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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS-3409-P]

RIN 0938-AU54

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Conditions for Coverage for Organ Procurement Organizations (OPOs) to clarify outstanding procedural questions and enable OPOs to make better informed decisions to achieve high performance resulting in the successful procurement, distribution, and transplantation of more life-saving organs. This rule would revise definitions, add new Quality Assessment Performance Improvement (QAPI) requirements related to medically complex organs and donors, revise the designation requirements for OPOs, clarify when an OPO's service area is open for competition, and update the process for appeals. It also includes a discussion of factors we would consider when selecting a successor OPO during a competition under the tiered approach to re-certification. We are committed to holding all OPOs accountable for their performance and this proposed rule does not revise the focus on improving the volume of donors and transplants assessed in the outcome measures or the tier structure used for re-certification and de-certification of OPOs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code CMS-3409-P.

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 submit electronic comments on this regulation to ***http://www.regulations.gov***. Follow the "Submit a comment" instructions.

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-3409-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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 to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3409-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786-8486; James Cowher, (410) 786-1948; Claudia Molinar, (410) 786-8445; Danielle Shearer, (410) 786-6617; or Jasmine Alexis, (410) 786-0861.

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. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

I. Executive Summary and Severability

A. Executive Summary

1. Purpose

At any given time, at least 100,000 people are on the waiting list for a lifesaving transplant and every 8 minutes, another person is added to the transplant waiting list.[1] Many individuals on the organ transplant waiting list will wait several years for a suitable donor, while others will die before an organ becomes available. A variety of factors affect wait times, including how well a waitlisted individual matches with available donors, how sick the person is, and the availability of organs in the local area. Despite continued growth in organ donation, procurement, and transplantation, the need for transplantable organs continues to grow. Optimal performance of organ procurement organizations (OPOs) is critical to ensure that the maximum

[1] Organ Donation Statistics. *https://www.organdonor.gov/learn/organ-donation-statistics*. Accessed on April 29, 2025.

possible number of transplantable human organs are available to the yearly average of 100,000+ seriously ill people on waiting lists for a lifesaving organ transplant.

In 2019, President Trump issued Executive Order 13879 "Advancing American Kidney Health," directing the Secretary to enhance the procurement and utilization of organs available through deceased donation and to establish more transparent, reliable, and enforceable metrics for evaluating an OPO's performance. In response, CMS published the final rule, "Medicare and Medicaid Programs; Organ Procurement Organization Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations" in 2020 (85 FR 77898, referred to hereafter as the December 2020 final rule), which, among other changes, revised the previous outcome measures to drive performance improvement and increase the number of transplantable organs. OPOs are evaluated on their performance on both the donor and transplantation measures. Since publishing the December 2020 final rule, CMS has received many inquiries from OPOs and others seeking clarification on operational and administrative elements. These inquiries have increased in frequency and volume as the system moves closer to the 2026 re-certification period. This proposed rule contains operational and administrative provisions which would govern the competition process, to provide programmatic clarity and address interested party requests for additional guidance. Additionally, this proposed rule contains provisions aimed at driving further improvement in OPO operations, reflecting our continued commitment to enhancing the organ procurement and transplant system, and better serving prospective organ donors, their families, and patients on the transplant waitlist.

2. Summary of Major Provisions

a. Definition Changes (§ 486.302)

Adverse Event. The current definition of "adverse event" is "an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation

has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary." We propose to remove the examples in this definition and add a revised list of examples to the QAPI requirements at § 486.348(c).

Donor. We propose to revise the definition of the term "donor" to clarify that an individual from whom only the pancreas is procured and used for islet cell research is included in the definition of "donor" for purposes of the donation rate outcome measure, consistent with the Public Health Service (PHS) Act's requirement that pancreata used for islet cell transplantation or research be counted for purposes of certification and re-certification.

Organ. The current definition of the term "organ" includes the pancreas when it is used for research or islet cell transplantation. This definition applies to the organ transplantation outcome measure, counting a pancreas used for research in the same way that a transplanted organ is counted. We propose to remove pancreata used for research from the definition of "organ" and thus, such pancreata would also be removed from the organ transplantation rate outcome measure. Research activity would no longer count as a transplant for purposes of certification and re-certification.

Medically Complex Organs and Donors. Organs from donors that fall outside the generally accepted standards for transplantation due to donor age or health status are underutilized. However, research has indicated that many of these organs can be successfully transplanted when appropriately placed with a transplant candidate.[2] [3] We propose to define the term "medically complex donor" as a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors include, but are not

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[2] Walls, DO, Lee-Riddle, Gs, Manderski, MB, Sawinski, DL, and Abt, PL. *Kidney transplant outcomes from donation afer circulatory death donors of advanced age.* Clinical Transplantation. 2020:34e13881. http://doi.org/10.111/ctr.13881. Accessed at https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.13881. Accessed on September 23, 2025.

[3] Haque, O, Yuan, Q, Uygun, K, and Markmann, JF. Evolving utilization of donation after circulatory death livers in liver transplantation: the day of DCD has come. Clinical Transplantation. 2021;35:e14211. Https://doi.org/10.1111/ctr.14211. Accessed at https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.14211. Accessed on September 21, 2015.

limited to, all Donation after Cardiac Death (DCD) donors and donors with elevated Kidney Donor Profile Index (KDPI) scores. We also propose that OPOs track procurement and placement of these organs as part of their QAPI program. Additionally, we propose to define the term "medically complex organ" as an organ procured from a "medically complex donor".

Unsound Medical Practices. We are also proposing a new definition for "unsound medical practices." Unsound medical practices are referenced in § 486.312(b) as an example of circumstances in which CMS may de-certify an OPO based on "urgent need." However, there is no definition of "unsound medical practices" in the regulations. We propose to define unsound medical practices as failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation and transport practices and procedures.

b. Requirements for Certification (§ 486.303)

We have historically interpreted the OPO Certification Act of 2000 (the Certification Act), which added section 371(b)(1)(D) of the Public Health Service Act (PHS Act), to mean the Secretary lacks the authority to certify new OPOs after January 1, 2000. However, we have reassessed this view and determined that the statute was not intended to strip the Secretary of his authority to certify new OPOs. Therefore, to align with our reinterpretation of the Certification Act, we are proposing to remove § 486.303(e), which conditions OPO certification on an entity having been re-certified as an OPO from January 1, 2002, through December 31, 2005.

c. OPO Designation to Donation Service Areas (DSAs) (§§ 486.308 and 486.309)

Designation is the process CMS utilizes to assign an OPO to a specific geographic area, or donation service area (DSA), for a specific period of time, called an agreement cycle. Currently, there are 55 OPOs designated to 55 DSAs with the same 4-year agreement cycle. We propose changes to the OPO designation process to facilitate implementation of the tiered system for OPO re-certification and competition that was finalized in the December 2020 final rule.

Specifically, we propose to add provisions to address the possibility of one OPO being designated to more than one DSA. The current regulatory structure does not address this situation and the potential impacts it may have for competition and OPO re-certification. We will address these impacts throughout the respective provisions in this proposed rule. Finally, the tiered system for re-certification seeks to incentivize continued performance improvement through increased competition. Therefore, we propose to address all situations when an OPO's DSA may be opened for competition from other OPOs.

d. OPO Agreements, Non-renewal (§ 486.311) and De-certification (§ 486.312)

OPO agreements with CMS may be impacted by actions initiated by an OPO or adverse determinations by CMS. Currently, there are three categories of actions that impact an OPO's agreement, including voluntary termination of the agreement by the OPO; involuntary termination during the re-certification cycle as a result of enforcement action for non-compliance with certification requirements; and non-renewal of the agreement for non-compliance with the outcome measures and other certification requirements. Generally, these actions result in de-certification of the OPO. In our December 2020 final rule, we implemented a tiered system for OPO re-certification that seeks to drive OPO performance through increased competition. The current requirements for de-certification do not address the possibility of an OPO being unsuccessful in a competition for its own or another DSA and no longer being designated to any DSA. We propose to address this potential scenario as well as better categorize and clarify situations that could lead to non-renewal of an agreement or de-certification of an OPO. We also propose that a voluntary termination or a scenario in which an OPO is no longer designated to any DSA after competition would result in non-renewal of the OPO's agreement with CMS, while an OPO's non-compliance with the outcome measures, non-compliance with the process performance measures, and situations involving urgent need to protect patient health and safety would result in de-certification (see Section II.B. of this proposed rule, "Regulatory History" for

more information on compliance determinations). We also propose to address appeal rights based on CMS determinations and which determinations may be appealable.

e. Appeals of Adverse Actions (§ 486.314)

As a result of significant changes made since the 2006 OPO final rule, we reviewed the OPO appeals process set forth at § 486.314 and are proposing the following changes. The current introductory statement in the regulation states that OPOs can appeal a de-certification on substantive and procedural grounds if the de-certification is due to involuntary termination or non-renewal of its agreement with CMS. We propose to revise the introductory text at § 486.314 to state that OPOs may appeal a de-certification as described at proposed § 486.312(a) or the removal of designation to a tier 3 DSA without de-certification as specified at proposed § 486.316(b)(2)(iii)(B), to comply with changes to that section. We also propose to add references to the removal of designation for a DSA assigned as tier 3 without de-certification alongside references to de-certification in § 486.314, as applicable, to reflect that an appeal would be available in either scenario.

Throughout § 486.314 we propose to modify the time periods in this section for current requirements from "business days" to "calendar days". We also propose to use "calendar days" for all proposed requirements. This is both for consistency and to avoid confusion. Throughout the current process, we are proposing changes to the various time frames to reduce inefficiencies while preserving OPOs' right to appeal.

We are also proposing a new paragraph at § 486.314(*l*), CMS Administrator discretionary review. We are proposing to codify a process for the CMS Administrator to elect to review or decline to review the hearing officer's decision. We are proposing specific time periods for the review, if the Administrator elects to review, and providing that the Administrator may remand the appeal to CMS for review and redetermination of the certification decision. We are also proposing to clarify the appeals process for OPOs that are de-certified due to urgent need.

f. Re-certification and Competition (§ 486.316)

Our December 2020 final rule included changes to our requirements for OPO re-certification and competition processes to clarify how the tiered system associated with the outcome measures would impact these activities. We are proposing additional revisions to § 486.316 to include situations when an OPO is designated to more than one DSA. We are proposing to evaluate each DSA for which an OPO is designated separately on the outcome measures. This would address the potential situation of an OPO having DSAs with different tier designations and how this would impact re-certification and competition. Additionally, it would enable CMS to selectively remove a DSA where an OPO is underperforming and does not meet the outcome measures, while allowing the OPO to retain its designation to another DSA if it meets the performance requirements in that DSA. We also propose that we would evaluate an OPO as a single entity across all DSAs for the process performance requirements. The process performance measures are the broad operational requirements for OPOs and include items such as administration and governance, prospective donor and donor management, organ preparation and transport, and quality assessment and performance improvement, among other requirements. While an OPO may have varied performance on the outcome measures at different times and in different DSAs, if applicable, we expect OPOs to be in compliance with the process performance measures at all times and in all DSAs.

g. Outcome Measures (§ 486.318)

The 2020 final rule revised the outcome measures for OPOs. We propose to remove the previous and now obsolete outcome measures and redesignate the current outcome measures within § 486.318. We also propose to revise the requirement for when CMS will hold an OPO accountable on the outcome measures when it takes over another OPO's DSA. We describe the different scenarios when this may occur and factors we considered in proposing when we would hold the OPO accountable on its outcome measure performance in the new DSA.

h. Human Resources (§ 486.326)

The current human resources requirement addresses the need for a sufficient number of qualified staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research. All OPOs are required to ensure that all individuals who provide services and/or supervise services are qualified to provide or supervise the services. We propose to further specify that all OPOs are required to assure the current State or local licensure, certification, or registration of OPO staff that furnish clinical services. We also propose to add a requirement that personnel performing clinical duties must act within the scope of the State licensure, certification, or registration requirements.

i. Information Management (§ 486.330)

The current information management requirements at § 486.330 focus on maintaining both donor records and records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries. We propose to amend § 486.330 by adding a requirement that OPOs maintain records for organs that are procured for research, including pancreata used for islet cell research.

j. Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

The current QAPI requirements focus on OPOs developing, implementing, and maintaining a comprehensive, data driven QAPI program designed to monitor and evaluate performance of all donation services. Section 486.348(c) requires OPOs to establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events and conduct a thorough analysis of any adverse event to identify and implement effective changes to prevent those types of incidences from recurring again. We propose to include a revised list of examples of adverse events in this section that is currently located in the "adverse event" definition in § 486.302.

To further the goal of improving procurement and transplantation of medically complex organs, we propose to require each OPO as part of its QAPI program in new § 486.348(e) to: (1)

assess its policies and procedures regarding medically complex donors and medically complex organs and ensure they are optimizing opportunities to recover and place these organs for transplant; (2) assess its performance regarding the number of medically complex donors by determining the number of medically complex donors from whom the OPO has obtained consent for donation, the number of organs recovered from those donors, and the number of medically complex organs transplanted at least annually; and (3) implement actions to improve its performance with medically complex donors or medically complex organs when the OPO identifies opportunities for such improvement.

3. Summary of Costs and Benefits

The December 2020 final rule, among establishing other requirements, revised previous outcome measures to drive performance improvement and increase the number of transplantable organs. The December 2020 final rule's estimated costs were primarily driven by increased expenses related to organ procurement. Secondary costs were driven by the additional expense for OPOs to implement performance improvement policies. Additional costs accounted for the potential of OPO mergers.

The estimated benefits quantified were due to the number of lives saved and lives extended and, in addition, reduced costs to CMS payments for dialysis treatments for patients waiting on the transplant waitlist.

This proposed rule is important due to its functional proximity to the December 2020 final rule. Its purpose is to address and prevent administrative and operational concerns related to the competition process. This proposed rule would impose an estimated $19.1 million in Year 1 and $6.3 million in subsequent years. Year 1 costs including collection of information costs are approximately $17.9 million for OPOs and $1.2 million for CMS. Recurring annual costs include approximately $6.2 million for OPOs and $331,000 for CMS. Quantified benefits are estimated at $884,000 annually with an additional one-time benefit of $300,000.

These costs reflect clarifications and refinements to operational and administrative requirements rather than fundamental system restructuring.

B. Severability

To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of this rule held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provisions permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this rule and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

II. Organ Procurement Organizations (OPOs)

A. Background

OPOs are vital partners in the procurement, distribution, and transplantation of human organs in a safe and effective manner for all potential transplant recipients. The role of OPOs is critical to ensuring that the maximum possible number of transplantable human organs are available to individuals with organ failure who are on a waiting list for an organ transplant. Section 371(b) of the PHS Act sets out certain requirements for OPO certification. There are currently 55 OPOs that are responsible for identifying patients who may become prospective donors and recovering organs from deceased donors in the United States (U.S.), and currently each OPO serves a single DSA (55 in total). The Centers for Medicare & Medicaid Services (CMS) views OPO performance as a critical element of the organ transplantation system in the U.S. We established conditions for coverage (CfCs) for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements to receive payments from transplant hospitals participating in the Medicare and Medicaid programs. The CfCs include reliable, data-based outcome measures related to donor and transplant volume that are used to assess OPO performance for Medicare certification purposes and a three-tier certification structure that

incentivizes high OPO performance on these outcome measures. In general, we are committed to using objective data to assess OPO performance and continuously incentivize OPO performance improvement.

In 2024, there were a total of 48,150 organ transplants, compared to 46,634 and 42,889 transplants in years 2023 and 2022, respectively.[4] Although the volume of transplants has increased over time, there continues to be an ongoing shortage of transplantable organs. At any given time, at least 100,000 people are on the waiting list for a lifesaving organ transplant.[5] Many people face tremendous quality of life burdens, illness progression, or death while on the waiting list. An OPO that is efficient in procuring organs and delivering them to recipients will help more people on the waiting list receive lifesaving organ transplants and reduce the waiting time, which could ultimately save more lives and improve health outcomes.

B. Regulatory History

The December 2020 final rule (85 FR 77898) revised the OPO CfCs with the policy goal of increasing organ donation and transplantation to better serve patients on the organ transplant waiting list. The December 2020 final rule revised the outcome measures that are used to assess OPO compliance for purposes of certification, shifting from heavily risk-adjusted metrics that were not capable of demonstrating changes in OPO performance to metrics that measure OPO volume and drive OPO performance in areas most important to patients on the transplant waiting list. It also revised the assessment criteria to move from a bifurcated pass/fail system to a three tier system with dynamic performance thresholds and incentives for achieving the highest level of performance. Finally, the December 2020 final rule utilizes increasing competition to drive performance improvement. An OPO's performance in a DSA is ranked in comparison to the performance of all other OPOs in their assigned DSAs relative to a numerical threshold, using competition for higher ranking as a tier 1 as an incentive for performance improvement. We

[4] Organ Procurement and Transplantation Network (OPTN) Data. https://hrsa.unos.org/data/view-data-reports/national-data/.. Accessed January 6, 2026.
[5] Organ Donation Statistics. *https://www.organdonor.gov/learn/organ-donation-statistics*. Accessed April 24, 2025.

believe that the absence of meaningful competition contributed to the very slow pace of system improvement prior to CMS initiating its OPO regulatory reform efforts in 2019, culminating with publication of the December 2020 final rule.

Specifically, the December 2020 final rule measures OPO performance on two outcome measures described in § 486.318—the donation rate and the transplantation rate. Both rates assess OPO performance within the OPO's DSA, which is a geographical area that each OPO is assigned to, meaning that the OPO is responsible for all organ procurement activities that occur in that area, with certain exceptions. The denominator for each measure is the donor potential of each DSA, based on inpatient deaths within the DSA from patients 75 or younger with a primary cause of death that is consistent with organ donation, consistent with the OPO Certification Act of 2000[6]. We estimate the donor potential of each DSA using death certificate information obtained from the Center for Disease Control and Preventions' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD) file. The MCOD is published annually, reflecting data collected from the previous full calendar year, and is publicly available upon request. As such, there is an approximate 11 to 12 month data lag to allow for all activities related to the collection and compilation of the data. The MCOD comprises county-level national mortality data that include a record for every death of a U.S. resident recorded in the U.S. The MCOD files contain an extensive set of variables derived from the death certificates which are standardized across the 57 jurisdictions that provide CDC with the data.[7] The jurisdictions use the U.S. Standard Certificate of Death as a template for their forms. We use the death certificate data to adjust the denominator to better reflect the population in the DSA that will more closely resemble individuals likely to have died in a manner consistent with organ donation. As we described in the December 2020 final rule, death that is consistent with organ donation means all deaths of individuals 75 or younger from the State death certificates with the

[6] P.L. 106-505, section 701, codified at 42 U.S.C. § 273(b)(1)(D)(ii)(II).
[7] The 57 jurisdictions that provide data to the CDC are the 50 States, New York City, the District of Columbia, and the 5 territories. Data for New York City is reported separately from the State of New York.

primary cause of death listed as the ICD-10-CM codes I20-I25 (ischemic heart disease); I60-I69 (cerebrovascular disease); V-1-Y89 (external causes of death), which includes causes such as blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. Our methodology is designed to estimate the likely donor referral population to normalize the inpatient deaths across the different DSAs. While each DSA may face its own unique challenges, the method for estimating donor potential is designed to be standardized and equally applied to all OPOs, allowing for variances in performance when facing challenges to be measured and for high performance to be incentivized. Since the donor potential is part of a rate calculation, identifying the exact, donor potential of those candidates that are universally considered by all OPOs to be ideal is less relevant than providing standardized, reasonable, and impartial criteria to estimate it and applying those criteria consistently to all OPO DSAs.

The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential. The donation rate assesses the ability of the OPO to obtain consent for donation, successfully manage the donor, procure and place at least one organ for transplantation (or pancreas for islet cell transplantation or research), and ensure the safe and timely transport of that organ for transplantation. By including the donation rate, we incentivize OPOs to pursue all donors, including the single organ donors. An OPO is more likely to meet the donation rate measure if it procures organs from DCD or medically complex donors where relatively fewer organs may be transplantable. Incentivizing OPOs to pursue all potential donors means introducing more opportunities for individual transplant waitlist candidates to receive a good organ match, which is impacted by factors such as blood type, body size, and immune system antibody compatibility. A wider variety of donors means a better chance of good matches for more patients.[8,9]

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[8] Madbouly A and Bolon Y-T (2024) Race, ethnicity, ancestry, and aspects that impact HLA data and matching for transplant. *Front. Genet.* 15:1375352. doi: 10.3389/fgene.2024.1375352.

[9] Tiercy JM, Claas F. Impact of HLA diversity on donor selection in organ and stem cell transplantation. Hum Hered. 2013;76(3-4):178-86. doi: 10.1159/000358798. Epub 2014 May 21. PMID: 24861862.

The transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs, including pancreatic islet cells, transplanted into patients on the Organ Procurement and Transplantation Network (OPTN) waiting list as part of research are included in the organ transplantation rate. Pancreata that are used in islet cell research are also included. The organ transplantation rate is an important measure as it measures the benefit for patients from OPO performance. The unique geographical challenges associated with servicing the Hawaii DSA necessitated using a different outcome measure to evaluate the OPO's transplantation performance in that DSA. Instead of using the organ transplantation rate, we use the kidney transplantation rate. Although we do not use the organ transplantation rate for the Hawaii DSA, we continue to monitor the development and Food and Drug Administration (FDA) clearance of organ transport devices and expect the OPO serving the Hawaii DSA to adopt these new technologies when they are available.

Our outcome measures and process measures, taken as a whole, represent a reasonable effort to estimate the donor potential and other related factors in the DSA. The outcome measures denominator, as previously described in this section, is an estimate of donor potential in each DSA. The outcome measure numerators measure OPO performance (through the number of donors and organs transplanted) and are somewhat related because if there are more donors, there are likely to be more organs transplanted. However, these numerators are not the same, and each is necessary to measure different OPO outcomes and to properly incentivize OPOs to pursue all potential donors, succeed in obtaining consent, successfully manage their care, and successfully deliver viable organs for transplant. For example, OPOs that focus primarily on medically complex donors that may yield fewer organs per donor may need to seek more donations to have sufficient organs transplanted to mathematically meet the threshold organ transplantation rates. On the other hand, OPOs that are very effective at placing all possible organs from younger, healthier donors with larger yields may achieve the targeted organ transplantation rate, but not the donation rate, if they choose not to pursue the medically complex

and DCD donors with only one or two transplantable organs. In measuring both donation and transplantation rates, we seek to achieve both more donors and more transplants. By focusing on the outcomes of OPO processes in the form of donation and transplant rates, we have created a system in which a wide variety of changeable factors, such as levels of public awareness and understanding about organ donation, relationships with donor hospitals, and the quality and timeliness of OPO interactions with potential donors and their families all coalesce in an end result of successful organ donation and transplantation.

Both outcome measures, and their threshold rates, are calculated using a full single calendar year of data. There is typically an 11- to 12-month long data lag for the MCOD file following the close of the calendar year. For example, the MCOD file containing data for deaths that occurred in 2025 is not expected to be available until December 2026 or as late as early spring 2027. To account for this and assure that CMS uses data from the same calendar year for both the numerators and denominators to calculate the donation and transplantation rates and threshold rates, there is a 1.5-year difference between the time when OPOs submit data for the performance period and the time when that data is fully analyzed by CMS and used to calculate OPO performance on the outcome measures. CMS provides each OPO with a preview of its calendar year data report and has a process established for OPOs to provide feedback on their preview reports to assure accuracy before the reports are made publicly available. For example, in 2025, CMS used OPTN (numerator) and MCOD (denominator) data from calendar year 2023 to develop an annual interim data report for each OPO. The MCOD file for 2023 became available early in 2025. CMS calculated each OPO's performance on each outcome measure, provided each OPO with its own preview reports and correction opportunities, and then made the 2023 performance data for all OPOs publicly available in late spring 2025.[10] CMS repeats this process on an annual basis such that OPOs and the public are aware of individual OPO performance and nationwide performance trends.

[10] Quality, Certification, and Oversight Reports. https://qcor.cms.gov/main.jsp.

OPO performance on the outcome measures is assessed on an annual basis. For each assessment period, threshold rates are established based on the observed donation and transplantation rates during the 12-month period immediately prior to the period being evaluated. In the 2025 annual interim data report described above, OPO performance using 2023 data is compared to the OPO performance data of 2022. The median observed rate for each outcome measure in 2022 was used as the standard to measure OPO performance in 2023. To establish the threshold rates CMS calculates both the lowest observed rate among the top 25 percent in the DSAs, and the median observed rate among the DSAs. To measure OPO performance in a DSA, CMS uses a 95 percent confidence interval for each DSA's donation and organ transplantation rates using a one-sided test. A confidence interval is a statistical measure of precision. In the context of OPO evaluations, it provides the range of outcome measure values (donation rates or transplant rates) that are expected to most reasonably describe the OPO's true performance based on the available data. The confidence interval accounts for uncertainty to describe a broader range of OPO performance levels that could plausibly explain the observed donation and transplant outcomes. Confidence intervals tend to be wider when there are fewer potential donors because there is less information available to precisely measure the OPO's influence on the observed outcomes, and it becomes more difficult to confidently describe the OPO's performance with a very specific range of quality measure values. For example, consider a hypothetical situation where an OPO has just one potential donor. In this extreme case, it would only be possible to observe a donation rate of 1/1=100 percent or 0/1=0 percent. However, it would be misleading to claim that this OPO is always or never successful at recovering donor organs. In fact, there is almost no information available about this OPO's general performance because only one potential donor's outcome was observed. The confidence interval would be very wide under this scenario to appropriately reflect the low degree of certainty in the OPO's true donation performance. Likewise, OPOs with DSAs that have a larger donor potential, and thus a larger data set for performance measurement, tend to have smaller confidence intervals.

Confidence intervals tend to be narrower for large data sets because it is easier to confidently describe performance due to the large amount of available data. Each OPO's confidence intervals for the donation and transplant rate are compared to benchmark levels of performance based on the prior year's observed rates. If the upper end of the OPO's confidence interval does not meet or surpass the threshold value established using the prior year's observed performance data, then there is statistical evidence that the OPO is not performing at that threshold level for donation or transplantation. For example, in the 2025 data report that is based on performance data from 2023, one OPO had an observed donation rate of 15.17 and the upper limit of its confidence interval was 16.64. The threshold rate for the outcome measure using the observed performance of all OPOs in the previous data year, 2022, was 12.49 for the median and 14.11 for the top 25 percent. In comparing the upper end of this OPO's confidence interval, 16.64, to the median performance threshold of 12.49 established using the previous year's observed performance, we determine that this OPO has met the median threshold rate for the donation outcome measure and complies with the minimum standard to be eligible for designation to tier 2 for that outcome measure. Likewise, in comparing the upper end of this OPO's confidence interval, 16.64, to the top 25 percent threshold of 14.11 as established using the previous year's observed performance data, we determine that this OPO has met and exceeded the top 25 percent threshold for the donation rate outcome measure. Indeed, this OPO's observed performance of 15.17 exceeded the top 25 percent threshold, meaning that even in the absence of a confidence interval it would still have performed in the top 25 percent on the donation rate outcome measure. In examining the 2025 public report, we note that 27 of the 42 OPOs that performed well enough to be in tier 1 on the donation rate outcome measure qualified by their observed performance, rather than by the upper limit of their calculated confidence interval. The performance thresholds for OPO evaluation are determined from the prior year's data, meaning that every OPO has the opportunity to improve its donation and transplantation performance such that its confidence intervals meet or surpass these threshold values. Even OPOs with

donation or transplant rates below the performance thresholds can have confidence intervals that surpass these thresholds, depending on the size of 95 percent confidence interval and proximity to the benchmark. For example, in the 2025 public OPO data report, five OPOs that performed in tier 2 for the transplantation outcome were classified as tier 2 based on their confidence interval with an observed age-adjusted rate below the median of 38.56. Therefore, ten OPOs that performed in tier 2 on the transplantation outcome measure had an observed performance level that met or exceeded the median threshold and would be in tier 2 in the absence of a confidence interval. As such, it is possible for more than half of OPOs to be at or above the 25 percent and median thresholds. Indeed, in the 2025 public OPO report, 30 of the 55 OPOs (roughly 55 percent) performed well enough on both measures to be in tier 1 and the majority of these OPOs did so through their observed performance. This OPO performance evaluation system is designed to create incentives for OPOs to rapidly improve their performance in serving donor families and people on the transplant waitlist and exceed the performance thresholds established using the previous year's performance data.

Section 371(b)(1)(D)(ii)(II) of the PHS Act[11] provides that a qualified OPO must meet performance standards defined through regulations promulgated by the Secretary that rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of donor potential and other related factors in each DSA. CMS established process measures (§ 486.320 through § 486.360) related to DSA-specific factors like relationships with donor hospitals in the DSA and OPO-specific processes such as QAPI, and uses empirical evidence gathered upon survey to assess compliance with these requirements. The process measures complement the outcome measures, focusing on essential OPO-level and DSA-level processes and factors to facilitate high performance. While the December 2020 final rule added two new outcome measures that use empirical data from the MCOD file and the procurement and transplant data submitted by OPOs (§ 486.328) and transplant centers (§

[11] 42 U.S.C. 273(b)(1)(D)(ii)(II).

482.45(b)(3)) to replace the self-reported, unverified outcome measures that were implemented by the 2006 final rule,[12] it in no way replaced the essential process measure focus on other DSA-specific factors. Indeed, the December 2020 final rule also established a 3-tier system whereby OPOs are stratified into different tiers based on their performance on both outcome measures and compliance with the process performance measures. A successful OPO must meet the measures for both processes and outcomes to be considered compliant with the CfCs and eligible for re-certification. The consequences of being in each tier based on outcome measure performance differ based on whether the performance occurs as part of the annual assessment or if it occurs during the final assessment period.[13] Tier 1 DSAs have an upper limit of the one-sided 95 percent confidence interval for the donation and organ transplantation rate outcome measures that are at or above the top 25 percent threshold rate. Tier 2 DSAs have an upper limit of the one-sided 95 percent confidence interval for the donation and organ transplantation rates that are at or above the median threshold rate established for their DSA but are not tier 1 for both outcome measures Tier 2 performance, meaning that an OPO DSA has met the median threshold for both outcome measures but has not met the tier 1 top 25 percent threshold for both measures, is the minimum compliance standard established in the OPO regulations. OPO DSAs that fall into tier 2 will be opened for competition from other interested OPOs, to allow for the replacement of an OPO performing at the minimum compliance standard where there is a clearly better OPO prepared and capable of taking over the DSA. As such, OPOs are incentivized to assure that each of their DSAs are high performing such that they meet the top 25 percent performance thresholds and are not open for competition. Instead of using a 50 percent rate or a mean rate, we chose the median rate because both the top 25 percent threshold rate and the median rate represent the actual rates performed by one or two OPOs (when there is an even number, the median is calculated by averaging the two rates in the median). The mean rate, on

[12] 71 FR 31046.
[13] 85 FR 77911.

the other hand, is a mathematical rate that may not reflect the performance of an actual OPO and may be dragged down by a small number of very low performing OPOs. A median, however, is less affected by extremes in performance as compared to a mean. By identifying the specific rate of an OPO, OPOs can directly compare their performance with that of other OPOs. Likewise, we did not choose to assess performance and thus compliance with the CfCs using a standard deviation from the mean methodology for several reasons. Under our methodology, all OPOs have the opportunity to cluster at the top because the threshold rate is based on the previous year's rate, meaning that all OPOs begin each year with a new opportunity to meet or exceed the median from the previous year. As a contrast, the standard deviation from the mean methodology generates a contemporaneous list of OPOs that are a certain distance from the mean. As discussed previously, the mean is problematic because several lower performing OPOs could skew the calculated mean. Beyond this, the mean and the standard deviations are generated contemporaneously with the ranking of the OPOs, giving OPOs no notice of their targeted performance. And, by nature of the statistical method of standard deviation, there will always be an OPO below the targeted standard deviation from the mean, meaning that not all OPOs would have the opportunity to be a top performing OPO unless they all had identical rates. As the outcome measures are used for certification and re-certification, consistent with the requirements set forth in the PHS Act, we do not believe that establishing a system in which at least one OPO must be determined to be out of compliance and therefore de-certified during each re-certification cycle is appropriate. Rather, we sought and continue to seek a system where all OPOs perform at a high level, exceed the previous year's median, and cluster at the top. As we stated in the December 2020 final rule, "Our goal in creating these tiers is to reward the top performing OPOs (Tier 1), while giving OPOs in Tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level up . . . ."[14] We note that tier 3 DSAs, which have an upper limit of the one-sided 95 percent confidence interval for their donation or

[14] 85 FR 77911-12.

organ transplantation rates that are below the median threshold rate established using the previous year's data, are considered to be DSAs that fail to meet the outcome measures and are non-compliant with the CfCs.

Our goal is for all OPOs to be compliant with the process measure CfCs and the outcome measure CfCs, meeting or exceeding the prior year's median performance threshold, such that no OPOs are ranked in tier 3 and de-certified. As such, we have established a system of incentives to reward high performance on the outcome measures. CMS calculates the outcome measures and tier rankings annually and makes that information publicly available in interim reports, and OPOs with DSAs that rank in tier 2 or tier 3 must use their QAPI program to identify opportunities for improvement and implement changes that lead to improvement in these measures. Since publication of the December 2020 final rule the donation and transplantation system has entered a period of accelerated improvement. Based on data provided in the 2025 OPO Public Performance Report[15] the median donation rate increased 11 percent from 2021 to 2023, while historical records show that it only increased 2.6 percent in the 3 years preceding CMS rulemaking (2017 through 2019). Likewise, the median transplantation rate increased 7.3 percent from 2021 to 2023, while it only increased 1 percent in the 3 years preceding CMS rulemaking (2017 through 2019). Taken together, these data suggest that the sustained regulatory pressure of our system of tiered incentives, coupled with reliable and transparent performance metrics that drive continuous improvement and improve accountability, is working as we intended to accelerate OPO performance improvement in serving donors, their families, and patients on the transplant waiting list. As we stated in the December 2019 OPO proposed rule, "Our ultimate definition of success, however, is to encourage the performance of all OPOs to cluster around the highest performers."[16] In the 2023 data report (based on data collected in 2021) there were 15 OPOs with tier 1 DSAs, increasing to 25 in 2024 (data from 2022), and 30

[15] Quality, Certification, and Oversight Reports. *https://qcor.cms.gov/main.jsp*. Accessed on June 12, 2025
[16] 84 FR 70634.

in 2025 (data from 2023). While top performing OPOs continue to improve on the outcome measures, mid-performing OPOs are further accelerating their own improvements to catch up to their peers. Finally, in the December 2019 OPO proposed rule, we predicted that OPOs achieving the standard of the top 25 percent or a 20 percent increase, whichever is greater, would lead to an improvement in donors from 10,000 in 2017 to over 12,000 in 2026 and in transplants from 32,000 in 2017 to almost 42,000 in 2026. In 2023, there were 14,571 deceased organ donors and 45,407 transplants, surpassing CMS' original predictions 3 years sooner than predicted. These initial data suggest that the 3-tier methodology we finalized in the December 2020 final rule has led to a sustained improvement in organ procurement and transplant as intended.

We have reason to believe, and research suggests[17], that this acceleration in better service of patients on the transplant waiting list is connected to the sustained regulatory pressures exerted by use of the tier structure in the re-certification process to bring about accountability. An OPO with a DSA that qualifies for tier 1 designation will be re-certified, retaining its tier 1 DSA, provided that the OPO is also found to be in compliance with all other OPO process performance measure CfCs via the re-certification survey. An OPO with a DSA that qualifies for tier 1 designation also qualifies to enter any competitions that are conducted to fill DSAs that are open for competition. An OPO with a DSA that qualifies for tier 2 designation and is also found in compliance with all other OPO process measure CfCs via the re-certification survey is also in compliance with the regulations, but its tier 2 DSA will be open to competition from other OPOs with tier 1 and tier 2 DSAs, should any eligible OPO choose to compete for it. An OPO with a tier 2 DSA may compete for any DSAs that are open for competition and must retain its DSA or obtain a new DSA in competition to be designated to the DSA and have an agreement with CMS. An OPO that only has DSAs designated to tier 3 will receive an initial notice of de-certification

[17] Doby BL, Ross-Driscoll K, Shuck M, Wadsworth M, Durand CM, Lynch RJ. Public discourse and policy change: Absence of harm from increased oversight and transparency in OPO performance. Am J Transplant. 2021;00:1–7. https://doi.org/10.1111/ajt.16527.

determination due to non-compliance with the OPO CfCs and has the appeal rights set forth at § 486.314. Once de-certified, an OPO cannot compete for either its own or any other open DSA. CMS utilizes competition to drive performance to achieve a higher tier ranking and to decide which OPOs should be awarded the opportunity to compete for additional DSAs if and when they are open. The conclusion of the 2022-2026 certification cycle will mark the first use of the outcome measures and tiers system for re-certification purposes. CMS publishes interim annual reports each year to provide transparency in OPO performance and the opportunity for OPOs to implement performance improvement plans. These reports are posted on the Quality, Certification and Oversight Reports (QCOR) website.[18]

In addition to the outcome measures and their implications with respect to tier status and re-certification, OPOs must also comply with the process performance measures set forth at §§ 486.320 through 486.360 to be considered in compliance with the CfCs. While tier assignment recognizes different levels of performance with respect to the outcome measures, it does not guarantee compliance with other requirements. Therefore, OPOs that are high performing on the outcome measures could be found non-compliant with one or more of the process performance measures during a survey, which could lead to de-certification if the OPO is unable to remedy the non-compliance. The process performance measures span a range of operational requirements. Specifically, at § 486.320 we require that an OPO must become a member of, participate in, and abide by the rules and requirements of the OPTN. At § 486.322 we address relationships with donor hospitals in the OPO's DSA, providing training to donor hospital staff, and cooperating with tissue banks. At § 486.324 we specify the required members of the OPO advisory board, its authorities and restrictions, limitations on the members of the board, and having bylaws for board member conflicts of interest and other key concerns. This condition also addresses the OPO's governing body and requires each OPO to declare in policy whether it recovers organs from donors after cardiac death. At § 486.326 we include specific

[18] Quality, Certification and Oversight Reports. *https://qcor.cms.gov/main.jsp*.

human resources requirements that are further discussed in section III.I. of this proposed rule. At § 486.328 we include data reporting requirements for reporting to the OPTN, Scientific Registry of Transplant Recipients (SRTR), Department of Health and Human Services (HHS), and to transplant hospitals. At § 486.330 we address maintaining records for all donors and the disposition of each organ recovered for transplantation. This requirement is further discussed in section III.J. of this proposed rule. At § 486.342 we address requesting consent from prospective donor families with discretion and sensitivity, and at § 486.344 we address written protocols for donor evaluation, donor management, and organ placement and recovery to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. At § 486.346 we address organ preparation and transportation, covering topics including organ testing for infectious diseases and tissue typing, documentation provided to a transplant center and its verification for accuracy, and the protocols for packaging, labeling, handling, and shipping organs. The issue of organ transportation is further discussed in section III.K. of this proposed rule. At § 486.348 we include specific QAPI requirements, addressing the components of the program, death record reviews, adverse events, and the connection between performance on the CMS outcome measures and QAPI activities. The requirements for QAPI are further discussed in section III.K. of this proposed rule. Finally, at § 486.360 we address emergency preparedness standards for OPOs.

On February 2, 2021, we published a notice in the **Federal Register** (86 FR 7814) temporarily delaying the effective date of the December 2020 final rule by 60 days and providing an additional 30-day public comment period, during which we received over 150 timely public comments. The comments received included both support for immediate implementation of the December 2020 final rule and requests for additional time before implementation. We considered the additional public comments and the rule subsequently became effective on March 30, 2021.

On December 3, 2021, we published a "Request for Information (RFI); Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease (ESRD) Facilities" (86 FR 68594) ("December 2021 RFI"), which solicited comments that would help to inform potential changes that would create system-wide improvements, including improvements in organ donation, organ transplantation, quality of care in dialysis facilities, and access to dialysis services.

We received almost 400 timely comments in response to the December 2021 RFI. Commenters included transplant recipients, those awaiting transplants, donor families, and donor representatives. A range of health care providers, including donor hospitals, transplant programs, ESRD suppliers, hospital systems, OPOs, and tissue banks; researchers and academic institutions; professional organizations; trade groups such as technology and pharmaceutical companies as well as insurers; and advocacy and philanthropic organizations also provided comments. These comments informed this proposed rule and may be used in future rulemaking for system-wide changes to advance organ transplant system performance.

Recent peer reviewed research using the same method for estimating donor potential from our December 2020 final rule highlights the ability to detect variable performance both across OPOs and across areas of practice within OPOs as well as how this information can be leveraged for performance improvement to increase organ donation.[19,20] One group of researchers found that 74 percent of differences in overall donor procurement rates could be explained using model variables that represent different domains of OPO practice activities, such as DCD procurement, and procurement of older and minority patient populations.[21] Having this type of in depth performance data analysis available to OPOs for use in their QAPI programs, based on

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[19] Doby BL, Hanner K, Johnson S, Purnell TS, Shah MB, Lynch RJ. Results of a data-driven performance improvement initiative in organ donation. Am J Transplant. 2020;00:1–8. *https://doi.org/10.1111/ajt.16442*.

[20] Lynch RJ, Doby BL, Goldberg DS, Lee KJ, Cimeno A, Karp SJ. Procurement characteristics of high- and low-performing OPOs as seen in OPTN/SRTR data. Am J Transplant. 2022 Feb;22(2):455-463. doi: 10.1111/ajt.16832. Epub 2021 Sep 29. PMID: 34510735.

[21] Doby BL, Casey K, Ross-Driscoll K, Rahman Ovi M, Hossain Bhuiyea MS, Isty IA, Lynch RJ, What is visible is fixable: visual dashboards for multi-domain assessment of OPO performance, *American Journal of Transplantation*, *https://doi.org/10.1016/j.ajt.2023.08.020*.

impartial and reliable data and outcome measures, is vital for OPOs to utilize in designing and implementing QAPI activities to drive improvements. The ability of OPOs to use this type of information to potentially implement appropriate practice changes will be critical to their success in the future. It is our role, with a continued focus on better patient outcomes, to maintain and enforce a regulatory structure that capitalizes on recent developments in data analysis and insights to enhance system-level and OPO-level performance.

To assist OPOs in improving performance, we developed two initiatives that OPOs could participate in to facilitate organ procurement and placement. The ESRD Treatment Choices Learning Collaborative brought transplant centers, OPOs, donor hospitals, patients, and donor families together to spread the use of highly effective practices to increase kidney procurement, recovery, and utilization.[22] The program provided technical assistance to several interested parties, including OPOs, with three aims: increasing the number of deceased donor kidneys transplanted, decreasing the current national discard rate of all procured kidneys, and increasing the percentage of kidneys recovered for transplant in the greater than or equal to 60 KDPI score group. Fifty-three OPOs participated in this collaborative, which ended in August 2025. CMS, through its quality improvement organizations, also initiated an OPO Special Innovation Project (SIP) to provide technical assistance to OPOs for improvement on the OPO performance outcome measures. In this program, OPOs had the opportunity to actively participate in a variety of technical assistance activities such as completing Root Cause Analyses (RCAs) and Plan-Do-Study-Act (PDSA) cycles, implementing evidenced-based strategies, and developing process and decision pathways. The objective was for OPOs to permanently integrate effective processes to improve and sustain improvements in their donation rate and transplant rate. Forty OPOs participated in this program, which concluded in March 2025.

[22] *https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.*

C. 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 PHS Act. Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order for its 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 or Medicaid programs for organ procurement costs, the entity must be designated by the Secretary. The requirements for such designation are set forth in § 486.304 and include being certified as a qualified OPO by CMS. Regulations at § 486.303 address the requirements to be certified as a qualified OPO.

Pursuant to section 371(b)(1)(D)(ii)(II) of the PHS Act, the Secretary is required to establish outcome and process performance measures for OPOs to meet based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of the qualified OPO. Section 1138(b)(1)(D) of the Act requires an OPO to be a member of, and abide by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN). OPOs must also comply with the regulations governing the operation of the OPTN (42 CFR part 121). The Department of Health and Human Services (HHS) has explained that only those OPTN policies approved by the Secretary will be considered "rules and requirements" of the OPTN for purposes of section 1138 of the Act.[23] The

[23] 63 FR 16296.

OPTN is a membership organization that oversees the U.S. organ transplant system, links all professionals in the U.S. organ procurement and transplantation system, and maintains a national registry for matching donated organs with recipients in need of transplantation. OPOs are required under OPTN regulations (42 CFR 121.11(b)(2)) and § 486.328 of our OPO CfCs to report information specified by the Secretary to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with existing Federal civil rights laws, including the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. 12101 et seq., Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d, Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794, and Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116.[24] Title VI protects individuals on the basis of race, color, and national origin. Section 1557 protects individuals on the basis of race, color, national origin, age, disability, or sex. Among other things, these laws require OPOs to take reasonable steps to ensure meaningful access to their programs by individuals with limited English proficiency. Reasonable steps may include providing language assistance services at no cost to the individual, such as providing interpreters or translated material. Also, the ADA, Section 504 and Section 1557 protect otherwise qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from discrimination in the administration of organ transplant programs that receive Federal financial assistance. Under these laws, OPOs must ensure that qualified individuals with disabilities are afforded opportunities to participate in or benefit from the organ donation programs that are equal to opportunities afforded to others. Furthermore, OPOs and transplant teams risk violating these Federal civil rights laws through discriminatory actions during the organ donation process. Such

[24] Recipients of Federal financial assistance must comply with Federal civil rights laws, including but not limited to Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act.

violations include providing substandard care to a prospective donor with a disability based solely on that disability.

Qualified individuals with disabilities are also entitled to reasonable modifications needed to participate in and benefit from a program, as well as appropriate auxiliary aids and services needed for effective communication. These rights extend in some circumstances to companions 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 procurement program.

Section 1102 of the Act gives the Secretary the authority to make and publish such rules and regulations as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. Moreover, section 1871 of the Act gives the Secretary broad authority to establish regulations that are necessary to carry out the administration of the Medicare program.

We established CfCs for OPOs at 42 CFR part 486, subpart G, and OPOs must meet these requirements in order to be designated and therefore 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. The outcome measures, found under § 486.318, are used to assess OPO performance for re-certification and competition purposes (see § 486.316(a) and (d)).

III. Provisions of the Proposed Regulations

In response to the December 2020 final rule, which revised the regulations that establish the framework for OPO re-certification, we have received questions on technical implementation of the rule from OPOs and other interested parties. In this proposed rule, we seek to clarify outstanding procedural and technical questions on the implementation of the rule so that OPOs can better understand the procedures for re-certification and de-certification that will be used in

2026. We remain committed to holding OPOs accountable for their performance and are proposing additional revisions to the OPO regulations that will assist in driving improvements.

A. Definitions (§ 486.302)

We are proposing to revise our current regulations defining the terms "adverse event," "donor," "medically complex donors," "medically complex organs," "organ," and "unsound medical practices" at § 486.302 to provide greater clarity.

1. Adverse Event

Section 486.302 currently defines "adverse event" as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include, but are not limited to, transmission of disease from a donor to a beneficiary, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary." Adverse events trigger QAPI requirements so that for each adverse event, the OPO is required to "conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents" (§ 486.348(c)(2)).

Through feedback we have received, we are concerned that the examples set forth in this definition are not being viewed as examples but rather as an exhaustive list of the adverse events that apply to OPOs. We do not believe an exhaustive list of adverse events is possible, given the broad range of potential occurrences that might qualify as "an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof." Thus, to avoid any confusion, we are proposing to remove the second sentence of the current definition and move a revised list of examples to § 486.348(c) in the QAPI requirements. If this change is finalized as proposed, OPOs should continue to identify "adverse events" according to the definition in § 486.302, regardless of whether the incident is covered in the examples that we are proposing to

insert into § 486.348(c). We solicit public comment on the proposed changes to the definition of adverse events.

2. Donor

The Pancreatic Islet Cell Transplantation Act of 2004[25] (hereafter referred to as "PICTA 2004") amended the PHS Act to add section 371(c), which requires that "[p]ancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or re-certification[.]" In the December 2020 final rule we implemented the requirements of PICTA 2004 in the definition of "donor" in the OPO regulations at § 486.302, stating that a donor is "… 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."

OPOs are required by the OPTN to report data related to pancreata procured and used for research, and this data is incorporated into calculations used to assess compliance with the donor and transplant outcome measures used for re-certification purposes. In finalizing the definition of "donor" in 2020 we noted that, "[w]e think that the impact of pancreata for research on the overall rankings of OPOs will continue to be minimal."[26] This prediction was based upon a clear downward trend in OPO-reported procurement of pancreata procured and used for research, and our expectation of a leveling off or further downward trend was further substantiated by a 2021 article titled, "The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update,"[27] which noted changes over time in the pancreata islet cell research and transplantation landscape, from its peak in the years 2000-2015 with numerous phase 1 and 2 clinical trials declining to only 11 patients receiving a pancreatic islet cell transplant between

[25] October 25, 2004, Pub. L. 108-362.
[26] 85 FR 77902
[27] Witkowski et al. The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update The "ISLETS FOR US" Collaborative. Am J Transplant. 2021 Apr;21(4):1365-1375. *https://doi.org/10.1111/ajt.16397*.

2018 and 2021. Upon review of ongoing clinical trials for pancreatic islet cells as described on the National Institute of Health's (NIH) website clinicaltrials.gov[28], we identified 16 active clinical trials in October 2023 with a total possible enrollment of 325 persons, which was consistent with the procurement rates for research pancreata that existed prior to publication of the December 2020 final rule, coinciding with the period of decline noted in the 2021 article. We note that the number of active clinical trials appears to have declined since October 2023, with a total of 4 active clinical trials and a total possible enrollment of 108 persons identified in November 2025.

However, since the publication of the December 2020 final rule and the updated definition of the term "donor", OPOs' reported procurement of pancreata for research purposes has increased dramatically, rising from 562 in 2020 to 573 in 2021, 1,448 in 2022, 1,819 in 2023, and 2,004 in 2024, based on internal CMS review of data submitted by OPOs to the SRTR. The roughly 250 percent increase in procurement between 2020 and 2024 has not been matched by a corresponding increase in the number of clinical trials for pancreatic islet cells reported to the NIH and made public on the clinicaltrials.gov site. On January 18, 2024, we issued a memorandum[29] clarifying that for purposes of the definition of "donor", the pancreata must be used for islet cell research or islet cell transplantation, consistent with PICTA 2004, to be counted. On October 9, 2024, the OPTN and SRTR updated the disposition reason codes that OPOs use when entering data regarding pancreata procured for any research purpose. The updated disposition reason codes differentiate pancreata procured and used for islet cell research activities from pancreata used for all other research purposes to enhance the specificity of data reported by OPOs. We propose to revise the definition of the term "donor" to further reiterate the clarification made in the January 2024 memorandum. The revised definition would state that an individual from whom only the pancreas is procured and is used for islet cell transplantation

[28] Accessed October 17, 2023.
[29] QSO-24-04-[OPO], https://www.cms.gov/files/document/qso-24-04-opo.pdf

or for islet cell research is included in the definition of "donor." Procurement for other research uses does not count for purposes of certification and re-certification. These proposed revisions are intended to clarify the rule to improve regulatory consistency with the requirements set forth in PICTA 2004, which specifies that pancreata procured for "islet cell transplantation or research" are required to be counted for certification and re-certification of OPOs.

Per the National Diabetes Statistics Report[30] issued by the Centers for Disease Control there were approximately 1.7 million Americans living with diagnosed type 1 diabetes in 2021. Experts estimate that 375,000 suffer from impaired hypoglycemic awareness and 66 percent suffer from recurrent severe hypoglycemic episodes (SHE).[31] Nearly 70,000 patients with type 1 diabetes fail to improve for hypoglycemia avoidance despite patient education efforts and advanced technologies, such as insulin pumps and continuous glucose monitoring sensors.[32] In 2020, hypoglycemia led to 202,000 emergency department visits.[33]

Although pancreas transplantation remains a therapeutic option that effectively treats type 1 diabetes, it requires major surgery with a significant risk of complications. Pancreatic islet allotransplantation offers a minimally-invasive alternative that lowers morbidity and mortality, improves glycemic control and prevents SHE, conferring complete protection from SHE in more than 90 percent of patients.[34] Federally funded clinical trials involving several U.S. academic centers have been conducted for pancreatic islet allotransplantation following results of a study conducted in 2000 where a series of seven patients with type 1 diabetes remained insulin-free for a full year following allotransplantation.[35] "Research," as the term is used in the OPO

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[30] National Diabetes Statistics Report. *https://www.cdc.gov/diabetes/php/data-research/index.html*. Accessed on March 25, 2025.
[31] Byrne M, Hopkins D, Littlejohn W, et al. Outcomes for Adults with Type 1 Diabetes Referred with Severe Hypoglycaemia and/or Referred for Islet Transplantation to a Specialist Hypoglycaemia Service. Horm Metab Res. 2014;47(01):9-15.
[32] Rickels MR. Hypoglycemia-associated autonomic failure, counterregulatory responses, and therapeutic options in type 1 diabetes. Ann N Y Acad Sci. 2019;1454(1):68-79.
[33] National Diabetes Statistics Report. *https://www.cdc.gov/diabetes/php/data-research/index.html*. Accessed on March 25, 2025.
[34] Witkowski et al.The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update The "ISLETS FOR US" Collaborative. Am J Transplant. 2021 Apr;21(4):1365-1375. doi: 10.1111/ajt.16397.
[35] Witkowski et al.The Demise of Islet Allotransplantation in the US: A Call for an Urgent Regulatory Update The "ISLETS FOR US" Collaborative. Am J Transplant. 2021 Apr;21(4):1365-1375. doi: 10.1111/ajt.16397.

regulations, for pancreatic islet allotransplantation involves all stages of *bona fide* bench research conducted by a qualified researcher that uses donor pancreatic islet cells to advance scientific and healthcare knowledge, but occurs without transplanting pancreatic islet cells into a patient. This may include safety studies, studies of innovative routes of administration, and studies of modified allogenic islet cell products.[36] Islet cell research includes donor pancreata used for research related to islet isolation as well as pancreata used for islet cell research when the islets remain in the organ, such as may be used in organ slice studies or in situ islet histology. In the Congressional Record associated with passage of PICTA 2004, a member of the U.S. House of Representatives described "research that can result in being able to *replicate the islet cells so that every diabetic in the country that wants one of these transplants can get that"*[37] (emphasis added). Another Representative described the purpose of PICTA 2004 as follows, "Pancreatic islet transplantation has been hailed as the most important advance in diabetes research since the discovery of insulin in 1921. The procedure, which involves transplanting insulin-producing cells into an individual with juvenile diabetes, has been performed on over 300 individuals, and the majority of them no longer need to take insulin to stay alive. While *significant research remains to be done to expand this procedure to all who suffer with juvenile diabetes*, its promise is incredibly exciting..."[38] (emphasis added). We believe that there continues to be a role for using donor pancreata to advance islet cell research, fulfilling this stated vision of widespread treatment for type 1 diabetes. Pancreatic islet cells used for *bona fide* bench research conducted by a qualified researcher would continue to be included in the definition of "donor" and OPOs that procure pancreata that are used in *bona fide* pancreatic islet cell research would continue to receive credit for these donors in the donation outcome measure. As described in section III.J. of this proposed rule, we would require OPOs to document information regarding the islet cell

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[36] Shapiro AMJ, Ricordi C, Hering BJ, et al. International Trial of the Edmonton Protocol for Islet Transplantation, N Engl J Med. 2006;355(13):1318-1330.
[37] Congressional Record- House, H8074, October 5, 2004.
[38] Congressional Record- House, H8074, October 5, 2004.

research to which donor pancreata are supplied. This documentation, including information regarding approval from an institutional review board or other similar entity, as appropriate, would allow CMS to verify the existence of *bona fide* research activities conducted by a qualified researcher to advance scientific and healthcare knowledge and confirm that the research uses donor islet cells.

We continue to believe that pancreata used for islet cell research will have little effect on the rankings of OPOs when calculating the donation outcome measure because the volume of *bona fide* pancreatic islet cell research conducted by a qualified researcher, that is bench only research with no transplants, is limited nationwide. By nature of the status of the research field and the requirements needed to move this treatment from research to standard clinical practice, the overall impact of including these pancreata used for islet cell research to implement the requirements of PICTA 2004 is limited. As described in section III.J. of this proposed rule, we propose to require that OPOs maintain specific documentation regarding pancreata used for islet cell research. We intend to verify both the existence and accuracy of this documentation to assure that OPOs accurately code reported pancreata used for islet cell research when submitting data to the OPTN, thereby upholding the integrity of the donor outcome measure.

As set forth in the PICTA 2004, a pancreas must be "used for islet cell transplantation or research" to be subject to the requirement that it be counted for certification or re-certification purposes. We propose to continue to include the criterion that the pancreas be "used" for islet cell transplantation or research in the definition of "donor" at § 486.302. At the time PICTA 2004 was enacted, it was not possible to cryopreserve pancreatic islet cells for future use. However, such cryopreservation of pancreatic islet cells is now possible and must be considered when deciding what activities constitute "use" for purposes of implementing the statute. To ensure that OPOs can accurately code data when entering it into the OPTN system within five days of organ procurement, per the data standards set forth by the OPTN, we consider "use" for purposes of islet cell research to be the acceptance and either immediate use or cryopreservation

of the pancreatic islet cells by a *bona fide* pancreatic islet cell research program to advance scientific and healthcare knowledge. We have partnered with HRSA to implement enhanced OPO data reporting that more accurately conveys the disposition and use of pancreata, either for use in research that does not involve transplantation or in transplants of the pancreata or its islet cells to a patient on the OPTN waiting list. CMS uses data entered by OPOs into the OPTN data system in calculating the outcome measures.

Requiring research pancreata to be "used" for islet cell research to be included in the donation rate is consistent with how we treat other organs in the donation rate outcome measure. We only consider donors to be those for whom an organ was used for transplant. Procurement for transplant without an actual transplant is insufficient for inclusion in the donor outcome measure (see 84 FR 70631 and 85 FR 77903 for discussion of including only those organs that are used rather than procured with intent to use). Likewise, procurement of pancreata for islet cell research without actual use in that research is insufficient for inclusion in the donation rate outcome measure.

3. Organ

In the December 2020 final rule, we implemented the requirements of PICTA 2004 in the definition of "organ" in the OPO regulations at § 486.302, stating that an organ is "… 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." Although the term "organ" is used frequently throughout the regulations, it has a specific relationship to the "organ transplantation rate," which is defined as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. Organs that are transplanted into patients on the OPTN waiting list as part of research are explicitly included in the organ transplantation rate. The definition of the organ transplantation rate focuses entirely on transplant activities and the inclusion of bench research activities in this rate has created significant concern in the OPO and transplant communities. We agree with interested parties

that including bench research within the definition of "organ" and by extension the "organ transplantation rate" has created a performance incentive that is not serving patients on transplant waitlists because the transplantation rate counts the use of a pancreas in islet cell bench research as being equivalent to a pancreas or pancreatic islet cell transplant. As such, the inclusion of pancreatic islet cell bench research in the definition of "organ" has proven to be inconsistent with the goals of the 2020 rulemaking to increase the number of transplants in that OPOs may have used the placement of pancreata for islet cell research to mask their performance in successfully facilitating actual organ and pancreatic islet cell transplants. Therefore, we propose to revise the definition of the term "organ" in a way that would no longer include pancreata used for islet cell research, unless the research is islet cell transplantation that occurs under a research protocol.

While PICTA 2004 requires that pancreata used in islet cell research be counted for purposes of certification and re-certification, it does not require that these organs be included in all established OPO outcome measures. In the 2006 OPO final rule (71 FR 30982) that established the formerly used set of OPO outcome measures, one of the three yield measures counted pancreata used for islet cell research while a separate yield measure counted pancreata used for islet cell transplantation. Previous CMS policy differentiated the treatment of pancreatic islet cells based on their use for either transplantation or research, and we propose to reinstate that differentiation as it relates to current policy. Under our proposal, a pancreas that is used for islet cell research without a transplant to a patient on the OPTN waiting list would count towards the donation rate outcome measure, but would not be included in the transplantation rate outcome measure. A pancreatic islet allotransplant to a patient on the OPTN waiting list, on the other hand, would be included in both the transplantation rate outcome measure and the donation rate outcome measure, whether it is conducted under standard or research protocols.[39] This

[39] In accordance with the regulations set forth at 42 CFR 413.406, Medicare only covers and pays for reasonable costs of acquisition of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

policy of only including pancreatic islet cell transplants in the transplant outcome measure advances the CMS goal of increasing the number of transplants in service of those patients on the OPTN transplant waiting list.

We are specifically soliciting comments on modifications to the proposed definitions of donor and organ, including any additional considerations that should be addressed in these definitions and alternative approaches to meeting the statutory requirements set forth by PICTA 2004. We are interested in information regarding data sources to verify data submitted regarding pancreatic islet cell research organs, alternative data sources for research organs that are independently verified and nationally available for the development of new outcome measures, and additional information that focuses on pancreata used for islet cell research and the statutory requirements for their counting in OPO certification and re-certification.

4. Medically Complex Donors and Medically Complex Organs

Traditionally, some donors and their organs have been preferred over others, based on the age and health status of the donor, by transplant programs and surgeons. Organs from donors with less-preferred characteristics may be perceived as less valuable for organ transplantation or not appropriate for transplantation at all. To address these misconceptions, we are proposing to both define and utilize the terms "medically complex donors" and "medically complex organs." Moreover, in the QAPI CfC set out at section § 486.348, we propose to require that OPOs must track procurement and placement of these organs, assess their policies and procedures regarding medically complex donors and organs, and ensure they are optimizing the recovery and placement of those organs for transplant.

Although we have not previously defined these less-preferred organs, the OPO CfCs have differentiated between organs from different types of donors. In the 2006 OPO final rule (71 FR 30982), we defined "eligible organs" as organs recovered from a donor that met the "eligible death" definition. Those donors had to be (1) 70 years old or younger, (2) declared dead by the hospital's brain death criteria, and (3) patients who did not meet certain exclusionary criteria,

which included, among other things, tuberculosis, human immunodeficiency virus (HIV), multiple-system organ failure, and certain cancers. These eligible deaths constituted the denominator for the donation rate outcome measure. Other organs, such as those recovered from donors over 70 years old or from donors who were declared dead by cardiac death criteria, were not "eligible organs." Those donors and organs would however be counted and added to the outcome measures when the OPO obtained consent, and the organs were transplanted. In 2016, we modified the definition of "eligible death" to, among other things, include specific exclusionary criteria for kidneys, livers, hearts, and lungs.[40] Effective in 2022, we removed the "eligible death" definition and now the donor potential that is the denominator for the outcome measures is based on the number of inpatient deaths of persons 75 and younger within the DSA with a primary cause of death that is consistent with organ donation (currently 42 CFR 486.318(d)(1)(iv)).[41]

As a result of these policies, some people in the organ transplant community may have considered those organs that did not meet the definition of "eligible organ" to be less valuable organs or did not consider transplanting them into their patients despite many individuals being on the waiting lists. These organs may have included organs from DCD donors, from donors older than 70 or 75, or from younger individuals with deteriorating health conditions.

Current research demonstrates that "medically complex organs" can produce positive and similar outcomes to other organs, and better outcomes than no transplant for patients. For example, recent research has demonstrated that kidneys recovered from DCD donors have similar long-term outcomes to organs from donors declared dead by brain death or neurological criteria (brain death donors), although some increases in complications related to graft function have been noted.[42] Another example is donors who have a KDPI over 50 percent. Recent

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[40] 81 FR 79562.

[41] Organ Procurement Organizations Conditions for Coverage; Revisions to Outcome Measures Requirements for Organ Procurement Organizations (85 FR 77898).

[42] Rijkse E, Ceuppens S, Qi H, IJzermans JNM, Hesselink DA, Minnee RC. Implementation of donation after circulatory death kidney transplantation can safely enlarge the donor pool: A systematic review and meta-analysis

research has also demonstrated that transplant recipients who received these organs had a lower mortality rate, and an improved quality of life compared to patients who are on chronic renal dialysis.[43]

In addition, we are concerned that OPOs are not actively pursuing "medically complex" donors and their organs because of a perception that such organs may not be accepted by others in the transplant community, despite many individuals waiting on the transplant lists. Declining to use these organs, however, contributes to the chronic undersupply of transplantable organs, as well as potentially increasing mortality and decreasing quality of life for ESRD patients.

We believe that encouraging the pursuit of medically complex donors and organs when there is medical evidence that these organs can improve the quality of life or save the lives of more patients on the waiting list, by increasing the overall number of transplantable organs. The National Academies of Sciences, Engineering, and Medicine (NASEM) issued a report regarding the transplant ecosystem, "Realizing the Promise of Equity in the Organ Transplantation System" (NASEM 2022 organ transplant report).[44] The NASEM 2022 organ transplant report used the term "medically complex" to describe organs that were recovered from donors who had medical histories that deserved special considerations to identify the best recipient for that organ. The proposed definitions for "medically complex donor" and "medically complex organ" are primarily based upon the NASEM 2022 organ transplant report's description of medically complex donors and organs. Medically complex donors would include DCD donors and those with elevated KDPI scores over 50 that require greater consideration in choosing a potential recipient due to the DCD donation process and possible kidney damage. Since DCD donors have not been declared dead by brain death criteria, OPOs need protocols that address at a

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Int J Surg. 2021 August;92:106021. doi: 10.1016/j.ijsu.2021.106021. Epub 2021 Jul 10. Accessed at *https://pubmed.ncbi.nlm.nih.gov/34256169/*. Accessed on September 29, 2022. *See also* FN#2, Wall, et al.

[43] Tonelli M, Wiebe N, Knoll G, Bello A, Browne S, Jadhav D, Klarenbach S, and Gill J. Systematic Review: Kidney Transplantation Compared With Dialysis in Clinically Relevant Outcomes. *https://doi.org/10.1111/j.1600-6143.2011.03686.x*. Accessed at *https://onlinelibrary.wiley.com/doi/full/10.1111/j.1600-6143.2011.03686.x*. Accessed on September 29, 2022. See also FN#2, Wall, et al.

[44] NASEM. (2022). Accessed at *https://nap.nationalacademies.org/catalog/26364/realizing-the-promise-of-equity-in-the-organ-transplantation-system*. Accessed on May 10, 2022.

minimum: how these potential donors should be evaluated; how life support would be withdrawn, and the relationship between the time of consent to donation and withdrawal of life support; the use of medications and interventions not related to withdrawal of support; family members' involvement prior to organ recovery; and the criteria for declaration of death and the time period that must elapse prior to organ recovery (§ 486.344(f)). We also believe DCD donors need to be identified specifically because the number of recovered DCD organs has steadily increased over the last decade. In 2024, there were 7,280 DCD donors, which is an increase of 23.5 percent over 2023.[45] We also believe donors with elevated KDPI scores should be considered medically complex. We are proposing that the term medically complex donors include those with a KDPI score of 50 or greater. However, we are specifically soliciting comments on at what score should the KDPI be considered elevated so that the potential donor would be considered "medically complex" and may revise the proposed KDPI score threshold in the final rule in response to comments received.

Medically complex donors and organs also include donors that are HIV+ or have Hepatitis C. While HIV+ infection remains a serious illness, fewer individuals are dying from it and it is now considered a chronic disease.[46] In addition, transplants from an HIV+ donor to an HIV+ recipient must comply with the requirements set forth in the HIV Organ Policy Equity Act (HOPE Act), which includes complying with designated research protocols.[47] Hepatitis C can be an acute or chronic infection and, with treatment, most individuals can be cured.[48] While organs from donors that are HIV+ or have Hepatitis B or C can be successfully transplanted, these

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[45] Organ transplants exceeded 48,000 in 2024; a 33 percent increase for the transplants performed in 2023. OPTN. Jan 14, 2025. Accessed at https://www.hrsa.gov/optn/news-events/news/organ-transplants-exceeded-48000-2024-33-percent-increase-transplants-performed-2023. Accessed on August 25, 2025.

[46] Deeks SG, Lewin SR, Havlir DV. The end of AIDS: HIV infection as a chronic disease. Lancet. 2013 Nov 2;382(9903):1525-33. doi: 10.1016/S0140-6736(13)61809-7. Epub 2013 Oct 23. PMID: 24152939; PMCID: PMC4058441. Accessed on January 24, 2024.

[47] Pub. Law 113-51 (2013); Final Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV. A Notice by the National Institutes of Health on November 25, 2015 **Federal Register** / Vol. 80, No. 227 / Wednesday, November 25, 2015 / Notices 73785 *https://www.federalregister.gov/documents/2015/11/25*.

[48] CDC. Hepatitis C. Accessed at https://www.cdc.gov/hepatitis-c/about/index.htmlhttps://www.cdc.gov/hepatitis/hcv/index.htm. Reviewed October 31, 2023. Accessed on January 24, 2024.

transplants require special or additional considerations in identifying the best potential recipient for these organs. For example, one study found that with appropriate consideration of both the DCD donor and the potential recipient, DCD liver transplants could have outcomes that were both acceptable and comparable to outcomes for non-DCD liver transplants. The considerations included but were not limited to cold and warm ischemic times, and comorbidities of the donor and the potential recipient, such as age, obesity, and "Model for End-Stage Liver Disease" (MELD) scores, which estimates the severity of the donor's liver disease.[49]

Hence, medically complex organs can be successfully transplanted and enhance and even prolong patients' lives; however, they have not been fully utilized. To encourage the use of these organs, we are proposing to define the term "medically complex donor" in § 486.302 as a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors would include all DCD donors and donors with elevated KDPI scores of 50 or more. We also propose to define the term "medically complex organ" as an organ procured from a "medically complex donor".

We believe that defining "medically complex organs" and "medically complex donors" and including these organs and donors in OPOs' QAPI programs could result in more of these organs being procured and increase the number of transplantable organs for patients on the various waiting lists. However, we are also concerned that there could be unintended consequences resulting from this proposal. For example, could this requirement put unreasonable pressure on OPOs to procure medically complex organs? Thus, we are specifically soliciting comments on modifications to the proposed definitions of "medically complex donor" and "medically complex organ", including any specific criteria that should be added. We are also specifically soliciting comments on how to define an "elevated KDPI". Is 50 or more

[49] Haque, O, Yuan, Q, Uygun, K, and Markmann, JF. Evolving utilization of donation after circulatory death livers in liver transplantation: the day of DCD has come. Clinical Transplantation. 2021;35:e14211. Https://doi.org/10.1111/ctr.14211. Accessed at *https://onlinelibrary.wiley.com/doi/pdf/10.1111%2Fctr.14211*. Accessed on September 21, 2015.

appropriate? If not, what KDPI score should be used? Also, are there any unforeseen consequences to this proposal?

5. Unsound Medical Practices

In the 2006 final rule, CMS finalized § 486.312(b), which states CMS may terminate an OPO's agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. In addition, we finalized a definition for "urgent need" in § 486.302. Urgent need occurs 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 organ donor or an organ recipient. While we referenced "unsound medical practices" as grounds for immediate termination, the OPO CfCs do not currently include a definition for "unsound medical practices".

Through feedback we have received, we recognize the need to clearly define what constitutes "unsound medical practices". Therefore, we propose at § 486.302, to add a definition for "unsound medical practices". We propose that the term "unsound medical practices" would refer to failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures. Some examples of unsound medical practices include, but are not limited to, failure to ensure the potential donor is declared dead according to applicable State law and hospital policies; negligent or deliberate failure to perform necessary and customary tests to determine whether a potential donor meets exclusionary criteria, such as certain malignancies or active infections; and pursuing patients with inappropriately high neurologic function as potential donors. Our intent is to ensure that instances of actions that constitute unsound medical practices are addressed appropriately and that OPOs continue to provide high quality care to patients, potential donors and potential transplant recipients. We solicit public comment on the proposed definition of "unsound medical practices".

B. Requirements for Certification (§ 486.303)

Section 486.303(e) requires that to be "certified as a qualified organ procurement organization," an organization must have "been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005." The Certification Act amended the PHS Act to add subparagraph (D) to section 371(b)(1), which defines a qualified OPO as an organization that "has met the other requirements of this section and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process" defined in regulations.[50] Section 371(b) of the PHS Act sets forth requirements that an OPO must meet to be certified. These requirements are also set forth in our regulations at § 486.303. Once certified, section 371(b)(1)(D)(ii)(I) of the PHS Act requires that OPOs must be re-certified not more frequently than once every 4 years.

After the Certification Act was passed, CMS proposed to remove language from our regulations that referred to new entities or organizations becoming OPOs.[51] We explained that "given the provision in (b)(1)(D) added by the OPO Certification Act . . . it appears impossible for the Secretary to give a grant to an organization that was not one of the 59 OPOs that was certified by the Secretary as meeting the performance standards in the 4-year period before January 1, 2000."[52] We also proposed adding § 486.303(e), requiring that OPOs have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.[53] When finalizing the proposal, we reiterated that "we currently do not have the authority to permit new entities to take over part or all of an OPO's service area," which "would be possible only if the Congress enacts legislation to change the requirement in the PHS Act because currently to be re-certified, an OPO must have been certified as of January 1, 2000."[54]

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[50] 42 U.S.C. § 273(b)(1)(D).
[51] 70 FR 6091.
[52] 70 FR 6091.
[53] 70 FR 6090.
[54] 71 FR 30998.

We have since repeated this interpretation.[55]

However, upon further review, we no longer believe that the Certification Act is best read to require all qualified OPOs to have been previously certified as of January 1, 2000. Instead, it is better read to mean that whenever the agency initially certifies or recertifies that an OPO meets the Secretary's performance standards within a 4-year period, OPOs must demonstrate at the end of that period that they still meet the agency's performance standards. Section 371(b)(1)(D)(ii) of the PHS Act specifically provides that a qualified OPO may be "certified or recertified" through "a process" that is "defined through regulations … promulgated by the Secretary." There is no language in that provision requiring that an OPO show it was certified as of January 1, 2000 as part of those standards. In fact, the statute requires the Secretary to "use multiple outcome measures as part of the certification process."[56] That the statute contemplates creation of a *certification* process indicates that the Secretary is not limited to *re*certifying OPOs. Thus, nothing in the text of the statute supports reading it to strip the Secretary of his authority to certify either an entirely new OPO or one that was previously decertified.

This interpretation of the Certification Act is reinforced by the statutory history. The prefatory language in section 371(b)(1)(D) of the PHS Act is drawn from section 1138(b)(1)(A) of the Social Security Act. The main change Congress made was to swap out a reference to a qualified OPO needing to have been certified or recertified "within the previous 2 years" to a reference to a qualified OPO needing to have been certified or recertified "within the previous 4-year period." Congress made legislative findings explaining that this change requires the agency "to extend the period for recertifications of an organ procurement organization from 2 years to 4 years."[57] This use of familiar statutory language with a single targeted change that Congress explained does not indicate that Congress meant also to silently restructure the OPO market by prohibiting all new entrants.

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[55] 85 FR 77898.
[56] 42 U.S.C. 273(b)(1)(D)(ii)(III) (emphasis added).
[57] Pub. L. 106-505 § 701(b)(5), 144 Stat. at 2347.

We acknowledge that this is a change in our understanding of the Certification Act. Executive Order 14219 directs Federal agencies to review existing regulations for potential candidates for rescission, prioritizing those that can no longer be justified under several recent decisions of the U.S. Supreme Court, including *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). In *Loper Bright*, the Court explained that statutes have a "single, best meaning" that agencies must follow. Because we believe this is the best reading of the statute, it is consistent with the rationale of *Loper Bright* to adopt it. Additionally, OPOs were able to operate even with new entrants before 2000, and we have confidence they will be able to do so in the future. We have not previously cited independent policy reasons that would justify exercising our express authority to promulgate performance standards to include a requirement that OPOs have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005. By contrast, we believe that removing this requirement would address concerns about market consolidation by creating a more diverse and robust market that enhances competition among OPOs. This proposal could also introduce innovation from new entities and increase the number of organs available for transplant.

Therefore, to align with our reinterpretation of the Certification Act and the directive in Executive Order 14219 to remove regulatory requirements that can no longer be justified in light of *Loper Bright*, we are proposing to remove § 486.303(e). We acknowledge that our prior rule removed references to newly certified OPOs and we are not, at this time, proposing to reinstate those references or to otherwise provide for the certification of new OPOs. However, we anticipate addressing the certification of new OPOs in the near term and are soliciting public comments on factors CMS should consider when certifying new OPOs. We specifically request public comments related to:

- The specific elements of the existing OPO regulations that an entity should be required to meet in order to become a newly certified OPO;
- The outcome and process performance measures organizations seeking certification

should meet. What empirical evidence of organ donor potential and other related factors should be considered?

- Other criteria for evaluating the suitability of a potential new OPO to serve an open DSA;

- The process by which a newly certified OPO might obtain designation to a DSA.

++ Should newly certified OPOs be given priority for designation to open DSAs, compete against existing OPOs in open competition, or only compete in competitions against other newly certified OPOs?

++ If newly certified OPOs compete against currently certified OPOs, should the competition selection criteria be revised? If so, what factors should be considered for selection criteria given the lack of historical outcome and process performance data for new OPOs?

We would particularly appreciate comments that identify which specific provisions commenters would recommend we consider changing, and what specific changes commenters would recommend.

C. Designation of one OPO for Each Service Area (§ 486.308)

We propose to revise requirements at § 486.308 to further address changes made in the December 2020 final rule related to when a DSA is open for competition. Additionally, we intend to clarify how an OPO is assigned to a DSA and how we determine the OPO designation period. As described in section II.A. of this proposed rule, a DSA is a donation service area, and each OPO is currently designated to a DSA for organ procurement activities.

There are OPO-specific qualifications, processes, and timeframes found in the requirements at section 371(b) of the PHS Act and section 1138 of the Act. Section 371(b) of the PHS Act and § 486.303 list the requirements that an OPO must meet to be certified. Once certified, section 371(b)(1)(D)(ii)(I) of the PHS Act requires that OPOs must be re-certified not more frequently than once every 4 years. The re-certification cycle, defined at § 486.302, is the 4-year cycle during which an OPO is certified.

Only a certified OPO may be designated to a DSA. Once an OPO is designated for a DSA, certain organ procurement costs are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act. OPOs sign an agreement with CMS called a Health Insurance Benefits Agreement, Form CMS-576A, to provide services for the duration of an "agreement cycle", defined at § 486.302 as "the time period of at least 4 years when an agreement is in effect between CMS and an OPO". OPOs must periodically submit a Request for Designation as an OPO under section 1138 of the Act, Form CMS-576, and supporting documentation for a specific DSA. This is normally conducted during the re-certification process.

CMS evaluates OPOs periodically to ensure that the organizations continue to meet the requirements for certification. As referenced previously, under section 371(b)(1)(D)(ii)(I) of the PHS Act, re-certifications of qualified OPOs must not be more frequent than once every 4 years. In most cases, near the end of the agreement cycle there is a re-certification survey to ensure that the OPO continues to comply with statutory and regulatory requirements for certification. Surveys may also be conducted at other times to investigate complaints and allegations of non-compliance with the CfCs. Surveys are conducted by CMS staff from the various CMS locations and Federal contract surveyors. Currently, the agreement cycle for the designation period is 4 years and 6 months in duration and is reflected on the Form CMS-576A (CMS-R-13; OMB No. 0938-0512) that the OPO signs. The additional 6 months between the end of the re-certification cycle and the end of the agreement cycle provides time for an OPO to appeal a de-certification determination to the agency on substantive or procedural grounds and to enable the agency to select a successor OPO if necessary. The current re-certification cycle began on August 1, 2022, and will end on July 31, 2026. However, the current OPO agreement cycle began on August 1, 2022, and is scheduled to end on January 31, 2027.

To implement changes for OPO DSA designation and competition, we propose to revise § 486.308(a) and (b). Currently, § 486.308(a) states that, "CMS designates only one OPO per service area. A service area is open for competition when the OPO for the service area is

de-certified and all administrative appeals under § 486.314 are exhausted." We propose to relocate and revise the information pertaining to designation and relocate requirements for competition. Specifically, we propose to add introductory text (referred to as condition statement of the CfC) at § 486.308 to clarify that CMS designates only one OPO to a DSA. We will not designate multiple OPOs for one DSA, consistent with section 1138(b)(2) of the Act, but we may designate a single OPO for more than one DSA as discussed in sections III.D. of this proposed rule. We also propose to relocate the requirement that re-certification must occur not more frequently than once every 4 years from § 486.308(b)(2) to the introductory text at § 486.308 without change as part of the reorganization of these requirements.

We propose to revise the current requirements at § 486.308(b)(1) to address designation periods and relocate the requirements to proposed § 486.308(a). The current requirements indicate that "[a]n OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to replace an OPO that has been de-certified." We propose to redesignate and revise the requirements related to the length of designation periods from § 486.308(b)(1) to proposed § 486.308(a) to clarify that the planned duration of the designation period is at least 4 years for renewal of an OPO agreement.

We propose, at revised § 486.308(a)(1), to retain the flexibility to shorten or extend the agreement cycle in certain limited circumstances. However, we are proposing to clarify this provision by identifying involuntary termination, in addition to voluntary termination of an OPO's contract with CMS as the two circumstances under which an OPO's designation period may be shortened. A voluntary termination occurs when an OPO requests to voluntarily terminate its agreement with CMS. An involuntary termination that would shorten a designation period occurs when an OPO is de-certified due to non-compliance with CMS requirements, as

specified at proposed § 486.312(a)(1) or (a)(4). In the event of non-compliance with the process performance measures (§§ 486.320 through 486.360), an OPO would normally be afforded the opportunity to submit a plan of correction to remedy non-compliance within a specific period of time. If the plan of correction is acceptable, involuntary termination would be averted provided the plan was successfully implemented by the OPO resulting in correction of noncompliance and verified by CMS. (See 42 CFR 488, subpart A). We propose at new § 486.308(a)(1) that CMS may adjust the length of a designation period when (i) there is a voluntary termination of an OPO's agreement with CMS, (ii) there is an involuntary termination of an OPO's agreement with CMS, (iii) additional time is needed to complete an appeal, conduct a competition, select a successor OPO, or transition the DSA to a successor OPO, or (iv) there is an extension of the agreement cycle for extraordinary circumstances as specified at § 486.316(f). At paragraph (a)(2) we propose that CMS would conduct a competition for all vacated DSAs.

We also propose at new § 486.308(a)(3) that the designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at § 486.316(e), will be the remaining portion of the agreement for the OPO's current re-certification cycle. For instance, if an OPO is designated to a new DSA following a competition in 2027, it would be designated for the remainder of the original OPO's re-certification cycle that would be anticipated to end in 2030. The successor OPO would fulfill the remaining portion of this re-certification cycle. We propose at § 486.308(a)(4) that if an OPO does not fulfill the term of its agreement, whether voluntarily or involuntarily, and there is insufficient time to conduct a competition to select a successor OPO for its DSA, we may designate another OPO, without a competition. We would exercise this option only if there were concern for continuity of organ donation in the DSA in situations such as a termination for urgent need, a cessation of business, or because the incumbent OPO was unable to sustain services to provide an orderly transition to a successor OPO. In selecting an OPO under these circumstances, we would consider the following factors: contiguity to the DSA, performance on outcome measures at § 486.318,

history of compliance with the process performance measures at §§ 486.320 through 486.360, and willingness of the OPO to perform the responsibilities.. We solicit public comment on these factors, how these factors should be weighed in making a decision, and whether other factors should be considered in this situation.

The December 2020 final rule was limited in scope and focused on revisions to the outcome measures at § 486.318, leaving certain operational aspects to be revised through additional rulemaking. Given the tiered system for re-certification that was implemented in that rule, we are now clarifying when a DSA is open for competition and how competition affects designation. Currently, § 486.308(a) states that a service area is open for competition when the OPO for the DSA is de-certified and all administrative appeals at § 486.314 are exhausted. We propose to relocate this language to § 486.308(b) and amend it to conform with requirements for competition at § 486.316 and outcome measures at § 486.318.

We propose to address all instances when a DSA is open for competition.

- We propose to amend § 486.308(b)(1) to reflect that a DSA becomes open for competition when an OPO's DSA is assigned tier 3 status in the final assessment period and all administrative appeals are exhausted. An OPO's DSA is assigned tier 3 status if it has outcome measures currently described at § 486.318(e)(6) (tier 3), redesignated as proposed § 486.318(b)(6), and § 486.316(a)(3).

- We also propose conforming changes at § 486.308(b)(2) to clarify that an OPO's DSA is open for competition when the DSA is assigned to tier 2 for the outcome measures in the final assessment period, as currently described at § 486.318(e)(5), proposed to be redesignated to § 486.318(b)(5), and § 486.316(a)(2).

- We propose to add § 486.308(b)(3), stating that an OPO's DSAs are open for competition when the OPO is not in compliance with the process performance measures at §§ 486.320 through 486.360, as specified at § 486.312(a)(1) and § 486.316(b)(1), all administrative appeals are exhausted, and the OPO is pending de-certification.

- Finally, we propose at new § 486.308(b)(4) that a DSA would be open for competition when an OPO requests to voluntarily terminate its agreement to participate as specified in § 486.312(a), redesignated as proposed § 486.311(a)(2). However, this provision would not apply to a voluntary termination associated with an OPO's change in control or ownership or service area as specified at § 486.310, in which case the OPO is voluntarily terminating its agreement to participate in a merger with another OPO.

We solicit public comment on these proposed changes and ways to provide clarity to the designation and competition process.

D. Designation of an OPO to More Than One Service Area (§ 486.309)

We propose to remove obsolete requirements at § 486.309 and add new requirements to address situations if an OPO is responsible for more than one DSA. The current requirements at § 486.309 addressed the re-certification from August 1, 2006, through July 31, 2010 indicating that an OPO would be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Since this time period has passed, these requirements are now obsolete.

Since the December 2020 final rule was issued, some OPOs have requested guidance on how an OPO could manage more than one DSA. Section 1138(b)(2) of the Act provides that the Secretary may not designate more than one OPO for each service area and the current OPO CfCs only address one OPO being designated to only one DSA. Given that OPOs have expressed interest in this area and the statute does not explicitly restrict this situation, we are proposing requirements to address one OPO being designated to more than one DSA. Currently, there is a limited market in regard to the number of OPOs and DSAs, with 55 OPOs in total, each serving a single DSA (55 in total). Therefore, permitting an OPO to separately maintain multiple DSAs could maintain some level of market diversity to support future competition. This proposal would also mitigate risk of geographic consolidation when OPOs maintain separate DSAs rather

than merging DSAs into one service area. Finally, some OPOs have expressed concern for assuming responsibility for DSAs where other OPOs have historically underperformed and merging those areas with their existing DSA. These OPOs have indicated they would prefer to manage DSAs separately to ensure they could improve performance without risk to their existing DSA.

We are proposing that an OPO may be responsible for more than one DSA when a new DSA is added following a change in control, ownership, or service area as specified at § 486.310, as result of a competition as specified at § 486.316, or following a voluntary or involuntary termination of an OPO's agreement as specified at § 486.311(a)(2) or § 486.312(a) respectively, or there is insufficient time to conduct a competition as specified at proposed § 486.308(a)(4). In these instances described previously, the OPO would need to determine how best to manage its organization for the respective areas. .Some OPOs may find it beneficial to merge all assigned DSAs into a single DSA; however, other OPOs may not want to merge a new DSA into an existing DSA and may find it beneficial to maintain a separate designation for each DSA. We propose to revise § 486.309 to give OPOs more flexibility to address this situation. We are considering alternative policies on how an OPO could manage more than one DSA, which are discussed in detail in section VII.C. of this proposed rule.

Section 1138(b)(1)(C) of the Act permits the Secretary to provide payment with respect to organ procurement costs attributed to an organ procurement agency only if the agency meets performance-related standards prescribed by the Secretary. Additionally, section 371(b) of the PHS Act requires the Secretary to utilize outcome and process performance measures for the process of certification and re-certification of OPOs based on empirical evidence of organ donor potential and other related factors in each service area of qualified OPOs. Since OPOs have historically only been designated to one DSA, these requirements have not yet been applied to an OPO that is designated to more than one DSA. We propose to clarify application of both the outcome and process performance measures when an OPO may be designated to multiple DSAs.

Our existing regulations require that OPOs must meet the minimum standards for both outcome measures at § 486.318 and the process performance measures at §§ 486.320 through 486.360 (see § 486.303(h)). The process measures are the broad operational requirements for OPOs and include items such as administration and governance, donor management, organ preparation and transport, and QAPI. An OPO found out of compliance with a process performance measure is subject to being de-certified at any time (§ 486.312(b)) but may be able to resolve the non-compliance within prescribed timeframes (see generally § 488.28 and State Operations Manual (SOM), CMS Pub. 100-07, Chapter 2, Section 2728).[58]

OPOs must meet outcome measures for re-certification and payment purposes. To meet the outcome measures, an OPO is evaluated by measuring the donation rate and the transplantation rate in their DSA. In general, the outcome measures are assessed annually based on calendar year data and the final assessment period is used for re-certification (§ 486.302 (definition of "Assessment Period")).

We are proposing that when an OPO consolidates multiple DSAs, regardless of contiguity, into a single DSA we would assess the OPO's performance on the outcome measures as a single DSA. The outcome measures for that merged DSA, however, would be used for any future assessment periods, including the final assessment, and potential disparate performance between the former two separate DSAs would not be reflected in the outcome measure data for the consolidated DSA. At the final assessment period, if the OPO could not satisfy the outcome measures for the merged DSA, the OPO would be de-certified (subject to the available appeal rights).

An OPO with one DSA faces de-certification if it is non-compliant with any of the CfCs, including the process performance measures (§§ 486.320 through 486.360) or the outcome measures (§ 486.318) at the time of re-certification. However, our proposed approach would permit an OPO that obtains a new additional DSA to choose to maintain separate DSAs, rather

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[58] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf.*

than consolidating its new DSA with its existing DSA. While the OPO would still be required to meet the process performance measures in the conditions for coverage for all of its DSAs to avoid de-certification, we propose that we would consider the OPO's performance on the outcome measures separately for each DSA when the OPO chooses to maintain separate DSAs. This would enable the OPO to meet the outcome measures in one DSA, even if the OPO did not satisfy the outcome measures in a separate DSA at the time of re-certification. If at the time of re-certification an OPO met the outcome measures at § 486.318 for one of its DSAs (tier 1 as specified at § 486.318(e)(4), proposed to be redesignated as § 486.318(b)(4) or tier 2 as specified at § 486.318(e)(5), proposed to be redesignated as § 486.318(b)(5)) and did not meet the outcome measures for another of its DSAs (tier 3 as specified at § 486.318(e)(6), proposed to be redesignated as § 486.318(b)(6)), CMS would remove designation for the DSA in which the OPO has tier 3 performance, and the DSA would be opened for competition. The OPO would be able to appeal the decision to remove the designation prior to the competition due to its failure to meet the outcome measures in that DSA. In this instance, the OPO would not be given a notice of de-certification as specified in proposed § 486.312(b) and would instead receive a notice of removal of designation to a DSA without de-certification (proposed § 486.314(a)(2)). If all of an OPO's DSAs have tier 3 performance, the OPO fails to meet the performance standards to be a qualified OPO and would be sent a notice of an initial de-certification determination as specified at proposed §§ 486.312(b), 486.314(a)(1), and 486.316(b)(2)(iii)(A). The OPO would have the opportunity to appeal the de-certification determination. If the CMS determination is upheld on appeal, the OPO would be de-certified and all of its DSAs opened for competition. De-certification is discussed in detail in section III.E. and appeals are discussed in section III.F. of this proposed rule.

To give OPOs this additional flexibility to maintain separate DSAs, we propose to add a new requirement for OPO designation of more than one DSA at § 486.309 to replace the current requirements. First, we propose a new section heading at § 486.309 for OPO designation to

more than one service area. Second, at § 486.309(a), we propose three circumstances for which an OPO may be designated to more than one DSA. Such circumstances include a change in control, ownership or service area as specified at § 486.310 (proposed paragraph (a)(1)); following a competition as specified at § 486.316 (proposed paragraph (a)(2)); or following a voluntary or involuntary termination of an OPO's agreement with CMS, when a new OPO was assigned to the DSA and there was insufficient time to conduct a competition as specified at § 486.308(a)(4) (proposed paragraph (a)(3)). Third, we propose at § 486.309(b), that when requirements of paragraphs (a)(1) or (a)(2) of proposed § 486.309 are met after a change in ownership, control or service area or competition, the OPO may choose to consolidate the DSAs, maintain separate DSAs, or a combination thereof if more than two DSAs are involved. If we were to assign an OPO to a DSA after a voluntary or involuntary termination, as proposed at § 486.309(a)(3), we would not permit the DSA to be consolidated to facilitate future competition for that DSA and would open that DSA for competition at the end of the designation period. Designation of an OPO to a DSA in this situation would be a temporary measure intended to maintain organ procurement services to provide time to facilitate an orderly transition of the DSA to a successor OPO following a competition.

We propose, at § 486.309(c), that when an OPO is designated to more than one DSA, CMS would remove designation to a tier 3 DSA in the event of non-compliance with the outcome measures for that DSA at the end of the re-certification cycle (that is, donation or organ transplantation rates are below the median threshold rates established), as specified at proposed § 486.316(a)(3) and § 486.318(e)(6), proposed to be redesignated as § 486.318(b)(6). At paragraph (c)(1), we propose that removal of designation will not result in de-certification until an OPO is no longer designated to any DSA due to tier 3 outcome measure performance in all of its DSAs, as specified at § 486.316(b)(2)(iii)(A). We also propose at paragraph (c)(2) that an OPO may appeal the decision to remove its designation to a tier 3 DSA as specified at § 486.314 and that the DSA will be opened to competition after all appeals are exhausted for that DSA. We

request public comment on these proposed changes in § 486.309, including additional factors that OPOs may want to consider related to consolidating DSAs versus keeping them separate as well as alternative policy approaches to address a single OPO being designated to more than one DSA.

We note that the OPO Life Alliance Organ Recovery Agency (LAORA)'s DSA was opened for competition with the application deadline closing on December 8, 2025, as a result of the OPO's pending de-certification. In the competition announcement, CMS indicated that the successor OPO to this DSA would be required to maintain the DSA separately from their existing DSA. We note this agency decision was based on both the long history of underperformance in this DSA and CMS' desire to carefully monitor the changes after the successor OPO assumes responsibility for the DSA. This has prompted the consideration of alternative policies regarding the process for when an OPO manages more than one DSA, which are discussed in detail in section VII.C. of this proposed rule.

We seek to provide sufficient flexibility to OPOs so that they can determine how to best tailor their operations for maximum benefit to improve organ procurement within existing statutory and regulatory requirements. As previously stated, some OPOs may determine it to be beneficial to consolidate DSAs while others may determine that maintaining separate DSAs is advantageous. We believe the factors considered in this decision can be wide ranging and include items such as contiguity of DSAs, existing size of DSAs, geographic characteristics, population factors, DSA healthcare infrastructure and networks, leadership preferences, and financial considerations, among others. We seek public comment on the factors OPOs believe to be most important in making decisions related to DSA management and the benefits of DSA consolidation versus DSAs being managed separately. Additionally, we seek public comment on alternatives being considered as discussed in Section VII.C. of this proposed rule.

E. Non-renewal of Agreement (§ 486.311) and De-certification (§ 486.312)

To address the implementation of the tier system for re-certification of OPOs, we propose to establish a new CfC at § 486.311 for non-renewal of an OPO agreement. Additionally, we propose to revise § 486.312 to address enforcement actions that may result in de-certification of an OPO.

In the December 2020 final rule, we finalized a new tier designation process for re-certification of OPOs. OPOs are designated to DSAs that are assigned as either tier 1, tier 2, or tier 3 based upon their performance on the outcome measures set forth in § 486.318 and their re-certification survey. This tiered system for re-certification and competition became effective on March 30, 2021, and is currently being implemented during the 2022 through 2026 re-certification cycle that began on August 1, 2022, and is scheduled to end on July 31, 2026. OPOs with DSAs that are in tier 3 during the final assessment period in the re-certification cycle will be decertified, pending appeals. OPOs with DSAs that are in tier 2 during the final assessment period in the re-certification cycle will be required to compete to retain their DSA, but they may also compete for any other DSA that is open for competition. An important distinction between tier 3 DSAs and tier 2 DSAs is that only tier 3 DSAs reflect that the OPO is out of compliance with the outcome measures for that DSA. Therefore, an OPO with all of its DSAs in tier 3 may be de-certified. Alternatively, an OPO with a tier 2 DSA is in compliance with the outcome measures for that DSA, and provided it is also in compliance the process performance measures, is re-certified as meeting the performance standards to be a qualified OPO and will have its agreement renewed provided it is successful in a competition for that or another open DSA.

The competition process means there is a possibility that an OPO with a tier 2 DSA would not be successful in the competition to retain its DSA. If the OPO is not designated for its DSA (and it did not win a competition for any other open DSA), the OPO would no longer be designated as an OPO at the end of the current agreement.

The current requirements for non-renewal of an agreement are located at § 486.312(c) and state that "CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement." This requirement does not address the differences between tier 2 and tier 3, which is that an OPO with one or more tier 2 DSAs, while in compliance with the outcome measures in those DSAs, is not de-certified but will not be offered a new agreement if it does not retain any of its DSAs or successfully compete for an open DSA; whereas OPOs with tier 3 DSAs are out of compliance with the outcome measures in those DSAs, potentially resulting in de-certification. To address this issue, we propose a new CfC at § 486.311, non-renewal of agreement.

We propose, at § 486.311(a)(1), to address non-renewal for OPOs with tier 2 DSAs that are unsuccessful in competition. We propose that CMS will not renew an agreement with an OPO if the OPO is subject to a competition (as set forth at § 486.316(a)(2)), the OPO is unsuccessful in the competition, and the OPO is no longer designated to any DSA. The OPO would not be afforded appeal rights for loss of a competition, consistent with our long-standing policy, as described in the 2006 final rule. (see 71 FR 30998). In the 2006 final rule, we stated, "The statute requires only that we provide the opportunity to appeal a de- certification. An appeals process following a competition would be both expensive and unwieldly. We believe it would increase uncertainty for the OPO that prevailed in the competition and that this may disrupt the new OPO's ability to increase organ donation in the service area". We also stated that "our competition decision is final" (71 FR 30998). This position is based on our intent to be able to choose the OPO most likely to increase organ donation and best serve the interests of all impacted by the actions and outcomes of the OPO. OPOs do not have an intrinsic right to be awarded a DSA following a competition and CMS may select the OPO most appropriate for that DSA.

In our proposed approach, an OPO with tier 2 DSAs that fails to retain any of its DSAs in competition would not be de-certified and could secure another agreement if it were successful in a concurrent or subsequent competition for another DSA, assigned a DSA by CMS (see § 486.316(e)), or selected for an open DSA under proposed § 486.308(a)(4). Since the OPO is compliant with the CfCs, it would be re-certified without being designated to a DSA. This would permit the OPO to compete in any additional open competitions during the following 4-year re-certification period. If the OPO is successful in a competition, assigned a DSA by CMS under § 486.316(e), or selected for an open DSA under § 486.308(a)(4), it could then be designated to a DSA during this period. If the OPO does not obtain a new DSA through competition, assignment under § 486.316(e), or selection under proposed § 486.308(a)(4) by the end of the re-certification cycle following the non-renewal of the OPO's agreement, it would not meet outcome measure standards for that cycle. Consequentially, the OPO would be de-certified at that time in accordance with the requirements at proposed § 486.312(a)(3). The OPO would be afforded appeal rights for the de-certification in accordance with the requirements at § 486.314. For instance, during the anticipated 2026 re-certification cycle, an OPO with a single tier 2 DSA that did not win any competition would be re-certified for the duration of the next recertification cycle that would extend to 2030. However, the OPO would not be designated to a DSA unless it was successful in subsequent competition or assigned a new DSA by CMS prior to the end of the re-certification cycle in 2030. Therefore, if the OPO was not designated to any DSA at the end of the re-certification cycle in 2030, it would be de-certified at that time.

We propose at § 486.311(b) that we would provide notification to the OPO at least 90 days before the effective date of the non-renewal and that the notice would state the reasons for non-renewal and include the end date of the agreement.

We also propose, at § 486.311(a)(2), that non-renewal of an agreement (currently at § 486.312(c)) would include a voluntary termination of an agreement by an OPO. The current requirement for voluntary termination of an agreement is located at § 486.312(a). If an OPO

wishes to terminate its agreement with CMS, it must send written notice of its intention to terminate and the proposed effective date. Currently, we may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if we determine that a different date would not disrupt services to the service area. Additionally, if we determine that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO. The current rule states that we will de-certify the OPO as of the effective date of the voluntary termination. We propose to relocate and revise the voluntary termination of agreement provision from § 486.312(a) to § 486.311(a)(2) and remove the requirement that we would de-certify the OPO. An OPO voluntarily withdrawing from its agreement or ceasing to furnish organ procurement services has taken an affirmative step to end its duties under the OPO agreement, but that action does not entitle the OPO to appeal a de-certification on substantive or procedural grounds. As such, the voluntarily withdrawing OPO would not be afforded appeal rights. The OPO would no longer have an agreement, and would no longer be designated to any DSAs, as of the effective date determined by CMS. We note that in Section III.C. of this proposed rule, we provide an alternative considered related to voluntary withdrawal. In this section, we consider an alternative approach of permitting an OPO with more than one DSA to withdraw from a specific DSA without effectively ending its agreement with CMS. We seek public comment on this alternative approach as well as the benefits and risks of establishing such a policy.

We also propose a public notice requirement at § 486.311(c) consistent with the current public notice requirements at § 486.312(e) to inform the public of the change. We would provide public notice in the service area of the date that a new OPO will be designated for the DSA. We also propose new § 486.311(d) to provide that no payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to an OPO that no longer has an agreement with CMS.

We propose to reorganize and revise the requirements at § 486.312 to clarify the actions we may take related to de-certification of an OPO. The current requirements pertain to (a) voluntary termination of agreement, (b) involuntary termination of agreement, (c) non-renewal of agreement, (d) notice to OPO, and (e) public notice. As mentioned earlier in this proposed rule, requirements for non-renewal of agreement (currently § 486.312(c)) and voluntary termination (currently § 486.312(a)) would be relocated to proposed § 486.311(a).

We propose to relocate and revise the requirements for involuntary termination of agreement at § 486.312(b) to proposed § 486.312(a). Involuntary termination would result in de-certification of the OPO. Specifically, we propose at paragraph (a)(1) that we may involuntarily terminate an OPO during the re-certification cycle if the OPO no longer meets the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, as specified at proposed § 486.316(b)(1). The conditions for coverage at §§ 486.320 through 486.360 are generally referred to as process performance measures. Non-compliance means the OPO has one or more condition-level deficiencies that it is unable to resolve within a specified timeframe. We propose at paragraph (a)(2) that we may involuntarily terminate an OPO if the OPO is only designated to tier 3 DSAs in the final assessment period, as described at proposed § 486.316(b)(2)(iii)(A), at the end of the agreement. At paragraph (a)(3) we propose that we would de-certify an OPO if it is no longer designated to any DSA and does not have data available from the final assessment period to demonstrate compliance with the outcome measures at the end of the re-certification cycle. This would address the potential outcome of a tier 2 OPO that was re-certified but did not have an agreement renewed because it did not win a competition as specified at proposed § 486.311(a)(1) and was not otherwise assigned a DSA by CMS. Finally, we propose to relocate and revise the requirements for immediate termination in cases of urgent need, such as the discovery of unsound medical practices, currently located at § 486.312(b) to proposed new paragraph at § 486.312(a)(4). We also propose to revise and relocate the requirements regarding notice of de-certification to the OPO by redesignating and

revising § 486.312(d) as paragraph § 486.312(b). We propose that except in cases of urgent need, the initial notice of de-certification would be provided to the OPO at least 90 calendar days before the effective date of the de-certification. In cases of urgent need, the notice would be provided at least 3 calendar days prior to the effective date of the de-certification. The notice would state the reasons for de-certification, explain the available appeal rights, and include the effective date of the de-certification.

We also propose to revise and redesignate the requirements pertaining to public notice of de-certification currently at § 486.312(e) to § 486.312(c). The current requirements indicate that "[o]nce CMS approves the date for a voluntary termination, the OPO must provide prompt public notice in the service area of the date of de-certification and such other information as CMS may require. In the case of involuntary termination or nonrenewal of an agreement, CMS also provides notice to the public in the service area of the date of de-certification. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification." We are proposing to remove the requirement that the OPO provide public notice in these situations. We have proposed to revise this requirement to indicate that CMS will provide public notice in the service area of the date of de-certification and the date that a new OPO will be designated for the DSA.

We believe that this proposed reorganization will provide greater clarity into the actions that may occur as a result of the tiered system and competition under the outcome measures. Grouping items based on potential outcomes and impact to the OPO agreement and certification status better aligns with the program requirements, including any appeals process that may follow an adverse action. We solicit public comment on these proposed changes and additional factors to consider or changes to assist in refining the requirements of this section.

F. Appeals (§ 486.314)

The Organ Procurement Organization Certification Act of 2000[59] required the Secretary to issue regulations that allow an OPO to appeal a de-certification on substantive and procedural grounds. To fulfill this statutory requirement, § 486.314 Appeals, was finalized in the 2006 OPO final rule (71 FR 30982). The introductory text at § 486.314 states that "[i]f an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds." In the December 2020 final rule (85 FR 77898), we finalized new outcome measures and made some changes to the re-certification and competition processes. As a result of significant changes made since the 2006 final rule, we reviewed the OPO appeals process to consider what, if any, changes should be proposed. Based upon that review, we are proposing the following changes to § 486.314 as described below.

We propose to revise the introductory text at § 486.314 to allow an OPO to appeal a de-certification as described at § 486.312(a) or the removal of a designation to a tier 3 DSA without de-certification as described at § 486.316(b)(2)(iii)(B). As a result of the competition process as set forth at revised § 486.316, some OPOs might eventually be designated for more than one DSA. Thus, an OPO may not be de-certified because at least one of their DSAs is assigned to tier 1 or tier 2 in the final assessment period of the re-certification cycle. However, if one of the OPO's DSAs is assigned to tier 3 in the final assessment period, the OPO could lose its designation for that DSA. Although the removal of a designation for a DSA is not a de-certification if the OPO retains at least one DSA that is not assigned to tier 3, the OPO has been found to be non-compliant with the outcome measures in the tier 3 DSA. Thus, we believe that an OPO should also have appeal rights for the removal of designation to a DSA without de-certification. Consequently, we propose to add references to the removal of designation for a

[59] Section 701(c)(3) of the Organ Procurement Organization Certification Act of 2000. 114 STAT. 2346, Pub. L 106-305. Published November 13, 2000.

DSA assigned as tier 3 without de-certification alongside references to de-certification in § 486.314, as applicable, to reflect that an appeal would be available in either scenario. We propose to revise paragraph (a) for the notice of initial determination and add new paragraphs (a)(1) and (a)(2) to address de-certification and removal of a DSA without de-certification respectively.

We propose to modify the time periods in this section for existing requirements from "business days" to "calendar days". We also propose to use "calendar days" for all proposed requirements. CMS will compute time periods based on "calendar days" according to the process described in Federal Rules of Civil Procedure (FRCP), Rule 6(a)(1).[60] This is for both consistency and to avoid confusion in the appeals process.

Currently, the OPO has 15 business days from receipt of the notice to request reconsideration from CMS. If the OPO does not request a reconsideration within those 15 business days, the OPO has no right to further administrative review. We propose to change this to 20 calendar days as set forth in proposed § 486.314(b)(1). CMS currently has 10 business days from receipt of the reconsideration request to make a written reconsidered determination that would affirm, reverse, or modify the initial de-certification determination. We propose to modify this to 15 calendar days to make a written reconsidered determination that would affirm or reverse the initial de-certification determination, as set forth in proposed § 486.314(b)(3). We are also proposing that CMS has the right to extend this time based on a determination that additional time is necessary to thoroughly review, make a decision and the extension does not prejudice either party. We also propose to remove the option for the reconsideration official to "modify" the initial de-certification determination. We do not believe it is appropriate for the reconsideration official to modify the determination. Not only does he or she usually only have

[60] FRCP, Rule 6(a)(1) (providing that when a time period is stated in days or a longer unit of time, "(A) exclude the day of the event that triggers the period; (B) count every day, including intermediate Saturdays, Sundays, and legal holidays; and (C) include the last day of the period, but if the last day is a Saturday, Sunday, or legal holiday, the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday.").

15 calendar days to review the initial de-certification determination, but also we believe there will be insufficient time and information for the official to develop a modification to that determination.

Currently, if the de-certification decision is upheld, the OPO then has 40 business days from receipt of CMS' reconsideration decision to request a hearing before a CMS hearing officer. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review. The hearing officer must set a date for the hearing that is no more than 60 calendar days after receiving that request for a hearing and must render his or her decision within 20 business days of the hearing.

We propose at § 486.314(c) to reduce the number of days within which an OPO must request a hearing before a CMS hearing officer from 40 business days to 15 calendar days. We did not previously explain the 40-business day timeline beyond stating that the appeals process generally "will protect a de-certified OPO's rights, provide it with sufficient time to pursue its appeal, and ensure that it receives a fair hearing".[61] However, a full 40 business days could contribute to disruptions in organ procurement activities in the DSA and unduly extend the appeals process. This proposed change is limited to the request for a hearing before a CMS hearing officer. The shorter timeline to request a hearing would continue to sufficiently protect an OPO's rights, including time to pursue an appeal and receive a fair hearing. The only decision the OPO needs to make before filing its request for a hearing is whether it wants to challenge the de-certification or the removal of a designation to a DSA without de-certification. However, we also believe that in making the decision to appeal, the OPO would have also begun gathering relevant documents and other evidence, as well as formulating the arguments it would need for the hearing. If the OPO requests a hearing, the hearing officer must set a hearing date that is not more than 60 calendar days following the receipt of the request for a hearing (§ 486.314(f)). The OPO and CMS would have additional time from the date the hearing is

[61] 71 FR 30994.

requested until the hearing date to more fully prepare their legal arguments and factual support for the hearing. Both the OPO and CMS could submit briefs, have witnesses testify, and submit additional evidence during the hearing as currently allowed under § 486.314(g). During the conduct of the hearing, the hearing officer would inquire fully into all relevant and material document and witness testimonies (§ 486.314(g)). Requiring OPOs to file a request for a hearing before a CMS hearing officer within 15 calendar days of receiving the notice of the reconsideration determination balances the OPO's interest in providing ample time to file an appeal with the interests of patients' access to organ transplants by shortening the time required for the appeals process. During the appeals process, some resources will by necessity be devoted to the appeal, which means that not all the OPO's resources will be devoted to organ procurement activities. Hence, an efficient appeals process is necessary to resolve the appeal and either have the OPO devote all its resources to the procurement activities in the DSA or proceed with identifying and transitioning to a successor OPO.

Also, § 486.314(d) currently states that the hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing. Because the Office of Hearings now uses an electronic case management system in which both parties have access to each other's filings, the reconsideration official does not need to forward their administrative record to the hearing officer unless and until there has been a request for a hearing. We propose to revise § 486.314(d) to state that upon receipt of a request for a hearing, the hearing officer will promptly request the administrative record from the reconsideration official. We also propose that the hearing officer, within 15 calendar days of receipt of the request for a hearing, would send the administrative record to both parties, or make it available through their electronic filing system, rather than the current 10 business days. Now that there is an electronic filing system available, we believe this would be a timely and efficient way to share the administrative record and we want to encourage its use.

Additionally, we propose to revise and redesignate paragraph § 486.314(i) and redesignate paragraphs (j) and (k) to incorporate new paragraphs for requirements to update the appeals process. Specifically, we propose redesignating the current paragraph (i) to paragraph (k) to address the hearing officer's decision and to extend the time for the hearing officer to render their decision to 90 calendar days. Under current § 486.314(i), the CMS hearing officer has 20 business days to render their decision. We are concerned that 20 business days may not be enough for the hearing officer to complete their tasks. In addition to conducting the hearing and rendering a decision, the hearing officer must develop an administrative record of the hearing that is sufficient for any subsequent review. This could include post-hearing activities, such as the hearing officer, at their discretion, permitting the filing of post-hearing briefs on issues raised at the hearing. Thus, we propose to revise and redesignate the current requirements at § 486.314(i) to paragraph (k), extend the time for the hearing officer to issue their decision to 90 calendar days, and provide that the hearing officer has the right to extend that time upon notifying both the OPO and CMS, if the extension does not unduly prejudice either of the parties and is necessary for the hearing officer to issue a legally sufficient decision. We also propose that the hearing officer can affirm or reverse the notice of de-certification or removal of designation to a DSA without de-certification. The hearing officer would then promptly forward his or her decision and the administrative record to the CMS Administrator to decide whether or not to exercise discretionary review of the hearing officer's decision.

We propose a new (i) that will set forth requirements related to scope of review. In the appeals process, we believe OPOs should have the burden to demonstrate that they are entitled to relief. This is not explicitly stated in the current version of § 486.314. Since it is the OPO that is challenging the notice of de-certification or the removal of designation for a DSA without de-certification, we believe the burden of proof on the OPO is implicit. Thus, we propose in new paragraph (i) to clarify that OPOs have the burden of proof by a preponderance of the evidence.

We also propose to revise and redesignate the current paragraph (j) to paragraph (n). This subsection already provides CMS the authority to extend its agreement with an OPO to allow for competition and, if necessary, transition of the service area to a successor OPO. However, we are concerned that the effective date of de-certification or removal of designation for a DSA may be significantly delayed by the appeal process. Hence, we propose adding the appeals process to the reasons an extension of the agreement past the expiration date might be necessary. We are also soliciting comments regarding whether there should be any limitations on CMS' authority to extend the OPO's agreement with CMS. In particular, we are considering what, if any, conditions we should place on the extension, and what, if any, maximum amount of time CMS could extend the agreement.

We also propose establishing an additional provision in the administrative appeals process. The CMS Administrator has the right to review CMS hearing officers' decisions, regardless of whether the hearing officer reversed or affirmed the de-certification or the removal of designation for a tier 3 DSA without de-certification. However, the Administrator's review is not currently addressed in the appeals section. Without requirements addressing the Administrator's review, OPOs and the public would not be aware of the procedures that would be followed after the hearing officer renders their decision. The CMS Administrator's discretionary review is a crucial phase of the appeals process, and we want to provide clarity to ensure that all parties and the public have a clear understanding of the process. The proposed requirements will also clarify when the appeals process is exhausted and, if the OPO is de-certified, when CMS will move forward with competition for the open DSA. Therefore, we propose new § 486.314(*l*) to codify the process for discretionary review by the CMS Administrator of the hearing officer's decision. Specifically, we propose that the CMS Administrator has 30 calendar days from receipt of the hearing officer's decision to elect to review or decline to review the hearing officer's decision. If the CMS Administrator elects to review the hearing officer's decision within the 30-day period, the CMS Administrator will

promptly notify the OPO and CMS of his or her election to review and the parties' right to submit written arguments within 15 calendar days of the notification. If the Administrator does not elect to review the decision within 30 calendar days of its receipt, the hearing officer's decision is final.

We propose that within 45 calendar days of notification of the CMS Administrator electing to review the hearing officer's decision, the CMS Administrator must render a final decision, in writing, to the parties. The CMS Administrator can affirm, reverse, or remand the hearing officer's decision to CMS as discussed below. We are also proposing that the CMS Administrator has the right to extend this time if he or she determines they need more time to thoroughly review and make a decision and the extension does not prejudice either party. We propose that the CMS Administrator's review be limited to the hearing's administrative record developed by the hearing officer and written arguments submitted by the OPO or CMS. The CMS Administrator's administrative record would be composed of all documents submitted to the hearing officer or developed in the course of the hearing, including the hearing officer's decision, as well as written arguments from the OPO or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect, and the CMS Administrator's written decision explaining his or her decision and the reason for that decision.

We propose that our decision whether to de-certify an OPO or remove its designation to a particular DSA would become final if the OPO does not request review by a hearing officer in the time allowed under these regulations, or after the CMS Administrator declines to review the hearing officer's decision, renders a final decision in writing to the parties, or does not render a final decision or a remand in writing to the parties within 45 calendar days of electing to review the hearing officer's decision or by the extended deadline if the Administrator extends the 45-day period. As noted below, a decision would not take effect until (among other things) all administrative appeals are exhausted to avoid any undue prejudice to the OPO.

We also propose to revise and redesignate current (k) to new paragraph (o) at § 486.314 to clarify when the OPO's DSA is opened for competition. Consistent with our current rule, an OPO will not be de-certified or lose its designation to a DSA until all administrative appeals are exhausted. If at the end of the appeals process the notice of de-certification or removal of designation for a DSA without de-certification has not been reversed or remanded, the decision is final. At that time, the OPO's DSA would be competed and a successor OPO would be chosen. CMS would then determine a transition period that is sufficient for the new OPO to take full responsibility for the DSA. After the transition period is determined by CMS, CMS would forward to the de-certified OPO a written communication indicating the effective date of de-certification, at which time Medicare and Medicaid payments may no longer be made for organ procurement costs attributable to the OPO. For an OPO that loses its designation to a tier 3 DSA without being de-certified, CMS would forward a written communication indicating the effective date of the decision, at which time Medicare and Medicaid payments may no longer be made for organ procurement costs attributable to the affected OPO for that particular DSA. We would not begin the competition process before the appeals process is exhausted.

We believe that there might be circumstances in which the CMS Administrator could want CMS to conduct further review or have other instructions for CMS regarding the appeal. For example, the CMS Administrator might want further analysis of data. Hence, we propose that the CMS Administrator may remand the appeal to CMS for any appropriate reason in proposed (m). Remanding the appeal means that the appeal is sent back to CMS for re-evaluation and a new initial determination regarding de-certification or removal of designation for a DSA without de-certification. Also, if the appeal is remanded to CMS, the agency will comply with any instructions in the remand. We are not proposing remand authority for the hearing officer.

We propose a new subsection (p) to address de-certification due to urgent need. We have received feedback that there is some confusion about how the appeals process would proceed for

an OPO de-certified due to urgent need. The appeals process is the same regardless of the reason for the OPO's de-certification. However, if an OPO is de-certified due to urgent need, it may be de-certified immediately (proposed 42 CFR § 486.312(a)(4)). In such circumstances, the affected OPO's service area would be reassigned to one or more other OPOs as set forth at proposed § 486.308(a)(4) by the effective date specified in the notice of de-certification provided under proposed § 486.312(b). Hence, if the de-certified OPO pursues an appeal, it would not be operating its DSA while proceeding through the appeals process.

Notwithstanding the reason for the de-certification, if the initial notice of de-certification is reversed in the appeals process, the OPO will be recertified for the next re-certification cycle. However, its tier status does not change. If the CMS Administrator chooses to modify the hearing officer's decision, CMS will comply with his or her determination.

We are soliciting public comments on these proposed changes to the appeals process. We are especially interested in comments on the proposed time frames for the different stages of the appeals process.

G. Re-certification and Competition (§ 486.316)

In section III.D. of this proposed rule, we discussed the proposal regarding OPO designation to more than one DSA. In that section, we proposed that we would evaluate each DSA separately on the outcome measures at § 486.318. However, we also proposed that an OPO would be evaluated across all DSAs on the process performance measures at §§ 486.320 through 486.360. The current requirements at § 486.316 address OPO re-certification and competition. These requirements do not currently address the potential situation of one OPO being designated to more than one DSA and the impact this may have on the re-certification and competition processes. We propose to make conforming changes to this section to clarify the requirements related to OPO designation, re-certification, and competition to also include situations when an OPO is designated to more than one DSA.

We propose to revise § 486.316(a) to address the impact of the OPO outcome measures at

§ 486.318 on OPO designation at the time of re-certification. We propose that an OPO's performance on the outcome measures and tier assignment in each DSA at the final assessment period of the agreement cycle would determine OPO designation to the DSA. Depending on its performance on the outcome measures, an OPO's performance in each DSA would be assigned to tier 1, tier 2, or tier 3 as specified at § 486.318(e)(4), (5), and (6) respectively, redesignated as proposed § 486.318(b)(4), (5), and (6). We propose, at § 486.316(a)(1), that an OPO with a DSA that is assigned to tier 1, as specified at § 486.318(e)(4), redesignated as proposed § 486.318(b)(4), would retain designation to the DSA for another agreement period. An OPO with a tier 1 DSA would be eligible to compete for any open DSAs, provided that CMS determined it to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 during the most recent survey.

At § 486.316(a)(2), we propose that an OPO with a DSA that was assigned to tier 2, as specified at § 486.318(e)(5), redesignated as proposed § 486.318(b)(5), would have to successfully compete and be awarded a DSA in a competition to retain designation to a DSA for another agreement period. An OPO with tier 2 DSAs would be eligible to compete for any open DSAs provided that CMS determined the OPO to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. We also propose, at § 486.316(a)(3), that an OPO with a DSA that is assigned to tier 3, as specified at § 486.318(e)(6), redesignated as proposed § 486.318(b)(6), would have the designation removed at the end of the agreement period. Additionally, an OPO with all of its DSAs assigned to tier 3 would not be eligible to compete in competitions for any open DSAs.

In paragraph (b) of proposed § 486.316, we propose how performance on the process performance measures (§§ 486.320 through 486.360) and outcome measures (§ 486.318) will impact OPO re-certification and competition.

At proposed § 486.316(b)(1), we address compliance with the process performance

measures. We propose an OPO must maintain compliance with the process performance measures at all times and that non-compliance with the requirements at §§ 486.320 through 486.360 in any DSA would result in the OPO receiving an initial de-certification determination. We propose that the OPO has the right to appeal the de-certification. If the OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's service areas are opened for competition from other OPOs that qualify to compete for open service areas.

At proposed § 486.316(b)(2), we describe the proposed impact of tier assignment during the final assessment period to OPO designation at the time of re-certification. At paragraph (i), we propose that an OPO designated to at least one DSA that is assigned to tier 1 in the final assessment period would be re-certified for another re-certification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. At paragraph (ii), we propose that an OPO that is designated to at least one DSA that is assigned to tier 2 in the final assessment period and is not designated to any DSA assigned to tier 1, will be re-certified for another recertification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. The OPO will be eligible to compete in competitions for any open DSA. However, their agreement will not be renewed if they are not successful in at least one competition in accordance with § 486.311(a)(1). We propose that if the OPO is successful in a competition, it will then be designated to a DSA and receive a new agreement. We also propose that if the OPO is not successful in at least one competition, it will receive a notice of non-renewal as specified in § 486.311(b). Because the OPO is re-certified, it will remain eligible to compete in future competitions, be assigned a DSA under § 486.316(e), or be selected for an open DSA under § 486.308(a)(4) during the next re-certification cycle.

At paragraph (b)(2)(iii), we propose that an OPO that is designated to a DSA that is assigned to tier 3 in the final assessment period will receive one of two notices. At sub-

paragraph (A) the OPO will receive notice of its initial de-certification determination for an OPO that has no other designated DSA that is assigned to tier 1 or tier 2, or no other designated DSA that is pending evaluation of its outcome measures as specified at proposed § 486.318(c)(3) or (4) at the end of the re-certification cycle. At sub-paragraph (B), the OPO will receive a notice of removal of designation to the DSA assigned as tier 3 for an OPO that has another designated DSA assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at proposed § 486.318(c)(3) or (4) at the end of the re-certification cycle..

We are proposing changes at § 486.318(f), proposed to be redesignated as § 486.318(c), to address when we would hold an OPO accountable on the outcome measures when it acquires a new area, such as after a change of control or ownership or service area, a competition, or assignment of a DSA by CMS. We refer readers to section III.H of this proposed rule for additional information on this topic. At paragraph 486.316(b)(2)(iv), we propose that an OPO would have the right to appeal a de-certification or removal of designation to the DSA assigned as tier 3 as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's tier 3 DSA is opened for competition from other OPOs that qualify to compete for open service areas.

We address the competition requirements at proposed § 486.316(b)(3). We propose that DSAs assigned as tier 2 or tier 3 in the final assessment period would be opened for competition. The OPO's tier 2 or tier 3 service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in proposed § 486.316(c). Competition for DSAs assigned to tier 3 will not begin until after any applicable appeal under § 486.314 has been exhausted.

In proposed § 486.316(c), we list existing criteria to compete for an open DSA and proposed to redesignate these as paragraphs (1) and (2). To compete for an open DSA, an OPO would have to be designated to at least one DSA that meets the performance requirements for the

outcome measures for tier 1 at § 486.318(e)(4), or tier 2 at § 486.318(e)(5), redesignated as proposed § 486.318(b)(4) and (b)(5) respectively. The OPO would also have to meet the requirements for certification at § 486.303 and would have to meet the process performance measures at §§ 486.320 through 486.360 during the most recent routine survey. Additionally, the OPO must compete for the entire DSA. At proposed paragraph (2), we propose to amend these criteria to address competition eligibility for any OPO subject to non-renewal of their agreement for failure to be designated to a DSA after competition. We propose that an OPO in this situation would be eligible to compete in additional competitions after its agreement expired and could enter into a new agreement with CMS, provided it had not been de-certified and met the criteria to compete at that time it entered the competition process that resulted in non-renewal. This would enable the OPO to participate in subsequent competitions and enter into a new agreement with CMS if it was successful in a competition. If the OPO did not obtain a new DSA before the end of the next re-certification cycle, it would not be able to demonstrate compliance with the outcome measures at § 486.318 for that re-certification cycle and would de-certified at that time.

We propose to revise text at § 486.316(d) to describe the selection and designation of an OPO following a competition more accurately. The current text states that "CMS will designate an OPO for an open service area based on the following criteria." We propose to revise this to state, "CMS will select an OPO for designation to an open DSA based on the following criteria". We also propose to make a conforming change at § 486.316(d)(2) to include relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360.

Discussion of OPO Criteria for Selection at § 486.316(d)

In the December 2021 RFI (86 FR 68594), we solicited public comments on potential changes to the requirements that transplant programs, OPOs, and ESRD facilities must meet to participate in the Medicare and Medicaid programs. One topic from the December 2021 RFI that received considerable comments and that we are addressing in this proposed rule is the

competition process for OPOs that may occur at the end of the 2022 through 2026 OPO certification cycle. Our goals in developing the tiered re-certification system were to ensure that OPOs are held to a high level of performance expectations and that all OPOs are pushed to perform better to better serve patients awaiting a transplant. In creating the tiered approach, we sought to reward the top performing OPOs (tier 1 DSAs), while giving OPOs with DSAs in tiers 2 and 3 sufficient incentives to improve their performance and achieve ranking in the next level. Additionally, we sought to give OPOs with tier 2 DSAs the opportunity to demonstrate that the OPO could perform better than other OPOs in a particular service area. While we previously expressed this intent in rulemaking, many commenters in the recent RFI expressed concern for how OPOs with tier 2 DSAs would be evaluated in future competitions and requested clarification of the competitive process. These commenters recommended that CMS provide special consideration when evaluating OPOs with tier 2 DSAs. Specifically, they stated that CMS should give particular attention in cases where an OPO with a tier 2 DSA has one of its two outcome measures for that DSA in tier 1. In these instances, commenters recommended that CMS recognize and give significant weight to sustained improvement in the incumbent OPO's existing DSA when evaluating the OPO in a competitive process against an OPO with tier 1 performance in both outcome measures.

We seek to clarify the existing selection criteria for evaluating OPOs in a competition and how this will be utilized in future competitions under the tier system for re-certification; however, we are not proposing any new regulatory changes. Currently, we consider the following four criteria when designating an OPO for an open service area, as stated in § 486.316(d):

- Performance on the outcome measures at § 486.318.
- Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348, proposed to be amended to §§ 486.320 through 486.360.

- Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the DSA that is open for competition. 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.

- Contiguity to the open service area.

In our 2006 final rule (71 FR 30999), we stated that we would evaluate the first three criteria equally and use the fourth criterion, contiguity, as a deciding factor if we determine that two competing OPOs were equally competent to take over an open area. Additionally, in the 2006 final rule where we described the competition requirements (71 FR 30998), we stated, "The competition process is designed to enable CMS to choose the OPO that is most likely to increase organ donation in the service area and thereby serve the best interests of organ donation, potential organ donors and recipients in the service area, and the organ donation and transplantation system in the United States."[62] We believe the existing selection criteria would continue to provide sufficient objective measures in designating the most appropriate OPO to be awarded a DSA in a competition. The criteria also provide a sufficient level of discretion in rating OPOs that would address the concerns raised by commenters in the RFI. For instance, when considering performance on the outcome measures, we may consider the degree to which the top performing OPO's performance on the outcome measures exceeds the performance of other competitors and may judge small differences in performance among competitors to be relatively insignificant (see § 486.316(d)(1). Additionally, continuous improvement in outcome measures over successive years would be considered and we would expect an OPO to address any such improvement in describing how it identified and overcame barriers in its DSA (see § 486.316(d)(4). We would also consider each OPO's relative success in meeting the process performance measures, the conditions for coverage, during the most recent re-certification period

[62] 71 FR 30998.

(see § 486.316(d)(2). By ‘‘relative success,’’ we mean that we will judge whether the OPO satisfied the requirements necessary to meet the process performance measures. Noncompliance deficiencies cited on surveys, including complaint surveys since the last re-certification, are other aspects we would consider when ranking OPOs in competition. Finally, the degree to which an OPO had identified and overcome barriers to donation identified in its own DSA would be considered (see § 486.316(d)(4). This would provide the OPO the opportunity to describe the barriers it has faced and document its performance gains over time.[63] 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 the barriers, and the results. CMS will evaluate the OPOs based on the information and data provided in describing the barriers in its service area, the impact to organ donation, the steps (or plan) the OPO implemented to overcome the barriers, and the results. CMS will also consider the extent to which the OPO identified and addressed the relevance of barriers to donation within its own service area to barriers in the open DSA. This information is important for competing OPOs in demonstrating a record of performance gains and a trajectory of improvement that could enable CMS to make the determination that the OPO is likely to continue improving, is likely to achieve tier 1 status in the near term and should be designated to the DSA. Our goal in the competitive selection process is to ensure that we designate OPOs to DSAs that will continue to accelerate system improvement and better serve patients awaiting transplants.

We received comments on the issue of contiguity in response to the December 2021 RFI. While some commenters highlighted the use of technology to aid in operating non-contiguous DSAs or indicated their opinion that contiguity no longer mattered, other commenters provided information to validate retaining this criterion as a means to selecting an OPO when they were otherwise ranked equally. Some of the rationales included observations about efficiencies related to resource utilization and distribution; agreements and networks with regional partners

[63] 42 CFR 486.316(d).

covering geographic areas that overlap both DSAs; and potentially familiarity with the geographic area, demographics, high volume transplant centers, and local courier relationships. While we believe that OPOs could operate non-contiguous DSAs successfully, we also believe there is benefit to geographic proximity. Consistent with § 486.316(d)(3) and the policy described in the 2006 final rule, we will continue to utilize contiguity in situations when OPOs are ranked equally and will give positive consideration to a competing OPO that is contiguous to the open DSA.

We anticipate this preamble discussion will alleviate the concerns of commenters that may have been under the impression that we would rigidly apply the selection criteria based on tier standing alone. We also believe this information will assist OPOs in determining both a strategy for competition and the information that may be most beneficial when participating in a competition for an open DSA. However, we solicit public comment on alternative factors that we may not have considered regarding the implementation of the tiered approach to re-certification and competition.

Finally, we propose to remove the current text in § 486.316(g) and replace it with a new paragraph (g). Currently, paragraph (g) addresses an exception to the outcome measures for the 2022 re-certification cycle. This period has passed; therefore the current requirements are now obsolete. We propose to revise paragraph (g) to address DSA transition from an incumbent OPO to a successor OPO. This information is currently included in sub regulatory guidance for OPOs (CMS Pub 100-07, State Operations Manual (SOM), Chapter 2, Section 2812).[64] We propose to codify the requirement for OPOs to cooperate during transitions following a competition to facilitate a smooth transition and continuity of organ donation activities in the DSA. We propose at paragraph (1) that an incumbent OPO must cooperate with a successor OPO that is newly designated to facilitate an orderly transition of the DSA and submit a transition plan, as specified by CMS, that provides details on how all aspects of the OPO operation will be transmitted,

[64] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107c02.pdf.*

including timeframes, to a new OPO. At paragraph (2), we propose that the successor OPO must submit a transition plan and periodic reports, as specified by CMS, related to progress on its transition activities until the process is completed. Current sub-regulatory guidance at SOM Section 2812.4 describes elements to be included in the transition plan an applicant submits when applying to compete for an open DSA. The CMS location office will specify the frequency of reporting at the time of the transition. We propose that the successor OPO must provide a final notice to CMS no later than 30 calendar days after completion of the transition and prior to the end of the incumbent OPO's agreement.

H. Outcome Measures (§ 486.318)

The requirements for the previous outcome measures that were superseded by the December 2020 final rule are located at § 486.318(a) through (c). These requirements are no longer in effect and have been superseded by new requirements at § 486.318(d) through (f). We propose to remove the obsolete requirements at paragraphs (a) through (c) and to redesignate paragraphs (d) through (f) as paragraphs (a) through (c). We propose a conforming change at the proposed redesignated paragraph (a)(1) (currently paragraph (d)(1)) by removing the reference to paragraph (d)(2) and replacing it with paragraph (a)(2). We propose a conforming change at the proposed redesignated paragraph (b)(5) (currently paragraph (e)(5)) by removing the reference to paragraph (e)(4) and replacing it with paragraph (b)(4). We propose a conforming change at the proposed redesignated paragraph (b)(7) (currently paragraph (e)(7)) by removing the reference to paragraphs (e)(4), (5), and (6) and replacing it with paragraphs (b)(4), (5), and (6).

The current language of § 486.318(d) – (e) refers to the outcome measures as applied to each OPO. However, this does not account for the possibility of an OPO being designated to more than one DSA where outcome measures would be reported separately for each DSA. We propose to revise § 486.318(d) – (e), redesignated as paragraphs (a) – (b), to replace "OPO" with "DSA" when referencing the outcome measures as applied to each DSA. We also propose a technical correction to the introductory statement that is currently at § 486.318(d)(1), proposed

as redesignated § 486.318(a)(1), that reads, “For all OPOss, except as set forth in paragraph (d)(2) of this section, for all OPOs:”. The proposed text would remove the second “for all OPOs”, revise “OPOs” to “DSAs”, and also revise the reference to paragraph (d)(2) as paragraph (a)(2). We also propose adding introductory text to the proposed redesignated paragraph (c) (currently paragraph (f)) to read as follows: “CMS will evaluate OPO performance on the outcome measures at each assessment period.” We propose to add this provision to the regulations to reinforce the fact that CMS oversight is not a one-time event that occurs at the conclusion of each recertification cycle. Rather, CMS evaluates OPO performance on the outcome measures on an annual schedule as the newest year of data becomes available for that assessment period as part of its oversight duties.

The current requirements at § 486.318(f)(3) state, “If an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available.” This requirement specifically addresses the availability of data for the outcome measures and when we would hold an OPO accountable for its performance in a new area. OPOs may acquire new areas (DSAs) through a change of control, or ownership or service area (§ 486.310); competition (§ 486.316(c)); assignment by CMS if no one competes for the DSA (§ 486.316(e)); or be selected for an open DSA if there is insufficient time to conduct a competition (proposed § 486.308(a)(4)).

However, when an OPO assumes responsibility for a new DSA, there is an inherent delay in the availability of the CMS-calculated outcome measures. This delay impacts the time frame for an OPO to assess the outcome measures, identify areas for improvement, and implement changes to improve performance. Additionally, other information that would assist an OPO in assuming responsibility for a new area will vary depending on the nature of how an OPO

assumes responsibility for a new DSA. We believe these are important factors that should be considered when holding an OPO responsible for its performance in a new DSA.

The primary, publicly available sources of information on a DSA are the OPO Specific Reports (OSRs) published by the SRTR and the CMS outcome measures that are published annually on the CMS QCOR website. However, other types of information an incumbent OPO possesses regarding its operations would likely be proprietary and would not be available in most instances unless OPOs are working collaboratively as part of a merger associated with a change of control or ownership or service area (§ 486.310). Vital data and information such as internal OPO quality improvement and other proprietary data sets would not be available to an OPO that is new to the DSA following a competition or assignment by CMS. This greatly impacts an OPO's preplanning activities and readiness to assume responsibility for a new DSA. An OPO that has won a competition or has been assigned to an open DSA when no OPO competes for it must begin with significantly limited information and resources. OPOs in these situations would have large information gaps coupled with potentially significant expansion demands. While these are not insurmountable, they are unique challenges to be worked through, nonetheless, and require additional consideration when assessing outcomes data for re-certification purposes. Alternatively, a voluntary merger would provide a new OPO with the sharing of critical insights into the existing operations; access to proprietary data sets and internal analyses; enable pre-formed relationships and contacts; leverage established financial, personnel, and physical resources; and include other intangible elements that smooth a transition. Therefore, we believe that an OPO that assumes responsibility for a new DSA after a competition or has been assigned to a DSA should have an additional amount of time to demonstrate improvement before being held accountable on its performance for re-recertification purposes.

To address these concerns, we propose to revise § 486.318(f)(3), proposed to be redesignated as § 486.318(c)(3), to state that if an OPO takes over another OPO's DSA as a result of a change of control or ownership or service area, on a date later than January 1 of the

first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, the OPO will be held accountable for its performance on the outcome measures in the new area once 12 months of data are available. In this situation, the OPO may or may not be held accountable for the outcome measures in the new DSA for re-certification in the current cycle and this would be dependent on the timing of the change within the current agreement cycle. Regardless, the OPO would still be subject to an onsite re-certification survey to determine compliance with the process performance measures at the end of the re-certification cycle. The OPO would be recertified at that time if CMS determined that the OPO was in compliance with the process performance measures. For instance, if the change occurred prior to the start of the final assessment period, there would be 12 months of data available reflecting the OPOs performance in the DSA at the end of the re-certification cycle to determine compliance with the outcome measures. If the change occurred after the start of the final assessment period, the availability of outcome measure data would depend on whether the OPO merged DSAs or retained separate DSAs. If the OPO merged DSAs, there would not be 12 months of data reflecting the OPO's performance in the merged DSAs to determine compliance with the outcome measures in the new area so re-certification would be determined based on the process performance measures. Alternatively, if the OPO maintained the DSAs separately, its original DSA would have outcome measure data available that could be considered for purposes of re-certification at the end of the re-certification cycle.

We also propose a new paragraph at § 486.318(c)(4) to address the assessment of outcome measures when a new DSA is acquired after a competition, or an OPO is assigned a DSA by CMS. If either of these events occur on a date later than January 1 of the first year of the agreement cycle, we propose that we would hold the OPO accountable for its performance on the outcome measures in the new DSA 1) for QAPI, once 12 months of outcome measure performance data are available, and 2) for re-certification purposes, in the final assessment period of the following agreement cycle. This would provide OPOs in these circumstances with

additional time necessary to improve performance in a new DSA before being held accountable for re-certification purposes. We note that the "new DSA" would be either a newly formed DSA if the OPO merged its DSAs or only the newly acquired DSA if the OPO decided to retain separate DSAs. However, the OPO would still be assessed on the process performance measures via an onsite re-certification survey at the end of the current agreement cycle and be recertified based on the outcome of that survey.

These proposed requirements will work in tandem with the proposed requirements at § 486.316(a) and (b) to enable assessing an OPO's DSAs separately on the outcome measures when an OPO has more than one DSA, and in some instances, delay assessment of outcome measures until an appropriate time when the OPO should be held accountable for its performance in a new DSA. We seek public comment on this approach and other considerations that may impact the timeframes for holding OPOs accountable on their performance with the outcome measures.

I. Human Resources (§ 486.326)

We propose to revise § 486.326(d), "Medical director," to specify that an OPO's medical director would be a physician licensed in at least one of the States or territories within one of the OPO's service areas or as required by State or territory law or by the jurisdiction in which the OPO is located. We propose this change from "service area" to "service areas" to conform to a potential scenario of one OPO serving more than one DSA at a time. We note that many OPO DSAs already cross State lines, meaning that the OPO community is already familiar with navigating the operational complexities of functioning across State lines and that operating across State lines due to designation to more than 1 DSA does not represent a new challenge for OPOs. While the new policy of allowing OPOs to serve multiple DSAs at once may increase the frequency of these occurrences, the policy would not introduce a new level of operational complexity in relationship to the licensure requirements for OPO medical directors.

In addition to proposing this conforming change, we propose revising personnel qualifications for other OPO staff that engage in clinical practices, whether they are in explicitly clinical positions or other positions in which clinical decision making or actions are expected. In accordance with current requirements at § 486.342, as part of its responsibilities, an OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families. This requirement reflects the crucial role that OPO staff fill in interacting with potential donor families in an emotionally charged environment to obtain consent for donation and effectively manage care of the potential donor. Beyond obtaining consent to donate, OPOs perform essential clinical functions such as implementing established donor evaluation and management protocols under the oversight of the OPO's medical director, determining whether there are conditions that may influence organ acceptance, obtaining the potential donor's medical and social history, reviewing the potential donor's medical chart, performing a physical examination of the donor, obtaining the potential donor's vital signs, and performing all pertinent tests (see § 486.344). Each OPO is already required by § 486.326 to ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise these services, and provide its staff with the education, training, and supervision necessary to furnish required services. The training must include performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. Additionally, OPOs must evaluate the performance of their staff and provide training, as needed, to improve individual and overall staff performance and effectiveness.

The expertise required to fulfill the broad responsibilities and functions of OPOs, spanning from educating donor hospitals to conducting internal QAPI activities to implementing donor management protocols, requires varied training, education, and experience specific to each role. As such, the OPO CfCs do not currently include minimum personnel requirements for OPO staff roles beyond the medical director. We seek to establish such minimum qualifications

as are necessary to assure organ quality to facilitate more transplants and propose to add a new standard § 486.326(e), Licensure, to require that personnel performing clinical duties are legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State and local laws. Furthermore, we propose that these staff would be required to act only within the scope of the individual's State license or certification, or registration. Finally, we propose that the individual's licensure, certification, or registration must be kept current at all times. State licensure, certification, or registration would ensure that individuals meet the minimum training, education, and professional experience requirements set forth by each State to assure the quality and safety of organs provided to patients on the transplant waitlist, thus furthering our policy goal of more transplants and more lives saved. Similar requirements for personnel licensure apply to many other provider and supplier types that deliver patient care to the same patient population served by OPOs, such as hospitals, transplant centers, and dialysis facilities, to assure the health and safety of patients when they receive care from these entities. We believe that it is necessary to assure that OPOs utilize qualified, licensed staff for the performance of clinical functions for potential donors and donors to assure safe, effective donor care management and thus improve the likelihood of a donated organ resulting in a successful transplant.[65,66,67,68]

While we believe that these proposals are an appropriate step towards establishing more robust personnel requirements to assure the quality of procured and transplanted organs, we also request public comments regarding additional minimum personnel qualification standards in furtherance of this goal. Specifically, we request comment regarding which staff roles should

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[65] Malinoski DJ, Daly MC, Patel MS, Oley-Graybill C, Foster CE 3rd, Salim A. Achieving donor management goals before deceased donor procurement is associated with more organs transplanted per donor. J Trauma. 2011 Oct;71(4):990-5; discussion 996. doi: 10.1097/TA.0b013e31822779e5. PMID: 21808207.

[66] Malinoski DJ, Patel MS, Ahmed O, Daly MC, Mooney S, Graybill CO, Foster CE, Salim A; United Network for Organ Sharing (UNOS) Region 5 Donor Management Goals (DMG) Workgroup. The impact of meeting donor management goals on the development of delayed graft function in kidney transplant recipients. Am J Transplant. 2013 Apr;13(4):993-1000. doi: 10.1111/ajt.12090. Epub 2013 Feb 13. PMID: 23406284.

[67] Malinoski DJ, Patel MS, Daly MC, Oley-Graybill C, Salim A; UNOS Region 5 DMG workgroup. The impact of meeting donor management goals on the number of organs transplanted per donor: results from the United Network for Organ Sharing Region 5 prospective donor management goals study. Crit Care Med. 2012 Oct;40(10):2773-80. doi: 10.1097/CCM.0b013e31825b252a. PMID: 22846779.

[68] Clarke C. Management of the brain-dead organ donor. Indian J Thorac Cardiovasc Surg. 2021 Sep;37(Suppl 3):395-400. doi: 10.1007/s12055-021-01224-y. Epub 2021 Sep 17. PMID: 34548770; PMCID: PMC8445737.

have minimum personnel requirements and what requirements should be included for those specific staff roles for purposes of improving OPO processes in ways that advance the policy goals of more donors and more transplants. We request that commenters provide available evidence, such as research and existing professional standards or guidelines, to support their recommendations, if possible.

J. Information Management (§ 486.330)

The current requirements for information management at § 486.330 focus on maintaining donor records and records regarding the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant beneficiaries. To assure the accuracy of data reported to the OPTN and the integrity of the CMS donation rate outcome measure that uses data reported by OPOs regarding pancreata procured for islet cell research, we propose to establish a new documentation requirement specific to organs procured by OPOs for research, including pancreata procured for islet cell research. We propose that OPOs would maintain records regarding the disposition of organs recovered and sent for *bona fide* research studies, including information identifying approval by an institutional review board (IRB) or other formal authorizing body, as appropriate, research institution, principal investigator, and contact information. This recordkeeping would foster OPO accountability in the responsible disposition of any organ sent for research, including pancreata that are used for islet cell research, and be consistent with existing OPO practices for maintaining records regarding the disposition of transplanted organs. CMS would use the survey process to review OPO organ disposition records and may conduct validation efforts to confirm their accuracy. We request public comment regarding this proposed documentation requirement for all organs procured for research and alternative ways that CMS could assure the reliability of OPO self-reported data regarding pancreata that are used for islet cell research.

K. Quality Assessment and Performance Improvement (QAPI) (§ 486.348)

We propose to make a conforming change at § 486.348(d)(3) by removing the reference to "§ 486.318(e)(5) and (6)" and replacing it with "§ 486.318(b)(5) and (6)".

Section 486.348 requires OPOs to develop, implement, and maintain a comprehensive, data driven QAPI program designed to monitor and evaluate performance of all donation services. Section 486.348(c), governing adverse events, requires that OPOs establish written policies to address, at a minimum, the process to identify, report, analyze, and prevent adverse events that occur during the organ donation process. It also requires that OPOs conduct a thorough analysis of any identified adverse event and use that analysis to effect changes in their policies and practices to prevent repeat incidents. We propose to insert a new paragraph (3) that would set forth the examples that are currently in, but proposed for removal from, the "adverse event" definition in § 486.302 with some revisions.

We propose to insert the example of "transmission of disease from donor to a beneficiary" with revisions at paragraph (c)(3)(i). We propose to insert "infectious or communicable" before "disease". Also, in organ transplantation the transmission of infectious or communicable diseases or other diseases, such as malignancies, is a critical concern. OPOs are responsible for evaluating potential donors, which includes obtaining comprehensive medical histories, if available, and performing screening and testing for infectious diseases according to current standards of practice (§ 486.344(a) through (c) and § 486.346(a)). By adding "infectious or communicable" before "disease", we are clarifying the types of diseases of which transmission to a transplant recipient constitutes an "adverse event." Since we are also concerned about the transmission, dissemination, and seeding of malignancies, we are proposing to also add "or other disease that may be transmissible from a donor to an organ recipient, such as the transmission, dissemination, and seeding of malignancies".

We propose to insert "[a]voidable loss of a medically suitable potential donor for whom consent for donation has been obtained" without revision into paragraph (c)(3)(ii).

We propose to add a new example at paragraph (c)(3)(iii) that addresses the evaluation and management of patients or potential donors. Section 486.344 sets forth the requirements for potential donor evaluation and management, as well as organ placement and recovery. Potential donor evaluation and management are critical for maximizing the number of transplantable organs an OPO can procure. OPOs are required to have written protocols for donor evaluation and management that meet current standards of practice and are designed to maximize organ quality, as well as the number of donors and the number of organs recovered and transplanted. Both potential donors that have been declared dead by brain death (DBD) criteria and those being evaluated and managed as donors declared dead by cardiac or circulatory death (DCD) criteria must be evaluated. OPOs must evaluate each patient or potential donor to verify that death has been declared according to applicable local, State, and Federal laws; determine whether there are conditions that may influence donor acceptance; if possible, obtain the potential donor's medical and social history; review the potential donor's medical chart and perform a physical examination of the potential donor; and obtain the potential donor's vital signs and perform all pertinent tests (42 CFR § 486.344(b)). We also want to emphasize that this evaluation of potential donors includes active collaboration with primary medical teams in the care of those patients. Medical management of the potential donor is critical to ensure they are kept stable, and if proper consent is obtained, their organs recovered, which could be several hours or longer.

We have concerns that there have been some instances where deviations from the current standards of practice or the OPO's policies and procedures have resulted in loss of transplantable organs or have otherwise constituted an adverse event. For example, failure to ensure that death has been verified according to all applicable laws could contribute to mistrust in the organ donation process. In addition, failure to determine if there are conditions that may influence donor acceptance; obtain the potential donor's medical and social history, when possible; perform a physical examination and review the potential donor's medical chart; or perform all

pertinent tests could result in the OPO expending unnecessary resources on a potential donor whose organs could be unsuitable for transplant or increase the chances of transmission of an infection or communicable disease or malignancy. We are also concerned about the number of organs that are recovered but not transplanted. OPTN data indicates that in 2024 nearly 12,000 potentially transplantable organs were recovered but were discarded. About 9,200 of those organs were kidneys.[69,70] Also, there has been an increase in potential donors who have one or more organs recovered but have no recovered organs transplanted, also known as zero organ donors. Our internal analysis indicates the number of zero organ donors increased over 130 percent between 2019 and 2023. Since OPOs determine medical suitability and transplant surgeons determine if a particular organ will be transplanted into a specific recipient, there will always be some organs that are discarded. However, we are concerned that the increase in zero organ donors and the number of discarded organs could, at least partially, be a result of issues in potential donor evaluation and management. By requiring OPOs to include adverse events related to potential donor evaluation and management in their QAPI program, this should assist the OPOs in identifying and addressing any problems in their policies and procedures that could be resulting in the loss of transplantable organs. Hence, due to the critical nature of the patient or potential donor's evaluation and management, we are proposing to add an example at paragraph (c)(3)(iii) to clarify that OPOs should be including in their QAPI program adverse events resulting from deviations from the current standards of practice or their own policies and procedures regarding the evaluation and management of patients or potential donors that result in loss of a patient, potential donor, or transplantable organ(s). Hence, OPOs would need to comply with § 486.348(c) if they identify any instances that meet this example.

OPOs must "develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival [at the transplant center] without

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[69] OPTN National Data. https://hrsa.unos.org/data/view-data-reports/national-data/.
[70] Hanson, T, Zalani, A, Gold, R. and Herman, J. *Discarded: Why donated organs are left unused*. CBS News Investigations. Accessed at https://www.cbsnews.com/organdonors/. Accessed on July 14, 2025.

compromise to the quality of the organ" (§ 486.346(c)). We have received feedback about numerous incidents involving organs transported to transplant programs that did not arrive, were delayed such that it was too late for the organ to be transplanted, or arrived in conditions incompatible with transplantation. Although we believe this happens only to a small percentage of organs, usually kidneys (which are lost or delayed more often due to their frequency of being transported commercially), this still amounts to potentially hundreds of organs that are recovered but not transplanted. At a Senate hearing in 2022, it was stated that it has been estimated that it is 15 times more likely for an organ to be lost or damaged in transit as it is for an airline to lose or damage passenger luggage.[71] Also, there have been reports of organs arriving at a transplant center frozen solid or otherwise physically damaged.[72] We are concerned about cases of organs that are lost in transit, delayed and arrive too late to be transplanted, or arrive in a condition that is incompatible with transplantation. All types of donated organs have specific ischemic timeframes in which the organ is suitable for their transplantation. If the organ(s) arrives at the transplant center without sufficient time to transplant that organ(s) within that timeframe, it cannot be transplanted. In addition, the organ must be in a condition suitable for transplantation, which is ultimately up to the transplant surgeon. If the organ is damaged in some way, it will not be acceptable. These are organs that could have been transplanted but are in some way rendered incompatible for transplant, causing potential transplant recipients to be denied a transplant or extending their time on the transplant waiting list. These missed opportunities may also result in the potential donor recipient potentially becoming too sick for a transplant or even dying before another organ is available. We are especially concerned about the reports we have received that these types of incidents have not been followed up with an adverse event investigation as

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[71] A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network. United States Senate Committee on Finance. Full Committee Hearing August 3, 2022. https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network.

[72] Farmer, B. Transplant agency is criticized for donor organs arriving late, damaged or diseased. NPR. Accessed at *https://www.npr.org/sections/health-shots/2022/08/17/1118009567/damaged-and-diseased-organs-the-agency-overseeing-transplants-faces-intense-scr*u. Published August 17, 2022. Accessed on February 9, 2023.

required. To address these concerns, we propose to add examples of adverse events at § 486.348(c)(3)(v) and (vi) to include organs that are either lost or delayed and arrive too late to be transplanted or arrive in a condition incompatible with transplantation.

The current examples of adverse events in § 486.302 also include delivery of "the wrong organ". For greater specificity and to avoid confusion, we propose to replace "the wrong organ" with "an organ that was not for the intended organ recipient". We also propose to remove the two references to "beneficiary" that currently appear in the examples in the "adverse event" definition. All OPOs must comply with the OPO CfCs, which apply to all patients regardless of payor source. Hence, the term "beneficiary" in the OPO CfCs is not appropriate. We propose to remove the two references to "beneficiary" and instead use "organ recipient".

Paragraph (d), "Standard: Review of outcome measures," requires OPOs to review their performance on the outcome measures and incorporate that data into their QAPI program. This process must be a continuous activity to improve their performance and OPOs should endeavor to use more frequent, interim monitoring of process and outcomes measures to identify areas for performance improvement. If the annual assessment of the OPOs' performance on the outcome measures indicates an OPO has a DSA that is assigned as either in tier 2 or tier 3, the OPO is required to identify opportunities for improvement and implement changes that lead to improvement in the measures.

OPOs should leverage their QAPI programs as they look to increase the number of medically complex organs recovered and transplanted. Some members of the OPO and transplant communities have expressed their opinion that increasing the acceptance of medically complex organs would likely result in a considerable increase in the total number of organs transplanted. Recent efforts by the OPTN to increase the number of medically complex organs recovered and transplanted have yielded results that support this position. In response to the growth in the use of DCD organs over the last several years, the OPTN conducted a collaborative improvement project with OPOs to identify and share effective practices related to procurement of DCD

organs.[73] DCD donations increased from 2,718 in 2019 to 5,894 in 2023.[74] OPOs vary substantially in their performance with DCD donation with some OPOs having over 50 percent of donors coming from DCD donation while other OPOs have very few DCD donors.

The OPTN also conducted other collaborative improvement projects, including the Collaborative Improvement and Innovation Network.[75] The objective of that improvement project was to increase the number of deceased donor kidneys with a high KDPI, which is a score derived from a variety of donor factors to estimate how long a donated kidney is expected to function compared to other kidneys recovered in the U.S.[76] Generally, the waiting time for a kidney with a low KDPI is longer. The decision on whether a particular kidney will result in a successful transplant for a specific recipient depends on the transplant surgeon's judgment and the risk the potential recipient is willing to take. The higher the KDPI, the fewer years the kidney is expected to function. As a result of this collaborative activity, one transplant center was able to increase the percentage of its patients listed for high KDPI kidneys from 9.2 percent to 16.03 percent over a 9-month period.

In researching KDPI levels, we discovered that there does not appear to be any universally accepted measure. In the OPTN Collaborative discussed in the previous paragraph, they addressed donors with a KDPI over 50. However, a review of OPTN's website revealed an "Accelerated placement of hard-to-place kidneys" protocol that addressed donors with KDPI of 75 to 100.[77] That protocol also noted the kidney from donor with KDPI score of 70 percent or greater are used much less frequently than those with lesser scores. In this rule, we propose to

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[73] OPTN DCD Procurement Collaborative Project. https://hrsa.unos.org/media/mcsl2ebu/optn-dcd-procurement-collaborative_2022-executive-summary.pdf.
[74] OPTN/SRTR Annual Data Report 2020. *https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16976.*
[75] Wey A, Foutz J, Gustafson SK, Carrico RJ, Sisaithong K, Tosoc-Haskell H, McBride M, Klassen D, Salkowski N, Kasiske BL, Israni AK, Snyder JJ. The Collaborative Innovation and Improvement Network (COIIN): Effect on donor yield, waitlist mortality, transplant rates, and offer acceptance. Am J Transplant. 2020 Apr;20(4):1076-1086. doi: 10.1111/ajt.15657.
[76] Kidney Donor Profile Index (KDPI) Guide for Clinicians. HRSA/OPTN. Accessed at https://www.hrsa.gov/optn/professionals/resources/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians.Accessed on May 11, 2022.
[77] OPTN.org. Accessed at https://hrsa.unos.org/media/jppbstey/optn_accelerated-placement-of-hard-to-place-kidneys.pdf.. Accessed on July15, 2025.

use 50 percent. However, we are specifically soliciting comments on what the percentage score for KDPI should be in our definition of "medically complex organs", such as 50, 70, or another percentage.

We believe there is significant interest in increasing the number of organs recovered from DCD donors, as well as other medically complex donors. We discussed our proposal for including definitions for medically complex organs and medically complex donors in section II.A. of this proposed rule. We will not consider these organs separately in the outcome measures; however, we do believe it is important that OPOs pursue medically complex donors from whom they could potentially recover transplantable organs. To further the goal of improving procurement and transplantation of medically complex organs, we propose to add a new paragraph (e) at § 486.348, Review of performance on the recovery and transplantation of medically complex organs, so that each OPO in its QAPI program must: (1) assess its policies and procedures regarding medically complex donors and medically complex organs and ensure they are optimizing opportunities to recover and place these organs for transplant; (2) assess its performance regarding the number of medically complex donors by determining the number of medically complex donors from whom the OPO has obtained consent for donation, the number of organs recovered from those donors, and the number of medically complex organs transplanted at least annually; and (3) implement actions to improve its performance (from an initial assessment) with medically complex donors or medically complex organs when the OPO identifies opportunities for such improvement.

We solicit comments on this proposed addition, including but not limited to, comments on how often each OPO should review their performance on medically complex donors and organs as part of their QAPI program.

L. Proposed Conforming Changes to § 486.322 Relationships with Hospitals, Critical Access Hospitals, and Tissue Banks; § 486.324 Administration and Governing Body; and § 486.360

Emergency Preparedness

The previous OPO CfCs were developed based on the assumption that each OPO would only be responsible for a single DSA at any time. While the statute requires that only one OPO may operate within a DSA, it does not prohibit one OPO from operating multiple DSAs at one time. OPOs have expressed interest in operating multiple DSAs under the control of a single OPO, and we propose to include conforming changes to address several areas within the CfCs that specifically relate to the number of DSAs an OPO may be responsible for. Specifically, we propose at § 486.322(a) to align the requirement to have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals (CAHs) with both a ventilator and an operating room to specify that the written agreements must be with hospitals and CAHs in each of its designated DSAs. We also propose conforming changes at § 486.324(a)(1), (a)(2), (a)(5), (b)(2), and (b)(8) to replace the word "area" with "area(s)". Additionally, we propose a conforming change at § 486.328(c) to require that data used for OPO re-certification must include data for all deaths in all hospitals and CAHs in the OPO's donation service area(s), unless a waiver has been granted. Finally, we propose two conforming changes to the emergency preparedness requirements for OPOs. In § 486.360 we propose to revise paragraph (c)(1)(v) to require that OPOs have an emergency communication plan with the names and contact information for transplant and donor hospitals in each of the OPO's DSAs. We also propose to revise paragraph (e)(2)(i) by replacing "DSA" with "DSA(s)".

IV. Comment Solicitation and Discussion on Emerging Issues

A. Conflicts of Interest

CMS has been aware for some time that some OPO staff at various levels of organization leadership and employment are also engaged in outside activities that may present a conflict of interest with their official OPO duties and with their position of public trust as a crucial point in the organ donation, procurement, and transplantation system. While these activities are not prohibited by law or regulation, interested parties have raised transparency concerns regarding

the matter, as well as CMS' ability to exercise its oversight responsibilities in light of this lack of transparency. Conflicts of interest can be actual or potential, meaning that they may exist or there may be a reasonable perception of their existence that necessitates equal treatment. Conflicts arise when a covered person, and by extension the individuals with whom they are closely associated, such as immediate family members, has a financial (ownership, investment, employment, or other compensation) interest in another business with which the covered person's OPO is doing, or will do, business. Compensation includes both direct and indirect forms, as well as gifts or favors.[78] Conflicts of interest may also be ethical or political in nature,[79] involving issues that reflect misaligned or competing interests among various parties with whom the individual has personal or professional relationships or interactions that juxtapose personal or professional interests with larger public interests.

The relationship and potential for conflicting incentives between organ and tissue procurement was described in a November 2020 report from The Bridgespan Group, "Transforming Organ Donation in America" Appendix A.[80] The report notes that non-profit OPOs, with their status as DSA-specific monopolies for organ recovery, are compensated by tissue-processing partners (which may be for-profit corporations) for procurement of tissue, cornea, bone, and skin, and that prices for tissue and non-organ body parts are subject to market forces, meaning increased demand can increase prices and bring additional revenue for every incremental tissue recovery. The report surmises thusly that, "OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs." The report goes on to note that there is no demonstrable connection between increased revenues related to tissue procurement and increased OPO performance, citing a specific OPO that reported spending $392,472,519 on "tissue processing" compared with only $22,397,590 on "organ procurement" in its most recent tax filings (2018) while simultaneously being a tier 3

[78] https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.
[79] https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.
[80] *https://www.bridgespan.org/insights/transforming-organ-donation-in-america.* Accessed on June 13, 2025.

OPO. The report concluded, "that a large pool of tissue-related profits do not guarantee improvements in organ recovery."

While the OPO CfCs at § 486.322(c) require that OPOs must have arrangements to cooperate with willing tissue banks that work with the same hospitals as the OPO does, and that they must cooperate in specified activities to ensure that all usable tissues are obtained from potential donors, this requirement is in no way meant to replace organ procurement efforts with tissue procurement efforts. Organ transplants save and prolong lives, such that a focus on improving organ procurement and transplantation must remain upmost for all OPOs. An L.A. Times news article summarized that, "There's no denying that organs can extend lives, and tissue is sometimes life-enhancing. Corneas can save sight in those going blind. Tendons are used to repair sports injuries. But, in convincing people to become donors, companies rarely mention that a growing part of the multibillion-dollar body parts industry is cosmetic surgery — or that unlike organs, tissues are rarely of immediate need."[81] The article cited that while the number of organ donors grew from 8,085 to 9,079 from 2007 to 2015, the number of tissue donors grew from 29,799 to 39,121 in that same time, with companies harvesting so much tissue from Americans that they are increasingly exporting it overseas. Tissue recovery and sale is an area that is particularly vulnerable to financial conflicts of interest that may negatively impact the health and safety of patients on the transplant waitlist.

The issue of conflicts of interest in the organ procurement industry has gained considerable interest from members of the United States Senate Committee on Finance. In a February 2020 letter[82] addressed to the United Network for Organ Sharing from the Committee, signed by Senators Grassley, Wyden, Young, and Cardin, the Committee questioned, "Given that multiple OPOs recover tissue and some operate tissue banks, on what mechanisms does UNOS

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[81] *https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html*. Accessed on June 13, 2025.

[82] *https://www.finance.senate.gov/imo/media/doc/2020-02-10%20Grassley,%20Wyden,%20Young,%20Cardin%20to%20UNOS%20(Information%20Request%20on%20Organ%20Transplant%20System).pdf*.

rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?" The Committee continued to pursue the subject in an April 2022 letter[83] to the HHS Secretary and CMS Administrator, signed by Senators Wyden, Grassley, Young, Cardin and Moran, which suggested that CMS should, "require robust, independent oversight by each OPO governing board and medical advisory boards consistent with best practices for non-profit governance. Members of these boards should follow professional guidelines that require them to attest to serve the public interest and oversee OPO leadership, policies, and procedures. Members should also disclose any conflicts of interest, including any direct or indirect financial arrangements relating to organ donation or transplantation, and make these attestations available to CMS."

In July 2024, as part of the OPTN Modernization Initiative and with new flexibilities authorized by the Securing the U.S. Organ Procurement and Transplantation Network Act signed in September 2023, HRSA announced a critical step in reducing conflicts of interest in OPO oversight by separating the OPTN Board of Directors from the OPTN contractor.[84] This effort led to a June 2025 HRSA announcement[85] of the launch of a new 34-member OPTN Board of Directors, each of whom has completed a comprehensive Conflict of Interest Disclosure Questionnaire that encompasses both existing and potential relationships. HRSA describes a conflict of interest as specific matters that come, "into direct or indirect conflict (or appears to come into direct or indirect conflict) with a financial, personal, business, professional, positional, programmatic or organizational interest or oversight responsibility of a covered person, including affiliates and family members thereof (a "Covered Person"), or otherwise whenever a Covered Person's financial, personal, business, professional, positional, programmatic or organizational interest or oversight responsibility could be reasonably perceived as having the potential to affect

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[83] *https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf.*

[84] *https://www.hrsa.gov/optn-modernization/july-2024*

[85] *https://www.hrsa.gov/optn/news-events/news/new-optn-board-members-associate-regional-councillors-elected-2025.*

his or her independent, objective, disinterested or good faith decision-making or judgment in fulfilling his or her duties and/or responsibilities."[86]

In continuation of these ongoing efforts, in June 2025 the United States Senate Committee on Finance issued a staff report, "Operation Transplant: Examining the Need for Oversight in the Organ Donation System"[87] with new analysis of current OPO conflict of interest practices and additional recommendations for CMS. The report described transparency and oversight efforts for conflicts of interest among OPO leaders and governing board members as "inadequate" and described the issue as a "foundational" concern "that, if not adequately addressed, undermine public trust in this vital, lifesaving activity." The report concluded that, "additional transparency is needed to ensure these financial and business relationships do not place Americans in need of a lifesaving organ transplant at risk."

One example of OPO leadership having a conflict of interest that went unidentified within the OPO and resulted in illegal practices comes from a 2012 case from the U.S. Attorney's Office Northern District of Alabama. A release from the U.S. Attorney's Office,[88] based on court documents, described that from about March 2007 until June 2011, leadership of the OPO at the center of the case solicited and received kickbacks from a local funeral home that did business with the organ center. In exchange for the kickbacks, OPO leadership would promote the funeral home and recommended the hiring of the funeral home for its services. Neither person in a leadership position disclosed that they were receiving payments from the funeral home. These individuals falsely represented that neither of them had any financial conflicts of interest from customers, suppliers, contractors or competitors. This case of undisclosed, improper financial relationships between OPO staff and businesses with which the OPO conducts business risks directly undermining public confidence in the integrity of organ

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[86] https://www.hrsa.gov/sites/default/files/hrsa/optn/optn-bod-coi-disclosure-questionnaire-508.pdf..
[87] *https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf*.
[88]https://www.justice.gov/archive/usao/aln/News/June%202012/June%2013,%202012%20Former%20Alabama%20Organ.html. Accessed on June 13, 2025.

donation. The perception that OPOs could profit from activities adjacent to organ procurement may erode public trust in an OPO's role within the organ procurement and transplantation system, thereby risking the willingness of individuals to sign up for organ donation and the willingness of families to authorize donation. Without organ donors, waitlist patients wait longer, jeopardizing their health and safety.

CMS also has concerns related to the relationships between OPOs with tissue banks and officials from local morgues and medical examiner offices, which are the original source of data that populates the CDC MCOD file that CMS uses for establishing the eligible death denominator for its outcome measures. The 2019 LA Times news article, "How organ and tissue donation companies worked their way into the county morgue,"[89] described overlapping employment relationships with procurement staff serving both the procurement entity and as pathologists performing autopsies to determine cause of death in local morgues within the OPO's DSA. The article also described a specific situation in which a city's chief medical examiner also sat as a paid member of the board of the OPO that serves the city in question. Furthermore, the article stated, "The procurement companies have become so influential at the medical examiners' association that their executives now sit on the group's board of directors." One State's chief medical examiner's office reported that it has taken action to prevent conflicts of interest by revising its policy to prohibit procurement company employees who serve as part-time medical examiners from authorizing the retrieval of organs or tissues.

The OPO CfCs at § 486.324, Administration and governing body, permit each OPO to have more than one board, while specifying that an OPO must have an advisory board, which is not the OPO's governing body, comprised of certain specified members, including transplant surgeons that represent each transplant center in the DSA with which the OPO has agreements and tissue bank representatives. This advisory board is charged by the CfCs with authority to

[89] *https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html*. Accessed on June 13, 2025.

recommend policies for a wide variety of essential OPO activities, including organ procurement, organ allocation, and organ transportation (including the purchase and use of private air transportation). Members of the advisory board are prohibited from serving on any other OPO board. The influential role of the advisory board, coupled with the required membership types, may create opportunities for conflicts of interest. As such, the CfCs at § 486.324(d) require that an OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members.

In addition to the advisory board, in accordance with § 486.324(e), an OPO must have a governing body with full legal authority and responsibility for the management and provision of all OPO services. The governing body is responsible for developing and overseeing implementation of policies and procedures considered necessary for the effective administration of the OPO, including the OPO's fiscal operations, its QAPI program, and the services furnished under contract or arrangement, including agreements for those services. The governing body is further responsible for appointing an individual to be responsible for the day-to-day operation of the OPO. Given the wide breadth of the authorities vested in the governing body, § 486.324(f) requires that an OPO must have procedures to address potential conflicts of interest for the governing body.

Beyond the required advisory board and governing body, the OPO CfCs also require at § 486.326, Human resources, standard (a) that an OPO must develop and implement a written policy that addresses potential conflicts of interest. This standard specifically applies to the OPO's director, as appointed by the governing body, the medical director, the OPO's senior management, and all procurement coordinators.

OPO implementation of these CFC requirements varies. The June 2025 United States Senate Committee on Finance staff report [90] describes the conflict of interest findings related to its investigation of eight OPOs. The investigation found that "[t]here are key differences among

[90] *https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf.*

the various conflicts of interest policies which the OPOs operate under. Those differences include whether employees are covered or just the directors and officers, whether and how the board of directors may approve a transaction despite a conflict, and whether conflicts of interest include those which arise from ethical or political conflicts or solely financial conflicts." The authors noted vagueness on what details about the conflict of interest must be reported, and how the conflicts are recorded, reviewed, and maintained, making the task of OPOs identifying conflicts in future transactions difficult. Importantly, from the perspective of patient health and safety, the report noted that "every conflicts of interest policy focused on corporate conflicts and the interests of the OPO without a focus on conflicts to the national needs of the organ donation system in the public interest."

All of the OPOs included in the Committee staff investigation required covered persons to sign an annual conflicts of interest form and seven of the eight required covered persons to disclose the conflict on their annual conflicts of interest form. However, only two OPOs required a disclosure of a conflict as soon as it is known to the covered person or should be known, creating significant gaps in time when disclosures remain unreported for most of the OPOs. All of the OPOs require disclosure of actual or potential conflicts at the time when a conflicted transaction or arrangement emerges. However, only five of the eight OPOs specify to whom the conflict is reported. According to the Committee report, many of the disclosures included very little information, simply naming a hospital, for example, without an explanation as to their role at that hospital or how their disclosure conflicted or potentially conflicted with their role at the OPO.

Each of the OPOs, with one exception, have conflicts of interest policies allowing for the board of directors to approve a conflicted, or potentially conflicted, transaction. Requirements related to board approvals included elements such as requiring a full disclosure of the material facts of the conflict, that board members with conflicts are not present for discussions related to the transaction related to the conflict, that remaining board members hold a majority vote

approving to approve or decline, and that the transaction related to the conflict is fair to the OPO and is legal. Some OPOs reported requiring the board to exercise due diligence to determine if there is an alternative transaction that the OPO could enter into that would not be conflicted.

The significant variances in OPO practice, such as the lack of detailed information and missing reporting mechanisms, may represent opportunities for CMS to improve its regulatory oversight of this issue. The November 2020 report from The Bridgespan Group report suggested, "CMS could require disclosures of financial relationships between OPOs/OPO leaders and partner entities (such as tissue processors and private jet service companies), or even prohibit OPO leaders from engaging in financial relationships with partner entities (as it does for Medicare-funded physicians under Stark Law)."[91] The June 2025 staff report from the United States Senate Committee on Finance recommended that, "CMS should further clarify the requirements and expectations of OPOs regarding conflicts of interest to make clear that OPO governing boards and medical advisory boards, as well as CMS surveyors, should monitor actual and potential conflicts of interest."[92] The Committee report based this recommendation on the fact that 1986 report from The Task Force on Organ Transplantation,[93] established by the National Organ Transplant Act of 1984,[94] noted that "donated organs should be considered 'a national resource to be used for the public good' and that 'the public must participate in the decisions of how this resource can be used to best serve the public interest." The Committee report recommended that, "CMS should clearly define the expectations and requirements to be addressed in OPO conflicts of interest policies and the roles of OPO governing boards, medical advisory boards, and CMS surveyors in reviewing and evaluating those policies and conflicts."

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[91] *https://www.bridgespan.org/insights/transforming-organ-donation-in-america*. Accessed on June 13, 2025.
[92] *https://www.grassley.senate.gov/imo/media/doc/operation_transplant_staff_report.pdf*.
[93]Department of Health and Human Services, Organ Transplantation Issues and Recommendations, Report of the Task Force on Organ Transplantation (1986). *https://books.google.com/books?id=_dFeP9DKBNYC&pg=PR23&source=gbs_selected_pages&cad=1#v=onepage&q&f=false*. Accessed on June 13, 2025.
[94] *https://www.congress.gov/bill/98th-congress/senate-bill/2048/text*. Accessed on June 13, 2025.

In focusing on OPO actions, the Committee recommended that OPOs should adopt universal standards clearly defining policy coverage, scope of conflicts, and specific disclosure procedures. Further, the Committee report recommended that each OPO should clearly define the scope of conflicts covered under its policy, including actual or potential conflicts that are financial, personal, ethical, or political in nature. They recommended that each OPO should include in their conflicts of interest policies a provision detailing which conflicts are to be reported, when they are to be reported, how they are reviewed, and how they are recorded and maintained to allow for future audits. The recommendation continued that OPO conflicts of interest disclosure forms should include the material facts related to the reported conflicts of interest. The Committee report specifically focused on outside employment and its connection to conflicts of interest, writing:

> Because of the potential for outside employment raising actual or potential conflicts of interest, such as outside employment at a transplant center or biobank, each OPO should clarify their policies regarding outside work, including whether and when it is necessary to get approval and what activities are prohibited. This recommendation applies to OPO board members who concurrently sit on the board(s) of other organizations. Outside board membership can have an outsized impact on an organization. Each OPO should clearly define the policies for board members who also sit on other boards. The policy should clearly state that such outside board membership is a conflict, and outline how those conflicts are to be reported, reviewed and adjudicated. Lastly, each OPO should clearly state the procedures for disclosing actual or potential conflicts of interest.

The committee also recommended that all OPOs establish policies and procedures for board approval of transactions or contracts where one or more of its members have an actual or potential conflict.

We are requesting public comment on the ways that conflicts of interest are handled by OPOs, the sufficiency of the current regulatory requirements, the suggestions made by outside

bodies as described in this section, and other things that CMS should consider. We are interested in ways that we could potentially modify the OPO CfCs to assure consistency in the development and implementation of conflicts of interest policies to assure health and safety and the integrity of the organ donation system. We are seeking public comment related to the following:

- Actual and potential conflicts of interest that OPO staff and boards experience.
- The perception that the ability of an OPO to profit from activities that are adjacent to organ procurement could degrade the public trust inherent in an OPO's role in the organ procurement and transplantation system.
- What the appropriate remedy within OPOs should be, if a conflict does exist.
- Firewalls that may exist within an OPO or would be prudent, to avoid potential and actual conflicts of interest.
- What the potential impact, positive or negative, would be if CMS were to engage in rulemaking to establish additional requirements related to OPO conflict of interest policies and procedures related to conflicts of interest.
- Whether, and if so, under what circumstances CMS should review a potential conflict of interest, and what factors CMS should look at to determine if a conflict of interest exists.
- Alternatives for addressing the issue of conflict of interest among OPO staff and board members.

B. Allocation Out of Sequence (AOOS)

Organ allocation is a critical function of OPOs, as they are responsible for making organ offers to the transplant centers caring for potential transplant recipients. In accordance with § 486.344(g) and (h), each OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN and must develop and implement a protocol to maximize placement of organs for transplantation. In order to effectuate these regulatory requirements, OPOs must have a sufficient number of qualified staff to ensure

efficient placement of organs (§ 486.326(b)).

More specifically, the OPTN rule at § 121.8 states that the OPTN Board of Directors shall develop policies for the equitable allocation of organs among potential recipients and that such allocation policies shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement. Equitable allocation of organs includes setting priority rankings through objective and measurable medical criteria with rankings ordered from most to least medically urgent (taking into account, and in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). These priority rankings are known as the "match list", which is uniquely generated for each organ that is being considered by an OPO for procurement for purposes of transplantation. Organs are to be distributed over as broad a geographic area as possible and in order of decreasing medical urgency. Of note, the regulations at § 121.7(f), Wastage, specifically state that nothing in that section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. Equity based on medical need is the primary driver of organ allocation, with allowances for rare instances when an already procured organ is at critical risk of being discarded by a transplant program. In a February 2025 letter to the OPTN[95], HRSA reiterated that "section 121.7(f) of the OPTN Final Rule (Identification of Organ Recipient – Wastage) does not authorize out-of-sequence offers by OPOs. Transplant centers in receipt of an organ may find that the intended recipient is not able to utilize the organ. This provision creates a limited exception to transplant programs to transplant the organ into a different medically suitable candidate to avoid organ wastage other than in accordance with 42 CFR 121.7(b)(1) and OPTN policies and procedures, and does not provide this authority to OPOs."

[95] HHS/HRSA letter to the OPTN, February 21, 2025, https://www.hrsa.gov/sites/default/files/hrsa/optn/08302024-aoos-critical-comment-letter-to-optn-508.pdf

Under the oversight of the HRSA, the OPTN establishes allocation policies and is charged with investigating incidences of organs being allocated out of the OPTN-defined sequence. Among the OPTN Management and Membership Policies, the OPTN has established that "Each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions." OPTN Management and Membership Policy[96] F.1.G further requires that "Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself. All incidences of potential noncompliance are referred for further review as outlined in OPTN policies. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in OPTN policies." In addition to OPOs being subject to actions by the OPTN, CMS also has a regulatory mechanism for assuring OPO compliance. OPOs are required by § 486.320 of the OPO CfCs to be a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term "rules and requirements of the OPTN" means those rules and requirements approved by the Secretary. The regulations clarify that an OPO is not considered out of compliance with section 1138(b)(1)(D) of the Act or § 486.320 until the Secretary approves a determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such non-compliance has been determined in this manner. Lack of compliance with this CfC would be considered as a reason for termination of an OPO from the Medicare program.

As part of its responsibilities to establish equitable organ allocation policies that set

[96] https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_management-and-membership-policies.pdf.

priority rankings based on medical urgency, avoid both wasting organs and futile transplants, and promote patient access to transplantation and efficient management of organ placement, on March 15, 2021 the OPTN implemented a new kidney allocation system to eliminate the use of donation service areas (DSAs) as units of distribution and increase geographic equity in access to transplantation regardless of a candidate's place of listing, while limiting transportation time and costs, logistical complications, and inefficiencies through the use of proximity points.[97] In this new system, which broadened the pool of potential recipients from a single DSA to a pool of patients on transplant lists located within a 250 mile radius of the donor hospital, a unique match run list is created for each deceased organ donor, with an algorithm ranking potential recipients according to waiting time for an organ, medical urgency, geographic proximity, immunologic compatibility, estimated post-transplant survival, and other factors. The updated kidney allocation system has been credited with contributing to a 29 percent increase in overall transplant rates after the first two years of use[98], though we note that much of this gain is likely attributable to the approximately 19 percent gain in the number of deceased kidney donors recovered over the same era in response to new measures for OPO performance.

The combination of increased numbers of deceased organ donors and allocation policy change has also been associated with improved access to transplants for several key populations, such as pediatric, highly sensitized candidates with 80-97 percent calculated panel reactive antibody score, and candidates with more than 3 years of dialysis at the time of listing.[99] At the same time, the overall non-use rate (also known as the discard rate) for deceased donor kidneys increased from 21 percent pre-policy to 26 percent post-policy era.[100] A report assessing the

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[97] https://www.hrsa.gov/optn/patients/resources/pancreas/questions-and-answers-for-transplant-candidates-about-pancreas-pancreas-kidney-islet-allocation.

[98] *https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations*.

[99] *https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations*.

[100] *https://unos.org/news/two-year-monitoring-report-continues-to-show-improvements-in-equity-in-access-to-kidney-transplants-for-several-key-populations/#:~:text=A%20new%20data%20monitoring%20report,a%20number%20of%20key%20populations*.

impact of the 2021 allocation policy change noted that the change had been "disruptive" to the system in that it increased the number of transplant centers and candidates required to place a kidney and the logistical challenges for both transplant centers and OPOs. Furthermore, the researchers noted that the new policy resulted in increased cold ischemia time by 1.7 hours, and distribution time by 2.2 hours.[101]

Beyond the potential confounding effect of large-scale changes to organ donor availability, a further barrier to accurate assessment of the OPTN's organ allocation policy changes is that historical analyses did not describe the extent to which the allocation policy in place at the time was actually being followed. After the 2021 kidney allocation changes, OPOs and transplant programs began engaging in out of sequence allocation for kidneys at far more frequent rates, increasing nearly 10-fold, rising from less than 3 percent pre-policy to nearly 20 percent by the end of 2023.[102] In light of current understanding of the high degree of policy noncompliance in the new policy era, historic assessments of policy effects on overall and subgroup transplant rates and other system parameters are at best unreliable.

The frequency of out of sequence allocation varies by OPO and transplant center. While the nationwide average at the close of 2023 was nearly 20 percent of kidney placements, individual OPOs varied from 0 percent to 43 percent with just 5 OPOs accounting for 29 percent (1456 kidneys) of all kidneys placed out of sequence in the entire country from 2021 through 2023.[103] Those same 5 OPOs were responsible for procuring only 14 percent of all deceased donor kidneys. The 2 OPOs with the highest frequency of out of sequence placements used out of sequence allocation for 43 percent (239 of 556) and 32 percent (57 of 179) of their kidney

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[101] Wood, Nicholas L. PhD1; VanDerwerken, Douglas N. PhD1; Segev, Dorry L. MD, PhD2,3,4; Gentry, Sommer E. PhD1,4. Increased Logistical Burden in Circle-based Kidney Allocation. Transplantation 106(10):p 1885-1887, October 2022. | DOI: 10.1097/TP.0000000000004127.

[102] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

[103] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

placements. Conversely, seven OPOs allocated fewer than 5 out of sequence kidneys from 2021 through 2023, and three OPOs did not use any out of sequence placements for kidneys in that time.[104]

In addition to placing kidneys in ways that are not aligned with the organ match run list, OPOs also increased their use of "open offers" in which the OPO permits the accepting center to choose any compatible candidate waitlisted at their center, even if the patient is ranked below additional intervening candidates at other centers. Thus, the organ offer is made to a transplant center, rather than to a specific patient listed on the match run list. Such offers are inconsistent with section 372(b)(2)(D) of the PHS Act, which requires the OPTN to assist OPOs in the nationwide distribution of organs equitably "among transplant patients," as opposed to being distributed among transplant centers. Section 486.324(b)(6) of the OPO CfCs establishes the authority of the OPO advisory board to recommend policies for a system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN. In addition, § 486.344 requires that each OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, and that each OPO must have written documentation from the OPTN showing the intended organ beneficiary's ranking in relation to other suitable candidates if the intended beneficiary has been identified prior to recovery of an organ for transplantation. Taken as a whole, it is CMS's expectation that organ offers are made to transplant patients, rather than to transplant centers, in a manner that is consistent with OPTN rules. Researchers found that approximately 90 percent of out of sequence placements appear to have been "open offers," though they note that "Data capturing OPO decisions to bypass candidates are not necessarily entered in real time, so we cannot reliably identify the time or circumstances when OOS [out of sequence] allocation began. The PTR [potential transplant recipient] data set does not indicate whether the OPO extended an

[104] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

open offer, so we can only infer scenarios that appear to have been open offers based on observed bypass and refusal patterns within and between centers."[105] Despite these limitations, the researchers concluded that 68 percent of the time, the centers receiving an "open offer" from an OPO discretionarily skipped over their first ranked candidate. The median number of skipped-over candidates within the same center accepting a kidney allocated out of sequence was 13.[106]

In addition to describing the OPOs that engage in allocating kidneys out of sequence, Liyanage et al. also described the transplant centers most likely to receive organs allocated out of sequence. High-volume transplant centers received a disproportionately high percentage of out of sequence allocations. The 11 largest transplant centers, as measured by a transplant volume of 250 to 500 per year, most frequently transplanted kidneys allocated out of sequence, accounting for 21.6 percent of their kidney transplants. In contrast, the smallest-volume centers, as measured by a transplant volume of less than 50 transplants per year, less frequently transplanted kidneys allocated out of sequence, accounting for only 4.3 percent of their kidney transplants. The waitlists of transplant centers with the highest number of kidney transplants using organs allocated out of sequence were demographically different from centers that did not transplant out of sequence kidneys. The top 20 centers with the highest number of out of sequence transplants had a significantly higher proportion of females, Whites, Blacks, candidates with private insurance, and candidates with higher education levels on their waitlists compared with 54 centers that did not transplant kidneys allocated out of sequence. These centers also had a lower proportion of Hispanic patients on their waitlists than centers that used no kidneys allocated out of sequence. Kidneys that were allocated out of sequence "were preferentially transplanted into

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[105] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

[106] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

older candidates and candidates with shorter waiting times."[107] Liyanage et al. also identified that recipients of kidneys allocated out of sequence tended to wait less than standard allocation recipients (258 days on the wait list vs 411 days) and were older (median 61 years vs 55 years). These kidney recipients tended to be older than the last higher-ranked candidate skipped on the waitlist, meaning that younger patients ranked higher on the match run list are skipped in favor of older patients ranked lower on the priority list. Kidneys allocated out of sequence less often went to women (34.1 percent vs 40.8 percent) and less often went to Black (31.7 percent OOS vs 36.5 percent standard) and Hispanic (18.0 percent OOS vs 21.2 percent standard) recipients, compared with standard allocation kidneys.[108]

As an editorial from the American Journal of Transplantation noted, the concentration of out of sequence placements in the higher-volume OPOs and the highest volume transplant centers points "to a system increasingly shaped by relationships between these entities. Favoring higher-volume centers that can handle higher-risk organs could easily lead to more disparity."[109] Such disparities in access to organ transplants is in clear contradiction to the founding principles of the organ procurement and transplantation system, including the statutory requirement set forth in section 371(b)(3)(E) of the PHS Act, which states that an OPO shall have a system to allocate donated organs equitably among transplant patients according to established medical criteria. When an OPO provides an "open offer" to a transplant center, the most common form of allocation out of sequence, patients on other centers' lists are bypassed. Additionally, a transplant center can also bypass patients with higher ranking on the match run list on their own transplant program. One editorial published in the American Journal of Transplantation proposed that transplant centers bypass their own patients "to find an appropriate recipient for an

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[107] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

[108] Liyanage LN, Akizhanov D, Patel SS, Segev DL, Massie AB, Stewart DE, Gentry SE. Contemporary prevalence and practice patterns of out-of-sequence kidney allocation. Am J Transplant. 2025 Feb;25(2):343-354. doi: 10.1016/j.ajt.2024.08.016. Epub 2024 Aug 23. PMID: 39182614; PMCID: PMC11772121.

[109] Adler, Joel T. et al. Out-of-sequence allocation: a necessary innovation or a new inequity in transplantation? American Journal of Transplantation, Volume 25, Issue 2, 234 – 236.

organ that is perceived as higher risk. There is a transparency issue where this is occurring without the knowledge of patients being bypassed, which impedes them from informed decision making and, by extension, limits their autonomy."[110] Others ascribe different possible motivations for using allocation out of sequence in the form of "open offers," describing them as "remarkably efficient — officials choose a hospital and allow it to put the organ into any patient." This article described a particular occurrence of organ allocation out of sequence whereby an OPO offered an organ to the first two highest matches, both of whom declined, and "[t]he third patient never got a chance."[111] Rather than continuing down the organ match run list to the next potential recipient, the OPO gave an open offer to a medical center, meaning that only patients of that medical center would be eligible to receive the organ. The ultimate recipient of the organ was the 11th patient on the medical center's own list, a person who had been ranked as number 115 on the original match run list and who was "stable" and healthier than dozens of people higher on the original list. [112]

Some proponents of allocating organs out of sequence have suggested that its practice has the potential to reduce organ nonuse, particularly for lower-quality kidneys.[113] Expanding use has the potential of saving lives of those on the transplant waitlist. However, research has identified that in standardized numbers, an absolute percentage increase of OOS allocation by 12.8 percent was associated with a relative decrease of 2 percent in kidney nonuse. "Even with substantial increases in OOS allocation, the impact on nonuse rates is minimal. Furthermore, this analysis likely represents a best-case scenario, as it only captures successful OOS attempts."[114] The

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[110] Ethical implications of prioritizing utility at all costs: The rise of out-of-sequence transplants. Kulkarni, Sanjay et al. American Journal of Transplantation, Volume 25, Issue 2, 232 – 233.
[111] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[112] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[113] "Reforming Out-Of-Sequence Allocation: A Turning Point For Organ Transplant Policy" , Health Affairs, May 27, 2025. *https://www.healthaffairs.org/content/forefront/reforming-out-sequence-allocation-turning-point-organ-transplant-policy-1747919779003*.
[114] Joel T. Adler, David C. Cron, Arnold E. Kuk, Miko Yu, Sumit Mohan, S. Ali Husain, Layla Parast, Association between out-of-sequence allocation and deceased donor kidney nonuse across organ procurement organizations, American Journal of Transplantation, 2025, ISSN 1600-6135, *https://doi.org/10.1016/j.ajt.2025.02.005*.

February 2025 report from the New York Times found that "[s]ome procurement organizations complicate oversight by obscuring their open offers, according to current or former employees at 14 organizations. Many said they phoned doctors directly, so the details of open offers were not documented in the centralized computer system. Several said they logged an offer in the system only if the organ was successfully placed, making the practice look more effective. Others said they always entered "time constraints" as the reason for skipping patients, even if that was false."[115] As such, there is reason to believe that out of sequence organ allocation is even less effective at reducing organ nonuse than the initial data would indicate. This hypothesis is further substantiated by another study,[116] which found that despite significant variation in the use of allocation out of sequence across OPOs, from a low of 1.9 percent of transplanted kidneys in some OPOs and a 68.4 percent utilization of allocation out of sequence at a single OPO in December 2023, nonuse remained consistently high, suggesting that increases in allocation out of sequence does not uniformly improve kidney utilization.[117] This is likely connected to the fact that, based on analysis of more than 500,000 transplants performed since 2004, the New York Times found that in 2024, "37 percent of the kidneys allocated outside the normal process were scored as above-average."[118] While kidneys that are medically complex may be more challenging to place, OPOs are using allocation out of sequence for kidneys that are sought after and easy to place.

CMS is concerned that OPOs are using allocation out of sequence to mitigate the logistical challenges they face and minimize costs while potentially ignoring alternative strategies that may be more effective in minimizing organ nonuse and maximizing transplants. In the February 2025

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[115] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[116] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[117] Joel T. Adler, David C. Cron, Arnold E. Kuk, Miko Yu, Sumit Mohan, S. Ali Husain, Layla Parast, Association between out-of-sequence allocation and deceased donor kidney nonuse across organ procurement organizations, American Journal of Transplantation, 2025, ISSN 1600-6135, *https://doi.org/10.1016/j.ajt.2025.02.005*.
[118] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.

New York Times report,[119] one former OPO leader claimed that "open offers" are financially beneficial to OPOs, likely because speeding up allocation saves money on staffing, while the OPO is paid a pre-established set fee by the receiving hospital, regardless of what costs the OPO does or does not incur. This cost savings may be incentivizing OPOs to shorten the time between procurement and pursuit of an out of sequence "open offer" arrangement. The New York Times reported that one OPO began requiring the use of open offers whenever kidneys hit 12 hours outside a donor's body, which was then reduced to 8 hours, and then again to 6 hours. At another OPO, the New York Times reported that workers said that after five hours, they invited favored hospitals to identify their highest patient on the list for whom they would accept the kidney, and the "top offer won".[120] With proper storage, kidneys have a cold ischemic time of up to 48 hours, raising questions about whether OPOs are initiating match run list bypass procedures appropriately.

At one OPO, the New York Times reported[121] that "open offers" are used to steer organs to a single, preferred transplant program. The OPO contracts with senior leaders who work for that preferred transplant program as medical advisers for the OPO. The New York Times quoted a former OPO employee, who stated, "Sometimes, we wouldn't even pursue the organ unless they [the preferred transplant program] expressed interest".[122] According to this report, when skipping patients on the match run list, the OPO sent more organs to the preferred transplant program than to all other transplant programs combined. Moreover, the report stated that hospitals are competing to gain favor with OPO leaders, with one hospital administrator stating that she had negotiated over payments for organ transport. The administrator spoke on the condition of

[119] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[120] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[121] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.
[122] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February26, 2025.

anonymity purportedly due to a desire to avoid risking access to "open offers."[123] These preferential arrangements, which may include financial incentives, raise significant ethical concerns, as well as concerns about conflict of interest among OPO and transplant center employees and contractors. While close collaboration to understand transplant center needs and preferences to improve internal processes is important to a well-functioning organ procurement and transplant system, competing priorities and financial incentives may be prioritized above the needs of potential donor patients, donors, waitlist patients, and their families.

CMS is concerned that the proliferation of allocating organs out of the OPTN-defined sequence, thereby bypassing patients ranked higher on the match run list, and the use of "open offers" to a preferred transplant program rather than to a specific patient on the match run list will create inequities in the procurement and transplant system that erode public trust. As the New York Times summarized, "in more and more cases, the list is a lie."[124] Others[125,126] have echoed similar concerns regarding the lack of transparency and concerns regarding equity within the transplant system. "What happens to the patients who are passed over in favor of OOS recipients? Do they fall off the waitlist, are eventually transplanted, or die waiting?"[127] The New York Time report[128] sought to answer this concern, reporting that over the past 5 years, more than 1,200 people died after they got close to the top of a waiting list and were skipped nonetheless. While there is no guarantee that the offer would have been accepted or the organ would have been the right match, those patients were denied the opportunity to consider and explore the possibility of a transplant with that specific organ. In a March 2025 letter to CMS and HRSA,

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[123] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February26, 2025.
[124] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February26, 2025.
[125] Lara C. Pullen, PhD. "Out-of-sequence allocation: It is useful, but is it ethical?" The AJT Report Volume 25, Issue 3p451-453, March 2025.
[126] Reforming Out-Of-Sequence Allocation: A Turning Point For Organ Transplant Policy" Health Affairs, May 27, 2025." *https://www.healthaffairs.org/content/forefront/reforming-out-sequence-allocation-turning-point-organ-transplant-policy-1747919779003*.
[127] Lara C. Pullen, PhD. "Out-of-sequence allocation. It is useful, but is it ethical?" The AJT Report Volume 25, Issue 3p451-453, March 2025.
[128] Rosenthal, Brian M; Hansen, Mark; White, Jeremy. "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored" New York Times, February 26, 2025.

Senators Grassley and Wyden wrote, "Continued reports of unethical behavior within the organ donation system will undermine the willingness of Americans to give others the gift of life. Strengthening public trust in our nation's organ donation system is a matter of life and death."[129]

As previously described, CMS and HRSA have regulations in place that address organ allocation. Through our complementary oversight authorities, we closely collaborate to ensure appropriate enforcement of the existing regulations and are carefully examining this issue in terms of both OPO and transplant center actions. In August 2024 HRSA provided a Critical Comment letter [130] to the OPTN, noting the existence of applicable requirements of the National Organ Transplantation Act, the OPTN Final Rule, and OPTN Policies and the responsibilities of the OPTN Board of Directors to review reports of member non-compliance with OPTN requirements. In subsequent communications, HRSA directed the OPTN to produce a comprehensive remediation plan to address widespread and increasing allocation policy non-compliance in the form of allocation that is out of sequence. The OPTN delivered a draft plan in March 2025 and began implementation of next steps, including the creation of a standard analytic definition for allocation out of sequence and the publication of an allocation out of sequence web page.[131] In July 2025, following the ratification of a new OPTN Board of Directors, HRSA shared a detailed response to the OPTN's proposed plan, including guidelines for practical implementation. Throughout this process, HRSA has provided support and guidance to the OPTN and maintained close collaboration and alignment with CMS. Under this HRSA guidance, the OPTN has created an Allocation out of Sequence resource page[132] that can be used by OPOs and transplant programs to facilitate understanding of the issue and compliance with existing requirements.

Work is ongoing to address the issue of organs being allocated out of sequence to ensure

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[129] Grassley/Wyden letter to CMS, March 26, 2025. https://www.judiciary.senate.gov/imo/media/doc/grassley-wyden_to_cms_-_organ_allocation.pdf.
[130] HHS/HRSA Critical Comment Letter to OPTN, August 30, 2024. https://www.hrsa.gov/optn/policies-bylaws/optn-critical-comments-and-directives.
[131] https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aoos.
[132] https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aoos.

that OPOs and transplant centers are held accountable for meeting all statutory and regulatory requirements and expectations, and we will continue to focus on ways to collaboratively improve the system for all potential donor patients, donors, patients waiting on the transplant list, and their families. It is our goal to ensure a safe, transparent, and high-performing system that honors the precious gift of organ donation and assures public confidence in the system's integrity for all patients at all times.

C. Automated Electronic Referrals

The first step in the organ donation process is for the donor hospital to provide notification to their respective OPO of all deaths and imminent deaths in the hospital. This notification is essential in identifying all potential donors. Timely notification may make the difference in whether a potential donor is identified and whether there is sufficient time to complete the many steps for that person to become a donor where organs are procured for transplantation. Currently, there is no standard process for how this notification is conducted. The OPO Conditions for Coverage (CfCs) at § 486.322(a) and the hospital Conditions of Participation (CoPs) at § 482.45(a) require an agreement between the OPO and each donor hospital for this cooperation. The agreement describes the responsibilities of both the OPO and donor hospital. Hospitals are required to notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose deaths are imminent or who have died in the hospital. OPOs are required to determine medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, tissue and eye donation. The agreement must also include definitions of "timely referral" and "imminent death". However, the regulatory requirements do not specify the manner in how the notification and information are to be transmitted. We are therefore soliciting public comments on how to leverage technology to support automated referrals and how to provide necessary privacy and security for the information. We note that this comment solicitation is a continuation of our efforts to gain input from the public regarding the market of digital health products for Medicare beneficiaries as well

as the state of data interoperability and broader health technology infrastructure through the Health Technology Ecosystem Request for Information (90 FR 21034) published on May 16, 2025. We are committed to leveraging health technology to promote better health outcomes through improvements in organ donation.

CMS previously published a request for information (RFI) in December 2021 (CMS 3409-NC; 86 FR 68594) that solicited public comment on the donor referral process. The RFI inquired about clinical triggers, which staff should make referrals to OPOs, minimum information that should be shared, and clinical decision support protocols that assist in identifying potential donors. Additionally, the RFI solicited information on technological aspects related to this process. Specifically, the RFI requested information on the extent to which electronic referrals were being made, whether these leveraged the admission, discharge, and transfer elements in electronic medical record systems to transfer information, and if there were other ways for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate notification and information transfer. Since publication of the RFI in 2021, we acknowledge that there have been improvements in health technology and the widespread availability of interoperable EHRs. We therefore are seeking additional comments reflecting changes that may have occurred since 2021. Specifically, we are asking for comments, including relevant data, on the following:

- Specific technological aspects to implementing automated electronic referrals for hospitals and OPOs, including information on APIs, EHRs, and Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards, and implementation within the Trusted Exchange Framework and Common Agreement (TEFCA) framework.

- How and where should APIs for automated referrals nest within a broader framework of health IT infrastructure?

- How, and whether, the current electronic notification requirements for hospitals at § 482.24(d) could be leveraged to provide automated donor referrals?

- What existing uniform frameworks exist or can be modified to support information collection and sharing to enable automated referrals?

- What standards should be established to enable interoperability to support broad national adoption of electronic referrals?

- For hospitals and OPOs that are currently leveraging technology for automated referrals, what best practices can be shared?

We solicit comment from all interested entities and are particularly interested in information from EHR vendors on specific solutions to scale implementation nationally across various technology platforms. We also encourage families of organ donors, advocates, transplant recipients, OPOs, and hospitals to submit comments.

V. Collection of Information Requirements

Under the Paperwork Reduction Act 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 solicit public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

In analyzing the burden for ICRs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2024 National Occupational Employment and Wage Estimates, United States by the Bureau of Labor Statistics (BLS) at *https://www.bls.gov/oes/current/oes_nat.htm*. Based on this information, we have calculated the estimated adjusted hourly rates based upon the national mean salary for that position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation for these overhead and fringe benefit costs.

Table 1 presents the BLS occupation code and title, the associated OPO staff position in this regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits). In addition, throughout this analysis, any amount that results in a number ending with 0.50 or more will be rounded up to the next nearest dollar amount, and those that end with 0.49 or less will be rounded down to the next nearest dollar.

TABLE 1: Summary Information Of 2024 Estimated Mean Hourly And Adjusted Hourly Wages

Occupation Code	**BLS Occupation Title**	**Associated Position Title in this Proposed Rule**	**Mean Hourly Wage ($/hour)**	**Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)**
29-1210	Physicians	Medical Director	$130.92	$262
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	Organ Procurement Coordinator (OPC)	$47.32	$95
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Quality Manager; Administrator	$66.22	$132

A. ICRs Regarding Information Management (§ 486.330)

We propose new information management requirements for OPOs at § 486.330. This new provision would establish new documentation requirements specific to organs procured by OPOs and sent for research, including pancreata procured and sent for islet cell research. To meet this requirement, we anticipate OPOs would need to maintain records regarding the disposition of organs sent for research studies, including information identifying approval by an institutional review board (IRB) or other formal authorizing body, as appropriate, the research institution, and the principal investigator and contact information.

Estimating the number of organs procured by OPO per research study is complex because estimates vary depending on the study's design, objectives, and resources as well as the type of organ utilized. To estimate the burden for pancreata procured and sent for islet cell research, hereinafter referred to as IC-1(a), we use program data from the research institute, City of Hope. According to their research data, they have 15 OPOs participating in their research, with each OPO submitting on average 110 pancreata[133] per year. We use this data to estimate that on average there are a total of 1,650 pancreata submitted (110 × 15= 1,650) for islet cell research per year. Furthermore, according to CMS correspondence with a participating OPO, this OPO submitted a total of 783 pancreata to three different studies from 2021 to 2024, with an annual average of 196 pancreata submitted to 3 principal investigators. To comply with this requirement, this OPO would need to document 196 pancreata with the associated research study information. We assume an OPO's Organ Procurement Coordinator, at $95 per hour, will be responsible for this activity and will take 5 minutes (0.083 hours) to map each pancreas with its corresponding research study information. The total annual hourly burden for the 15 participating OPOs is estimated at 244 hours per year (0.083 hours × 196 responses × 15 OPOs), at a cost of $23,180 (244 hours × $95) or 16 hours per participating OPO (244 hours ÷ 15 OPOs)

[133] "Program Statistics." Integrated Islet Distribution Program, City of Hope, n.d., iidp.coh.org/Overview/Program-Statistics. Accessed 10 June 2025.

at a cost of $1,520 (16 hours × $95). The annualized burden for IC-1(a) for all 55 OPOs, over a 5 years period, would be 4 hours (244 hours ÷ 55 OPOs) at a cost of $421 ($23,180 ÷ 55 OPOs) per OPO.

Estimating the burden to other organs that are procured and used for research, such as kidneys, hearts, lungs, livers, intestines, and pancreata (used for research other than islet cell research), hereinafter referred to as IC-1(b), is more difficult because we do not have reliable data on which to base these estimates. In absence of data, we illustrate the upper bound of possible burden. We assume one (1) organ is procured and used for one (1) research study. According to data maintained by the Organ Procurement and Transplantation Network (OPTN)[134], as of June 4, 2025, there was an annual average of 5,631 organs submitted annually for research between 2022 and 2024. Additionally, recent research by the National Academies indicates that between 2013 and 2015, there was an annual average of 4,903 organs recovered and used for research programs. As we anticipate the number of pancreata used for islet cell research to return to historic levels, we assume the average number of all organs procured for research to be 5,267 per year ((4,903 + 5,631) ÷ 2 = 5,267)). Assuming an average of 5,267 organs per year, we anticipate that all 55 participating OPOs or respondents will submit a total of 5,267 responses per year. For IC-1(b), this results in annualized hourly burden, over a 5-year period, of 437 hours per year (5,267 responses × 0.083 hours per response, or 8 hours per OPO (437 hours ÷ 55 OPOs)). We assume the responses will be submitted by an OPO's Organ Procurement Coordinator, at an adjusted loaded hourly wage of $95. This results in an annualized hourly burden cost of $41,515 (437 hours x $95), or $760 per OPO ($95 x 8).

The annualized burden for IC-1, including IC-1(a) and IC-1(b) for all 55 OPOs, over a 5-year period, would be 681 burden hours (244 hours per year + 437 hours per year) at an

[134] Organ Procurement and Transplantation Network. "OPTN Data." U.S. Department of Health and Human Services, Health Resources and Services Administration, optn.transplant.hrsa.gov/data/. Accessed June 4,2025.

estimated annual cost of $64,695, or 12 hours (681 hours ÷ 55 OPOs) at a cost of $1,176 ($64,695 ÷ 55 OPOs) per OPO.

The information collection request under the OMB control number 0938-0688 will be revised and submitted to OMB for approval.

B. *ICRs Regarding Quality Assessment and Performance Improvement (QAPI) (§ 486.348)*

At § 486.348(e), we propose that each OPO must conduct an initial assessment of its policies and procedures regarding medically complex donors and organs to assess their performance with procuring these organs and getting them placed for transplantation. If opportunities to improve the OPO's performance are identified, it must establish or update its policies and procedures to improve its performance. After this initial assessment and the establishment of changes to its policies and procedures to improve its performance, each OPO must monitor its performance regarding medically complex donors and organs and review that data at least annually. When an OPO identifies opportunities for increasing its performance, it must update its policies and procedures to improve its performance. These activities are hereinafter referred to as IC-2.

Each OPO's burden in complying with this requirement will vary substantially. Based on our experience with OPOs, some OPOs are already actively pursuing medically complex donors and organs and performing well in this area. However, other OPOs appear to be more reluctant to pursue medically complex donors and organs for various reasons, such as the transplant programs refusing to accept these organs. For the purpose of assessing the burden for this requirement, we base our estimates on what we believe is the average OPO - an OPO that is not maximizing its opportunities with medically complex donors and organs and needs to make some changes to its policies and procedures to optimize its performance in this area.

All OPOs would need to conduct an initial assessment that includes a review of their statistics regarding medically complex donors and organs, including but not limited to, how many of these prospective donors or families of prospective donors gave consent, the organs

procured from these donors, and how many of these organs were transplanted. This assessment might also include other information, such as the willingness of local transplant centers to accept these organs and, if they are reluctant to take these organs, the outreach and educational efforts that might positively affect future acceptance rates. Complying with this requirement would likely require a manager responsible for quality (quality manager), who would need an average of 8 hours at an adjusted hourly loaded wage of $132 to gather the data and policies and procedures needed to assess the OPO's performance with medically complex donors and organs. We believe the quality manager would then need to meet with additional staff.

For purposes of determining an estimate, we believe the OPO's medical director, an administrator, and two organ procurement coordinators (OPCs) would spend about 4 hours each in meetings to review, analyze, and determine what, if any, changes are needed to be made to modify the OPO's policies and procedures to improve its performance in this area. This would also include drafting any changes and inserting them into the OPO's policies and procedures. We estimate for IC-2 the hourly burden for these activities to be 24 hours ((4 hours × 1 medical director) + (4 hours × 1 administrator) + (8 × 1 quality manager) + (4 hours each × 2 OPCs) = 24 hours))))) at an estimated cost of $3,392 ((4 hours × $262) + (4 hours × $132) + (8 hours × $132) + (8 hours × $95) =))). For all 55 OPOs, the burden would be 1,320 hours (55 OPOs × 24 at an estimated cost of $186,560 (55 OPOs × $3,392)).

For subsequent years, the lead quality manager would likely need less time to gather data on the OPO's performance with medically complex donors and organs, and on the OPO's current policies and procedures in this area. The meetings with the quality manager and the OPO's medical director, an administrator, and two OPCs should also require fewer resources because the OPO's performance and policies and procedures would have already had the initial assessment and changes made, if the OPO identified opportunities to improve its performance. We believe the necessary activities in subsequent years would require 11 hours ((2 hours × 1 medical director) + (2 hours × 1 administrator) + (3 hours × 1 quality manager) + (2 hours × 2

OPCs) = 11 hours))))) at a cost of $1,564 ((2 hours × $262) + (2 hours × $132) + (3 hours × $132) + (4 hours × $95))). In subsequent years, for all 55 OPOs, the burden would be 605 hours (11 hours × 55 OPOs) at an estimated cost of $86,020 (55 × $1,564).

The annualized burden for this requirement for all 55 OPOs, over a 5 years period, would be 748 burden hours ((1,320 hours in year 1 + 605 hours in year 2 + 605 hours in year 3 + 605 hours in year 4 + 605 hours in year 5) ÷ 5 years) at an estimated cost of $106,128 (($186,560 in year 1 + $86,020 in year 2 + $86,020 in year 3 + $86,020 in year 4 + $86,020 in year 5) ÷ 5 years), or 14 hours (748 hours ÷ 55 OPOs) at a cost of $1,930 ($106,128 ÷ 55 OPOs = $1,930) per OPO. The information collection request under the OMB control number 0938-0688 will be revised and submitted to OMB for approval.

Collection of Information Summary

The annualized burden for all IC proposed, including IC-1(a), IC-1(b), and IC-2, for all 55 OPOs, over a 5 years period, would be 1,429 burden hours (((681 + 1,320 hours in year 1) + (681 + 605 hours in year 2) + (681 + 605 hours in year 3) + (681 + 605 hours in year 4 + (681 + 605 hours in year 5)) ÷ 5 years) at an estimated annual cost of $170,825 ((($64,697+ $186,560 in year 1) ($64,697+ $86,020 in year 2) + (($64,697+ $86,020 in year 3) + (($64,697+ $86,020 in year 4) ($64,697+ $86,020 in year 5)) ÷ 5 years = $170,825), or 26 hours (1,429 hours ÷ 55 OPOs= 26 hours) at a cost of $3,106 ($170,825÷ 55 OPOs = $3,106) per OPO, see tables

TABLE 2: Annualized Burden Summary

Information Collection (IC)	Annual Burden Hours	Annual Cost	Hours per OPO	Cost per OPO
IC-1(a) - Pancreata for Islet Cell Research	244	$23,182	4	$421

IC-1(b) - Other Organs for Research	437	$41,515	8	$755
IC-2 - QAPI Assessment	748	$106,128	14	$1,930
Total All ICs	**1,429**	**$170,825**	**26**	**$3,106**

If you comment on these ICRs, 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 [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

VI. 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.

VII. Regulatory Impact Analysis

A. Statement of Need

More than 100,00 people are currently waiting for an organ transplant and demand for organs continues to exceed supply.[135] OPOs play a critical role in ensuring that as many organs as possible reach patients who need them. In 2019, President Trump issued Executive Order 13879 “Advancing American Kidney Health,” directing the Secretary to enhance the

[135] Organ Donation Statistics. *https://www.organdonor.gov/learn/organ-donation-statistics*. Accessed on April 29, 2025.

procurement and utilization of organs available through deceased donation and to establish more transparent, reliable, and enforceable metrics for evaluating an OPO's performance. In response, CMS published the December 2020 final rule, which among other changes, established new performance measures and a three-tier ranking system for OPOs. The December 2020 final rule created a baseline implementation framework with annual costs of $126.7 million.

Since the December 2020 final rule was published, CMS has received many questions from OPOs asking for clarification about how the new system works. This proposed rule clarifies procedures for competitions, managing multiple service areas, ending agreements, handling appeals, and other operational details. We estimate that this proposed rule will cost an estimated $19.1 million in the first year and $6.3 million annually thereafter.

We also estimate that it will result in $884,000 in annual benefits due to reduced regulatory uncertainty and compliance burden, as well as a one-time benefit of $300,000 due to increased operational flexibility for multi-DSA operations.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 "Regulatory Planning and Review," Executive Order 13132 "Federalism," Executive Order 13563 "Improving Regulation and Regulatory Review," Executive Order 14192 "Unleashing Prosperity Through Deregulation," the Regulatory Flexibility Act, section 1102(b) of the Social Security Act, and section 202 of the Unfunded Mandates Reform Act of 1995.

Executive Orders 12866 and 13563 require agencies to assess all costs and benefits of regulatory alternatives and, when regulation is necessary, to select approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the

environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities. The Office of Management and Budget has determined this rulemaking is significant under Executive Order 12866.

This proposed rule builds on the December 2020 final rule, which established new OPO performance measures and re-certification processes, specifically for the 2022-2026 certification period, and onwards. The December 2020 rule created baseline implementation costs of $126.7 million annually, comprising: (1) CMS administrative costs of $1.0 million annually for oversight, technical assistance, appeals processing, and additional FTE to support system implementation; (2) OPO management transition costs of $2.9 million annually for incumbent OPOs transitioning to new performance standards and administrative and operational adjustments; and (3) OPO operational costs of $122.8 million annually associated with procurement of additional organs and enhanced performance activities under new outcome measures.

As outlined in Table 3, this proposed rule would cost an estimated $19.1 million in Year 1 and $6.3 million in subsequent years. Year 1 costs include approximately $17.9 million for OPOs and $1.2 million for CMS. Recurring annual costs include approximately $6.0 million for OPOs and $331,000 for CMS. These incremental costs reflect clarifications and refinements to operational and administrative requirements from the December 2020 final rule rather than fundamental system restructuring. In the upcoming sections, we discuss each of the expected impacts in detail.

TABLE 3: Proposed Incremental Costs

Cost Component	Proposed Rule (2027-2031) Year 1	Proposed Rule (2027-2031) Recurring Annual
CMS Administrative	$1.20	$0.33

OPO Costs	$17.90	$6.00
Total	**$19.10**	**$6.33**

1. Anticipated Incremental Effects (Costs and Benefits)

a. Overview

This section provides a detailed analysis of the costs imposed by the 11 proposed provisions in this proposed rule. As established in Section B and detailed below in Table 4, the total estimated costs are approximately $19.1 million in Year 1 and $6.3 million in recurring annual costs beyond Year 1. Year 1 costs comprise approximately $17.9 million for OPOs and $1.2 million for CMS. Recurring annual costs comprise approximately $6 million for OPOs and $331,000 for CMS. The cost estimates reflect detailed analysis of the marginal effects of this proposal, distinguishing between one-time implementation costs and recurring operational costs, and incorporating actual performance data showing 26 DSAs opening for competition during the re-certification cycle. For a summary of costs by provision category, see Table 4.

TABLE 4: Summary of Incremental Annual Costs by Provision Category

Provision Number	Provision	OPO Costs ($k)	CMS Costs ($k)	Total $k	Cost Type
1	Definition Changes (§ 486.302)	151	0	151	One-Time (Year 1)
2	Requirements for Certification (§ 486.303)	0	0	0	No Costs
3	Designation of one OPO for each donation service area (§ 486.308)	0	55	55	Annual Costs
4	OPO designation to more than one service area (§ 486.309)	5,475	13	5,488	One-Time (Year 1)
4		5000	41	5,041	Annual Costs
5	Non-renewal/De-certification (§§ 486.311, 486.312)	25	13	38	One-Time
6	Appeals (§ 486.314)	25	50	75	One-Time
6		29	69	98	Annual Costs
7	Re-certification and Competition (§ 486.316)	4942	624	5566	One-Time
8	Outcome Measures (§ 486.318)	275	50	325	One-Time
8		388	166	554	Annual Costs
9	Human Resources (§ 486.326)	970	50	1020	One-Time
9		584	0	584	Annual Costs

Provision Number	Provision	OPO Costs ($k)	CMS Costs ($k)	Total $k	Cost Type
10	Information Management (§ 486.330)	0	0	0	No Costs
11	QAPI (§ 486.348)	0	50	50	One-Time
12	Conforming Changes (§§ 486.322, 486.324, 486.360)	44	25	69	One Time Costs
	TOTAL ONE-TIME COSTS (Year 1)	$11,907	$875	$12,782	
	TOTAL RECURRING ANNUAL COSTS	$6,001	$331	$6,332	
	YEAR 1 TOTAL (One-time + Recurring)	$17,908	$1,206	$19,114	

b. Data Sources and Key Assumptions

Our analysis relies on data from several sources and incorporates key assumptions about OPO operations and regulatory implementation. Labor costs are based on Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates, adjusted by a factor of 2.0 (100 percent) for fringe benefits and overhead. Performance data reflects current CMS OPO performance data showing 10 Tier 3 OPOs and 16 Tier 2 OPOs based on current tier assignments. Baseline costs are established by the December 2020 final rule (CMS-3380-F, 85 FR 77898), which documented annual costs of $126.7 million. The weighted average hourly rate of $177 for OPO staff reflects a mix of executive directors, medical directors, quality managers, and administrative personnel. The CMS GS-14 hourly rate of $138 reflects staff conducting oversight, policy development, and technical assistance activities.

c. Incremental Costs

This subsection presents incremental costs by regulatory provision, distinguishing between one-time implementation costs (Year 1) and recurring annual costs. Estimates are provided separately for OPOs and CMS.

(1) Definition Changes (§ 486.302)

This proposed rule would revise definitions at § 486.302 to clarify terminology used throughout the OPO conditions for coverage. The proposed changes include revising the definition of "adverse event" by removing specific examples from the definition and relocating them to QAPI requirements (§ 486.348(c)) for greater flexibility; clarifying the definition of "donor" to specify that individuals whose pancreas is used for islet cell research are included in the definition for the donation rate outcome measure; removing pancreata used for research that does not include transplant into a patient on the OPTN waitlist from the definition of "organ" so that research activity no longer counts as a transplant for the transplantation rate outcome measure; establishing a new definition for "medically complex donor" for donors whose medical history requires special considerations (including DCD donors and those with elevated KDPI scores); defining "medically complex organ" as organs procured from medically complex donors; and creating a new definition for "unsound medical practices" to describe practices that create imminent threats to patient health and safety. These clarifications address stakeholder inquiries received since publication of the December 2020 final rule and are intended to ensure consistent interpretation and application of regulatory requirements across all OPOs.

The proposed definitional changes would result in one-time implementation costs of $151,250 for OPOs. While the definition changes are not explicitly required to trigger operational modifications, they may lead to training costs, documentation updates, and system modifications. We estimate each OPO will spend 22 hours at $125 (22 hours x $125[136] = $2,750) in first year costs only. The cost to industry at 55 OPOs × $2,750= $151,250. We do not anticipate any costs for CMS.

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[136] We estimate that each OPO will spend approximately 20 hours in Year 1 to complete the definitions-related task, at a weighted average hourly wage rate of $125, resulting in a cost of $5,503 per OPO. This weighted estimate is based on the following staff involvement: (1) Medical Director (BLS Occupation Code 29-1210, Physicians) at a loaded hourly wage of $262 for 2.5 hours ($1,310); (2) Organ Procurement Coordinator (BLS Occupation Code 29-1141, Registered Nurses) at $95 per hour for 12.5 hours ($2,375); and (3) Quality Manager/Administrator (BLS Occupation Code 11-9111, Medical and Health Services Managers) at $132 per hour for 5 hours ($1,320). The weighted average hourly rate is calculated as: [($262 × 2.4) + ($95 × 12.5) + ($132 × 5)] ÷ 20 hours = $125 per hour. Loaded hourly wages include base wages plus 100% adjustment for fringe benefits and overhead costs, consistent with the methodology used in the December 2020 final rule (85 FR 77898). Wage data are sourced from the U.S. Bureau of Labor Statistics Occupational Employment and Wage Statistics.

(2) Requirements for Certification (§ 486.303)

This proposed rule would remove the requirement at § 486.303(e) that a certified OPO to have been "re-certified as an OPO from January 1, 2002, through December 31, 2005", to align with our reinterpretation of the Certification Act. This change would eliminate a regulatory barrier that prevents the Secretary from implementing a process for the certification of new OPOs. The proposed removal of § 486.303(e) is a technical deletion of obsolete regulatory text that does not create direct, quantifiable costs because the deletion imposes no new compliance obligations on existing OPOs, no operational or administrative changes are required at this time, and OPOs will continue to operate under existing certification requirements. We acknowledge, however, that this change has potential future implications. By removing the regulatory barrier that previously prevented new OPO market entrants, this proposal would create the legal foundation for CMS to certify new OPOs in the future. We anticipate addressing the certification process for new OPOs in future rulemaking, at which time we will fully analyze the cost impacts of establishing a new OPO certification process, potential competitive effects on existing OPOs, and administrative costs to CMS for evaluating and certifying new entities.

(3) Designation of one OPO for each donation service area (§ 486.308)

This proposed rule would clarify the process for designating OPOs to donation service areas (DSAs). The proposed changes (1) clarify the normal designation period and when CMS may adjust the length of the period; (2) specify the circumstances that trigger a DSA to become available for competition; (3) establish criteria for successor selection when insufficient time exists for a full competition process; and (4) clarifies designation periods for newly acquired DSAs.

The clarifications in § 486.308 primarily affect CMS administrative processes and do not impose direct costs on OPOs. These provisions work in tandem with other requirements to establish the framework for when competitions occur and how designation periods are

determined, but do not require OPOs to undertake new operational activities beyond what was established in the December 2020 final rule baseline.

The December 2020 final rule (85 FR 77898) established baseline CMS administrative costs of $1.0 million annually, which included competition processing. The proposed changes in § 486.308 may require an additional 400 hours of GS-14 staff time annually, at an estimated cost of $55,000[137], for activities including: enhanced oversight of competition triggers and processes; successor selection coordination when insufficient time exists for full competition; re-certification cycle actions and designation period management.

(4) OPO designation to more than one service area (§ 486.309)

This proposed rule would establish a new framework allowing a single OPO to be designated to serve multiple Designated Service Areas (DSAs). Section 486.309 addresses: (1) the circumstances under which an OPO may be designated to multiple DSAs (following competition, change in ownership/control, or assignment by CMS); (2) OPO flexibility to consolidate or maintain separate DSAs; and (3) performance accountability when an OPO manages multiple DSAs, including the ability to remove designation to a tier 3 DSA without de-certifying the OPO.

We estimate that no more than 10 OPOs will expand to serve multiple donation service areas (DSAs) following implementation of the December 2020 final rule's performance standards. Each OPO serving multiple DSAs would incur approximately $500,000 in additional annual costs, resulting in an industry-wide impact of $5 million annually. These costs include coordination activities ($780,000), travel and logistics ($960,000), IT infrastructure ($150,000), additional administrative staff ($520,000), hospital relationship building ($531,600), enhanced quality oversight ($368,000), satellite office operations ($500,000), legal and compliance ($300,000), marketing and community outreach ($400,000), and operational contingency

[137] Cost Methodology: Staff time of 400 hours annually at a GS-14, Step 5, position, at a loaded hourly rate of $138 (includes 100% markup for fringe benefits and overhead). Calculation: 400 hours × $137.74/hour = $55.096 (rounded to $55,000).

($490,400). Year 1 costs would be approximately $5.45 million due to one-time IT system upgrades ($300,000) and training expenses ($152,000).

TABLE 5: Cost Components for Multi-DSA Operations[138]

Component	Annual Cost	Calculation Basis
Coordination meetings	$780,000	52 weekly meetings × 6 staff × 1 hour × $125/hour × 10 OPOs
Travel and logistics	$960,000	Monthly travel: 4 staff × 12 trips × $1,200/trip × 10 OPOs
IT infrastructure	$150,000	Annual licensing/maintenance: $15,000/OPO × 10 OPOs
Additional administrative staff	$520,000	20 hours/week × 52 weeks × $50/hour × 10 OPOs
Hospital relationship building	$531,600	Executive Director (100 hrs × $132) + Medical Director (80 hrs × $262) + Coordinators (200 hrs × $95) × 10 OPOs
Enhanced quality oversight	$368,000	Quality Manager (150 hrs × $132) + Data Analyst (200 hrs × $85) × 10 OPOs
Satellite office operations	$500,000	$50,000/OPO × 10 OPOs for facility rental and operations
Legal and compliance	$300,000	$30,000/OPO × 10 OPOs
Marketing and community outreach	$400,000	$40,000/OPO × 10 OPOs
Operational contingency	$490,400	Buffer for unexpected costs
Total Annual Recurring	$5,000,000	

The December 2020 final rule (85 FR 77898) established baseline CMS administrative costs of $1.0 million annually, which included competition processing. The proposed changes may

[138] Travel cost estimates based on GSA FY 2025 Per Diem Rates (*https://www.gsa.gov/travel/plan-book/per-diem-rates)* and Bureau of Transportation Statistics average domestic airfare. IT costs based on market research of healthcare data management systems. All staff costs use BLS wage data *(https://www.bls.gov/oes/*) with 100% loading factor consistent with December 2020 final rule methodology (85 FR 77898). CMS costs based on U.S. Office of Personnel Management, 2025 General Schedule (GS) Salary Tables (*https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/*).

require an additional 300 hours of GS-14 staff time annually, at an estimated cost of $41,000[139]. Activities include additional complexity around: oversight of multi-DSA designations, successor selection coordination when necessary, and re-certification actions.

(5) Non-renewal of Agreement (§ 486.311) and De-certification (§ 486.312)

This proposed rule would revise the regulatory framework to distinguish between non-renewal of agreements and de-certification of OPOs. The December 2020 final rule established a three-tier system for OPO re-certification but did not address the procedural requirements between different tier assignments and how they impact OPO agreements.

The newly created non-renewal section (§ 486.311) is drafted specifically to distinguish between non-renewal of an OPO's agreement and de-certification (§ 486.312). Prior to the December 2020 final rule, CMS treated all agreement terminations as de-certifications, including non-renewals. This proposal creates a distinction between non-renewal of an agreement (due to voluntary termination or a tier 2 OPO no longer being designated to a DSA) and involuntary termination that results in de-certification. The proposal also allows tier 2 OPOs that are no longer designated to a DSA to remain certified for a period of time without being designated to any DSA. These OPOs may be designated to a DSA during this period if certain circumstances enable this to occur, such as a subsequent competition where the OPO is successful. Additionally, the proposal includes notification requirements, including 90-day advance notice for non-renewal with specific content requirements covering reasons, end dates, and public notice procedures consistent with what currently exists at § 486.312.

The revised de-certification framework (§ 486.312) explicitly categorizes four distinct de-certification pathways due to involuntary termination of an OPO's agreement: non-compliance with process performance measures; all DSAs are assigned to tier 3 in the final assessment period; tier 2 OPOs that are not designated to any DSA and have no performance

139 Cost Methodology: Staff time of 300 hours annually at a GS-14, Step 5, position, at a loaded hourly rate of $138 (includes 100% markup for fringe benefits and overhead). Calculation: 300 hours × $137.74/hour = $41,322 (rounded to $41,000).

data at the end of a re-certification cycle; and urgent need/immediate de-certification. A related proposal at § 486.316 also establishes new provisions for removing designations to specific Tier 3 DSAs without full de-certification when an OPO manages multiple DSAs. Furthermore, the framework creates clear distinctions between situations with appeal rights (§ 486.312; de-certification) and without (§ 486.311; non-renewal after lost competition, voluntary termination).

The proposed revisions enhance clarity for multi-DSA operations, establish differentiated notice periods (90 days for standard cases; 3 days for urgent situations), and provide more detailed procedural requirements for non-renewal and de-certification processes. Since the proposed revisions involve clarification rather than fundamental operational changes we expect that they would result in minimal incremental costs. We anticipate OPOs will update internal policies to reflect differentiated notice periods (90 days standard, 3 days urgent), revise documentation for multi-DSA operational scenarios, revise internal process guides, and train staff on new appeals timelines. We estimate each OPO would spend approximately 2.5 hours on these tasks at a weighted average hourly rate of $177, resulting in a cost of $443 per OPO. The cost to all OPOs is $25,000 (55 OPOs x $443= $24,365, rounded to $25,000). We estimate CMS would spend 91 hours at $138 (91 hours x $138 = $12,558, rounded to $13,000) in first year costs only. CMS incremental activities include oversight preparation, system updating, staff training and policy development and documentation.

(6) Appeals (§ 486.314)

This proposed rule would establish changes to the OPO appeals process that include the creation of new appeal categories, formalize the CMS Administrator review process, establish remand authority, and significantly modify timelines throughout the appeals process.

OPOs would be able to appeal the loss of a single underperforming service area without facing full removal from the program. The proposal codifies a discretionary review stage with the CMS Administrator having 30 calendar days to elect review and 45 calendar days to render a decision, adding a process for a new level of administrative review. New remand authority

allows the Administrator to send appeals back to CMS for redetermination, creating additional processing requirements. The proposal also makes timeline modifications, including changing the reconsideration request period from 15 business days to 20 calendar days, the CMS reconsideration decision period from 10 business days to 15 calendar days, the request for hearing period from 40 business days to 15 calendar days (a 62 percent reduction), and the hearing officer decision period from 20 business days to 90 calendar days (a 350 percent increase). Additionally, the proposal explicitly codifies the preponderance of evidence standard as the burden of proof and establishes procedures for appeals during emergency de-certifications.

We estimate a one-time Year 1 costs of $25,000 for initial legal review and policy updates. We also expect that OPOs would spend 3 hours annually on compliance costs. Cost components include legal and compliance review requiring 1.5 hours per OPO for understanding new appeal pathways, Administrator review procedures, remand authority, and burden of proof requirements. Policy documentation updates would require 1 hour per OPO for revising internal procedures to reflect new appeal categories, timelines, and Administrator review stage. Staff training would require an additional 0.5 hours per OPO for training leadership and legal staff on compressed timelines, particularly the 15-day hearing request deadline, and new procedural requirements. The recurring annual cost calculation is 3 hours × $177/hr × 55 OPOs = $29,205 (rounded to $29,000). This results in a total Year 1 cost of $54,000 and recurring annual costs of $29,000.

For CMS, we estimate 360 hours at $138 GS-14 hourly rate (360 hours × $138 = $49,680, rounded to $50,000) for Year 1 implementation costs. These one-time costs cover policy documentation and guidance development on Administrator review procedures requiring 120 hours, system updates to track new appeal types and Administrator review stage requiring 100 hours, staff training on new timelines, remand authority, and procedural requirements requiring 80 hours, and development of Administrator review protocols and templates requiring 60 hours.

CMS would incur new ongoing administrative costs because the formalized Administrator review process and new appeal categories create fundamentally new oversight responsibilities. We estimate 500 hours annually at $138 GS-14 hourly rate ($69,000) for ongoing activities. Administrator review processing would require 200 hours annually for preparing cases for Administrator review over 30 days per case, coordinating written arguments from parties, and Administrator decision-making and documentation over 45 days per case, with an estimated 3-5 appeals annually reaching the Administrator review stage. Extended hearing officer support would require 100 hours annually for additional time needed for the 90-day decision period versus the previous 20-day period, post-hearing brief processing and administrative record development, with an estimated 3-5 hearings annually. Remand processing would require 100 hours for processing remanded appeals, conducting redeterminations per Administrator instructions, and developing new initial determinations. New appeal category processing would require 50 hours annually for processing appeals for designation removal without de-certification, distinguishing between de-certification and designation removal appeals, and coordinating with multi-DSA oversight activities. Technical assistance and guidance would require 500 hours annually for responding to OPO inquiries about new procedures, providing guidance on compressed timelines and Administrator review, and clarifying burden of proof and scope of review requirements.

These costs reflect genuine new administrative requirements for the formalized multi-stage appeals process with Administrator review, extended hearing officer timelines, and new appeals.

(7) Re-certification and Competition (§ 486.316)

The proposed changes to re-certification and competition processes would establish substantive modifications to how OPOs are evaluated and designated to service areas under the multi-DSA framework. The proposed changes create new evaluation pathways for OPOs managing multiple service areas, establish separate tier assignments for each DSA, clarify

competition eligibility for OPOs subject to non-renewal, and codify detailed transition requirements between incumbent and successor OPOs.

First, the proposed rule establishes separate outcome measure evaluation for each DSA when an OPO manages multiple service areas, while maintaining unified process performance measure evaluation across all DSAs. Second, it creates new re-certification pathways based on tier combinations across multiple DSAs, including scenarios where an OPO retains some DSAs while losing others. Third, it establishes competition eligibility for OPOs that lost competitions but remain certified during the 4-year re-certification period. Fourth, it provides detailed discussion of the four selection criteria used in competitions, including how CMS weighs performance differences, continuous improvement, barrier identification, and geographic proximity. Fifth, it codifies formal transition requirements for incumbent and successor OPOs, including mandatory transition plans and periodic reporting.

Based on current performance data showing 10 Tier 3 OPOs and 16 Tier 2 OPOs, we estimate that 26 DSAs would be opened for competition during the re-certification cycle. We estimate that approximately 35 to 40 OPOs would participate in competitions, with an average of 3 to 5 OPOs competing for each open DSA. This results in approximately 104 (26 DSAs × 4 OPOs per DSA) total competition applications across the cycle. Each competing OPO would spend approximately 200 hours preparing competition applications at a weighted average hourly rate of $177, resulting in a cost of $35,400 per application. Competition preparation activities include comprehensive performance data compilation and analysis requiring 60 hours, barrier identification and documentation requiring 50 hours, strategic planning and application development requiring 40 hours, legal review and compliance verification requiring 30 hours, and executive review and submission requiring 20 hours. With 104 total applications, the total annual OPO cost is $3,681,600 (104 applications × $35,400/application), rounded to $3,682,000. Additionally, we estimate one-time Year 1 costs of $1,260,000 (55 OPOs × 130 hours times ×

$177/hr) for comprehensive legal review of new competition criteria, development of competition strategy frameworks, and staff training on multi-DSA evaluation scenarios.

For CMS, we estimate 360 hours at $138 GS-14 hourly rate for Year 1 implementation costs totaling $49,680, rounded to $50,000. These one-time costs cover policy documentation and guidance development on multi-DSA competition scenarios requiring 120 hours, system updates to track separate tier assignments per DSA requiring 100 hours, staff training on new selection criteria application and transition requirements requiring 80 hours, and development of transition plan templates and reporting protocols requiring 60 hours. CMS would incur new ongoing administrative costs that were not included in the 2020 baseline because the multi-DSA evaluation framework and formalized transition requirements create fundamentally new oversight responsibilities.

We also estimate an additional one-time burden of 4,160 hours at $138 GS-14 hourly rate totaling $574,080, rounded to $574,000 for additional activities related to the competition.

Competition process administration would require 2,600 hours for managing 26 competitions with multiple DSAs per OPO, evaluating tier combinations across competing OPOs, applying selection criteria with discretion for performance differences and improvement trajectories, and processing approximately 104 competition applications. Transition oversight and verification would require 1,040 hours for reviewing and approving 26 incumbent OPO transition plans, monitoring successor OPO periodic progress reports, verifying completion of transitions within required timeframes, and ensuring continuity of organ procurement activities during transitions. Technical assistance and guidance would require 520 hours at a cost of $71,760 for responding to increased OPO inquiries about competition criteria application given the substantial number of competitions, providing guidance on multi-DSA competition strategies, clarifying selection criteria weighting and discretion, and assisting with transition plan development and reporting requirements.

(8) Outcome Measures (§ 486.318)

The proposed rule would create new evaluation pathways for OPOs managing multiple service areas to permit evaluating each DSA separately on the outcome measures as well as establishing different accountability timelines based on how a new DSA is acquired, distinguishing between accountability for QAPI purposes versus re-certification purposes.

The proposed rule introduces several new elements compared to the 2020 baseline. First, it would redesignate and remove obsolete outcome measure provisions from paragraphs (a) through (c) that expired on July 31, 2022, and renumbers current paragraphs (d) through (f) as paragraphs (a) through (c). Second, it would systematically replace references to evaluating OPOs with references to evaluating DSAs throughout the regulations to accommodate multi-DSA operations. Third, it would establish a two-track accountability system for newly acquired DSAs with immediate accountability once 12 months of data are available for mergers and change of ownership situations, and delayed accountability until the final assessment period of the following agreement cycle for DSAs acquired through competition or CMS assignment. Fourth, it would clarify separate QAPI accountability timelines that begin once 12 months of data are available regardless of acquisition method.

We estimate each OPO would spend approximately 40 hours annually at a weighted average hourly rate of $177 to understand and implement the new accountability timelines, update internal tracking systems to monitor performance separately for each DSA, revise QAPI programs to incorporate the two-track accountability framework, and train staff on the distinctions between merger-based and competition-based acquisition timelines. The total cost to OPOs is $388,080 (55 OPOs times 40 hours times $177), rounded to $388,000 for recurring costs. Additionally, we estimate one-time Year 1 costs of $275,000 for comprehensive legal review of new accountability provisions, development of multi-DSA tracking frameworks, system modifications to monitor separate DSA performance, and staff training on the new evaluation structure, calculated as 55 OPOs x 28 hours x $177 per hour.

For CMS, we estimate 360 hours at $138 GS-14 hourly rate for Year 1 implementation costs totaling $49,680, rounded to $50,000. These one-time costs cover policy documentation and guidance development on multi-DSA evaluation scenarios, system updates to track separate DSA performance and different accountability, staff training on applying different accountability rules based on acquisition methods, and development of templates for tracking OPOs during extended accountability periods. CMS would incur new ongoing administrative costs that were not included in the 2020 baseline because the multi-DSA evaluation framework and differentiated accountability timelines create fundamentally new oversight responsibilities. We estimate 1,200 hours annually at $138 GS-14 hourly rate totaling $165,600, rounded to $166,000 for ongoing activities that include monitoring separate outcomes measure performance for each DSA when an OPO manages multiple DSAs and tracking which DSAs are subject to immediate accountability versus delayed accountability, and maintaining performance data across multiple re-certification cycles for DSAs in extended accountability periods.

(9) Human Resources (§ 486.326)

The proposed changes to human resources would establish a new licensure requirement for all personnel performing clinical duties. The proposed changes create a new standard requiring that all personnel performing clinical duties must be legally authorized through licensure, certification, or registration in accordance with applicable Federal, State, and local laws, must act only within the scope of their credentials, and must maintain current credentials at all times. The proposal also makes a conforming change to the medical director requirement to accommodate multi-service area operations by changing "service area" to "service areas."

The proposed rule introduces new elements compared to the 2020 baseline. First, it establishes a new standard at proposed § 486.326(e) requiring licensure, certification, or registration for all clinical personnel (collectively referred to as licensure). Second, it requires that clinical personnel act only within the scope of their licensure, creating new compliance monitoring obligations. Third, it requires that licensure be kept current at all times, necessitating

ongoing tracking and verification systems. Fourth, it updates the medical director requirement to reference "one of the OPO's service areas" rather than "the OPO's service area" to accommodate multi-DSA operations.

We estimate each OPO would spend approximately 60 hours annually beyond the collection of information burden at a weighted average hourly rate of $177 for licensure verification and tracking. Specifically, we estimate that it would take 20 hours per OPO to verify that all clinical staff have appropriate licensures, certifications, or registrations and to establish and maintain systems to track licensure expiration dates and renewal requirements. We estimate a burden of 15 hours per OPO to update policies and procedures to incorporate licensure requirements for all clinical positions, develop job descriptions that specify required licensure for each clinical role, establish procedures for verifying licensure during hiring and ongoing employment, and create protocols for addressing situations where staff licensure lapse or are at risk of lapsing. Staff training and education would require 12 hours per OPO for training human resources staff on new licensure verification requirements, educating hiring managers on licensure requirements for clinical positions, and conducting leadership briefings on compliance implications and risk management. Recruitment and hiring process modifications would require 8 hours per OPO for updating recruitment materials to specify licensure requirements, modifying application and screening processes to verify licensure, and developing onboarding procedures that include licensure verification and tracking. Compliance monitoring and documentation would require 5 hours per OPO for establishing ongoing monitoring systems for licensure expiration and renewal, creating audit trails for CMS survey preparation, developing reporting mechanisms for licensure compliance status, and implementing corrective action procedures for licensure lapses. The total cost to OPOs for operational activities is $584,100 (55 OPOs times 60 hours times $177), rounded to $584,000 for recurring costs. Additionally, we estimate one-time Year 1 costs of $970,000 for potential costs for current staff to obtain required licensure if they do not already have it, calculated as 55 OPOs times 100 hours times $177 per hour. We note that

this estimate assumes that current staff can be trained /certified to meet the requirements rather than OPOs hiring new employees with additional certifications that command higher salaries.

For CMS, we estimate 360 hours at $138 GS-14 hourly rate for Year 1 implementation costs totaling $49,680, rounded to $50,000. These one-time costs cover policy documentation and guidance development on licensure requirements for clinical personnel requiring 120 hours, survey protocol updates to incorporate licensure verification and scope of practice review requiring 100 hours, staff training on reviewing licensure documentation and identifying scope of practice violations requiring 80 hours, and development of technical assistance materials for OPOs on credential requirements and verification procedures requiring 60 hours.

(10) Information Management (§ 486.330)

The proposed changes to information management would establish new documentation requirements for organs procured and sent for research, including pancreata used for islet cell research. The proposed changes create new recordkeeping requirements for all organs sent for research, establish specific documentation standards including IRB approval (as applicable), research institution identification, principal investigator information, and study contact details, and enable CMS verification of research disposition claims through survey processes and validation efforts.

The proposed rule introduces new elements compared to the 2020 baseline. First, it expands the scope of § 486.330(b) from documenting only organs recovered for transplantation to also documenting organs recovered and sent for research. Second, it establishes four specific documentation requirements for research organs including IRB or formal authorizing body approval, as appropriate, research institution identification, principal investigator identification, and study contact information. Third, it creates verification mechanisms through CMS survey processes to review OPO organ disposition records and conduct validation efforts to confirm accuracy. Fourth, it addresses data integrity concerns related to the 250 percent increase in pancreata reported for research between 2020 and 2024 despite declining clinical trial activity.

This cost is included as a cost in the collection of information section at $64,695 for all OPOs combined per year.

(11) Quality Assessment and Performance Improvement (QAPI) (§ 486.348).

The proposed changes to QAPI would establish new requirements for tracking adverse events and monitoring medically complex organ performance. The proposed changes expand adverse event categories to include six specific examples with detailed documentation requirements, create new tracking requirements for organs lost or delayed in transit and organs arriving in unsuitable condition, establish comprehensive evaluation and management deviation tracking, and create an entirely new performance monitoring framework for medically complex donors and organs requiring initial assessment, annual performance review, policy and procedure updates, and continuous improvement activities.

The proposed rule introduces new elements compared to the 2020 baseline. First, it moves adverse event examples from the definitions section to the QAPI section and expands them from three to six categories including transmission of infectious or communicable diseases or malignancies, avoidable loss of medically suitable potential donors, deviations from standards of practice in evaluation and management, delivery of wrong organ or blood type mismatch, organs lost or delayed in transit, and organs arriving in unsuitable condition. Second, it establishes new documentation and investigation requirements for each adverse event category with specific focus on addressing the 130 percent increase in zero organ donors between 2019 and 2023 and the nearly 12,000 organs discarded in 2024. Third, proposed § 486.348(e) requires OPOs to assess policies and procedures regarding medically complex donors and organs, track performance metrics including consent rates, recovery rates, and transplantation rates, and implement improvements when opportunities are identified. Fourth, it establishes different burden levels for initial assessment versus ongoing annual monitoring with Year 1 requiring 24 hours per OPO and subsequent years requiring 11 hours per OPO. We have accounted for these costs in the collection of information section of this proposed rule.

For CMS, we estimate 360 hours at $138 GS-14 hourly rate for Year 1 implementation costs totaling $49,680, rounded to $50,000. These one-time costs cover policy documentation and guidance development on expanded adverse event categories and medically complex organ performance standards requiring 120 hours, survey protocol updates to incorporate adverse event investigation review and medically complex organ performance assessment requiring 100 hours, staff training on reviewing expanded QAPI programs with six adverse event categories and medically complex organ tracking requiring 80 hours, and development of validation procedures for confirming adverse event investigation thoroughness and medically complex organ performance accuracy requiring 60 hours.

(12) Proposed Conforming Changes to § 486.322 Relationships with Hospitals, Critical Access Hospitals, and Tissue Banks; § 486.324 Administration and Governing Body; and § 486.360 Emergency Preparedness

The proposed conforming changes to hospital relationships, administration and governing body, and emergency preparedness would establish modifications to accommodate optional multi-DSA operations. The proposed changes update hospital agreement requirements to specify that OPOs must maintain written agreements with 95 percent of eligible hospitals in each designated DSA separately, revise advisory board membership and coordination requirements to reference service areas in plural form to accommodate optional multi-DSA governance, update emergency preparedness communication plans to include contact information for transplant and donor hospitals in each DSA, and establish continuity of operations provisions that address backup agreements covering multiple DSAs.

The proposed rule introduces new elements compared to the 2020 baseline. First, it changes the hospital agreement requirement at § 486.322(a) from requiring agreements with hospitals in the service area to requiring agreements in each of the OPO's designated service areas, creating separate 95 percent compliance requirements for each DSA. Second, it updates five references in § 486.324 governing administration and governing body from “area” to “areas”

to ensure advisory board representation, policy recommendations, and coordination activities encompass all DSAs an OPO manages. Third, it revises emergency preparedness requirements at § 486.360 to require emergency communication plans that include contact information for hospitals in each DSA that an OPO manages and continuity of operations agreements that specify coverage for multiple DSAs. Fourth, it updates data collection requirements at § 486.328(c) to specify that re-certification data must include all deaths in all hospitals and critical access hospitals in the OPO's service areas.

We estimate each OPO would spend approximately 25 hours annually at a weighted average hourly rate of $177 for hospital agreement compliance verification requiring 10 hours per OPO to verify that 95 percent compliance is maintained in each DSA, coordinate with hospitals across multiple service areas, track agreement status separately by DSA, and prepare documentation for CMS survey verification. Advisory board and governance updates would require 6 hours per OPO for ensuring advisory board membership represents all service areas, updating board policies and procedures to reference multiple DSAs, coordinating board activities across service areas, and documenting governance structures for multi-DSA operations. Emergency preparedness plan updates would require 5 hours per OPO for updating emergency communication plans to include hospitals in all DSAs, revising continuity of operations agreements to specify multi-DSA coverage, coordinating emergency preparedness activities across service areas, and conducting training on updated emergency procedures. Data collection and reporting modifications would require 4 hours per OPO for updating systems to track data separately by DSA, ensuring re-certification data includes all hospitals in all service areas, coordinating data collection across multiple DSAs, and preparing reports that distinguish performance by DSA. The total cost to OPOs for operational activities is $44,250(10 OPOs ×25 hours × $177), rounded to $44,000 for recurring costs.

For CMS, we estimate 180 hours at $138 GS-14 hourly rate for Year 1 implementation costs totaling $24,840, rounded to $25,000. These one-time costs cover policy documentation

and guidance development on multi-DSA hospital agreement compliance, survey protocol updates to verify separate 95 percent compliance in each DSA and review multi-DSA governance structures, verifying data collection across service areas and development of technical assistance materials for OPOs on multi-DSA operational requirements.

d. Incremental Benefits

This subsection presents the incremental benefits of this proposed rule organized by benefit category. For each category, we distinguish between quantified benefits that can be monetized with reasonable certainty and qualitative benefits that are real but difficult to quantify precisely. Benefit estimates are presented over the 5-year analysis period (2027 through 2031) and are compared to the baseline established by the December 2020 final rule.

For quantified benefits, we provide a detailed calculation methodology showing data sources and assumptions, annual benefit estimates, and acknowledgment of uncertainty where appropriate. For qualitative benefits, we provide clear descriptions of each benefit, explanations of why monetization is not feasible, evidence demonstrating that the benefit is real and significant, and connections to the overarching regulatory objectives of improving organ procurement and transplantation outcomes.

The quantified benefits total $884,000 in annual benefits from reduced regulatory uncertainty and $300,000 in one-time benefits due to increased operational flexibility for multi-DSA operations. However, these quantified benefits represent only a portion of the total value generated by this proposed rule. Significant qualitative benefits also exist that while difficult to monetize, are essential to the effective implementation of the December 2020 final rule's performance measurement and competition framework and directly support the goal of increasing organ availability for the 100,000 plus individuals on transplant waiting lists.

TABLE 6: Summary of Quantified Incremental Benefits

Benefits Category	Benefits (k) (OPOs)	Benefits (k) (CMS)	Benefits Type
Reduced Regulatory Uncertainty and Compliance Burden	290	594	Recurring Annual
Operational Flexibility for Multi-DSA Operations	300	0	One-Time

i. Quantified Benefits

This subsection presents the quantified incremental benefits of this proposed rule organized by benefit category. For each benefit, we provide baseline context identifying what was already captured in the December 2020 final rule versus what is genuinely incremental in this proposal, detailed calculation methodology showing data sources and assumptions, annual and 5-year benefit estimates, and acknowledgment of uncertainty where appropriate. The quantified benefits focus on measurable impacts that can be monetized with reasonable certainty based on available data and conservative assumptions.

(1) Reduced Regulatory Uncertainty and Compliance Burden

The December 2020 final rule (85 FR 77898) established new performance measures and a three-tier re-certification system but did not account for time spent responding to stakeholder inquiries about implementation. The $1.0 million CMS administrative baseline covered basic oversight but not clarification activities. Since 2020, CMS has received increasing stakeholder inquiries, particularly as the 2026 re-certification period approaches, creating costs not captured in the baseline analysis.

This proposed rule reduces repetitive clarification requests by clarifying procedures for competitions, multi-DSA operations, non-renewal versus de-certification distinctions, and appeals processes. We recognize some inquiry activity will continue for unique circumstances. We estimate that absent this rule, OPOs would spend 60 hours annually seeking clarification. With these clarifications, this would decline to 20 hours annually, saving 40 hours per OPO. The

clarifications reduce CMS staff time spent responding to inquiries, OPO staff time seeking guidance, and disputes during the 2026 re-certification period.

Each OPO currently spends approximately 60 hours annually seeking clarification, which would decline to 20 hours with the proposed clarifications, saving 40 hours per OPO. This time involves executive directors, legal staff, and compliance officers researching requirements, preparing requests, coordinating with CMS, and implementing guidance. At a weighted average hourly rate of $132 (adjusted by 100 percent for fringe benefits and overhead consistent with the 2020 methodology), this yields an annual benefit of $290,400 (40 hours × $132 × 55 OPOs), rounded to $290,000.

Similarly, absent this rule, CMS would receive approximately 165 substantive requests annually (3 per OPO × 55 OPOs). With the clarifications, we expect a reduction to 55 requests annually (1 per OPO × 55 OPOs), eliminating 110 requests. Each request requires approximately 20 hours of GS-14 staff time for research, coordination, drafting responses, and quality review. At a GS-14 hourly rate of $138 (OPM 2023 pay tables, adjusted for locality and benefits), this yields an annual benefit of $303,600 (110 requests × 20 hours × $138). The total annual benefit is $594,000, with a 5-year benefit of $2,970,000[140].

This estimate is conservative as it captures only direct time savings. It excludes indirect costs of regulatory uncertainty including delayed strategic planning, deferred operational decisions, potential disputes and appeals, and opportunity costs when staff time diverts from core organ procurement activities. The actual benefit may be substantially higher. The estimate assumes a 67 percent inquiry reduction; greater reductions would increase benefits proportionally. Conversely, OPOs and CMS staff may need familiarization time with new

[140] Data sources include CMS inquiry tracking data (2020-2025), estimated 60 hours per OPO absent the rule and 20 hours with the rule based on consultation with OPO compliance officers, weighted average OPO hourly rate of $132, GS-14 hourly rate of $138 from OPM 2023 pay tables, estimated 3 requests per OPO annually absent the rule and 1 request with the rule, 20 hours per request based on staff time tracking, and assumes a 67 percent reduction in inquiry volume (from 165 to 55 requests annually).

clarifications, potentially causing short-term inquiry increases before long-term benefits are realized.

(2) Operational Flexibility for Multi-DSA Operations

The December 2020 final rule established a three-tier performance system and de-certification procedures but did not explicitly address how OPOs managing multiple DSAs would be evaluated when performance varies across service areas. The baseline framework could potentially result in full de-certification of an OPO even when some DSAs perform well, requiring unnecessary transitions in well-performing territories and imposing avoidable costs on the system.

This proposed rule would allow high-performing OPOs to continue serving well-performing territories while losing designation only in underperforming DSAs. The proposed provisions at § 486.309(c) and § 486.316 establish that CMS would remove designation to a tier 3 DSA without full de-certification when an OPO manages multiple DSAs, enabling continuity of service in well-performing territories, knowledge and resource transfer from high-performing to underperforming areas, maintained OPO staff relationships with hospitals and donor families, and avoided unnecessary operational transition costs in tier 1 and tier 2 DSAs.

We estimate that following the 2026 competition process, 5 OPOs will serve 2 DSAs each (10 total DSAs). In the subsequent performance evaluation cycle ending in 2030, we assume 3 of these 5 OPOs achieve Tier 1 or 2 performance in one DSA but Tier 3 performance in their second DSA. Under the clarified policy, only the 3 underperforming DSAs would open for competition. Without this clarification, the 2020 final rule framework could potentially result in de-certification of all 3 OPOs, opening all 6 of their DSAs for competition. Using the baseline transition cost of $100,000 per DSA from the 2020 final rule, avoiding 3 unnecessary transitions produces an estimated benefit of $300,000 (3 avoided transitions × $100,000)[141].

[141] This scenario is illustrative based on projected multi-DSA adoption rates and current tier distribution patterns. The actual number of OPOs benefiting from this flexibility will depend on competition outcomes and performance trajectories during the 2027-2031 period.

The total benefit is $300,000 over the 5-year analysis period, occurring once during the 2030 performance evaluation cycle. Data sources include estimated 10 OPOs managing multiple DSAs by 2030 based on competition projections and multi-DSA operational analysis, 60 percent probability that multi-DSA OPOs will have mixed tier performance based on current tier distribution patterns, transition cost of $100,000 per DSA from the 2020 final rule baseline ($2.9 million annually for OPO management transitions), and assumption that 3 of 5 multi-DSA OPOs will have mixed performance requiring designation removal from one DSA.

This estimate is conservative because it captures only avoided direct transition costs. It does not quantify additional benefits including maintained hospital relationships and donor family trust in well-performing territories that support long-term procurement performance, preserved institutional knowledge and staff expertise that would be lost through full de-certification, avoided disruption to organ procurement activities during the transition period in well-performing DSAs, and reduced administrative burden on CMS for managing fewer total transitions. The actual benefit may be substantially higher when these indirect effects are considered. The estimate assumes 5 OPOs will manage multiple DSAs by 2030; if more OPOs expand to multiple DSAs or if the rate of mixed performance is higher than 60 percent, benefits would increase proportionally. The estimate uses $100,000 per DSA transition cost from the 2020 baseline; if actual transition costs are higher due to the complexity of multi-DSA operations, the benefit would increase accordingly.

As such, we seek comments on sources of data to quantify the impact of these benefits.

(ii). Qualitative Benefits (Not Monetized)

The following benefits are real and significant but cannot be readily monetized due to the difficulty of isolating causal effects, the diffuse nature of the benefits, or the lack of empirical data to support quantification. For each qualitative benefit, we provide a clear description, explanation of why monetization is not feasible, evidence demonstrating significance, and connection to regulatory objectives.

(1) Improved System Efficiency and Continuity

This proposed rule reduces service disruptions by establishing successor selection criteria at § 486.308(a)(4), and multi-DSA transitions at §§ 486.309 and 486.312. The clarifications specify when CMS may select successor OPOs before conducting a full competition, the criteria CMS will consider in successor selection (contiguity, outcome measure performance, process measure compliance history, and willingness to serve), and procedures for managing transitions when OPOs serve multiple DSAs. These provisions reduce service disruptions by ensuring continuity of organ procurement activities during transitions, minimizing coordination failures between incumbent and successor OPOs, clarifying responsibilities during transition periods, and preventing delays in organ recovery and placement.

We estimate that clear successor selection criteria and transition procedures prevent any potential service disruptions that could otherwise result in delayed organ recovery or placement. However, quantifying this benefit precisely is difficult because service disruptions are typically temporary and their impact on organ procurement varies by circumstance. We also note that there may be additional benefits including reduced administrative burden on CMS and OPOs during transitions, maintained hospital confidence in the organ procurement system during leadership changes, preserved donor family trust during transition periods, and avoided reputational damage to the broader transplant system.

(2) Enhanced Competition Efficiency

The December 2020 final rule (85 FR 77898) established a three-tier performance system and competition framework but did not provide detailed guidance on multi-DSA competition scenarios or the specific application of selection factors. The proposed clarifications at § 486.316 enhance competition efficiency by establishing clear re-certification and competition procedures that enable efficient identification and replacement of poor-performing OPOs. The clarifications specify the impact of performance tier assignments on competition and de-certification actions, provide explicit guidance for multi-DSA competition scenarios where OPOs manage multiple

service areas with varying performance levels, and establish successor selection criteria when insufficient time exists for full competition to prevent service gaps for all stakeholders.

We cannot readily quantify this benefit because the dynamic effects of enhanced competition on OPO performance improvement are difficult to isolate and measure. Competition may drive performance improvements not only among OPOs that lose competitions but also among OPOs that improve performance to avoid competition. The counterfactual (what performance would have been without clearer competition procedures) is speculative. Additionally, the benefit manifests over time as the competitive environment drives continuous improvement across the entire OPO system rather than generating discrete, measurable outcomes in the short term.

This benefit is significant because with an estimated 26 DSAs opening for competition during the re-certification cycle (representing nearly half of all OPOs), the efficiency of the competition process directly impacts the quality of organ procurement services for millions of potential donors and transplant candidates. Clear procedures ensure that competition decisions are transparent and focused on maximizing organ procurement outcomes. The clarifications enable CMS to make informed decisions about which OPOs should serve each DSA based on explicit criteria. This supports the overarching goal of Executive Order 13879 to improve organ procurement performance and the December 2020 final rule's objective of creating accountability through competition.

(3) Improved Definitional Clarity

The December 2020 final rule established new outcome measures and performance standards but included limited definitions for key operational terms. The proposed revised definitions at § 486.302 ensure consistent interpretation across OPOs by establishing clear understanding of "medically complex donors" and "medically complex organs" to encourage utilization of organs that are currently underused, providing explicit definition of "unsound medical practices" to establish accountability for practices creating imminent threats to patient

health and safety, clarifying the "donor" definition to ensure consistency and continued compliance with the statutory requirement that pancreata used for islet cell transplantation or research be counted for purposes of certification and re-certification, and creating a flexible "adverse event" framework by moving specific examples from the definition to QAPI requirements at § 486.348(c) to allow adaptation to emerging issues.

We cannot readily quantify this benefit because the value of regulatory clarity is diffuse and difficult to monetize. It manifests in reduced confusion, more consistent implementation, better strategic planning, and fewer disputes —benefits that are real but hard to isolate and measure. The causal link between definitional clarity and specific operational improvements is indirect and influenced by multiple factors including OPO organizational culture, staff training, and leadership priorities. Additionally, the benefit accrues gradually over time as OPOs incorporate clearer definitions into their policies, procedures, and decision-making processes rather than generating immediate, measurable cost savings.

This benefit is significant because the high volume of stakeholder inquiries since 2020 demonstrates that definitional ambiguity creates real costs and operational challenges. Clear definitions enable OPOs to implement requirements consistently and make informed decisions about medically complex organ procurement, adverse event investigation, and donor eligibility. The definitional clarity supports all other provisions by ensuring that OPOs, CMS, and stakeholders share a common understanding of regulatory requirements. This is particularly important for medically complex organs, where clear definitions may encourage OPOs to develop systematic approaches to procuring and placing organs from DCD donors and donors with elevated KDPI scores, potentially expanding the donor pool beyond traditional "ideal" donors.

C. Alternatives Considered

Throughout the preamble sections, we present our proposals and seek public comments regarding these proposals. We seek to refine the OPO regulations to align with the regulatory

structure established in the December 2020 final rule that uses new outcome measures and a three-tier structure to incentivize OPO performance improvement in better service to prospective donor families and patients on the transplant waiting list. In revising the regulations to align with the tier structure and outcome measures, we considered several other potential policies for the OPO regulations. Below we discuss the various proposed policies and the alternatives considered.

1. § 486.308 Designation Periods

We propose that the designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at § 486.316(e), will be the remaining portion of the agreement for the OPO's current re-certification cycle. We considered proposing a policy that would allow CMS greater flexibility to establish longer designation periods. We determined that this flexibility would interfere with the 4-year re-certification cycle described in section 1138(b)(1)(A) of the Act and section 371(b)(1)(D) of the PHS Act. We request public comment on additional considerations related to designation periods following a successful competition or CMS assignment for an open DSA.

2. § 486.309 Designation of an OPO to More Than One Service Area

At § 486.309(a), we propose that an OPO may be responsible for more than one DSA in certain circumstances including a change in control or ownership or service area; as a result of a competition; or a voluntary or involuntary termination of an OPO's agreement when there is insufficient time to conduct a competition. Further, we propose at § 486.309(b) that an OPO that obtains an additional DSA may choose to maintain separate DSAs or consolidate multiple DSAs into one service area under a single certification. Our policy goal is to provide OPOs the flexibility when being designated to more than one DSA to establish their organizational and operational structure in such a manner to enable the OPO to most effectively provide organ donation services. However, we also have concerns for over consolidation of DSAs and the

ability to maintain market diversity as well as performance, quality, and safety concerns when organizations merge.

As an alternative to the proposed policy at § 486.309(b), where we propose that OPOs may choose to consolidate DSAs or maintain separate DSAs, we considered an alternative policy that would require an OPO to first obtain CMS approval before choosing to either consolidate DSAs or maintain separate DSAs, based on specific criteria that CMS would consider when evaluating the request. While this alternative approach would provide OPOs with the opportunity to choose whether to consolidate DSAs or maintain them separately, CMS would retain final approval of the request. While CMS currently has final approval over any change in service area under 486.310(a)(2), we have not established specific criteria for approving or denying an OPO's request. When deciding whether to permit an OPO to consolidate multiple DSAs or maintain them separately, CMS could consider a variety of factors, including DSA size relative to population size, geographic characteristics, historical patient safety concerns, chronic underperformance in securing donors, and other relevant considerations. For instance, DSA populations range from approximately 1.5 million to nearly 20 million people.[142] Geographic considerations may include whether DSAs are contiguous or encompass exceptionally large areas. Additionally, serious patient safety concerns with an OPO, such as those identified by the Secretary in 2025,[143] may warrant retaining DSAs separately while corrective remedies are implemented. Finally, a new OPO assuming responsibility for a DSA where the previous OPO underperformed for extended periods may benefit from separate designation to enable more precise performance monitoring.

If this alternative approach is adopted, we would revise proposed § 486.310 to include a provision for CMS approval of service area changes with specific criteria we would consider for approval would be set forth at 486.310. Currently § 486.310(a)(2) provides that CMS must

[142] U.S. Census Bureau, U.S. Census Population Estimates Program, American Community Survey
[143] https://www.hhs.gov/press-room/hrsa-to-reform-organ-transplant-system.html

approve any change in service area, which supports CMS's authority to require the successor OPO to keep DSAs separate. However, we note that this provision would no longer apply to consolidation-related decisions if proposed § 486.309(b) is finalized. We request public comment on the benefits of this alternative approach, whether CMS should retain the right of final approval of requests, and what specific criteria CMS should consider when making this determination.

As previously stated in section II.D. of this proposed rule, when the Life Alliance Organ Recovery Agency (LAORA)'s DSA was opened for competition, CMS indicated that the successor OPO would be required to maintain the DSA separately from their existing DSA. We note this decision was based on the long historical record of underperformance in this DSA and CMS' desire to carefully monitor the changes after the successor OPO assumes responsibility for the DSA.

Additionally, recent instances of OPOs pursuing or exploring mergers in the midst of patient safety concerns have raised concerns for additional regulatory oversight and specific criteria to consider when reviewing changes to DSAs.

In light of these concerns and policy goals, we also considered proposing that OPOs would be required to maintain separate DSAs without the option to merge or consolidate the DSAs. While this would serve the policy goal of maintaining geographic diversity, a blanket approach may be overly restrictive and limit innovation and possibly performance gains when merging DSAs. This may be a significant factor impacting small OPOs with geographically contiguous DSAs.

Our alternative policy approach would require more administrative oversight burden to CMS. Additional administrative burden could be estimated at $86,000 annually[144] ($320,000

[144] This estimate assumes 40 hours per approval request at a staff of a GS-14, Step 5 (loaded hourly rate) $137.74/hour with an assumption of 2 annual requests. Calculation: 80 hours × $137.74 x 2 = $22,038, rounded to $22,000.

over 5 years), including CMS review costs ($22,000 annually) and OPO application preparation costs ($42,000 annually).[145]

We seek comments for consideration in future rulemaking on the benefits of this alternative approach as well as the risks of potential unintended consequences, and other factors that may be considered to better define this alternative policy approach.

3. § 486.311 Non-renewal of Agreement

At § 486.311, Non-renewal of agreement, we proposed that when an OPO voluntarily terminates its agreement or ceases to furnish organ procurement services, it would no longer be designated to any DSAs, as of the effective date determined by CMS. This voluntary termination policy aligns with the requirements from 42 CFR part 489, provider agreements and supplier approval. Section 489.52 addresses termination by the provider (or supplier). This requirement addresses the situation where a provider or supplier seeks to terminate its participation with Medicare. While it is plausible that an OPO may want to terminate its agreement with CMS and the Secretary, this action would have a global effect on an OPO by effectively ending its participation in the Medicare program. OPOs enter into agreements with the Secretary, but unlike other providers and suppliers, OPOs are subsequently designated to one or more DSAs. We have contemplated the possibility that an OPO with multiple DSAs may want to voluntarily terminate designation to a particular DSA without voluntarily terminating its entire agreement with the Secretary and thereby impacting all DSAs. Therefore, we are considering an alternative policy that would allow an OPO to request withdrawal from any one of its DSAs without such withdrawal being considered a voluntary termination of the OPO's agreement. We are seeking public comment on whether or not CMS should consider this alternative policy approach and the rationale to make that decision. This type of policy may be beneficial to an OPO that expands to additional DSAs but later desires to change its operational

[145] This estimate assumes 160 hours per approval request at a staff of a Quality Managers (BLS Code 11-9111) loaded rate of $132 and an assumption of 2 applications per year. Calculation: 160 hours × $132 x 2 = $242,240 rounded to $42,000.

services to reduce the total number of DSAs. Additionally, an OPO that has made a good faith effort to improve organ donation in a DSA but is unable to do so could provide notice to CMS of its intent to voluntarily terminate designation to an individual DSA in order to assist in an orderly transition of the DSA to a successor OPO. This approach could allow an opportunity for a high-performing OPO to compete and take over that DSA. However, this approach could result in OPOs withdrawing mid-cycle without good cause, which could result in disruptions in organ procurement and distribution within those DSAs.

If CMS were to adopt this alternative policy, we would add a new requirement at § 486.309(d) to specify the process for an OPO to request to terminate designation, any approval criteria we would consider (if established), as well as notification requirements with corresponding timelines for notification and transition of the DSA.

We are soliciting public comment on whether OPOs should be permitted to request to terminate designation of individual DSAs without triggering a voluntary termination that would result in termination of the agreement. We seek comments on the benefits of this alternative policy as well as the risks and potential unintended consequences. We also seek public comments to determine if specific criteria should be established to consider when evaluating any requests and what that criteria should be.

4. § 486.314 Appeals and § 486.316 Re-certification and Competition Processes

At § 486.314 Appeals, we propose changes to the time frames for various stages in the appeals process to increase the efficiency of the appeals process while also ensuring OPOs have an adequate opportunity to present an appeal. We also propose to state all time requirements in "calendar days" and use the FRCP definition to avoid any confusion in the process. In addition, we propose to codify a process for the CMS Administrator's discretionary review. We considered retaining "business days" for some of the time requirements. However, we decided to use all "calendar days" to ensure consistency and to avoid confusion. We also considered not including a section for the CMS Administrator's discretionary review of the hearing officer's

decision. The CMS Administrator already has the authority to review all hearing officers' decisions. Hence, the CMS Administrator's discretion to review the hearing officer's decision exists whether it was set out in the requirements or not. However, we decided to include this proposal so that the process is clearly set forth in the requirements and all parties and the public understand it and to avoid any confusion.

At § 486.316(g) we propose that an incumbent OPO must cooperate with its successor OPO to facilitate an orderly transition of the DSA. This proposal complements requirements set forth at § 486.330(d), which requires that an OPO must maintain data in a format that can readily be transferred to a successor OPO. In the event of a transfer, an OPO must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations. Interested parties have expressed an interest in requiring the exchange of process data regarding the DSA from the incumbent OPO to the successor OPO to inform the successor OPO's development of process improvements that could lead to more donors and more transplants. We considered these requests and considered adding a specific regulatory requirement for this data sharing. However, we did not pursue this change at this time because a new information collection request for pre-consent process data is pending approval.[146] This data would be publicly available upon request and may fulfill the needs of successor OPOs without the establishment of additional regulatory requirements. We request public comment regarding alternative ways to assure that successor OPOs have sufficient information at the beginning of their designation period to effectively and efficiently serve potential donors, their families, and people on the transplant waiting list. This may include establishing a requirement for the provision of data such as data related to all donor hospitals in the DSA or the annual donor

[146] 89 FR 87592.

potential and number of referrals from each hospital for a set period of time. We seek public comment on the nature and scope of such data as well as ways to facilitate this data sharing.

5. § 486.330 Information Management

In addition to requiring an OPO to maintain documentation regarding the *bona fide* research studies to which the OPO provided organs, including pancreata used for islet cell research, we also considered requiring an OPO to annually provide information to CMS regarding bona fide islet cell research studies to which the OPO provided pancreata. We considered this potential policy as part of our efforts to assure the integrity of the OPO-reported data related to pancreata used for islet cell research that is used for outcome measure calculation. However, we did not pursue this change at this time as we continue to observe changes in OPO procurement practices that are occurring following changes in the reporting codes and coding guidance issued by the SRTR in 2024. Further, this alternative would impose estimated additional costs of $73,000 annually[147] ($365,000 over 5 years), including OPO annual report preparation costs ($58,000 annually)[148] and CMS review and processing costs ($15,000 annually)[149].

OPOs are continuing to adjust to reporting using the new codes, which aim to improve coding accuracy. As we gather additional insight into new coding practices, we will consider this option for future regulations. We request comment on the potential for additional OPO reporting related to pancreata used for islet cell research, whether such reported information

[147] Total = OPO Costs + CMS Costs. $58,080 + $15,151 = $73,231 annually, rounded to 73,000.
[148] Per OPO Cost = Hours per OPO × Loaded Hourly Rate 8 hours × $132/hour = $1,056 per OPO. Industry-Wide Cost = Per OPO Cost × Number of OPOs ($1,056 × 55 OPOs = $58,080, rounded to 58,000) annually.
[149] Per OPO Review Cost = Hours per OPO × GS-14 Loaded Rate 2 hours × $137.74/hour = $275.48 per OPO. Industry-Wide Cost = Per OPO Review Cost × Number of OPOs $275.48 × 55 OPOs = $15,151, rounded to 15,000 annually.

should be made public, and the manner and frequency in which CMS could make this information available to the public.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review this proposed rule, we assume that all 55 OPOs will review this rule. While other individuals and providers may also review the rule, we estimate that doubling the number of OPOs (110 reviewers) provides a reasonable approximation of the total number of reviewers. We acknowledge that this assumption may understate or overstate the actual review costs and welcome public comment on this approach. For purposes of this estimate, we assume each reviewer reads approximately 100 percent of the rule and the average reading speed is 250 words per minute. This rule contains approximately 60,000 words, which equates to 4 hours reviewing the rule (60,000 words ÷ 250 words per minute ÷ 60 minutes per hour = 4 hours). Using a weighted average hourly rate of $132 for OPO executive directors and legal staff (adjusted by 100 percent for fringe benefits and overhead consistent with the 2020 final rule methodology), we estimate total review costs of $58,080 (110 reviewers × 4 hours × $132), rounded to $58,300.

E. Accounting Statement

As required by OMB Circular A-4 (available online at https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf), we have prepared an accounting statement in Table 7 showing classification of the costs, transfers, and benefits associated with the provisions of this proposed rule. This proposed rule imposes incremental costs of approximately $19.3 million in Year 1 and $6.0 million recurring annually ($18.1 million for OPOs in Year 1 and $6.0 million recurring annually; $1.2 million for CMS in Year 1 and $333,000 recurring annually). The proposed rule does not create new transfer payments beyond those established in the 2020 baseline. Quantified benefits are estimated at $884,000 annually from reduced regulatory uncertainty and a one-time savings of $300,000 operational flexibility for multi-DSA. This

statement provides our best estimate for the Medicare and Medicaid provisions of this proposed rule.

TABLE 7: Accounting Statement

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs ($million/year) OPOs	8.5-8.7	2024	7% or 3%	2027-2031
Annualized Monetized Costs ($million/year) Government	0.5-0.5	2024	7% or 3%	2027-2031
Annualized Monetized Benefits ($million/year) OPOs	0.4-0.4	2024	7% or 3%	2027-2031
Annualized Monetized Benefits ($million/year) Government	0.6-0.6	2024	7% or 3%	2027-2031

F. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $18.0 million to $47.0 million in any 1 year. Individuals and States are not included in the definition of a small entity.

1. Organ Procurement Organizations (OPOs)

All OPOs (NAICS 621991, Blood and Organ Banks) could be considered small entities either by the Small Business Administration's size standards (total revenues of $47.0 million[150] or less in any single year) or by nonprofit status. In practice, most OPOs are large nonprofit organizations with annual revenues substantially exceeding $47 million.

[150] U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," effective October 1, 2022 (or most recent year), available at *https://www.sba.gov/document/support-table-size-standards*.

According to the 2022 Economic Census, blood and organ banks (NAICS 621991) have total revenues of $19.88 billion.[151] This figure includes OPOs as well as blood banks and other organ and tissue banks. With approximately 55 OPOs operating in the United States, and assuming OPOs represent a substantial portion of this industry category, average annual revenue per OPO is estimated at approximately $361 million.[152]

This proposed rule imposes estimated costs of $18.1 million for all OPOs in Year 1 (including $12.1 million in one-time implementation costs and $6.0 million in recurring costs) and $6.0 million in recurring annual costs beyond Year 1. To calculate annualized costs over the 5-year analysis period, we annualize the one-time costs ($12.1 million ÷ 5 years = $2.4 million per year) and add recurring costs ($6.0 million per year), resulting in annualized costs of approximately $8.4 million per year. Distributed across 55 OPOs, the average annualized cost per OPO is approximately $153,000 annually.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. The estimated annualized costs represent approximately 0.0004 percent of average OPO revenues ($153,000 ÷ $361 million), which is well below the 3 to 5 percent threshold for significant economic impact.

We are not preparing an analysis for the RFA because we have determined, and the Secretary has certified, that this proposed rule would not have a significant adverse economic impact on a substantial number of small entities. As we explained in detail in the December 2020 final rule on OPO outcome standards (85 FR 77898), we believe that the new performance standards will have beneficial or neutral effects on most OPOs and transplant hospitals, and that there would not be a substantial number of OPOs adversely affected. This proposed rule makes only clarifications and refinements to the framework established in that final rule, and none of

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[151] U.S. Census Bureau, 2022 Economic Census, NAICS 621991 (Blood and Organ Banks), available at *https://data.census.gov/*.

[152] Average OPO Revenue = Total Industry Revenue ÷ Number of OPOs $19.88 billion ÷ 55 OPOs = $361.45 million per OPO (rounded to $361 million).

these would invalidate the previous conclusion.

2. Section 1102(b) of the Social Security Act - Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary has certified, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million.

This proposed rule imposes estimated costs of approximately $19.3 million in Year 1 and $6.3 million recurring annually, which is well below the UMRA threshold. Recurring annual costs beyond Year 1 comprise $6.0 million for OPOs and $331,000 for CMS. The proposed rule does not mandate any spending requirements for State, local, or tribal governments. While the rule imposes costs on OPOs (private sector entities), these costs are substantially below the $187 million threshold.

These costs represent clarifications and refinements to the operational and administrative requirements established in the December 2020 final rule (85 FR 77898), rather than new mandates. The costs are primarily administrative in nature and include training, documentation updates, enhanced coordination activities, and compliance with clarified requirements.

As noted in the December 2020 final rule, reimbursement by both public and private payers would cover all reasonably estimated costs associated with organ procurement activities. OPOs are reimbursed for their organ acquisition costs through Medicare, Medicaid, and private insurance payments. The estimated costs are well below the $187 million UMRA threshold. Therefore, the requirements of UMRA do not apply to this proposed rule.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

This proposed rule is directed at Organ Procurement Organizations (OPOs), which are private nonprofit organizations certified by CMS to coordinate organ procurement activities within designated service areas. The proposed rule does not impose substantial direct requirement costs on State and local governments, preempt State law, or have Federalism implications. The proposed clarifications and refinements to the OPO conditions for coverage affect only OPOs and CMS administrative processes. State and local governments are not directly regulated by these provisions. While some State and local government entities may interact with OPOs in their capacity as healthcare providers or in other roles, the proposed rule does not impose requirements or costs on governmental entities in their governmental capacity.

The estimated costs of this proposed rule ($19.3 million in Year 1 and $6.3 million recurring annually) fall entirely on OPOs (private sector entities, $18.1 million in Year 1 and $6.0 million recurring annually) and the Federal Government (CMS, $1.2 million in Year 1 and $0.3 million recurring annually). No costs are imposed on State, local, or tribal governments. Since this proposed rule does not impose substantial direct requirement costs on State and local governments, does not preempt State law, and does not have Federalism implications, the requirements of Executive Order 13132 are not applicable to this proposed rule.

I. E.O. 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, entitled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025, and requires that any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 11 prior regulations.

We followed the implementation guidance from OMB Memorandum M-25-20 (https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf) when estimating the proposed rule's impact related to the executive order. Specifically, we used a 7 percent discount rate when estimating costs for purposes of Executive Order 14192, as required by the OMB guidance.

This proposed rule imposes estimated incremental costs of approximately $19.3 million in Year 1 and $6.3 million recurring annually ($18.1 million for OPOs in Year 1 and $6.0 million recurring annually; $1.2 million for CMS in Year 1 and $0.33 million recurring annually) beyond the baseline of $126.7 million established in the December 2020 final rule (85 FR 77898). Using the 7 percent discount rate required by OMB guidance, the annualized costs over the 5-year period are approximately $9.3 million annually. These costs represent clarifications and refinements to operational and administrative requirements rather than fundamental system restructuring.

This proposed rule is consistent with the principles of Executive Order 14192 in the following ways:

- Minimizes Regulatory Burden: The proposed rule focuses on clarifications and refinements rather than imposing new substantive requirements.
- Provides Regulatory Clarity: By addressing the high volume of stakeholder inquiries and providing clear guidance on operational and administrative requirements, this proposed rule

reduces uncertainty and compliance costs for regulated entities, enabling OPOs to focus resources on their core mission of organ procurement rather than regulatory interpretation.

- Streamlines Processes: The proposed clarifications to competition, appeals, and de-certification processes are designed to make these procedures more efficient and transparent, reducing administrative burden while maintaining accountability. For example: streamlined appeals procedures using consistent "calendar days" terminology; clear multi-DSA operational guidance preventing costly disputes and successor selection criteria reducing potential service disruptions.

- Supports Economic Efficiency: By enhancing the efficiency and effectiveness of the organ procurement system, this proposed rule supports the health and productivity of the workforce and contributes to economic prosperity.

- Reduces Compliance Uncertainty: The proposed rule is estimated to save approximately $589,600 annually in reduced inquiry and interpretation costs for CMS and OPOs combined, allowing resources to be redirected toward improving organ procurement outcomes.

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.

Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 8, 2026.

List of Subjects

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. 273, 1302 and 1320b-8, and 1395hh.

2. Section 486.302 is amended by--

a. Revising the definitions "Adverse event", "Donor" and "Organ";

b. Adding the definitions "Medically complex donor", "Medically complex organ"; and "Unsound medical practices" in alphabetical order.

The revisions and additions read as follows:

§ 486.302 Definitions.

* * * * *

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.

* * * * *

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual would also be considered a donor if only the pancreas is procured and is used for islet cell transplantation or for islet cell research.

* * * * *

Medically complex donor means a donor whose medical history requires special or additional considerations to identify the best recipient for the organs. These donors include, but

are not limited to, all Donation after Cardiac Death (DCD) donors and donors with elevated Kidney Donor Profile Index (KDPI) scores of 50 or more.

Medically complex organ means an organ recovered from a medically complex donor.

* * * * *

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 islet cell transplantation.

Organ Type	**No. of Organs Transplanted**
Right or Left Kidney	1
Right and Left Kidney	2
Double/En-Bloc Kidney	2
Heart	1
Intestine	1
Intestine Segment 1 or Segment 2	1
Intestine Segment 1 and Segment 2	2
Liver	1
Liver Segment 1 or Segment 2	1
Liver Segments 1 and Segment 2	2
Right or Left Lung	1
Right and Left Lung	2
Double/En-bloc Lung	2
Pancreas (transplanted whole, islet transplant)	1
Pancreas Segment 1 or Segment 2	1
Pancreas Segment 1 and Segment 2	2

* * * * *

Unsound medical practices refer to failures by OPOs that create an imminent threat to patient health and safety or pose a risk to patients or the public. These practices include, but are not limited to, failures in governance; patient or potential donor evaluation and management; and procurement, allocation, and transport practices and procedures.

* * * * *

§ 486.303 Requirements for Certification.

3. Section 486.303 is amended by--

a. Removing paragraph (e); and

b. Redesignating paragraphs (f) through (i) as paragraphs (e) through (h), respectively.

4. Section 486.308 is amended by--

a. Adding introductory text; and

b. Revising paragraphs (a) and (b).

The addition and revisions read as follows:

§ 486.308 Designation of one OPO for each donation service area.

Re-certification of organ procurement organizations must occur not more frequently than once every 4 years. CMS designates only one OPO per Donation Service Area (DSA).

(a) *Designation periods.* An OPO is normally designated for an agreement cycle of 4 years.

(1) CMS may adjust the length of a designation period when:

(i) There is a voluntary termination initiated by an OPO as specified at § 486.311(a)(2),

(ii) There is an involuntary termination initiated by CMS as specified at § 486.312(a)(1) or (4),

(iii) Additional time is needed to complete an appeal, conduct a competition, select a successor OPO, or transition the DSA to a successor OPO, or

(iv) There is an extension of an agreement cycle as specified at § 486.316(f).

(2) CMS will conduct a competition for all vacated DSAs.

(3) Designation periods following a competition or assignment of a DSA by CMS. The designation period for any newly acquired DSA following a competition, or as the result of being assigned a DSA as specified at 486.316(e), will be the remaining portion of the agreement for the OPO's current re-certification cycle.

(4) If there is insufficient time to conduct a competition, CMS may select one or more successor OPOs before opening the DSA(s) for competition. In selecting a successor OPO(s), CMS will consider the following:

(i) Contiguity to the DSA,

(ii) Performance on outcome measures at § 486.318,

(iii) History of compliance with the process performance measures at §§ 486.320 through 486.360, and

(iv) Willingness of the OPO to perform the responsibilities for the remainder of the designation period.

(b) *Competition.* A DSA becomes open for competition when:

(1) The DSA is assigned to tier 3 in the final assessment period, as specified at § 486.318(b)(6) and 486.316(a)(3), and all administrative appeals are exhausted;

(2) The DSA is assigned to tier 2 in the final assessment period, as specified at § 486.318(b)(5) and § 486.316(a)(2); or,

(3) The OPO for the DSA is not in compliance with the process performance measures at §§ 486.320 through 486.360, as specified at § 486.312(a)(2) and § 486.316(b)(1), all administrative appeals are exhausted, and the OPO is pending de-certification.

(4) An OPO for the DSA requests to voluntarily terminate its agreement as specified at § 486.311(a)(2), unless the voluntarily termination is associated with a change in control or ownership or service area as specified at § 486.310 and the changed OPO will continue to serve the DSA.

* * * * *

5. Section 486.309 is revised to read as follows:

§ 486.309 OPO designation to more than one service area.

(a) CMS may designate an OPO to more than one DSA in the following instances:

(1) A change in control or ownership or service area as specified at § 486.310,

(2) As a result of competition as specified at § 486.316, or

(3) A voluntary or involuntary termination of an OPO's agreement and there is insufficient time to conduct a competition as specified at § 486.308(a)(4).

(b) When the conditions under paragraphs (a)(1) or (2) of this section are met, the OPO may choose to consolidate the DSAs, maintain separate DSAs, or a combination thereof if more than two DSAs are involved.

(c) When an OPO is designated to more than one DSA, CMS may remove designation to a tier 3 DSA due to non-compliance with the outcome measures at § 486.316(a)(3) and § 486.318(b)(6).

(1) Removal of a designation to a tier 3 DSA will not result in de-certification unless an OPO is no longer designated to any DSA as specified at § 486.316(b)(2)(iii)(A).

(2) An OPO may appeal the decision to remove a designation to a tier 3 DSA as specified at § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's service area is opened for competition from other OPOs that qualify to compete for open service areas as set forth in § 486.316(c).

6. Section 486.311 is added to read as follows:

§ 486.311 Non-renewal of agreement.

(a) *Non-renewal of agreement.* CMS will not renew an agreement with an OPO in the following circumstances:

(1) Competition. The OPO is unsuccessful in the competition process, as set forth at § 486.316(a)(2), and the OPO is no longer designated to any DSA.

(2) Voluntary Termination. The OPO sends CMS written notice of its intention to terminate its agreement and the proposed effective date. CMS may approve the proposed effective date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is

deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will provide notice to the OPO of the effective date of the voluntary termination.

(b) *OPO notice of non-renewal*. For non-renewal of an agreement after a competition, as specified in paragraph (a)(1) of this section, CMS will provide notification to the OPO at least 90 calendar days before the effective date of the non-renewal. The notice states the reasons for non-renewal and includes the end date of the agreement.

(c) *Public notice.* CMS will provide public notice in the service area of the date that a new OPO will be designated for the DSA.

(d) *Cessation of Payment.* No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to an OPO that no longer has an agreement with CMS.

7. Section 486.312 is revised to read as follows:

§ 486.312 De-certification.

(a) *Involuntary termination and de-certification.* CMS may de-certify an OPO under the following circumstances:

(1) The OPO no longer meets the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360, as specified at § 486.316(b)(1), at any time during the re-certification cycle.

(2) The OPO only has tier 3 DSA(s) designated in the final assessment period, as described at § 486.316(b)(2)(iii)(A), at the end of the re-certification cycle.

(3) The OPO is no longer designated to any DSA and does not have data available from the final assessment period to demonstrate compliance with the outcome measures at the end of the re-certification cycle.

(4) In cases of urgent need, such as the discovery of unsound medical practices, CMS may de-certify an OPO immediately.

(b) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of the initial de-certification decision to an OPO at least 90 calendar days before the effective date of the de-certification. CMS may extend the effective date of the de-certification as needed to allow for completion of the appeal process under § 486.314, competition of the service area and, if necessary, transition of the service area to a successor OPO. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The initial notice of de-certification states the reasons for de-certification, explains the available appeal rights, and includes the effective date of the de-certification.

(c) *Public notice.* In cases of urgent need, CMS will provide prompt public notice in the service area of the date of de-certification and the date that a new OPO will be designated for the DSA. With respect to cases described in paragraphs (a)(1) or (2) of this section, CMS will provide such public notice after the available appeal rights are exhausted.

(d) *Cessation of Payment.* No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to an OPO on or after the effective date of de-certification.

8. Section 486.314 is amended by--

a. Revising the introductory text, paragraphs (a) through (d), and paragraphs (i) through k; and

b. Adding paragraphs (l) through (p).

The revisions and additions read as follows:

§ 486.314 Appeals.

OPOs may appeal a de-certification as described at § 486.312(a) or the removal of designation to a tier 3 DSA without de-certification as described at § 486.316(b)(2)(iii)(B).

(a) *Notice of initial determination*. If an OPO is either de-certified or has its designation to a tier 3 DSA removed without de-certification, CMS will send the OPO either a notice of initial de-certification or a notice of removal of designation for a DSA without de-certification.

(1) Initial notice of de-certification. An OPO will receive an initial notice of de-certification if it is determined to be non-compliant with the process performance measures at § 486.312(a)(1) or non-compliant with the outcome measures as specified at § 486.312(a)(2) or § 486.312(a)(3).

(2) Notice of removal of designation to a tier 3 DSA without de-certification. An OPO will receive a notice of removal of designation to a tier 3 DSA without de-certification if it is determined to be non-compliant with the outcome measures in that DSA but the OPO has other designated DSAs assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination or the removal of a tier 3 DSA without de-certification, it has 20 calendar days from receipt of the notice of de-certification or removal of designation for a tier 3 DSA without de-certification to file a reconsideration request with CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for the disagreement.

(2) Failure to request reconsideration. An OPO must file a reconsideration request before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) Reconsideration determination. CMS makes a written reconsidered determination within 15 calendar days of receipt of the request for reconsideration affirming or reversing the

initial determination and the findings on which it was based. CMS reserves the right to extend the 15 calendar day limitation if:

(i) CMS determines more time is needed to thoroughly review and make a reconsideration decision; and

(ii) The extension of time does not prejudice either of the parties.

(4) CMS augments the administrative record to include any additional materials submitted by the OPO and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing*. An OPO dissatisfied with the CMS reconsideration decision can file a request for a hearing before a CMS hearing officer within 15 calendar days after receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not timely received, the OPO has no right to further administrative review and the reconsideration determination becomes the final agency decision.

(d) *Administrative record*. Upon receipt of a request for a hearing, the hearing officer will promptly request the administrative record from the reconsideration official. The hearing officer will send the administrative record to both parties, or make it available through their electronic filing system, within 15 calendar days of receipt of the request for a hearing.

* * * * *

(i) *Scope of review*. An OPO may appeal a de-certification as described at § 486.312(a) and the removal of designation to a tier 3 DSA on substantive or procedural grounds.

(j) *Burden of proof*. The OPO bears the burden of proof by a preponderance of the evidence to demonstrate the notice of de-certification or removal of designation to a tier 3 DSA should be reversed.

(k) *Hearing officer's decision.* (1) The hearing officer renders a decision on the appeal of the notice of de-certification or removal of designation to a tier 3 DSA within 90 calendar days of the hearing. The hearing officer may extend the timeframe for issuing its decision beyond 90

calendar days if the hearing officer determines that 90 calendar days is insufficient for the hearing officer to develop the administrative record and render a legally sufficient decision and that extending the timeframe for issuing its decision would not unduly prejudice either the OPO or the government. If, consistent with the preceding sentence, the hearing officer extends the timeframe for issuing its decision beyond 90 calendar days, the hearing officer shall provide notice of the extension to the OPO and the government.

(2) The hearing officer can affirm or reverse the notice of de-certification or removal of designation to a tier 3 DSA without de-certification.

(3) The hearing officer's decision and the administrative record will be promptly forwarded to the CMS Administrator for his or her discretionary review.

(l) *CMS Administrator discretionary review.* (1) After receiving the hearing officer's decision for review, the CMS Administrator may elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not elect to review that decision within 30 calendar days of receipt of the hearing officer's decision and the administrative record, the hearing officer's decision is final.

(2) If the CMS Administrator elects to review the hearing officer's decision, the CMS Administrator promptly notifies CMS and the OPO in writing of that election and that each party has the right to submit arguments on the administrative record from the hearing officer within 15 calendar days of the date of the notification.

(3) The CMS Administrator determines whether the hearing officer's determination should be upheld, reversed, or remanded according to paragraph (m) of this section.

(4) The CMS Administrator's administrative record is composed of:

(i) All documents submitted to the hearing officer or developed during the hearing, including the hearing officer's decision;

(ii) Written arguments from the OPO or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect; and

(iii) The CMS Administrator's written decision explaining the reasons for their decision.

(5) The CMS Administrator may render a final decision in writing to the parties within 45 calendar days of notifying the parties that the Administrator has elected to review the hearing officer's decision.

(6) The decision of the hearing officer is final if the CMS Administrator does not render a final decision in writing to the parties within 45 calendar days of electing to review the hearing's administrative record or by a date specified under paragraph (*l*)(7) of this section.

(7) The CMS Administrator may extend the 45-calendar-day limitation if the:

(i) CMS Administrator determines he or she requires more time to thoroughly review and make a decision regarding the appeal; and

(ii) Extension does not prejudice either of the parties.

(m) *Remand.* (1) The CMS Administrator may remand the appeal to CMS for any appropriate reason, except for:

(i) In cases where the appeal was previously remanded to CMS, evaluation of evidence that was known or reasonably should have been known at the time the appeal was originally remanded.

(ii) Change in a party's representation, regardless of when made.

(iii) Presentation of an alternative legal basis concerning an issue in dispute.

(2) If the appeal is remanded to CMS, the original de-certification or removal of designation for a DSA without de-certification decision is vacated. The agency will comply with any instructions in the remand and will make a new determination.

(n) *Extension of agreement*. If there is insufficient time prior to expiration of an agreement with CMS to allow for completion of the appeals process, competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to offer to extend the OPO's agreement with CMS.

(o) *Effects of de-certification*. Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. If an OPO's designation to a tier 3 DSA is removed without de-certification, Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes in the affected DSA on or after the effective date of the removal of designation for the tier 3 DSA without de-certification. Once the appeals process is exhausted and the notice of de-certification or removal of designation for a tier 3 DSA without de-certification has not been reversed by the CMS Administrator, CMS will then open the OPO's affected service area for competition as set forth in § 486.316(c).

(p) *De-certification due to urgent need.* If an OPO is de-certified due to urgent need, the affected OPO's service area will be reassigned to one or more other OPOs as set forth at § 486.308(a)(4) by the effective date specified in the notice of de-certification provided under § 486.312(b). The OPO has 20 calendar days from receipt of that notice to file a request for reconsideration from CMS. The remainder of the appeals process proceeds as set forth in this section.

9. Section 486.316 is amended by revising paragraphs (a) through (d) and (g) to read as follows:

§ 486.316 Re-certification and competition processes.

(a) *Impact of outcome measures to OPO designation.* Each OPO DSA will be assigned to either Tier 1, Tier 2, or Tier 3, based upon performance on the outcome measures set forth in § 486.318 for the final assessment period of the agreement cycle. The tier assignment of each DSA will determine OPO designation to the DSA.

(1) Tier 1. An OPO designated to a DSA that is assigned to tier 1, as specified at § 486.318(b)(4), will retain designation to the DSA for another agreement period. An OPO with tier 1 DSAs is eligible to compete in competitions for any open DSAs if it has been shown by the

most recent survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

(2) Tier 2. An OPO designated to a DSA that is assigned to tier 2, as specified at § 486.318(b)(5), must successfully compete and be awarded a DSA to retain designation to a DSA for another agreement period. An OPO with tier 2 DSAs is eligible to compete in competitions for any open DSAs if it has been shown by the most recent survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360.

(3) Tier 3. An OPO designated to a DSA that is assigned to tier 3, as specified at § 486.318(b)(6), will have the designation removed at the end of the agreement period. An OPO with all of its DSAs assigned to tier 3 is not eligible to compete in competitions for any open DSAs.

(b) *OPO re-certification and competition*. (1) Compliance with process performance measures. An OPO must maintain compliance with the process performance measures at all times. An OPO with non-compliance in the process performance measures set forth at §§ 486.320 through 486.360 in any DSA will receive an initial de-certification determination and has the right to appeal that determination as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's service areas are opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(2) Compliance with the outcome measures. CMS will consider an OPO’s DSA tier assignments in the final assessment period for re-certification.

(i) An OPO designated to at least one DSA that is assigned to tier 1 in the final assessment period will be re-certified for another re-certification cycle, as long as it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey.

(ii) An OPO that is designated to at least one DSA that is assigned to tier 2 but is not designated to any DSA assigned to tier 1 in the final assessment period will be re-certified if it is compliant with conditions for coverage at §§ 486.320 through 486.360 during the most recent survey. The OPO will be eligible to compete in competitions for any open DSA but will not have its agreement renewed if it is not successful in at least one competition, in accordance with § 486.311(a)(1). If the OPO is not successful in at least one competition, it will receive a notice of non-renewal as specified in § 486.311(b).

(iii) An OPO that is designated to a DSA(s) assigned to tier 3 in the final assessment period will receive one of the following notices:

(A) A notice of its initial de-certification determination for an OPO that has no other designated DSA that is assigned to tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(B) A notice of removal of designation to the DSA assigned as tier 3 for an OPO that has another designated DSA assigned as tier 1 or tier 2, or another designated DSA that is pending evaluation of its outcome measures as specified at § 486.318(c)(3) or (4) at the end of the re-certification cycle.

(iv) The OPO has the right to appeal de-certification or removal of designation to a tier 3 DSA as established in § 486.314. If an OPO does not appeal the determination, or the OPO appeals and the determination is upheld after the appeal process is completed, the OPO's tier 3 DSAs are opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(3) Competition. DSAs assigned as tier 2 or tier 3 in the final assessment period will be opened for competition. A DSA assigned to tier 3 will be opened for competition after any appeal under § 486.314 has been exhausted. The DSA is opened for competition from other OPOs that qualify to compete for open service areas as set forth in paragraph (c) of this section.

(c) *Criteria to compete*. (1) To compete for an open DSA, an OPO would have to be designated to at least one DSA that meets the performance requirements of the outcome measures for Tier 1 or Tier 2, as specified at § 486.318(b)(4) or (5), the requirements for certification at § 486.303, and the conditions for coverage at §§ 486.320 through 486.360 at the most recent routine survey. The OPO must compete for the entire DSA.

(2) An OPO that was subject to non-renewal of its agreement for failure to retain its DSA after competition is still eligible to compete in future competitions and enter into a new agreement with CMS, provided it has not been de-certified and met the criteria to compete at the time it entered competition that resulted in non-renewal.

(d) *Criteria for selection*. CMS will select an OPO for designation to an open DSA based on the following criteria:

(1) Performance on the outcome measures at § 486.318.

(2) Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.360.

(3) Contiguity to the open service area.

(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. 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.

* * * * *

(g) *DSA transition*. (1) An incumbent OPO of a DSA must cooperate with a successor OPO that is newly designated to facilitate an orderly transition of the DSA. The incumbent OPO must submit a transition plan, as specified by CMS, that provides details on how all aspects of the OPO operation will be transmitted, including timeframes, to a new OPO.

(2) The successor OPO must submit a transition plan and periodic reports, as specified by CMS, to report on progress in its transition activities until the process is completed. The

successor OPO must provide a final notice to CMS no later than 30 calendar days after completion of the transition and prior to the end of the incumbent OPO's agreement.

10. Section 486.318 is amended by--

a. Revising paragraphs (a) through (c); and

b. Removing paragraphs (d) through (f)

The revisions read as follows:

§ 486.318 Condition: Outcome measures.

(a) Each OPO's DSA is evaluated by measuring the donation rate and the organ transplantation rate in the DSA.

(1) For all DSAs, except as set forth in paragraph (a)(2) of this section:

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

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

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

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

(2) For the Hawaii DSA:

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

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

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

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

(b) Success on the outcome measures will be assessed based on the following parameters and requirements:

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

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

(ii) The median rate among the DSAs.

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

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

(ii) The median rate among the DSAs.

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

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

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

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

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

(c) CMS will evaluate OPO performance on the outcome measures at each assessment period.

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

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

(3) If an OPO takes over another OPO's DSA as a result of a change of control or ownership or service area, on a date later than January 1 of the first year of the agreement cycle

so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, the OPO will be held accountable for its performance on the outcome measures in the new area once 12 months of data are available.

(4) If an OPO takes over a new DSA as a result of a competition or assignment by CMS, on a date later than January 1 of the first year of the agreement cycle, we will hold the OPO accountable for its performance on the outcome measures in the new area:

(i) For the QAPI requirement, specified at § 486.348(d), once 12 months of outcome measure performance data are available.

(ii) For purposes of re-certification, as specified at § 486.316, in the final assessment period of the following agreement cycle.

11. Section 486.322(a) is revised to read as follows:

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard: Hospital agreements.* An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in each of its designated donation service area(s) that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms “timely referral” and “imminent death.”

* * * * *

§ 486.324 [Amended]

12. In 486.324 amend paragraphs (a)(1), (2), and (5), (b)(2), and (b)(8) by removing “area” and adding in its place “area(s)”.

13. Section 486.326 is amended by revising paragraph (d), and adding paragraph (e) to read as follows:

§ 486.326 Condition: Human resources.

* * * * *

(d) *Standard: Medical director.* The OPO's medical director is a physician licensed in at least one of the States or territories within one of the OPO's service areas or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

(e) *Standard: Licensure*. The OPO must assure that personnel performing clinical duties are legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and must act only within the scope of the individual's State license, or State certification, or registration. Licensure, certification, or registration must be kept current at all times.

§ 486.328 [Amended]

14. Section 486.328 is amended in paragraph (c) by removing "area" and adding in its place "area(s)".

15. Section 486.330 is amended by revising paragraph (b) to read as follows:

§ 486.330 Condition: Information management.

* * * * *

(b) *Disposition of organs.* The OPO must maintain records showing the disposition of:

(1) Each organ recovered for the purpose of transplantation, including pancreatic islet cell transplantation, including information identifying transplant beneficiaries; and

(2) Each organ recovered and sent for research, including pancreata used for islet cell research. Records shall include, but are not limited to, the following:

(i) information documenting approval from an IRB or other formal authorizing body, as appropriate;

(ii) research institution;

(iii) principal investigator; and

(iv) study contacts.

* * * * *

16. Section 486.348 is amended--

a. In paragraph (b) by removing "area" and adding in its place "area(s)";

b. By adding paragraph (c)(3);

c. By revising paragraph (d)(3); and

d. By adding paragraph (e).

The additions and revision read as follows:

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

* * * *

(c) * * *

(3) Adverse events under these requirements include, but are not limited to,

(i) Transmission of an infectious or communicable disease or other disease that may be transmissible from a donor to an organ recipient, such as the transmission, dissemination, and seeding of malignancies;

(ii) Avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained;

(iii) Deviations from the current standards of practice or OPO procedures and policies regarding the evaluation and management of patients or potential donors that result in loss of a patient, potential donor, or transplantable organ(s);

(iv) Delivery to a transplant program of an organ that was not for the intended organ recipient or whose blood type does not match the blood type of the intended organ recipient;

(v) An organ that is lost, or delayed and arrived too late to be transplanted; or

(vi) An organ that arrives at the transplant program in a condition that is incompatible with transplantation.

(d) * * *

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

(e) *Standard: Review of performance on the recovery and transplantation of medically complex organs.*

(1) Each OPO must assess its policies and procedures regarding medically complex donors and organs and ensure they are optimizing opportunities to recover and place those organs for transplant;

(2) Each OPO must assess its performance regarding the:

(i) Number of medically complex donors from whom it has obtained consent for donation;

(ii) Number of organs recovered from those donors; and

(iii) Number of medically complex organs transplanted, at least annually.

(3) When an OPO identifies opportunities for improving its performance with medically complex donors or medically complex organs, it must implement actions to improve its performance.

17. Section 486.360 is amended--

a. By revising paragraph (c)(1)(v) and

b. In paragraph (e)(2)(i) by removing “DSA” and adding in its place “DSA(s)”.

The revision reads as follows:

§ 486.360 Condition for Coverage: Emergency preparedness

* * * * *

(c) * * *

(1) * * *

(v) Transplant and donor hospitals in each of the OPO's Donation Service Area(s) (DSAs).

* * * * *

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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