

Attachment B

Exhibits for the Rate of the Number of Organ Donors to the Potential Donors in an Organ Procurement Organization's (OPO) Donation Service Area (DSA) in a Calendar Year

CBE ID #5604, Full Measure Submission, Spring 2026

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Measure Definitions

To facilitate uniformity and standardization in the proposed measures, the following list of definitions were developed in cooperation with Organ Procurement Organization (OPO) subject matter experts.

Exhibit 1: Measure Definitions

Term	Definition
Approach	<p>Any type of conversation in person, over the telephone, or via telehealth with the intent to make donation a possibility after preliminary suitability has been determined by the OPO staff. This includes situations where the:</p> <ul style="list-style-type: none">• Patient appears to meet DBD criteria but is not formally declared;• Patient is declared to be brain dead and appears to be a suitable donor (at least one organ); or• OPO has determined patient is a suitable DCD candidate and has talked to family about organ donation. <p>This definition does not change regardless of outcome or rule out circumstances (e.g., family declines, patient expiration, medical examiner denial, or other rule-out status). This does not include courtesy calls where a family has requested information about donation, but the OPO has already chosen not to investigate further or pursue donation.</p>
Adverse Event	<p>Adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable donor for whom authorized donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended beneficiary, or an organ infected with a transmissible disease that should have been identified by the OPO prior to transplant.</p>
Authorization	<p>Written first-person authorization (donor designation), or agreement by the next of kin or by Uniform Anatomical Gift Act hierarchy of a donor to continue with first-person authorization for organ donation, or agreement by the next of kin on behalf of a donor to donate organs.</p>
Calendar Year	<p>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. For Multiple Cause of Death (MCOB) and Scientific Registry of Transplant Recipients (SRTR) data, a death is attributed to the calendar year based on the time of death as recorded on the death certificate.</p>
Contraindications to Donation	<p>See Potential Donor Population.</p>

Term	Definition
Donation Service Area (DSA)	A CMS designated geographical region where the OPO is responsible for coordinating organ donation. Hospitals may request a CMS waiver to participate in a DSA other than the one where they are geographically located.
Donor	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.
Donor Hospital	A hospital that has a signed agreement with an OPO to participate in referrals of organ donors .
Donor With Transplanted Organs	A deceased individual from whom at least one organ was recovered for transplant and transplanted into a recipient.
Eligible Death	See Potential Donor Population .
Hospital Waivers From Donation Service Area	Hospitals with a written waiver from CMS to work with an OPO other than the OPO in their geographic DSA .
Multiple Cause of Death File	Mortality data from the National Center for Health Statistics (NCHS) based on death certificate data for all deaths occurring in the United States. The provisional and final versions of this data are available at https://wonder.cdc.gov/mcd.html .
Organ	Human kidney, heart, lung, liver, pancreas, intestine, or a vascularized composite allograft .
Organs Available for Transplant	See Recovered Organs .
Organs Recovered for Research	The number of organs recovered and placed for research at an institution or organization that has an ongoing program of research to improve transplantation or support the discovery of cures for organ-related conditions, such as diabetes.
Potential Donor	A hospitalized patient that meets the following clinical criteria for donation: <ul style="list-style-type: none"> • Brain death or imminent death from severe brain injury or trauma, cerebrovascular insult, anoxic injury, amyotrophic lateral sclerosis, or • Assist device dependent (e.g., extracorporeal membrane oxygenation (ECMO)), or • Referred as outlined in each OPO to Hospital Memorandum of Understanding (MOU).¹

¹ OPOs maintain MOUs with donor hospitals regarding hospital notification of imminent deaths. These MOUs are specific to each hospital and generally require hospitals to make referrals within 1 to 3 hours of a ventilated patient meeting any of the following established clinical triggers and prior to the withdrawal of mechanical and/or pharmacological support: (a) patient with a neurological and/or life-threatening injury, (b) loss of neurological function without sedation, (c) patient meeting a Glasgow Coma Scale (GCS) of 5 or less, (d) anticipated family meeting to discuss end-of-life care, or (e) prior to the discontinuation of ventilator support, the family asks to discuss donation options.

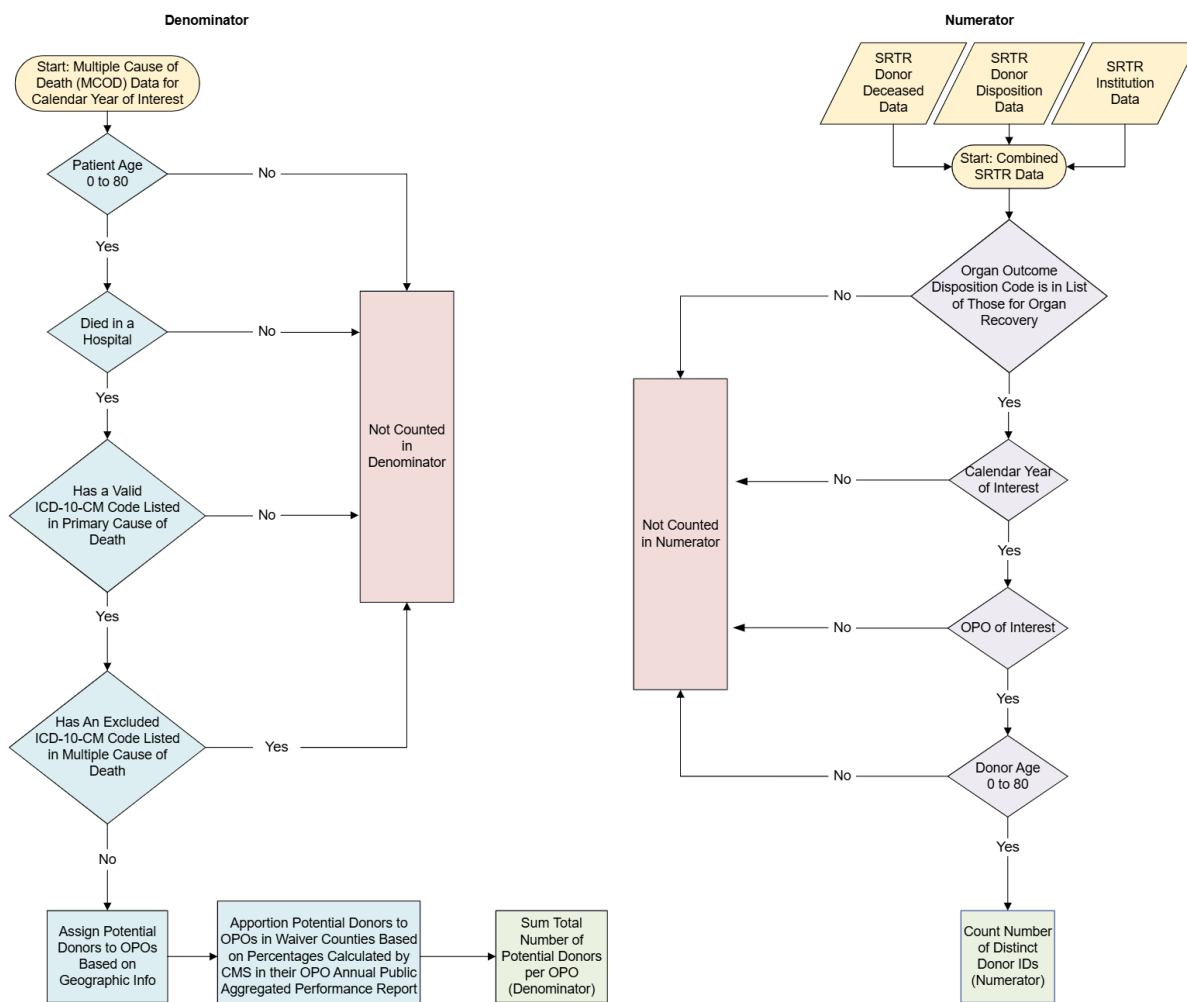
Potential Donor Population	<p>The potential donor population is calculated by using the NCHS Provisional National Vital Statistics System (NVSS) Multiple Cause of Death (MCOD) file and following these steps:</p> <ul style="list-style-type: none"> • Determine which deaths are within a DSA. • Exclude deaths of anyone: <ul style="list-style-type: none"> ◦ Over the age of 80; or ◦ With no discernible cause of death; or ◦ Who died outside a hospital. • Identify deaths with one of the following ICD–10–CM codes listed as the primary cause of death: <ul style="list-style-type: none"> ◦ 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. • From that pool of deaths, remove any deaths with any of the following ICD–10–CM codes listed among any of the multiple causes of death: <ul style="list-style-type: none"> ◦ Bacterial: <ul style="list-style-type: none"> ▪ A15-A19, B90 (tuberculosis) ▪ K46.1, K45.1 (gangrenous bowel) ▪ K63.1 (perforated bowel) ▪ A40-A41 (intra-abdominal sepsis) ◦ Viral: <ul style="list-style-type: none"> ▪ B20 (HIV infection by serologic or molecular detection)² ▪ 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: <ul style="list-style-type: none"> ▪ B45 (active infection with cryptococcus) ◦ Parasites: <ul style="list-style-type: none"> ▪ B55 (leishmania) ▪ B78.7 or B78.9 (strongyloides - widespread infection) ▪ B50-B54 (malaria (plasmodium sp.)) ◦ Prion: <ul style="list-style-type: none"> ▪ 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:
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Term	Definition
	<ul style="list-style-type: none"> ▪ C90.1, C91-C95 (leukemia) ▪ C81 (Hodgkin's disease) ▪ C82-C88 (lymphoma) ▪ C90.0 (multiple myeloma)
Recovered Organs	Organs recovered for the purpose of transplant, regardless of whether transplanted or used successfully.
Referral	The telephonic or electronic notification by a donor hospital of a potential donor based on clinical criteria. A referral is attributed to a calendar year based on the date of the referral, not the date of death. Referred potential donors are counted as referrals regardless of whether the referral was made using accurate clinical criteria for donation (donor referral triggers).
Registration	The written provision of first-person authorization to a state, other legally recognized registry, physician, or hospital of the person's intent or wish to become an organ donor .
Terminal Conversation	See Approach .
Transplant	<p>Organ transplants include solid organ transplants and islet infusions. An organ transplant begins at the start of organ anastomosis or the start of an islet infusion.</p> <p>An organ transplant procedure is complete when any of the following occurs:</p> <ul style="list-style-type: none"> • The chest or abdominal cavity is closed and the final skin stitch or staple is applied. • The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed. • The islet infusion is complete.
Vascularized Composite Allograft	A body part that includes multiple types of tissue, such as skin, bone, muscle, nerves, and blood vessels (see organ).

² HIV is not a contraindication to donation where HIV-positive donors and donor organs are able to be matched with an HIV-positive recipient. Therefore, we propose excluding HIV-positive donors from the potential donor population count for the purposes of calculation, because this would have a neutral impact on the calculations of the measure that utilizes this definition.

1.18a Measure Score Calculation Diagram

Exhibit 2: Measure Score Calculation Diagram



Donation Rate Per 100:

$$\frac{\text{Total Number of Donors for OPO in Calendar Year}}{\text{Total Number of Potential Donors for OPO in Calendar Year}} \times 100$$

See measure specifications for detailed coding and definitions.

2.4 Performance Gap

Exhibit 3: Donation Rates by OPO

Donation Rate	OPO 1	OPO 2	OPO 3	OPO 4	OPO 5	OPO 6
Measure Rate per 100	11.57	17.35	11.47	10.82	17.82	14.96
N of Entities	1	1	1	1	1	1

Donation Rate	OPO 1	OPO 2	OPO 3	OPO 4	OPO 5	OPO 6
N of Persons Numerator*	1,343	2,741	523	1,009	1,130	717
N of Persons Denominator*	11,604	15,800	4,558	9,329	6,341	4,794

* These are counts where the age is not missing and the age is 0 to 80 years old.

5.1.3 Characteristics of Measured Entities

Exhibit 4: OPO Characteristics

OPO Performance Tiers	Testing OPOs	All OPOs
1 – Passing	3	30
2 – Underperforming	3	16
3 – Failing	0	10
OPO Population Sizes		
Less than 2.9 million	1	13
2.9 to 5 million	1	13
5 to 7.2 million	1	13
Greater than 7.2 million	3	17
OPO Locations		
States and territories*	6	56

* OPOs provide donation services across all 50 states, plus the District of Columbia, the U.S. Virgin Islands, and Puerto Rico.

5.1.4 Characteristics of Units of the Eligible Population

Exhibit 5: OPO Demographic Table (2021–2024, Ages <= 80)

Age	SRTR		MCOD Potential Donors (Donation Rate)	
	Count	%	Count	%
0 to less than 1	55	0.74	203	0.39
1 to 17	402	5.39	898	1.71
18 to 24	582	7.80	1,254	2.39
25 to 69	6,195	83.01	28,388	54.15
70 to 75	159	2.13	11,124	21.22
76 to 80	70	0.94	10,558	20.14
Total	7,463	100	52,426	100

	SRTR		MCOB Potential Donors (Donation Rate)	
Race	Count	%	Count	%
Non-Hispanic White	5,308	71.12	37,204	70.97
Non-White*	2,155	28.88	15,221	29.03
Unknown	N/A	N/A	N/A	N/A
Total	7,463	100	52,426	100
Gender	Count	%	Count	%
Female	2,912	39.02	19,133	36.49
Male	4,551	60.98	33,293	63.51
Unknown	N/A	N/A	N/A	N/A
Total	7,463	100	52,426	100

* Due to external factors, "Hispanic" was coded as a mutually exclusive race and included in the "Non-White" counts.

Acronyms

Exhibit 6: Acronym List

Acronym	Definition
ACIN	AOPO Confirmation Information Network
AHRQ	Agency for Healthcare Research and Quality
AOPO	Association of Organ Procurement Organizations
API	Application Programming Interface
ASPE	Office of the Assistant Secretary for Planning and Evaluation
BD	Brain Death
CBE	Consensus-Based Entity
CMS	Centers for Medicare & Medicaid Services
DBD	Donation after Brain Death
DCD	Donation after Circulatory Death
DCU	Donor Care Unit
DMG	Donor Management Goals
DSA	Donation Service Area
DUA	Data Use Agreement
ECMO	Extracorporeal Membrane Oxygenation
EDR	Electronic Donor Record
EHR	Electronic Health Record

Acronym	Definition
EMS	Emergency Medical Services
FPA	First-Person Authorization
FRaT	Family Readiness Assessment Tool
GCS	Glasgow Coma Scale
HCT	Health Care Team
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HRSA	Health Resources & Services Administration
ICC	Intraclass Correlation Coefficient
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
MCOD	Multiple Cause of Death
ME	Medical Examiner
MOU	Memorandum of Understanding
NASEM	National Academies of Sciences, Engineering, and Medicine
NCHS	National Center for Health Statistics
NRP	Normothermic Regional Perfusion
NTIS	National Technical Information Service
NVSS	National Vital Statistics System
OPO	Organ Procurement Organization
OPTN	Organ Procurement & Transplantation Network
OR	Operating Room
QA	Quality Assurance
SRTR	Scientific Registry of Transplant Recipients
TEP	Technical Expert Panel
UAGA	Uniform Anatomical Gift Act