Attachment B

Exhibits for the Rate of Referred Patients that are Approached for an Organ Donation in the Organ Procurement Organization's (OPO) Donation Service Area (DSA) in a Calendar Year

CBE ID #5602, Full Measure Submission, Spring 2026

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Measure Definitions

Exhibit 1: 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.

Term	Definition
Approach	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: • 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. 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.
Adverse Event	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.
Authorization	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.
Calendar Year	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 (MCOD) 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.
Contraindications to Donation	See Potential Donor Population.

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 allograph.
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: • 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.

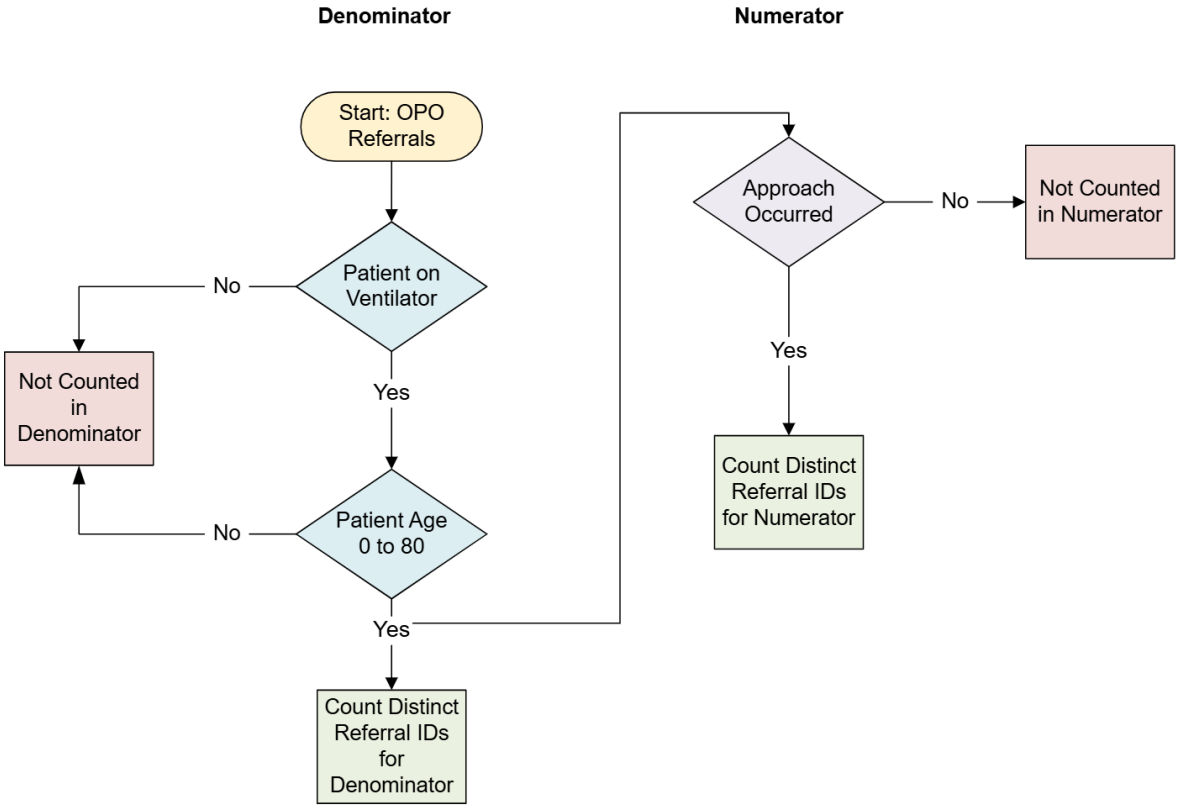
Potential Donor Population	The potential donor population is calculated by using the NCHS Provisional National Vital Statistics System (NVSS) Multiple Cause of Death (MCOD) file and following these steps:
	• Determine which deaths are within a DSA.
	• Exclude deaths of anyone:
	  ◦ Over the age of 80; 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:
	  ◦ 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:
	  ◦ 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)[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:
	  ▪ 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)

Term	Definition
	▪ 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	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. An organ transplant procedure is complete when any of the following occurs: • 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 Allograph	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



Approach Rate Per 100:

$$\frac{\text{Number of Approaches for OPO in Calendar Year}}{\text{Number of Referrals for OPO in Calendar Year}} \times 100$$

We stratified scores by demographic information for gender, race and age.

See measure specifications for detailed coding and definitions.

2.4 Performance Gap

Exhibit 3: Approach Rates by OPO

	OPO 1	OPO2	OPO 3	OPO 4	OPO 5	OPO 6
Measure Rate per 100	16	36	13	19	18	18
N of Entities	1	1	1	1	1	1

	OPO 1	OPO2	OPO 3	OPO 4	OPO 5	OPO 6
N of Persons*	18,734	19,199	7,131	12,887	13,511	8,634

* These are counts of ventilated referrals 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 Data Demographic Table (2021–2024,* Ages <=80)

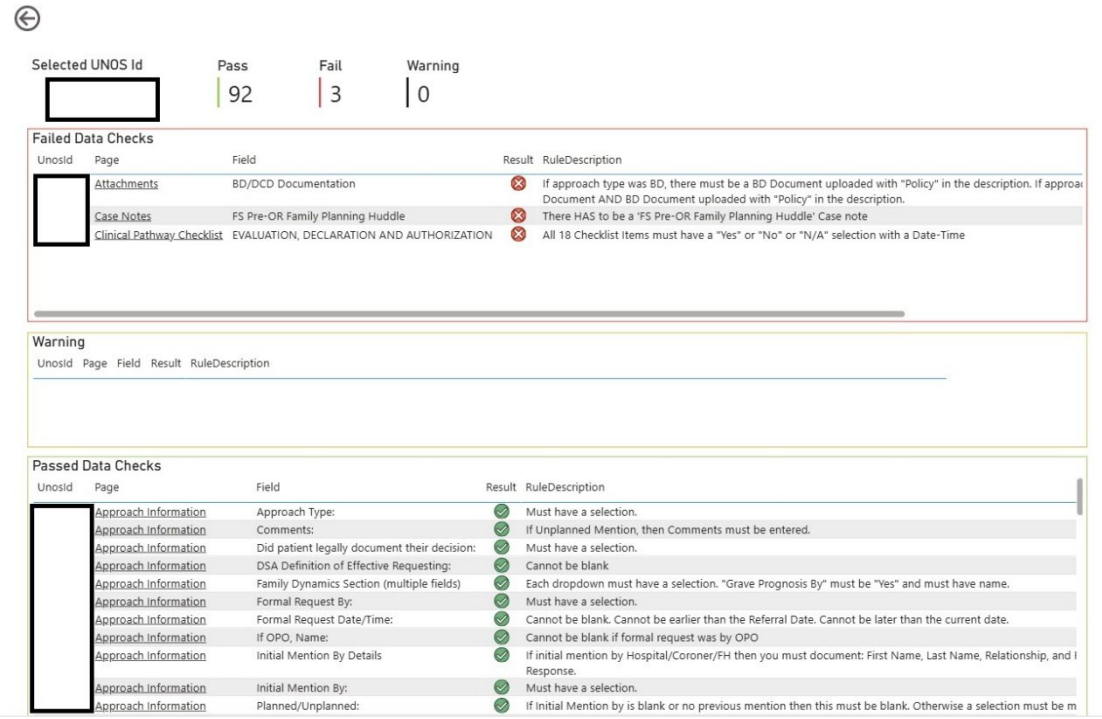
	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*	
Age	**Count**	**%**	**Count**	**%**
0 to less than 1	224	1.31	1,216	1.52
1 to 17	897	5.24	1,891	2.36
18 to 24	1,018	5.95	2,435	3.04
25 to 69	13,731	80.23	54,212	67.68
70 to 75	786	4.59	12,128	15.14
76 to 80	458	2.68	8,214	10.26
Total	17,114	100	80,096	100
Race	**Count**	**%**	**Count**	**%**
Non-Hispanic White	11,002	64.29	53,171	66.38
Non-White**	5,885	34.39	24,845	31.02
Unknown	227	1.33	2,080	2.60
Total	17,114	100	80,096	100

	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*	
Gender	**Count**	**%**	**Count**	**%**
Female	6,656	38.89	32,381	40.43
Male	10,458	61.11	47,673	59.52
Unknown	N/A	N/A	42	0.05
Total	17,114	100	80,096	100

* One OPO provided less than 4 full years of data (2021–2024).
** Due to variation in coding for race across OPOs, “Hispanic” was coded as a mutually exclusive race and included in the “Non-White” counts.

5.2.2 Method(s) of Reliability Testing

Exhibit 6: Example of Data Confirmation for Approach Records



5.3.4 Validity Testing Results

Exhibit 7: Comparison of OPO Data to MCOD Data

	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*		MCOD Potential Donors (Referral Rate)	
Age	**Count**	**%**	**Count**	**%**	**Count**	**%**
0 to less than 1	224	1.31	1,216	1.52	198	0.39
1 to 17	897	5.24	1,891	2.36	879	1.72

	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*		MCOD Potential Donors (Referral Rate)	
18 to 24	1,018	5.95	2,435	3.04	1,216	2.38
25 to 69	13,731	80.23	54,212	67.68	27,658	54.04
70 to 75	786	4.59	12,128	15.14	10,869	21.24
76 to 80	458	2.68	8,214	10.26	10,361	20.24
Total	17,114	100	80,096	100	51,182	100
Race	**Count**	**%**	**Count**	**%**	**Count**	**%**
Non-Hispanic White	11,002	64.29	53,171	66.38	36,522	71.36
Non-White**	5,885	34.39	24,845	31.02	14,659	28.64
Unknown	227	1.33	2,080	2.60	N/A	N/A
Total	17,114	100	80,096	100	51,182	100
Gender	**Count**	**%**	**Count**	**%**	**Count**	**%**
Female	6,656	38.89	32,381	40.43	18,652	36.44
Male	10,458	61.11	47,673	59.52	32,530	63.56
Unknown	N/A	N/A	42	0.05	n/a	n/a
Total	17,114	100	80,096	100	51,182	100

* One OPO provided less than 4 full years of data (2021–2024).
** Due to variation in coding for race across OPOs, “Hispanic” was coded as a mutually exclusive race and included in the “Non-White” counts.

5.4.3 Variable Distribution Across Measured Entities

Exhibit 8: Demographic Tables (2021–2024,* Vented Only, Ages <=80)

	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*	
Age	**Count**	**%**	**Count**	**%**
0 to less than 1	224	1.31	1,216	1.52
1 to 17	897	5.24	1,891	2.36
18 to 24	1,018	5.95	2,435	3.04
25 to 69	13,731	80.23	54,212	67.68
70 to 75	786	4.59	12,128	15.14
76 to 80	458	2.68	8,214	10.26
Total	17,114	100	80,096	100
Race	**Count**	**%**	**Count**	**%**
Non-Hispanic White	11,002	64.29	53,171	66.38
Non-White**	5,885	34.39	24,845	31.02
Unknown	227	1.33	2,080	2.60
Total	17,114	100	80,096	100

	OPOs Vented Approaches Only*		OPOs Vented Referrals Only*	
Gender	**Count**	**%**	**Count**	**%**
Female	6,656	38.89	32,381	40.43
Male	10,458	61.11	47,673	59.52
Unknown	N/A	N/A	42	0.05
Total	17,114	100	80,096	100

* One OPO provided less than 4 full years of data (2021–2024).
** Due to variation in coding for race across OPOs, "Hispanic" was coded as a mutually exclusive race and included in the "Non-White" counts.

5.4.6 Interpretation of Risk/Case-Mix Factor Findings

The rate is created by dividing the total number approaches for the relevant category by the number of referrals in that category. The rate can be interpreted as the number of approaches per 100 referrals by the OPO.

The team used a stratification approach to better understand the risks for different demographic groups and how the approach rate varied based on different patient characteristics. Our work was guided by previous research and approaches to risk adjustment and stratification (CMS, 2023; CMS, 2025; NQF, 2014; HHS/ASPE, 2020; Vogel & Chen, 2018).

Our team conducted Chi-Square tests to see if the differences in proportions of approaches to non-approaches were statistically significantly different than zero. We then tested the difference in proportions for the overall rate and the rate for each stratification category. For the significance tests, we interpreted the differences in Male vs. Female and White (Non-Hispanic) and Non-White. Due to the multiple age categories, we do not interpret our results for age because they are not meaningful.

The approach counts reflect the general patterns in referrals and approaches. Most approaches were in the 25–69 age group, as displayed in Exhibit 9.

Exhibit 9: Approach Counts by Age

Age Groups	0	1–17	18–24	25–69	70–75	76–80	Total
OPO 1	41	154	213	2,447	40	14	2,909
OPO 2	63	370	314	5,287	517	339	6,890
OPO 3	19	44	62	750	52	26	953
OPO 4	58	147	175	1,959	56	12	2,407
OPO 5	17	120	176	2,052	20	10	2,395
OPO 6	26	62	78	1,236	101	57	1,560
Total	224	897	1018	13,731	786	458	17,114
Average	37	150	170	2,289	131	76	2,852
Median	34	134	176	2,006	54	20	2,401

Approach Rates were fairly even in the ages 1–69. Age 0 rates were slightly lower, and rates in the 70–80 range were relatively low. This makes intuitive sense since many older donors may have contraindications to donation that were unobserved before the approach stage. While one OPO had higher Approach Rates for all groups over age 0, their pattern was generally similar to the other OPOs. (Approaches are made to a subset of the total referrals received by the OPO from regional hospitals.) Please refer to Exhibit 10.

Exhibit 10: Approach Rates per 100 by Age

Age Groups	0	1–17	18–24	25–69	70–75	76–80	Non-Stratified Rate
OPO 1	18	41	41	19	1	1	16
OPO 2	20	61	54	41	19	17	36
OPO 3	35	44	34	16	4	3	13
OPO 4	21	40	40	22	3	1	19
OPO 5	8	41	37	22	1	1	18
OPO 6	21	43	33	22	6	6	18
Overall Rate	18	47	42	25	6	6	21

Approach counts by race are generally higher for people in the Non-Hispanic White group, but the pattern is inconsistent. There are also a small number of people of “unknown” race included in our counts (Exhibit 11).

Exhibit 11: Approach Counts by Race

Race Groups	Non-Hispanic White	Non-White	Unknown	Total
OPO 1	1,621	1,206	82	2,909
OPO 2	4,286	2,562	42	6,890
OPO 3	470	482	1	953
OPO 4	1,660	736	11	2,407
OPO 5	1,618	693	84	2,395
OPO 6	1,347	206	7	1,560
Total	11,002	5,885	227	17,114

Approach Rates by race are relatively even but slightly higher for Non-Whites, with the exception of one OPO where they are equal. The Unknown race category has the lowest Approach Rates, but this is largely an artifact of the group’s small size. Our Chi-Square tests showed that one-third of OPOs had a significant difference in approach for Non-Hispanic Whites compared to the overall rate; one-half of OPOs had a significant difference in their approach for Non-Whites compared to the overall rate; and two-thirds had a significant difference when comparing Non-Hispanic Whites and Non-Whites (Exhibit 12).

Exhibit 12: Approach Rates per 100 by Race

Race Groups	Non-Hispanic White	Non-White	Unknown	Non-Stratified Rate
OPO 1	15	17	11	16
OPO 2	36	36	19	36
OPO 3	12	15	9	13
OPO 4	17	23	10	19
OPO 5	17	21	9	18
OPO 6	18	20	9	18
Overall	21	24	11	21

Approach counts are somewhat higher for males, which is expected based on the higher death rates for men. This pattern holds true for all OPOs (Exhibit 13).

Exhibit 13: Approach Counts by Gender

Race Groups	Male	Female	Total
OPO 1	1,774	1,135	2,909
OPO 2	4,141	2,749	6,890
OPO 3	563	390	953
OPO 4	1,483	924	2,407
OPO 5	1,534	861	2,395
OPO 6	963	597	1,560
Total	10,458	6,656	17,114

The Approach Rates for gender are very similar for men and women, although slightly higher for men for some OPOs. This indicates very little difference in Approach Rates by gender. The Chi-Square tests for approach were significant for Male vs. Overall in only one of the six tests. For Female vs. Overall, only one-third (two) of the tests were significantly different than zero. When comparing Male vs. Female, half (three) of the tests were statistically significant (Exhibit 14).

Exhibit 14: Approach Rate per 100 by Gender

Race Groups	Male	Female	Non-Stratified Rate
OPO 1	16	14	16
OPO 2	36	36	36
OPO 3	14	12	13
OPO 4	19	19	19
OPO 5	19	16	18
OPO 6	19	17	18
Overall Rate	22	21	21

In summary, stratification by race showed the most unpredictable patterns of the different stratification risk factors. Approach Rate by race is a potentially useful process measure for OPOs that want to better understand how they are reaching their potential donor population.

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Acronyms

Exhibit 15: 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

Acronym	Definition
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
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

Acronym	Definition
TEP	Technical Expert Panel
UAGA	Uniform Anatomical Gift Act