

**CBE ID**

5604

**Title**

Rate of the Number of Organ Donors to the Potential Donors in an Organ Procurement Organization's Donation Service Area in a Calendar Year.

**Project**

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

**Endorsement Status**

New

**Is Under Review**

Yes

**Next Maintenance Cycle**

Spring 2026

**Steward**

Other

**1.0 New or Maintenance**

New

**1.1 Measure Structure**

Single Measure

**1.3 Electronic Clinical Quality Measure (eCQM)**

No

**1.6 Measure Description**

This measure is the rate of donors out of the potential donor population in an Organ Procurement Organization's (OPO's) donation service area (DSA) in a calendar year.

**1.7 Measure Type**

Outcome

**1.8 Level of Analysis**

Other

**1.8b Other Level of Analysis**

Organ Procurement Organization - a non-profit organization responsible for the evaluation and procurement of deceased-donor organs for transplantation. OPOs also educate the public to increase awareness and participation in organ donation.

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## 1.9 Care Setting

Other

### 1.9b Other Care Setting

The OPO is the care setting for which this measure is specified and tested.

## 1.10 Measure Rationale

This measure identifies the rate of donors out of the potential donor population in an Organ Procurement Organization's (OPO's) donation service area (DSA) in a calendar year. We refer to this measure as the Donation Rate measure. The Donation Rate measure assesses how often patients with no contraindications to donation become organ donors. An OPO's donation rate is essential for each OPO to evaluate how effective they are at converting potential donors into actual donors using strategies in hospital engagement, donor management, staff training, and family communication. An increase in the Donation Rate indicates that the OPO is improving its processes to obtain hospital referrals, follow up with referred patients or their next of kin through an approach conversation, and acquire authorization for donation.

Effective hospital engagement is a key factor in increasing the Donation Rate. Gibson et al. (2023) demonstrated the importance of collaboration between the donor hospital and OPO. After reviewing trauma mortality cases and performance improvement metrics with their OPO hospital liaison, they implemented a multidisciplinary performance improvement initiative to create a more donation-friendly culture for their facility. Hospital administrative engagement, staff education, and increased OPO program visibility were key approaches used. Donor conversion rates improved from 66.6 percent in 2017 to 86.1 percent in 2021. The relationship between OPOs and donor hospitals is a vital link to improving organ donation outcomes.

OPOs that emphasize effective communication across the transplant system help ensure that organs are available for transplant. Siminoff et al. (2024) identified the importance of OPO clinician training related to family conversations for donation, due to the need for both technical expertise and strong relational communication skills. The Donation Rate measure adds value and encourages the adoption of best practices across the organ procurement community, ultimately increasing organ availability and saving more lives.

### References:

Gibson, J. E., Campbell, T., Gibson, K., Kottemann, K., Krause, M. A., & Pack, L. (2023, June 15). Collaborative approach to organ donation in a level II trauma center. *AACN Adv Crit Care*, 34(2), 88-94. doi: 10.4037/aacnacc2023552.

Siminoff, L. A., Alolod, G. P., McGregor, H., et al. (2024). Developing online communication training to request donation for vascularized composite allotransplantation (VCA): Improving performance to match new US organ donation targets. *BMC Med Educ*, 24, 77. <https://doi.org/10.1186/s12909-024-05026-9>.

## 1.13 Data Dictionary

Attached

### **1.13a Attach Data Dictionary**

[CBE-5604-1.13a-Donation-Rate-Data-Dictionary-Attachment-A-Spring2026.pdf](#)

### **1.14 Numerator**

The numerator is the number of donors in an OPO's DSA in a calendar year.

#### **1.14a Numerator Details**

The numerator for this measure uses data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services provides oversight to OPTN and SRTR contractor activities.

The numerator for the Donation Rate measure is the number of donors in an OPO's DSA in the calendar year. A donor is defined as a deceased individual from whom at least one organ was recovered for transplant, regardless of whether the organ was transplanted. An individual would also be considered a donor if only the pancreas is procured and is used for islet cell research or transplantation.

An organ is defined as having been recovered for transplant if it has one of the following Scientific Registry for Transplant Recipients (SRTR)-defined organ dispositions: 501 (Organ Transplanted Locally), 502 (Organ Transplanted Shared), 503 (Recovered for Transplant: Discarded Locally), 504 (Recovered for Transplant: Shared and Discarded), 505 (Recovered for Transplant: Submitted for Research), 506 (Recovered for Transplant: Sent for Heart Valves), 508 (Recovered for Transplant: Whole PA/PI, processed for islets, not transplanted or transplant unknown), 509 (Recovered for Transplant: Sent for Ex-corp Liver), 514 (Recovered for Transplant: Sent for Hepatocytes), 520 (Recovered for Transplant: Pancreas sent for Technical Reasons (for DMS use only)), 521 (521: Islet Cells Transplanted), 522 (Exported Out of U.S., transplanted), 523 (Exported, not transplanted or transplant unknown), 524 (Recovered for Transplant: Sent for non-islet cell research), 525 (Recovered for Transplant: Accepted for islet cell research), 530 (Organ Transplanted in the U.S.), or 531 (Recovered for Transplant: Discarded).

Please refer to Attachment B for a list of definitions and acronyms associated with this measure submission.

### **1.15 Denominator**

The denominator is the number of individuals in the potential donor population in an OPO's DSA in a calendar year.

#### **1.15a Denominator Details**

The denominator uses the National Vital Statistics System (NVSS) Multiple Cause of Death (MCO) data, which are mapped by county in the OPO's DSA. The NVSS MCO data are compiled

from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Potential donors are then apportioned to OPOs in counties with a waiver hospital based on the percentages calculated by CMS in their OPO Annual Public Aggregated Performance Report.

The denominator of the Donation Rate measure is the number of individuals in the potential donor population in the OPO's DSA in a calendar year. The potential donor population includes patients who died in a hospital and are aged 0 to 80 years old who died within a hospital and with one of the following ICD-10-CM codes listed as the primary cause of death:

- I20-I25 (ischemic heart disease); or
- I60-I69 (cerebrovascular disease); or
- V01-Y89 (external causes of death): blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation.

In addition, the individual must have had no contraindications to donation listed in the secondary causes of death, as noted in the denominator exclusions in Section 1.15b.

For the Multiple Cause of Death (MCO) data, a death is attributed to the calendar year based on the time of death (time between 12:00 a.m. on January 1 of a calendar year and 11:59 p.m. on December 31 of that same year), as recorded on the death certificate.

### **1.15b Denominator Exclusions**

The denominator for the Donation Rate measure excludes patient deaths over the age of 80 years old, with no discernible cause of death, and/or who did not die in a hospital. The denominator further excludes patient deaths with any of the following ICD-10-CM codes listed among the multiple causes of death:

- Bacterial:
  - A15-A19, B90 (tuberculosis)
  - K46.1, K45.1 (gangrenous bowel)
  - K63.1 (perforated bowel)
  - A40-A41 (intra-abdominal sepsis)
- Viral:
  - B20 (HIV infection by serologic or molecular detection)
  - A82 (rabies)
  - A83-86, B33.3, B97.3 (retroviral infections including viral encephalitis)
  - B27 (acute Epstein-Barr virus (mononucleosis))
  - A92.3 (West Nile virus infection)
  - A98.4 (Ebola virus)
- Fungal:
  - B45 (active infection with cryptococcus)
- Parasites:
  - B55 (leishmania)
  - B78.7 or B78.9 (strongyloides - widespread infection)
  - B50-B54 (malaria (plasmodium sp.))

- Prion:
  - A81.0 (Creutzfeldt-Jakob disease)
- D60-D61 (aplastic anemia)
- D70 (agranulocytosis)
- C00-C97 (current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease)
- Z85.820 (history of melanoma)
- Hematologic malignancies:
  - C90.1, C91-C95 (leukemia)
  - C81 (Hodgkin's disease)
  - C82-C88 (lymphoma)
  - C90.0 (multiple myeloma)

### **1.15c Denominator Exclusions Details**

Please see Section 1.15b Denominator Exclusions for details on denominator exclusions.

### **1.15d Age Group**

Other

### **1.15e Age Range in Years**

Patients who are 0 to 80 years of age.

### **1.16 Type of Score**

Rate/proportion

### **1.17 Measure Score Interpretation**

Better performance = Higher score

### **1.18 Calculation of Measure Score**

To calculate the numerator for the Donation Rate, begin by joining the SRTR Donor Disposition data (to determine the final disposition of organs from a donor) using the Donor ID and the SRTR Institution data (to determine the OPO for the donor) using the Center ID to the SRTR Donor Deceased data. These data are filtered to the Organ Dispositions for organ recovery (listed in Section 1.14a), the calendar year(s) and OPO(s) of interest, and where the donor is aged 0 to 80 years old. Then, for each OPO and calendar year, count the number of distinct Donor IDs. This is the number of organ donors per OPO and year.

To calculate the denominator for the Donation Rate, we use the MCODE data from the National Center for Health Statistics (NCHS) and NVSS for the calendar year of interest. The NVSS MCODE data are compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. The death information is filtered based on potential organ donor criteria (see Sections 1.15a and 1.15b for full descriptions of potential donor requirements and exclusions). Each death is then assigned to their respective OPO based on the geographic location where the potential organ donor died. Alongside this, potential donors are apportioned to OPOs in

counties with a waiver hospital based on the percentages calculated by CMS in their 2025 OPO Annual Public Aggregated Performance Report. The total number of potential donors per OPO are summarized; this is the total number of potential donors in an OPO in a calendar year.

To calculate the Donation Rate, divide the numerator (the number of organ donors for an OPO for the calendar year) by the denominator (the number of potential donors in an OPO's DSA for the calendar year) to determine the Donation Rate for an OPO for the calendar year. This value is multiplied by 100, as the rate is expressed as X per 100 deaths. Please refer to Exhibit 2: Measure Score Calculation Diagram in Attachment B for additional details.

### **Reference:**

Centers for Medicare & Medicaid Services. (2025, July). *OPO public performance report*. Quality, Certification & Oversight Reports. <https://qcor.cms.gov/OPOs>.

## **1.19 Measure Stratification Details**

This measure is not stratified.

## **1.20 Types of Data Sources**

Registries, Other

### **1.20a Other Data Source**

Multiple Cause of Death data from the National Center for Health Statistics and National Vital Statistics System, compiled from data provided by the 57 vital statistics jurisdictions. Registry data from the Scientific Registry of Transplant Recipients.

### **1.20d Format: Other Data Source**

Digital

### **1.21a Data Collection Tool URL(s)**

<http://example.com>

## **1.25 Data Source Details**

The denominator for the Donation Rate uses the Multiple Cause of Death (MCOD) file, which is from vital statistics data gathered by the National Vital Statistics System (NVSS) and managed by the National Center for Health Statistics (NCHS) (CDC, 2025). These data were well-structured, defined, and cleaned and presented no feasibility, reliability, and/or validity challenges for the analysis. The NVSS MCOD data are compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

The numerator for the Donation Rate uses data from the Scientific Registry of Transplant Recipients (SRTR), available at <https://www.srtr.org/> (SRTR, 2025). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by members of OPTN. HRSA within the U.S. Department of Health and Human Services provides oversight to OPTN and SRTR contractor activities. Our use and analysis of the data were

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reviewed by an Institutional Review Board and determined to be exempt.

The data come from transplant hospitals, OPOs, and immunology laboratories (Leppke et al., 2023). These data are supplemented by data from CMS (<https://www.cms.gov/>) and the National Technical Information Service (NTIS) Death Master File (DMF) (<https://dmf.ntis.gov/>). The specific variables used for this measure were originally collected from OPO electronic donor records (EDRs) and transplant centers. To obtain a version of the data used in this measure development, Econometrica entered into a Data Use Agreement (DUA) with SRTR. These data were well-structured, defined, and cleaned and presented no feasibility, reliability, and/or validity challenges for the analysis.

### References:

Centers for Disease Control and Prevention. National Center for Health Statistics. <https://www.cdc.gov/nchs/>. July 2025.

Leppke, S., Leighton, T., Zaun, D., Chen, S. C., Skeans, M., Israni, A. K., Snyder, J. J., & Kasiske, B. L. (2013). Scientific Registry of Transplant Recipients: Collecting, analyzing, and reporting data on transplantation in the United States. *Transplantation reviews (Orlando, Fla.)*, 27(2), 50-56. <https://doi.org/10.1016/j.trre.2013.01.002>.

Scientific Registry of Transplant Recipients. Request for Information. Requested on July 24, 2025.

## 1.26 Minimum Sample Size

There is no minimum sample size.

## 2.1 Attach Logic Model

[CBE-5604-2.1-Donation-Rate-Logic-Model-Attachment-C-Spring2026.pdf](#)

## 2.2 Evidence of Measure Importance

To validate the importance of the Donation Rate measure and ensure accurate and comprehensive information when developing the measure, we performed an environmental scan of literature about the organ donation and transplant ecosystem (Rahman et al., 2025). We reviewed relevant literature for potential measures or data sources that had already been explored and had potential as candidate measures. Based on this review, no appropriate measures were identified, and the team continued exploring alternative evidence for measures and amplified importance.

A thorough review of existing measures in the CMS Measures Inventory Tool (CMIT) also indicated that there were no measures comparable to the one proposed for endorsement (CMIT, n.d.). The current CMS Donation Rate measure implemented in the 2020 CMS Final Rule is not a Consensus-Based Entity (CBE)-endorsed measure (CMS Final Rule, 2020). Therefore, we continued identifying potential measures using the CMS Blueprint Measure Lifecycle as a validated measure development framework.

The CMS Blueprint Measure Lifecycle was used to guide our work due to its rigorous and

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established approach to measure development and validation (CMS, n.d.). Econometrica operationalized the Blueprint by systematically integrating the conceptualization, specification, testing, implementation, measure use, evaluation, and maintenance phases into the project plan.

To gain a better understanding of OPO operations, identify considerations for measure development, and reinforce measure importance, we conducted 7 site visits with U.S. OPOs, including organizations with Donor Care Units, totaling 45 individual interviews with OPO leadership, directors, managers, and other essential OPO frontline staff. Econometrica conducted a qualitative analysis of all interviews that informed the development of the ecosystem map and logic model (Rahman et al., 2026a).

We convened four meetings with a Technical Expert Panel (TEP) (Rahman et al., 2026b) and assembled an OPO stakeholder group (Rahman et al., 2026c) to gather targeted, informed feedback over five sessions (June 2025 to February 2026). The purpose of the TEP was to provide expert guidance on project strategy, measure development, and recommendations for new measures. The OPO stakeholder group served to engage OPOs in informing and testing measures and supporting the development of a shared logic model. In Fall 2025, our team solicited feedback from OPO stakeholders on a list of structural, process, and outcome measure candidates. This activity narrowed the list of measure candidates, with the Donation Rate receiving a high percentage of agreement for advancement to the testing phase (Rahman et al., 2026c). During OPO Stakeholder Meeting 3, Econometrica continued in-depth discussions with stakeholders, further solidifying the final measures selected for the testing phase, including Donation Rate (Rahman et al., 2026c).

We also conducted a qualitative study to explore the perspectives of donor families, transplant recipients, and OPO stakeholders to better understand the emotional, practical, and systemic aspects of organ donation and transplantation (Arellano et al., 2025). Although we did not identify findings that had implications for the Donation Rate measure, the importance of developing appropriate measures was emphasized.

In collaborative sessions with our TEP and OPO stakeholder group, and in accordance with the CMS Blueprint Measure Lifecycle, we also identified measure selection criteria to guide the development and testing of quality measures (CMS, n.d.; Rahman et al., 2026b; Rahman et al., 2026c). These criteria were refined and prioritized to evaluate whether a measure was regarded as meaningful, actionable, and feasible. Our TEP and OPO stakeholders also emphasized that measures under consideration should improve upon current CMS measures and be rigorously developed, evidence-based, replicable, and verifiable. In addition to these standards, our TEP and OPO stakeholders recognized the need for flexibility in new measures to reflect the evolving science and medicine of organ donation. They identified that new measures should be aligned across the transplantation system (i.e., hospitals, OPOs, and transplant centers), oriented toward optimizing transplant outcomes, developed inclusively, and assessed for the potential to promote unethical behavior (induce individuals or organizations to seek out organs that will not be used). We took these guiding criteria into account as we developed and tested the Donation Rate measure.

The Donation Rate provides insight into the overall factors in a DSA that contribute to how often people who could be organ donors actually become organ donors. In applying the CMS Blueprint Measure Lifecycle and engaging a range of stakeholders, including OPOs, there was agreement

that this type of global outcome metric, if used appropriately, supports OPOs in the adoption of effective strategies in donor management, staff training, and family communication (Rahman et al., 2026c).

Based on OPO stakeholder insights, it is important to note that the universe of people who could be organ donors is not the number of people who are ultimately medically eligible and therefore represents an overestimation (Rahman et al., 2026c). Based on our literature review, there is currently no available data source for actual potential organ donors, as there is no single national source capturing deaths of patients on ventilators in hospitals. Furthermore, final medical eligibility is determined only after an individual who could be an organ donor undergoes repeated medical evaluation through laboratory and other clinical testing during the donation process. This information is not readily ascertainable or available on the death certificate; therefore, the use of the phrase “could be” is intentional to ensure that there is no misuse or misinterpretation of the measure results. Despite these concerns, OPOs agreed that if there were a realistic and meaningful way of calculating the measure, and if misuse of the measure were avoided, it could help their overall understanding of their performance.

The proposed Donation Rate measure reflects many factors that contribute to an outcome of donation. Reporting Donation Rates encourages collaboration and the adoption of best practices across the donation ecosystem, ultimately increasing organ availability and saving more lives. The Donation Rate is a consistent indicator of OPO activities across DSAs and has internal and external validity, as the measurement is quantifiable and consistent across OPOs and uses data that is independently verified (NVSS files). Furthermore, decreases in the Donation Rate may indicate the presence of external factors such as a decline in public trust, which impacts the number of organs donated and leads to further loss of life among patients awaiting transplants (NASEM, 2022).

The 2025 National Survey of Organ Donation Attitudes and Practices found that support for organ donation has generally remained between 90.4 and 94.9 percent from 1993 to 2025 (HHS, 2025). However, among respondents who were not registered donors, the most common survey responses included health reasons (30 percent), the need for more information (21 percent), and concerns that doctors would not treat them if they were in serious medical need (16 percent). This research highlights the importance of transparency, education, and trust-building by OPOs to the greater public.

Through our conversations during OPO sites visits and with TEP members and OPO stakeholders, we identified a wide range of inputs and outcomes related to this measure. Please refer to the Donation Rate Logic Model in Attachment C for these details. In this logic model, we identify how organ donation activities affect short-term and intermediate outcomes. The structural outcome of reduced organ waste would impact the overall health outcome of more organs transplanted.

## References:

Arellano, O., Rahman, M., O'Connor, J., & Rajakannan, T. (2025). *Perspectives and experiences in organ donation and transplantation: A qualitative study* [Internal document]. Econometrica, Inc., Bethesda, MD.

Centers for Medicare and Medicaid Services. (n.d.). *Centers for Medicare and Medicaid Services*

*Measures Inventory Tool (CMIT)*. <https://cmit.cms.gov/cmit#1/>.

Centers for Medicare and Medicaid Services (CMS) Measures Management System. (n.d.) *Blueprint Measure Lifecycle*. <https://mmshub.cms.gov/blueprint-measure-lifecycle-overview>.

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule. Published in the Federal Register on December 2, 2020, as 85 Fed. Reg. 77898. <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

Rahman, M., Arellano, O., Lind, C., Newton, L., O'Connor, J., Paraboschi, J., & Rizvi, S. (2025, June 20). *OPO measurement literature review report* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., Lind, C., Newton, L., O'Connor, J., & Paraboschi, J. (2026a, April 7). *OPO site visit final report* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., & O'Connor, J. (2026b). *Organ Procurement Organization (OPO) performance measurement technical expert panel (TEP) meetings 1–4 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1–5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration, Health Systems Bureau. (2025). *2025 National survey of organ donation attitudes and practices: Report of findings*. Rockville, Maryland: U.S. Department of Health and Human Services.

## 2.3 Anticipated Impact

A new, standardized, objective, and verifiable donation measure will allow the transplant community to evaluate respective DSAs and OPOs and establish best practices (NASEM, 2022). These best practices could include innovation, continuous improvement initiatives, improved efficiency, greater transparency, enhanced patient safety, and stronger collaboration between OPOs, donor hospitals, and transplant centers. As noted in the prior section, we anticipate many short- and long-term outputs from the proposed donation measure, with the overall outcome of more organs transplanted.

The proposed Donation Rate measure is an adaptation of CMS, OPTN, and SRTR donation measures. A measure of Donation Rate using a more narrowly defined denominator allows OPOs to develop quality improvement efforts directed at increasing donations.

We have adjusted the measure's denominator to further discriminate between medically acceptable and unacceptable donors. In doing so, we consulted with organ procurement and transplant medical directors to identify deaths with specific ICD-10-CM codes that are not acceptable for donation. This adjustment reduces the inclusion of medically unacceptable donors, which provides a more precise metric to guide OPO performance improvement and positively impact the number and quality of organs procured. We also proposed increasing the donor age to 80 years old to capture a larger potential donor population. This age commonly appeared in our testing data, and evidence from other countries, such as France, shows that transplant recipients can still experience substantial survival benefits from kidneys donated by older individuals (Aubert et al., 2019). We also consulted the TEP and medical professionals associated with organ donation, who agreed that if a person is otherwise healthy and up to about age 80, age would not rule out donation potential. While medical suitability for donation does decline with age in the general population, there is no commonly accepted medical or public health justification for using age 75 if the goal is simply to estimate the likely maximum potential donor population. Donation after 80 does occur, but it is significantly rarer than for the 80 and below age ranges.

Additionally, we discussed the exclusion criteria with the TEP, medical professionals, and OPOs and distributed it for comment to ensure that the list of exclusions reflected the current state of transplant science. For example, we discussed specific infectious diseases for inclusion and exclusion, as well as types of cancer, to arrive at the proposed method for calculating the numerator and denominator.

The Donation Rate may also be an indicator of registration rates. For instance, if the Donation Rate in a particular DSA is low, registration rates may be a contributing factor. Targeted interventions can be used to influence registry rates in specific populations, with public education campaigns effectively increasing knowledge and registration rates. A study by Salim et al. (2010) determined that public and media education significantly improved organ donor demographics for Southern California during a 2-year time period. Furthermore, educational campaigns have helped dispel common myths and fears surrounding organ donation (Olawade et al., 2025). A study by DuBay et al. (2018) determined that targeted intervention strategies within African American participants helped registered organ donors overcome barriers to communicating their wishes to their families.

Building trust and confidence in the transplant system is essential, as reducing public fear can influence donor registration rates and ultimately expand the potential donor pool.

### References:

Aubert, O., Reese, P. P., Audry, B., et al. (2019). Disparities in acceptance of deceased donor kidneys between the United States and France and estimated effects of increased US acceptance. *JAMA Intern Med*, 179(10), 1365–1374. doi:10.1001/jamainternmed.2019.2322.

DuBay, D. A., Ivankova, N. V., Herbey, I., et al. (2019). An African American perspective on familial notification of becoming a registered organ donor. *Progress in Transplantation*, 29(2), 164–172. doi:[10.1177/1526924819835837](https://doi.org/10.1177/1526924819835837).

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press.

<https://doi.org/10.17226/26364>.

Olawade, D. B., Marinze, S., Qureshi, N., Weerasinghe, K., & Teke, J. (2025). Transforming organ donation and transplantation: Strategies for increasing donor participation and system efficiency. *European Journal of Internal Medicine*, 133, 14–24. <https://doi.org/10.1016/j.ejim.2024.11.010>.

Salim, A., Malinoski, D., Schulman, D., Desai, C., Navarro, S., & Ley, E. J. (2010, August). The combination of an online organ and tissue registry with a public education campaign can increase the number of organs available for transplantation. *J Trauma*, 69(2), 451–4. doi: 10.1097/TA.0b013e3181e7847a. PMID: 20699756; PMCID: PMC2927713.

## 2.4 Performance Gap

The measure is being submitted for initial endorsement.

We used SRTR data between 1/1/2021 and 12/31/2024.

We used MCOB data between 1/1/2021 and 12/31/2024.

The donation rates per 100 for our 6 test site OPOs are presented in Exhibit 3: Donation Rates by OPO in Attachment B.

### Table 1. Performance Scores by Decile

The donation rates per 100 for our 6 test site OPOs are presented in Exhibit 3: Donation Rates by OPO in Attachment B.

## 2.5 Health Care Quality Landscape

The consensus study report from the National Academies of Sciences, Engineering, and Medicine (2022) identified an absence of established, consensus-based measurement development and endorsement processes for organ donation measures, such as those administered by the Partnership for Quality Measurement. Specifically, the authors called for the creation of standardized performance measures, based on a consensus-driven process with limited reporting burden on health professionals or patients. Such measures would ultimately support collaboration between OPOs, donor hospitals, and transplant centers to reduce the number of patients on the transplant waiting list.

CMS currently uses two related outcome measures—Donation Rate and Organ Transplantation Rate—to assess the performance and quality of OPOs and to determine whether an OPO can be recertified or decertified. Neither of the CMS measures underwent a consensus or endorsement process. Concerns regarding these existing measures were reported during the 2020 CMS rule-making public comment period, site visit interviews, and meetings with the TEP and OPO stakeholders (CMS Final Rule, 2020; Rahman et al., 2026a; Rahman et al., 2026b; Rahman et al., 2026c). In our assessment of more than 90 sets of public comments (drawn from the 2020 CMS rule public comment period, as well as from additional feedback obtained through our

independent 2025 solicitation of public comments conducted as part of the environmental scan), we found general agreement that the Donation Rate should be adjusted to reflect success at converting potential organ donors into actual organ donors and that the denominator calculation should be distinct from the transplantation rate (O'Connor & Lind, 2025). The denominator pool should not include individuals with contraindications for donation, and it should include a consensus-based approach to age restriction. Commenters also noted that data should be taken from an accurate and reliable source, and the instructions for calculating the measures should be clear and transparent and use publicly available data files. Furthermore, the 2022 NASEM report recommended developing a Donation Rate measure derived from a consensus-based process. Finally, both commenters and NASEM warned against the use of a single Donation Rate measure or outcome measures alone for OPO certification, as not enough is known about the factors that impact population-level changes in Donation Rates over time.

For these reasons, we believe that the Donation Rate measure proposed here for CBE consideration, which reflects a consensus-based approach for assessing organ donation rates in designated OPO service areas, is an improvement over the CMS measure proposed 6 years ago, which has not been updated since. The proposed measure updates the age, medical indications and contraindications to donation, and calculation methods; simplifies the data sources necessary for calculation; and recommends the use of a rate and stratification, thereby enabling OPOs to use the measure for quality improvement.

## References:

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule. Published in the Federal Register on December 2, 2020, as 85 Fed. Reg. 77898. <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

O'Connor, J., & Lind, C. (2025, August 22). *Public comment report* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., Lind, C., Newton, L., O'Connor, J., & Paraboschi, J. (2026a, April 7). *OPO site visit final report* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., & O'Connor, J. (2026b). *Organ Procurement Organization (OPO) performance measurement technical expert panel (TEP) meetings 1-4 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1-5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

## 2.6 Meaningfulness to Target Population

During our conversations with OPO stakeholders, we consistently heard concerns about the limitations of the current CMS Donation Rate measure and the need for an estimation of donation rate that better informs their work. The CMS measure is particularly harmful in part because of how difficult it is to calculate, but also because, under the 2020 CMS Final Rule, the Donation Rate and Organ Transplantation Rate are combined into a league scorecard. OPOs that do not rank within the top 25 percent (Tier 1) must either recompetete (Tier 2) or face potential replacement (Tier 3), based on their donation and transplantation rate performance (CMS Final Rule, 2020). They also emphasized that a low Donation Rate under the CMS measures does not always reflect true underperformance; however, this nuance does not shield OPOs from review or the risk of decertification. They noted that, while organ donation is most directly tied to OPO activities, the measure is also influenced by transplant center behaviors and other external factors, creating a level of interdependence within the system (NASSEM, 2022).

Given these concerns, OPO stakeholders expressed strong interest in improving the current Donation Rate measure so that it more accurately reflects their performance and helps them understand and address the factors that influence it. For example, OPOs are interested in pursuing process improvements related to allocation, including using innovative strategies for placing medically complex organs and algorithms for expedited allocation and organ offers. Allocation occurs between referral, approach, and authorization and impacts the Donation Rate. During our site visits, many OPOs discussed the technological enhancements and innovations they have already implemented to improve processes and outcomes. These include using various technologies/systems to pursue more donors from the donor pool and implementing Electronic Medical Record enhancements such as electronic referrals, alerts when clinical triggers are met, and remote chart reviews. A small number of OPOs also discussed transportation-related innovations that have helped address challenges and barriers, including owning and leasing donation-specific aircraft or couriers (Rahman et al., 2026a). A transparent Donation Rate would allow OPOs to identify the impacts of these changes over time by providing a more stable outcome variable for difference-in-differences calculations.

OPOs also emphasized the need for standardized definitions and criteria that can be applied in a consistent and equitable manner and reflected on how the current CMS approach to calculating the potential donor population negatively impacted their efforts to promote a scientifically valid and ethical approach to organ donation. They identified a need for metrics that are meaningful and consistent, as well as a shift toward objective, clearly defined, realistic, and easily measured metrics. This further emphasizes the need for metrics that capture processes and outcomes. Some OPOs expressed concern about using OPO self-reported data and the need to ensure accuracy in data collection from OPOs (Rahman et al., 2026a; Rahman et al., 2026c).

There is strong stakeholder interest in developing an outcome measure that accurately reflects OPO activities and their effectiveness in engaging the public, increasing donation, and improving transplant patient outcomes. This proposed Donation Rate measure will assist in achieving that goal and support adoption of best practices across the organ procurement community, ultimately increasing organ availability and saving more lives.

## References:

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule. Published in the Federal Register on December 2, 2020, as 85 Fed. Reg. 77898. [Federal Register: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.](#)

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

Rahman, M., Arellano, O., Lind, C., Newton, L., O'Connor, J., & Paraboschi, J. (2026a, April 7). *OPO site visit final report* [Internal document]. Econometrica, Inc., Bethesda, MD.

Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1-5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

### 3.1 Contributions Towards Closing Care Gaps

This domain is optional for the Spring 2026 cycle.

#### 4.1a Data Structure and Availability

The MCODE file is from vital statistics data, which is part of NVSS and managed by NCHS. The MCODE data presented no missing information and are available electronically.

All OPOs collect and track their data elements electronically in EDRs in structured fields and submit organ donor data to OPTN/SRTR. These data, collected by OPTN and managed by SRTR, are supplemented by data from CMS and the NTIS Death Master File (DMF). The SRTR data presented no missing information and are available electronically.

#### References:

National Technical Information Service. (n.d.). *Death master file (DMF)*. <https://dmf.ntis.gov/>.

Organ Procurement and Transplantation Network. (n.d.). Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/>.

#### 4.1b Implementation Costs and Burden

Our measure testing indicates that the burden associated with calculating this measure is minimal.

The proposed numerator definition aligns with data collection for SRTR's definition of a Donor, minimizing additional burden.

For the denominator, the measure relies on the MCODE NVSS dataset, which is collected by state vital records offices. Because these data do not require direct involvement from OPOs, the denominator component does not introduce added burden for them. The minimal cost of obtaining MCODE data and recalculating deaths by DSA is something that can be managed by AOPO on behalf of all OPOs.

#### **4.1c Confidentiality**

The data are collected by OPOs as part of their routine care, stored in secure electronic data record systems, and submitted to SRTR through a secure portal. For testing, the data from the MCODE and SRTR files did not include patient names or any other detailed information. We kept the data confidential in alignment with the DUAs that included a guarantee to store it in a secure location and not link the data files.

#### **4.3 Feasibility Informed Final Measure**

There are no feasibility issues associated with the dataset. The denominator for the Donation Rate is from the MCODE file, which is cleaned and validated by NCHS. The numerator uses SRTR files, and these are similarly cleaned and standardized and present no feasibility challenges. The only potential feasibility issue is if CMS fails to publish the hospital waivers each year in a timely manner. However, most OPOs are familiar with their waiver hospitals and could estimate the effect on their DSA if necessary.

#### **4.4 Proprietary Information**

Not a proprietary measure and no proprietary components

#### **5.1.1 Data Used for Testing**

The denominator uses the MCODE file from vital statistics data, which is part of NVSS and managed by NCHS. To obtain the dataset, Econometrica entered into a DUA with NCHS. The DUA explained our purposes for using the data, which included a replication of CMS measures and the current development of new measures. MCODE data include the number of potential organ donors in a DSA in a calendar year and their age, race, and gender.

The numerator for the Donation Rate used data from SRTR. SRTR receives data collected by other organizations, primarily OPOs and other participants in OPTN. Data that come from OPOs originate from EDRs. SRTR data also include the number of actual deceased donors in a DSA in a calendar year and their age. These data are supplemented by data from CMS and the NTIS DMF. To obtain a version of the data that would allow us to replicate CMS measures and develop new measures, Econometrica entered into a DUA with SRTR. However, the type of SRTR data used here are also available in OPO donor records and systems without a DUA. The interpretation and reporting of these data are the responsibility of the author(s) and should not be considered an official policy or interpretation of SRTR or the U.S. Government.

#### **5.1.1a Dates of Testing Data**

The SRTR and MCOB data used were for the calendar year (1/1 through 12/31) for years 2021 through 2024.

### 5.1.2 Differences in Data

The reliability testing used the same data that were used to construct this measure. No specific exclusions were made.

### 5.1.3 Characteristics of Measured Entities

There are 56 OPOs currently meeting the Conditions for Coverage under CMS regulations as of 2023 (CMS, 2020b). CMS categorizes OPOs by population size of their DSA. Six of the 56 OPOs volunteered to participate in measure testing by submitting anonymized patient data, data dictionaries, and definitions and by participating in surveys and discussions about their submitted data, definitions, data capture processes, and data quality checks.

Of the six test sites that contributed data, one was in the “less than 2.9 million” size, one was in the “2.9-5 million” size, one was in the “5-7.2 million” size, and three were in the “greater than 7.2 million” size (OPTN, 2025).

Our six test sites were from six states and included OPOs that were ranked as “underperforming” (three OPOs) and “passing” (three OPOs) under the current CMS performance tiers for the existing Donation Rate and Transplant measures (based on 2023 CMS data) (OPTN, 2025; CMS, 2025). Five of the 6 OPOs have DSA coverage in more than 1 state, bringing the total count of states in this analysis to 13 states.

Exhibit 4 in Attachment B includes the characteristics of the six test OPOs. The 6 sites are reasonably representative of the 56 OPOs, although no sites with a “failing” status from CMS were available to participate in the pilot. We actively sought to recruit these sites; several declined, citing the current pressure of CMS regulation and staffing shortfalls as a result of anticipated decertification.

#### References:

Centers for Medicare & Medicaid Services. (2020b). Medicare and Medicaid programs; organ procurement organizations conditions for coverage; revisions to the outcome measure requirements for organ procurement organizations. A rule by the Centers for Medicare & Medicaid Services. <https://www.federalregister.gov/d/2020-26329/p-195>.

Centers for Medicare & Medicaid Services. (2025, July). *OPO public performance report*. Quality, Certification & Oversight Reports. <https://qcor.cms.gov/OPOs>.

Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2023 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2025. Accessed February 2026. <https://srtr.transplant.hrsa.gov/annualdatareports>.

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## 5.1.4 Characteristics of Units of the Eligible Population

Please refer to Exhibit 5 in Attachment B for the OPO demographic information.

### 5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter-abstractor reliability), Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

### 5.2.2 Method(s) of Reliability Testing

Documentation of organ donation has been shown to be highly reliable and valid at (1) the patient or encounter level and (2) the population level.

#### **Person or Encounter Level**

The denominator data for this measure draw from the restricted-use MCODE mortality data from NCHS and NVSS. This data file provides mortality data by multiple causes of death for all deaths occurring within the United States. Each record is based on information abstracted from death certificates filed in vital statistics offices in each state and the District of Columbia. Records include 1 underlying cause and up to 20 additional contributing causes of death coded according to the International Classification of Diseases, Ninth Revision 1991-1998, and the Tenth Revision 1999 (ICD-9 and ICD-10). Variables describing infant cause of death, infant age, and geographic details are included.

To create the final MCODE dataset, NCHS uses the Automated Classification of Medical Entities (ACME) and Translation of Axis (TRANSAX) programs to parse and standardize cause-of-death data, creating “record axis” codes that resolve inconsistencies. “Entity axis” codes reflect the verbatim order on the certificate, whereas “record axis” codes are preferred for research because they reduce redundancies and standardize findings.

The reliability and validity, or overall quality, of death certificate data have been extensively studied and written about in the literature; therefore, we did not attempt to replicate studies of the reliability or validity of NVSS. Several well-known data collection and coding issues affect the quality and accuracy of U.S. death certificate data, particularly in the coding of cause-of-death information by medical examiners and the assignment of other demographic information. Variability in reporting practices among physicians and coroners can affect data quality, especially for conditions that are underreported or difficult to diagnose. Current estimates suggest that approximately 20 to 30 percent of death certificates have issues with completeness (NCHS, 2020). One study found that 20.1 percent of the frequently occurring patterns in death certificate data were discordant with expert knowledge data (Hoffman, 2018).

While the accuracy and quality of these records continue to evolve, there have also been ongoing efforts to progressively improve their accuracy and utility for public health purposes (NASEM, 2021). NCHS states that they are “always working towards 100% completeness and accuracy of death certificates.” They monitor the quality of the data with ongoing reviews of death certificates as they are received; follow up with state vital records offices to verify and correct inaccuracies;

provide trainings and tools for certifiers, such as online courses to improve cause-of-death reporting and a Cause of Death mobile app; and offer death certificate reporting guidance to help certifiers more accurately complete the cause-of-death section on death certificates.

Furthermore, periodic revisions to the ICD-10 classification (as well as ICD-9 and earlier revisions) used to show cause of death are made to incorporate and capture changes in medical knowledge. Studies assessing comparability between ICD revisions are routinely conducted as part of the implementation of each new revision (NCHS, 2024). The ICD-10 scheme used in the analysis for these measures has been in place since 1999, minimizing the risk of reliability or validity issues related to ICD codes.

We also explored the reliability and validity of SRTR data. SRTR data is often used in transplant-related studies (Wolfe et al., 2004) and is also used as a comparison point for new data sources (Dickinson et al., 2004). Most of the SRTR data comes from Organ Procurement and Transplant Network (OPTN) based registries from hospitals, as well as from organ procurement organizations (OPOs) and immunology laboratories (Leppke et al., 2013). OPTN data is linked via United Network for Organ Sharing (UNOS) to the Social Security Death Master File for validity (Massie et al., 2014). Notably, SRTR data is also used in reports to HRSA, organ allocation policy, and quality assurance surveillance for CMS. Though this data is not without issues (Malamon & Kaplan, 2023), those concerns have been underscored by validity checks and there has been active work to fix any data inconsistencies. Since the SRTR data includes all data on solid organ transplantation in the U.S. and partially comes from OPOs, this includes data from the OPOs included in our study.

### **Accountable Entity Level**

Reliability testing was conducted using the repeated split-sample methodology described by Nieser and Harris (2024), as recommended by the PQM Endorsement and Maintenance Guidebook (2025).

For each of the six OPOs and for each year in the range 2021-2024, the data used to compute the numerator (count of donations meeting all applicable inclusion and exclusion criteria, obtained from SRTR data) were repeatedly resampled to create pairs of half-sample datasets, with each record randomly assigned to one half-sample or the other. The number of repetitions was 200, which is the approximate size of the smallest OPO-year dataset used for reliability analysis. Each of the 200 half-samples of numerator data was then merged with denominator data (count of potential organ donor deaths meeting all applicable inclusion and exclusion criteria for the same OPO and year, obtained from MCODE data), and the Donation Rate was then computed for each half-sample. This allowed the creation of a dataset containing 200 records for each OPO and year, with each record containing the OPO and year, and the rates for each of the two half-samples.

The data for each of the 200 sets of OPO-year pairs were then analyzed separately to obtain the correlation between the rates of the two randomly assigned half-samples. The measure of correlation used was the intraclass correlation coefficient (ICC) for a one-way random effects model—ICC(1)—obtained from the covariance estimates provided by a hierarchical generalized linear model. The ICC(1) provides a measure of the total proportion of total variance of the Donation Rate that is explained by the OPO and year. (We do not currently have data from a sufficient number of OPOs to compute a statistically valid measure of correlation by OPO alone.)

The average value of ICC(1) across the 200 repetitions, which is the measure of reliability, was then computed.

## References:

Dickinson D, Bryant P, Williams M, Levine G, Lia S, Welch J, Keck B, Webb R. (2004) Transplant data: sources, collection, and caveats. *American Journal of Transplantation*, 4: 13-26.

Hoffman, R. A., Venugopalan, J., Qu, L., Wu, H., & Wang, M. D. (2018, August). Improving validity of cause of death on death certificates. *ACM BCB, 2018*,178–183. doi: 10.1145/3233547.3233581. PMID: 32558825; PMCID: PMC7302107.

Leppke S, Leighton T, Zaun D, Chen S, Skeans M, Israni A, Snyder J, Kasiske B. (2013) Scientific Registry of Transplant Recipients: Collecting, analyzing, and reporting data on transplantation in the United States. *Transplantation Reviews*, 27(2): 50-56.

Malamon JS, Kaplan B. Validation of the Integrity of the OPTN/UNOS Transplantation Registry Data. *Transplantation*. 2023 Dec 1;107(12):e324-e325. doi: 10.1097/TP.0000000000004793. Epub 2023 Sep 20. PMID: 37726887.

Massie AB, Kucirka LM, Segev DL. Big data in organ transplantation: registries and administrative claims. *Am J Transplant*. 2014 Aug;14(8):1723-30. doi: 10.1111/ajt.12777. Erratum in: *Am J Transplant*. 2014 Nov;14(11):2673. Kuricka, L M [corrected to Kucirka, L M]. Erratum in: *Am J Transplant*. 2014 Nov;14(11):2673. doi: 10.1111/ajt.13038. PMID: 25040084; PMCID: PMC4387865.

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<https://doi.org/10.17226/3395>.

National Center for Health Statistics (U.S.). (2020). *Understanding death data quality: Cause of death from death certificates*. National Center for Health Statistics. Retrieved March 26, 2025, from <https://www.cdc.gov/nchs/data/nvss/coronavirus/cause-of-death-data-quality.pdf>.

National Center for Health Statistics (U.S.). (2024, March 11). Comparability of cause-of-death between ICD revisions. National Center for Health Statistics. Retrieved March 26, 2026, from [https://www.cdc.gov/nchs/nvss/mortality/comparability\\_icd.htm](https://www.cdc.gov/nchs/nvss/mortality/comparability_icd.htm).

Nieser, K. J., & Harris, H. S. (2024). Comparing methods for assessing the reliability of health care quality measures. *Statistics in Medicine*, 43(23).

Partnership for Quality Measurement, Endorsement and Maintenance Guidebook, National Consensus Development and Strategic Planning for Health Care Quality Measurement, October 2025, p.71.

Wolfe R, Schaubel D, Webb R, Dickinson D, Ashby V, Dykstra D, Hulbert-Shearon T, McCullough K. (2004) Analytical approaches for transplant research. *American Journal of Transplantation*, 4 (Suppl. 9): 106–113.

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## 5.2.3 Reliability Testing Results

### Person or Encounter Level

Please refer to Section 5.2.2 Methods of Reliability Testing.

### Accountable Entity Level

The Donation Rate reliability as estimated by the average ICC(1) value has a mean value of 0.9592, with a 95-percent confidence interval of [0.9572, 0.9611].

## 5.2.4 Interpretation of Reliability Results

### Person or Encounter Level

Please refer to Section 5.2.2 Methods of Reliability Testing.

### Accountable Entity Level

The estimated Donation Rate reliability is 0.9592, which surpasses the minimum reliability threshold of 0.6. Therefore, this measure meets the CBE requirements for reliability.

## Table 2a. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Please refer to Section 5.2.2 Methods of Reliability Testing and Section 5.2.3 Reliability Testing Results.

## Table 2b. Accountable Entity Level Reliability Testing Results by Reliability Score

Please refer to Section 5.2.2 Methods of Reliability Testing and Section 5.2.3 Reliability Testing Results.

## 5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

## 5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

## 5.3.3 Method(s) of Validity Testing

### Person or Encounter Level

At the person level, reliability and validity are difficult to separate. Similar to the information provided for reliability, the denominator data for this measure draw from the restricted-use MCODE mortality data from NVSS and NCHS. This data file provides mortality data by multiple causes of death for all deaths occurring within the United States. Each record is based on information abstracted from death certificates filed in vital statistics offices in each State and the District of Columbia. Records include one underlying cause and up to 20 additional contributing causes of death coded according to the International Classification of Diseases, Ninth Revision 1991-1998, and the Tenth Revision 1999 (ICD-9 and ICD-10). Variables describing infant cause of death, infant age, and geographic details are included. To create the final MCODE dataset, NCHS uses ACME and TRANSAX programs to parse and standardize cause-of-death data, creating “record axis” codes that resolve inconsistencies. “Entity axis” codes reflect the verbatim order on the certificate, whereas “record axis” codes are preferred for research because they reduce redundancies and standardize findings.

The reliability of death certificate data has been extensively studied and written about in the literature; therefore, we did not attempt to replicate studies of the reliability or validity of NVSS. Several well-known data collection and coding issues affect the quality and accuracy U.S. death certificate data, particularly in the coding of cause-of-death information by medical examiners and the assignment of other demographic information. Variability in reporting practices among physicians and coroners can affect data quality, especially for conditions that are underreported or difficult to diagnose. Current estimates suggest that approximately 20 to 30 percent of death certificates have issues with completeness (NCHS, 2020). One study found that 20.1 percent of the frequently occurring patterns in death certificate data were discordant with expert knowledge data (Hoffman, 2018).

While the accuracy and quality of these records continue to evolve, there have also been ongoing efforts to progressively improve their accuracy and utility for public health purposes (NASEM, 2021). NCHS states that they are “always working towards 100% completeness and accuracy of death certificates” (NCHS, 2020). They monitor the quality of the data with ongoing reviews of death certificates as they are received; follow up with state vital records offices to verify and correct inaccuracies; provide trainings and tools for certifiers, such as online courses to improve cause-of-death reporting and a Cause of Death mobile app; and offer death certificate reporting guidance to help certifiers more accurately complete the cause-of-death section on death certificates.

Furthermore, periodic revisions to the ICD-10 classification (as well as ICD-9 and earlier revisions) used to show cause of death are made to incorporate and capture changes in medical knowledge. Studies assessing comparability between ICD revisions are routinely conducted as part of the implementation of each new revision (NCHS, 2024). The ICD-10 scheme used in the analysis has been in place since 1999, minimizing the risk of reliability or validity issues related to ICD codes.

For the SRTR Data (the numerator) we also explored reliability and validity of the data. SRTR data is often used in transplant-related studies (Wolfe et al., 2004) and is also used as a comparison point for new data sources (Dickinson et al. 2004). Most of the SRTR data comes from Organ Procurement and Transplant Network (OPTN) based registries from hospitals, as well as from organ procurement organizations (OPOs) and immunology laboratories (Leppke et al., 2013). OPTN data is linked via United Network for Organ Sharing (UNOS) to the Social Security Death

Master File for validity (Massie et al., 2014). Notably, SRTR data is also used in reports to HRSA, organ allocation policy, and quality assurance surveillance for CMS. Though this data is not without issues (Malamon & Kaplan, 2023), those concerns have been underscored by validity checks and there has been active work to fix any data inconsistencies.

### Accountable Entity Level

We considered both face validity, which is the assumption that the measure reflects what it says it does, and criterion validity.

**Face validity:** The data used for this measure comes from death certificates and the SRTR data. While there are other sources of in-hospital mortality, such as the State Inpatient files, mortality data is the best nationally comparative and consistent source of death data. The SRTR data provides information on the total number of donors and is the only source of data that contains donation and transplant information. We therefore believe the donation rate data has face validity, given the nature of the data sources.

**Criterion validity:** Criterion is the extent to which the measure relates to or predicts an outcome. Criterion validity includes both concurrent validity, which compares the measure in question to another outcome assessed at the same time such as from another data source, and predictive validity, which compares the measure to an outcome.

To test concurrent validity, we used the CMS Donation Rate measure. Our results were similar. The only differences in our definitions are an increase in the age threshold (to 80 years or younger) and the addition of exclusionary criteria; the latter caused a decrease in the denominator, and our findings remain in line with the CMS measure.

**Predictive Validity:** We understand the gold standard to demonstrate validity is to determine the degree to which the performance on the measure predicts an outcome. We used simple regression to compare the Donation Rate with the number of organs transplanted per 100 potential donors (see Table 1). As the Donation Rate increases, the number of organs per 100 potential donors increases. While a small N is a significant limitation of this analysis, we conducted it to ensure that all avenues for analysis were pursued.

**Table 1. Donation Rate vs. Transplant Rate, R-Squared Value = 0.648**

	OPO 1	OPO 2	OPO 3	OPO 4	OPO 5	OPO 6
Donation Rate	12	17	11	11	18	15
Transplanted Organs Per 100 Potential Donors	31	43	43	32	53	44

### References:

Dickinson D, Bryant P, Williams M, Levine G, Lia S, Welch J, Keck B, Webb R. (2004) Transplant data: sources, collection, and caveats. *American Journal of Transplantation*, 4: 13-26.

Hoffman, R. A., Venugopalan, J., Qu, L., Wu, H., & Wang, M. D. (2018, August). Improving validity

of cause of death on death certificates. *ACM BCB*, 2018, 178–183. doi: 10.1145/3233547.3233581. PMID: 32558825; PMCID: PMC7302107.

Leppke S, Leighton T, Zaun D, Chen S, Skeans M, Israni A, Snyder J, Kasiske B. (2013) Scientific Registry of Transplant Recipients: Collecting, analyzing, and reporting data on transplantation in the United States. *Transplantation Reviews*, 27(2): 50-56.

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Massie AB, Kucirka LM, Segev DL. Big data in organ transplantation: registries and administrative claims. *Am J Transplant*. 2014 Aug;14(8):1723-30. doi: 10.1111/ajt.12777. Erratum in: *Am J Transplant*. 2014 Nov;14(11):2673. Kuricka, L M [corrected to Kucirka, L M]. Erratum in: *Am J Transplant*. 2014 Nov;14(11):2673. doi: 10.1111/ajt.13038. PMID: 25040084; PMCID: PMC4387865.

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Wolfe R, Schaubel D, Webb R, Dickinson D, Ashby V, Dykstra D, Hulbert-Shearon T, McCullough K. (2004) Analytical approaches for transplant research. *American Journal of Transplantation*, 4 (Suppl. 9): 106–113.

### **5.3.4 Validity Testing Results**

Please refer to Section 5.3.3 Methods of Validity Testing.

### **5.3.5 Interpretation of Validity Results**

Please refer to Section 5.3.3 Methods of Validity Testing.

#### **5.4.1 Methods Used to Address Risk Factors**

No risk adjustment or stratification

#### **5.4.1b Rationale For No Adjustment or Stratification**

We did not risk-adjust this measure. We explored how this measure could be risk-adjusted on social or demographic factors across OPO DSAs and reviewed the literature, particularly as it relates to risk adjustment on social or demographic factors, in the Medicare and Medicaid program (CMS, 2023; CMS, 2025; ASPE, 2020; NQF, 2014). We considered the potential rationale for risk-adjusting based on nationally available data sources—such as race and gender, as well as indices such as the Area Deprivation Index—that would be available at the DSA level. We did not consider age because age is already included in the measure numerator and denominator.

We also asked OPOs and our TEP about their perspectives regarding risk adjustment for this measure (Rahman et al., 2026b; Rahman et al., 2026c). While there was agreement that risk adjustment would be desirable if it were feasible—particularly for comparing OPOs—there was also consensus that the most useful risk factors to adjust for would be structural factors within DSAs. These factors could include mean, minimum, and maximum travel time and distance to air transportation; whether state laws allow OPOs to rely solely on First Person Authorization (rather than requiring next-of-kin authorization) for donor authorization; and the number and types of transplant programs within 300 nautical miles of the OPO, which affect the likelihood that donated organs can be transplanted. We determined that these structural factors are not currently collected at a national level to be used for risk adjustment and would be better developed as independent structural measures over time. The Association of Organ Procurement Organizations has noted this recommendation and is working toward this goal. We also considered guidance from the literature and Medicare program materials, which indicated that outcome measures, especially those that are not composite patient safety measures, are not typically risk-adjusted (ASPE, 2020; Vogel & Chen, 2018). We noted that CMS does not risk-adjust its current version of the Donation Rate.

We also considered and explored the appropriateness of stratifying this measure by race and gender. However, we felt that stratification might unnecessarily complicate the interpretation of this measure and is better done on process measures, as recommended in the literature.

## References:

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Rahman, M., Arellano, O., & O'Connor, J. (2026b). *Organ Procurement Organization (OPO) performance measurement technical expert panel (TEP) meetings 1-4 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

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Vogel, W. B., & Chen, G. J. (2018). An introduction to the why and how of risk adjustment. *Biostatistics & Epidemiology*, 4, 84-97. <https://doi.org/10.1080/24709360.2018.1519990>.

### 6.1.1 Current Status

In use

### 6.1.2 Current or Planned Use(s)

Public Reporting, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

### 6.1.3 Program Details

Name of the program and sponsor

Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs)

URL of the program

<https://www.cms.gov/medicare/health-safety-standards/conditions-coverage-partic...>

Purpose of the program

The Centers for Medicare & Medicaid Services (CMS) is an Operating Division within the Department of Health and Human Services (HHS) responsible for administering the most extensive Federal healthcare programs, Medicare and Medicaid. CMS establishes Conditions for Coverage (CfCs) (Bryan et al., 2025; CFR, 2025; CMS, 2020) that OPOs must meet in order to participate in the Medicare and Medicaid programs. These regulations set forth the certification and re-certification processes, outcome requirements, and process performance measures for OPOs. The regulations are intended to promote competition between OPOs and satisfy requirements for process and outcome measures established by the National Organ Transplant Act of 1984 (NOTA, 1984).

### References:

CMS, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," 85 Federal Register 77898, December 2, 2020, <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid>



reporting; and regulatory and accreditation programs.

Because this is an outcome measure, we considered risk-adjusting this measure. We explored how this measure could be risk-adjusted on social or demographic factors across OPO DSAs and reviewed the literature, particularly as it relates to risk adjustment on social or demographic factors, in the Medicare and Medicaid program (CMS, 2023; CMS, 2025; ASPE, 2020; NQF, 2014). We considered the potential rationale for risk-adjusting based on nationally available data sources—such as race and gender, as well as indices such as the Area Deprivation Index—available at the DSA level. We did not consider age because age is already included in the measure numerator and denominator.

We also asked OPOs and our Technical Expert Panel (TEP) about their perspectives regarding risk adjustment for this measure (Rahman et al., 2026b; Rahman et al., 2026c). While there was agreement that risk adjustment would be desirable if feasible—particularly for comparing OPOs—there was also consensus that the most useful risk factors to adjust for would be structural factors within DSAs. These factors could include mean, minimum, and maximum travel time and distance to air transportation; whether state laws allow OPOs to rely solely on First Person Authorization (rather than requiring next-of-kin authorization) for donor authorization; and the number and types of transplant programs within 300 nautical miles of the OPO, which affect the likelihood that donated organs can be transplanted. We determined that these structural factors are not currently collected at a national level to be used for risk adjustment and would be better developed as independent structural measures over time. We also considered guidance from the literature and Medicare program materials, which indicated that outcome measures, especially those that are not composite patient safety measures, are not typically risk-adjusted (ASPE, 2020; Vogel & Chen, 2018). We noted that CMS does not risk-adjust its current version of the Donation Rate. We also considered and explored the appropriateness of stratifying this measure by race and gender. However, we concluded that stratification may unnecessarily complicate the interpretation of this measure and is better done on process measures, as recommended in the literature.

In discussions with OPOs, they reported that, if used appropriately, this measure could help establish best practices. These may include innovation, continuous improvement initiatives, improved efficiency, greater transparency, enhanced patient safety, and stronger collaboration between OPOs, donor hospitals, and transplant centers. Furthermore, decreases in the Donation Rate may indicate the presence of external factors, such as a decline in public trust, which impacts the number of organs donated and leads to further loss of life among patients awaiting transplants.

## References:

Centers for Medicare & Medicaid Services. (2023, August). *Risk adjustment and risk stratification in quality measurement*. Supplement material to the CMS Measures Management System (MMS) Hub. <https://mmshub.cms.gov/sites/default/files/Risk-Adjustment-in-Quality-Measurement.pdf>.

Centers for Medicare & Medicaid Services. (2025, May). *Ways to account for risk*. CMS Measures Management System (MMS). <https://mmshub.cms.gov/measure-lifecycle/measure-specification/risk-adjustment/ways-to-account-for-risk>.

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Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. (2020). *Second report to Congress on social risk factors and performance in Medicare's Value-Based Purchasing Program*. [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files/195191/Second-IMPACT-SES-Report-to-Congress.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/195191/Second-IMPACT-SES-Report-to-Congress.pdf).

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## 6.2.1 Actions of Measured Entities to Improve Performance

This measure provides OPOs with a picture of their overall Donation Rate, which is an outcome measure. Because this is an outcome measure, OPOs will need to look to upstream measures and opportunities to improve performance. Upstream measures include Referral Rate, Approach Rate, and Authorization Rate, as well as other factors that influence transplantation. OPOs will use Plan-Do-Study-Act quality improvement cycles to make tests of change, supported by national organizations as part of a quality improvement initiative. Some of the potential activities or tests of change that they could undertake include the following:

- Referral Rate Activities:
  - Engaging in collaboration-building activities, such as more frequent visits, with donor hospitals to ensure awareness and accessibility of the OPO staff.
  - Collaborating with donor hospitals on training for frontline staff on referral protocols.
  - Holding listening sessions with acute care and ICU staff regarding their barriers to referral or reasons for over-referral, and then making changes to protocols accordingly.
  - Providing job aids for frontline staff on referrals, such as pocket cards or instructional guides in nursing stations.
  - Engaging with hospital leadership to ensure that donation and referral are a priority for the hospital.
  - Enabling electronic referrals.
- Approach Rate Activities:
  - Maintaining a visible presence in donor hospitals to build relationships and collaboration.

- Evaluating all OPO staff orientation and training materials for the inclusion of effective approach strategies and communication techniques.
- Collaborating with donor hospitals to ensure that referral criteria are understood and utilized correctly.
- Utilizing readiness assessments and tools to evaluate family receptivity to donation.
- Offering structured Q&A content and supporting materials to improve family understanding and decision-making.
- Engaging hospital leadership to help establish donation as a priority in their facility.
- Performing in-depth case reviews of all missed approaches to identify patterns in the data and guide focused areas for training.
- Authorization Rate Activities:
  - Strengthening collaboration with hospital staff and clinical partners.
  - Enhancing community outreach and public education efforts.
  - Implementing family readiness and engagement assessments.
  - Conducting comprehensive case reviews for both authorized and not authorized outcomes.
  - Providing initial and ongoing staff training.
- Donor Care and Management:
  - Timely verification and testing.
  - Implementation of Donor Management Goals and related checklists.
  - Implementation of new and innovative technologies to improve quality (e.g., perfusion, NRP).
  - Advanced training in critical care for OPO staff.
  - Resource assessments (e.g., specialists, OR space).
  - Retrospective donor management case reviews.
- Adverse Event Prevention:
  - Frequent reviews of the overall donation process from referral to donation.
  - Frequent donor record audits and safety reviews.
  - Standardization of critical workflows and checklists.
  - Collaboration with hospital quality and safety staff.
- Allocation Processes:
  - Strengthening processes to prevent late declines and avoid organ discard.
  - Case reviews on allocation.
  - Collaboration and training with transplant center staff.
- Organ Transportation:
  - Implementation of real-time tracking to mitigate delays or mishandling.
  - Assessment of partnerships with air and ground transport providers.
  - Standardization of protocol for transportation coordination, including redundancy planning.
- Relationships with Transplant Centers:
  - Frequent collaborative case reviews.
  - Identification of dedicated champions for collaboration.
  - Strengthening the understanding of OPO processes through education and training.

During our engagement with OPOs, we have learned that they are receptive to quality improvement initiatives and strongly motivated to incorporate best practices into their organizations (Rahman et al., 2026a). OPOs are well-versed in quality assessment and

performance improvement (QAPI) activities, as required under the CMS Conditions for Coverage (42 CFR §486.348), which state that “the OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.” While challenges may arise, overcoming them will rely on clear communication and close collaboration between OPOs and hospital partners. Evidence supporting this is demonstrated in a study by Gibson et al. (2023), in which hospitals partnered with their OPO hospital liaison to review trauma mortality cases and performance improvement metrics. Through multidisciplinary collaboration, administrative engagement, staff education, and increased OPO program visibility, hospitals fostered a more donation-supportive culture, resulting in measurable improvements in donor conversion rates.

### References:

Centers for Medicare & Medicaid Services. 42 CFR §486.348. *Condition: Quality assessment and performance improvement (QAPI)*. Electronic Code of Federal Regulations. Updated 2025. Accessed April 2, 2026. <https://www.ecfr.gov/current/title-42/part-486/section-486.348>

Gibson, J. E., Campbell, T., Gibson, K., Kottemann, K., Krause, M. A., & Pack, L. (2023, June 15). Collaborative approach to organ donation in a level II trauma center. *AACN Adv Crit Care*, 34(2), 88–94. doi: 10.4037/aacnacc2023552.

Rahman, M., Arellano, O., Lind, C., Newton, L., O’Connor, J., & Paraboschi, J. (2026a, April 7). *OPO site visit final report* [Internal document]. Econometrica, Inc., Bethesda, MD.

### 6.2.2 Feedback on Measure Performance

CMS currently uses two related outcome measures—Donation Rate and Organ Transplantation Rate—to assess the performance and quality of OPOs and to determine whether an OPO can be recertified or decertified. Neither of the CMS measures underwent a consensus or endorsement process. Concerns regarding these existing measures were reported during the 2020 CMS rule-making public comment period, site visit interviews, and meetings with the TEP and OPO stakeholders (CMS Final Rule, 2020; Rahman et al., 2026a; Rahman et al., 2026b; Rahman et al., 2026c). In our assessment of more than 90 sets of public comments (drawn from the 2020 CMS rule public comment period, as well as from additional feedback obtained through our independent 2025 solicitation of public comments conducted as part of an environmental scan), we found general agreement that the Donation Rate should be adjusted to reflect success at converting potential organ donors into actual organ donors and that the denominator calculation should be distinct from the transplantation rate (O’Connor & Lind, 2025). The denominator pool should not include individuals with contraindications for donation, and it should include a consensus-based approach to age restriction. Commenters also noted that data should be taken from an accurate and reliable source, and the instructions for calculating the measures should be clear and transparent and use publicly available data files. Furthermore, the 2022 NASEM report recommended developing a Donation Rate measure derived from a consensus-based process. Finally, both commenters and NASEM warned against the use of a single Donation Rate measure or outcome measures alone for OPO certification, as not enough is known about the factors that impact population-level changes in Donation Rates over time.

OPO stakeholders expressed strong interest in improving the current Donation Rate measure so that it more accurately reflects their performance and helps them understand and address the factors that influence it. For example, OPOs are interested in pursuing process improvements related to allocation, including using innovative strategies for placing medically complex organs and algorithms for expedited allocation and organ offers. Allocation occurs between referral, approach, and authorization and impacts the Donation Rate. During our site visits, many OPOs discussed the technological enhancements and innovations they have already implemented to improve processes and outcomes. These include using various technologies/systems to pursue more donors from the donor pool and implementing Electronic Medical Record enhancements such as electronic referrals, alerts when clinical triggers are met, and remote chart reviews. A small number of OPOs also discussed transportation-related innovations that have helped address challenges and barriers, including owning and leasing donation-specific aircraft or couriers (Rahman et al., 2026a). A transparent Donation Rate would allow OPOs to identify the impacts of these changes over time by providing a more stable outcome variable for difference-in-differences calculations.

### References:

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule. Published in the Federal Register on December 2, 2020, as 85 Fed. Reg. 77898. <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>.

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

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Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1-5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

### 6.2.3 Consideration of Measure Feedback

The Donation Rate measure provides insight into the overall factors in a DSA that contribute to how often people who could be organ donors actually become organ donors. In engaging a range of stakeholders, including OPOs, there was agreement that this type of global outcome metric, if

used appropriately, supports OPOs in the adoption of effective strategies in donor management, staff training, and family communication (Rahman et al., 2026c).

The proposed Donation Rate measure is an adaptation of CMS, OPTN, and SRTR donation measures. A measure of Donation Rate using a more narrowly defined denominator allows OPOs to develop quality improvement efforts directed at increasing donations. We have adjusted the measure's denominator to further discriminate between medically acceptable and unacceptable donors. In doing so, we consulted with organ procurement and transplant medical directors to identify deaths with specific ICD-10-CM codes that are not acceptable for donation. This adjustment reduces the inclusion of medically unacceptable donors, which provides a more precise metric to guide OPO performance improvement and positively impact the number and quality of organs procured. We also proposed increasing the donor age to 80 years old to capture a larger potential donor population. This age commonly appeared in our testing data, and evidence from other countries, such as France, shows that transplant recipients can still experience substantial survival benefits from kidneys donated by older individuals (Aubert et al., 2019). We also consulted the TEP and medical professionals associated with organ donation, who agreed that if a person is otherwise healthy and up to about age 80, age would not rule out donation potential. While medical suitability for donation does decline with age in the general population, there is no commonly accepted medical or public health justification for using age 75 if the goal is simply to estimate the likely maximum potential donor population. Donation after 80 does occur, but it is significantly rarer than for the 80 and below age ranges.

Additionally, we discussed the exclusion criteria with the TEP, medical professionals, and OPOs and distributed it for comment to ensure that the list of exclusions reflected the current state of transplant science. For example, we discussed specific infectious diseases for inclusion and exclusion, as well as types of cancer, to arrive at the proposed method for calculating the numerator and denominator.

### References:

Aubert, O., Reese, P. P., Audry, B., et al. (2019). Disparities in acceptance of deceased donor kidneys between the United States and France and estimated effects of increased US acceptance. *JAMA Intern Med*, 179(10), 1365–1374. doi:10.1001/jamainternmed.2019.2322.

Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1-5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

## 6.2.4 Progress on Improvement

During our conversations with OPO stakeholders, we consistently heard concerns about the limitations of the current CMS Donation Rate measure and the need for an estimation of donation rate that better informs their work. The CMS measure is particularly harmful in part because of how difficult it is to calculate, but also because, under the 2020 CMS Final Rule, the Donation Rate and Organ Transplantation Rate are combined into a league scorecard. OPOs that do not rank within the top 25 percent (Tier 1) must either recompetete (Tier 2) or face potential replacement (Tier 3), based on their donation and transplantation rate performance (CMS Final

Rule, 2020). They also emphasized that a low Donation Rate under the CMS measures does not always reflect true underperformance; however, this nuance does not shield OPOs from review or the risk of decertification. They noted that, while organ donation is most directly tied to OPO activities, the measure is also influenced by transplant center behaviors and other external factors, creating a level of interdependence within the system (NASEM, 2022). Given these concerns, OPO stakeholders expressed strong interest in improving the current Donation Rate measure so that it more accurately reflects their performance and helps them understand and address the factors that influence it.

### References:

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. Final Rule. Published in the Federal Register on December 2, 2020, as 85 Fed. Reg. 77898. [Federal Register: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.](#)

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

## 6.2.5 Unexpected Findings

The proposed Donation Rate measure reflects many factors that contribute to an outcome of donation. The Donation Rate is a consistent indicator of OPO activities across DSAs and has internal and external validity, as the measurement is quantifiable and consistent across OPOs and uses data that is independently verified (NVSS files). Furthermore, decreases in the Donation Rate may indicate the presence of external factors such as a decline in public trust, which impacts the number of organs donated and leads to further loss of life among patients awaiting transplants (NASEM, 2022).

Based on OPO stakeholder insights, it is important to note that the universe of people who could be organ donors is not the number of people who are ultimately medically eligible and therefore represents an overestimation (Rahman et al., 2026c). Based on our literature review, there is currently no available data source for actual potential organ donors, as there is no single national source capturing deaths of patients on ventilators in hospitals. Furthermore, final medical eligibility is determined only after an individual who could be an organ donor undergoes repeated medical evaluation through laboratory and other clinical testing during the donation process. This information is not readily ascertainable or available on the death certificate; therefore, the use of the phrase “could be” is intentional to ensure that there is no misuse or misinterpretation of the measure results.

Despite these concerns, OPOs agreed that if there were a realistic and meaningful way of calculating the measure, and if misuse of the measure were avoided, it could help their overall understanding of their performance.

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## References:

National Academies of Sciences, Engineering, and Medicine. (2022). *Realizing the promise of equity in the organ transplantation system*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

Rahman, M., Arellano, O., & O'Connor, J. (2026c). *Organ Procurement Organization (OPO) stakeholder group meetings 1-5 summary overview* [Internal document]. Econometrica, Inc., Bethesda, MD.

### 6.2.5a Potential Unintended Consequences

We believe that the benefits of this measure outweigh the potential unintended consequences associated with it. We identified two potential unintended consequences through discussions with OPOs:

1. There is a risk that regulatory agencies will misunderstand the appropriate use of this measure. CMS currently uses a version of the Donation Rate in an all-or-nothing model for OPO certification. OPOs and other experts consider this use inappropriate for that purpose because there is no scientific basis for determining an appropriate level of performance, and comparing OPOs solely on this measure is not necessarily indicative of their performance. However, the ability for OPOs to better calculate and track their Donation Rate over time is a critical component of monitoring outcomes and collaborating with transplant centers to build shared understanding and accountability. It will also provide the basis for benchmarking performance over time.
2. OPOs noted that the Donation Rate measure may increase pressure on donor hospitals within their DSAs and on transplant centers to work with OPOs. While this consequence is not unintended, there is a risk that—if not communicated collaboratively and with clear limitations on its use—solely focusing on this outcome could promote unethical or unsafe donation practices or influence decisions about pursuing medically complex donors.

Overall, OPOs indicated that the benefits of this measure generally outweigh any potential unintended consequences.

### 7.1 Supplemental Attachment

[CBE-5604-7.1-Donation-Rate-Supplemental-Attachment-B-Spring2026.pdf](#)

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