DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS–3409–F]

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: Final rule.

SUMMARY: This final rule revises the Conditions for Coverage for Organ Procurement Organizations (OPOs) to clarify outstanding procedural questions and provide additional operational flexibility for OPOs to achieve high performance resulting in the successful procurement, distribution, and transplantation of more life-saving organs. This rule revises definitions, revises the designation requirements for OPOs, clarifies when an OPO's service area is open for competition, and updates the process for appeals. We are committed to holding all OPOs accountable for their performance and this final 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: These regulations are effective on January 4, 2027.

FOR FURTHER INFORMATION CONTACT: The Clinical Standards Group, (410) 786–6633, *HealthandSafetyInquiries@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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 for an organ transplant, including how well a waitlisted individual matches with available donors, how sick the person is, and the availability of organs in the region. Despite continued growth in organ donation, procurement, and transplantation, the need for transplantable organs continues to grow. The success of organ procurement organizations (OPOs) in performing their essential functions (obtaining consent for donation, working with the Organ Procurement and Transplantation Network (OPTN) to match organs with recipients, procuring viable organs, and delivering those organs in transplantable condition to their recipients) is a rate limiting factor on the success of the entire organ transplant system. Therefore, optimal performance of OPOs is critical to ensure that the maximum possible number of transplantable human organs are available to the yearly average of more than 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 OPO 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 OPO final rule, CMS has received many inquiries from OPOs and others seeking clarification on operational and administrative elements. These inquiries increased in frequency and volume as the system moved closer to the end of the 2022–2026 re-certification cycle. Therefore, CMS published a proposed rule, ''Medicare and Medicaid Programs; Organ Procurement Organization Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations'' on January 30, 2026 (91 FR 4190, hereinafter referred to as the January 2026 OPO proposed rule).

The proposed rule contained operational and administrative provisions which would govern the competition process, provide programmatic clarity, and address interested party requests for additional guidance. Additionally, the proposed rule contained provisions aimed at driving further quality and 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.

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 as 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.

C. Summary of Costs and Benefits

This final rule is important due to its functional relationship to the December 2020 OPO final rule. Its purpose is to clarify and refine operational and administrative requirements related to OPO designation, re-certification, competition, appeals, information management, and Quality Assessment and Performance Improvement (QAPI), while maintaining the accountability framework established in the December 2020 OPO final rule.

We estimate that this final rule will cost approximately $16.5 million in the first year and $7.9 million annually thereafter. These costs are incremental to the broader framework established in the December 2020 OPO final rule and reflect targeted operational and administrative refinements rather than fundamental system restructuring. We also estimate that this final rule will result in approximately $598,000 in annual benefits due to reduced implementation inquiry and compliance-interpretation burden, as well as an additional one-time benefit associated with clarified requirements and implementation efficiencies.

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

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 Public Health Service (PHS) Act sets out certain requirements for OPO certification. There are currently 54 OPOs that are responsible for identifying patients who may become prospective donors and recovering organs from deceased donors in the United States (U.S.). These 54 OPOs currently serve 55 Donation Service Areas (DSAs), because each OPO serves at least one DSA and one OPO currently serves more than one DSA. 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 for their organ procurement costs to be eligible for payment under 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 and re-certification purposes and a three-tier 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 2025, there were a total of 49,065 organ transplants, compared to 48,150 and 46,634 transplants in years 2024 and 2023, respectively.[2] 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.[3] 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 OPO 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 OPO 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 OPO final rule utilizes increasing competition to drive performance improvement. An OPO's performance in its DSA(s) 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 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 OPO final rule.

On February 2, 2021, we published a notice in the **Federal Register** (86 FR 7814) temporarily delaying the effective date of the December 2020 OPO 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 OPO 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 the proposed rule and may be used in future rulemaking for system-wide changes to advance organ transplant system performance.

On January 30, 2026, we published the January 2026 OPO proposed rule (91 FR 4190). In the rule we proposed to: revise several definitions; remove the requirement that an OPO have been re-certified from 2002 through 2005 to be eligible for certification; revise the designation framework to account for scenarios where an OPO is designated to more than one DSA and clarify when DSAs are open for competition; clarify and categorize actions affecting OPO agreements, including non-renewal and de-certification; revise the appeal process; refine re-certification and competition policies, including evaluating each DSA separately for outcome measures and an OPO as a single entity for process performance; address OPO accountability on outcome measures when taking over another OPO's DSA; require appropriate staff licensure; expand information management requirements to include records for organs procured for research; and add new Quality Assessment and Performance Improvement (QAPI) requirements related to medically complex donors and organs.

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 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

[2] Organ Procurement and Transplantation Network (OPTN) Data. *https://hrsa.unos.org/data/view-data-reports/national-data/*. Accessed May 12, 2026.

[3] Organ Donation Statistics. *https://www.organdonor.gov/learn/organ-donation-statistics.* Accessed May 12, 2026.

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, as described in section 371(b) of the PHS Act, 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 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 as enforceable will be considered ''rules and requirements'' of the OPTN for purposes of section 1138 of the Act.[4] The 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 (§ 121.11(b)(2)) and § 486.328 of the OPO CfCs to report information specified by the Secretary to the OPTN, including the data used to calculate the outcome measures for OPOs.

In addition, OPOs are required to comply with existing Federal civil rights laws, including Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d, section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, section 1557 of the Affordable Care Act, 42 U.S.C. 18116, and the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq*.[5] Title VI protects individuals from discrimination on the basis of race, color, and national origin. Section 1557 of the Affordable Care Act protects individuals from discrimination on the basis of race, color, national origin, age, disability, or sex. Among other things, these laws require OPOs to ensure nondiscrimination on the bases protected in the operation of their programs. Also, section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act protect qualified individuals with a disability, including prospective organ recipients with a disability and prospective organ donors with a disability, from discrimination in the administration of covered organ transplant programs. 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 violations may include providing a prospective donor with a disability with a benefit or service that is not as effective as the benefits or services provided to those prospective donors without 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, covered 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 for 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. 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 outcome performance for re-certification and competition purposes (see § 486.316(a) and (d)).

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

In response to the January 2026 OPO proposed rule, we received 129 timely pieces of correspondence. Commenters included individual OPOs, transplant hospitals, national associations and coalitions, academic researchers, advocacy organizations, health care professionals and corporations, donor families, and numerous individuals from the general public.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and an explanation for any changes in the policies that we are finalizing. We note that this final rule is written in order by topic as they appear in the regulations.

A. General Comments

Comment: Most commenters supported CMS' overarching goals of strengthening safety, accountability, and public trust in the organ donation and transplantation system. A commenter stated that the recent increase in organ procurement demonstrates the effectiveness of increased accountability under the 2020 framework. However, some commenters expressed concerns about whether the proposed rule would drive meaningful improvement and recommended that CMS provide greater clarity regarding certain proposals.

Response: We believe the proposals we are finalizing will enforce accountability in organ procurement and support broader goals of improving patient safety and transparency in the organ procurement and transplantation system. We have reviewed the proposals and, where appropriate, have revised or clarified provisions in this final rule to better reflect the intent of the underlying policy and to support effective implementation. These revisions are discussed in detail in the

[4] 54 FR 51802.

[5] Recipients of Federal financial assistance must comply with applicable 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 Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act.

relevant sections later in this section of the preamble.

Comment: Many commenters expressed concern that the proposed rule does not adequately address their longstanding concerns with the 2020 Final Rule, particularly with respect to the outcome measures. Specifically, commenters stated that the outcome metrics: (1) do not reliably or accurately assess the comparative performance of OPOs, noting that the donation and transplantation measures are calculated using the same denominator; (2) are biased against large OPOs; (3) fail to account for demographic and geographic differences across service areas; (4) evaluate OPOs based on factors outside their control; and (5) are calculated using data that does not accurately estimate donor potential and contains errors. Commenters also expressed concern that significant fluctuations in the data confirm that a 12-month measurement period is insufficient as a basis for CMS' outcome metric calculations. Commenters recommended that CMS replace the tiering system with an Observed-to-Expected (O/E) model; replace the use of cause, age, and location consistent with organ donation (CALC) methodology and death certificate data with hospital referral data, include risk adjusted outcome measures; and use multi-year measurement periods.

Response: The comments regarding the type of outcome measures that CMS uses, risk adjustment, data sources, and the number of data years used for assessing compliance with the CfCs, all set forth in the December 2020 OPO final rule, are outside the scope of this final rule, which is intended to clarify and refine CMS policies and processes for implementing the accountability framework established in the December 2020 OPO final rule. While we proposed a regulatory refinement that will affect the outcome measures as it relates to the inclusion of pancreata used for islet cell research in those calculations, we did not propose any changes to the type of outcome measures that CMS uses, risk adjustment of those measures, data sources, or the number of data years used for assessing compliance with the CfCs. We stand by the underlying outcome measure framework set forth in the December 2020 OPO final rule.

Comment: Commenters stated that the current tiered system creates perverse incentives for OPOs to prioritize increasing donation and transplant rates over patient-centered care and ethical decision-making.

Response: Procuring organs from donors in a safe, ethical, and transparent manner supports performance on the CMS outcome measures. Research has shown that approaching potential donor families with sensitivity and compassion, providing adequate explanations of brain death, and allowing potential donor families sufficient time to make decisions all support higher donation rates.[6] By extension, we believe that OPOs that do not engage in patient-centered care and violate the CfCs (for example, pressuring next of kin for consent for organ donation) ultimately harm their own performance and that of the entire transplant system as these practices contribute to public mistrust in the system. CMS policies holding OPOs accountable for their outcomes, thereby increasing the number of lifesaving organs available for transplantation, are not responsible for poor OPO decision making. Additionally, under the process measures, an OPO is responsible for ensuring proper training and supervision of its staff (§ 486.326(c)) and otherwise maintaining compliance with process performance requirements at §§ 486.320 through 486.360 and should never jeopardize the health and safety of potential donors in the interest of bolstering its performance.

Comment: Several commenters stated that CMS would de-certify and replace an unreasonable number of OPOs, potentially disrupting the organ donation and transplantation system. They emphasized that stability is critical to maintaining relationships with donor families and hospital partners and to ensuring that organs are not lost due to operational disruption. They recommended that CMS prioritize sustainable performance improvement strategies such as technical assistance and corrective action plans and establish alternative pathways for remediation and performance improvement as a means of avoiding de-certification and minimizing disruption to the system. Commenters stated these options would enable a cure for any non-compliance, be less burdensome than an appeal, and provide a collaborative resolution-focused approach that would better serve patients.

Response: We disagree with the commenters' premise that prioritizing system stability and retaining current OPOs in their low performing DSAs is preferable to replacing these low performers with OPOs that have demonstrated better performance. The outcome measures and tier system are designed such that all OPOs have an equal opportunity to succeed. OPO performance in a DSA is measured against the median observed performance level of the previous year, meaning that each OPO begins each assessment period with a blank slate and need only achieve the performance level of the previous year's median. All OPOs are capable of meeting the previous year's median performance level in their DSAs and it is our intent to drive improved performance across all OPOs to the extent that the minimum performance standard is met in every DSA, and, ultimately, to save more lives.

We appreciate commenters' recommendations to establish alternative remediation pathways prior to de-certification. These pathways already exist and are required by regulation. Section 486.348(d) requires OPOs to identify and address performance deficiencies that might lead to regulatory action (that is, de-certification). The performance of each OPO is assessed annually, and this information is provided to each OPO. OPOs are required to evaluate their outcome measure performance through their Quality Assessment and Performance Improvement (QAPI) programs and implement corrective actions when performance falls statistically significantly below the top 25th percentile during an assessment period. As such, lower performing OPOs are already expected to develop plans to correct their actions in ways that improve performance and ultimately meet the minimum CMS performance standards. In addition, for the 2022–2026 certification cycle, CMS provided direct technical assistance to OPOs through the OPO Special Innovation Project (SIP), conducted by CMS-funded Quality Improvement Organizations (QIOs) from December 2023 through March 2025, and facilitated OPO collaboration through the ESRD Treatment Choices Learning Collaborative.

OPOs may remedy non-compliance with the process performance measures at §§ 486.320 through § 486.360 by submitting an acceptable plan of correction to CMS (see § 488.28) and implementing corrective actions to achieve and sustain compliance. However, there is no opportunity to remedy past failure to meet the minimum standards for compliance with the outcome measures at § 486.318 because those standards are based on OPO performance in the final assessment period of the re-certification cycle. Actions taken after the final

[6] Rodrigue JR, Cornell DL, Howard RJ. Organ donation decision: comparison of donor and nondonor families. Am J Transplant. 2006 Jan;6(1):190–8. doi: 10.1111/j.1600–6143.2005.01130.x. PMID: 16433774; PMCID: PMC2365918.

assessment period cannot cure the OPO's failure to meet the outcome measure standards as set forth at § 486.318. As discussed previously in this final rule, OPOs have an opportunity to address performance deficiencies in advance of the final assessment period as set forth in § 486.348(d).

We did not propose to modify the outcome measure performance standards to allow for alternative pathways to compliance, and any suggestions to that effect are outside the scope of this rule. Furthermore, as we explained in the December 2020 OPO final rule, allowing a poorly performing OPO to continue serving the DSA through a systems improvement agreement or similar mechanism would not benefit the patients in that DSA who would be better served by a higher performing OPO (85 FR 77912). OPOs that do not meet the outcome measures in a DSA in the final assessment period will either be de-certified under the requirements of § 486.312(a)(2) or (3) or have designation removed from the DSA if it has more than one DSA as specified at § 486.316(a)(3).

While we agree with commenters that system stability is a factor for consideration, we also note that such stability led to stagnation in performance. We do not agree with the premise that replacing a low performing OPO with a higher-performing OPO that is willing and able to provide those services will result in long term system disruptions that decrease donation and transplantation or otherwise disrupt the overall accelerated progress that the system has made in light of increased oversight. Retaining an OPO in a DSA where it has failed to meet CMS regulatory standards would not best serve the people in that DSA or the system at large. We are committed to ensuring that any transition between OPOs is conducted in a manner that minimizes disruption to organ procurement activities.

We also note that Health Resources and Services Administration (HRSA) and the OPTN continue to provide resources and technical support to assist OPOs in improving performance and strengthening organ procurement and transplantation practices.

Comment: Commenters raised concerns regarding the timing of the proposed rule in relation to the 2022 through 2026 re-certification cycle. Many commenters requested that CMS refrain from issuing de-certification notices or conducting competitions and instead develop a revised re-certification process that more accurately and fairly measures OPO performance or delay implementation to allow time to assess the impact of new requirements on OPO performance. Some commenters stated that any finalized policies should not be applied to the 2022 through 2026 re-certification cycle, noting that OPOs cannot retroactively adjust past performance to comply with new standards. Several commenters requested clarity in when changes to the definitions would become effective. Some commenters expressed concerns that CMS would apply the changes retroactively.

Response: The January 2026 OPO proposed rule, and this subsequent final rule, seek to address operational questions that CMS has received from interested parties and provide additional detail on how the policies adopted in the December 2020 OPO final rule will be effectuated. CMS will not retroactively apply these provisions to any OPO, but will apply them prospectively, as of the effective date of this final rule, in effectuating the enforcement framework adopted in the December 2020 OPO final rule. While we proposed and are finalizing a change to the definition of ''organ'', which has implications for how the transplantation rate outcome measure will be calculated and reported to OPOs, this change will only apply as a regulatory requirement to outcome measure data reporting after the effective date of this final rule, beginning with the 2027 assessment period (as defined in § 486.302). In addition, we note that in assessing OPO performance in 2027, we will take steps to ensure OPO performance is appropriately and accurately compared to 2026 performance based on the updated definition of ''organ.'' Data from the 2027 assessment period will be used to calculate performance described in the 2029 OPO Public Performance Report. OPO performance in 2027 will be measured against the median and top 25 percent thresholds set by OPO performance in 2026. To ensure that 2027 performance is appropriately measured against 2026 performance, for purposes of the 2029 OPO Public Performance Reports we will recalculate the median and top 25 percent thresholds for 2026 applying the revised definition of ''organ'' that excludes pancreata used for islet cell research and not transplanted from the transplantation rate. This recalculation will model what the transplantation rate outcome measure performance would have been in 2026, had the revised definition been effective at that time. This will ensure a comparison of like data sets, establish an accurate and consistent performance threshold for the 2027 performance data to be measured against, and ensure that OPOs are not evaluated against 2026 performance data that include a broader range of procured organs in the transplantation rate. Therefore, the 2029 OPO Public Performance Report, based upon the 2027 assessment period performance data evaluated against recalculated 2026 performance thresholds for the transplantation rate, will provide OPOs with accurate information about their performance. We will continue applying the revised definition to future outcome measure calculations.

We note that the data reported by OPOs and the coding guidance that they use to perform this data reporting will not change when the revised definition of ''organ'' is applied to the organ transplantation rate. Existing data coding practices, as required by the OPTN (consistent with § 486.328) already support CMS' ability to calculate performance on the organ transplantation rate outcome measure with and without pancreata used for islet cell research. What will change is how CMS selects the organ disposition codes that OPOs and transplant programs already enter into the data reporting system and applies those codes to the organ transplantation rate calculation.

Likewise, OPOs will not be required to comply with changes to the CfCs finalized in this rule, such as changes to address situations in which a single OPO is simultaneously designated to more than one DSA, until the effective date of this final rule. As some commenters noted, OPO performance for the 2022 through 2026 re-certification cycle is already complete. Given that the policies finalized in this rule will not impact OPO performance for the 2022 through 2026 re-certification cycle, there is no need to delay enforcement decisions for that cycle to assess any impact of this rule on OPO performance.

Comment: Several commenters stated that the proposed rule placed disproportionate emphasis on OPO performance without adequately accounting for the roles of other interested parties in the donation and transplant system. They stated that greater shared accountability is needed across OPOs, donor hospitals, and transplant centers, including improved transparency around transplant center acceptance practices and better alignment of performance expectations across the system.

Response: We agree that organ transplantation is a system that includes many actors, each performing their essential functions to the best of their

ability. Coordination and collaboration among OPOs, donor hospitals, and transplant centers are important to supporting timely organ recovery, placement, and transplantation. We will consider these comments for potential future rulemaking for other related members of the organ donation and transplantation ecosystem.

Comment: Several commenters suggested that CMS issue guidance prior to implementation. They encouraged CMS to continue interested parties' engagement and collaborate with HRSA and OPTN to ensure alignment and avoid duplicative or conflicting regulatory requirements.

Response: We appreciate the commenters' suggestions, and we intend to continue working closely with HRSA and the OPTN to avoid duplicative or conflicting regulatory requirements. We will provide guidance through sub-regulatory channels, including updates to the State Operations Manual (SOM), to support compliance with these requirements.

Comment: CMS received several comments pertaining to issues that are outside the scope of the proposed rule. Those comments concerned transplant program outcome measures/harmonizing outcome measures, inclusion of new risk-adjusted outcome measures, harmonization of Federal requirements with State anatomical gift laws, donor registry enrollment and informed consent, the intersection between donation after circulatory death (DCD) processes and first-person authorization (FPA), public education regarding clinical processes associated with organ donation, including DCD, revising the definition of organ to include lifesaving tissue, clearer authorization communication requirements, the use of a DNA-authenticated blockchain system to secure the organ transplant process, a requirement to make all patient records available to a potential donor's next of kin, and donor care units/organ recovery centers.

Response: We thank the commenters for their feedback. However, these issues are outside the scope of the final rule.

B. Definitions (§ 486.302)

We proposed 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. General Comments

Comment: Commenters urged CMS to test any new definitions more thoroughly to assess downstream effects on measures and re-certification decisions.

Response: We have carefully considered the impact of these definition changes on the meaning and application of the regulations where these terms are used, as well as public comments we received on these proposed changes. The changes are prospective in nature and OPOs are expected to comply with them upon the effective date of this final rule. We do not expect significant downstream effects on measures and re-certification decisions as a result of any definition changes finalized in this rule. For example, we conducted an internal analysis based on preliminary data used for the 2026 OPO report to assess the projected impact of revising the definition of ''organ'' to exclude pancreata used for islet cell research from the organ transplantation rate and noted minimal effects on OPO tier status. We expect similarly minimal effects on OPO tier status when this change takes effect. In addition, the change to the definition of organ is appropriate to meet our regulatory goals of incentivizing organ transplants while complying with the requirements of the Pancreatic Islet Cell Transplantation Act of 2004 (PICTA 2004).

Comment: Some commenters recommended that any definitions should be aligned or harmonized with OPTN and HRSA definitions to promote consistency in interpretation and implementation of requirements. A few commenters noted that OPTN and HRSA are working on revising various requirements that could affect proposed changes to definitions.

Response: CMS and HRSA continually work to align policies as appropriate to the statutory authorities that govern our actions and the regulatory approaches that we employ. We note that ''alignment'' does not always require exact duplication, as there are instances when a compatible, nuanced approach is better suited to addressing an issue than a broad, standardized approach. Currently, the OPTN does not have a comprehensive, standardized definition for ''adverse events.'' However, the OPTN does require that a narrow set of high-severity patient safety events (''HRSA-reportable'' or ''Wakefield'' events) be reported to HRSA and to the OPTN Patient Safety Reporting Portal. Those events include: (1) wrong organ transplants or near misses, (2) transplants into the wrong recipient or near misses, and (3) suspected or confirmed donor-derived HIV transmission.[7] Our current definition of ''adverse event'' is broad enough to encompass the OPTN and HRSA requirements for reportable events. Additionally, alignment of requirements is one factor that CMS considered related to the proposed definitions for medically complex organ and medically complex donor. Please see section III.B.4. of this final rule for additional discussion.

2. 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.'' We proposed to relocate the illustrative examples of adverse events from the definition of ''adverse event'' to the QAPI requirements at § 486.348(c). We also proposed revising the list to clarify that the list of examples does not constitute an exhaustive list of adverse events. We solicited public comment on the proposed changes to the definition of adverse events. The following is a summary of the comments we received and our responses.

Comment: Commenters stated that the proposed definition of ''adverse events'' was overly broad, ambiguous, and susceptible to inconsistent interpretation by both OPOs and surveyors. They expressed concern that legitimate disagreements between the OPO and a surveyor on whether an incident was an adverse event could result in inappropriate and inconsistent deficiency determinations and other inconsistent enforcement actions, which would limit the QAPI requirements' usefulness as a quality improvement tool.

Response: While we proposed to move a revised, non-exhaustive list of examples of adverse events from the definitions section to the QAPI section at § 486.348(c)(3), we note that the

[7] Organ Procurement and Transplantation Network. OPTN Policies, 18.5 Reporting of Patient Safety Events. Accessed at *https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_policies.pdf.* Accessed on May 22, 2026 and Letter from HRSA Administrator Dr. Mary Wakefield to OPTN President Dr. John Lake dated August 5, 2011.

remaining definition at § 486.302, defining an ''adverse event'' as ''an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof,'' is the same one that was adopted in the 2006 final rule (71 FR 30982, 31046). CMS and OPOs have been applying this definition for the last 20 years. We are not aware of any evidence that inconsistent interpretation by OPOs or surveyors or legitimate disagreements between the OPO and a surveyor on whether an incident was an adverse event has resulted in inappropriate or inconsistent deficiency determinations or other inconsistent enforcement actions. We encourage OPOs to seek guidance from CMS related to whether an incident is an adverse event if they are ever unsure about a particular incident. In addition, CMS provides sub-regulatory guidance, particularly surveyor guidelines in Appendix Y of the State Operations Manual.

Comment: Several commenters requested objective criteria to ensure clarity and uniformity. They recommend limiting the definition of ''adverse events'' to clinical or operational failures that pose risks to patient safety. Others recommend restricting the scope of reportable ''adverse events'' to violations of the OPO's internal policies, OPTN policies and bylaws, and Federal regulations.

Response: While we agree with the commenters that clinical or operational failures that pose risks to patient safety and violations of the OPO's internal policies, OPTN policies and bylaws, and Federal regulations may all constitute ''adverse events'', we disagree that the regulatory definition of the term should be restricted to them. We believe that a restrictive definition would likely leave out possible incidents that should be identified as ''adverse events'' and require compliance with § 486.348(c)(1) and (2). We believe the definition of the term ''adverse events'' set forth in § 486.302, coupled with the revised, non-exhaustive list of examples we proposed to move to the QAPI requirements at § 486.348 (c)(3) provides sufficient guidance on whether an incident constitutes an adverse event.

Comment: Most commenters supported our proposed revision to move the list of examples of incidents that would be considered ''adverse events'' from the definition in § 486.302 to the QAPI section at § 486.348 of the regulations. Some commenters agreed that this shift from defining the term with examples to using them in the context of QAPI emphasized that the list was not exhaustive. However, some commenters disagreed with relocating the list of examples, and a commenter suggested that removing the list of examples would result in more confusion.

Response: We agree that retaining and revising the examples and moving them to the QAPI section of the regulations clarifies that the list of examples is not exhaustive. We reiterate that the list of examples is not being removed from the CfCs. It is being moved to the QAPI requirements related to adverse events (§ 486.348(c)(3)), which should reduce confusion.

Comment: Several commenters sought clarification about whether ''risk thereof'' includes near-misses or latent safety conditions.

Response: The definition of ''adverse events'' would include actions or omissions that could have resulted in death or serious injury but were somehow stopped before that could happen (that is, a ''near miss''). We would also note that OPTN Patient Safety Portal reportable events [8] also include events that could have resulted, but did not, in death or serious injury. Regarding latent safety conditions, we believe that depends upon whether the latent safety conditions resulted in an incident sufficient to constitute an adverse event. We believe these instances would be very fact-specific scenarios and would encourage an OPO to speak with or consult with CMS for further guidance.

Final Rule Action: After consideration of the public comments, we are finalizing the ''adverse event'' definition as proposed.

3. Donor and Organ

Section 486.302 currently defines ''donor'' as ''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.'' We proposed 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 transplantation or for islet cell research is included in the definition of ''donor'' for purposes of the donation rate outcome measure. This clarification would ensure consistency and continued compliance with the statutory requirement [9] that pancreata used for islet cell transplantation or research be counted for purposes of certification and re-certification. We solicited public comment on the proposed changes to the definition of ''donor''.

Additionally, section 486.302 currently defines ''organ'' as ''. . . 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.'' The inclusion of pancreata used for islet cell bench research within the definition of ''organ''—and by extension the ''organ transplantation rate''—is inconsistent with CMS' goals to increase the number of actual transplants, as it creates a perverse performance incentive that allows OPOs to count research activity as equivalent to a transplant, potentially masking poor performance in facilitating actual organ placements for patients on transplant waitlists. Therefore, we proposed to remove pancreata used for research from the definition of ''organ'', meaning that such pancreata are removed from the organ transplantation rate outcome measure. Research activity would no longer count as a transplant for purposes of certification and re-certification. We solicited public comment on the proposed changes to the definitions of ''donor'' and ''organ''. The following is a summary of the comments we received and our responses.

Comment: The majority of commenters were supportive of the proposed changes to the definitions of ''donor'' and ''organ''. However, some commenters indicated that the proposed changes did not go far enough and recommended additional changes. Many commenters stated that pancreata procured for islet cell research should be removed entirely from the outcome measures while others proposed alternative ways to count pancreata. Several commenters stated that CMS should create a separate outcome measure specifically for pancreata. A commenter recommended creating a process performance measure for pancreatic islet cell procurement.

Response: We appreciate the support for revisions to the definitions of ''donor'' and ''organ''. PICTA 2004, which amended the PHS Act to add section 371(c), requires pancreata procured and used for islet cell transplantation or research to be counted for certification and re-

[8] Organ Procurement and Transplantation Network. OPTN Policies, 18.5 Reporting of Patient Safety Events, Table 18–3 Required Reporting by Transplant Hospitals. *https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_policies.pdf.* Accessed on May 22, 2026.

[9] Section 371(c) of the PHS Act.

certification purposes. Therefore, we cannot remove pancreata from the numerical outcome measures entirely or assess compliance through an observed process performance measure. At this time, establishing a separate outcome measure is contrary to CMS policy goals, as it would overly incentivize pursuit of donors for islet cell research, likely to the detriment of pursuit of donors for transplantable organs. The organ quality standards and procurement process for research organs differ from those of organs for transplant, focusing less on optimal organ transplant viability that may require precise organ retrieval timing and techniques and costly perfusion equipment for delivery to the transplant program. Establishing a standard that may be easier for OPOs to meet could incentivize OPOs to shift procurement resources away from transplantable organs, and that shift would not be consistent with patient needs and our policy goals. As such, we believe the proposed changes to the definitions are the most appropriate approach to accomplish our policy goals. This would enable counting donors when pancreata were procured for islet cell transplantation or islet cell research, but pancreatic islet cells would only count as a transplant when actually transplanted into a recipient, including transplantation that is conducted under research protocols.

Comment: Several commenters recommended narrowing the scope of research that would qualify for inclusion of pancreata in the outcome measures. A commenter recommended that CMS only include ''pancreata recovered for research focused on pancreatic islet cell transplantation and conducted under FDA approved clinical research.'' Another commenter stated that OPOs may not have access to requested research protocols or other documentation necessary to evidence that the pancreata were actually used for bona fide islet cell research.

Response: We thank commenters for these recommendations. Our proposed revisions to the definition of ''donor'' were intended to emphasize that pancreata must be procured and used for islet cell research or islet cell transplantation, consistent with PICTA 2004, to be counted in the outcome measures. We previously clarified this point in a memorandum issued on January 18, 2024. With respect to the commenter's suggestion to restrict pancreatic islet cell research to only include ''FDA approved clinical research,'' PICTA 2004 requires pancreata procured by an OPO and used for islet cell transplantation or research to be counted for certification or re-certification decisions. That statutory requirement is not limited to clinical research that FDA has allowed to proceed. We also note that we have previously worked with HRSA to revise and clarify coding for pancreata submitted for research (See QSO–24–19–OPO). If an OPO is unable to obtain records demonstrating the pancreata were used for research for islet cell transplantation, it should not code the disposition as ''accepted for islet cell research'' to be included in the CMS outcome metrics.

Comment: Several commenters stated they supported the changes and the exclusion of pancreata islet cells used for research from the transplant rate when the islet cells are not transplanted. A commenter indicated that the proposal strikes a balance between the statutory requirements and concerns about accurate measurement of transplantation rates, suggesting it will facilitate more consistent reporting.

Response: We thank commenters for acknowledging the importance of this change. In our proposed rule, we stated 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. Our proposed change to the definitions of ''donor'' and ''organ'' are refinements to remove pancreatic islet cell bench research from the transplant rate while appropriately retaining it in measurement of the donation rate. These changes better incentivize both pancreata islet cell research and transplantation via the donation rate and pancreatic islet cell transplantation via the transplant rate while more precisely measuring performance and complying with the PICTA 2004.

Comment: Several commenters indicated that research on pancreatic islet cells when not transplanted, sometimes called ''bench research'', does not involve living persons so approval by an institution review board (IRB) is generally not required. In these instances, the OPO would not have a record of approval from an IRB.

Response: We acknowledge this consideration and how it may impact records for organ disposition when those organs are sent for research. The requirements at § 486.330(b)(2) as finalized in this rule only require an OPO to maintain information documenting approval of an IRB or other formal authorizing body ''as appropriate.'' Where no such approval is required, the OPO is not required to maintain approval documentation. The OPO would, however, continue to be required to maintain records showing the disposition of the organ as set forth in § 486.330(b)(2), including the research institution, principal investigator, and study contacts. Regardless of the information that is available, if an OPO is coding and reporting pancreata procurement and disposition in a manner that would count in the outcome measures, it must be able to provide CMS and the OPTN with sufficient records to support and justify the coded disposition for pancreatic islet cell research.

Comment: Several commenters state that the changes risk creating inconsistent treatment of pancreata across the two outcome measures that may introduce gaming.

Response: The changes to the definition of ''donor'' and ''organ'' increase specificity of reporting and better align the incentives of the measures (more donors and more transplants) to mitigate any potential gaming. These changes fairly count donors of organs that are used for transplantation or islet cell research and transplants that directly benefit patients on the waitlist while complying with the PICTA 2004.

Comment: A commenter questioned the rationale for excluding pancreata used for bona fide islet cell research from the transplant rate. The commenter stated that this exclusion could inadvertently discourage OPOs from supporting research that advances transplantation science.

Response: Pancreata will continue to be counted in the donation rate when procured for islet cell research regardless of whether the final disposition is bench research or transplantation. Pancreatic islet cells will continue to be counted in the transplant rate when actually transplanted. This change continues to incentivize transplant science and transplantation of pancreatic islet cells.

Comment: A commenter recommended that CMS allow supplemental QAPI tracking for pancreata recovered for islet cell research to enhance the integrity of tracking this information.

Response: We appreciate this comment. While we have not proposed a corresponding QAPI requirement for tracking pancreata procured for islet cell research at this time, nothing prevents OPOs from utilizing their QAPI program for this purpose. We will continue to monitor procurement practices in this area and may consider a corresponding QAPI requirement in future rulemaking.

Final Rule Action: We are finalizing as proposed the definition of ''donor'', at § 486.302, as a deceased individual

from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted. An individual will also be considered a donor if only the pancreas is procured and is used for islet cell transplantation or for islet cell research. Additionally, we are finalizing as proposed the definition of ''organ'' as 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.

4. Medically Complex Donors and Medically Complex Organs

We proposed to add a definition for ''medically complex donor'' and ''medically complex organ''. We proposed 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 would include all DCD donors and donors with elevated KDPI scores of 50 or more. We also proposed to define the term ''medically complex organ'' as an organ procured from a ''medically complex donor''. These definitions are linked to a proposed new QAPI requirement that would require OPOs to facilitate appropriate placement and utilization of these organs, to increase the pool of organs available for transplantation. We solicited public comments on the proposed definitions of ''medically complex donors'' and ''medically complex organs''. The following is a summary of the comments we received and our responses.

Comment: Comments on the definition for ''medically complex donor'' were mixed. Some commenters strongly supported DCD and HIV+ patients being included in the definitions. While some supported a KPDI of 50 or greater, others suggested a score of 85 or greater. Other commenters wanted to include additional comorbidities, such as hypertension or diabetes. Several commenters stated that the proposed definition already applied to most of their deceased donors and raised burden concerns. Other commenters expressed concern that the proposed thresholds, such as KDPI scores, could disadvantage underserved communities. Some commenters recommended using other criteria, such as the criteria previously used for expanded criteria donors (ECDs). Some commenters mentioned considering clinical indications, in addition to medical history.

Response: We would like to thank all the commenters for their valuable input into this definition. After considering the public comments we received, we have determined that there is a lack of consensus among relevant interested parties as to what constitutes a ''medically complex donor.'' Comments on this topic varied significantly, making it extremely difficult to describe a narrowed or specific population of donors. Some commenters recommended utilizing the previous construct of ''expanded criteria donor.'' However, this is no longer utilized by the OPTN nor is it reported by the SRTR. Commenters raised valid concerns regarding burden if the definitions were overly broad which could hamper their QAPI activities from those donors that they believe to be most challenging for placement of organs. In addition, evolving practice patterns, such as the increase in DCD donation, and increased use of technology, such as advanced perfusion technology, are advancing the recovery and placement of organs that were previously considered difficult to place for transplantation. Hence, after consideration of public comments, we are not finalizing these definitions at this time. We will monitor for new constructs that may emerge in the future that would support this proposal, including a consensus on consistent, nationally accepted standards for what constitutes a medically complex donor. Therefore, we will continue to monitor this issue and consider revisiting a proposal regarding medical complexity in the future.

Comment: Some commenters stated that the usefulness of this requirement for OPOs will be limited without corresponding requirements for donor hospitals and transplant programs. For example, some commenters thought that transplant programs should be held accountable for not accepting medically complex organs.

Response: As explained previously in this final rule, we will not be finalizing these definitions. However, we may consider proposing requirements regarding medical complexity in the future. If we do, the commenters' recommendations about corresponding requirements for donor hospitals and transplant programs and accountability will be considered. at that time.

Final Rule Action: After consideration of the public comments we received, we are not finalizing the following definitions: ''Medically complex donor'' and ''Medically complex organ''. Additionally, we are not finalizing the corresponding QAPI requirement as discussed in section III.L. of this final rule.

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''.

We proposed 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.'' This definition was proposed to ensure that unsound medical practices would be addressed appropriately, and that OPOs would continue to provide high quality care to patients, potential donors and potential transplant recipients. We solicited public comment on the proposed definition of ''unsound medical practices''. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for CMS' goal of clarifying the definition of ''unsound medical practices'' and establishing strong regulatory consequences for conduct that poses an imminent threat to patient safety. Commenters generally agreed that egregious breaches of medical or ethical standards warrant serious enforcement action and that OPOs engaging in reckless or dangerous practices should be held accountable. However, many commenters expressed concerns that the proposed definition of ''unsound medical practices'' is overly broad and vague. They stated that the definition, as proposed, could permit CMS to penalize OPOs even when they are in compliance with existing regulations and may grant CMS excessive discretion, potentially leading to inconsistent or arbitrary enforcement.

Response: We appreciate the opportunity to clarify our intent in proposing this definition. The proposed definition of ''unsound medical practices'' was intended to provide a

clear, enforceable basis for urgent de-certification to protect patients and maintain public trust in the donation and transplantation system. We chose not to be overly prescriptive and specify the exact practices or instances that constitute unsound medical practice, as a narrow definition would risk creating regulatory gaps that could allow unsafe practices to go unaddressed. Rather, we focused on the outcomes of those specific practices and instances and their impacts on health and safety so that we could evaluate each case individually. We disagree that this outcome-oriented approach would lead to arbitrary or inconsistent enforcement. Making individualized determinations that are based on health and safety impacts does not equate to arbitrary enforcement. When we receive complaints or identify potential issues, trained surveyors investigate allegations of unsafe practices that arise, and all determinations are based on the evidence gathered during those investigations. CMS surveyors receive extensive training in assessing facilities for non-compliance, determining the seriousness of outcomes that pose imminent threats to patient health, and deciding when rapid action is needed to ensure safety to eliminate a risk to patients or the public. Additionally, any determination of unsound medical practices would be made carefully after consideration by CMS, given the seriousness of this determination and enforcement actions that would ensue.

Comment: Several commenters expressed concerns that the proposed definition could be interpreted to permit de-certification based on a single, isolated incident. They recommended that CMS clarify that findings of unsound medical practices would be based on objective evidence of repeated or sustained failures and that immediate de-certification would be reserved for the most egregious cases involving clear, severe violations that pose an imminent threat to patient safety or public trust.

Response: A single event may constitute ''unsound medical practices'' and the finding of ''unsound medical practices'' is not limited to patterns of repeated unsafe practices. If a single event creates an imminent threat to patient health and safety or poses a risk to patients or the public, then it can constitute ''unsound medical practices'' and CMS can act immediately to protect patients. This gives CMS a clear, enforceable basis for urgent de-certification to protect patients and maintain public trust in the system. The question is not whether the situation is isolated or recurring, but whether it meets the threshold established by the definition. We will evaluate each situation based on the totality of the evidence and the specific circumstances involved before making a determination.

Comment: Many commenters requested that CMS more clearly distinguish between ''adverse events'' and ''unsound medical practices,'' noting that the two concepts carry different regulatory consequences. They also requested clarification on how QAPI findings would be used in enforcement decisions and suggested that less severe or correctable deficiencies be addressed through standard compliance mechanisms such as plans of correction and enhanced oversight, consistent with CMS' approach to immediate jeopardy with other provider types.

Response: We agree that ''adverse events'' and ''unsound medical practices'' are distinct concepts that carry different regulatory consequences. Adverse events, while serious, generally can be addressed through an OPO's internal QAPI program if they do not rise to the degree of severity and impact on patient or public health and safety to be considered unsound medical practices. Section 486.348(c) 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 drive process improvement by effecting changes in their policies and practices to prevent repeat incidents. ''Unsound medical practices'' are failures by the OPO in which the OPO knows, or should have known, that its inaction, actions, or outcomes has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient, creating an imminent threat to patient health and safety or public safety. The critical distinction between an ''adverse event'' that can be addressed through a QAPI program under § 486.348(c) and ''unsound medical practices'' that may support de-certification for urgent need lies not in whether an incident is isolated or repeated, but rather in the degree of severity and impact on patient or public health and safety and the need for immediate action. If an adverse event is of such severity and impact to health and safety that it rises to the level of an unsound medical practice, standard compliance mechanisms such as QAPI are insufficient to address the concern. Therefore, CMS would apply its regulatory standards for unsound medical practices within the context of de-certification due to urgent need and proceed accordingly. Less severe deficiencies would be addressed through standard compliance mechanisms—such as acceptable plans of correction and additional oversight. We believe the definitions of adverse events and unsound medical practices strike the appropriate balance between providing CMS with the enforcement flexibility necessary to protect patient and public safety and ensuring that enforcement actions are based on objective, evidence-based findings.

Comment: Several commenters objected to the inclusion of ''failures in governance'' within the definition, stating that governance issues are administrative rather than clinical in nature and do not directly threaten patient health and safety.

Response: We disagree that ''failures in governance'' are solely administrative in nature or that they cannot directly threaten patient health and safety. Governance establishes the oversight and accountability framework necessary to ensure that clinical practices are performed safely and in accordance with applicable requirements. For example, a circumstance in which an OPO's governing board directs staff to undertake actions that are inconsistent with standards of practice, OPO policies, CMS rules and requirements, and/or local, State, or Federal laws that knowingly create an imminent threat to patient health/safety or pose a risk to patients or the public, would reflect a failure in governance. Specifically, it would reflect a failure of the governing board to enforce established policies and procedures, placing patients at immediate risk of serious harm. Therefore, we are finalizing a definition of unsound medical practices that includes failures in governance.

Comment: A commenter recommended that CMS expand the definition to include OPO staff conduct toward patients' families, such as overly assertive behavior in the consent process and failure to collaborate with hospital staff in establishing referral criteria and donation protocols.

Response: Approaching donor families with compassion, sensitivity, and respect during the donation process and allowing for adequate time to make a decision are incredibly important practices and have been shown to improve donation consent rates.[10]

[10] Rodrigue JR, Cornell DL, Howard RJ. Organ donation decision: comparison of donor and nondonor families. Am. J. Transplant. 2006 Jan;6(1):190–8. doi: 10.1111/j.1600–6143.2005.01130.x. PMID: 16433774; PMCID: PMC2365918.

Families should never feel rushed, coerced, or disregarded when making decisions about organ donation. Overly assertive or pressuring behavior not only undermines public trust in the donation system but may also constitute a violation of existing requirements under § 486.342, which mandates that OPOs encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families. Complaints against an OPO may be submitted through various channels, including CMS,[11] State survey agencies, HRSA,[12] the OPO, or the hospital. Similarly, CMS emphasizes the importance of strong collaboration between OPOs and hospital staff throughout the donation and procurement process. These collaborative responsibilities are reflected in existing requirements under § 486.322(a), which requires OPOs and donor hospitals to establish written agreements defining certain responsibilities and protocols—including definitions of ''timely referral'' and ''imminent death.'' Additional guidance is available in the SOM, Appendix Y—Organ Procurement Organizations. While we are not expanding the definition of ''unsound medical practices'' to include these areas at this time, the existing regulatory framework provides clear expectations for OPO conduct toward patients' families, such as overly assertive behavior in the consent process and failure to collaborate with hospital staff in establishing referral criteria and donation protocols.

Comment: Several commenters objected to the term ''unsound medical practices'' itself, stating that OPOs do not practice medicine or provide care to living patients and instead function in a coordination and procurement role. They suggested alternative terms such as ''unsound donation practices'' or ''unsound procurement practices,'' to better reflect OPO responsibilities and reduce potential confusion among interested parties and the public.

Response: The term ''unsound medical practices'' is not intended to refer to clinical activities outside the scope of an OPO's activities; rather, it is intended to encompass the full range of OPO activities during the donation and procurement process, including transport of a viable organ intended for a living person. We do not believe that either ''unsound procurement practices'' or ''unsound donation practices'' adequately captures that full range. For instance, ''unsound procurement practices'' would be too narrow because the proposed definition includes ''procurement . . . practices and procedures'' as a subset of unsound medical practices. Similarly, ''unsound donation practices'' may be overly limiting and would not necessarily encompass additional activities included in the definition, such as transport practices and procedures. The term ''unsound medical practices'' best reflects the full range of OPO activities the definition is intended to cover and avoids the ambiguity that either alternative term would introduce.

Comment: Many commenters expressed concerns that examples of ''unsound medical practices'' provided in the proposed rule are unclear, overly broad, and, in some cases, inconsistent with the role of OPOs. Commenters stated that the example, ''failure to ensure the potential donor is declared dead according to applicable State law and hospital policies,'' inaccurately suggests that OPOs are responsible for, or influence, the clinical determination of death. They recommended that CMS revise the example to clarify that the OPO's role is limited to verifying that death has been declared in accordance with applicable requirements.

Several commenters also raised concerns that the phrase ''necessary and customary tests'' lacks specificity and is not clearly defined. They recommended that CMS provide additional detail regarding what constitutes such testing and align any requirements with existing OPTN policies governing donor evaluation. Commenters further emphasized that OPOs should only be held accountable for testing activities within their direct control. Some commenters expressed concern that unclear or expanded testing requirements could create operational burdens, delay the donation process, and potentially increase organ non-use.

Additionally, commenters stated that the example ''pursuing patients with inappropriately high neurologic function'' lacks clinical specificity and is not defined in current CMS or OPTN policy. They cautioned that this language could lead to inconsistent interpretation and discourage appropriate donor evaluation, including for patients with severe neurologic injury, donation after circulatory death candidates, or individuals with conditions such as ALS or spinal cord injury, thereby potentially reducing donation opportunities.

A commenter suggested expanding the examples of unsound medical practices to include failures by OPOs to utilize perfusion technologies when procuring and transplanting organs. Overall, several commenters urged CMS to revise the examples to more clearly reflect OPO responsibilities and include objective clinical criteria where applicable.

Response: We appreciate commenters' requests for additional clarification regarding the scope and intent of the examples discussed in the proposed rule. The examples referenced in the proposed rule are illustrative only and are not intended to be interpreted as part of the regulatory definition of ''unsound medical practices.''

Regarding the example referencing ''failure to ensure the potential donor is declared dead according to applicable State law and hospital policies,'' we note that the decision to withdraw life support and the subsequent declaration of death, if death occurs, are solely the responsibility of the patient's attending physician or a hospital physician designee in accordance with hospital policy and applicable State law.[13] OPOs may not be involved in the decision to withdraw life support, the timing of withdrawal, or the declaration of death in any way. However, OPOs are required to verify that the pronouncement of death for potential donors adheres to applicable local, State, and Federal laws (§ 486.344(b)(1)), including in cases involving DCD. Following the declaration of death and prior to initiating the organ recovery process, the OPO should confirm that death has been pronounced and obtain documentation of the pronouncement of death.

Regarding the example referencing ''necessary and customary tests,'' we do not intend to establish a new requirement or expand existing testing expectations. Under OPTN Policy 2.9, OPOs are required to ensure that infectious disease testing is performed for all potential deceased donors. This includes standardized screening for communicable diseases, as well as additional testing as clinically indicated by donor risk assessment. OPOs are also responsible for ensuring that specimens are collected within appropriate timeframes, that testing is performed in Clinical Laboratory Improvement Amendment (CLIA) certified laboratories, and that all required and relevant results are accurately documented and communicated to transplant centers in a timely manner.

[11] Complaints or issues related to OPOs may be submitted to the following email address: *SOG-OPO@cms.hhs.gov.*

[12] Reporting Allegations of Misconduct. *https://www.hrsa.gov/optn/about/contact-us/report-misconduct.* Accessed May 26, 2026.

[13] Organ Procurement Organizations (OPOs) and Donor Hospitals' Responsibilities Memo. *https://www.cms.gov/files/document/qso-26-05-opo-original-release-date-2026-03-11-pdf.pdf.*

These testing requirements align with § 486.346 by promoting safe organ recovery and minimizing the risk of disease transmission through transplantation.

Finally, regarding the example referencing ''pursuing patients with inappropriately high neurologic function,'' this example is not intended to establish clinical eligibility criteria, define neurologic thresholds, substitute for clinical judgment, or discourage OPOs from pursuing particular categories of potential donors. Rather, it is intended to emphasize the importance of adhering to established clinical and regulatory safeguards, including requirements related to the determination of death and appropriate donor evaluation, to protect patient safety. OPOs are expected to immediately cease the procurement process if signs of life are observed at any point before or during organ recovery. A prior declaration of death by the attending hospital physician does not authorize an OPO to continue the donation process if signs of life are subsequently detected. Failure to adhere to these safeguards could constitute conduct that poses an imminent threat to patient health and safety.[14]

Comment: Several commenters urged CMS to align implementation guidance with OPTN and HRSA standards and to consider issuing additional surveyor guidance to promote national consistency.

Response: We intend to develop and issue implementation and surveyor guidelines to provide additional clarity regarding the application of the definition of ''unsound medical practices,'' including how surveyors will identify, document, and evaluate any conduct that may constitute unsound medical practices.

Final Rule Action: After consideration of the public comments we received, we are finalizing as proposed. We 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.

[14] Additional information regarding the roles of OPOs and donor hospitals during the organ donation and procurement process is available via sub-regulatory memoranda (QSO–26–05–[OPO & Transplant]), accessible at *https://www.cms.gov/files/document/qso-26-05-opo-original-release-date-2026-03-11-pdf.pdf.*

C. Requirements for Certification (§ 486.303)

CMS has historically interpreted the OPO Certification Act of 2000 (the Certification Act), which added section 371(b)(1)(D) of the PHS Act, to mean the Secretary lacks the authority to certify new OPOs. Upon recent reassessment, however, we determined that the statute was not intended to strip the Secretary of his authority to certify new OPOs. Therefore, we proposed 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. This eliminates a regulatory barrier that prevents the Secretary from implementing a process for certifying new OPOs. We also believe that removing this requirement would address concerns about market consolidation by creating a more diverse and robust market that enhances competition among OPOs.

We also solicited public comments on a process to certify new OPOs. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that CMS lacks statutory authority to certify new OPOs and that CMS' reinterpretation of the PHS Act expands its authority beyond what Congress authorized. Commenters stated that Congress unambiguously used the past tense in requiring OPOs to ''ha[ve] been certified or re-certified by the Secretary within the previous 4-year period,'' 42 U.S.C. 273(b)(1)(D), and that entities not yet in existence as of January 1, 2000, cannot satisfy that requirement.

Additionally, commenters noted that Congress required the Secretary to ''use multiple outcome measures as part of the certification process,'' (42 U.S.C. 273(b)(1)(D)(ii)(III)). Commenters stated that outcomes are, by definition, retrospective and therefore Congress must have intended that CMS could certify only OPOs already in existence.

Commenters also stated CMS cannot create new performance measures to justify certifying new entities or lawfully permit newly certified OPOs to compete with established, statutorily qualified organizations, and noted that the statute does not authorize CMS to favor new entrants. They recommended that any policy changes to allow the certification of new OPOs should be pursued through legislative action rather than regulatory interpretation.

Response: We appreciate these comments and disagree that CMS lacks the authority to certify new OPOs. 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 re-certified 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.

While we have previously interpreted the Certification Act to strip CMS of its prior authority to certify new OPOs, we no longer believe that interpretation to be the best reading of the statute. 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, the statute is better read to mean that whenever the agency initially certifies a new OPO or recertifies an existing OPO as meeting the Secretary's performance standards within a 4-year period, OPOs must demonstrate at the end of that period that they continue to meet those standards. We note also that 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.

Section 371(b)(1)(D)(ii) of the PHS Act specifically provides that a qualified OPO is an OPO that, among other things, ''has been certified or re-certified . . . within the previous 4-year period'' through ''a process'' that is ''defined through regulations . . . promulgated by the Secretary.'' There is no language in that provision requiring an OPO to demonstrate that it was certified as of January 1, 2000, as part of those standards. This language is past tense in that it refers to an OPO that ''has been'' certified or re-recertified within the previous 4-year period. But the statutory language does not indicate that the ''previous 4-year period'' refers only to the 4-year period prior to enactment of the statute, as commenters suggest. A new OPO could meet this standard upon initial certification. In addition, the statute requires the Secretary to ''use multiple outcome measures as part of the certification process'' (emphasis added). The fact that the statute contemplates a certification process that uses outcome measures, rather than restricting the application of outcome

measures to re-certification, further indicates that the Secretary is not limited to recertifying existing OPOs and that Congress considered it possible to use outcome measures in the certification process. 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 de-certified.

Comment: A few commenters supported CMS' goal of ensuring that all communities are served by high-performing OPOs and acknowledged that permitting new entities may improve accountability and performance across the system, but only if the new entities can demonstrate sufficient readiness and capability. Many commenters expressed concern that certifying organizations without an established performance history could disrupt continuity of care and negatively affect both donors and transplant recipients. These commenters emphasized that any certification of new entities should be contingent on demonstrated operational readiness and capability, rather than projected performance.

Commenters offered a range of recommendations on the certification of new OPOs. Many commenters suggested that new entities must be nonprofit organizations, while one OPO recommended that CMS allow any entity to become an OPO regardless of nonprofit status. Another commenter recommended that any new entity be required to meet all existing CfCs under 42 CFR part 486, subpart G, prior to certification, without exception or phased implementation. A commenter suggested that, in the absence of historical outcome data, CMS should permit new entities to demonstrate readiness through alternative evidence—such as leadership experience, operational readiness, and systems capability—while still requiring compliance with applicable CfCs and process performance requirements. Two commenters proposed alternative certification pathways—one through an expedited process for applicants demonstrating clinical infrastructure, transplant center partnerships, and sufficient financial reserves, and another through accreditation by national accrediting organizations. Commenters also requested additional clarity on how new OPOs would be monitored, measured, and benchmarked, including whether they would be evaluated differently from incumbent OPOs. Commenters also sought clarification on whether OPOs de-certified in one cycle could be re-certified in a subsequent cycle and, if so, under what conditions.

Commenters also offered a range of recommendations on the designation of a DSA to a new OPO. A few commenters stated that, at a minimum, new OPOs should be subject to the same competition selection criteria as existing OPOs when applying for an open DSA. Another commenter recommended that CMS develop a standardized DSA Readiness Assessment to ensure that a new OPO is capable of performing immediately upon designation. This commenter suggested that at a minimum, this assessment should include: established clinical and operational capacity with qualified staffing and 24/7 readiness; demonstrated ability to effectively engage with donor families and communities; data-driven and third-party validated analysis of donor potential; and evidence of financial stability to sustain operations. A commenter stated that new OPOs should not receive any advantage in the selection process, as they lack experience and historical performance data and cannot be presumed to outperform existing OPOs. Another commenter suggested that CMS limit the certification of new entities to scenarios in which an OPO has been de-certified and no existing OPO seeks to compete for the open DSA.

Response: We agree that each DSA should be served by a qualified OPO capable of performing organ procurement services. Given the complexity and significance of establishing a certification process for new OPOs, we did not propose a specific initial certification framework in the January 2026 OPO proposed rule. We intend to address certification of new OPOs and the process by which a newly certified OPO might be designated to a DSA in future rulemaking and will take the recommendations received into consideration at that time.

Final Rule Action: After consideration of the public comments we received, we are finalizing as proposed removing § 486.303(e). We will address the process to certify new OPOs, as well as the process by which a newly certified OPO might be designated to a DSA, in future rulemaking.

D. Designation of One OPO for Each Service Area (§ 486.308)

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 proposed to revise requirements at § 486.308 to further address changes made in the December 2020 OPO final rule related to when a DSA is open for competition. Additionally, 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. Additionally, the period may be shorter due to involuntary termination of an OPO due to non-compliance with the process performance measures (§§ 486.320 through 486.360). 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 proposed to clarify how an OPO is assigned a DSA and how we determine the OPO designation period. Specifically, we proposed to (1) clarify the normal designation period and when CMS may adjust the length of the period; (2) clarify designation periods for newly acquired DSAs; (3) specify the circumstances that trigger a DSA to become available for competition; and (4) establish criteria for successor selection when insufficient time exists for a full competition process.

We proposed to clarify all circumstances when a designation period may be adjusted. We proposed at § 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).

We proposed at § 486.308(a)(2) that CMS would conduct a competition for all vacated DSAs. We also proposed at § 486.308(a)(3) that the designation period for any newly acquired DSA, whether following a competition or as the result of being assigned a DSA, will be the remaining portion of the agreement for the acquiring OPO's existing re-certification cycle. We proposed at § 486.308(a)(4) that if an OPO does not fulfill the terms of its agreement, whether voluntarily or involuntarily, and there is insufficient time to conduct a competition to select a successor OPO for its DSA, CMS may designate another OPO without first

conducting a competition. We stated that 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, CMS 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.

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 proposed to amend this language to conform with requirements for competition at § 486.316 and outcome measures at § 486.318 to implement the tiered system for competition from the December 2020 final rule and clarify competition requirements if an OPO were to voluntarily terminate its agreement. Additionally, with the exception of de-certification for urgent need, revisions to this section clarify that de-certification would not occur until after any applicable appeal is completed, competition for the open DSA is completed, and the DSA is transitioned to the successor OPO.

Specifically, we proposed to address all circumstances under which a DSA is open for competition. A DSA is 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 to tier 2 for outcome measures in the final assessment period;
- An OPO is not in compliance with the process performance measures at §§ 486.320 through 486.360, all administrative appeals are exhausted, and the OPO is pending de-certification; or
- An OPO requests to voluntarily terminate its agreement to participate, except where the voluntary termination is associated with a change in control, ownership, or service area resulting from a merger with another OPO.

We solicited public comment on these proposed changes at § 486.308. The following is a summary of the comments we received and our responses.

Comment: A commenter recommended that CMS revise the OPO certification period to end on December 31 of the last year of the re-certification cycle and start the next cycle on January 1. The commenter stated that this would provide the public and the OPO community more time to verify the outcome measures, appeals, and competition. The commenter stated that the outcome measures from the final assessment period should be available for at least 6 months prior to the expiration of the OPO contracts. The commenter stated that these changes would effectively minimize potential disruptions in the area if the incumbent OPO is not redesignated to the DSA.

Response: The dates of the re-certification cycle and the OPO agreement period are not within the scope of this rule, as we did not propose any changes to them. We note that once OPO annual public aggregated performance reports are published, OPOs are provided a preview period to verify their data and outcomes and raise any concerns to CMS prior to the public report being posted. Re-certification cycles end on July 31 every four years. However, the current OPO agreements end 6 months later on January 31, 2027. Additionally, we may extend agreements beyond this timeframe under § 486.314(n) (revised and moved from § 486.314(j)), if necessary to complete appeals and any necessary competitions and facilitate an orderly transition of the DSA. An extension of an agreement under § 486.314(j), or § 486.314(n) as finalized in this rule, serves the limited purpose of allowing for these processes, where necessary, and does not extend the agreement cycle.

Comment: A commenter stated that the designation of a DSA to an OPO in the middle of the OPO's current agreement period should not shorten the designation period for the OPO. The commenter recommended that an OPO be permitted to complete the remainder of the agreement period for the newly designated DSA and should be re-certified at the end of that agreement period for at least another 4-year agreement term regardless of manner or circumstance of the designation of the new DSA.

Response: We appreciate the opportunity to clarify the designation periods described at § 486.308(a)(3), as finalized in this rule, and existing requirements at § 486.310(b)(2) and our rationale for the requirements for when OPOs would be held accountable on the outcome measures at § 486.318(c)(3) and (4), as finalized in this rule. If an OPO is designated to a DSA mid-cycle, meaning after August 1 of the first year of the re-certification cycle, we will designate the OPO to the new DSA for the remainder of that re-certification cycle regardless of the reason for the designation. The OPO's re-certification and designation to the new DSA for the subsequent re-certification cycle would be based on the nature of the circumstances that resulted in the designation and availability of outcome measures from the final assessment period. If the initial designation was the result of a competition or resulted from CMS assigning the DSA to the OPO, we would re-certify the OPO at the end of the re-certification cycle, provided it is in compliance with the process performance measures, and redesignate the OPO to the DSA to provide additional time for it to operate in the DSA before holding it accountable on the outcome measures in the subsequent re-certification cycle as specified at § 486.318(c)(4). This policy is due to the greater challenge of assuming responsibility for a DSA in potentially contentious or unanticipated circumstances. If the designation was the result of a change of control or ownership or service area under § 486.310, which generally occur under planned, cooperative circumstances, we would hold the OPO accountable on the outcome measures after 12 months of data are available as specified at § 486.318(c)(3). Re-certification and redesignation to the DSA would depend on the timing of the change that resulted in being designated to a new DSA and the availability of outcome measures for that DSA under new leadership. A change of control or ownership or service area results from extensive pre-planning, cooperation, and sharing of information, all of which are likely to advantage the OPO in meeting the CMS outcome measure standards. Given these built in features that support more timely compliance with the outcome measure standards, it is our policy that if outcome measure data are available for the new DSA at the time of re-certification, CMS would hold the OPO accountable on the outcome measures for that DSA. The OPO's re-certification and redesignation would depend on the OPO's performance and tier standing in the final assessment period, provided the OPO met all other process performance requirements. We believe this approach balances performance expectations and timeframes with the circumstances and challenges posed by the nature of the change. Therefore, we are not adopting the commenter's recommendations.

Comment: Several commenters stated that an OPO that is involuntarily assigned a DSA will expend significant administrative and clinical resources in the newly assigned DSA to the possible

detriment of the OPO's original DSA. These commenters stated that the OPO should not be disadvantaged by the involuntary assignment and accommodation should be made to that OPO for both of its DSAs if performance decreases.

Response: We thank the commenters for sharing these concerns. The instances when CMS would assign a DSA to an OPO include when there is insufficient time to conduct a competition as specified at § 486.308(a)(4), as finalized in this rule, and if there are no competitors in a competition as specified at § 486.316(e). While we appreciate the additional responsibility that the OPO would be taking on, we will continue to require OPOs to meet the minimum performance standards on the outcome measures. However, in response to the concerns raised by commenters regarding the potential for assignment to temporarily lower an OPO's performance in its existing DSAs, and to avoid disadvantaging OPOs that are assigned a new DSA without a competition, we are adding a provision to § 486.316(a)(2) to provide that when CMS assigns an OPO to a new DSA under § 486.308(a)(4) or § 486.316(e), that OPO's new and existing DSAs will not be opened for competition at the end of that re-certification cycle if the OPO's performance in those DSAs qualifies for tier 2 in the final assessment period. But an OPO must satisfactorily meet the outcome measures in its original DSAs by achieving tier 1 or tier 2 performance in the final assessment period to retain those DSAs. This provision would partially address concerns by commenters regarding the impact of unplanned expansion to an OPO's other DSAs. However, we cannot permit an OPO to retain its other DSAs if performance in those DSAs decreases to tier 3. Therefore, if an OPO's performance in its original DSA decreases to the extent that the DSA is assigned to tier 3, we would issue an initial notice of de-certification or a notice of removal of designation to a tier 3 DSA without de-certification in accordance with the process set forth at § 486.314(a). If the assignment occurs on a date later than January 1 of the first year of the agreement cycle, the OPO will be held accountable for its performance in the newly assigned DSA as set forth at § 486.318(c)(4).

Comment: Several commenters expressed concern with proposed designation requirements at § 486.308(a)(4), in the circumstance when CMS would designate an OPO to a DSA where there is insufficient time to conduct a competition. Commenters stated that the DSA should not be opened for competition and the OPO should retain designation until a full re-certification cycle is completed. Commenters stated that the OPO should retain the DSA if its performance is acceptable at that time. Commenters highlighted the significant undertaking of accepting a DSA in this circumstance and stated that they should be given the opportunity to retain the DSA if its performance supports this.

Response: We agree with the commenters on this issue. While our standard approach is to provide competition for open DSAs, the commenters raise valid concerns regarding the commitment of administrative and clinical resources necessary to stabilize a DSA under these circumstances. We are modifying proposed § 486.308(a)(2) and (4) to indicate that we would not open a DSA for competition following assignment of the DSA to an OPO under the circumstances described in § 486.308(a)(4). The OPO would retain designation to the DSA for the remainder of the designation period rather than opening for competition at the earliest possible time. In response to the concerns raised by commenters, we are modifying proposed § 486.308(a)(3) to include assignment of a DSA where there is insufficient time to conduct a competition as another scenario in which the OPO will be designated for the remaining portion of the current re-certification cycle. We are also modifying the language of proposed § 486.318(c)(4) to make clear that that an OPO that is assigned a new DSA under either § 486.308(a)(4) or § 486.316(e) will be assessed on the outcome measures in the new DSA for re-certification purposes based on the final assessment period of the next full re-certification cycle. However, to facilitate assessment of the OPO's performance in the newly assigned DSA, we will retain the language of proposed § 486.309(b), which excludes assignment of a DSA due to insufficient time to conduct a competition from the scenarios in which an OPO may choose to consolidate DSAs. Finally, we are adding regulatory references for competition (§ 486.316(d)) and assignment of a DSA by CMS (§ 486.308(a)(4)).

Comment: Several commenters recommended that CMS better define the circumstances at § 486.308(a)(4) under which it would designate an OPO to a DSA without conducting a competition. Commenters stated that CMS should prioritize continuity of donation operations and provide realistic timelines, recognizing that transitions involve complex operational, legal, and governance factors in addition to clinical operations. Another commenter stated that CMS should clearly explain how the objective factors identified to guide designation decisions are weighed when competition is not feasible.

Response: We thank commenters for sharing these concerns and recommendations. While it may be difficult to predict every circumstance when we would assign a DSA to an OPO without conducting a competition as specified at § 486.308(a)(4), we anticipate this would be an extremely rare occurrence that would be utilized to ensure continuity of organ donation activities. De-certification due to urgent need, as set forth at § 486.312(a)(4), or an OPO ceasing operations or voluntarily terminating its agreement with CMS without adequate notice to conduct a competition could all necessitate CMS assignment of a DSA to preserve organ donation activities. Although we did not receive any comments specifying alternative factors to consider when assigning a DSA in this situation, a commenter requested information about how we would weigh various factors under consideration. These factors include 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 for the remainder of the designation period. Additionally, we are finalizing a modification to the proposed language at § 486.308(a)(4) to indicate that we would assign the DSA to a single OPO, rather than ''one or more''. Given that CMS will only select a successor OPO under § 486.308(a)(4) when there is insufficient time to conduct a competition, we expect that there would also be insufficient time in that scenario to take additional action to divide the DSA among multiple successor OPOs. Accordingly, we are finalizing a modification to the proposed language of § 486.308(a)(4) to reflect that CMS would only select a single successor OPO for designation to the DSA when that provision applies.

Final Rule Action: We are finalizing the proposed changes to § 486.308 with modifications to paragraphs (a)(2), (3), and (4). After considering public comments, we are modifying paragraph (a)(2) to add ''except as noted in paragraph (4)'' to include an exception to opening a DSA for competition. We are modifying paragraph (a)(3) to add regulatory references ''§ 486.316(d)'' and ''§ 486.308(a)(4)'' to the paragraph to identify all instances when CMS may

assign a DSA to an OPO. In paragraph (a)(4), we are removing the provision that we would open the DSA for competition after assigning a DSA to an OPO. Additionally, we are modifying the first sentence to indicate that we would select a single OPO when assigning a DSA in this situation. We are also modifying § 486.316(a)(2) to address concerns of commenters to ensure that an OPO is not disproportionately impacted in the event an OPO's performance decreases or fails to improve after being assigned a DSA by CMS.

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

Since the December 2020 OPO 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 proposed to replace obsolete requirements at § 486.309 related to the re-certification of OPOs during August 1, 2006, through July 31, 2010 with new requirements to address situations in which an OPO is responsible for more than one DSA.

Permitting an OPO to separately maintain multiple DSAs could maintain some level of market diversity to support future competition. OPOs have also 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 if they were to combine DSAs and have outcome measures assessed for the combined areas. To give OPOs additional flexibility to maintain separate DSAs, we proposed that an OPO could be assigned to more than one DSA: (1) following a change in control, ownership, or service area; (2) as the result of a competition; or (3) as a result of CMS assignment when there is insufficient time to conduct a competition. In these instances, the OPO would need to determine how best to manage its organization for the respective areas. We proposed that if an OPO was made responsible for more than one DSA following a change in control, ownership, or service area, or a competition, the OPO could choose to consolidate the DSAs, maintain separate DSAs, or a combination thereof if more than two DSAs were involved. Additionally, we proposed that if CMS were to assign a DSA to an OPO following a voluntary or involuntary termination, the OPO would be required to maintain the newly assigned DSA separately to facilitate future competition. We also proposed that the DSA would be opened for competition at the end of the designation period, as designation of an OPO to a DSA in this situation would be a temporary measure intended to maintain organ procurement services and to provide time to facilitate an orderly transition of the DSA to a successor OPO following a competition.

We also proposed an approach for the application of both the outcome and process performance measures when an OPO is designated to multiple DSAs. We proposed that when an OPO consolidated multiple DSAs, regardless of contiguity, into a single DSA, we would assess the OPO's performance on the outcome measures as a single 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 obtained a new additional DSA to choose to maintain separate DSAs, rather 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 proposed 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. Specifically, we proposed 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. We proposed that such removal of designation would not result in de-certification unless an OPO is no longer designated to any DSA due to tier 3 outcome measure performance across all of its DSAs (see corresponding requirements at § 486.316). We also proposed that an OPO may appeal the decision to remove its designation to a tier 3 DSA, and that the removed DSA would be opened for competition after any appeal for that DSA is exhausted and the decision is upheld.

We solicited public comment on the proposed changes in § 486.309. The following is a summary of the comments we received and our responses.

Comment: Some commenters were supportive of the proposal allowing OPOs to choose to maintain separate DSAs. They were also generally supportive of allowing OPOs the flexibility to manage their DSAs in a manner that best suits their organizational and operational needs, noting that the factors considered in these decisions may vary based on the DSA and the OPO. A commenter supported CMS retaining final authority over multi-DSA arrangements with clear criteria, including operational capacity and accountability safeguards, while still allowing OPOs the flexibility to maintain separate DSAs, as appropriate.

Response: We agree that OPOs designated to serve more than one DSA should have flexibility to establish their organizational and operational structure in a manner that best enables them to most effectively provide organ procurement services. There are many organizational and operational factors OPOs would need to consider in determining how to best design their operations. As a result, some OPOs may determine that consolidating DSAs into a single DSA is beneficial, while others may determine that maintaining separate DSAs is more appropriate.

Comment: A commenter requested confirmation that an OPO is permitted to establish a distinct Standard Acquisition Charge (SAC) for each DSA, regardless of whether those DSAs are operated through separate legal entities or unincorporated divisions within a single legal entity. The commenter also sought clarification on CMS' expectations for allocating shared overhead, executive, and administrative expenses across multiple DSAs in distinct cost reports, specifically asking whether time studies conducted one week per month would be a sufficient methodology or if an alternative mechanism is recommended.

Response: We thank the commenter for raising this concern. We will develop and issue guidance to address cost reporting questions for OPOs with multiple DSAs.

Final Rule Action: After consideration of the public comments we received, we are finalizing changes to § 486.309 as proposed.

F. 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 proposed to establish a new CfC at § 486.311 for non-renewal of an OPO agreement. Additionally, we proposed to revise § 486.312 to address enforcement actions that may result in de-certification of an OPO.

We proposed changes to address implementation of the tiered system for re-certification and competition from the December 2020 final rule and to clarify the difference between non-renewal of an agreement and de-certification. We also proposed to revise the public notice requirements for when there is a non-renewal or de-certification to clarify that CMS would be providing these notices.

We proposed that CMS would not renew an agreement with an OPO if the following conditions are met: the OPO's DSA is subject to a competition and the OPO is unsuccessful in the competition to retain its 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). We proposed that CMS 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 proposed that CMS would not renew an agreement in the case of a voluntary termination of an agreement by an OPO.

In our proposed approach, an OPO with only tier 2 DSAs that fails to retain any of its DSAs in competition would be re-certified without designation to a DSA. This would permit the OPO to compete in any additional open competitions during the following 4-year certification period. If the OPO is successful in a concurrent or subsequent competition, assigned a DSA by CMS, or selected for an open DSA when there is insufficient time to conduct a competition, it could then be designated to another DSA during this period. If the OPO does not obtain a new DSA through competition, assignment, or selection (including circumstances where there is insufficient time to conduct a competition) for an open DSA by the end of the next re-certification cycle following the non-renewal of the OPO's agreement, it would not meet outcome measure standards for that cycle. Consequently, the OPO would be de-certified at that time. The OPO would have appeal rights for de-certification. While an appeal would not be available for the assignment of a DSA to tier 2 or the result of a competition, all OPOs are provided with a preview of their outcome measure results and an opportunity to raise concerns with the data before performance reports are finalized.

The current requirement for voluntary termination of an agreement is located at § 486.312. We proposed to relocate the voluntary termination of agreement provision from § 486.312 to new § 486.311 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 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.

For non-renewal of an agreement after a competition, we proposed that we would provide notification to the OPO at least 90 calendar days before the effective date of the non-renewal, and the notice would state the reasons for non-renewal and include the end date of the agreement.

We also proposed a public notice requirement consistent with the current public notice requirements at § 486.312 to inform the public in the affected service areas. We would inform the public of the date on which a new OPO will be designated for that DSA. We also proposed to retain the policy which states 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 proposed to revise the requirements at § 486.312 to clarify the actions we may take to de-certify an OPO. Specifically, we proposed that we may de-certify an OPO if the OPO no longer meets the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360. We proposed that we may de-certify an OPO if the OPO is designated only to tier 3 DSAs in the final assessment period at the end of the re-certification cycle as specified at 486.318(b)(6) and 486.316(b)(iii)(3)(A). We also proposed 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 and was not otherwise assigned a DSA by CMS.

We also proposed to relocate and revise the provision allowing for immediate de-certification in cases of urgent need, such as the discovery of unsound medical practices.

We proposed to revise and relocate the requirements regarding notice of de-certification to the OPO. We proposed 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.

Finally, we proposed to revise and redesignate the requirements pertaining to public notice of de-certification. We proposed to replace the requirement that the OPO provide public notice in situations of involuntary termination and de-certification with a new process that CMS will provide public notice. We proposed that CMS would notify the public within the service area of both the date of de-certification and the date that a new OPO will be designated for the DSA. We solicited public comment on these proposed changes in §§ 486.311 and 486.312. The following is a summary of the comments we received and our responses.

Comment: Several commenters were supportive of the proposed changes in clarifying the differences between non-renewal and de-certification in the competition framework. These commenters recommended advance notice and transition plans to allow for orderly transfer of operations to the successor OPO. A commenter recommended collaboration with HRSA in implementing changes to relevant information technology (IT) systems.

Response: We thank commenters for their support and recommendations. We are establishing notification requirements for non-renewal at § 486.311(c) and (d) for both the OPO and the public respectively. Additionally, we are finalizing a requirement at § 486.316(g) for transition plans to facilitate an orderly transfer of a DSA between an incumbent and successor OPO. CMS and HRSA have coordinated the transition of DSAs for several mergers and a recent de-

certification. We continue to collaborate to refine this process and ensure continuity of IT systems during the transition.

Comment: Many commenters recommended due process considerations for an OPO that received a notice of non-renewal due to competition loss and was therefore no longer designated to a DSA. Commenters stated that non-renewal of an OPO's agreement would effectively be the same as de-certification and the lack of due process protections was unfair and lacked transparency. A commenter stated that the absence of any mechanism to challenge the underlying competitive determination would be a serious procedural gap. Several commenters stated that CMS should ensure that procedural safeguards are commensurate with the operational and public health consequences of DSA removal and recommended that CMS establish a structured administrative review pathway for OPOs in this situation. Another commenter raised concerns for procedural equity, indicating that tier 3 OPOs were afforded a pathway to contest de-certification, while tier 2 OPOs that lost their DSA through a competitive process would not have such a pathway.

Response: We thank commenters for sharing their concerns but disagree with their recommendations. 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. OPOs with tier 2 DSAs that are unsuccessful in competition and no longer designated to a DSA may compete in concurrent or subsequent competitions for other DSAs or be assigned a DSA by CMS throughout the term of the re-certification cycle. While there could be a gap in designation, impacted OPOs may have multiple opportunities to demonstrate that they are the best qualified OPO for a specific DSA.

Assignment of a DSA to tier 2 is not a determination that the OPO designated to that DSA is out of compliance with the outcome measure requirements. An OPO with a DSA that meets tier 2 performance standards has met the minimum performance standards for re-certification and will be re-certified, provided that it also meets the process performance measures at §§ 486.320 through 486.360. However, it will not automatically retain its designation to the tier 2 DSA for another full agreement cycle. Instead, an OPO with a tier 2 DSA would compete to retain its designation to the DSA for another agreement cycle.

To clarify this distinction between re-certification and the retention of designation to a DSA, we are revising § 486.311 to clarify that when an OPO is unsuccessful in the competition process, as set forth at § 486.316(a)(2), and the OPO is no longer designated to the DSA, CMS will not renew its agreement for designation to that DSA. This means that the OPO would enter into a new Form CMS 576A (Health Insurance Benefits Agreement) to reflect its re-certification for the next 4 year cycle, but the OPO would no longer be designated to a DSA as identified on its Form CMS 576 (Request for Designation as an OPO). This clarification reflects that OPOs that meet the tier 2 thresholds for the outcome measures and are compliant with the process performance measures will be re-certified and will maintain an agreement with CMS reflecting their status as a certified OPO, but must be successful in competition for an open DSA (their original DSA or a different one) in order to have an agreement for designation to a DSA for another full agreement cycle. We are also making a conforming change to § 486.316(b)(2)(ii) to clarify that an OPO with a tier 2 DSA will not have the agreement for designation to a DSA renewed if it is not successful in at least one competition.

When an OPO's DSA is assigned to tier 3 based on performance in the final assessment period, on the other hand, the OPO has failed to meet minimum outcome measure standards in that DSA, resulting in either de-certification or removal of designation to the tier 3 DSA. In light of this adverse determination, OPOs with tier 3 DSAs are granted an appeal. Furthermore, as we have previously explained, allowing appeals of competition results would be unwieldy and would create uncertainty, both for the OPO that prevailed in competition and within the DSA (71 FR 30998). As a result, we do not believe that appeal of competition results would best serve the interests of organ donation in the DSA. While some commenters cite operational and public health concerns for transitioning a DSA, we note the public health considerations for the nearly 100,000 people on the organ transplant waiting list, many of whom will die waiting for a lifesaving transplant. While OPOs with tier 2 DSAs meet minimum outcome measure requirements, they may not be the best OPO to serve a DSA if there is a more capable OPO that can demonstrate the ability to procure more lifesaving organs.

Comment: Several commenters indicated that consistent turnover of DSA assignments risks undermining important community relationships and could negatively affect donation rates in affected communities. A commenter was concerned that DSA reassignments and associated changes will lead to major setbacks in the important work Tier 3 OPOs have done in reaching out to diverse communities, educating the community, and establishing trust. The commenter stated that the loss of personnel, programs, and expertise that these communities have come to know and trust could upset the progress that has been made and detrimentally impact organ donation rates in these communities.

Response: We appreciate the concerns expressed by these commenters and recognize that many OPOs have invested in building deep community ties. We believe every community should be served by a high performing OPO that meets our performance standards. Additionally, we believe it is vital to continue improving donation rates in diverse communities and replacing underperforming OPOs with higher performers that have a demonstrated record of overcoming challenges in their DSA is one way to further this goal. We anticipate that successor OPOs will apply the lessons learned in their own DSAs to newly designated DSAs and build upon those successes to engage all population groups throughout its newly designated DSA, including those groups associated with historically low donation rates in the DSA. Additionally, as CMS develops future requirements for new entities seeking to become certified OPOs, we anticipate developing and proposing criteria to evaluate their plans to engage all population groups for organ donation.

Comment: A commenter recommended CMS consider other factors to cure tier 3 performance in a DSA when the OPO would be de-certified or have its designation removed. The commenter recommended that CMS retain the OPO's designation to the tier 3 DSA in the following circumstances: (1) if there were no competitors for the DSA; (2) if the OPO had substantially improved performance in the DSA despite remaining in tier 3; (3) if the subsequent year's performance improved significantly; or (4) if performance during the assessment year was aberrant due to a natural disaster or other unusual circumstance. Another commenter recommended that CMS implement a process for an OPO to develop and submit a performance improvement or corrective action plan

that would include peer-assisted improvement initiatives with measurable goals and frequent reporting requirements.

Response: We thank the commenter for sharing these recommendations. As previously explained, the outcome measure performance standards are set forth at § 486.318, and we did not propose to modify those performance standards to allow for alternative pathways to compliance. Under section 1138(b)(1) of the Act and section 371(b)(1)(D) of the PHS Act, an OPO must meet the Secretary's performance standards to be recertified and to remain eligible for payment of its organ procurement costs under Medicare or Medicaid. Accordingly, an OPO that does not meet minimum performance standards on the outcome measures (tier 3) in any of its DSAs in the final assessment period is not compliant with the Secretary's performance standards and will be de-certified under § 486.312(a)(2). An OPO that meets the minimum performance standards in at least one of its DSAs is eligible to be re-certified, but will have its designation removed from any DSA in which its outcome measure performance qualified as tier 3 as specified at § 486.316(a)(3). However, CMS regulations do allow for an extension of an OPO's agreement cycle in one limited scenario. Specifically, under § 486.316(f), an OPO can seek a 1-year extension of its agreement cycle if there are extraordinary circumstances beyond the control of the OPO that has affected the data of the final assessment period so that it does not accurately capture their performance. An OPO must request this extension within 90 days of the end of the occurrence of the extraordinary circumstance but no later than the last day of the final assessment period.

We note also that nothing in the current requirements prevent an OPO from engaging in a peer-assisted improvement initiative with another OPO and we encourage underperforming OPOs to consider this activity in advance of the final assessment period. However, this type of arrangement cannot be utilized to remedy non-compliance with the outcome measures based on tier 3 performance in the final assessment period.

Comment: A commenter stated that they support maintaining CMS' authority to de-certify an OPO immediately in cases of urgent need, including unsound medical practices. The commenter stated that patient safety must remain the paramount concern, and CMS should not be constrained in addressing serious failures that pose imminent risk to donors or recipients. Another commenter stated that they advocate for low-performing OPOs to be de-certified and believes that every community deserves to be served by a high-performing OPO.

Response: We thank the commenter for the support of this provision. We believe it is important to be able to respond swiftly in the event of urgent need, such as the discovery of unsound medical practices. We have undertaken further actions to strengthen this provision by adding a definition of ''unsound medical practices'' which could trigger an urgent need de-certification decision. See Section X of this final rule for more information on the definition of ''unsound medical practices''.

Final Rule Action: After considering public comments, we are finalizing § 486.311 with modifications to paragraphs (a)(1) and (b) clarify that the non-renewal of an agreement after loss of a competition is limited to the OPO's agreement for designation to a DSA, rather than a non-renewal of an agreement for certification. Additionally, we are finalizing § 486.312 as proposed with a minor wording change at § 486.312(b) to align with the corresponding requirement at § 486.314(a)(1). In the proposed rule, § 486.312(b) stated ''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.'' The corrected language in this final rule aligns with the title of § 486.314(a)(1) and is revised as follows: ''Except in cases of urgent need, CMS provides an initial notice of de-certification to an OPO in writing at least 90 calendar days before the effective date of the de-certification.''

G. Appeals (§ 486.314)

We proposed several changes to the appeals process. We proposed modifying the timeframes in the appeal process and converting all timeframes to calendar days. We proposed to codify a process for discretionary review by the CMS Administrator and clarify the appeal process for OPOs that are de-certified based on urgent need. Additionally, we proposed to allow an OPO to appeal the removal of a designation to a tier 3 DSA without de-certification for situations where an OPO has another DSA that is assigned to performance tier 1 or 2 in the final assessment period for re-certification. These changes would make sure that OPOs have timely appeal rights for any adverse determinations regarding an OPO's compliance with outcome measure standards in a particular DSA. For more details on the basis for our proposals related to the appeals process, see the January 2026 OPO proposed rule (91 FR 4209 through 4212).

We proposed to modify the time periods in this section for existing requirements from ''business days'' to ''calendar days'' to facilitate consistent implementation of the process. We also proposed to use ''calendar days'' for all proposed requirements to further facilitate consistent application.

Currently, the OPO has 15 business days from receipt of the notice to request reconsideration from CMS, and we proposed to change this to 20 calendar days. 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 proposed to modify this to 15 calendar days to make a written reconsidered determination that would affirm or reverse the initial de-certification determination. We also proposed that CMS would have the right to extend this time based on a determination that additional time was necessary to thoroughly review and make a decision and the extension did not prejudice either party. Finally, we proposed to remove the option for the reconsideration official to ''modify'' the initial de-certification determination. If the de-certification decision was upheld, the OPO then would have 40 business days from receipt of CMS' reconsideration decision to request a hearing before a CMS hearing officer. The hearing officer would have to set a date for the hearing that was no more than 60 calendar days after receiving that request for a hearing and would have to render his or her decision within 20 business days of the hearing. We proposed reducing the number of days within which an OPO could request a hearing before a CMS hearing officer from 40 business days to 15 calendar days.

The hearing officer would be required to send the administrative record to both parties (for example, CMS and OPO) 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 would not need to forward their administrative record to the hearing officer unless and until there had been a request for a hearing. We proposed that upon receipt of a request for a hearing, the hearing officer would

promptly request the administrative record from the reconsideration official. We also proposed 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.

We proposed establishing requirements related to the scope of review and burden of proof related to an appeal. We proposed that the scope of review would be limited to (1) de-certification of an OPO and (2) removal of designation to a tier 3 DSA. The appeal must be based on substantive or procedural grounds. We also proposed that the OPO would bear the burden of proof by a preponderance of the evidence to demonstrate that the adverse determination by CMS should be reversed.

Additionally, we proposed to change the time that the hearing officer would be allotted to render their decision to from 20 business days to 90 calendar days. We also proposed allowing the hearing officer to extend that time upon notifying both the OPO and CMS, if the extension did not unduly prejudice either of the parties and is necessary for the hearing officer to issue a legally sufficient decision. Consistent with CMS longstanding policy, the hearing officer could affirm or reverse the notice of de-certification. We proposed to add that the hearing officer could also affirm or reverse the removal of designation to a tier 3 DSA without de-certification. The hearing officer would then promptly forward the decision and the administrative record to the CMS Administrator.

We proposed to codify the process for discretionary review of the hearing officer's decision by the CMS Administrator. Specifically, we proposed that the CMS Administrator would have 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 elected to review the hearing officer's decision within the 30-day period, the CMS Administrator would promptly notify the OPO and CMS of his or her decision to review and the parties' right to submit written arguments within 15 calendar days of the notification. If the Administrator did not elect to review the decision within 30 calendar days of its receipt, the hearing officer's decision would be final.

We proposed that within 45 calendar days of notification of the CMS Administrator electing to review the hearing officer's decision, the CMS Administrator would be required to render a final decision, in writing, to the parties. The CMS Administrator could affirm, reverse, or remand the hearing officer's decision to CMS. We believed that there might be circumstances in which the CMS Administrator would want CMS to conduct further review or have other instructions for CMS regarding the appeal. Hence, we proposed that the CMS Administrator could remand the appeal to CMS for any appropriate reason. Remanding the appeal means that the appeal would be 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 was remanded to CMS, the agency would comply with any instructions in the remand. We did not propose to establish remand authority for the hearing officer.

We also proposed that the CMS Administrator would have the right to extend the review time if he or she determined they needed more time to thoroughly review and make a decision, provided the extension did not prejudice either party. We proposed that the CMS Administrator's review would be limited to the hearing's administrative record developed by the hearing officer and written arguments submitted by the OPO or CMS.

We proposed that CMS' reconsideration decision on de-certification or designation removal would become final if the OPO did not request review by a hearing officer in the time allowed under these regulations, or after the CMS Administrator declined to review the hearing officer's decision, render a decision in writing to the parties, or did 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 later in this section of the preamble, a decision would not take effect until (among other things) all administrative appeals were exhausted to avoid any undue prejudice to the OPO. Given the range of tasks that must be completed, we also proposed that CMS could offer to extend an OPO's agreement if additional time would be needed for completion of the appeals process, competition of the service area and, if necessary, transition of the service area to a successor OPO.

We proposed to clarify when the OPO's DSA would be opened for competition. Consistent with longstanding CMS policy, we proposed that an OPO would not be de-certified or lose its designation to a DSA until all administrative appeals were exhausted. If at the end of the appeals process the notice of de-certification or removal of designation has been confirmed, the decision would be final. At that time, the OPO's DSA would be opened for competition and a successor OPO would be chosen. CMS would then determine a transition period that was sufficient for the new OPO to take full responsibility for the DSA. After the transition period was determined by CMS, CMS would forward to the de-certified OPO a written communication indicating the effective date of de-certification. As of that effective date, Medicare and Medicaid payments would no longer be made for organ procurement costs attributable to the OPO. For an OPO that lost its designation to a tier 3 DSA without being de-certified, CMS would forward a written communication indicating the effective date of the decision. As of that effective date, Medicare and Medicaid payments would 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 was exhausted.

We also proposed to address special considerations regarding appeals in cases of de-certification due to urgent need. The appeals process would be the same for an OPO de-certified due to urgent need regardless of the reason for the OPO's de-certification. However, if an OPO was de-certified due to urgent need, it could be de-certified immediately. In such circumstances, the affected OPO's service area would be reassigned to one or more other OPOs by the effective date specified in the notice of de-certification provided. Hence, if the de-certified OPO pursued an appeal, it would not be operating its DSA while proceeding through the appeals process.

We solicited public comments on these proposed changes to the appeals process. The following is a summary of the comments we received and our responses.

General Comments

Comment: Most commenters generally supported the proposed change from using business days to calendar days.

Response: We thank the commenters for their support. We are finalizing the proposed change from calendar days to business days.

Comment: Some commenters were concerned about the status of OPOs during the appeals process. They wanted to know what happens to their agreements with CMS and their

payments for organ procurement activities during that time.

Response: When an OPO is going through the appeals process after receiving an initial notice of de-certification for non-compliance with the CfCs or a notice of removal of designation to a tier 3 DSA without de-certification, the OPO is still certified and designated to its DSA(s). During this period, the OPO's agreement is still in effect, and the OPO will remain eligible for payment. If the de-certification decision or the removal of designation decision is upheld, this status continues until the effective date of the de-certification or removal of designation to the tier 3 DSA. However, as set forth in § 486.314(p), 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 § 486.314. As the OPO's de-certification for urgent need is already in effect during the appeal timeframe, the OPO is not eligible for payment for organ procurement activities during the appeals process.

Comment: Some commenters questioned our authority to create an appeals process for OPOs and were concerned with the proposed timeframes. They indicated that with Medicare claim appeals there is typically a much longer timeframes for the provider to act, such as 120 calendar days to request a redetermination, 180 calendar days to file for a reconsideration, and 60 calendar days to request review by an administrative law judge.

Response: Section 371(b)(1)(D)(ii)(IV) of the PHS Act, added by the Certification Act,[15] requires the Secretary to issue regulations that provide for an OPO to appeal a de-certification to the Secretary on substantive and procedural grounds. Hence, an appeal process is explicitly required by statute and the Secretary delegated to CMS authority to implement this statutory requirement through the OPO CfCs. We are not persuaded by the commenters' argument regarding the extended timeframes allowed in the Medicare claims process, as that process applies to a matter entirely distinct from OPO certification. Every DSA can only have one OPO designated at a time, meaning that an OPO has a mandated monopoly on organ procurement services for an entire geographic area. An OPO that fails to meet the standards to be a qualified OPO should be removed as promptly as possible to reduce uncertainty in the OPO's DSA and support the entire organ donation and transplantation system. An OPO that receives an initial notice of de-certification (§ 486.314(a)(1), as finalized in this rule) continues to be designated for that DSA unless and until the OPO is de-certified. The DSA cannot be transitioned to a successor OPO until the appeals process has been exhausted. OPOs must be afforded the right to appeal a de-certification on substantive or procedural grounds; however, that appeals process must be conducted in a timely manner to reduce uncertainty in the DSA and protect the rights of the patients on the waiting list. We believe the proposed changes that we are finalizing in this rule not only provide the appropriate balance needed to provide OPOs an adequate opportunity to appeal a de-certification, but also ensure that the rights of the patients on the waiting list, including the right to have an OPO that is in compliance with the OPO CfCs and to avoid any unnecessary disruptions in the organ procurement and placement of organs, are preserved.

Comment: Some commenters were concerned that the appeals requirements were very burdensome and weakened the due process protections to which OPOs are entitled. Several commenters criticized the proposed changes to the appeals process, especially the change for OPOs to request a hearing from 40 business days to 15 calendar days, as denying OPOs' right to a meaningful due process in the appeals process. Commenters stated that OPOs facing de-certification deserve a meaningful appeals process with sufficient opportunity to prepare and defend against the de-certification. They stated that these appeals are complex and often require extensive preparation, such as review of multi-year performance and outcome data, statistical methods, hospital-level documentation, and thorough legal analysis. Commenters stated that this could be exceptionally difficult for smaller OPOs with fewer resources. Commenters further stated that the appeals process requires meaningful procedural protection, including clear standards, fair timelines, and transparent opportunities for participation. A few commenters recommended that the CMS hearing officer have the authority to grant filing extensions. This would provide flexibility for OPOs that need more time to file a request for hearing and still preserve their appeal rights.

Response: A request for the hearing is not a formal document in which an OPO is required to submit its arguments about why the OPO should not be de-certified. The request does not require all the information, data, or legal analysis needed for the hearing. It serves only as a notice that the OPO seeks a hearing before a CMS hearing officer. The OPO may continue preparing for the hearing, including reviewing relevant data and developing legal analyses, both before and after the request for hearing is filed. An OPO is free to file a request for hearing to preserve its appeal rights and later withdraw that request if, in the course of preparing for the hearing, it determines that it no longer wants to proceed with the appeal process. We believe that the proposed changes provide OPOs with clear, transparent standards for participation in the appeal process and a meaningful opportunity to appeal on substantive and procedural grounds, while still ensuring the appeals process moves forward in a timely manner to reduce uncertainty in the DSA and protect the interests of patients on the transplant waiting list.

Comment: Some commenters stated that the proposed changes to the appeals process granting CMS officials additional time, if needed, to fulfill their responsibilities without allowing OPOs to request additional time for required steps in the appeal process created an asymmetrical process that was inequitable and illegal. Other commenters were concerned about fairness and requested protection against conflicts of interest and for the hearing to have a standardized, objective process for all hearing officers. Some commenters recommended allowing the CMS hearing officer to grant extensions to file a request for a hearing.

Response: Section 371(b)(1)(D)(ii)(IV) of the PHS Act provides that an OPO is entitled to appeal a de-certification on substantive and procedural grounds. An OPO subject to de-certification for non-compliance with the CfCs will continue operating in its DSA pending resolution of any appeal unless the de-certification was based on urgent need. Accordingly, the appeals process must be efficient and timely to reduce any disruption to the organ procurement activities in the DSA and ensure that OPOs that fail to comply with minimum standards are removed as promptly as possible. We believe the requirements for appeals

[15] Public Law 106–505, section 701(c), 114 Stat. at 2347.

that are being finalized in this rule provide OPOs with adequate notice and a meaningful opportunity to pursue their appeal. Permitting CMS officials the opportunity to extend timelines supports this by assuring that CMS officials have enough time to adequately consider the OPO's arguments, particularly since CMS officials are likely to be responsible for multiple appeals simultaneously. In addition, the hearing officer may extend the timeframe for issuing its decision beyond 90 calendar days only 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. The hearing officer must also provide notice of the extension to the OPO and the government.

With respect to the commenters' concerns about fairness and conflicts of interest, we want to assure the commenters and the public that CMS hearing officers are highly qualified and hear numerous cases involving CMS and other parties across a range of programs and providers and suppliers. In addition, the powers and responsibilities of the hearing officer are clearly set out in § 486.314.

We do not believe it is necessary to grant the CMS hearing officer authority to grant an extension to file a request for a hearing. The appealing OPO should have sufficient time to file the request. As previously explained, the request for a hearing serves only as a notice that the OPO seeks a hearing before a CMS hearing officer. It does not require all the information, data, or legal analysis needed for the hearing. The OPO may continue preparing for the hearing, including reviewing relevant data and developing legal analyses, both before and after the request for a hearing is filed.

Comment: Some commenters supported codifying a process for the CMS Administrator's review. However, several commenters did not support the discretionary nature of the review and stated that, due to the severe consequence of de-certification as the loss of eligibility for designation and reimbursement under Medicare or Medicaid, the CMS Administrator should be required to review every hearing officer decision.

Response: We agree with commenters that de-certification warrants a meaningful opportunity to appeal on substantive and procedural grounds, as required by statute. We proposed that under § 486.314(k)(3), each hearing officer's decision and the accompanying administrative record would be promptly forwarded to the CMS Administrator for his or her discretionary review. Thus, the CMS Administrator will have access to each hearing officer decision when deciding whether to exercise discretionary review. We continue to believe that it is appropriate to permit the CMS Administrator to exercise his or her judgement in determining whether to review the hearing officer decision. It is also important to note that prior to the CMS Administrator's discretionary review, the appealing OPO would have gone through reconsideration by a CMS official and a hearing before a CMS hearing officer. Thus, the appealing OPO has already had a meaningful review of its initial notice of de-certification or notice of removal of designation to a tier 3 DSA without de-certification.

Comment: Some commenters stated that the OPOs should be allowed to submit new evidence during the appeals process, especially during the CMS Administrator's review. They pointed out that data used for the outcome measures could be up to two years old. As such, the OPO's performance could have substantially improved before it receives the initial notice of de-certification.

Response: We acknowledge that there is a delay in obtaining the outcome measure denominator data due to the nature of the data source, and that the performance reflected in the calculated outcome measures reflect data collected two years prior. However, as stated previously, OPOs have a 4-year re-certification cycle. The data that will be used for the outcome measures are not collected until the third year of the re-certification cycle, meaning that OPOs had time prior to the final assessment period to improve their performance. CMS provides annual performance data reports to every OPO and requires those OPOs that have DSAs in tier 2 and tier 3 to conduct performance improvement projects that will contribute to improved performance on the CMS outcome measures. OPOs have sufficient time, regulatory structure, and incentives to improve their performance, including getting assistance from OPTN, HRSA, CMS, or consultants, before the data that will be used for re-certification begins to be collected. Hence, we believe OPOs have sufficient time to ensure compliance with the OPO CfCs.

Final Rule Action: After consideration of the public comments we received, we are finalizing changes to § 486.314 as proposed. However, we are modifying § 486.314(p) to reflect a revision to § 486.308(a)(4) which has been revised to indicate that CMS would only select a single successor OPO for designation to the DSA when there is insufficient time to conduct a competition.

H. Re-Certification and Competition (§ 486.316)

The current requirements at § 486.316 address OPO re-certification and competition. These requirements do not currently address one OPO being designated to more than one DSA and the impact this may have on the re-certification and competition processes. We proposed 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 proposed to address the impact of the OPO outcome measures on OPO designation at the time of re-certification. We proposed to determine OPO designation to the DSA based on its performance on the outcome measures and tier assignment in each DSA at the final assessment period of the agreement cycle. 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.

We proposed that an OPO with a DSA that is assigned to tier 1 would retain designation to the DSA for another agreement period. We also proposed that an OPO with a DSA that is assigned to tier 1 would be re-certified, provided that CMS also determined that the OPO is compliant with the requirements for certification at § 486.303, including the process performance measures at §§ 486.320 through 486.360 during the most recent survey. Furthermore, we proposed that an OPO that was compliant with the requirements of §§ 486.320 through 486.360 and that has a tier 1 DSA would be eligible to compete for any open DSAs.

We proposed that an OPO with a DSA that was assigned to tier 2 would have to successfully compete and be awarded a DSA through a competition to retain designation to a DSA for another agreement period. We also proposed that an OPO with tier 2 DSAs would also need to be found compliant with the requirements for certification at § 486.303, including the conditions for coverage at §§ 486.320 through 486.360 during the most recent survey to be eligible for re-certification. We proposed that an OPO that was compliant with the conditions for coverage at §§ 486.320 through 486.360 and had a

DSA assigned to tier 2 would be eligible to compete for any open DSAs. We also proposed that if the OPO was not successful in at least one competition, it would receive a notice of non-renewal. As finalized in this rule, § 486.311(a) clarifies that this notice of non-renewal is limited to the OPO's designation to the DSA and would not impact the OPO's agreement with CMS reflecting its status as a certified OPO (Form CMS 576A, Health Insurance Benefits Agreement). Because the OPO was re-certified, we proposed that it would remain eligible to compete in future competitions, be assigned a DSA, or be selected for an open DSA during the next re-certification cycle.

We proposed that an OPO with a DSA that was assigned to tier 3 would have the designation to the tier 3 DSA removed at the end of the agreement period. Additionally, we proposed that an OPO with all of its DSAs assigned to tier 3 would not be eligible to compete in competitions for any open DSAs. We proposed that an OPO that was designated to a DSA that was assigned to tier 3 in the final assessment period would receive one of two notices. The OPO would receive an initial notice of de-certification, as specified at § 486.314(a)(1), 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 at the end of the re-certification cycle. The OPO would receive a notice of removal of designation to a tier 3 DSA without de-certification, as specified at § 486.314(a)(2), 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 at the end of the re-certification cycle. We proposed that an OPO would have the right to appeal a de-certification or removal of designation to the DSA assigned as tier 3. If an OPO did 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 also proposed updates to the re-certification and competition requirements. We proposed that an OPO would have to maintain compliance with the process performance measures at all times. We proposed that non-compliance with the requirements at §§ 486.320 through 486.360 in any DSA at any time during the re-certification cycle would result in the OPO receiving an initial de-certification determination and that the OPO would have the right to appeal the de-certification due to non-compliance with the requirements at §§ 486.320 through 486.360. If the OPO did not appeal the determination, or the OPO appeals and the determination was upheld after the appeal process was completed, the OPO's service areas would be opened to competition from other OPOs that were qualified to compete for open service areas.

We retained the existing policy that DSAs assigned as tier 2 or tier 3 in the final assessment period would be opened for competition, but proposed updated language to reflect that the tier assignment based on the outcome measures at § 486.318 would be specific to the DSA and not assigned globally to the OPO since OPOs may have more than one DSA. A tier 2 or tier 3 service area would be opened for competition from other OPOs that qualify to compete for open service areas. Competition for DSAs assigned to tier 3 would not begin until after any applicable appeal under § 486.314 had been exhausted.

We retained the existing criteria to compete for an open DSA, but proposed updated language to reflect that tier assignment for the outcome measures at § 486.318 would be specific to the DSA and not assigned globally to the OPO. 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 or tier 2, as specified at proposed § 486.318(b)(4) or (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 would have to compete for the entire open DSA. We proposed to revise 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 proposed 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. As explained in this final rule, we are clarifying that in this situation the OPO would enter into a new agreement with CMS reflecting its status as a certified OPO for the next re-certification cycle (Form CMS 576A, Health Insurance Benefits Agreement) but the OPO would no longer be designated to a DSA as identified on the Form CMS 576, Request for Designation as an OPO. This would enable the OPO to participate in subsequent competitions and enter into a new designation 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 for that re-certification cycle and would de-certified at that time.

Finally, we proposed a new requirement to facilitate DSA transitions. We proposed 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 proposed 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, including timeframes, to a new OPO. We proposed 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. We also proposed that the successor OPO would be required to 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.

We solicited public comment on these proposed changes to § 486.316. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to assess an OPO with multiple DSAs separately on the outcome measures. A commenter stated that evaluating each DSA separately on outcome measures ensures that OPOs serving multiple areas are held accountable for performance in each geographic region. Another commenter stated the specific proposals related to re-certification and competition for OPOs serving more than one DSA are logical and consistent with policies already finalized. Another commenter suggested that labeling the performance of the DSA rather than the OPO as a whole may decrease disincentives for high-performing OPOs to consider competing to provide service in a DSA with an outgoing underperforming (tier 3) OPO. Commenters stated that not only is this approach fair to an OPO on its face, but it may also advance the goal of ensuring continued provision of procurement

services to communities with an outgoing underperforming (tier 3) OPO.

Response: We thank commenters for these responses. Our intention for this proposal at § 486.316(a) was to support the provisions at § 486.309 that would enable an OPO to be designated to more than one DSA as well as mitigate the geographical consolidation of DSAs. We believe that evaluating DSAs separately on outcome measure performance, when an OPO decides to operate them separately, is a reasonable and equitable approach. This also supports OPOs in deciding how to best operate when expanding beyond their initial DSA.

Comment: A commenter requested clarification on how CMS would evaluate outcome measures when an OPO is designated to multiple DSAs and elects to merge or maintain separate DSAs. The commenter stated that each DSA is evaluated independently, resulting in the unit of accountability effectively shifting from the organization as a whole to the DSA level.

Response: We thank the commenter for seeking additional clarification on the evaluation framework. The framework of evaluating outcome measure performance at the DSA level enables CMS to evaluate an OPO both at the DSA level, carefully monitoring variations and enabling OPOs to conduct targeted performance improvement activities where they are most needed, while also retaining an overall evaluation and accountability structure that assesses compliance with the process measures at the organization level.

At § 486.316(b)(1), we address compliance with the process performance measures at §§ 486.320 through 486.360 and indicate that we will evaluate OPOs as a single entity across all DSAs. The process performance requirements are the broad operational requirements that are common across all DSAs and we expect compliance with these requirements at all times. Therefore, non-compliance with a process performance measure in one DSA would potentially impact an OPO's certification, affecting all DSAs if the OPO were to be de-certified. The OPO would have the opportunity to submit a corrective action plan to remedy the non-compliance and avoid de-certification, provided the plan of correction is acceptable in resolving the deficiency that resulted in the non-compliance determination.

At the time of re-certification, we will evaluate each DSA managed by an OPO separately on the outcome measures from the final assessment period as specified at § 486.316(a) to determine impact on DSA designation and subsequently make a re-certification decision based on the provisions at § 486.316(b)(2). Under this framework, an OPO that is 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, provided it is compliant with the process performance measures during the most recent survey as specified at § 486.316(b)(2)(i). Additionally, 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, provided it is compliant with the process performance measures during the most recent survey. The OPO will be eligible to compete in competitions for any open DSA but will not have its agreement for designation to a DSA renewed if it is not successful in at least one competition as specified at § 486.311(a)(1) or assigned a DSA under the provision at § 486.308(a)(4) or § 486.316(e) as specified at § 486.316(b)(2)(ii). Finally, OPOs with tier 3 DSAs in the final assessment period will have designation to those DSAs removed as specified at § 486.316(a)(3). We will consider the status of any other DSA in which the OPO is designated to make a re-certification decision as described at § 486.316(b)(2)(iii). If the OPO has no other DSA designated as tier 1 or tier 2, or no other DSA that is pending future evaluation of the outcome measures, as specified at § 486.318(c)(3) or (4), it will receive an initial notice of de-certification as specified at § 486.314(a)(1). If the OPO 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), it will be re-certified and receive a notice of removal of designation to a tier 3 DSA as specified at § 486.314(a)(2). This re-certification framework enables removing a DSA where an OPO is not meeting the outcome measure standards while maintaining the OPO's designation to DSAs where it has not been determined to be out of compliance on outcome measure standards.

Comment: A commenter urged CMS to provide details regarding the timeline for when the competition process will begin for open DSAs.

Response: Competition for tier 3 DSAs will occur once any administrative appeals have been exhausted. CMS will announce specific timelines and details for any competitions in advance of these events.

Comment: Several commenters recommended revisions to the criteria for selection. Other commenters recommended that CMS establish more objective criteria for selecting a successor OPO in a competition. Many of the commenters recommended giving weight to OPOs with a record of sustained performance improvement trajectories. Other commenters stated that incumbent tier 2 OPOs should be given priority when competing for their own DSA over other competitors.

Response: We thank commenters for these recommendations. We did not propose changes to the content of the existing selection criteria; therefore, we are not finalizing any changes at this time. However, we will consider these comments for potential changes to the selection criteria in future rulemaking. In the proposed rule we sought to clarify how we would apply the criteria under the tiered system for re-certification. Since implementing the 2020 final rule, OPOs have provided feedback expressing concern that CMS would rigidly apply the tiered structure in a competition and select a marginally better tier 1 OPO over a relatively high performing incumbent tier 2 OPO. They indicated that any benefit of selecting a higher performing OPO in this situation would be offset by the disruption from transitioning the DSA to another OPO. We indicated in the proposed rule that the selection criteria would not be applied rigidly when considering performance on the outcome measures and that we would consider the degree in performance differences among competitors and consider small differences to be relatively insignificant. Additionally, we do not believe that it is necessary to consider and weigh incumbency in a DSA independently of other factors because the current criteria will be sensitive to this issue when the performance difference between competing OPOs is relatively small. Additionally, in the proposed rule we discussed the issue of sustained improvements and how that would be considered when an OPO describes how it overcame barriers in its DSA.

Comment: Several commenters provided recommendations for considering contiguity in a competition. Some commenters recommended that CMS give greater weight to contiguity while others stated it is a less important factor.

Response: We continue to believe that contiguity is important, but it may not be the deciding factor in every situation. While contiguity may make the expansion of services easier from a logistics standpoint, it should not outweigh other considerations relevant

to decisions about the OPO who is most likely to achieve performance improvement and best serve a DSA. We are not revising the criteria at this time.

Comment: Several commenters requested greater specificity for expectations on what should be submitted to address the selection criteria. A commenter stated that CMS should provide a clear, objective definition of ''success overcoming barriers,'' specify what data and documentation CMS expects, and ensure the criteria are applied consistently and in a reviewable manner.

Response: In the proposed rule, we stated that the competition application process would provide an OPO the opportunity to describe the barriers it has faced and document its performance gains over time. The regulation at § 486.316(d)(4) states that we will consider an OPO's success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. The regulation further states that 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. This information is important for competing OPOs in demonstrating a record of performance gains and a trajectory of improvement that could enable us to make the determination that the OPO is likely to continue improving, has the potential to achieve tier 1 status in the DSA in the near term, and should be designated to the DSA.

We realize that an OPO may face different challenges over different time periods as it works to address performance in its DSA. We believe that it is important for OPOs to use a data driven approach to identify areas for improvement, monitor changes over time, and document actual performance improvement. Additionally, we expect clear identification of the barriers and evidence of a plan to address those barriers. Qualitative information can augment quantitative results in describing improvements. Data may include data reported to the OPTN, CMS outcome measures, and/or other data and information that is part of the OPO's QAPI program. Some OPOs have suggested that they have their own data teams that independently calculate and stratify CMS outcome measures to analyze performance. We encourage other OPOs and the SRTR to consider this approach as well. The SRTR could include this type of information in their OPO Specific Reports (OSRs).[16]

Comment: Several commenters shared concerns related to the proposal for DSA transitions, highlighting a range of issues that they believe may materialize. Commenters stated that there would need to be close coordination and cooperation among the incumbent OPO, successor OPO, and CMS since the competition and transition periods would occur over a relatively short timeframe. Several commenters stated that the incumbent OPO may have difficulty maintaining staff and services throughout the duration of the transition. Other commenters highlighted non-profit status requirements and State requirements such as licensure that would need to be met. A commenter mentioned that the successor OPO needed sufficient time to establish agreements with donor hospitals. Another commenter questioned how the transition would occur with two OPOs operating simultaneously during the transition.

Response: We acknowledge that the transition of a DSA to a successor OPO will be a significant undertaking, which is a reason we are codifying a requirement for OPOs to cooperate to facilitate a smooth transition and continuity of organ donation activities in the DSA. Additionally, we note the competition application procedures in the State Operations Manual Chapter 2 (CMS Pub 100–07) include many planning and transition elements to be included in the applicant's transition plan to support a stable transition of a DSA should the competitor be successful in a competition and eventually designated to the DSA. CMS worked closely with the OPOs involved in the recent transition of the Southern Florida DSA that was previously designated to the Life Alliance Organ Recovery Agency to monitor the process, assist in addressing any challenges, and ensure there was sufficient time to complete all requirements necessary to transition the designation to the successor OPO. Since only one OPO can be designated to a DSA, it is critical that all requirements be completed to transition the designation at the appropriate time. Therefore, the process must ensure that only one OPO is designated to a DSA at any given time with designation for the incumbent ending at the same time designation to the successor OPO begins. This activity also requires close coordination between CMS and HRSA to ensure a seamless transition in the information technology system that transmits information to support organ allocation activities.

Comment: A commenter stated that CMS does not have the authority to force a de-certified or replaced OPO to bear the costs of transitioning to a new OPO, specifically, the transfer of proprietary information without providing adequate compensation to the incumbent OPO for these activities. The commenter interpreted the proposed rule as suggesting that OPOs would be forced to transfer ''procedural manuals and other materials used in conducting OPO operations,'' that could include proprietary operational data, internal quality improvement analyses, workflow optimizations, and institutional knowledge developed by the incumbent OPO over an extended period of time.

Response: We thank the commenter for sharing this concern but disagree with their interpretation of the proposal. The requirement that was proposed at § 486.316(g) addresses transition of a DSA and requires that an incumbent OPO submit a transition plan that would provide details on how all aspects of the OPO operation will be transmitted, including timeframes, to a new OPO. This is separate from the existing information management requirement at § 486.330(d), most recently updated in our 2006 final rule, that OPOs must maintain data in a format that can readily be transferred to 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, but only to the extent necessary to ensure uninterrupted service by a successor OPO. An OPO should discuss any concerns it has regarding information sharing with CMS during a transition.

We expect the incoming OPO to have its own operations plan, including documentation and activities such as operational policies and procedures, QAPI data collection, and training programs, to serve the DSA in a way that improves performance, such that the type of information that the commenter characterizes as potentially proprietary would not be necessary to ensure uninterrupted service. Additionally, section 2812.4 of the SOM describes competition application materials to be submitted by an OPO competing for the DSA, including a transition plan that would address many of the operational aspects needed to transition the DSA. However, DSA-

[16] Organ Procurement Organization Reports (OSR). *https://www.srtr.org/transplant-professionals/organ-procurement-organization-report/organ-procurement-organization-reports-osr/*. Access May 27, 2026.

specific information maintained by the incumbent and necessary to ensure uninterrupted service, such as donor and recipient data, must be maintained in a format that can readily be transferred to a successor OPO and provided to CMS in the event of a transfer, consistent with the longstanding requirement set forth in § 486.330(d). Given that an OPO is required under § 486.330(d) to maintain this information in a format that can readily be transferred to a successor OPO, we would not expect the OPO to incur significant costs related to the transfer of such information.

Final Rule Action: We are finalizing the proposed changes to § 486.316 with a modification at § 486.316(a)(2) to address the impact of outcome measures to OPO designation when an OPO is assigned a new DSA by CMS. We are clarifying that when DSAs are assigned by CMS under the provisions at § 486.308(a)(4) or § 486.316(e) as discussed in section III.D., we will not open any tier 2 DSA managed by that OPO for competition until a full 4-year re-certification cycle is completed for the newly assigned DSA. We are also clarifying the language at § 486.316(b)(1) regarding the notice to the OPO. It is being revised from ''initial de-certification determination'' to an ''initial notice of de-certification'' as specified at § 486.314(a)(1). Additionally, we are revising § 486.316(c)(2) to clarify that a competition loss would result in non-renewal of the agreement for designation to a DSA.

I. Outcome Measures (§ 486.318)

We proposed to remove obsolete outcome measure provisions that expired on July 31, 2022. 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 proposed to remove the obsolete requirements at paragraphs (a) through (c) and to redesignate paragraphs (d) through (f) as paragraphs (a) through (c). We proposed 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 proposed 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 proposed 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).

We also proposed revisions to address OPOs managing multiple service areas, such as replacing ''OPO'' with ''DSA'' when referencing the outcome measures as applied to each DSA. We proposed tailored timelines for assuring OPO accountability in cases of adding new DSAs due to a change of control, ownership, or service area (CHOW), an expansion following a competition, or an expansion due to CMS assignment. Specifically, we proposed that if an OPO expands through the CHOW process after January 1 of the first year of the agreement cycle, the OPO would be held accountable for its QAPI responsibilities related to outcome measure performance in the new DSA once 12 calendar months of data are available. The timing of the CHOW in the re-certification cycle will impact whether the OPO is assessed for its performance on the outcome measures during the final assessment period for the current re-certification cycle or the subsequent re-certification cycle. For OPOs that acquire a new DSA through competition or CMS assignment after January 1 of the first year of the agreement cycle, we proposed that outcome measure accountability would apply: (1) for QAPI purposes, once 12 calendar months of data are available; and (2) for re-certification purposes, in the final assessment period of the following re-certification cycle. We proposed these changes based on the nature of the transaction and availability of data and information to support the change. For instance, 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. 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 an open DSA when no OPO competes for it must begin with significantly limited information and resources. OPOs in these situations could have large information gaps coupled with potentially significant expansion demands. Therefore, we believe that an OPO that assumes responsibility for a new DSA after a competition or has been assigned a DSA by CMS should have an additional amount of time to demonstrate improvement before being held accountable on its performance for re-recertification purposes.

We solicited public comment on these proposed changes to § 486.318. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that timeframe for accountability on the outcome measures for a new DSA acquired through a change of control or ownership or service areas, competition, or assignment by CMS should be the same. A commenter stated the proposal makes an arbitrary distinction between merger and competition. A commenter stated that the proposal puts OPOs that participate in mergers at a disadvantage due to the shorter timeframe for assessment on the outcome measures and risks related to a successor OPO taking over a DSA. Other commenters stated that impactful changes may take longer than 12 months with one commenter stating that operational integration in healthcare mergers typically unfold over a multi-year horizon due to the complexities involved. These commenters indicated that the timeframe for organizational stability as well as performance improvement is years. A commenter stated that last-minute changes will be more challenging even with good faith efforts and will take longer time frames.

Response: We understand the concerns of commenters and our proposed approach that we will be finalizing balances providing an appropriate level of time for improvement with the statutory requirements for performance accountability. We do believe there is a difference in challenges faced between a change of control or ownership or service area (§ 486.310), being awarded a DSA in a competition (§ 486.316(d)), or being assigned a DSA by CMS (§ 486.308(a)(4) or § 486.316(e)) and that we have provided the appropriate amount of time under each circumstance. We note that a change of control or ownership or service area that happens prior to the start of the final assessment period would be accountable for the outcome measures in the same re-certification period. Any changes after the start of the final assessment period would not have outcomes data available at the time of re-certification so the OPO would not be assessed for compliance on the outcome measures in the new DSA for re-certification purposes until the final assessment period of the next re-certification cycle. We believe the prior

planning that is afforded to OPOs in a change of control or ownership or service area warrants accountability on the outcome measures at that time when that data is available at the time of re-certification. Therefore, we will be finalizing this provision as proposed.

Comment: Several commenters were supportive of the changes related to accountability for the outcome measures when an OPO is designated to a new DSA. A commenter stated the different scenarios described in the proposed rule appropriately account for transition periods and the time needed for a new OPO to implement its operational approach in an acquired DSA. A commenter stated that they support revising the requirement for when CMS will hold an OPO accountable on the outcome measures when it takes over another OPO's DSA. Another commenter stated the timeframe for an OPO assuming responsibility of a DSA after a competition is appropriate.

Response: We thank commenters for support of this approach for tailoring accountability to the nature of the transaction, the availability of outcomes data, and the challenges anticipated with the different reasons for designation of a new DSA.

Comment: Several commenters requested clarity on how this provision would be implemented. A commenter stated CMS should specify which data period applies before performance accountability takes effect and how performance will be measured during transitional phases. Another commenter stated that CMS should clarify how it will measure performance for OPOs that assume responsibility for new DSAs following de-certification or reassignment, particularly given that the current outcome measures rely on data with a 1-to 2-year data lag.

Response: We appreciate the opportunity to provide clarity on this provision. We will provide the 2026 through 2030 re-certification period as an example. In the event of a change of control or ownership or service area (§ 486.310) that occurs prior to the start of the final assessment period in 2028, meaning prior to January 1, 2028, the OPO would be held accountable on the outcome measures in the new area at the time of re-certification in 2030. If the change was approved after the start of the final assessment period, outcome data would not be available so the OPO would be held accountable on the outcome measures for re-certification purposes for the first time in the new area in 2034 with outcome measures from 2032 (see § 486.318(c)(3)). Alternatively, an OPO that is designated to a DSA by assignment (§ 486.308(a)(4) or § 486.316(e)) or as the result of a competition (§ 486.316(d)) at any point during the 2026 through 2030 re-certification period, would be held accountable on the outcome measures in the new DSA for re-certification purposes for the first time in the new area with outcome measures from the final assessment period (2032) of next re-certification cycle (2030 through 2034). In each instance, the OPO would be surveyed at the time of re-certification in 2030 and must be in compliance with all process measures passing the survey at that time to be recertified. Additionally, an OPO that is designated to a DSA by assignment (§ 486.308(a)(4) or § 486.316(e)) would not have its original or new DSA opened for competition at the end of the re-certification cycle (for example, 2030) if the OPO's performance in those DSAs qualifies for tier 2 in the final assessment period.

Final Rule Action: We are finalizing the changes to § 486.318 as proposed.

J. Human Resources (§ 486.326)

We proposed to revise the medical director requirement to specify that an OPO's medical director would be required to 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. This proposed change was intended to accommodate the proposal that an OPO may be designated to more than one DSA while still having a single medical director. We also proposed revising personnel qualifications for other OPO staff that engage in clinical practice, whether they are in explicitly clinical positions or other positions in which clinical decision making or actions are expected. We proposed to require that personnel performing clinical duties be legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State and local laws. Furthermore, we proposed that these staff would be required to act only within the scope of the individual's State license, certification, or registration. Finally, we proposed that the individual's licensure, certification, or registration be required to be kept current at all times. While OPOs are 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 those services, we proposed these changes due to the expertise required to fulfill the broad responsibilities and functions of OPOs. These responsibilities span a range of activities from educating donor hospitals to conducting internal QAPI activities to implementing donor management protocols. We proposed licensure requirements to establish minimum qualifications to assure quality and to facilitate more organ transplants.

We solicited public comment on these proposed changes in § 486.326. The following is a summary of the comments we received and our responses.

Comment: CMS received a small number of comments related to the changes to the medical director requirement. Commenters requested more flexibility so that OPOs could have more than one medical director or be able to fulfill this role through flexible staffing models with multiple staff filling this position at various times.

Response: For purposes of clear and direct accountability, we require a single individual to fulfill the role of medical director and be responsible for the overall medical direction of the OPO's operations. Currently, the medical director must be licensed as a physician in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. Many OPOs currently have multi-state DSAs and have been operating under this requirement since it was implemented in the 2006 final rule (71 FR 30982). We continue to believe that a single person should be accountable for overall medical direction of an OPO's activities. Our proposed change to this provision is limited to a conforming change to reflect that an OPO may be designated to more than one DSA. Therefore, we are finalizing this requirement as proposed.

Comment: Many commenters raised concerns about the practical implications of requiring personnel performing clinical duties to be legally authorized (licensed, certified or registered) in accordance with applicable Federal, State and local laws, and to act only within the scope of the individual's State license, or State certification, or registration. Commenters indicated that the organ procurement and transplantation workforce operates in a unique, specialized, and complex clinical environment and that much of the work performed by OPO staff does not require medical licensure because it is not medical treatment. Commenters stated that licensure frameworks are focused on treatment of living patients and that State and local laws and regulations do not contemplate licensure of professionals engaged in deceased donor management and organ recovery.

Commenters highlighted that State licensure laws, including nurse and physician practice acts, are written to govern the care of living patients and do not define or contemplate the management of a legally deceased individual and drew the distinction that supporting clinical teams in donor management is operationally distinct from direct patient care. Additionally, commenters stated that there are many clinical roles in the OPO industry for which there is not a role-specific licensure, certification, or registration. Some commenters noted that nurses and paramedics, disciplines for which State licensure exists, often coordinate donations or transplants and that these non-clinical coordination tasks do not require the same licenses as working with living patients. A commenter stated that strict reliance on State licensure standards would ignore the specialized, multidisciplinary scope of practice inherent to organ procurement and another stated that if CMS were to implement this proposal, rigid application of State-specific licensure for every staff role would be problematic because no State-specific licensure requirement exists for every OPO staff role. Some commenters noted that organ recovery procedures are often completed by surgeons that received training in other countries and are not currently board-certified in the United States and by non-physician practitioners that are not typically licensed to perform surgical procedures on living patients. Commenters stated the proposal could create significant operational and compliance challenges for OPOs that would negatively impact the OPO workforce and donation activities. The commenters stated that requiring licensure of these procurement staff would be incredibly challenging, if not impossible, and suggested that such a requirement would negatively impact OPO ability to maintain the current level of donor cases by strictly relying only on fellows or transplant surgeons in an OPO's service area. Commenters stated the proposal could create significant operational and compliance challenges for OPOs that would negatively impact the OPO workforce and donation activities. In place of licensure requirements, some commenters focused on OPO onboarding and training processes and stated that CMS requirements for OPO staff should focus on training and demonstration of specific skills.

Response: We thank commenters for articulating the unique concerns and needs of the OPO workforce. While it was not our intent to require licensure for individuals that only perform non-clinical work, such as coordination logistics and obtaining consent for donation, we understand that the roles may be mixed and blurred within OPO operations such that operationalizing our original intent may create staffing difficulties that ultimately undermine organ donation and transplantation, contrary to our policy goals. We are committed to establishing CfC requirements to assure the safety of patients who may become donors and organ recipients. We continue to believe that there is an opportunity to better ensure such safety through the establishment of more robust personnel qualifications and training standards. We will work with HRSA, the OPTN, and our OPO partners to explore ways to drive improvements in OPO staffing that support safe organ procurement and more lifesaving transplants. Upon consideration of the public comments received, we are not finalizing the proposed requirement at § 486.326(e) for licensure at this time and will consider the information shared in any future rulemaking in this area.

Comment: While a commenter stated that the educational infrastructure to support a national credentialling requirement does not exist because there's only a single specialized transplantation and donation sciences training program serving the entire country, several other commenters stated that CMS should recognize national credentialing through the American Board for Transplant Certification (ABTC) as nationally recognized standards for training and competency. The commenters stated certifications for transplant procurement coordinators and transplant preservationists represent nationally recognized training and competency standards for personnel involved in organ donation coordination and recovery operations. The comment noted that there are currently 1,175 Certified Procurement Transplant Coordinators working directly in OPO environments across 48 OPOs. Another commenter stated that it is developing specific standards related to organ recovery for clinical personnel who procure organs and is advocating for a certification program for organ recovery staff.

Response: We thank commenters for this information. We note the certifications referenced by commenters assist in addressing the multidisciplinary roles fulfilled by OPO staff. While we are not finalizing the proposed licensure requirements at § 486.326(e) at this time, we encourage OPOs to apply existing standards for training and competency, as well as existing certification programs, to their hiring standards to support improvements in safety and performance.

Final Rule Action: After considering public comments, we are finalizing the medical director requirement at § 486.326(d) as proposed. However, we are not finalizing the proposed licensure requirement at § 486.326(e) at this time. We may consider comments from the licensure proposal in future rulemaking.

K. Information Management (§ 486.330)

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 proposed to establish a new documentation requirement specific to organs procured by OPOs for research, including pancreata procured for islet cell research. We proposed 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 solicited public comment on these proposed changes to § 486.330. The following is a summary of the comments we received and our responses.

Comment: Several comments requested CMS to define ''qualified researcher'' and ''bona fide research''. Another commenter recommended that CMS clarify that OPOs can base documentation on the principal investigator's home institution Institutional Review Board review and indicate that a separately arranged review is not necessary.

Response: We appreciate the commenters' requests for additional clarity related to these terms and the associated documentation requirements. In the 2020 final rule, we clarified that in counting pancreatic islet cell research for inclusion in the outcome measures, only bona fide research conducted by a

qualified researcher would be included (85 FR 77937). In memorandum QSO–24–19–OPO,[17] published August 29, 2024, addressing the reporting of data related to pancreata procured for research, we noted that research approved by the National Institutes of Health would be one example of bona fide research conducted by a qualified researcher. We have not specifically defined ''qualified researcher'' or ''bona fide research.'' We are relying on OPOs to provide organs for research to qualified researchers for bona fide research based on accepted industry standards and practices. This may involve placement directly to a researcher, institution, or to an intermediary that facilitates placement of the organs. Records related to organ disposition must provide sufficient information to validate disposition of the organ as it is coded in the OPTN data set. The records to be maintained include, but are not limited to, information documenting approval from an IRB or other formal authorizing body, as appropriate, research institution, principal investigator, and study contacts for the research. These records may be utilized if validation of the information is required at a later time.

Comment: A commenter recommended additional clarification on the types of documentation or information that could be used for record keeping purposes. The commenters recommended items such as researcher credentials, statements of research purpose with a description of how the organ would be used, material transfer agreements, and attestation forms. The researcher also suggested that CMS require OPO governing boards to periodically review research programs documentation against regulatory requirements and formally approve participation in research activities, specifically referring to pancreas research activities.

Response: We appreciate this comment and recommendations. We believe the current record keeping requirements are written broadly enough to capture the information recommended by the commenter; however, we encourage OPOs to record all available and necessary information to validate final disposition of organs sent for research. We also realize that in some instances there may be limited information provided to the OPO. An OPO should decide if the records received justify the final disposition of the organ adequately to appropriately code the information for OPTN reporting purposes. We did not propose for OPO governing boards to review research program documentation against regulatory requirements and formally approve participation in research activities as we believe this type of activity is a fundamental responsibility that is already under the purview of governing boards.

Comment: A commenter recommended that documentation expectations and validation approaches overlap with or include OPTN definitions, documentation expectations and validation approaches, and that CMS and HRSA work together to ensure consistency and safeguard data integrity while supporting continued advancement of islet cell research. Additionally, the commenter stated that CMS should clarify permissible research uses of pancreata, including circumstances where organs are designated for research prior to confirmation of a specific protocol or IRB approval.

Response: We thank the commenter for these recommendations. As CMS previously clarified in a memorandum issued January 18, 2024,[18] pancreata must be used for islet cell research or islet cell transplantation, consistent with PICTA 2004, to be included in the outcome measures. Moreover, we are finalizing changes to the definition of ''organ,'' such that pancreata procured for islet cell research will no longer be counted in the transplantation rate. We also note that CMS has previously worked with HRSA to revise and clarify coding for pancreata submitted for research (See QSO–24–19–OPO).[19] If an OPO is unable to obtain records demonstrating the pancreata was used for islet cell research, it should not code the disposition as ''accepted for islet cell research''. In regard to data integrity, we note that documentation expectations and validation approaches associated with data reporting requirements under the OPTN final rule (§ 121.11(b)(2)) [20] apply to all OPTN members reporting information to the OPTN. Additionally, the OPTN information technology system, UNet, terms of service [21] also include a requirement for data accuracy. OPOs, as OPTN members, must comply with these requirements for data integrity.

Final Rule Action: We are finalizing the requirement at § 486.330(b) as proposed.

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

We proposed revisions to the existing QAPI standards to revise and clarify the requirements for tracking adverse events and establish new requirements for monitoring medically complex organ performance.

We proposed to relocate the adverse event examples included in the current definition of ''adverse event'' to the QAPI requirements and expand the list 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 a wrong organ or blood type mismatch; organs lost or delayed in transit; and organs arriving in unsuitable condition. For greater specificity and to avoid confusion, we proposed to replace ''the wrong organ'' with ''an organ that was not for the intended organ recipient''. We also proposed 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 proposed to remove the two references to ''beneficiary'' and instead use ''organ recipient''.

To further the goal of improving procurement and transplantation of medically complex organs, we proposed to require each OPO, as part of its QAPI program, to: (1) assess its policies and procedures regarding medically complex donors and organs to ensure that opportunities for recovery and placement are being optimized; (2) assess its performance by tracking, at least annually, the number of medically complex donors from whom consent was obtained, organs recovered, and medically complex organs transplanted; and (3) implement improvement actions when opportunities are identified.

We solicited public comment on these proposed changes to § 486.348. The following is a summary of the comments we received and our responses.

Comment: Some commenters were concerned about how their QAPI programs would affect any enforcement actions. They were concerned that information contained in their QAPI program could result in deficiencies or

[17] *https://www.cms.gov/files/document/qso-24-19-opo.pdf.*

[18] Definition Clarification. *https://www.cms.gov/files/document/qso-24-04-opo.pdf.*

[19] Reporting Data Related to Pancreata Procured for Research. *https://www.cms.gov/files/document/qso-24-19-opo.pdf.*

[20] OPTN Final Rule. *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121.*

[21] UNOS Systems Terms of Use. *https://unos.org/wp-content/uploads/2023-UNOS-Systems-Terms-of-Use.pdf.*

otherwise negatively impact them. They also expressed concerns about how these requirements would be enforced, especially if they failed to identify any incident as an ''adverse event'' that a surveyor believed should have been identified as such.

Response: The QAPI requirements will be enforced through routine, and possibly complaint, surveys. Hence, the QAPI requirements will continue to be enforced as they have been. Surveyors will utilize Appendix Y of the State Operations Manual (CMS Pub 100–07) to guide survey activities.[22]

Adverse Events

Comment: Many commenters expressed concern regarding an adverse event being attributed to an OPO when another party, such as the donor hospital or transplant program, is responsible for the incident. They pointed out that an adverse event could occur during the organ recovery process, but the incident could be caused by an action or omission by the donor hospital or transplant program and not the result of any action or omission on the part of the OPO. This could result in the OPO being cited for a deficiency or other enforcement action and negatively impact their performance or outcome measures or re-certification. Commenters requested consistent guidance on how responsibility would be attributed for adverse events.

Response: We understand that the action(s) or omission(s) that result in an adverse event can be complicated and could even involve multiple parties. However, the party responsible, whether it is the OPO, donor hospital, or transplant program, would be incident specific as determined by the OPO's investigation. Hence, it would be inappropriate for us to provide specific guidance on attribution. This is why OPOs are required to establish policies to not only identify but also to report, analyze, and prevent adverse events that occur during the organ donation process (§ 486.348(c)(1)). Complying with this requirement is not an admission of responsibility by an OPO. An OPO's investigation could conclude another party was responsible for the adverse event; however, the OPO would still be responsible for conducting 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)). If the OPO's investigation concludes that another party was responsible for the adverse event, the OPO would need to work with that other party to address actions to take to prevent the adverse event from reoccurring in the future.

Comment: Some commenters requested clarity on what ''avoidable loss'' means in proposed § 486.348(c)(3)(ii), which identifies ''avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained'' as an example of an adverse event.

Response: This example was finalized in the 2006 final rule (71 FR 31046). We only proposed moving the example from the definition in § 486.302 to the QAPI requirements and did not revise any of the wording or meaning of this phrase. We believe that whether the loss of a medically suitable potential donor was avoidable should be based upon the OPO's judgement. If the OPO is unsure whether the incident should be considered an avoidable loss, we would encourage the OPO to seek guidance from CMS.

Final Rule Action: After consideration of the public comments we received, we are finalizing the requirement at § 486.348(c)(3) as proposed.

Medically Complex Donors and Medically Complex Organs

Comment: Several commenters supported the emphasis or focus on medically complex donors and medically complex organs. However, a few commenters thought OPOs were already actively pursuing medically complex donors and medically complex organs.

Response: We thank the commenters for their support for the focus on ''medically complex donors'' and ''medically complex organs.'' However, as explained previously in section III.B.4. of this final rule, we are not finalizing the definitions of ''medically complex donor'' or ''medically complex organ'' at this time. Hence, we will not be finalizing any of the QAPI requirements associated with those definitions in § 486.348(e). However, we encourage OPOs to utilize the existing QAPI framework to improve the procurement and placement of all organs from all donors.

Comment: Some commenters were concerned about unintended consequences due to the focus on medically complex donors and organs. They highlighted concerns that increased attention to medically complex cases could unintentionally discourage organ recovery if performance measures do not reflect clinical complexity, suggesting that OPOs could become risk averse. Other commenters were concerned that the emphasis on medically complex donors and medically complex organs could incentivize the use of organs that would result in poorer outcomes for patients.

Response: We acknowledge the commenters' concerns. However, as described previously in section III.B.4. of this final rule, we are not finalizing the definitions of ''medically complex donor'' or ''medically complex organ''. Hence, we will not be finalizing the corresponding QAPI requirements in section 486.348(e) that requires those definitions. However, we note research that we included in the proposed rule that demonstrates similar or better outcomes from these types of organs over traditional therapies (for example, dialysis) or no transplant.[23] [24] [25] Therefore, we will continue to evaluate research and practice patterns in this area and consider future changes that would enhance the utilization of all donated organs.

Comment: Some commenters were concerned that the emphasis for organ donation, including the proposed requirements for medical complex donors and medically complex organs could result in OPOs applying more pressure on potential donor families to obtain consent for donation.

Response: OPOs are required to encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families as set forth in § 486.342 Requesting Consent. Hence, OPOs should not be applying pressure on potential donor families to obtain consent for donation. If individuals believe that undue pressure is being applied, they should report that information to the donor hospital administration and/or the State Survey

[22] See Appendix Y in the State Operations Manual. Accessed at *https://www.cms.gov/files/document/qso-26-06-opo-original-release-date-2026-03-11.pdf.* Accessed May 22, 2026.

[23] Walls, DO, Lee-Riddle, Gs, Manderski, MB, Sawinski, DL, and Abt, PL. Kidney transplant outcomes from donation after 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.

[24] 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 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.

[25] 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.

Agency [26] so the information can be reported to CMS.

Final Rule Action: After consideration of the public comments we received, we are not finalizing the QAPI requirements for medically complex donors and medically complex organs at § 486.348(e).

M. 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 section 1138(b)(2) of the Act requires that only one OPO may be designated to a DSA, it does not prohibit one OPO from being designated to multiple DSAs at one time. OPOs have expressed interest in a single OPO being designated to multiple DSAs. We proposed conforming changes to address provisions in the CfCs related to the number of DSAs an OPO may be responsible for. Specifically, we proposed to require OPOs to have written agreements with 95 percent of Medicare and Medicaid participating hospitals and CAHs with both a ventilator and an operating room in each of their designated DSA. We proposed replacing ''area'' with ''area(s)'' in several provisions. Additionally, we proposed that data used for OPO re-certification must include data for all deaths in all hospitals and CAHs across all DSA(s), unless a waiver has been granted. Finally, we proposed to revise the emergency preparedness requirements for OPOs. We proposed that OPOs are required to have an emergency communication plan with the names and contact information for transplant and donor hospitals in each of the OPO's DSA(s), and to replace ''DSA'' with ''DSA(s)''. We did not receive comments opposing these conforming changes.

Final Rule Action: After consideration of the public comments, we are finalizing the conforming changes to §§ 486.322, 486.324, and 486.360 as proposed.

IV. Comment Solicitation and Discussion on Emerging Issues

A. Conflicts of Interest

We solicited public comment on how OPOs address conflicts of interest, the adequacy of current regulatory requirements, and potential modifications to the OPO CfCs to assure consistent development and implementation of conflicts of interest policies that protect health and safety and the integrity of the organ donation system. The following is a summary of the comments we received and our responses.

Comments: Several commenters expressed support for strong, transparent conflict of interest (COI) policies for OPOs, emphasizing their importance in maintaining public trust in the organ donation and transplantation system. While some commenters stated that current CMS requirements were sufficient, many welcomed clearer Federal guidance to ensure consistency across all OPOs. Other commenters raised concerns regarding the creation of additional requirements, noting that OPOs already operate under established nonprofit governance standards, including IRS requirements and existing conflict-of-interest policies. These commenters stated that new requirements could be duplicative and impose unnecessary administrative burden and recommended that any new requirements be evidence-based and aligned with broader healthcare governance practices.

A few commenters disagreed with the suggestion that tissue recovery activities conflict with OPO and organ donation operations. They stated that organ donation and tissue donation are not competing activities and that many OPOs maintain separate organ and tissue service lines with distinct budgets, staffing structures, and operational processes, which function as internal safeguards against potential conflicts of interest.

Some commenters recommended that CMS require OPOs to have formal, written COI policies that mandate disclosure of secondary employment and require routine disclosure and documentation of conflicts and their resolutions. These commenters also encouraged CMS to collaborate with HRSA and the OPTN to avoid duplicative or overlapping regulatory requirements.

Response: We thank commenters for their feedback. We note that the comments we received may be taken into consideration for potential future rulemaking.

B. Allocation Out of Sequence (AOOS)

We provided an overview of Federal organ allocation requirements to address recent concerns related to an increase in organ AOOS, which reflects a deviation from allocation policy and may only occur if necessary to prevent organ wastage due to discard. We clarified expectations for regulatory and policy compliance necessary for maintaining public trust. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed that inappropriate organ allocation out of sequence practices undermines fairness, accountability, and public trust in the transplant system. However, several commenters emphasized that AOOS reflects broader systemic challenges within the organ allocation system rather than solely OPO conduct. These commenters stated that outdated allocation technology, prolonged sequential allocation processes, and variability in transplant center organ acceptance practices all contribute significantly to AOOS and organ non-use. A commenter stated that the current allocation system cannot dynamically adjust as donor information changes and does not include transplant center acceptance behavior into allocation decisions.

While commenters acknowledged that there may be reasons for non-sequential placement, including clinical urgency, logistical constraints, or organ viability concerns, commenters stated that insufficient documentation or explanation of such deviations creates the perception that allocation decisions may occur outside established policy. They recommended stronger oversight and auditing of AOOS decisions, clear documentation requirements for deviations from standard allocation order, and increased transparency regarding expedited placement practices to preserve public confidence in the transplant system.

Several commenters raised concerns that AOOS may unintentionally disadvantage certain patient populations, including pediatric candidates, minority communities, medically complex recipients, and underserved populations. A commenter stated that multi-organ allocation and AOOS practices may divert suitable organs away from pediatric candidates or delay pediatric access to transplantation. Other commenters expressed concern that existing allocation and performance frameworks do not adequately account for disparities affecting minority populations or patients requiring medically complex transplants. Commenters recommended that CMS monitor allocation practices for unintended equity impacts, evaluate pediatric utilization separately, consider health equity impacts in oversight activities, and ensure that medically

[26] *https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/contact-information.*

complex organs are not disproportionately rejected or diverted in ways that worsen existing disparities in access to transplantation.

Some commenters stated that transplant center acceptance practices significantly contribute to AOOS and organ non-use. These commenters noted that transplant centers vary substantially in their willingness to accept medically complex organs and stated that current transplant program oversight and outcomes requirements create disincentives for transplant centers to accept higher-risk organs. They suggested that CMS work with transplant system interested parties to develop policies that (1) increase transparency regarding transplant center organ acceptance patterns, including accepting multiple offers for the same candidate and data on declines after acceptance; (2) encourage adoption of best practices for organ utilization; and (3) reduce unnecessary organ declines.

Several commenters emphasized the importance of coordination among CMS, HRSA, and the OPTN regarding AOOS and expedited placement policies. Commenters expressed concern that differing definitions and regulatory expectations related to medically complex organs, expedited placement, and AOOS may create confusion for OPOs and transplant centers. A few commenters suggested that CMS align its terminology and oversight expectations with OPTN policies related to expedited placement and allocation out of sequence practices.

Response: We thank commenters for sharing this information and recommendations. We believe the existing CMS regulatory requirements under §§ 486.324(b)(6) and 486.344 support an OPO's responsibilities for allocating organs in accordance with the rules and requirements of the OPTN. Section 486.324(b)(6) of the OPO CfCs enables the OPO advisory board to recommend policies for a system to allocate organs among transplant patients that is consistent with the rules and requirements of the OPTN. In addition, § 486.344 requires that each OPO 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 maintain 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. Consistent with these requirements, HHS regulations governing the operation of the OPTN also require that organ offers are made to transplant patients—rather than to transplant centers—in a manner that is consistent with OPTN policies.[27] OPTN Policy 5.4.B requires OPOs to offer organs to potential recipients in the order that they appear in the match run, as determined by OPTN policy. OPOs that become aware of potential noncompliance with OPTN policy—including by themselves—are obligated to report such instances to the OPTN. To support OPO and transplant program compliance, the OPTN has developed an Allocation Out of Sequence resource page[28] that provides guidance on existing requirements and facilitates understanding of this issue.

As part of these ongoing efforts, the OPTN and HRSA have introduced new monitoring tools—including the AOOS Dashboard and OPO Allocation[29] Compliance Reports[30]—that provide HRSA, the OPTN, patients, and the public with a more comprehensive means of monitoring AOOS instances and trends. Also, in January 2026, the AOOS Workgroup[31] delivered three draft OPTN policy proposals to HRSA and the OPTN Board of Directors. These draft proposals address: (1) creating a definition of an ''offer''; (2) an expedited protocol for the allocation of hard-to-place kidneys; and (3) proposed approaches to improve OPTN member compliance with OPTN policy.

CMS and HRSA continue to closely collaborate to ensure appropriate oversight of existing policy and are carefully examining the issue of organs being allocated out of sequence with respect to both OPO and transplant center actions.

C. Automated Electronic Referrals

We solicited public comment on how to leverage technology to support automated electronic referrals and ensure appropriate privacy and security protections for the information.

The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of requiring automated electronic referrals from donor hospitals to OPOs. Commenters noted that an automated referral process would streamline hospital workflows, reduce reliance on manual phone-based referrals, lower the risk of missed or delayed referrals, and provide OPOs with more accurate and timely clinical information. A commenter noted, however, that automated referrals should supplement rather than replace direct communication between hospital staff and OPO personnel, as clinical discussions and coordination between providers and OPO staff remain essential throughout the donation process. A few commenters expressed concerns about privacy and data security protections for both potential and actual organ donors and recommended that OPOs be required to comply with the Health Insurance Portability and Accountability Act (HIPAA).

Several commenters also recommended leveraging platform-independent standards, such as Fast Healthcare Interoperability Resources (FHIR®), to integrate automated referral systems across diverse software environments. FHIR is a widely used health information technology standard that enables different healthcare systems and software platforms to securely share and exchange patient data in a consistent format. By adopting FHIR-based standards, automated referral systems can be integrated across a wide range of software environments, reducing dependence on any single vendor and supporting ongoing innovation. Commenters noted that most electronic health record (EHR) systems currently include functionality to initiate actions based on defined clinical triggers. However, these triggers must typically be configured individually by each hospital, as no universal standard currently exists. Commenters encouraged the standardization of these clinical triggers and their consistent implementation across all healthcare organizations, noting that establishing a national standard would significantly streamline the deployment and scalability of automated referral systems.

Commenters also raised concerns about the operational and financial challenges associated with implementation, particularly for rural and under-resourced hospitals with limited information technology (IT) infrastructure, fragmented EHR systems, staffing limitations, or insufficient technical resources. Commenters recommended that CMS establish cost-sharing or incentive frameworks such as pilot grants or partnerships with health IT vendors to help offset implementation and maintenance costs.

[27] 42 CFR 121.7(b)(1) and (2).

[28] Allocation out of OPTN Sequence. *https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aoos#learn.*

[29] Allocation out of OPTN Sequence. *https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aoos#learn.*

[30] OPO Allocation Compliance Reports. *https://www.hrsa.gov/sites/default/files/hrsa/optn/sample-allocation-compliance-report.pdf.*

[31] AOOS Workgroup. *https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aoos/workgroup.*

Response: We thank commenters for their feedback. We note that the comments we received may be taken into consideration in potential future rulemaking.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to obtain approval from the Office of Management and Budget (OMB) before conducting or sponsoring a collection of information. A ''collection of information'' includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. This final rule contains information collection requirements associated with the information management requirements at § 486.330.

In the proposed rule, we provided a 60-day notice and solicited public comment on these information collection requirements, including the need for the information collection, the accuracy of our burden estimates, the quality, utility, and clarity of the information to be collected, and ways to minimize the information collection burden on affected entities. We considered the public comments received in developing this final rule. Commenters generally requested additional clarity regarding the meaning of ''bona fide'' research and ''qualified researcher'' under the information management requirements, and noted that much deceased donor research is bench research that may not require approval by an institutional review board. Commenters also raised concerns that expanded QAPI requirements could increase documentation burden, particularly with respect to medically complex donors and organs.

After consideration of public comments, we are finalizing the information management requirements at § 486.330 as proposed. In response to public comments raising concerns about the lack of a standardized and nationally recognized definition of medical complexity, we are not finalizing the proposed definitions of ''medically complex donor'' and ''medically complex organ'' at § 486.302, and we are not finalizing the QAPI requirement proposed at § 486.348(e). Accordingly, this final rule does not include the information collection burden associated with QAPI activities for medically complex donors and organs (IC–2) that was included in the proposed rule.

In analyzing the burden for these information collection requirements, we rely on wage and salary information. Unless otherwise indicated, we obtained salary information from the May 2025 National Occupational Employment and Wage Estimates, United States, from the Bureau of Labor Statistics (BLS). Based on this information, we calculated estimated adjusted hourly rates based on the national mean salary for each position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other 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 final rule, the estimated average hourly wage, and the adjusted hourly wage, with a 100 percent markup for fringe benefits and overhead. In addition, throughout this analysis, any amount ending with 0.50 or more is rounded up to the next nearest dollar amount, and any amount ending with 0.49 or less is rounded down to the next nearest dollar amount.

TABLE 1: 2025 Estimated Mean and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Final 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	$133.30	$267
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	Organ Procurement Coordinator (OPC)	$48.76	$98
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Quality Manager; Administrator	$67.77	$136

A. ICRs Regarding Information Management (§ 486.330)

This final rule establishes new information management requirements for OPOs at § 486.330. These requirements establish 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, OPOs must 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, the principal investigator, and study contact information.

Estimating the number of organs procured by OPOs 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, 15 OPOs participate in their research, with each OPO submitting on average 110 pancreata per year. We use this data to estimate that, on average there are a total of 1,650 pancreata submitted for islet cell research per year (110 pancreata × 15 OPOs).

Furthermore, according to CMS correspondence with a participating OPO, this OPO submitted a total of 783 pancreata to three different studies from 2021 through 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 an adjusted hourly wage of $98 per hour, will be responsible for this activity and will take 5 minutes, or 0.083 hours, to map each pancreas with its corresponding research study information.

The total annual burden for the 15 participating OPOs is estimated at 244 hours per year (0.083 hours × 196 responses × 15 OPOs). The total annual cost is $23,912 (244 hours × $98 per hour). This is approximately 16 hours per participating OPO (244 hours ÷ 15 participating OPOs), at a cost of $1,568 per participating OPO (16 hours × $98). When distributed across all 54 OPOs for purposes of presenting an average burden across the industry, the annualized burden for IC–1(a) is approximately 5 hours per OPO (244 hours ÷ 54 OPOs), at a cost of approximately $443 per OPO ($23,912 ÷ 54 OPOs).

Estimating the burden for 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 the absence of data, we illustrate the upper bound of possible burden. We assume one organ is procured and used for one research study.

According to data maintained by the Organ Procurement and Transplantation Network (OPTN), 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 organs + 5,631 organs) ÷ 2).

Assuming an average of 5,267 organs per year, we anticipate that OPOs will submit a total of 5,267 responses per year. For IC–1(b), this results in annual burden of 437 hours (5,267 responses × 0.083). Distributed across 54 OPOs, this is approximately 8 hours per OPO (437 hours ÷ 54 OPOs). We assume the responses will be completed by an OPO's organ procurement coordinator, at an adjusted hourly wage of $98 per hour. This results in an annual burden cost of $42,826 (437 hours × $98), or approximately $793 per OPO ($42,826 ÷ 54 OPOs).

The annual burden for IC–1, including IC–1(a) and IC–1(b), is estimated at 681 burden hours (244 hours + 437 hours), at an estimated annual cost of $66,738 ($23,912 + $42,826). Distributed across all 54 OPOs, this is approximately 13 hours per OPO (681 hours ÷ 54 OPOs), at a cost of approximately $1,236 per OPO ($66,738 ÷ 54 OPOs).

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

B. Collection of Information Summary

The annualized burden for all information collections finalized in this rule, including IC–1(a), IC–1(b) for all 54 OPOs would be approximately 681 burden hours at an estimated annual cost of $66,738. Distributed across all 54 OPOs, this equals approximately 13 hours per OPO per year, at a cost of approximately $1,236 per OPO per year.

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	$23,912	5	$443
IC-1(b) - Other Organs for Research	437	$42,826	8	$793
Total All ICs	**681**	**$66,738**	**13**	**$1,236**

Comment: Several commenters requested additional clarity regarding the meaning of ''bona fide'' research and ''qualified researcher'' under the information management requirements and noted that much deceased donor research is bench research that may not require approval by an institutional review board. Several commenters also expressed concern that expanded QAPI requirements, including requirements related to medically complex donors and organs, could increase documentation burden and divert resources from clinical operations.

Response: We considered these comments in developing this final rule. We are finalizing the information management requirements at § 486.330 as proposed. The final rule requires an OPO to maintain records showing the disposition of each organ recovered and sent for research, including, but not limited to, information documenting approval from an IRB or other formal authorizing body, as appropriate. We recognize that IRB approval may not be

required for certain types of research, including some bench research involving deceased donor organs. As set forth in § 486.330(b)(2)(i), an OPO is only required to maintain information documenting approval from an IRB or other formal authorizing body ''as appropriate.'' Where approval from an IRB or other formal authorizing body is not required, the OPO is not required to maintain documentation of such approval. In those circumstances, the OPO is still required to maintain records showing the disposition of the organ as reported as described in § 486.330(b)(2), including the research institution, principal investigator, and study contacts. In response to comments raising concerns about the lack of a standardized definition of medical complexity for medically complex donors and organs, we are not finalizing the proposed definitions of ''medically complex donor'' and ''medically complex organ,'' and we are not finalizing the related QAPI requirement proposed at § 486.348(e).

VII. Regulatory Impact Analysis

A. Statement of Need

More than 100,000 people are currently waiting for an organ transplant and demand for organs continues to exceed supply.[32] 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 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 OPO final rule, which, among other changes, established new performance measures and a three-tier ranking system for OPOs. The December 2020 OPO final rule created a baseline implementation framework with annual costs of $126.7 million.

Since the December 2020 OPO final rule was published, CMS has received many questions from OPOs and other interested parties seeking clarification about how the new system works, particularly as the system approaches the end of the 2022–2026 re-certification cycle. This final rule clarifies procedures for competitions, designation to multiple DSAs, non-renewal and de-certification, appeals, outcome-measure accountability, information management, QAPI, and other operational details. The final rule also reflects changes made in response to public comments, including not finalizing the proposed definitions of ''medically complex donor'' and ''medically complex organ'' and the related QAPI requirement at § 486.348(e), modifying the designation framework for certain CMS-assigned DSAs, and not finalizing the proposed licensure requirement for personnel performing clinical duties.

We estimate that this final rule will cost approximately $16.4 million in the first year and $7.9 million annually thereafter. These costs are incremental to the broader framework established in the December 2020 OPO final rule and reflect targeted operational and administrative refinements rather than fundamental system restructuring. We also estimate that this final rule will result in approximately $583,000 in annual benefits due to reduced implementation inquiry and compliance-interpretation burden, as well as a one-time benefit of $500,000 due to increased operational flexibility for OPOs designated to multiple DSAs.

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, section 202 of the Unfunded Mandates Reform Act of 1995, and the Congressional Review Act (5 U.S.C. 804(2)).

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 section 3(f) of Executive Order 12866 but not under section 3(f)(1).

This final rule builds on the December 2020 OPO final rule, which established new OPO performance measures and re-certification processes for the 2022 through 2026 certification period and future re-certification cycles. The December 2020 OPO final 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 final rule would cost an estimated $16.4 million in Year 1 and $7.9 million in recurring annual costs. Year 1 costs include approximately $15.11 million for OPOs and $1.37 million for CMS. Recurring annual costs include approximately $7.56 million for OPOs and $340,000 for CMS. These incremental costs reflect clarifications and refinements to operational and administrative requirements from the December 2020 OPO final rule rather than fundamental system restructuring. The final rule costs differ from the proposed rule estimates primarily because CMS is not finalizing the proposed licensure requirement for personnel performing clinical duties, is using updated tier-assignment data showing 35 DSAs expected to open for competition,[33] and is updating the estimated number of OPOs that may expand to serve multiple DSAs from 10 to 14. In the following sections, we discuss each of the expected impacts in detail.

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

[33] CMS, Release of the 2026 Organ Procurement Organization (OPO) Annual *Performance Preview and Final Reports, and Publication of the 2026 Annual Public Aggregate Performance Report.*

TABLE 3: Final Incremental Costs (in millions)

Cost Component	Final Rule Year 1	Final Rule Recurring Annual
CMS Administrative	$1.37	$0.34
OPO Costs	$15.11	$7.56
Total	**$16.48**	**$7.90**

1. Anticipated Incremental Effects (Costs and Benefits)

a. Overview

This section provides a detailed analysis of the incremental costs and benefits associated with the provisions finalized in this rule. As established in section B and detailed in Table 4, the total estimated costs are approximately $16.4 million in Year 1 and $7.9 million in recurring annual costs beyond Year 1.

BILLING CODE 4120–01–P

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)	91	0	91	One-Time
2	Requirements for Certification (§ 486.303)	0	0	0	No Costs
3	Designation of one OPO for each DSA (§ 486.308)	0	58	58	Recurring Annual
4	OPO designation to more than one service area (§ 486.309)	633	0	633	One-Time
4	OPO designation to more than one service area (§ 486.309)	7,000	44	7,044	Recurring Annual
5	Non-renewal/De-certification (§§ 486.311, 486.312)	7	13	20	One-Time
6	Appeals (§ 486.314)	25	52	77	One-Time
6	Appeals (§ 486.314)	30	73	103	Recurring Annual
7	Re-certification and Competition (§ 486.316)	6,514	864	7,378	One-Time
8	Outcome Measures (§ 486.318)	281	52	333	One-Time
8	Outcome Measures (§ 486.318)	402	174	576	Recurring Annual
9	Human Resources (§ 486.326)	0	0	0	No Quantified Costs
10	Information Management (§ 486.330)	67	0	67	Recurring Annual - COI
11	QAPI (§ 486.348)	0	0	0	One-Time
11	QAPI (§ 486.348)	0	0	0	Recurring Annual - COI
12	Conforming Changes (§§ 486.322, 486.324, 486.328, 486.360)	0	26	26	One-Time
12	Conforming Changes (§§ 486.322, 486.324, 486.328, 486.360)	65	0	65	Recurring Annual
	TOTAL ONE-TIME COSTS	**7,551**	**1,007**	**8,558**	
	TOTAL RECURRING ANNUAL COSTS	**7,564**	**349**	**7,913**	
	YEAR 1 TOTAL	**15,115**	**1,356**	**16,471**	
Totals may not sum precisely due to rounding.					

BILLING CODE 4120–01–C

b. Data Sources and Key Assumptions

Our analysis relies on data from several sources and includes key assumptions about OPO operations and regulatory implementation. Labor costs are based on Bureau of Labor Statistics (BLS) May 2025 National Occupational Employment and Wage Estimates, adjusted by a factor of 2.0 or 100 percent, for fringe benefits and overhead. Baseline costs are established by the December 2020 OPO final rule, which documented annual costs of $126.7 million. The weighted average hourly rate of $186 for OPO staff reflects a mix of executive directors, medical directors, quality managers, and administrative personnel.[34] The CMS GS–14 hourly rate of $145 reflects staff conducting oversight, policy development, and technical assistance activities, based on the 2025 General Schedule (GS) salary table for the Washington-Baltimore-Arlington locality pay area.

Recurring annual cost estimates in this RIA reflect the average annual cost of activities that recur each re-certification cycle, rather than a constant level of effort in every calendar year. For provisions tied to cycle-end events—including designation management, competition administration, and successor transitions under §§ 486.308 and 486.309—CMS expects activity to be concentrated in the year the re-certification cycle concludes and the following transition year, with comparatively limited activity in intervening years. The annualized figures presented reflect the total expected cost across the cycle, divided evenly for presentation purposes.

For this final rule, we use an assumption of 54 OPOs serving 55 DSAs. We also use updated performance data showing 14 tier 3 DSAs and 21 tier 2 DSAs, resulting in an estimated 35 DSAs 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. Because an OPO may apply for more than one open DSA, the estimated number of applications exceeds the estimated number of participating OPOs. This results in approximately 140 total competition applications across the cycle, calculated as 35 DSAs × 4 OPOs per DSA.

We also estimate that no more than 14 OPOs will expand to serve multiple DSAs following implementation of the December 2020 OPO final rule's performance standards and the designation framework finalized in this rule. The estimate that no more than 14 OPOs will expand to serve multiple DSAs reflects the number of OPOs expected to assume responsibility for at least one additional DSA, not the total number of DSAs that may be opened for competition. This estimate assumes a one-to-one relationship between expanding OPOs and newly opened DSAs. For example, the illustrative benefit estimate discussed under § 486.316 assumes that 14 tier 3 DSAs will be awarded across 14 successor OPOs. We acknowledge, however, that there could be cases where an OPO wins the competition for more than one additional DSA.

In response to public comments, CMS is not finalizing the proposed licensure requirement for personnel performing clinical duties. Therefore, the final RIA removes the proposed OPO and CMS costs associated with licensure verification, tracking, recruitment, training, and related monitoring. CMS is finalizing only the medical director conforming change at § 486.326(d), which is not expected to impose meaningful incremental costs.

c. Incremental Costs

This section 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)

The definition changes finalized at § 486.302 are expected to result in limited one-time implementation costs for OPOs. These costs are associated with reviewing the revised regulatory definitions, updating internal policies or guidance materials as needed, and conducting staff training or familiarization.

We estimate that each OPO will spend approximately 13 hours on these one-time implementation activities at a weighted average hourly rate of $129. This results in an estimated cost of $1,677 per OPO, calculated as 13 hours × $129.[35] Across 54 OPOs, the total estimated one-time cost is $90,558, rounded at $91,000 calculated as 54 OPOs × $1,677. We do not anticipate any costs for CMS. We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for the definition changes. Therefore, we are finalizing the one-time cost estimate for this provision without revision.

(2) Requirements for Certification (§ 486.303)

The removal of § 486.303(e) does not impose new implementation activities on existing OPOs or CMS in this final rule. This provision removes obsolete regulatory text but does not establish a new OPO certification process or require existing OPOs to undertake new operational, administrative, or reporting activities.

Therefore, we estimate no incremental costs to OPOs or CMS for this provision. Any costs associated with a future process for certifying new OPOs would be addressed in future rulemaking, if CMS proposes such a process.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision.

(3) Designation of One OPO for Each Donation Service Area (§ 486.308)

The finalized changes at § 486.308 primarily affect CMS administrative processes and do not impose direct incremental costs on OPOs. To the extent an OPO incurs operational costs from serving more than one DSA, those costs are addressed under § 486.309.

We estimate that the finalized changes at § 486.308 will require approximately 400 hours of CMS GS–14 staff time annually for designation-related administrative activities. At an estimated loaded hourly rate of $145, this results in a recurring annual CMS cost of $58,000, calculated as 400 hours

[34] The $186 weighted average hourly wage reflects a blended rate for OPO staff expected to perform implementation and compliance activities, using the same effective weighting underlying the $177 hourly wage used in the proposed rule. The updated rate reflects approximately 38.4 percent Medical Director and 61.6 percent Executive Director/Quality Manager/Administrator, using the BLS-based loaded wage rates summarized in Table 1: (1) Medical Director at $267 per hour; and (2) Executive Director/Quality Manager/Administrator at $136 per hour. The weighted average hourly wage is calculated as [($267 × 38.4 percent) + ($136 × 61.6 percent)] ≈ $186 per hour.

[35] The $129 weighted average hourly wage reflects a blended rate for OPO staff expected to review and implement the definition changes, using BLS-based loaded wage rates summarized in Table 1: (1) Medical Director at $267 per hour; (2) Organ Procurement Coordinator at $98 per hour; and (3) Quality Manager/Administrator at $136 per hour, weighted as [($267 × 2.5) + ($98 × 12.5) + ($136 × 5)] ÷ 20 hours = $129 per hour. The original 20-hour estimate reflected review and implementation activities across six defined terms revised or added at § 486.302. Because this final rule does not finalize the proposed definitions of ''medically complex donor'' and ''medically complex organ,'' the hours estimate is reduced proportionally to reflect the four remaining defined terms (adverse event, donor, organ, and unsound medical practices), calculated as 4/6 × 20 hours ≈ 13.3 hours, rounded to 13 hours.

× $145. These activities include tracking competition triggers, managing designation period adjustments, coordinating successor selection when competition is not feasible, monitoring CMS-assigned DSAs, and determining when competition is or is not required under § 486.308.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the recurring annual CMS cost estimate for this provision without revision.

(4) OPO Designation to More Than One Service Area (§ 486.309)

The cost-driving activities associated with § 486.309 are the operational activities required when an OPO expands to serve more than one DSA. These activities may include additional coordination, travel and logistics, information technology support, administrative staffing, hospital relationship-building, quality oversight, satellite office operations, legal and compliance activities, community outreach, and operational contingency planning.

We estimate that no more than 14 OPOs will expand to serve multiple DSAs following implementation of the designation framework finalized in this rule. We estimate that each OPO serving multiple DSAs will incur approximately $500,000 in additional recurring annual costs, resulting in an estimated recurring annual OPO cost of $7.0 million, calculated as 14 OPOs × $500,000.

We also estimate one-time Year 1 OPO costs of $632,800 for IT system upgrades and training expenses specific to multi-DSA operations. We do not include general DSA transition costs because those costs would occur whenever a DSA changes OPOs, regardless of § 486.309. The December 2020 baseline accounted for related governance and top-management costs, although it did not fully quantify every transition expense. Total Year 1 OPO costs for this provision are therefore estimated at $7,632,800, consisting of $7.0 million in recurring annual costs plus $632,800 in one-time costs.

CMS will also incur recurring administrative costs associated with oversight of multi-DSA designations, tracking performance accountability across DSAs, and related re-certification and designation activities. This cost does not reflect a change in the total number of DSAs CMS monitors; rather, it reflects the added administrative complexity of overseeing designation status when an OPO holds multiple DSAs—including tracking mixed-tier performance across an OPO's DSAs and processing removal of designation to a single tier 3 DSA without triggering de-certification of the OPO under § 486.309(c).

We estimate that CMS will require approximately 300 hours of GS–14 staff time annually for these activities. At an estimated loaded hourly rate of $145, this results in a recurring annual CMS cost of $43,500, rounded to $44,000, calculated as 300 hours × $145.

BILLING CODE 4120–01–P

TABLE 5A: Recurring Cost Components for Multi-DSA Operations*

Component	Annual Cost	Calculation Basis
Coordination meetings	$1,092,000	52 weekly meetings × 6 staff × 2 hour × $125/hour × 14 OPOs
Travel and logistics	$1,344,000	travel: 4 staff × 20 trips × $1,200/trip × 14 OPOs
IT infrastructure	$210,000	Annual licensing/maintenance: $15,000/OPO × 14 OPOs
Additional administrative staff	$728,000	20 hours/week × 52 weeks × $50/hour × 14 OPOs
Hospital relationship building	$744,240	Executive Director (100 hrs × $132) + Medical Director (80 hrs × $262) + Coordinators (200 hrs × $95) × 14 OPOs
Enhanced quality oversight	$515,200	Quality Manager (150 hrs × $132) + Data Analyst (200 hrs × $85) × 14 OPOs
Satellite office operations	$700,000	$50,000/OPO × 14 OPOs for facility rental and operations
Legal and compliance	$420,000	$30,000/OPO × 14 OPOs
Marketing and community outreach	$560,000	$40,000/OPO × 14 OPOs
Operational contingency	$686,560	Buffer for unexpected costs
Total Annual Recurring	**$7,000,000**	-

*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 OPO 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/*).

TABLE 5B: One-Time Cost Components for Multi-DSA Operations

One-time Year 1 component	Cost	Calculation Basis
IT system upgrades	$420,000	$30,000 per OPO × 14 OPOs
Training expenses	$212,800	$15,200 per OPO × 14 OPOs
Total One-Time Costs	**$632,800**	**$420,000 + $212,800**
Total Year 1 Multi-DSA Cost	**$7,632,800**	**$7,000,000 recurring + $632,800 one-time**
Note: General costs of transferring a DSA from one OPO to another are not included because they are not new costs caused by § 486.309. Table 5B includes only one-time costs specific to multi-DSA operations.		

BILLING CODE 4120–01–C

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the cost estimates for this provision without revision.

(5) Non-Renewal of Agreement (§ 486.311) and De-Certification (§ 486.312)

The finalized changes at §§ 486.311 and 486.312 are expected to result in limited one-time implementation costs for potentially affected OPOs and CMS. For OPOs, the estimate reflects limited senior-level familiarization with the revised non-renewal and de-certification provisions by the OPO administrator, legal counsel, and senior leadership. We do not assume broad front-line staff training or systemwide operational changes for all OPOs.

For purposes of this estimate, we assume that up to 14 OPOs may conduct this familiarization, using the 14 Tier 3 DSAs as a conservative proxy for potentially affected OPOs. We estimate that each potentially affected OPO will spend approximately 2.5 hours on these one-time familiarization activities at a weighted average hourly rate of $186. This results in an estimated cost of $465 per potentially affected OPO, calculated as 2.5 hours × $186. Across 14 potentially affected OPOs, the total estimated one-time OPO cost is $6,510, rounded to $7,000.

We estimate that CMS will spend approximately 91 hours on one-time implementation activities, including updating notice processes, internal procedures, systems, and staff guidance. At an estimated loaded hourly rate of $145, this results in a one-time CMS cost of $13,195, rounded to $13,000, calculated as 91 hours × $145.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the CMS cost estimate without revision and revising the OPO cost estimate to reflect limited familiarization by potentially affected OPOs.

(6) Appeals (§ 486.314)

The finalized changes at § 486.314 are expected to result in one-time and recurring costs for OPOs and CMS. OPO costs are associated with legal and compliance review, updating internal appeal procedures, and familiarizing appropriate leadership and legal staff with the revised appeal timelines and processes. CMS costs are associated with updating appeal procedures, supporting the CMS Administrator review process, processing appeals when they arise, and providing related technical assistance.

We estimate one-time Year 1 OPO costs of $25,000 for initial legal review and policy updates. We also estimate recurring annual OPO costs of $30,132, rounded to $30,000, calculated as 3 hours × $186 per hour × 54 OPOs. These recurring costs reflect limited annual familiarization and compliance monitoring and do not assume broad front-line staff training.

For CMS, we estimate one-time Year 1 implementation costs of $52,200, rounded to $52,000, calculated as 360 hours × $145 per hour. These one-time costs include policy documentation and guidance development, system updates to track appeal types and review stages, staff training on revised timelines and procedural requirements, and development of review protocols and templates.

CMS will also incur recurring administrative costs to maintain and operate the revised appeals process. We estimate 500 hours annually at the GS–14 hourly rate of $145, for recurring annual CMS costs of $72,500, rounded to $73,000, calculated as 500 hours × $145 per hour. These recurring costs include Administrator review processing, hearing officer support, remand processing if needed, processing appeals related to removal of designation to a Tier 3 DSA without de-certification, and technical assistance related to the revised appeals procedures. This estimate reflects administrative workload and readiness to process appeals when they arise during a re-certification cycle; it is not an estimate that CMS expects a specific number of OPO de-certifications or removals of designation each year.

Total Year 1 costs for this provision are estimated at $180,000, consisting of $55,000 in OPO costs and $125,000 in CMS costs. Recurring annual costs after Year 1 are estimated at $103,000, consisting of $30,000 in OPO costs and $73,000 in CMS costs.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the cost estimates for this provision without revision.

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

The finalized changes at § 486.316 are expected to result in one-time costs for OPOs and CMS associated with competition applications, CMS competition administration, transition-related review, and implementation of the revised re-certification and competition framework.

Based on current performance data, we estimate that 35 DSAs will be opened for competition during the re-certification cycle, calculated as 14 Tier 3 DSAs + 21 Tier 2 DSAs. The 21 Tier 2 DSAs are open for competition but do not involve de-certification. This estimate is used to calculate competition-related workload and is not an estimate that 35 OPOs will be de-certified or that all 35 open DSAs will transition to a different OPO.

We estimate an average of 4 OPO applications per open DSA, resulting in approximately 140 total competition applications, calculated as 35 open DSAs × 4 applications per DSA. We estimate that each competition application will require approximately 200 hours of OPO staff time at a weighted average hourly rate of $186. This results in an estimated cost of $37,200 per application, calculated as 200 hours × $186. Across 140 applications, the total estimated OPO competition-application cost is $5,208,000, calculated as 140 applications × $37,200.

The 200-hour estimate includes time for performance data compilation and analysis, barrier identification and documentation, application development, legal review and compliance verification, and executive review and submission.

We also estimate additional one-time OPO costs of $1,306,000 for legal review, competition strategy development, and staff training on the revised re-certification and competition framework, calculated as 54 OPOs × 130 hours × $186 per hour, rounded to $1,306,000.

Total one-time OPO costs for this provision are estimated at $6,514,000, consisting of $5,208,000 for competition applications plus $1,306,000 for legal review, strategy development, and training.

For CMS, we estimate one-time implementation costs of $52,200, rounded to $52,000, calculated as 360 hours × $145 per hour. We also estimate additional one-time CMS competition-administration costs of $812,000, calculated as 5,600 hours × $145 per hour. Of the 5,600 hours, we estimate that competition process administration and application review will require approximately 3,500 aggregate CMS staff hours, calculated as 140 applications × 25 aggregate CMS staff hours per application. The 25-hour estimate reflects combined CMS staff time across multiple reviewers and related coordination, documentation, and

application-processing activities; it is not a per-reviewer estimate. The remaining hours include transition oversight and verification and technical assistance related to the competition process. Total one-time CMS costs for this provision are estimated at $864,000.

This estimate does not reflect DSAs that may be assigned directly to an OPO under the insufficient-time exception at § 486.308(a)(4), which permits CMS to designate a successor OPO for the remainder of the designation period without a subsequent competition. Because this exception is expected to be used rarely, and because only one OPO currently serves more than one DSA, we have not separately quantified any resulting reduction in competition-application or CMS-administration costs.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the cost estimates for this provision without revision.

(8) Outcome Measures (§ 486.318)

The finalized changes at § 486.318 are expected to result in one-time and recurring costs for OPOs and CMS associated with implementation and administration of the outcome-measure accountability framework for OPOs that acquire or are assigned additional DSAs, including OPOs designated to multiple DSAs.

In the proposed rule, we estimated that each OPO would spend approximately 40 hours annually on activities associated with the outcome-measure accountability framework. We are retaining this proposed recurring estimate in the final rule, adjusted from 55 OPOs to 54 OPOs. The recurring estimate reflects ongoing compliance monitoring and maintenance of DSA-level outcome-measure accountability information, where applicable. It does not include recurring staff training, annual re-familiarization with accountability timelines, or routine QAPI revisions.

The total recurring cost to OPOs is $401,760 calculated as 54 OPOs × 40 hours × $186 per hour, rounded to $402,000. Additionally, we estimate one-time Year 1 OPO costs of $281,000 for legal and policy review of the outcome-measure accountability provisions and one-time updates to internal tracking frameworks or systems used to monitor DSA-level performance, where applicable. This estimate is calculated as 54 OPOs × 28 hours × $186 per hour, rounded to $281,000.

For CMS, we estimate 360 hours at the GS–14 hourly rate of $145 for Year 1 implementation costs totaling $52,200, rounded to $52,000. These one-time costs include policy documentation and guidance development, system updates to track separate DSA performance and different accountability timelines for newly acquired or assigned DSAs, internal staff familiarization, and development of templates for tracking the applicable accountability timelines under § 486.318(c)(3) and (4).

CMS will also incur ongoing administrative costs associated with monitoring outcome-measure performance separately for each DSA when an OPO is designated to multiple DSAs, tracking the applicable accountability timeline for newly acquired or assigned DSAs under § 486.318(c)(3) and (4), and supporting implementation of those timelines, including when 12 months of outcome-measure data are available and, for DSAs acquired through competition or CMS assignment, when the final assessment period of the following agreement cycle applies for re-certification purposes.

We estimate 1,200 hours annually at the GS–14 hourly rate of $145, totaling $174,000.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the cost estimates for this provision without revision, except to adjust the OPO count from 55 OPOs in the proposed rule to 54 OPOs in this final rule.

(9) Human Resources (§ 486.326)

The only finalized change at § 486.326 is the medical director conforming change for multi-DSA operations. OPOs are already required to have a medical director, and the finalized conforming change does not impose new quantified implementation costs on OPOs or CMS.

CMS is not finalizing the proposed licensure, certification, or registration requirement for personnel performing clinical duties. Therefore, no costs associated with that proposed requirement are included in the final RIA.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for the finalized medical director conforming change. Therefore, we estimate no incremental costs to OPOs or CMS for this provision.

(10) Information Management (§ 486.330)

The finalized changes at § 486.330 include information collection requirements associated with maintaining records for organs procured and sent for research. The burden for this provision is addressed in the Collection of Information section of this final rule and is included in the RIA as a recurring annual information collection cost.

As discussed in the Collection of Information section, we estimate the annual burden for this provision at 681 hours across all OPOs, with an estimated annual cost of $66,738, rounded to $67,000. This estimate includes 244 hours and $23,912 for pancreata procured and sent for islet cell research, and 437 hours and $42,826 for other organs procured and sent for research.

We do not estimate additional non-information-collection costs for OPOs or CMS for this provision.

We did not receive public comments that provided alternative data, assumptions, or quantitative estimates specific to the RIA cost estimate for this provision. Therefore, we are finalizing the cost estimate for this provision without revision.

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

In response to public comments raising concerns about the lack of a standardized, nationally recognized standards of medical complexity, CMS is not finalizing the proposed definitions of ''medically complex donor'' and ''medically complex organ'' at § 486.302, or the QAPI requirement proposed at § 486.348(e). Therefore, no costs associated with this proposed requirement are included in the final RIA.

(12) Conforming Changes to § 486.322 Relationships With Hospitals, Critical Access Hospitals, and Tissue Banks; § 486.324 Administration and Governing Body; § 486.328 Reporting of Data; and § 486.360 Emergency Preparedness

This final rule makes conforming changes to the requirements for relationships with hospitals, critical access hospitals, and tissue banks; administration and governing body; reporting of data; and emergency preparedness to accommodate circumstances in which an OPO may be designated to serve more than one DSA.

The final rule introduces several conforming changes compared to the

2020 baseline. First, it changes the hospital agreement requirement at § 486.322(a) from requiring agreements with hospitals in the OPO's service area to requiring agreements in each of the OPO's designated service areas, thereby creating separate 95 percent compliance requirements for each DSA. Second, it updates 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 to which an OPO is designated. Third, it revises § 486.328(c) to specify that data used for OPO re-certification must include all deaths in all hospitals and critical access hospitals in the OPO's service areas, unless a waiver has been granted. Fourth, it revises emergency preparedness requirements at § 486.360 to require emergency communication plans that include contact information for transplant and donor hospitals in each DSA to which an OPO is designated and continuity of operations agreements that specify coverage for multiple DSAs.

We estimate that each OPO serving multiple DSAs will spend approximately 25 hours annually at a weighted average hourly rate of $186 to implement these conforming changes. Hospital agreement compliance verification will require 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 will require 6 hours per OPO to ensure advisory board membership represents all service areas, update board policies and procedures to reference multiple DSAs, coordinate board activities across service areas, and document governance structures for multi-DSA operations. Emergency preparedness plan updates will require 5 hours per OPO to update emergency communication plans to include hospitals in all DSAs, revise continuity of operations agreements to specify multi-DSA coverage, coordinate emergency preparedness activities across service areas, and conduct training on updated emergency procedures. Data collection and reporting modifications will require 4 hours per OPO to update systems to track data separately by DSA, ensure re-certification data include all hospitals in all service areas, coordinate data collection across multiple DSAs, and prepare reports that distinguish performance by DSA.

Consistent with the updated assumption used in this final rule that no more than 14 OPOs will expand to serve multiple DSAs, the total recurring OPO cost for these conforming changes is $65,100, calculated as 14 OPOs × 25 hours × $186 per hour, rounded to $65,000.

For CMS, we estimate 180 hours at the GS–14 hourly rate of $145 for Year 1 implementation costs totaling $26,100, rounded to $26,000. These one-time costs include 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; review of data collection across service areas; and development of technical assistance materials for OPOs on multi-DSA operational requirements. We are not revising the CMS estimate based solely on the updated assumption that no more than 14 OPOs may expand to serve multiple DSAs because the CMS implementation activities are primarily guidance, survey-protocol, and technical-assistance activities that do not scale directly with the number of multi-DSA OPOs.

d. Incremental Benefits

This section presents the incremental benefits of this final 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 describe each benefit, explain why monetization is not feasible, and connect the benefit to the overarching regulatory objectives of improving organ procurement and transplantation outcomes.

The quantified benefits total approximately $598,000 in annual recurring benefits from reduced implementation inquiry and compliance-interpretation burden and $500,000 in one-time benefits due to increased operational flexibility for multi-DSA operations. These quantified benefits represent only a portion of the total value generated by this final rule. Significant qualitative benefits also exist that, while difficult to monetize, are important to the effective implementation of the December 2020 final rule's performance measurement, re-certification, designation, competition, and appeals 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	Total Benefits ($k)	Benefits Type
Reduced Implementation Inquiry and Compliance-Interpretation Burden	285	313	598	Recurring Annual
Operational Flexibility for Multi-DSA Operations	500	0	500	One-Time

(1) Quantified Benefits

This section presents the quantified incremental benefits of this final 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 final rule, 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.

(a) Reduced Implementation Inquiry and Compliance Interpretation Burden

The December 2020 final rule (85 FR 77898) established new performance measures and a three-tier system. As CMS, OPOs, and other interested parties have prepared to operationalize that framework, particularly as the end of the re-certification cycle approached, CMS has received inquiries regarding implementation of re-certification, designation, competition, appeals, and related operational processes. The benefit estimate below captures expected reductions in future time spent by CMS and OPOs on repetitive implementation inquiries and compliance-interpretation activities as a result of the clarifications finalized in this rule.

This final rule is expected to reduce repetitive implementation inquiries by clarifying procedures for competitions, multi-DSA operations, non-renewal versus de-certification distinctions, appeals processes, outcome-measure accountability, information management, and QAPI adverse event and outcome-measure requirements.

We expect the clarifications finalized in this rule to reduce CMS staff time spent responding to repetitive inquiries, OPO staff time spent reviewing and seeking guidance on implementation issues, and disputes during the re-certification and competition process.

We estimate that absent this final rule, each OPO would spend approximately 60 hours annually seeking clarification. With the clarifications finalized in this rule, we estimate this would decline to 20 hours annually, 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 OPO benefit of $285,120, calculated as 40 hours × $132 × 54 OPOs, rounded to $285,000.

Similarly, absent this rule, CMS would receive approximately 162 substantive requests annually, calculated as 3 requests per OPO × 54 OPOs. With the clarifications finalized in this rule, we expect a reduction to 54 requests annually, calculated as 1 request per OPO × 54 OPOs, eliminating 108 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 $145 (OPM 2025 pay tables, adjusted for locality and benefits), this yields an annual benefit of $313,200, calculated as 108 requests × 20 hours × $145, rounded to $313,000. The total annual benefit from reduced implementation inquiry and compliance-interpretation burden is therefore approximately $598,000, calculated as $285,000 in OPO benefits + $313,000 in CMS benefits. Over the 5-year analysis period, the undiscounted benefit is approximately $2.99 million, using the unrounded annual estimate.[36]

This estimate is conservative because it captures only direct time savings. It excludes indirect costs of associated with case-specific implementation questions, including delayed strategic planning, deferred operational decisions, potential disputes and appeals, and opportunity costs when staff time is diverted from core organ procurement activities. The actual benefit may be 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 the final clarifications, potentially causing short-term inquiry increases before long-term benefits are realized.

(b) 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. Without clarification, the baseline framework could potentially result in de-certification of an OPO even when some of its DSAs perform well, requiring unnecessary transitions in well-performing territories and imposing avoidable costs on the system.

This final rule allows OPOs designated to serve more than one DSA to continue serving well-performing DSAs while losing designation only for an underperforming tier 3 DSA, provided the OPO remains designated to at least one other DSA that is not tier 3. The final provisions at §§ 486.309 and 486.316 establish that CMS may remove designation to a tier 3 DSA without de-certification when an OPO is designated to other DSAs that are not tier 3. This enables continuity of service in well-performing territories, preserves OPO staff relationships with hospitals and donor families, and avoids unnecessary operational transition costs in tier 1 and tier 2 DSAs.

Using preliminary analysis of 2026 OPO performance data, we estimate that approximately 14 DSAs may be classified as tier 3 and therefore opened for competition as part of the 2026 re-certification process, after any applicable appeals are exhausted. Tier 2 DSAs will also be opened for competition; however, because a tier 2 OPO may retain its DSA through competition, we do not assume additional DSA transitions resulting from tier 2 competitions for purposes of this illustrative benefit estimate. For purposes of this estimate, we assume that the 14-tier 3 DSAs will be awarded to 14 successor OPOs, with each successor OPO assuming responsibility for one additional DSA.

In the subsequent performance evaluation cycle ending in 2030, we assume that 5 of these 14 successor OPOs will have mixed performance across their DSAs, meaning each will have at least one DSA with tier 1 or tier 2 performance and one DSA with tier 3 performance. Under the final policy, CMS would remove designation only for the underperforming tier 3 DSA, rather than de-certifying the OPO, provided the OPO remains designated to at least one other DSA that is not tier 3. For purposes of this estimate, we assume that this policy avoids one unnecessary transition for each of the 5 mixed-performance OPOs. Using the baseline transition cost of $100,000 per DSA from the December 2020 final rule, avoiding 5 unnecessary transitions produces an estimated one-time benefit of $500,000, calculated as 5 avoided transitions × $100,000 per transition.

This estimate is conservative because it captures only avoided direct

[36] 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 $145 from OPM 2025 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).

transition costs. It does not quantify additional benefits from maintaining hospital relationships, preserving staff knowledge, avoiding disruption in well-performing DSAs, or reducing CMS administrative burden associated with managing unnecessary transitions. The estimate also depends on the number of successor OPOs that are ultimately designated to multiple DSAs and the share of those OPOs with mixed-tier performance in the subsequent evaluation cycle.

(2) 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 describe the benefit, explain why monetization is not feasible, and connect the benefit to the regulatory objectives of improving OPO accountability, organ procurement, transplantation outcomes, and system stability.

(a) Improved System Efficiency and Continuity

This final rule reduces the risk of service disruptions by establishing clearer procedures for successor selection, multi-DSA transitions, non-renewal, de-certification, appeals, and transitions between incumbent and successor OPOs. The final rule clarifies when CMS may select a successor OPO when there is insufficient time to conduct a full competition, the criteria CMS will consider in successor selection, and how OPOs must cooperate during transitions.

In addition, this final rule includes targeted modifications in response to comments regarding CMS-assigned DSAs.

When CMS assigns an OPO to an additional DSA because no other OPO applies for competition or there is insufficient time to conduct a competition, CMS would not open the OPO's original DSA for competition solely because performance in the original DSA declines from tier 1 to tier 2 or fails to improve from tier 2 to tier 1, provided that the original DSA does not fall to tier 3. In practical effect, the OPO would not have to compete to retain its original DSA based solely on tier 2 performance following the CMS assignment. The final rule also allows an OPO assigned a DSA when there is insufficient time to conduct a competition to remain designated to that DSA for a full re-certification cycle. These final modifications may reduce disincentives for OPOs to accept CMS assignment and may support continuity of organ procurement services in DSAs that otherwise could experience disruption.

We cannot readily quantify this benefit because the number of future CMS assignments, changes in DSA tier assignments following CMS assignment, and transition scenarios is uncertain. The impact of any service disruption would vary based on DSA-specific circumstances, including hospital relationships, geography, staffing capacity, donor volume, and the operational readiness of the successor OPO. However, the benefit is important because maintaining continuity of organ procurement services during transitions supports the stability of the organ donation and transplantation system.

(b) Enhanced Competition Efficiency

The December 2020 final rule established a three-tier performance system and competition framework but did not provide procedural and technical details on multi-DSA competition scenarios, designation consequences, or transition requirements. This final rule enhances competition procedures, including separate DSA-level outcome-measure evaluation when an OPO is designated to multiple DSAs, OPO-level evaluation of process performance measures, competition eligibility for OPOs subject to non-renewal, and transition requirements between incumbent and successor OPOs.

Based on updated performance data, we estimate that 35 DSAs may open for competition during the re-certification cycle. Clear procedures are especially important given the scale of expected competition activity. The final rule helps OPOs understand when they may compete, how CMS will evaluate tier assignments across DSAs, how transition plans will be handled, and how CMS will apply the existing competition selection criteria. We cannot readily quantify this benefit because the dynamic effects of enhanced competition on OPO performance improvement are difficult to isolate and measure. The counterfactual—what performance would have been without clearer competition procedures—is speculative. The benefit also manifests over time as the competitive environment drives continuous improvement across the OPO system rather than generating a discrete, immediately measurable outcome.

This benefit is significant because the efficiency of the competition process directly affects the quality and continuity of organ procurement services in DSAs opened for competition. Clear procedures support transparent decision-making, reduce uncertainty for OPOs and CMS, and help ensure that competition decisions focus on maximizing organ procurement and transplantation outcomes.

(c) Improved Definitional Clarity

This final rule revises definitions at § 486.302 to support consistent interpretation across OPOs and CMS. These revisions include revising the adverse event framework, clarifying ''donor'' and ''organ'' for purposes of pancreata used in islet cell research, and defining ''unsound medical practices.''

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 difficult 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, leadership priorities, and transplant-center practices.

This benefit is significant because interested parties' inquiries and public comments demonstrate that definitional ambiguity creates operational challenges. Clear definitions help OPOs implement requirements consistently and support CMS survey and oversight activities.

C. Alternatives Considered

Throughout the preamble sections, we summarize the policies proposed in the January 2026 proposed rule, the public comments received, and the policies we are finalizing in this final rule. In developing this final rule, we considered alternative approaches that could have provided additional flexibility, imposed more prescriptive requirements, or retained the existing regulatory text without revision. We selected the policies finalized in this rule to provide clearer operational and administrative requirements, maintain OPO accountability, support continuity of organ procurement services, and avoid unnecessary burden or disruption.

With respect to the definitions of ''medically complex donor'' and ''medically complex organ'' and the related QAPI requirements, we considered finalizing the proposed definition with specific clinical criteria, including DCD donors and donors with elevated KDPI scores, as well as a modified, guideline-based definition. After considering public comments

raising concerns that no standardized, nationally recognized definition of a medically complex donor currently exists and that the associated QAPI requirement could increase documentation burden without a current consistent basis for identifying affected donors and organs, we are not finalizing the proposed definitions of ''medically complex donor'' or ''medically complex organ,'' and we are not finalizing the QAPI requirement proposed at § 486.348(e). CMS may consider this issue in future rulemaking if a consensus emerges to support a standardized definition of medically complex donor.

With respect to designation, re-certification, competition, and OPOs designated to more than one DSA, we considered alternative approaches that would have imposed more prescriptive requirements on how OPOs structure their operations when designated to multiple DSAs. These alternatives included requiring OPOs to maintain separate DSAs in all circumstances or adopting additional approval requirements before an OPO could determine whether to maintain separate DSAs or consolidate DSAs where permitted under the regulation. We also considered alternative approaches for CMS-assigned DSAs and the impact of assignment on an OPO's existing DSAs. After considering public comments, we are finalizing an approach that provides OPOs flexibility to structure operations in a manner appropriate for their DSAs while maintaining CMS oversight and accountability through the certification, designation, re-certification, competition, survey, and enforcement framework. We are also finalizing targeted modifications for CMS-assigned DSAs to reduce disincentives for OPOs to accept assignment while preserving accountability for tier 3 performance.

With respect to non-renewal, de-certification, appeals, and competition procedures, we considered retaining the existing regulatory text without further clarification. We also considered alternative approaches to the timing and structure of the appeals process and the transition process for DSAs opened for competition. We are finalizing revisions to clarify the distinction between non-renewal, de-certification, and removal of designation to a tier 3 DSA without de-certification; update appeal procedures; and establish transition requirements. We believe these final policies provide greater transparency and predictability for OPOs and CMS while supporting timely resolution of enforcement and designation decisions and continuity of organ procurement services.

With respect to human resources, we considered finalizing the proposed licensure, certification, or registration requirement for personnel performing clinical duties. Commenters raised concerns that the proposed requirement could create operational challenges because OPO staff roles are specialized, may not align neatly with State licensure frameworks, and may include activities that are distinct from direct patient care. After considering public comments, we are not finalizing the proposed licensure, certification, or registration requirement at this time. We are finalizing only the medical director conforming change for multi-DSA operations and may consider broader personnel qualification issues in future rulemaking.

With respect to information management, we considered whether to impose additional reporting or documentation requirements related to organs recovered and sent for research, including pancreata used for islet cell research. We are finalizing the recordkeeping requirement at § 486.330(b) as proposed because it supports CMS' ability to validate the disposition of organs sent for research while allowing OPOs flexibility in the types of records that may be maintained, provided they maintain documentation from an IRB or other formal authorizing body, as appropriate, the research institution, the principal investigator, and study contacts. We are not finalizing additional reporting requirements in this rule.

Overall, we believe the alternatives finalized in this rule appropriately balance accountability, operational flexibility, administrative clarity, and continuity of organ procurement services. The final policies clarify and refine the regulatory framework established by the December 2020 OPO final rule without imposing unnecessary requirements beyond those needed to support implementation, oversight, and continued improvement in the organ donation and transplantation system.

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 54 OPOs will review this rule. While other individuals and providers may also review the rule, we estimate that doubling the number of OPOs (108 reviewers) provides a reasonable approximation of the total number of reviewers. We acknowledge that this assumption may understate or overstate the actual review costs.

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. 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 $57,024, calculated as 108 reviewers × 4 hours × $132, rounded to $57,000.

E. Accounting Statement

As required by OMB Circular A–4 (available online at *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 final rule. This final rule imposes incremental costs of approximately $16.4 million in Year 1 and $7.91 million in recurring annual costs. Year 1 costs include approximately $15.11 million for OPOs and $1.36 million for CMS. Recurring annual costs include approximately $7.56 million for OPOs and $349,000 for CMS.

The final rule does not create new transfer payments beyond those established in the December 2020 final rule baseline. Quantified benefits are estimated at $583,000 annually from reduced implementation inquiry and compliance-interpretation burden, with an additional $500,000 one-time benefit due to increased operational flexibility for multi-DSA. This statement provides our best estimate for the Medicare and Medicaid provisions of this final rule.

TABLE 7: Accounting Statement

Category	Estimate	Units		
		Year Dollar	Discount Rate	Period Covered
Annualized Monetized Costs, OPOs	**$9.2 million to $9.4 million/year**	2024	3% or 7%	2027–2031
Annualized Monetized Costs, Government	**$0.55 million to $0.56 million/year**	2024	3% or 7%	2027–2031
Annualized Monetized Benefits, OPOs	**approximately $0.4 million/year**	2024	3% or 7%	2027–2031
Annualized Monetized Benefits, Government	**approximately $0.3 million/year**	2024	3% or 7%	2027–2031
Annualized OPO benefits include annual recurring benefits from reduced implementation inquiry and compliance-interpretation burden and annualized one-time benefits from operational flexibility for multi-DSA operations. Totals may not sum precisely due to rounding.				

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, we treat all OPOs as small entities. OPOs are classified under North American Industry Classification System code 621991 (Blood and Organ Banks), which has a SBA small business size standard of $40.0 million in annual receipts. Under 42 CFR 486.303(b), all OPOs must be non-profit entities. Under the RFA, a ''small entity'' includes a ''small organization,'' which includes a not-for-profit enterprise which is independently owned and operated and is not dominant in its field. While each OPO operates as the sole designated organ procurement entity within its localized Donation Service Area (DSA), no single OPO exercises a controlling influence or holds a dominant share in the national organ procurement sector (13 CFR 121.102(b)). Thus, they are not dominant in their field and qualify as small entities.

1. Organ Procurement Organizations (OPOs)

To assess the magnitude of the rule's economic impact, we use OPO-specific revenue data from Medicare cost reports rather than the SBA small-business size standard or industry-wide revenue data. Revenue data are available for 47 independent OPOs [37] and we used the most recently available revenue data for each OPO. Revenue amounts are expressed in 2025 dollars.[38] While all OPOs must be non-profit, the remaining OPOs are hospital-based organizations and do not separately report OPO-specific revenues in these cost reports. For the purposes of this analysis, we have excluded these hospital-based OPOs from our primary revenue calculations but we expect that since these OPOs are part of larger hospital systems, the requirements we are finalizing would not have an economically significant impact on them. For the remaining 47 independent OPOs, annual revenues range from approximately $7.5 million to $210.0 million.[39] In Year 1, we estimate total OPO costs of approximately $15.11 million. However, to evaluate the regulatory burden of this rule, we must distinguish between mandatory compliance requirements and voluntary business decisions under our competitive framework.

If an OPO's designated DSA is assigned to Tier 1, that designation is automatically retained without competition and the OPO is eligible for re-certification. While an OPO with a Tier 1 DSA designation may choose to compete for other open Tier 2 or Tier 3 DSAs, such actions represent discretionary business expansion decisions rather than mandatory compliance burdens. Conversely, an OPO designated to a DSA assigned to Tier 2 must successfully compete to retain its designation, making this a mandatory compliance cost. However, any participation by that OPO in a competition to acquire *additional, separate* DSAs is entirely optional. Small entities would only choose to incur these optional costs if they anticipated private business benefits (for example, geographical expansion and increased service revenues) that exceeded the associated application costs. Thus, when considering the net impact of these activities on small entities, we conclude that these activities do not represent an incremental burden and, all else equal, may represent an unquantified beneficial impact.

Consequently, we remove these optional, expansive competition costs from our mandatory compliance estimate reported in the regulatory impact analysis. Excluding approximately $4.43 million in optional competition application expenses results in a mandatory Year 1 compliance cost estimate of approximately $10.68 million, which equals an average mandatory compliance cost of approximately $198,000 per OPO.[40]

Rather than relying on sector-wide averages, our analysis of the distribution of these mandatory compliance costs relative to individual entity revenues

[37] CMS analysis of Organ Procurement Organization Medicare cost report data (Form CMS–216–94) from the Healthcare Cost Report Information System (HCRIS). CMS used the most recently available 2024 cost report data for independent OPOs, except for the Hawaii OPO, for which 2023 revenue data were used because of an error in the 2024 cost report. Form CMS–216–94 is used for independent OPOs and is not used by hospital-based OPOs.

[38] Revenue amounts were converted to 2025 dollars using the Federal Reserve Bank of Minneapolis Inflation Calculator, available at *https://www.minneapolisfed.org/about-us/monetary-policy/inflation-calculator.*

[39] CMS analysis of Medicare cost report revenue data for the 47 independent OPOs described previously in this final rule.

[40] CMS calculated the average Year 1 regulatory cost per OPO by dividing approximately $10.68 million in mandatory Year 1 OPO costs (which excludes $4.43 million in optional, expansive competition costs) by 54 OPOs, resulting in approximately $198,000 per OPO. Over the 5-year analysis period, approximately $7.56 million in annualized OPO costs divided by 54 OPOs results in an average annualized cost of approximately $140,000 per OPO.

shows that a flat Year 1 cost of $198,000 represents an economic impact ranging from 0.09 percent for the largest OPO (with $210.0 million in revenue) to 2.64 percent for the smallest OPO (with $7.5 million in revenue). Because the economic impact on 100 percent of independent OPOs is below the 3.0 percent significant economic impact threshold,[41] even for the OPO with the lowest revenue, we conclude that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing a final regulatory flexibility analysis.

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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. Although commenters raised concerns regarding rural and under-resourced areas, this final rule directly regulates OPOs and CMS administrative processes, not small rural hospitals. The final rule does not impose new direct compliance obligations on 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 2026, that threshold is approximately $193 million.

This final rule imposes estimated costs of approximately $16.4 million in Year 1 and $7.91 million in recurring annual costs, which is well below the UMRA threshold. Recurring annual costs beyond Year 1 comprise $7.56 million for OPOs and $349,000 for CMS. The final rule does not mandate any spending requirements for State, local, or tribal governments. While the rule imposes costs on OPOs, which are private sector entities, these costs are substantially below the UMRA threshold.

These costs represent clarifications and refinements to the operational and administrative requirements established in the December 2020 OPO final rule, rather than fundamental system restructuring. The costs are primarily administrative and operational in nature and include training, documentation updates, enhanced coordination activities, competition-related costs, transition planning, multi-DSA operational costs, and compliance with clarified requirements.

As noted in the December 2020 OPO final rule, reimbursement by both public and private payers would cover 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 UMRA threshold. Therefore, the requirements of UMRA do not apply to this final 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 final rule is directed at 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 final rule, approximately $16.4 million in Year 1 and $7.9 million in recurring annual costs, fall entirely on OPOs and the Federal Government. Year 1 costs include approximately $15.11 million for OPOs and $1.37 million for CMS. Recurring annual costs include approximately $7.56 million for OPOs and $349,000 for CMS. No costs are imposed on State, local, or tribal governments. Since this final rule does not impose substantial direct requirement costs on State or local governments, does not preempt State law, and does not have Federalism implications, the requirements of Executive Order 13132 are not applicable to this final rule.

I. Congressional Review Act

The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined that this final rule is not a ''major rule'' as defined by the Congressional Review Act (CRA), 5 U.S.C. 801–808 (originally enacted as subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996).

Consistent with 5 U.S.C. 801(a)(1)(A), which applies to all final rules regardless of major-rule status, CMS will submit this final rule and the required report to both Houses of Congress and the Comptroller General before the rule takes effect.

J. 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 10 prior regulations.''

For purposes of E.O. 14192 accounting, we followed OMB's *Accounting Methods under Executive Order 14192,* which applies a 7 percent discount rate, a perpetual time horizon, and expresses amounts as 2024 cost or savings equivalents.

This final rule imposes estimated incremental costs of approximately $16.4 million in Year 1 and $7.9 million in recurring annual costs beyond the baseline of $126.7 million established in the December 2020 final rule. Year 1 costs include approximately $15.11 million for OPOs and $1.37 million for CMS. Recurring annual costs include approximately $7.56 million for OPOs and $349,000 for CMS. We estimate that

[41] *See* HHS, *Guidance on Proper Consideration of Small Entities in Rulemakings* (May 2003). HHS generally considers an average annual economic impact of approximately 3 to 5 percent or more to be significant and 5 percent or more of affected small entities to constitute a substantial number.

this final rule will generate approximately $6.93 million in annualized costs, expressed in 2024-equivalent terms using a 7 percent discount rate and a perpetual time horizon. These costs represent clarifications and refinements to operational and administrative requirements rather than fundamental system restructuring. This final rule is consistent with the principles of Executive Order 14192 in the following ways:

- Minimizes Regulatory Burden: The final rule focuses on clarifications and refinements rather than fundamental restructuring of the OPO regulatory framework. In addition, CMS is not finalizing the proposed licensure requirement for personnel performing clinical duties, which avoids potential workforce and implementation burden raised by commenters.
- Provides Regulatory Clarity: By addressing interested parties inquiries and providing clearer guidance on operational and administrative requirements, this final 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 final clarifications to competition, appeals, non-renewal, de-certification, designation, and multi-DSA operations are designed to make these procedures more transparent and predictable while maintaining accountability.
- Supports Economic Efficiency: By enhancing the efficiency and effectiveness of the organ procurement system, this final rule supports better use of resources within the organ donation and transplantation system.
- Reduces Compliance Uncertainty: The final rule is estimated to save approximately $583,000 annually in reduced inquiry and interpretation costs for CMS and OPOs combined, allowing resources to be redirected toward improving organ procurement outcomes.

Dr. Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2026.

List of Subjects in 42 CFR Part 486

Administrative practice and procedure, Grant programs—health, Health facilities, Home health care, Medicare, Reporting and recordkeeping requirements, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR 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 definition of ''Unsound medical practices'' in alphabetical order.

The revisions and addition 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.

* * * * *

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

■ 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 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) 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, except when there is insufficient time to conduct a competition, as specified in paragraph (a)(4) of this section.

(3) Designation periods following a competition or assignment of a DSA by CMS. The designation period for any newly acquired DSA following a competition as specified at § 486.316(d), or as the result of being assigned a DSA as specified at paragraph (a)(4) of this section or § 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 a successor OPO for designation to the DSA. In selecting a successor OPO, 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) 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)(1) 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 paragraph (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 under undesignated center heading ''Requirements for Certification and Designation'' to read as follows:

§ 486.311 Non-renewal of agreement.

(a) *Non-renewal of the 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 a DSA. A non-renewal under this paragraph (a)(1) is limited to the OPO's agreement for designation to the 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 the agreement for designation to a DSA 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 provides an initial notice of de-certification to an OPO in writing 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 paragraph (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 and paragraphs (a) through (d) and (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) *Preparing the administrative record.* 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 another OPO 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. OPOs with DSAs assigned by CMS under the provisions at § 486.308(a)(4) or paragraph (e) of this section will not have any existing or newly assigned DSA opened for competition based on assignment to tier 2 until a full re-certification cycle is completed for the newly assigned DSA.

(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 notice of de-certification 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 the agreement for designation to a DSA

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 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 designation to a DSA 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 revised to 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 DSA's, 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) through (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, as specified at § 486.310, 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, as specified at § 486.316(d), or assignment by CMS as specified at § 486.308(a)(4) or § 486.316(e), 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 is amended by revising paragraph (a) 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. Section 486.324 is amended in paragraphs (a)(1), (2), and (5) and (b)(2), and (8) by removing the text ''area'' and adding in its place the text ''area(s)''.

■ 13. Section 486.326 is amended by revising paragraph (d) 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.

§ 486.328 [Amended]

■ 14. Section 486.328 is amended in paragraph (c) by removing the text ''area'' and adding in its place the text ''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 by:

■ a. Removing in paragraph (b) the text ''area'' and adding in its place the text ''area(s)'';

■ b. Adding paragraph (c)(3); and

■ c. Revising paragraph (d)(3).

The addition 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.

■ 17. Section 486.360 is amended by:

■ a. Revising paragraph (c)(1)(v); and

■ b. In paragraph (e)(2)(i), removing the text ''DSA'' and adding in its place the text ''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.

[FR Doc. 2026–22381 Filed 10–30–26; 4:15 pm]

BILLING CODE 4120–01–P