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OPO Annual Public Aggregated Performance Report – User Guide: 2026 Certification Period

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1 OVERVIEW

The OPO Annual Public Aggregated Performance Report provides information used to assess the OPOs according to <u>42 CFR Part 486 [CMS–3380–F] RIN 0938–AU02 Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations.</u> Specific donation and transplantation rate requirements are described at 42 CFR 486.318(a)-(d).

In a four-year cycle, there are three interim and one final assessment. For instance, for the 2026 survey cycle, the interim assessment years are 2023, 2024, and 2025; 2026 is the final assessment year. Data used for each assessment come from the calendar year that ended two calendar years before the assessment year. So the 2023 assessment is based on data from 2021. Each subsequent report includes one additional year, ending with the report released in 2026. Note, OPOs receive reports in 2021 and 2022, that are not part of the 2026 survey cycle, but allow OPOs to begin evaluating their performance under the new metrics.

The OPO Annual Public Aggregated Performance Report includes the following sheets.

- **Methodology**: Brief description of methods for reference.
- **YYYY Assessment**: Donation and transplant rates for each OPO for each annual assessment period, how these compare to the cutoffs, and which tier the OPO falls into. The total number of OPOs in each tier is also shown.
- **YYYY--Waiver Counties:** List of hospital assignments for counties with CMS approved waivers. There is a separate sheet corresponding to each annual assessment.

The remainder of this OPO Annual Public Aggregated Performance Report--User Guide provides detailed definitions and methods used in the calculation of the statistics included in the report.

Throughout, the text shown in grey boxes explains where various elements are found in the report.

2 COMPONENTS OF OPO DONATION AND TRANSPLANT RATES

The number of potential donors in an OPOs donation service area (DSA) is the basis for the calculation of the OPO's donation and transplant rates. The donation rate compares the number of donors in the OPO's DSA to the number of potential donors, and the transplant rate compares the number of transplants (or kidney transplants for the Hawaii OPO) to the number of potential donors.

2.1 POTENTIAL DONORS

The number of potential donors for the OPO is the denominator for both the donation and transplant rates. It is defined as the number of inpatient deaths within the DSA among patients aged 75 and under with a primary cause of death that is consistent with organ donation.

Potential donors for each year of interest are identified using data obtained from the Centers for Disease Control and Preventions' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD) file, which provides county-level mortality data based on death certificates of U.S. residents. A description of the "all counties" version of the MCOD files used for the potential donor calculations is available at <u>https://www.cdc.gov/nchs/data/nvss/detailed-mortality-file-description.pdf</u>. These are restricted files--OPOs interested in obtaining the data must request the data directly for their individual use. For information on how to apply for access to the Detailed MCOD files, please go to: <u>https://www.cdc.gov/nchs/nvss/nvss-restricted-data.htm</u>.

The ICD-10 codes used to identify potential donor deaths are:

- I20–I25 (ischemic heart disease)
- I60–I69 (cerebrovascular disease)
- V01–Y89 (external causes of morbidity and mortality): Blunt trauma, gunshot wound, drug overdose, suicide, drowning, and asphyxiation

This definition of potential donors is based on the cause, age, and location consistent (CALC) organ donation methodology developed by Goldberg, et al ¹.

Potential donors are assigned to OPOs based on the county of the hospital in which death occurs. For most counties, the donor potential of the county is assigned to a single OPO. For counties where there is a hospital with a CMS approved waiver, the donor potential of the county is split between the OPO which has the county as part of its DSA and the OPO servicing the waiver hospital. For each county where there is a waiver hospital, we split the potential donors between the relevant OPOs according to the percent of Medicare inpatient deaths in the county at the waiver hospital(s) and at all other hospitals in the county in the same year. The same proportions are used for all potential donor age categories. For hospitals with missing county information, ZIP code to county mapping is used to identify the county.

For each assessment year included in the report, there is a corresponding 'YYYY--Waiver Counties' sheet, listing the hospital OPO assignments for counties with a waiver hospital for that assessment year (Tables 2 and 4 for 2021 and 2022 respectively). If the listed hospital has a waiver, the OPO the hospital is 'waived from' and the OPO it is 'waived to' are shown. If the hospital does not have a waiver, the table indicates that the hospital is retained by the original OPO. The last column in the table shows the percentage of the county's potential donors that are attributed to each hospital for the purposes of assigning potential donors to OPOs. For example, if there are four hospitals in a county, each with 25% of the potential donors, and one hospital has a waiver, 25% of the potential donor count is assigned to the OPO serving the waiver hospital and 75% is assigned to the original OPO.

2.2 DONORS

The number of donors is the numerator for the donation rate and is defined as the number of deceased individuals from whom Scientific Registry of Transplant Recipients (SRTR) data show that at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) was transplanted. Donors with pancreata or islet cells that are either recovered for research, or recovered for transplant but submitted

for research, are included. While only donors age 75 and younger are counted in the number of *potential donors*, there is no actual restriction on the age of donors. OPOs are allowed to procure organs from donors of all ages. Organs procured from individuals over age 75 potentially increase the OPO's rate since these are added to the numerator, but not the denominator.

2.3 ORGANS TRANSPLANTED

This is the numerator for the transplant rate and is defined as the number of organs transplanted from deceased donors from SRTR data. Pancreata and islet cells that are either recovered for research or recovered for transplant but submitted for research, are also included. Table G1 below shows how transplanted organs are counted to calculate the transplant rate.

| Organ Type | Number of Organs Transplanted | Maximum Number for Organ Type |
|-----------------------------------|-------------------------------------|-------------------------------------|
| Right or Left Kidney | 1 | 2 |
| Right and Left Kidney | 2 | |
| Double/En-Bloc Kidney | 2 | |
| Heart | 1 | 1 |
| Intestine | 1 | 2 |
| Intestine Segment 1 or Segment 2 | 1 | |
| Intestine Segment 1 and Segment 2 | 2 | |
| Liver | 1 | 2 |
| Liver Segment 1 or Segment 2 | 1 | |
| Liver Segments 1 and Segment 2 | 2 | |
| Right or Left Lung | 1 | 2 |
| Right and Left Lung | 2 | |
| Double/En-bloc Lung | 2 | |
| Pancreas | 1 | 2 |
| Pancreas Segment 1 or Segment 2 | 1 | |
| Pancreas Segments 1 and Segment 2 | 2 | |

Table G1. Counting Organs Transplanted for the Transplant Rate.

3 OPO PERFORMANCE MEASURES

OPOs are assessed based on their donation and transplant rates. The calculations of these rates are summarized in Table G2 and described in more detail in the sections below. The donation rate used for assessment is unadjusted and applies to all OPOs. There are two transplant rates utilized. The OPO serving Hawaii is assessed based on the unadjusted kidney transplant rate while all other OPOs are assessed based on the age-adjusted transplant rate, which is an adjusted rate that includes all organs.

| Performance Measure | Denominator | Numerator | OPOs Assessed |
|-------------------------------------|------------------|----------------------|--------------------|
| Donation Rate (unadjusted) | Potential Donors | Donors | All OPOs |
| Age-Adjusted Transplant Rate | Potential Donors | Transplanted Organs | All but Hawaii OPO |
| Kidney Transplant Rate (unadjusted) | Potential Donors | Transplanted Kidneys | Hawaii OPO only |

Table G2: Overview of OPO Performance Measures

3.1 DONATION RATE

The **national donation rate** is an unadjusted rate, defined as the total number of donors in the nation per 100 total potential donors in the nation.

National Donation Rate = 100*((# donors in all OPOs) / (# potential donors in all OPOs))

The **OPO donation rate** is an unadjusted rate, defined as the total number of donors in the OPO per 100 total potential donors in the OPO's DSA.

OPO Donation Rate = 100*((# donors in the OPO) / (# potential donors in the OPO))

The **upper limit of the one-sided 95% confidence interval for the OPO's Donation Rate** is the value that is compared to the national median and top 25 percent cutoffs described in section 6 below. It is calculated as:

$$U = \min\left\{1, \frac{2np+z^2 + [z\sqrt{z^2 - \frac{1}{n} + 4np(1-p) - (4p-2)} + 1]}{2(n+z^2)}\right\},\$$

where n is the OPO's number of potential donors, p is the OPO's donation rate as a proportion of 1, and z=1.645 for a one-sided 95% confidence interval.

For each assessment year, there is a corresponding sheet named 'YYYY Assessment', The first table in each assessment sheet show the national donation rate for the assessment year (Tables 1a and 3a for 2021 and 2022 respectively). The second table in each (Tables 1b and 3b) show the donation rate and the upper limit of the one-sided 95% confidence interval of the donation rate for each OPO in the assessment year.

3.2 AGE-ADJUSTEDTRANSPLANT RATE

The **national transplant rate** is an unadjusted rate, defined as the total number of organs transplanted in the nation per 100 total potential donors in the nation.

National Transplant Rate = 100*(# transplants in all OPOs) / (# potential donors in all OPOs)

The **OPO observed transplant rate** is also unadjusted and is calculated as the number of organs transplanted per 100 potential donors in the OPO's DSA.

OPO Observed Transplant Rate = 100*(# transplants in the OPO)/(# potential donors in the OPO)

The OPO transplant rate is adjusted to account for differences in the age distribution of each OPO's potential donor population. This is done using indirect standardization, where an OPO's observed

Produced by The University of Michigan Kidney Epidemiology and Cost Center

unadjusted transplant rate is compared to an expected transplant rate based on national age-specific transplant rates.

Fifteen age categories are used for the adjusted transplant rate calculation: <1, 1-5, 6-11, 12-17, 18-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-75. Transplanted organs are categorized based on the age of the deceased donor and potential donors are categorized based on age at death. An age-specific national transplant rate (not shown in the report) is calculated for each age group, where only organs transplanted and potential donors from that age group are counted. Because potential donors are restricted to those aged 75 and below but transplanted organs include organs from donors of all ages, the rate for the 70-75 age group is the number of transplants from donors aged 70 and above divided by the number of potential donors aged 70-75.

The OPO expected transplant rate is calculated as

$$\sum_{g=1}^{G} d_g R_g \bigg/ \sum_g d_g$$

where d_g is the number of potential donors in the OPO in age group g, R_g is the age-specific national transplant rate in age group g, and $\sum_{g} d_{g}$ is the OPO's total number of potential donors. The age-specific national transplant rates by age group (R_g) are provided in Table G3 below.

Table G3: National Age-Specific Transplant Rates per 100 Potential Donors, 2020 (used for 2022 Assessment)

| Age | Transplant Rate |
|-------|----------------------------|
| Group | (per 100 potential donors) |
| < 1 | 71.73 |
| 1-5 | 119.11 |
| 6-11 | 171.38 |
| 12-17 | 189.07 |
| 18-24 | 181.50 |
| 25-29 | 166.17 |
| 30-34 | 146.26 |
| 35-39 | 119.76 |
| 40-44 | 91.23 |
| 45-49 | 62.21 |
| 50-54 | 39.80 |
| 55-59 | 26.13 |
| 60-64 | 10.61 |
| 65-69 | 4.20 |
| >70 | 1.35 |

The expected transplant rate can be interpreted as what an OPO's transplant rate would be if each of its age-specific transplant rates were equal to the corresponding national age-specific transplant rate. The variation in expected transplant rates between OPOs is based solely on differences in the age distribution of the potential donor population.

The age-adjusted transplant rate for the OPO is calculated as the ratio of the OPO's observed transplant rate to the OPO's expected transplant rate multiplied by the national unadjusted transplant rate.

OPO Age-Adjusted Transplant Rate = (Observed / Expected)* National Transplant Rate

The **upper limit of the one-sided 95% confidence interval** for the OPO's age-adjusted transplant rate is the value that is compared to the median and top 25 percent cutoffs. It is calculated as:

$$\mathbf{U} = \min\left\{1, R + z * \sqrt{\frac{P^2}{E^2} * \frac{\mathbf{O}}{\mathbf{d}}}\right\},\,$$

where R is the OPO age-adjusted transplant rate, z=1.645 for a one-sided 95% confidence interval, P is the unadjusted national transplant rate, E is the OPO expected transplant rate, O is the OPO's observed unadjusted transplant rate, and d is the OPO's number of potential donors.

In the 'YYYY Assessment' sheets, Tables 1a and 3a show the national transplant rate and Tables 1b and 3b show the expected, observed, and age-adjusted transplant rates and the upper limit of the one-sided 95% confidence interval of the age-adjusted transplant rate for each OPO. The OPO serving Hawaii does not appear in this table.

3.3 KIDNEY TRANSPLANT RATE

Due to the geographic challenge of placing non-renal organs, the OPO serving Hawaii is assessed based on the unadjusted kidney transplant rate.

The **national kidney transplant rate** is an unadjusted rate, defined as the total number of kidneys transplanted in the nation per 100 total potential donors in the nation. Age-specific national kidney transplant rates are not calculated.

National Kidney Transplant Rate =

100*(# kidney transplants in all OPOs) / (# potential donors in all OPOs)

The **OPO kidney transplant rate** is the number of kidneys transplanted per 100 potential donors.

OPO Kidney Transplant Rate =

100*(# kidneys transplants in the OPO)/(# potential donors in the OPO)

The **upper limit of the one-sided 95% confidence interval for the OPO kidney transplant rate** is the value that is compared to the median and top 25 percent cutoffs for the Hawaii OPO. It is calculated as:

$$U = \frac{0+1}{N} \left(1 - \frac{1}{9*(0+1)} + \frac{z}{3*\sqrt{0+1}}\right)^3,$$

where O is the number of kidneys transplanted, N is the number of potential donors, and z=1.645 for a one-sided 95% confidence interval.

In the 'YYYY Assessment' sheets, Tables 1a and 3a show the national kidney transplant rate and Tables 1c and 3c show the kidney transplant rate and the upper limit of the one-sided 95% confidence interval of the kidney transplant rate for the OPO serving Hawaii.

4 OPO ASSESSMENT

The donation rates and organ transplantation rates in each OPO are separately ranked to determine the median and top 25 percent cutoffs for assessment. The cutoffs used for assessment in a particular year are generated using the rates established in the prior year. The upper limit of the one-sided 95% confidence interval of the individual OPO donation rate is compared to the donation rate cutoffs and the upper limit of the one-sided 95% confidence interval of the individual OPO transplant rate is compared to the transplant rate cutoffs in order to designate a tier for each OPO.

4.1 MEDIAN AND TOP 25 PERCENT CUTOFFS

The median and top 25 percent cutoff values are determined separately for each rate (donation rate, standardized transplant rate, kidney transplant rate). The cutoffs for a particular rate are based on the distribution of OPO values for that rate from the prior year. For instance, the 2019 donation rate cutoffs are determined from the 2018 OPO donation rates. Note that although only the Hawaii OPO is assessed based on kidney transplant rates, the kidney transplant rate cutoffs are calculated based on kidney transplant rates for all OPOs. Similarly, although the Hawaii OPO is not assessed on the standardized transplant rate, the standardized transplant rate cutoffs are calculated based on all OPOs (including Hawaii).

The **median cutoff** for the donation rate is defined as the middle OPO donation rate from the prior year or, when the total number of OPOs is even, as the average of two middle rates. The median cutoffs for the standardized transplant rate and kidney transplant rates are calculated similarly.

The **top 25 percent cutoff** is calculated as the total number of DSAs multiplied by 0.25 and rounded to the closest integer (0.5 rounds to the higher integer). The donation rates in each DSA are ranked separately and the top 25 percent threshold rate is the rate that corresponds to that integer when counting down the ranking. For example, in 2018 there were 58 OPOs, so the top 25 percent cutoff is the 15th highest OPO rate, and the median is the average of the middle two OPO rates.

In the 'YYYY Assessment' sheets, Tables 1a and 3a show the national donation and transplant rates as well as the corresponding top 25 percent and median cutoff values. Tables 1b-c and 3b-c show the donation rate and transplant rates for each OPO and the upper limits of the one-sided 95% confidence interval for each rate. If the upper limit of the one-sided 95% confidence interval for transplant rate is below the corresponding top 25 percent cutoff, but at or above the median cutoff value, then the rate and upper confidence limit are highlighted in yellow. If the upper limit of the one-sided 95% confidence interval for the OPO's donation or transplant rate is below the corresponding top 25 percent cutoff, the upper limit of the one-sided 95% confidence limit are highlighted in yellow. If the upper limit of the one-sided 95% confidence interval for the OPO's donation or transplant rate is below the corresponding median cutoff, the donation rate and upper confidence limit are highlighted in red.

Tables 1b-c and 3b-c also show the number of additional donors needed for the upper limit of the 95% confidence interval of the OPO donation rate to meet the median and top 25% donation rate cutoffs. The number of additional organs needed for the upper limit of the 95% confidence interval of the OPO transplant rate to meet the median and top 25% transplant rate cutoffs are also shown. At the top of this table, the total number of additional donors and organs needed for all OPOs combined (except the OPO in Hawaii) to meet the median and top 25% cutoffs is reported. For the Hawaii OPO, the number of additional kidneys needed to meet the kidney transplant rate cutoffs are shown rather than the number of additional organs.

4.2 TIERS

Based on the upper limit of the one-sided 95% confidence interval for both the donation and transplant rate, each OPO is placed into one of the following three tiers:

- 1. **Tier 1 OPOs** have the upper 95% confidence limit at or above the top 25 percent cutoff for both the donation and transplant rate.
- 2. **Tier 2 OPOs** have both the upper 95% confidence limits at or above the median cutoff, but at least one upper 95% confidence limit below the 25 percent cutoff.
- 3. Tier 3 OPOs have one or more upper 95% confidence limits below the median cutoff.

In the 'YYYY Asssessment' sheets, the tier for each OPO is shown in the far right hand side of Tables 1b and 3b. Visually, if either rate is highlighted in red, the OPO is in Tier 3; if neither is highlighted red but at least one is highlighted in yellow, the OPO is in Tier 2; and if neither are highlighted, the OPO is in Tier 1. The tier for each OPO from prior assessments are also shown in these tables to make comparisons across assessment years easier. Figures 1 and 2 show the tier distribution of all OPOs.

5 REPORTING PERIODS

Reporting periods for each annual assessment during the 2026 certification period are shown in Table G4 below. The reporting periods are dictated by data availability. As described above, the donor potential for each OPO is derived from CDC NCHS MCOD files with adjustments for waiver hospitals calculated based on Medicare inpatient deaths. The number of donors and transplants in an OPO is obtained from SRTR data. MCOD files for a particular calendar year are released approximately one year after the end of that calendar year. SRTR and Medicare inpatient claims data for a particular calendar year are available more quickly, but rates cannot be calculated until MCOD files are available.

Table G4: Reporting Periods and Data Availability for the Annual Assessments for the 2026 Certification

 Period

| | Data Period for Top | Data Sources and Periods | | | |
|--------------------|---|---|--------------------------------------|------------------------------------|--|
| Assessment Year | 25% and Median Cutoff values for Upper Limit of the one-sided 95% CI | Donors and Transplants | Potential Donors | Publication Date | |
| CY2021 | Based on 2018 rates (not published) | CY2019 data submitted to SRTR as of May 31, 2021 | CY2019 deaths from NCHS MCOD file | July 2021 (first public report) | |
| CY2022 | Based on 2019 rates published in 2021 | CY2020 data submitted to SRTR as of December 31, 2021 | CY2020 deaths from NCHS MCOD file | Spring 2022 | |

6 **REFERENCES**

1. Goldberg D, Karp S, Shah MB, Dubay D, Lynch R, "Importance of incorporating standardized, verifiable, objective metrics of organ procurement organization performance into discussions about organ allocation," Am J Transplant. 2019;00: 1–6.