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Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS)

File Code CMS-3409-P Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage

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VIA ELECTRONIC FILING — https://www.regulations.gov/

March 31, 2026

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-8016

Re: CMS-3409-P, Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage

Dear Dr. Oz:

The **United Network for Organ Sharing (UNOS)** appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed updates to the **Organ Procurement Organizations (OPO) Conditions for Coverage (CfC)** under **File Code CMS-3409-P**, published in the Federal Register on January 30, 2026.

For more than four decades, UNOS has worked closely with the federal government and community stakeholders to increase transplants and strengthen the organ donation and transplant system for donors, patients, and their families as a contractor serving the Organ Procurement and Transplantation Network (OPTN), while also delivering innovative tools and data support that help the donation and transplant community improve outcomes.

We support CMS' goal of strengthening OPO accountability and improving performance to save more lives through transplantation but urge CMS to work in close coordination with the Health Resources and Services Administration (HRSA) and the OPTN to ensure OPO performance expectations are aligned with OPTN allocation policy, transplant program acceptance incentives, and emerging opportunities to modernize donor identification and referral processes.

For example, UNOS has long advocated for the adoption of automated deceased donor referrals (ADR) as a high impact, near-term opportunity to reduce missed or delayed referrals, improve data quality, and support timely donor evaluation – an approach that aligns with CMS' broader health IT and interoperability priorities. UNOS encourages CMS to leverage ADR and work with stakeholders to consider how broad implementation will impact OPO performance.

Further, we also encourage CMS to closely coordinate with HRSA and the OPTN to establish clear transition pathways for potential Tier 3 decertifications in 2026, including

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consolidation or new entrants, to strengthen accountability and protect continuity of patient care. To ensure coordinated and efficient transitions, it is essential that information between incumbent and successor OPOs is shared in a timely manner with those responsible for making associated changes to the OPTN system. UNOS strongly encourages CMS to ensure HRSA authorizes its OPTN contractors to communicate directly with affected OPOs during times of transition. Such direct communication will allow for timely implementation and minimal service disruptions.

UNOS remains committed to fostering collaboration, transparency, and continuous improvement throughout the organ donation and transplant system. In the following sections, we offer constructive recommendations intended to support CMS' objectives, promote collaboration across CMS, HRSA, and the OPTN, and advance practical, interoperable solutions, including ADRs, that can meaningfully increase organ donation and transplantation.

Provisions of the Proposed Regulations [Section III]

Definitions (§486.302) [Section III.A]

Adverse Event [Section III.A.1]

To promote consistent implementation, CMS should work with HRSA to ensure that OPO obligations under OPTN policies for adverse event reporting and member compliance reviews align with CMS' requirements for investigating adverse events under QAPI programs. This alignment will avoid duplicative reporting and unnecessary administrative burden while supporting meaningful QAPI oversight.

Donor [Section III.A.2]

We concur with CMS' clarification that an individual from whom a pancreata is procured and used for bona fide islet cell transplantation or bona fide islet cell research are appropriately counted as donors for certification and recertification purposes. We agree that acceptance and immediate use or cryopreservation should be considered necessary conditions for inclusion, consistent with statutory requirements and recent OPTN disposition code refinements. As science and technology continue to evolve in the organ donation and transplant field, we encourage CMS to clarify in the final rule whether permissible use includes the placement of pancreata for the purpose of developing biologics for treatment.

We recommend that, to the extent the final definitions, documentation expectations, and validation approaches incorporated in this Rule overlap with or incorporate OPTN definitions, documentation expectations and validation approaches, CMS and HRSA work together to ensure consistency and safeguard data integrity while supporting continued advancement of islet cell research.

Organ [Section III.A.3]

We agree with CMS' proposal to remove pancreata used solely for bench research from the definition of "organ" for purposes of the transplantation rate outcome measure. This change appropriately distinguishes research activity from patient-impacting transplants

and addresses CMS' concern that counting research as transplants could distort performance incentives.

As we suggested in the "Donor" subsection of **A. Definitions** above, as science and technology continue to evolve in the organ donation and transplant field, we encourage CMS to clarify in the final rule whether permissible use includes the placement of pancreata for the purpose of developing biologics for treatment. If so, we also recommend CMS clarify how such intended use should be reported to the OPTN or to CMS by the OPO.

We support CMS clearly describing how this change will be reflected in performance calculations, public reporting, and historical comparisons to ensure transparent implementation.

Medically Complex Donors and Medically Complex Organs [Section III.A.4]

UNOS observes that the proposed definition of medically complex organs would encompass the majority of organ donors with organs recovered in 2025, as 70% of recovered deceased donors in 2025 were either donation after circulatory death (DCD) donors or had a Kidney Donor Profile Index (KDPI) greater than 50%. We note that it may be much easier for an OPO to place an organ from a younger DCD donor with no comorbidities than an organ from an older donation after brain death (DBD) donor with comorbidities like hypertension or diabetes.

Recommendations:

1. CMS should review the OPTN definition of "hard-to-place kidney" developed by the OPTN Kidney Committee during 2024-2025 as it considers refinement to this definition[1].
2. Additionally, if CMS aims to understand or reduce variation in DCD organ procurement rates across OPOs, CMS may wish for OPOs to monitor DCD donation more broadly within their QAPI programs separately from other medically complex donors.
3. We recommend CMS implement a data-driven, phased approach to defining an "elevated KDPI" that recognizes variation in transplant-center acceptance practices and the potential for unintended consequences if thresholds are overly prescriptive. We support CMS using QAPI review to identify systemic barriers (e.g. misaligned incentives across OPOs and transplant programs) and to inform evidence-based policy refinement.

Unsound Medical Practices [Section III.A.5]

We recommend that CMS clarify if there are "necessary and customary tests" beyond those specified in OPTN policy that OPOs must perform "to determine whether a potential

[1] Health Resources and Services Administration, "Kidney Committee Meeting Summary," May 19, 2025, https://www.hrsa.gov/sites/default/files/hrsa/optn/20250519_kidney-committee-meeting-summary-1.pdf

donor meets exclusionary criteria[2]." If so, CMS should list them specifically and make them readily available.

We also encourage CMS to clarify how OPOS should identify "patients with inappropriately high neurologic function" or consider alternate definitions for identifying "unsound medical practices" in DCD cases. CMS should provide clear examples and thresholds to help distinguish urgent risks from routine survey findings, support predictability and due process, and drive appropriate escalation.

OPTN policy[3] requires "the medical and behavioral history for each potential deceased donor [to] include… any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient." There is specific required information by organ, and we recommend CMS define what it considers to be "necessary and customary."

Requirements for Certification (§486.303) [Section III.B]

Certification of New OPOs

UNOS endorses CMS' reinterpretation of the Certification Act and removal of §486.303(e), recognizing CMS' authority to certify new OPOs consistent with statutory text. It is critical that any future certification framework prioritizes continuity of donation services. New OPO entities should demonstrate readiness on core CfC and process performance requirements, while being permitted to submit alternative evidence in lieu of historical outcome data (e.g. leadership experience; operational readiness assessments; systems capability). Approaches should prioritize minimizing disruption to donor hospitals and transplant programs and require robust transition planning.

Designation of One OPO for Each Service Area (§486.308) [Section III.C]

Factors for Designation Without Competition

CMS should clearly explain how the objective factors identified to guide designation decisions are weighed when competition is not feasible. Such factors include contiguity, outcome performance, process compliance, and operational readiness. CMS-approved transition plans and progress reporting should also be required to protect continuity of donation services.

Clarity of Designation and Competition Process

We support CMS' efforts to consolidate and clarify all scenarios that open a DSA to competition. We recommend CMS use a single, transparent framework with plain-language implementation guidance, clear timelines, and standardized submission requirements to reduce uncertainty, support coordinated planning, and minimize disruption to ongoing donation and transplant activity.

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[2] Organ Procurement and Transplantation Network. (n.d.). *OPTN policies: Policy 2*. U.S. Department of Health and Human Services, Health Resources and Services Administration. https://www.hrsa.gov/sites/default/files/hrsa/optn/optn_policies.pdf

[3] Id.

Designation to More Than One Service Area (§486.309) [Section III.D]

It is critical that CMS work with HRSA and the OPTN to make sure the definitions underpinning this final rule, including the definition of an OPO and the definition of a DSA, are consistent. CMS and HRSA should also collaborate to identify additional changes that may be required in OPTN bylaws and policies, such as requirements for an OPO that is managing than one DSA and voting privileges for OPOs managing more than one DSA.

Non-renewal and De-certification (§§486.311–312) [Section III.E]

Alternative Approaches to Non-renewal

We agree with CMS' proposal to distinguish non-renewal from de-certification and to consider DSA-specific outcomes. If CMS permits termination of designation for individual DSAs without triggering full non-renewal, then the agency should require implementation of strict criteria, advance notice, and CMS-approved transition plans to protect patients and donor families and to avoid perverse incentives. CMS should also work with HRSA to ensure that any OPTN contractors responsible for implementing associated changes to the OPTN IT system are authorized to communicate directly with the affected OPO(s).

Refinements to Non-renewal and De-certification Requirements

We recommend CMS provide clear timelines, notice requirements, and implementation guidance to support orderly transitions and consistent application across regions.

Appeals (§486.314) [Section III.F]

Limitations on CMS Authority to Extend Agreements

CMS should define objective criteria and reasonable limits on the duration of OPO agreement extensions to promote predictability, accountability, and effective planning.

Appeals Process and Timeframes

CMS' proposal to standardize appeals timelines using calendar days and to clarify appeal rights for both de-certification and DSA-specific designation removal is appropriate. We recommend these timeframes balance meaningful review with the need to avoid prolonged instability. CMS' clear procedural guidance will strengthen fairness and efficiency.

CMS should consider whether OPOs in Tier 2 who are not renewed should also have the opportunity to appeal non-renewal. Permitting such appeals may help those OPOs resolve purported deficiencies more effectively and may also encourage more organizational and staff stability for such OPOs. This would create stability not only for the OPOs themselves but also for their hospital partners and donor families.

Re-certification and Competition (§486.316) [Section III.G]

Alternative Factors for Tiered Re-certification

We recommend CMS consider operational feasibility, including transition complexity, data and IT readiness, and the need to maintain donation activity during consolidation. The agency should ensure competition criteria reward sustained improvement and strong process compliance to support increased transplants. CMS should also work with HRSA to

ensure that OPTN contractors responsible for implementing OPO changes within the OPTN system are explicitly authorized to communicate directly with the affected OPOs. Clear authorization for direct communication would support timely and accurate implementation and help minimize disruption for professionals, donors, patients, and their families.

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

Ensuring continuity of organ donation activities within a DSA during periods of organizational change is essential to protecting patients, donor families, and hospital partners. In times of transition, it is important that CMS grants successor OPOs full transparency into all necessary information regarding an incumbent OPO's operations to enable informed planning and decision-making and minimize disruption. It is equally important that CMS work with HRSA to ensure OPTN contractors responsible for implementing OPO changes within the OPTN system are authorized to communicate directly with OPOs are provided timely access to operational information needed to ensure efficient implementation.

Transition planning and cooperation should be a shared responsibility between the incumbent and successor OPOs. Our experience supporting OPTN operations during DSA transitions demonstrates that clearly defined roles, timelines, and communication pathways are critical to minimizing disruption and maintaining donation performance.

With respect to the proposed requirement that the incumbent OPO cooperate with the successor OPO and submit a transition plan detailing how all aspects of OPO operations will be transmitted, UNOS supports CMS clarifying expectations for the scope of cooperation. Clarity surrounding data transfer, hospital relationships, donor referral processes, staffing coordination, and continuity of quality and safety oversight within a tightly defined window of time will be important. CMS-specified transition plans can promote consistency across regions and reduce uncertainty for hospitals and transplant programs.

Further, we also support CMS' proposal to require the successor OPO to submit a transition plan and periodic progress reports until the transition is complete, as well as 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. These requirements can enhance accountability and transparency while allowing CMS to monitor progress and intervene early if risks to continuity of operations arise.

At the same time, UNOS encourages CMS to retain flexibility in how transition plans are operationalized, recognizing that transitions may vary significantly based on DSA size, geography, staffing models, and whether transitions are voluntary or non-voluntary. Rigid, one-size-fits-all requirements could unintentionally divert resources away from active donor management during critical transition periods. In general, it is important that all affected parties – the OPOs, CMS, HRSA, and OPTN Contractors – are authorized to communicate directly. Direct communication will enable efficient implementation and minimize disruption of donation services. A principles-based framework that emphasizes

continuity of operations, timely communication, and clear accountability will best support CMS' objectives.

Outcome Measures (§486.318) [Section III.H]

Accountability Timeframes for Newly Acquired DSAs

We encourage CMS to align accountability timeframes with realistic transition and stabilization milestones, particularly where historical data is limited. Providing clear expectations will protect patients while supporting sustainable performance improvement.

Human Resources (§486.326) [Section III.I]

Minimum Personnel Qualification Standards

We recommend CMS clearly identify which roles are subject to the certification and scope-of-practice requirements and allow reasonable implementation periods to account for workforce availability. Flexibility will help OPOs comply without disrupting donor care.

Medical Director Specification

The medical director plays a critical role in donor evaluation, donor management, organ recovery oversight, and collaboration with transplant programs. The medical director serves as a central figure in both clinical quality and accountability, as recognized in the CMS discussion.

To ensure effective implementation, we encourage clarifications or refinements to the medical director's expectations that remain role-appropriate, scalable, and operationally feasible across OPOs of varying size, geography, and organizational structure. Experience with national OPTN operations demonstrates that effective medical oversight results from a combination of direct physician involvement, well-defined delegation, and multidisciplinary clinical teams—particularly in multi-DSA or transitioning environments.

Clarifying that the medical director responsibilities may be fulfilled through flexible staffing models, including part-time service, shared coverage, or contractual arrangements, will ensure that accountability, availability, and integration into QAPI and donor management processes are clearly defined. Rigid prescriptive requirements risk exacerbating existing physician workforce shortages without improving donor or transplant outcomes.

Recognizing the evolving clinical environment in which OPO medical directors operate, including increased reliance on standardized donor management protocols, telehealth consultation, and real-time data analytics, will help ensure that requirements support, rather than inhibit, modernized, technology-enabled models of care that promote consistency and quality across service areas.

Information Management (§486.330) [Section III.J]

Documentation for Organs Procured for Research

UNOS supports CMS' proposal to require documentation for organs procured for research, including pancreata used for islet cell research, to enhance data integrity and transparency. As previously noted in the "Donor" subsection of **A. Definitions** above, 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.

Documentation requirements should align with existing OPTN workflows and clearly delineate the point at which responsibility for organ viability and use transfers to the accepting research entity, recognizing that OPOs may not have visibility into whether or when an organ is ultimately used in a research protocol.

CMS should also provide surveyor guidance that accounts for delays in confirmation of research use and retrospective documentation updates that may occur outside the OPO's control. If CMS determines that additional data collection is necessary to support oversight of pancreata used for research, we recommend CMS work with HRSA to assess whether and how such requirements should be incorporated into OPTN data collection in a manner that is operationally feasible.

Quality Assessment and Performance Improvement (QAPI) (§486.348) [Section III.K]

When reviewing medically complex donors and organs as part of the QAPI requirements, CMS should allow for flexible review frequency based on volume and local practice patterns. We also recommend CMS emphasize the identification of barriers and corrective actions and share any key findings broadly to accelerate system-wide improvement.

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 [Section III.L]

UNOS favors CMS' proposed modifications to accommodate optional multi-DSA operations and agrees that related CfC must be updated to ensure clarity, accountability, and continuity of services across multiple service areas.

Hospital and Tissue Bank Agreements

We encourage CMS to provide clear guidance on how OPOs should document and maintain agreements during transitions or consolidations to avoid inadvertent lapses that could disrupt referral activity or hospital collaboration.

Administration, Governing Body, and Advisory Board Structure

UNOS supports CMS' proposal to revise advisory board membership and coordination requirements to reference service areas in the plural form to accommodate optional multi-DSA governance. Governance structures must evolve to reflect multi-DSA operations while preserving meaningful representation, oversight, and local engagement within each service area. See section **D. Designation to More Than One Service Area (§486.309)** above for our additional recommendations.

Our experience with OPTN governance underscores the importance of clear lines of accountability and communication when organizations operate across multiple regions. CMS' proposed clarification will help ensure advisory structures remain fit for purpose as OPO operational models evolve.

Emergency Preparedness and Continuity of Operations

UNOS agrees with CMS' proposal to require OPOs to update emergency preparedness communication plans to include contact information for transplant hospitals and donor hospitals in each DSA. Emergency preparedness planning must reflect the realities of multi-DSA operations and ensure timely, reliable communication across all service areas during emergencies. During emergency situations, it is critical that OPOs can communicate directly with the OPTN and its contractors. UNOS encourages CMS to work with HRSA to ensure that OPTN contractors are authorized to communicate directly with OPOs and CMS during emergency situations.

We also support CMS' proposal to require continuity of operations provisions that address backup agreements covering multiple DSAs. Our experience demonstrates that clearly defined backup arrangements are essential to maintaining donor management, organ recovery, and transportation activities during emergencies, staffing disruptions, or system outages.

We encourage CMS to allow flexibility in how OPOs structure backup agreements, provided that OPOs can demonstrate operational readiness, clear communication protocols, and the ability to maintain uninterrupted donation services across all DSAs.

Comment Solicitation and Discussion on Emerging Issues [Section IV]

Allocation Out of Sequence (AOOS) [Section IV.B]

UNOS encourages continued coordination between CMS and HRSA to reduce AOOS through transparency, consistent enforcement, and adherence to OPTN allocation policies. Coordination rather than fragmented oversight is critical to maintaining equitable allocation while addressing organ nonuse concerns. Accordingly, CMS should consider how encouraging OPOs to recover more medically complex organs and subsequently measuring OPOs on whether transplant programs choose to accept those organs might exacerbate pressures on OPOs to allocate out of OPTN sequence.

CMS describes the increase in overall kidney transplant rates following changes to kidney allocation in 2021 and says, "[...] we note that much of this gain is likely attributable to the approximately 19 percent gain in the number of deceased kidney donors recovered over the same era in response to new measures for OPO performance."[4] UNOS observes that this rapid expansion in kidney donors recovered also likely contributed to higher rates of kidney nonuse, as OPOs recovered more organs than transplant programs were willing to transplant[5].

[4] Centers for Medicare & Medicaid Services, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Conditions for Coverage," proposed rule, January 30, 2026, https://federalregister.gov/d/2026-01833.

[5] Keighly Bradbrook, David Klassen, Allan B. Massie and Darren E. Stewart, "Does a Changing Donor Pool Explain the Recent Rise in the United States Kidney Nonuse Rate?" American Journal of Transplantation (2025), https://doi.org/10.1016/j.ajt.2025.02.004.

CMS' Increasing Organ Transplant Access (IOTA) model considers organ offer acceptance rates as part of its scoring process to consider whether transplant programs should be awarded upside risk payments, but this model currently only applies to kidneys. Transplant program representatives expressed concern prior to the IOTA model's start as to whether the upside risk payments actually offset the cost of transplanting medically complex kidneys. Model performance data has not yet been released to provide insight into whether such concerns were justified.

In this proposed rule, CMS cites an editorial describing higher-volume centers as those that "can handle higher-risk organs," acknowledging that transplant program resources, capacity, and expertise to transplant medically complex organs vary. As such, CMS should collaborate with HRSA to identify mechanisms that simultaneously provide for "special or additional considerations to identify the best recipient" for medically complex organs while complying with federal law and regulations for equitable allocation of organs.

Furthermore, CMS should consider opportunities within its Rapid Cycle Innovation Program to rapidly share effective practices among OPOs regarding evaluation and management of medically complex donors and allocation of their organs that can be incorporated into OPO QAPI programs.

CMS should support HRSA's directive to the OPTN to define AOOS consistently and transparently, and work to avoid creating parallel CMS allocation enforcement, which risks fragmentation. CMS should drive these actions using transparency, standard definitions, and targeted corrective action to transplant as many organs as possible successfully.

Automated Electronic Referrals [Section IV.C]

UNOS strongly endorses CMS leveraging technology to support automated electronic donor referrals (ADR) and ensuring appropriate privacy and security protections for sensitive health information. We appreciate CMS' continued effort to build on prior stakeholder engagement, including the Health Technology Ecosystem Request for Information (90 FR 21034)[6], to which our team previously responded.

We recommend CMS foster consistency over fragmentation, transparency over opacity, interoperability over customization, and principles-based regulation grounded in real operating experience. This approach protects patient safety, equity, and public trust while preserving operational feasibility.

Technology, Standards, and Infrastructure

UNOS strongly supports CMS' focus on ADR as a high-impact modernization opportunity. ADR represents a high-impact opportunity to reduce missed or delayed referrals, streamline hospital workflows, and provide OPOs with more timely and complete clinical information. ADR systems built on interoperability between hospital EHRs and OPO systems can reduce reliance on manual, phone-based referrals, lower the risk of missed or

[6] Centers for Medicare & Medicaid Services, "Request for Information; Health Technology Ecosystem," May 16, 2025, https://federalregister.gov/d/2025-08701.

late referrals, streamline workflows for hospital staff, and equip OPOs with more accurate and timely clinical information.

We recommend CMS focus on the feasibility of EHR-embedded triggers, API-based notifications, and HL7® FHIR® interoperability within broader Trusted Exchange Framework and Common Agreement (TEFCA) aligned infrastructure or within the CMS Aligned Networks that supports secure, role-appropriate data sharing and interoperability. Automated referral systems are most effective when built on standards-based, vendor-agnostic interoperability, rather than proprietary solutions that may limit scalability or sustainability. Nesting automated referrals within a broader health IT ecosystem will support secure data sharing while reducing administrative burden for hospitals and OPOs.

We also support CMS' focus on privacy and security, including ensuring that automated referrals incorporate appropriate access controls, auditability, and safeguards consistent with HIPAA and other applicable requirements. Clear national expectations for data elements, security standards, and governance will accelerate adoption while protecting patient and donor information.

Leveraging Existing Hospital Notification Requirements

We support CMS exploring whether and how the existing electronic notification requirements at § 482.24(d) could be leveraged as a foundation for ADRs. This approach can reduce variability across hospitals and improve timeliness and completeness of referral data. Aligning ADR with existing hospital requirements could reduce variability, minimize burden, and accelerate adoption.

Frameworks, Best Practices, and National Adoption

UNOS encourages CMS to promote uniform national data elements and interoperability standards, and support pilot programs with EHR vendors to scale implementation nationally. We agree with CMS that broad adoption of ADR could represent a near-term opportunity to improve donation performance and reduce preventable organ loss, and that CMS' leadership in convening stakeholders would accelerate progress. We recommend the agency disseminate best practices from hospitals and OPOs already using automation while avoiding mandating a single vendor or platform to allow innovation while enforcing interoperability.

Collection of Information Requirements [Section V]

We agree with CMS evaluating information collection requirements to ensure they are necessary, accurate, and useful. We encourage CMS to prioritize automation and alignment with existing systems to minimize burden while supporting performance improvement.

Regulatory Impact Analysis [Section VII]

Operational Flexibility for Multi-DSA Operations [Section VII.B.d.]

UNOS agrees with CMS identifying data sources to quantify benefits of operational flexibility for multi-DSA operations, including transition timelines, stabilization outcomes, and sustained performance trends, supplemented by operational readiness indicators. Transparent measurement is critical and will support evidence-based policy refinement.

§ 486.308 Designation Periods [Section VII.C.1]

We support CMS considering additional factors related to designation periods following competition or assignment. Designation length should align with transition complexity and improvement timelines and require clear milestones and reporting during early periods. Predictability is necessary to support stable donation services.

§ 486.309 Designation of an OPO to More Than One Service Area [Section VII.C.2]

We favor CMS retaining final approval authority over multi-DSA arrangements with clear criteria, including operational capacity and accountability safeguards, while preserving flexibility to maintain separate DSAs where appropriate.

Alternatives Related to § 486.311 Non-renewal of Agreement [Section VII.C.3]

We support careful evaluation of alternative approaches to non-renewal, including DSA-specific termination, only with strong safeguards such as objective criteria, notice, continuity protections, and CMS-approved transition plans.

§ 486.314 Appeals and § 486.316 Re-certification and Competition Processes [Section VII.C.4]

CMS should explore requirements to ensure successor OPOs receive sufficient standardized data at the start of a designation period, aligned with transition planning and secure transfer mechanisms. Timely data access will support effective donor service delivery.

Reporting on Pancreata Used for Islet Cell Research (§ 486.330 Information Management) [Section VII.C.5]

We agree with implementing targeted reporting on pancreata used for islet cell research to improve transparency and integrity. CMS should ensure reporting aligns with OPTN data standards, clearly distinguishes research use from transplantation, and be released on a consistent, contextualized schedule. Reference the “Donor” and “Documentation for Organs Procured for Research” for additional information.

Regulatory Review Cost Estimation (D. Regulatory Review Cost Estimation) [Section VII.D]

We support CMS’ solicitation of comment on regulatory review cost assumptions and encourage estimates that reflect the operational realities of transitions, multi-DSA management, and expanded QAPI and reporting requirements.

Organ Transportation

UNOS supports CMS' proposal to address concerns related to organs that are lost, damaged, or delayed due to transportation issues, and agrees that improved accountability is necessary to identify root causes and drive system-wide improvement. OPTN policies currently require OPOs to report to the OPTN:

- if transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required using **TransNet℠**, the OPTN's organ packaging and labeling system;
- if a transplant hospital incorrectly receives an organ;
- the incorrect organ(s) delivered to the transplant hospital; or
- when a donor organ is identified as incorrect during pre-transplant processes.

We recommend CMS collaborate with HRSA to align workflows for connecting OPTN patient safety reports with QAPI adverse event investigations so that lessons learned can be applied at the system level.

We encourage CMS to require OPOs to define and report transportation-related adverse events and align reporting expectations with existing OPTN data standards and workflows to minimize duplication and administrative burden. Standardized definitions and reporting elements will be essential to ensure consistent data collection and meaningful analysis. Leveraging TransNet's data and integration with OPTN systems could facilitate streamlined, accurate reporting while minimizing manual data entry and supporting efficient quality improvement efforts.

UNOS also supports CMS' emphasis on the use of correct packaging and labeling to reduce the risk of loss, damage, or delay during transport. We encourage CMS to recognize the role of standardized labeling, packaging protocols, and emerging tracking technologies, such as TransNet, in improving reliability and accountability across the transportation process. TransNet's barcode-based system ensures that organs are labeled accurately and consistently, which is critical for safe and timely organ delivery.

CMS could also consider requiring OPOs to use real-time organ tracking services to complement existing OPTN policy for the labeling, packaging, and shipping of organs.[7] The use of organ tracking technology would provide OPOs with access to an organ's location in real-time and help improve safe and efficient organ transportation.

Overall, implementing learning-oriented reporting and corrective action and incorporating current and emerging transplant tools and technology will help drive error prevention, quality improvement, accountability, and collaboration across OPOs, transplant programs, and transportation partners.

[7] Health Resources and Services Administration, "Organ Transport Resources," https://www.hrsa.gov/optn/professionals/resources/organ-transport.

Conclusion

UNOS appreciates CMS' emphasis on accountability, data integrity, interoperability, and quality improvement. It is critical that CMS prioritize continued collaboration with HRSA and the OPTN to ensure reforms are implemented in a coordinated and operationally feasible manner. Transparency and direct communication between CMS, OPOs, HRSA and OPTN contractors will ensure alignment and efficient implementation of changes to the OPTN system, promote continuous improvement, and minimize disruption of donation services for patients, providers, and donor families.

We also strongly encourage CMS to continue advancing automated deceased donor referrals as a foundational modernization strategy that can reduce missed or delayed referrals, improve data quality, and strengthen donor identification across hospitals and OPOs nationwide.

UNOS looks forward to ongoing partnership with CMS to ensure these policy changes drive increased utilization, protect patients and donor families, and strengthen the organ donation and transplantation system.

Sincerely,

Mark Johnson
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United Network for Organ Sharing