
 - (1) Meets the performance requirements of the outcome measures at § 486.318 at the end of the certification cycle; and
 - (2) 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.

(b) *De-certification and competition.* If an OPO does not meet the performance requirements of the outcome measures as described in paragraph (a)(1) of this section at the final assessment prior to the end of the re-certification cycle or the requirements described in paragraph (a)(2) of this section 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.

(c) *Criteria to compete.* 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 conditions for coverage at §§ 486.320 through 486.360. The OPO must compete for the entire service area.

(d) *Criteria for selection.* CMS will consider the following criteria in designating an OPO for an open service area:

* * * * *

■ 4. Section 486.318 is revised to read as follows:

§ 486.318 Condition: Outcome measures.

(a) *Outcome measures.* An OPO is evaluated by measuring the donation rate and the organ transplantation rate in their DSA.

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

(2) The organ transplantation rate is calculated as the number of organs transplanted from organs procured in the DSA as a percentage of the donor potential.

(3) The numerator of donors and organs transplanted is based on the data submitted to the OPTN as required in § 486.328 and/or 42 CFR 121.11.

(4) The denominator is the donor potential and is based on inpatient deaths within the DSA from patients 75

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

or younger with any cause of death that is an absolute contraindication to organ donation. The data is obtained from the most recent 12 months data from state death certificates.

(5) These outcome measures will be effective beginning with the 2022 re-certification cycle.

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

(1) For the assessment period, a threshold rate will be established based on the lowest rate among the top 25 percent of donation rates during the 12-month period immediately prior to the period being evaluated.

(2) For the assessment period, a threshold rate will be established based on the lowest rate among the top 25 percent of organ transplantation rates during the 12-month period prior to the period being evaluated.

(3) The 95 percent confidence interval for each OPO will be calculated using a one-sided test.

(4) OPOs whose upper limit of the one-sided 95 percent confidence interval is less than the threshold rate established will be flagged.

(c) *Assessment and data for the outcome measures.* (1) An OPO's performance on the outcome measures is based on an assessment at least every

12 months with the most recent 12 months of data from the OPTN and state death certificates, beginning December 31 of the first year of the re-certification cycle and ending December 31, prior to the end of the re-certification cycle.

(2) If an OPO's performance falls below the outcome measure described in paragraph (b) of this section prior to the last cycle before the end of the certification period, the OPO must meet the requirements of § 486.348(d)(3).

(3) If an OPO takes over another OPO's service area on a date later than January 1 of the first year of the re-certification cycle so that 12 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until 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 cycle, except the final assessment before re-certification, is statistically significantly lower than the top 25 percent of donation rates or organ transplantation rates, the OPO must identify opportunities for improvement and implement changes that lead to improvement in these measures.

Dated: September 27, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 7, 2019

Alex M. Azar II,

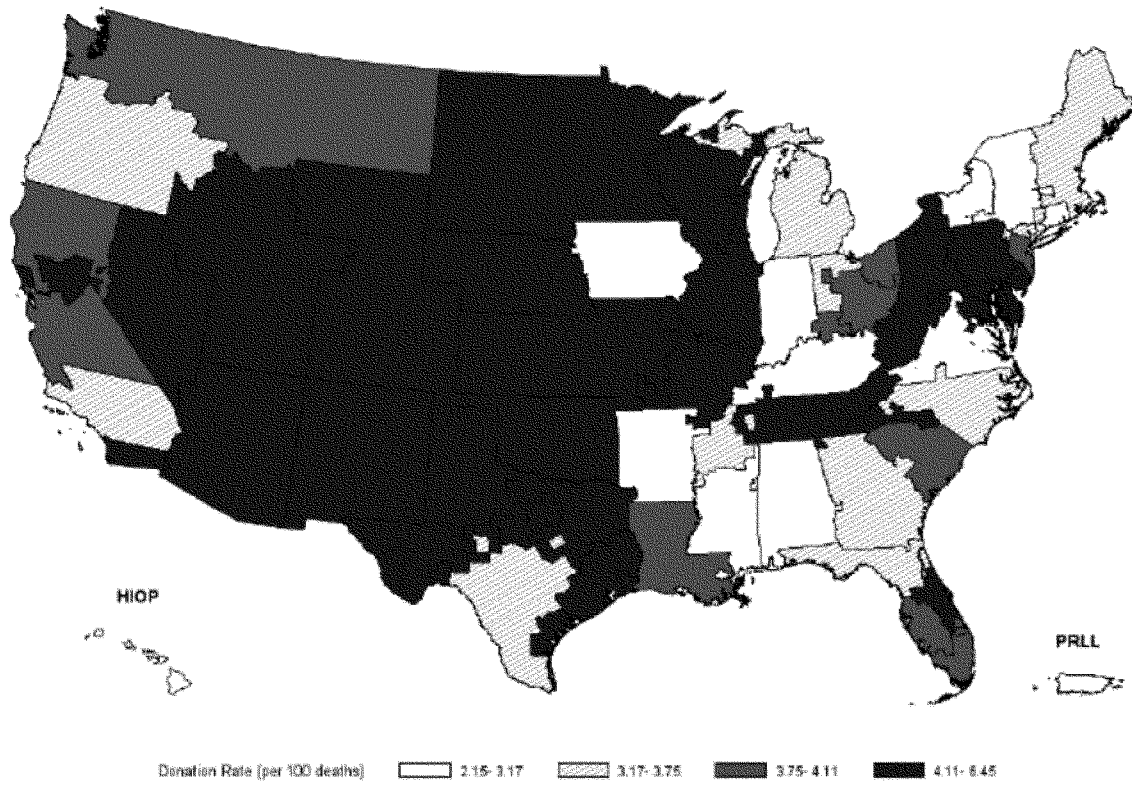
Secretary, Department of Health and Human Services.

Note: The following appendix will not appear in the Code of Federal Regulations.

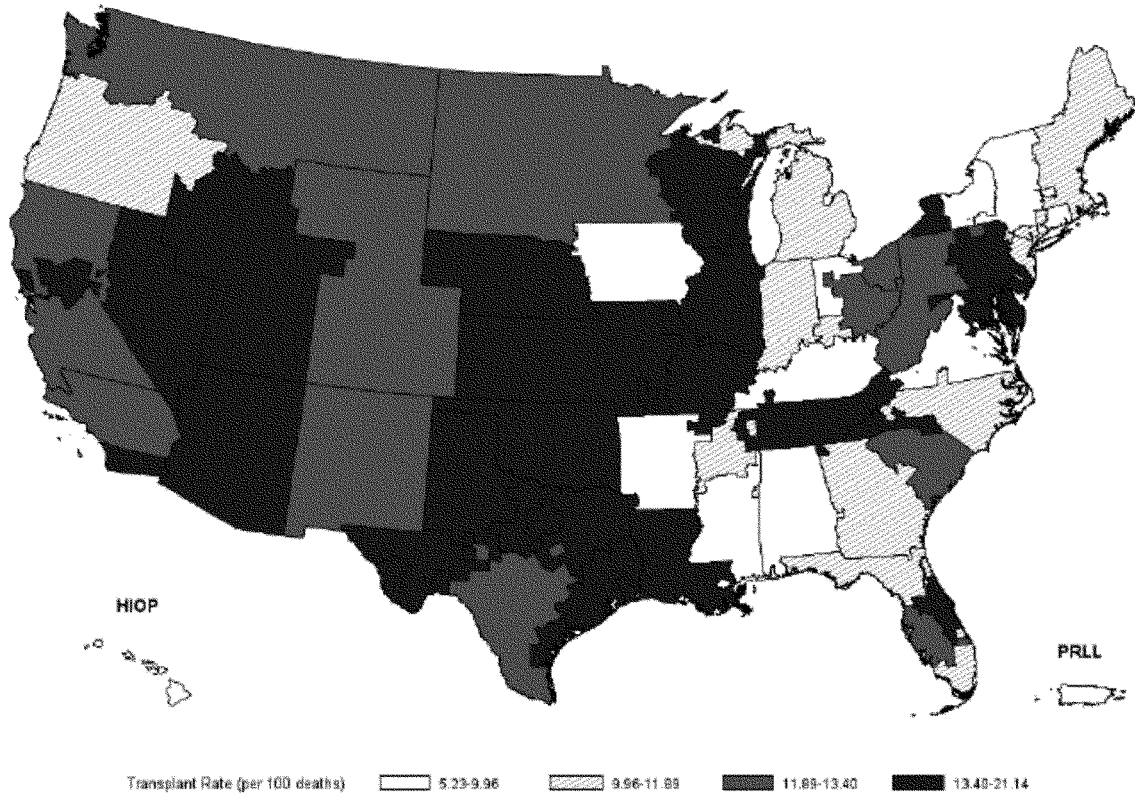
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Appendix

Donation Rate by OPO
January-December 2017
Cutoff Rate: 4.11



Transplant Rate by OPO
January-December 2017
Cutoff Rate: 13.73



[FR Doc. 2019-27418 Filed 12-17-19; 4:15 pm]

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