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ORIGINAL ARTICLE

The Centers for Medicare and Medicaid Services' proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients

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On December 23, 2019, the US Centers for Medicare and Medicaid Services proposed 2 new standards that organ procurement organizations (OPOs) must meet for recertification. An OPO's *organ donation rate* (deceased donors/potential donors) and *organ transplant rate* (organs transplanted/potential donors) must not fall significantly below the 75th percentile for rates among all OPOs. We examined how OPOs would have fared under the proposed performance standards in 2016-2017. Data on donors and transplants were from the Organ Procurement and Transplantation Network; donor potential was estimated from Detailed Multiple Cause of Death data collected by the Centers for Disease Control and Prevention. In 2017, 31 (53%) OPOs failed to meet the proposed donation rate standard, 36 (62%) failed to meet the proposed organ transplant rate standard, and 37 (64%) failed at least 1 standard. We found that adjusting for age, race, and Hispanic ethnicity altered the evaluation: 8 OPOs changed their pass/fail status for the donation rate and 5 for the proposed organ transplant rate standard. We conclude that the proposed new standards may result in over half of OPOs facing decertification, and risk adjustment suggests that underlying characteristics of deaths vary regionally such that decertification decisions may be affected.

KEYWORDS
clinical research/practice, organ procurement and allocation, Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR)

1 | INTRODUCTION

On July 10, 2019, the president of the United States issued Executive Order 13879.[1] Among other things, this order required that the secretary of Health and Human Services (HHS) propose a regulation within 90 days to enhance the procurement and utilization of organs available for transplant through deceased donation. On December 23, 2019, the Centers for Medicare and Medicaid Services (CMS)

Abbreviations: CDC, Centers for Disease Control and Prevention; CMS, Centers for Medicare and Medicaid Services; DDPS, Deceased Donor Potential Study; DSA, donation service area; NPRM, notice of proposed rulemaking; OPO, organ procurement organization; OPTN, Organ Procurement and Transplantation Network; SRTR, Scientific Registry of Transplant Recipients; TTS, The Transplantation Society; WHO, World Health Organization.

TABLE 1 Defining potential donors

Filtering step	CMS proposal	DDPS	Goldberg
Total deaths	2 851 313	2 851 313	2 851 313
Age <76 y	1 356 812 (48%)	1 356 812 (48%)	1 356 812 (48%)
Inpatient	460 634 (16%)	460 634 (16%)	460 634 (16%)
Without exclusionary diagnosis	271 260 (9.5%)	188 069 (6.6%)	NA
With inclusionary diagnosis	NA	50 273 (1.8%)	146 276 (5.1%)
Potential donors	271 260 (9.5%)	50 273 (1.8%)	146 276 (5.1%)

Abbreviations: CMS, Centers for Medicare and Medicaid Services; DDPS, Organ Procurement and Transplantation Network's Deceased Donor Potential Study.

under HHS issued a Notice of Proposed Rule Making (NPRM) that describes 2 new metrics to assess how well the 58 organ procurement organizations (OPOs) in the United States procure organs for transplant.[2] The goal is to dramatically increase the number of organs available for transplant, including doubling the number of kidneys available for transplant by 2030. The plan is to decertify OPOs that fail to meet CMS standards and HHS goals, recompeting those service areas to OPOs that do meet the standards.

CMS has proposed 2 new performance metrics:

- Donation Rate: the number of deceased donors divided by the number of potential donors within the OPO's donation service area (DSA).
- Organ Transplant Rate: the number of organs transplanted from deceased donors divided by the number of potential donors within the OPO's DSA.

The Scientific Registry of Transplant Recipients (SRTR), established by the National Organ Transplantation Act (NOTA)[3] and the Organ Procurement and Transplantation Network (OPTN) Final Rule,[4] is charged with assessing the performance of the nation's transplant system, including the performance of OPOs. Therefore, SRTR analyzed how the proposed metrics and standards for OPOs might affect the transplant system.

2 | MATERIALS AND METHODS

This study used data from SRTR. The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of OPTN. The Health Resources and Services Administration, US Department of HHS, provides oversight of the activities of the OPTN and SRTR contractors.

As proposed by CMS, we assessed potential donors using the Detailed Multiple Cause of Death (MCOD) data made available by the Department of Vital Statistics, National Center for Health Statistics, Centers for Disease Control and Prevention (CDC). We obtained the data for calendar years 2016 and 2017; 2017 was the most current year of data available at the time of data acquisition.

The proposed CMS metrics define potential donors as individuals meeting all of the following criteria:

- Age 75 years or younger, that is before the 76th birthday, on the date of death.
- Death occurred in an inpatient setting, defined by the CDC as "Hospital, Clinic, or Medical Center—Inpatient," excluding deaths that occurred in the emergency department or outpatient clinic, or deaths deemed dead on arrival.
- The decedent had no exclusionary diagnoses defined by *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) codes (CMS-3380-P, table 2). A death was excluded if any of these codes were present in any position on the death certificate.

In our analysis, only deaths occurring within the 50 States, the District of Columbia, Puerto Rico, and the US Virgin Islands were considered. In addition, we included deaths of non-US residents within those locations, as OPOs would be responsible for these deaths. Deaths were assigned to DSAs by the county in which they occurred, not the county of permanent residence, although both are available in the MCOD data. As the NPRM did not map counties to DSAs, we used the SRTR county assignments published semiannually in the SRTR OPO-specific reports (available at www.srtr.org). When counties are known to be shared or split between 2 different OPOs, we used the last known official CMS assignment of the county to assign all deaths within the county to the primary OPO serving the county. This resulted in a 1:1 mapping of counties to OPOs.

Deceased donors were identified in SRTR data and defined as follows:

- Deceased donor with a date of recovery between January 1, 2016, and December 31, 2017. Date of recovery was used rather than date of death because date of recovery resulted in counts matching the donor counts presented in the NPRM.
- Donors were limited as proposed in the NPRM to those from whom at least 1 organ was transplanted, or whose pancreas was used for research or islet cell transplant.

The number of organs transplanted was calculated per the NPRM, with an organ defined as "… a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplant." Right and left kidneys and lungs were counted separately, livers were counted as 2 if split, and intestines and pancreata were counted as 2 if segmented and both segments were transplanted.

Donation rate was calculated as the number of donors multiplied by 100 and divided by the number of potential donors, and organ transplant rate was calculated as the number of organs transplanted multiplied by 100 and divided by the number of potential donors. Confidence intervals were estimated as a 1-sided upper 95% confidence interval specified in the NPRM as "…the Wilson score interval with continuity correction (Newcombe 1998) is used to calculate the confidence interval for the donation rate of each OPO. The Wilson and Hilferty formula (Wilson and Hilferty 1931, Breslow and Day 1987, Kulkarni and Hemangi 2012) is used to calculate the confidence interval for the transplant rate of each OPO."

Although the assessments based on the metrics proposed in the NPRM were proposed to be unadjusted, we assessed the effects of adjusting for potential confounders in a Poisson regression model adjusting for the age, race, and Hispanic ethnicity of the decedent. Given that the metric numerators are based on OPTN data, while the donor potential denominator is based on CDC data, possible risk adjusters are restricted to elements found in both data sources. Both data sources include age, sex, race, Hispanic ethnicity, and cause of death. Because we cannot guarantee a 1:1 match of the potential donors to the actual donors, given the disparate data sources, risk adjusters were rendered categorical to ensure adequate cell sizes. Age was categorized as 0-5, 6-10, 11-18, 19-35, 36-50, 51-65, and 66-75 years. Race was categorized as white, black, Asian, or other. Adjusting for cause of death would require mapping ICD-10-CM coded causes into the 5 causes identified in the OPTN data (anoxia, cerebrovascular accident/stroke, central nervous system tumor, head trauma, and other), a difficult undertaking. Adjustment for sex could also be explored.

All analyses were performed using R (version 3.6.1, R Core Team, 2019). R: A language and environment for statistical computing. R Foundation for Statistical Computing) and SAS (version 9.4, SAS Institute).

3 | RESULTS

3.1 | Potential donors

In 2017, 2 851 313 deaths occurred in the US; 1 356 812 (48%) decedents were aged 75 years or younger; of these deaths, 460 634 (16%) occurred in inpatient settings (Table 1). Of these inpatient deaths, applying the proposed exclusionary diagnostic codes resulted in 271 260 meeting the proposed definition of a potential donor (9.5% of total deaths). We contrasted the CMS proposed definition with the inclusionary and exclusionary definitions used by both the OPTN's Deceased Donor Potential Study,[5] and the methodology employed by Goldberg[6] and also being considered by CMS to calculate its proposed metrics. The Deceased Donor Potential Study (DDPS) used approximately 200 additional exclusionary ICD-10-CM codes along with a series of inclusionary codes that must be present on the death certificate. This more restrictive definition resulted in 50 273 potential donors (1.8% of total deaths). Goldberg et al used a series of inclusionary diagnostic codes, but employed no exclusionary codes, resulting in 146 276 potential donors (5.1% of total deaths). Therefore, CMS's proposed methodology results in the largest number of deaths classified as potential donors.

Potential donors ranged from a low of 1086 in the Legacy of Life—Hawaii's (HIOP) service area to a maximum of 12 924 in OneLegacy's (CAOP) service area (mean 4677, standard deviation 2722, interquartile range 2329-5807). The 271 260 potential donors in our analysis differed from the 272 105 in the NPRM (CMS-3380-P, Table 3) by 845, possibly because of differences in how shared counties are tabulated and/or differences in interpretation of the ICD-10-CM exclusionary diagnostic codes (see Discussion).

3.2 | Donation rate and organ transplant rate

In our analysis, there were 9731 donors in 2017, matching what was reported in the NPRM (CMS-3380-P, table 3). Nationally, 3.59 donors were procured per 100 potential donors. Donation rates ranged from a low of 1.78 (AROR) to a high of 6.41 (WIUW) donors per 100 potential donors (Table 2).

Using CMS's proposed accounting of organs transplanted, we found 32 173 organs transplanted, again matching the NPRM (CMS-3380-P, table 4). The national organ transplant rate was 11.82 organs transplanted per 100 potential donors (Table 3). Organ transplant rates ranged from a low of 5.02 (NYFL) to a high of 21.46 (WIUW).

3.3 | Proposed performance standards

CMS has proposed a performance standard requiring each OPO's donation rate and organ transplant rate to not be statistically significantly lower than the 75th percentile of the prior year's donation and organ transplant rates. The 75th percentile of the 2016 donation rate was 4.11 donors per 100 potential donors. In 2017, 31 (53%) OPOs failed to meet this standard (Figures 1 and 2). The 75th percentile of the 2016 organ transplant rate was 13.69 transplanted organs per 100 potential donors (differing slightly from 13.73 published in the NPRM). In 2017, 36 (62%) OPOs failed to meet the standard (Figures 3 and 4). In 2017, 37 (64%) OPOs failed to meet at least 1 of the standards (Figure 5).

3.4 | Adjusting the performance metrics

CMS proposes using an unadjusted evaluation for both the donation rate and the organ transplant rate metrics. We examined how

TABLE 2 Proposed 2017 donation rate metric, SRTR analysis compared with CMS NPRM

OPO	Potential donors (CMS)	Total donors	Donation rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Donation rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
Arkansas Regional Organ Recovery Agency (AROR)	2604	46	1.77	2.27	Fail	2582	1.78	2.28	Fail
Finger Lakes Donor Recovery Network (NYFL)	2486	41	1.65	2.15	Fail	2213	1.85	2.41	Fail
Kentucky Organ Donor Affiliates (KYDA)	5389	107	1.99	2.33	Fail	5445	1.97	2.31	Fail
Legacy of Hope - Alabama (ALOB)	8025	159	1.98	2.26	Fail	8077	1.97	2.25	Fail
LifeLink of Puerto Rico (PRLL)	3205	78	2.43	2.94	Fail	3221	2.42	2.93	Fail
Iowa Donor Network (IAOP)	2136	52	2.43	3.07	Fail	2089	2.49	3.14	Fail
Mississippi Organ Recovery Agency (MSOP)	2927	74	2.53	3.07	Fail	2963	2.5	3.03	Fail
LifeNet Health (VATB)	5449	144	2.64	3.03	Fail	5517	2.61	3	Fail
Center for Donation and Transplant (NYAP)	2451	55	2.24	2.81	Fail	2095	2.63	3.29	Fail
Indiana Donor Network (INOP)	5783	161	2.78	3.17	Fail	5840	2.76	3.14	Fail
Mid-South Transplant Foundation (TNMS)	2305	67	2.91	3.56	Fail	2340	2.86	3.51	Fail
LiveOnNY (NYRT)	9385	278	2.96	3.27	Fail	9601	2.9	3.2	Fail
Carolina Donor Services (NCNC)	6781	199	2.93	3.3	Fail	6841	2.91	3.27	Fail
Life Connection of Ohio (OHLC)	2072	61	2.94	3.65	Fail	2075	2.94	3.64	Fail
Legacy of Life - Hawaii (HIOP)	1077	33	3.06	4.11	Pass	1086	3.04	4.07	Fail
LifeQuest Organ Recovery Services (FLUF)	4234	132	3.12	3.6	Fail	4272	3.09	3.57	Fail
Pacific Northwest Transplant Bank (ORUO)	3791	119	3.14	3.65	Fail	3839	3.1	3.61	Fail
Texas Organ Sharing Alliance (TXSA)	5079	162	3.19	3.63	Fail	5110	3.17	3.61	Fail
LifeLink of Georgia (GALL)	8573	280	3.27	3.6	Fail	8669	3.23	3.56	Fail
New Mexico Donor Services (NMOP)	1628	54	3.32	4.16	Pass	1641	3.29	4.13	Pass

(Continues)

TABLE 2 (Continued)

OPO	Potential donors (CMS)	Total donors	Donation rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Donation rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
Gift of Life Michigan (MIOP)	8736	289	3.31	3.64	Fail	8746	3.3	3.64	Fail
LifeCenter Organ Donor Network (OHOV)	2029	68	3.35	4.1	Fail	2039	3.33	4.08	Fail
LifeChoice Donor Services (CTOP)	2561	60	2.34	2.91	Fail	1798	3.34	4.14	Pass
Sharing Hope SC (SCOP)	4598	156	3.39	3.87	Fail	4644	3.36	3.83	Fail
Donor Network West (CADN)	8699	298	3.43	3.77	Fail	8785	3.39	3.73	Fail
OneLegacy (CAOP)	12 725	442	3.47	3.75	Fail	12 924	3.42	3.7	Fail
New England Organ Bank (MAOB)	8712	284	3.26	3.59	Fail	8216	3.46	3.81	Fail
LifeBanc (OHLB)	4149	147	3.54	4.06	Fail	4214	3.49	4	Fail
Life Alliance Organ Recovery Agency (FLMP)	4931	175	3.55	4.02	Fail	4987	3.51	3.97	Fail
Louisiana Organ Procurement Agency (LAOP)	5072	182	3.59	4.05	Fail	5108	3.56	4.03	Fail
Lifeline of Ohio (OHLP)	3587	122	3.4	3.95	Fail	3423	3.56	4.14	Pass
LifeLink of Florida (FLWC)	5665	205	3.62	4.06	Fail	5706	3.59	4.03	Fail
LifeSource - MN (MNOP)	4707	173	3.68	4.17	Pass	4775	3.62	4.11	Fail
LifeCenter Northwest (WALC)	6408	236	3.68	4.1	Fail	6513	3.62	4.03	Fail
Lifeshare Carolinas (NCCM)	2599	98	3.77	4.46	Pass	2613	3.75	4.43	Pass
Center for Organ Recovery and Education (PATF)	5500	212	3.85	4.31	Pass	5566	3.81	4.26	Pass
Donor Alliance (CORS)	3469	137	3.95	4.55	Pass	3509	3.9	4.49	Pass
Tennessee Donor Services (TNDS)	7189	283	3.94	4.34	Pass	7223	3.92	4.32	Pass
ConnectLife (NYWN)	1239	50	4.04	5.1	Pass	1257	3.98	5.03	Pass
Gift of Hope Organ & Tissue Donor Network (ILIP)	9108	372	4.08	4.45	Pass	9226	4.03	4.39	Pass
New Jersey Sharing Network (NJTO)	5093	184	3.61	4.08	Fail	4519	4.07	4.6	Pass
Mid-America Transplant Services (MOMA)	5266	217	4.12	4.61	Pass	5324	4.08	4.56	Pass
LifeGift (TXGC)	8579	356	4.15	4.52	Pass	8649	4.12	4.49	Pass

(Continues)

TABLE 2 (Continued)

OPO	Potential donors (CMS)	Total donors	Donation rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Donation rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
Southwest Transplant Alliance (TXSB)	8727	373	4.27	4.65	Pass	8823	4.23	4.6	Pass
Sierra Donor Services (CAGS)	2092	78	3.73	4.5	Pass	1843	4.23	5.1	Pass
OurLegacy - FL (FLFH)	3541	153	4.32	4.93	Pass	3574	4.28	4.89	Pass
Nebraska Organ Recovery (NEOR)	1519	66	4.34	5.33	Pass	1537	4.29	5.26	Pass
Washington Regional Transplant Community (DCTC)	3158	138	4.37	5.03	Pass	3196	4.32	4.97	Pass
LifeShare of Oklahoma (OKOP)	3954	177	4.48	5.06	Pass	4014	4.41	4.99	Pass
The Living Legacy Foundation of Maryland (MDPC)	3171	143	4.51	5.17	Pass	3210	4.45	5.11	Pass
Donor Network of Arizona (AZOB)	4991	241	4.83	5.36	Pass	5030	4.79	5.32	Pass
Nevada Donor Network (NVLV)	2367	118	4.99	5.8	Pass	2389	4.94	5.74	Pass
Gift of Life Donor Program (PADV)	9771	509	5.21	5.6	Pass	9881	5.15	5.53	Pass
DonorConnect (UTOP)	2048	107	5.22	6.12	Pass	2072	5.16	6.05	Pass
Midwest Transplant Network (MWOB)	4297	230	5.35	5.96	Pass	4346	5.29	5.89	Pass
Versiti (WIDN)	1844	92	4.99	5.92	Pass	1727	5.33	6.32	Pass
Lifesharing - A Donate Life Organization (CASD)	1986	109	5.49	6.42	Pass	2013	5.41	6.33	Pass
Organ Procurement Organization at U. of Wisconsin (WIUW)	2638	149	5.65	6.45	Pass	2325	6.41	7.32	Pass
Totals	272 105	9731	3.58			271 260	3.59		

Abbreviations: CI, confidence interval; CMS, Centers for Medicare and Medicaid Services; NPRM, Notice of Proposed Rule Making; OPO, organ procurement organization; SRTR, Scientific Registry of Transplant Recipients.

TABLE 3 Proposed 2017 transplant rate metric, SRTR analysis compared with CMS NPRM

OPO	Potential donors (CMS)	Transplanted organs	Transplant rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Transplant rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
Finger Lakes Donor Recovery Network (NYFL)	2486	111	4.47	5.23	Fail	2213	5.02	5.87	Fail
Arkansas Regional Organ Recovery Agency (AROR)	2604	149	5.72	6.56	Fail	2582	5.77	6.61	Fail
Legacy of Hope - Alabama (ALOB)	8025	496	6.18	6.66	Fail	8077	6.14	6.61	Fail
LifeLink of Puerto Rico (PRLL)	3205	217	6.77	7.58	Fail	3221	6.74	7.54	Fail
Kentucky Organ Donor Affiliates (KYDA)	5389	395	7.33	7.97	Fail	5445	7.25	7.88	Fail
Center for Donation and Transplant (NYAP)	2451	162	6.61	7.53	Fail	2095	7.73	8.81	Fail
Iowa Donor Network (IAOP)	2136	165	7.72	8.79	Fail	2089	7.9	8.99	Fail
Legacy of Life - Hawaii (HIOP)	1077	90	8.36	9.96	Fail	1086	8.29	9.87	Fail
Mississippi Organ Recovery Agency (MSOP)	2927	255	8.71	9.66	Fail	2963	8.61	9.55	Fail
Life Connection of Ohio (OHLC)	2072	180	8.69	9.83	Fail	2075	8.67	9.82	Fail
LifeNet Health (VATB)	5449	493	9.05	9.75	Fail	5517	8.94	9.63	Fail
Mid-South Transplant Foundation (TNMS)	2305	214	9.28	10.4	Fail	2340	9.15	10.24	Fail
LiveOnNY (NYRT)	9385	907	9.66	10.21	Fail	9601	9.45	9.98	Fail
Pacific Northwest Transplant Bank (ORUO)	3791	376	9.92	10.8	Fail	3839	9.79	10.67	Fail
LifeQuest Organ Recovery Services (FLUF)	4234	430	10.16	11	Fail	4272	10.07	10.9	Fail
Gift of Life Michigan (MIOP)	8736	888	10.16	10.74	Fail	8746	10.15	10.73	Fail
LifeLink of Georgia (GALL)	8573	883	10.3	10.89	Fail	8669	10.19	10.77	Fail
Life Alliance Organ Recovery Agency (FLMP)	4931	515	10.44	11.23	Fail	4987	10.33	11.11	Fail
Carolina Donor Services (NCNC)	6781	710	10.47	11.14	Fail	6841	10.38	11.04	Fail
New Mexico Donor Services (NMOP)	1628	171	10.5	11.92	Fail	1641	10.42	11.83	Fail
LifeCenter Organ Donor Network (OHOV)	2029	215	10.6	11.86	Fail	2039	10.54	11.81	Fail
LifeChoice Donor Services (CTOP)	2561	190	7.42	8.37	Fail	1798	10.57	11.92	Fail
Indiana Donor Network (INOP)	5783	627	10.84	11.58	Fail	5840	10.74	11.47	Fail

(Continues)

TABLE 3 (Continued)

OPO	Potential donors (CMS)	Transplanted organs	Transplant rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Transplant rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
New England Organ Bank (MAOB)	8712	920	10.56	11.15	Fail	8216	11.2	11.82	Fail
OneLegacy (CAOP)	12 725	1468	11.54	12.04	Fail	12 924	11.36	11.86	Fail
LifeBanc (OHLB)	4149	479	11.54	12.45	Fail	4214	11.37	12.26	Fail
Texas Organ Sharing Alliance (TXSA)	5079	581	11.44	12.25	Fail	5110	11.37	12.18	Fail
LifeLink of Florida (FLWC)	5665	650	11.47	12.24	Fail	5706	11.39	12.15	Fail
LifeCenter Northwest (WALC)	6408	743	11.59	12.32	Fail	6513	11.41	12.12	Fail
Center for Organ Recovery and Education (PATF)	5500	637	11.58	12.37	Fail	5566	11.44	12.22	Fail
Donor Alliance (CORS)	3469	410	11.82	12.83	Fail	3509	11.68	12.68	Fail
Lifeline of Ohio (OHLP)	3587	410	11.43	12.4	Fail	3423	11.98	13	Fail
Donor Network West (CADN)	8699	1058	12.16	12.8	Fail	8785	12.04	12.67	Fail
Sharing Hope SC (SCOP)	4598	564	12.27	13.15	Fail	4644	12.14	13.02	Fail
LifeSource - MN (MNOP)	4707	589	12.51	13.4	Fail	4775	12.34	13.2	Fail
ConnectLife (NYWN)	1239	156	12.59	14.38	Pass	1257	12.41	14.17	Pass
New Jersey Sharing Network (NJTO)	5093	565	11.09	11.89	Fail	4519	12.5	13.4	Fail
Louisiana Organ Procurement Agency (LAOP)	5072	667	13.15	14.02	Pass	5108	13.06	13.92	Pass
Tennessee Donor Services (TNDS)	7189	944	13.13	13.86	Pass	7223	13.07	13.79	Pass
LifeShare of Oklahoma (OKOP)	3954	528	13.35	14.35	Pass	4014	13.15	14.14	Pass
Lifeshare Carolinas (NCCM)	2599	349	13.43	14.67	Pass	2613	13.36	14.59	Pass
Gift of Hope Organ & Tissue Donor Network (ILIP)	9108	1243	13.65	14.3	Pass	9226	13.47	14.12	Pass
Mid-America Transplant Services (MOMA)	5266	719	13.65	14.52	Pass	5324	13.5	14.36	Pass
Sierra Donor Services (CAGS)	2092	260	12.43	13.77	Pass	1843	14.11	15.63	Pass
OurLegacy - FL (FLFH)	3541	506	14.29	15.38	Pass	3574	14.16	15.24	Pass
LifeGift (TXGC)	8579	1244	14.5	15.2	Pass	8649	14.38	15.07	Pass
Southwest Transplant Alliance (TXSB)	8727	1275	14.61	15.3	Pass	8823	14.45	15.13	Pass
Washington Regional Transplant Community (DCTC)	3158	462	14.63	15.8	Pass	3196	14.46	15.61	Pass
Nevada Donor Network (NVLV)	2367	367	15.5	16.9	Pass	2389	15.36	16.75	Pass

(Continues)

TABLE 3 (Continued)

OPO	Potential donors (CMS)	Transplanted organs	Transplant rate (CMS)	95% CI upper bound (CMS)	Pass/fail (CMS)	Potential donors (SRTR)	Transplant rate (SRTR)	95% CI upper bound (SRTR)	Pass/fail (SRTR)
The Living Legacy Foundation of Maryland (MDPC)	3171	500	15.77	16.98	Pass	3210	15.58	16.77	Pass
Nebraska Organ Recovery (NEOR)	1519	245	16.13	17.93	Pass	1537	15.94	17.72	Pass
Gift of Life Donor Program (PADV)	9771	1575	16.12	16.8	Pass	9881	15.94	16.62	Pass
Donor Network of Arizona (AZOB)	4991	847	16.97	17.96	Pass	5030	16.84	17.82	Pass
DonorConnect (UTOP)	2048	353	17.24	18.82	Pass	2072	17.04	18.61	Pass
Versiti (WIDN)	1844	314	17.03	18.7	Pass	1727	18.18	19.96	Pass
Midwest Transplant Network (MWOB)	4297	821	19.11	20.24	Pass	4346	18.89	20.01	Pass
Lifesharing - A Donate Life Organization (CASD)	1986	386	19.44	21.14	Pass	2013	19.18	20.86	Pass
Organ Procurement Organization at U. of Wisconsin (WIUW)	2638	499	18.92	20.37	Pass	2325	21.46	23.11	Pass
Totals	272 105	32 173	11.82			271 260	11.86		

Abbreviations: CI, confidence interval; CMS, Centers for Medicare and Medicaid Services; NPRM, Notice of Proposed Rule Making; OPO, organ procurement organization; SRTR, Scientific Registry of Transplant Recipients.

TABLE 4 Comparison of donation rates for 2 OPOs by Hispanic ethnicity

	OPO A			OPO B		
Ethnicity	Potential donors	Donors	Donation rate per 100 potential donors	Potential donors	Donors	Donation rate per 100 potential donors
Hispanic	599	36	6.01	107	7	6.54
Non-Hispanic	1404	73	5.20	1620	85	5.25
Total (unadjusted)	2003	109	5.44	1727	92	5.33
Adjusted for Hispanic ethnicity			5.35			5.50

Note: The red and green are meant to convey which are better (green) or worse (red) and to point out that the unadjusted and adjusted evaluations lead to reversed conclusions (one being red, the other green).

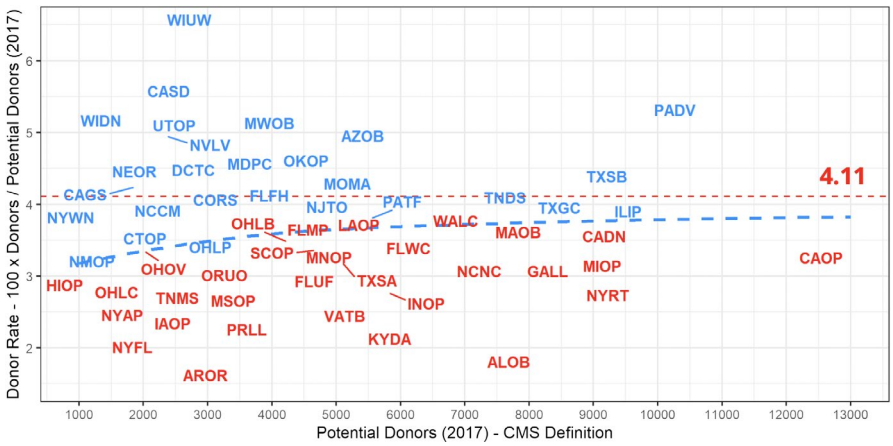
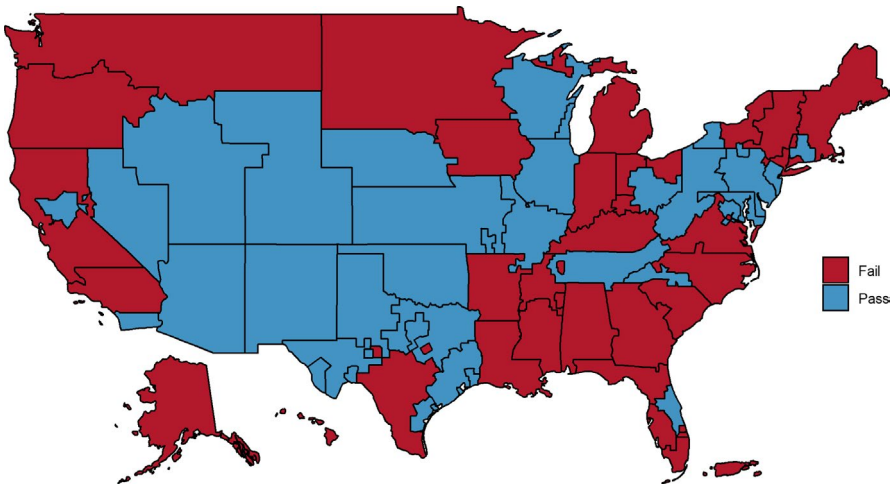


FIGURE 1 Donation rate evaluation, 2017. The donation rate per 100 potential donors is shown, stratified by the potential donor count. The performance standard is based on the 75th percentile of the 2016 donation rate and is shown as the red dashed line at 4.11. The blue dashed line shows the critical threshold below which an OPO's donation rate would be statistically significantly lower than the performance threshold. 31 of 58 (53%) OPOs failed to the meet the 2016 standard in 2017. OPO labels may be shifted slightly to avoid overlapping labels. OPOs failing to meet the standard are displayed in red. OPO, organ procurement organization

FIGURE 2 Map of the donation rate evaluation, 2017. OPOs failing to meet the 2016 standard based on 2017 data are shown in red. OPO, organ procurement organization



differences in characteristic of the deaths occurring within the OPOs' service areas may affect the proposed metrics. Adjusting the donation rate and organ transplant rate for age, race, and Hispanic ethnicity affected whether or not OPOs failed to meet each performance standard (Figures 6 and 7). After adjustment, 8 OPOs changed their pass/fail status for the donation rate and 5 for the organ transplant rate.

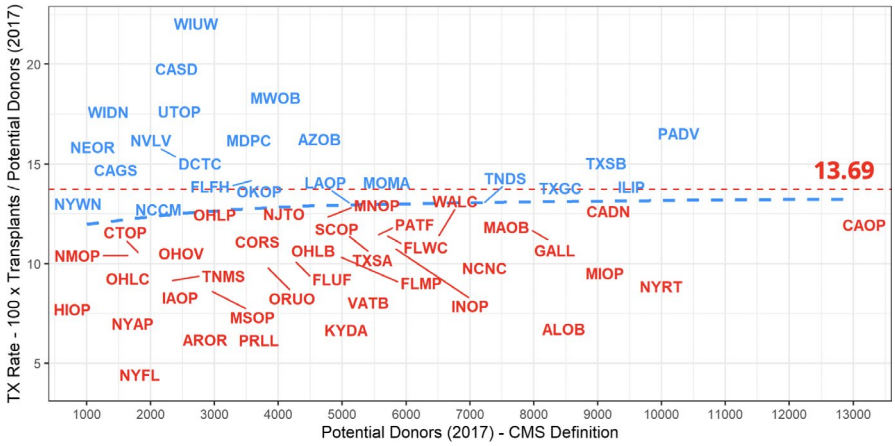


FIGURE 3 Organ transplant rate evaluation, 2017. The organ transplant rate per 100 potential donors is shown, stratified by the potential donor count. The performance standard is based on the 75th percentile of the 2016 organ transplant rate and is shown as the red dashed line at 13.69. The blue dashed line shows the critical threshold below which an OPO's donation rate would be statistically significantly lower than the performance threshold. 36 of 58 (62%) OPOs failed to the meet the 2016 standard in 2017. OPO labels may be shifted slightly to avoid overlapping labels. OPOs failing to meet the standard are displayed in red. OPO, organ procurement organization

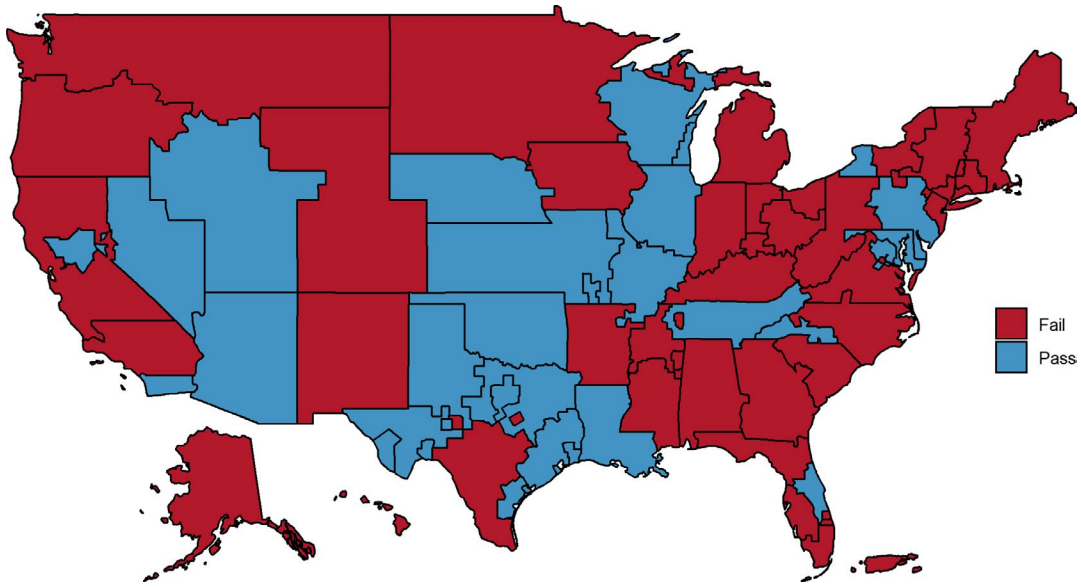


FIGURE 4 Map of the organ transplant rate evaluation, 2017. OPOs failing to meet the 2016 standard based on 2017 data are shown in red. OPO, organ procurement organization

4 | DISCUSSION

CMS is proposing that the CDC's MCOD data be used to calculate a donation rate and an organ transplant rate to assess the performance of the 58 OPOs. With the proposed definition, 9.5% of all deaths in the United States would be classified as potential donors. Accordingly, 3.59 donors are currently procured per 100 potential donors, and 11.82 organs are transplanted (or are pancreata sent for research or islet transplant) per 100 potential donors. Our assessment of 2017 performance based on 2016 performance thresholds finds that 37 (64%) of the 58 OPOs failed at least 1 of the 2 performance standards.

We used the same data sources as proposed in the NPRM to examine the proposed metrics. While we were able to replicate the donor and transplant counts in the NPRM, we were unable to replicate the potential donor count, either nationally or within each DSA. This may be due to how counties are assigned to OPOs or how counties that are shared by more than 1 OPOs are tabulated. CTOP had the largest discrepancy, with our analysis finding 30% fewer potential donors (NPRM: 2561; SRTR: 1798). New Haven county in Connecticut is shared between MAOB and CTOP. SRTR attributes all deaths in New Haven county (n = 812) to MAOB as all referrals from this county in 2017 were handled by MAOB. However, our analysis suggests that CMS may have attributed all deaths within this county to both MOAB and CTOP; for example adding the 812 potential donors in New Haven to the 1798 potential donors we identified in CTOP's DSA yields 2610 potential donors, which is closer to the 2561 in the NPRM. This could explain why CMS's total

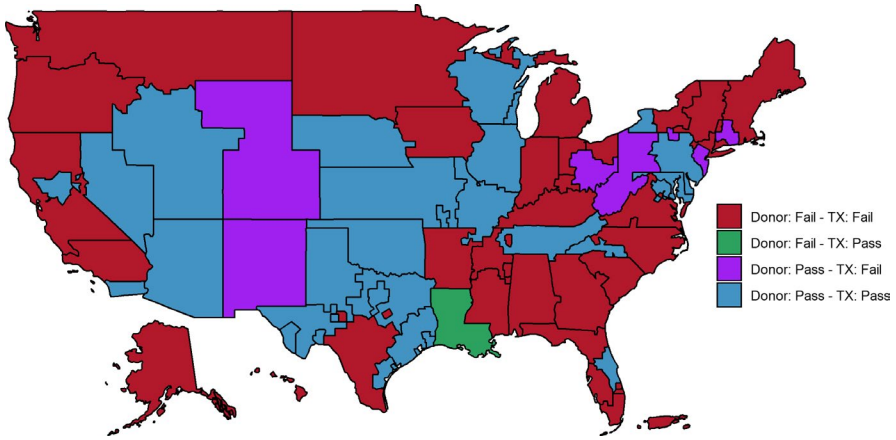


FIGURE 5 Map of the combined evaluation of donation rate and organ transplant rate, 2017. OPOs failing to meet the 2016 standard based on both metrics are shown in red. OPOs failing to meet the donation rate metric but not the organ transplant rate metric are shown in green. OPOs failing to meet the organ transplant rate metric but not the donation rate metric are shown in purple. OPO, organ procurement organization

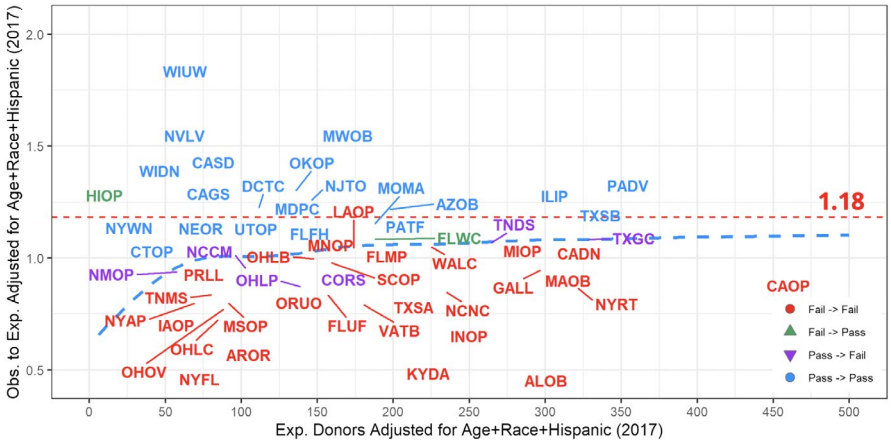


FIGURE 6 Adjusted donation rate ratio, adjusted for age, race, and Hispanic ethnicity. The adjusted donation rate ratio (observed donors divided by expected donors, O/E) is shown, stratified by the expected donor count. The performance standard is based on the 75th percentile of the 2016 adjusted donation rate ratio O/E and is shown as the red dashed line at O/E = 1.18. The blue dashed line shows the critical threshold below which an OPO's donation rate ratio would be statistically significantly lower than the performance threshold. 35 of 58 (60%) of OPOs failed to the meet the 2016 standard in 2017. OPO labels may be shifted slightly to avoid overlapping labels. Colors represent a comparison of the unadjusted evaluation with the adjusted evaluation: red = fail on both unadjusted and adjusted, blue = pass on both unadjusted and adjusted, green = fail the unadjusted but pass the adjusted, and purple = pass the unadjusted but fail the adjusted. OPO, organ procurement organization

donor potential was often higher than in our analysis (Figure 8). The other OPOs with the largest discrepancies in donor potential also had shared counties. This highlights the need to clarify which counties are assigned to which OPO and how shared counties are handled.

Beyond uncertainty in how CMS assigned counties to DSAs, we found possible errors in the ICD-10-CM exclusionary code table in the NPRM (CMS-3380-P, table 2). For example, "Melanoma and other malignant neoplasms of skin" is replicated in 2 rows of the table, with 1 row indicating removal of ICD-10-CM code C43 (malignant melanoma of skin) and another row indicating "all" ICD-10-CM codes in this category, which would include code C44 (other malignant neoplasms of skin). Our analysis excluded code C44 since we suspect that duplication of this row is an error and non-melanoma skin cancers do not generally preclude donation. This may have caused our donor potential estimate to be slightly lower than that calculated by CMS. Finally, malignant neoplasms of the urinary tract (codes C64-C68) were not included in the set indicated in the NPRM but are present in the document CMS references for the source of the ICD-10-CM codes.[7] We did not include malignant neoplasms of the urinary tract to be consistent with the NPRM, but these issues highlight the need to clarify the set of ICD-10-CM exclusionary codes.

CMS's proposed definition of a donor (at least 1 organ transplanted or the pancreas sent for research or used for islet transplant) differs from the standard OPTN definition of a donor and the definition endorsed by the World Health Organization (WHO) and The Transplantation Society (TTS).[8,9] OPTN, WHO, and TTS define a donor as a decedent from whom at least 1 organ was procured for the purpose of transplant. We compared CMS's proposed definition of a donor with the standard OPTN definition. Using the OPTN definition, 7 OPOs change their pass/fail status on the donation rate metric, 4 from passing to failing and 3 from failing to passing (Figure 9).

Counting pancreata sent for research or used for islet transplant also differs from standard OPTN and SRTR practice. In 2017, 25 deceased donors had zero organs transplanted, but the pancreas was

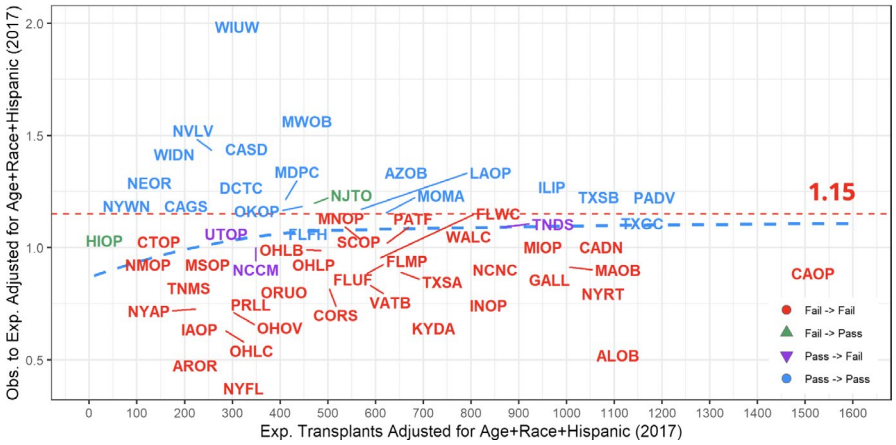


FIGURE 7 Adjusted organ transplant rate ratio, adjusted for age, race, and Hispanic ethnicity. The adjusted organ transplant rate ratio (observed transplanted organs divided by expected transplanted organs, O/E) is shown, stratified by the expected transplanted organ count. The performance standard is based on the 75th percentile of the 2016 adjusted organ transplant rate ratio O/E and is shown as the red dashed line at O/E = 1.15. The blue dashed line shows the critical threshold below which an OPO's organ transplant rate ratio would be statistically significantly lower than the performance threshold. 37 of 58 (64%) OPOs failed to the meet the 2016 standard in 2017. OPO labels may be shifted slightly to avoid overlapping labels. Colors represent a comparison of the unadjusted evaluation with the adjusted evaluation: red = fail on both unadjusted and adjusted, blue = pass on both unadjusted and adjusted, green = fail the unadjusted but pass the adjusted, and purple = pass the unadjusted but fail the adjusted. OPO, organ procurement organization

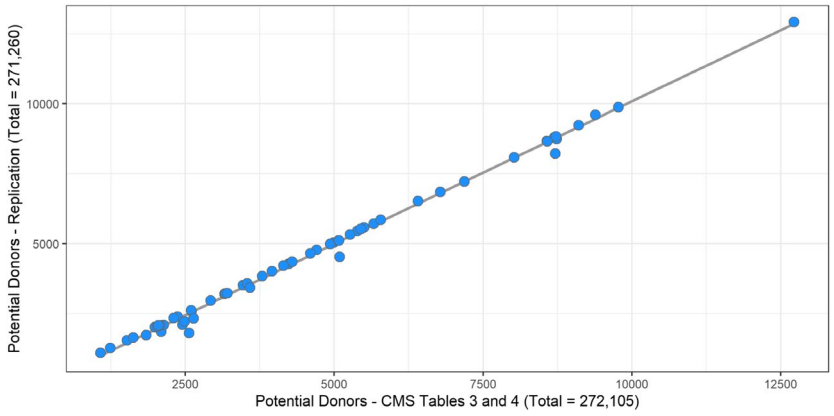


FIGURE 8 Comparison of CMS's donor potential count with SRTR's attempted replication. CMS, Centers for Medicare and Medicaid Services; SRTR, Scientific Registry of Transplant Recipients

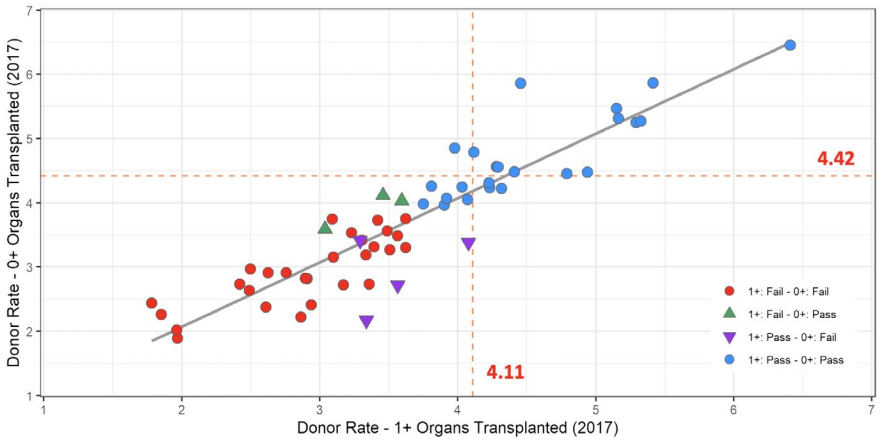


FIGURE 9 Comparison of CMS's proposed definition of a donor (1+ organ transplanted) to OPTN's definition (0+ organs transplanted). CMS, Centers for Medicare and Medicaid Services

recovered for research. There were no recorded instances of decedents with no organs recovered for transplant (and therefore were not donors according to OPTN), but the pancreas was recovered for research.

This analysis did not attempt to address whether the MCOD data are appropriate for estimating donor potential; however, it is important to highlight that the CDC Wonder public database cannot be used to calculate these metrics because (a) it contains place of permanent residence of the decedent rather than place of death; (b) it excludes non-US citizens; and (c) it excludes deaths occurring in Puerto Rico and the US Virgin Islands. The Detailed Mortality—All Counties data must be obtained from the CDC's Department of Vital Statistics, National Center for Health Statistics.

Risk adjustment could help ensure that a correct decision is made when comparing metrics across OPOs. Differences in the underlying characteristics of the decedents in the OPOs' service areas could cause some OPOs to appear better or worse than others due to underlying differences in the populations served. Intercounty variation in cause-specific death rates have been well described.[10] Given that the types of deaths in a DSA are out of the OPO's control, risk adjustment may be worth considering. As an illustration, we compared 2 OPOs, 1 with a donation rate of 5.44 (OPO A) and 1 with a donation rate of 5.33 (OPO B) (Table 4). If unadjusted, OPO A would be described as performing better than OPO B. However, when stratifying the results by Hispanic ethnicity, OPO B actually has higher donation rates in *both* the Hispanic and the non-Hispanic populations. Because these OPOs had very different distributions of Hispanic patients, the unadjusted conclusion was opposite from the adjusted conclusion, a phenomenon known in statistics as Simpson's paradox.[11] Adjusting for Hispanic ethnicity would lead to the conclusion that OPO B is the higher performer with 5.50 donors per 100 vs 5.35 donors per 100 for OPO A, after adjustment.

CMS has proposed using the 75th percentile of the previous calendar year as the standard of performance for both the donation rate and the organ transplant rate metrics. The standard is met if the current year's upper bound of the 1-sided 95% confidence interval is above the standard. As our results indicate, this performance standard resulted in 64% of the OPOs failing based on 2017 data. Of note, a performance boundary based on the 75th percentile (or the 75th quantile) will be biased against OPOs with more potential donors (large OPOs), and, conversely, biased in favor of OPOs with fewer potential donors (small OPOs). This is apparent in Figures 1 and 3, which show more small OPOs passing the standards. This happens because the variance of the donation rate (and transplant rate) statistic is inversely proportional to the sample size, that is the number of potential donors. Given this, the 75th quantile for smaller OPOs will be higher than the 75th quantile for larger OPOs simply because the variance of the estimates is larger in smaller OPOs. Therefore, the overall 75th quantile will be too low for small OPOs and too high for large OPOs.

In conclusion, our analysis of the NPRM found that 64% of the 58 OPOs would have failed the standards if the metrics were applied to calendar year 2017. Risk adjustment affects which OPOs fail to meet the proposed standards. Keys to understanding the proposed metrics include defining how deaths within counties are assigned to OPOs, the exact ICD-10-CM exclusionary codes used, and how donors are defined. Statistical properties of the proposed performance standards also affect the outcomes for OPOs. While measuring the performance of our nation's OPOs is challenging, finding the most useful metrics and performance standards to further the field of organ donation will ultimately save more lives through the gift of transplant.

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CONFLICT OF INTEREST

JS reports membership on the Board of Directors of Donate Life America, the Board of Directors for the Organ Donation and Transplantation Alliance, and the Clinical Policy Board of LifeSource (Upper Midwest Organ Procurement Organization, Inc). HHRI provides research support to The Living Legacy Foundation of Maryland.

DATA AVAILABILITY STATEMENT

Data are available from the Scientific Registry of Transplant Recipients and the Centers for Disease Control and Prevention.

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