February 20, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: [CMS-3380-P] Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage; Revisions to the Outcome Measure Requirements for Organ Procurement Organizations

Dear Administrator Verma:

The Association of Organ Procurement Organizations (AOPO) appreciates the opportunity to comment on the above-captioned Centers for Medicare and Medicaid Services (CMS) proposed rule addressing Organ Procurement Organizations (OPOs) conditions for coverage and outcome measure requirements (Proposed Rule). AOPO firmly supports the Proposed Rule's stated objectives to increase procurement opportunities for transplantation, increase organ utilization and ultimately save lives through donation and transplantation.[1] In keeping with those common goals, AOPO offers the following key recommendations in relation to the Proposed Rule, which are discussed in more detail below, with the pertinent section where each is addressed identified in parentheses:

- AOPO supports the proposed donation rate outcome measure and suggests that CMS improve the data underlying the measure (Section II(A));
- AOPO recommends that the performance threshold for the donation rate be set through an identified calculation of standard deviation from the mean utilizing a statistical methodology (Section II(B));
- AOPO recommends that CMS use the existing observed to expected yield measure and develop an appropriate performance threshold (Section II(C) rather than implement the proposed organ transplantation rate outcome measure that overlaps significantly with the proposed donation rate measure);
- Zero organ donors should not be excluded from the definition of donors (Section II(D));
- OPO outcome measures should be risk adjusted (Section II(E));
- Revisions to the outcome measures be implemented in the 2022-2026 recertification cycle (Section II(F);
- In conjunction with the improvements to OPO outcome measures, CMS take other actions to increase the donation and transplantation of organs, particularly those from medically complex donors (Sections II(G) and II(I));
- CMS consider mitigating factors and a performance improvement plan prior to OPO decertification (Section II(H));

[1] 84 Fed. Reg. 70628, 70630 (Dec. 23, 2019).

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- CMS carefully consider a number of key factors related to decertification that are discussed herein (Section II(I));
- CMS would continue to have alternative, risk adjusted measures for non-contiguous OPOs (Section II(J)); and
- CMS should not open the service area for competition at the conclusion of every recertification cycle (Section II(K)).

BACKGROUND

AOPO is the non-profit association with membership from the fifty-eight federally designated OPOs, serving more than 300 million Americans. As a professional organization, AOPO is dedicated to providing education, information sharing, research and technical assistance and collaboration with OPOs and other healthcare organizations and federal agencies. Member organizations bring their collective voices to the national conversation about organ and tissue donation to: 1) represent the donors and donor families who make organ transplant possible, and 2) provide hope within reach to the men, women, and children across the country waiting for a lifesaving organ transplant.

AOPO strongly supports the intent of the American Kidney Health Initiative announced by President Trump to reduce the toll of kidney disease on individuals, families and our nation. AOPO supports the Administration's stated goals in the Proposed Rule to increase organ donation and transplantation, and thus save lives. In 2019, OPOs increased organ donation by 10.7%, the ninth consecutive year of growth, and organ donation increased by 49% over that period. As a result of these improvements since 2010, there are now, on average, 109 lifesaving, deceased donor organ transplants per million population, and 132 living and deceased transplants per million. These are world-leading rates of transplantation, and that has helped shrink the transplant waitlist.

AOPO agrees with CMS that revisions to the OPO conditions for coverage (CfCs) are among the actions needed to stimulate even further increases in donation and transplantation and support the continual performance improvement efforts of the 58 OPOs to lessen and ultimately ameliorate patient deaths while on a waitlist for organ transplantation. But, there are other steps that CMS can undertake to help OPOs and donor hospitals collaborate on every donation opportunity and to facilitate transplant centers accepting far more of the thousands of organs that they currently decline. Together, we can continue the growth in organ donation, the amount of organ transplantation and greatly diminish, if not end, deaths on the waitlists. AOPO's comments herein are shared with that goal in mind.

I. GENERAL DISCUSSION

Before turning to specific aspects of the Proposed Rule, AOPO believes that it is important to set forth a number of overarching and intersecting principles that guide AOPO's response to the Proposed Rule.

A. Understanding that Improvement is Essential

All agree that the United States organ donation and transplantation system can and must continue to improve, as there are thousands of people who would benefit from increased system performance. At the same time, it is important to recognize that the United States organ donation and transplantation system has a demonstrated history of achieving positive change and outcomes. The U.S. donation and transplantation rates were the highest in the world in 2019 due to the collaborative work of the donor hospitals, transplant centers, organ procurement organizations, donors, donor families, recipients, public and community partners. The improvements in donation rates and increases in transplantation are the result of multiple factors, including: medical innovation, increases

in deaths consistent with organ donation, OPO performance through implementation of best practices, and changes in transplant practices to better utilize organs from medically complex donors.[2]

The advancements to date are not sufficient to meet the growing need for transplantation. Growth has not been evenly achieved across all 58 OPOs for a variety of reasons that need to be fully understood to continue to improve the system. A shared focus on continual performance improvement can result in more donations, more organs available for transplant and less deaths on the waiting list. In order to sustain positive change, it is critical to evaluate multiple measures of performance and to also institute a structure that accommodates continuous change and improvement based upon shared best practices and timely and accurate assessments of donation and transplant potential versus actual performance. Enhancing performance and accountability through new outcome measures is one part of the equation supported by the donation community.

B. The Importance of Adopting Transparent and Verifiable Measures which Advance Performance Improvement

In order to drive performance improvement and accountability, outcome measures should incorporate verifiable data points that assess different aspects of performance. Additionally, data used to calculate measures should be as current as possible, rather than subject to lag time that may have associated demographic changes that undermine the validity of the data as an accurate assessment of present performance.

In the early years of donation, CMS measured performance in terms of donors per million population, but living population was demonstrated to be a poor measure of donation potential because of large variances in death rates. The current donation rate measure is limited by the failure of the definition of eligible to include (i) patients who appear brain dead and are not declared, and (ii) donation after cardiac death (DCD) potential. This could contribute to an under estimation of donor potential and should be explored. The measures in the Proposed Rule, which look to more accurately assess "donor potential," will assist in evaluating and driving change if some modifications are accommodated.

C. Collaboration and Implementing Shared Best Practices are Vital to Overall Performance Improvement

Significant improvements have been a direct result of the structured collaboration sponsored by HHS' Health Resources and Services Administration's Division of Transplant. The Organ Donation Breakthrough Collaborative (ODBC) was established in 2003 to improve donation rates and utilize six different measures to assess performance. Notably a Change Package was developed to share and spread these best practices. During the ODBC period, the number of total US organ donors increased 22.5 percent − four times greater than the preceding period.[3]

In 2017, the National Kidney Foundation convened a conference on reducing kidney discard rates. The conference report, as well as other research, demonstrates a significant opportunity exists for improvement in transplantation rates by better utilizing organs currently available.[4] High

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[2] In 2019, the United States achieved a rate 109.3 deceased donor organ transplants per million, surpassing Spain's prior international record of 107.6 deceased organ transplants per million in 2018.

[3] Shafer et al, US Organ Donation Breakthrough Collaborative Increases Organ Donation. Crit Care Nurs Q. 2008; 31(3): 190-210.

[4] Cooper M, Formica R, Friedewald J, et al. Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards. Clin Transplant. 2019; 33:e13419. https://doi.org/10.1111/ctr.13419.

variability remains among transplant centers for utilization of organs, which could be aided by further collaboration between OPOs and transplant centers, in addition to targeted regulatory changes.

Concurrent with the release of the Proposed Rule is the initiation of End-Stage Renal Disease Treatment Choices Kidney Transplant Learning Collaborative aiming to decrease the kidney discard rate from 20 percent to 15 percent relying on the sharing of best practices. Local and international experiences where transplant and procurement entities are aligned demonstrates these goals are achievable.[5]

Recognizing the interdependencies among the stakeholders and ensuring that procurement organizations and transplant centers are fully aligned requires coordinated system changes. Key themes include the need to create an environment of data sharing, cultivating a community of partnerships through enhanced relationships and collaboration in order to grow a more cohesive and efficient community.[6] AOPO cautions that any regulatory framework adopted continue to support and advance collaboration and implementation of shared best practices among the various stakeholders and agencies.

D. Defining the Donor Pool is Essential

An important starting point is to define the donor pool. Published estimates range from10,500[7] to 24,000[8] to 37,000[9] to a staggering 272,000[10]; however, literature and published studies based on review of hospital records suggest a figure closer to 20,000 to 24,000.[11]

CMS proposes to use an administrative data set in calculating the donor pool for the outcome measures. While the proposed data set may serve as an interim step to compare OPO performance, there should be an on-going effort to understand the actual donor pool based on a patient-level medical record system.

Recognizing that there are likely a smaller and finite number of actual organ donors does not diminish the importance of addressing underperformance. Instead, it points to why every single donor and every single organ is critical and reinforces why any outcome measure should encourage and promote the same standard. It also emphasizes the message of urgency and the need for building

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5 Mohan S. "Kidney Transplantation, Good Intentions and Missed Opportunities Leave Patients Behind," Lecture presented at AOPO Winter Meeting, January 2020, San Diego, CA. Stewart D, Vece G, Ibrahim M, Callaghan C. "An International Comparison of Kidney Utilization in the United States and United Kingdom: What Can Be Learned?" [abstract]. Am J Transplant. 2019; 19 (suppl 3). https://atcmeetingabstracts.com/abstract/an-international-comparison-of-kidney-utilization-in-the-united-states-and-united-kingdom-what-can-be-learned/. Accessed January 28, 2020. Aubert O, Reese PP, Bouatou Y, et al. "Kidney Transplant Outcomes and Organ Acceptance Practice Patterns: Nationwide Analyses of the US and France" [abstract]. Am J Transplant. 2019; 19 (suppl 3). https://atcmeetingabstracts.com/abstract/kidney-transplant-outcomes-and-organ-acceptance-practice-patterns-nationwide-analyses-of-the-us-and-france/. Accessed January 28, 2020.

6 Neil H, Overacre B, Rabold M, et al. "Ad Hoc Systems Performance Committee Report." June 2019. https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf. Accessed January 28, 2020.

7 Sheehy E, Conrad SL, Brigham LE, et al. "Estimating the Number of Potential Organ Donors in the United States." N Engl J Med 2003; 349: 667–674.

8 Goldberg D, Kallan M J, Fu L, et al. "Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States." Am J Transplant 2017; 17: 1-10.

9 Klassen D K, Edwards L B, Stewart D E, et al. "The OPTN Deceased Donor Potential Study: Implications for Policy and Practice." Am J Transplant 2016; 16: 1707–1714.

10 84 Fed. Reg. at 70648.

11 *See* Goldberg, *supra* at n.8. *See also* Halpern S, Hasz R, Abt P. "Incidence and Distribution of Transplantable Organs from Donors after Circulatory Determination of Death in U.S. Intensive Care Units." Ann Am Thorac Soc 2013; 10(2): 73–80. Nathan H, Jarell BE, Broznik B, et al. "Estimation and Characterization of the Potential Renal Organ Donor Pool in Pennsylvania. Report of the Pennsylvania Statewide Donor Study." Transplantation. 1991; 51(1): 142-149.

support of every individual registering to become a donor. This message is equally relevant to donor hospitals to reinforce the importance of pursuing every single opportunity.

II. DISCUSSION OF SPECIFIC PROPOSALS

A. Donation Rate Outcome Measure Data

Under the Proposed Rule, CMS would revise the existing outcome measures for recertification in 42 C.F.R. § 486.318 by replacing the existing outcome measures with two new measures. The first proposed new measure ("donation rate") would calculate the percentage of possible deceased donors who become actual donors. In this measure, the numerator is the number of actual deceased donors in the donor service area (DSA) who had at least one organ transplanted, and the denominator would be the number of total inpatient deaths within the DSA among patients 75 years or younger with a cause of death that would not be a contraindication to organ donation. CMS would use data obtained from state death certificates, obtained from the Center for Disease Controls' (CDC), National Center for Health Statistics' (NCHS's) Detailed Multiple Cause of Death (MCOD), in calculating the denominator.[12]

A primary concern of AOPO is the use of data from death certificates for the following reasons:

- Accuracy – Death Certificates have repeatedly been found to be inaccurate. A literature review finds 30-60 percent of death certificates inaccurately reported the cause of death, with a Texas study stating, "Physicians are generally not trained on how to complete death certificates and determine causes of death in medical school, whereas, it is part of the training to become a board certified medical examiner."[13] Other researchers have reached similar conclusions.[14] The lack of accuracy and training are important because most organ donor death certificates are completed by hospital physicians, not Medical Examiners.

- Insufficiency of Information – Death certificate instructions do not call for reporting secondary diagnoses that are unrelated to the cause of death but affect the donor pool.

    - For example, based on the death certificate a death due to head trauma from an accident in which a patient with an underlying history of cancer would be included in the calculation. Such a patient would never be medically acceptable for donation and transplant. These types of secondary diagnoses may rule out thousands of possible donors every year.[15]

- Variation in Cause of Death Associated with Organ Donation – There is geographic variation in the causes of death. A review of the CDC data of the 7 causes of death most closely associated with the donor pool (overdoses, firearms, accidents, strokes, hypertension, homicides, and suicide) finds the highest rate to be in West Virginia at 259.1 deaths versus New York at 104.7,

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12 84 Fed. Reg. at 70631-32.

13 Improving the Quality of Cause of Death Information on Texas Death Certificates, Texas Department of Health Services, Oct 2018.

14 Lloyd J, Jahanpour E, Angell B, Ward C, Hunter A, Baysinger C, Turabelidze G. "Using National Inpatient Death Rates as a Benchmark to Identify Hospitals with Inaccurate Cause of Death Reporting – Missouri, 2009-2012." Morbidity and Mortality Weekly Report 2017: 66(1): 19-22 ("an average of 45.8% of reviewed death certificates were completed incorrectly"). McGivern L, Shulman L, Carney J, Bundock E. "Death Certification Errors and the Effect on Mortality Statistics." Public Health Reports 2017; 132(6): 669-675 (53% of the 601 original death certificates examined had major errors).

15 These differences are identifiable through a review of CDC data on reporting of cause of death by state, which is available at https://www.cdc.gov/nchs/pressroom/stats_of_the_states.htm.

a variance of 247% and 28.2 standard deviations.[16] Causes of death are not evenly distributed across the country, and the CDC data show that highest to lowest state variances in firearms deaths vary some 980%, overdoses 714%, homicides 655%, strokes 208%, hypertension 385%, accidents 303%, and suicide 357%.[17]

- Time Lag – Although not explicitly addressed in the Proposed Rule, AOPO's understanding is that there is a significant lag in the availability of data from death certificates – currently two years. Measuring donation performance of each OPO in a survey year against death data from two years earlier is concerning given significant changes can occur in that time period. This assumes a statistically reliable year over year correlation of deaths, death rates, and causes of death within each OPO's DSA, which has not been demonstrated.

- Confidence Intervals – The use of confidence intervals appears intended to address the higher variability in performance experienced by smaller OPOs due simply to their size. However, mathematically, the proposed confidence intervals cause a methodological bias that negatively affects OPOs with larger populations.

AOPO recognizes that the statute requires that pancreata procured for islet cell transplantation or research be considered as part of OPO performance assessment. At the same time, AOPO has concerns about including pancreata utilized for research in the data used to calculate the numerator of either proposed measure. The utilization of pancreata for research is driven by demand of local researchers. Inclusion of pancreata for research in the data utilized for the numerator may skew comparisons of OPOs in that category and potentially lead to inaccurate conclusions. AOPO recommends CMS consider balancing the statutory requirement related to pancreata and its desire to improve organ transplantation rates.

While AOPO supports the utilization of the proposed outcome measure, the above comments are meant to help optimize the reliability of the measure to evaluate OPO performance. If CMS is considering an action such as decertification it would be prudent to take into account the impact of the variability, potential inaccuracies and time lag of the data being used for such determination.

B. Consider a Performance Threshold That is Statistically Supported

CMS proposes a performance threshold set as the top 25th of OPO performance as established prior to the subsequent recertification cycle. While the goal of moving all OPOs towards the highest performance is shared by AOPO, the placement of a performance threshold should be carefully considered in light of what the consequences of not meeting the threshold could be. We propose the utilization of the performance threshold to be a first step in a screening process for identification of OPOs to be reviewed for mitigating factors and/or placed into a structured performance improvement process. However, if the consequence of not meeting the performance threshold is immediate decertification without the opportunity to present mitigating factors or an improvement plan then the threshold should be set at a level consistent with clear underperformance. If the goal is system improvement, AOPO recommends CMS reconsider setting the 25th percentile as the performance threshold.

[16] These data are available at https://www.cdc.gov/nchs/pressroom/stats_of_the_states.htm.

[17] CDC data illustrate this wide variability across various causes of death: firearms (24.5 in Alaska v. 2.5 in Hawaii), overdose (57.8 in West Virginia v. 8.1 in Nebraska), suicide (28.9 in Montana v. 8.1 in New York), accident (100.3 in West Virginia v. 33.1 in California), stroke (51.1 in Mississippi v. 24.6 in New York).

One of the ways to establish an appropriate performance threshold is to evaluate larger datasets.

- For example, when the Scientific Registry of Transplant Recipients (SRTR) developed the Bayesian-based flagging boundary that is currently in use by the OPTN for monitoring post-transplant outcomes for transplant programs, the flagging boundary was set based on >60,000 simulations with a false positive rate of approximately 5 percent across the range of program volumes. The quality of a set performance threshold should be quantified based on true positives, false positives, sensitivity, and specificity. These four factors need to be carefully evaluated by CMS before implementing a new performance threshold for OPOs based on newly developed measures, using newly sourced data.

AOPO recommends that CMS establish a performance threshold for the donation rate measure based on a calculation of a specified standard deviation from the mean rather than a set percentage of "top" performance. Utilizing a performance threshold based on a calculation of standard deviation from the mean is a more accurate method to fairly assess relative performance. It balances the need to incentivize continual performance improvement while establishing a rational basis for such a threshold as supported by the data and valid statistical methodology.

C. AOPO Recommends that CMS Retain the Current Observed to Expected (O:E) Outcome Measure in Lieu of Adopting the Organ Transplantation Rate Outcome Measure

The second new outcome measure CMS proposes would calculate the rate of organs transplanted after procurement ("organ transplantation rate"). In this measure, the numerator is the number of actual organs transplanted based on data obtained from the OPTN, and the denominator again would be the number of total inpatient deaths within the DSA among patients 75 years or younger with a cause of death that would not be an absolute contraindication to organ donation (also using data from state death certificates).[18] As an alternative, AOPO believes the current O:E is more statistically valid in terms of ensuring the maximum number of organs are transplanted per donor.

1. Consider Alternatives to Adoption of the Proposed Organ Transplantation Rate Measure

The "organ transplantation rate" measure does not adjust for underlying differences in organ transplant potential which significantly affects the probability of transplant centers acceptance of an organ for transplantation. The measure assumes an equal distribution of donors and organ types across all OPOs without accounting for known factors beyond control of the OPO which affects the ability to place organs for transplantation. For example, the ratio of potential brain-dead donors to DCD donors significantly varies between DSAs. The organs transplanted measure penalizes an OPO that has a larger DCD donor pool and advantages an OPO with a smaller DCD donor pool, thus undermining the validity of the measure as an accurate assessment of performance. The lack of adjustment of the measure for the DCD donor pool where the donor acceptance rate is lower than in the brain dead donor needs to be factored in. AOPO is concerned that the proposed measure will not accurately reflect the performance of OPOs and could lead to incorrect conclusions as to actual performance. We suggest CMS consider utilizing the O:E in place of the transplantation rate as this measure accounts for the differences in transplantation rates of DCD donor organs versus brain dead donor organs.

[18] 84 Fed. Reg. at 70631-32.

AOPO is concerned with the high correlation of this proposed organ transplantation rate measure with other measures being proposed. Outcome measure assessment must contemplate the evaluation of separate aspects of the donation process focusing on both the ability to secure an authorized donation and secondly to maximize utilization of available organs. Using the same denominator as the proposed donation rate outcome measure, by definition, leads to a transplant rate highly dependent on factors related to the donation rate (timely identification of potential donors, authorization, donor management). As such, it would not be an independent measure of effectiveness of organ allocation and placement for transplantation.

An OPO's performance on the proposed organ transplantation rate measure, as a second measure, will be almost solely dependent on its performance under the first proposed donation rate measure. An SRTR analysis to replicate the CMS report for 2017 demonstrates that only 1 of 32 OPOs which fails on the first proposed measure would pass on the second proposed measure. Similarly, 6 of 26 OPOs which fail on the first measure would fail on the second measure.[19] Further, even the information CMS cites in supporting the proposed outcome measures supports AOPO's concern about the correlation of the two proposed measure. Specifically, CMS cites a 2017 publication by Goldberg, et. al. as support for the proposed measures.[20] Yet, the same Goldberg study cited recognizes the limitation of the analysis by identifying that the two measures as highly correlated (Spearman correlation coefficient = .88).[21]

The statute requires OPOs to meet multiple standards. However, by using the same denominator, the proposed measures do not assess different and distinct parts of the donation process – conversion of potential donors and placement of organs for transplant. As a result, the two proposed measures do not seem to align with the statute.[22] In contrast, the O:E yield is completely independent of the new proposed first measure, and more accurate in measuring OPO performance in placing organs for transplantation (as compared to measuring an OPO's ability to convert potential donors to actual donors which is what the donation rate is measuring). Further, O:E measures are the norm in measuring transplant program performance. Replacement of O:E yield with the proposed second measure would be a significant step backwards in promoting increased transplantation.

In addition, the proposed organ transplantation rate measure does not adjust for known variation in the age of decedents and suitability of organs for transplantation among the donor pool. Donor age has a highly significant effect on the probability of transplant center acceptance of organs and this second measure does not adjust for the variation in age of death for potential donors. For example, in 2019 there were only 21 DCD organ donors over the age of 65 in the entire U.S. because transplant programs will not currently transplant organs from these donors. If a DSA has a disproportionate amount of older DCD donors within their pool, the OPO will be significantly disadvantaged under the proposed organ transplantation rate measure. This furthers AOPO's concern that the proposed organ transplantation rate measure would not serve the agreed upon goal of increasing organ donation and transplantation. Alternatively, the AOPO recommended O:E measure will account for differences in donor characteristics as a better indicator of OPO performance.

2. Retain and Revise the Current Observed to Expected Outcome Measure

AOPO believes that the current SRTR Observed to Expected (O:E) Yield measure should be retained as the measure of organ transplantation rates. The observed versus expected ratio calculates the number of organs that would be <u>expected</u> to be transplanted from a given donor (based upon

19 Personal communication with Jon Snyder, PhD. Manuscript submitted for publication.
20 84 Fed. Reg. at 70647.
21 *See* Goldberg *supra* at n. 8 (page 3187).
22 Public Health Service Act § 371(b)(1)(D)(ii)(III).

20,000 plus actual donors) and then compares it to the number of organs the OPO actually provides for transplant. If the ratio is 1.0, the OPO is performing as expected, if the ratio is > 1.0 the OPO is exceeding expectation, and if the ratio is < 1.0 the OPO is performing below expectation. The data is independently reported, verifiable, calculated, and analyzed by the SRTR. The O:E measure was developed by OPTN in 2010 and was adopted by CMS in 2016.

As described on the SRTR website,

> "In addition to [organs transplanted per donor], SRTR performs an assessment of whether or not the number of organs transplanted is above or below expectation for the donor. To do this, SRTR uses a series of complex statistical models that take into account various characteristics of the donor. These models attempt to estimate the likelihood of successful organ transplant based on how often organs from similar donors were successfully transplanted nationally. This comparison results in an observed-to-expected yield ratio, or O/E ratio. If the O/E ratio is 1.0, then the OPO successfully places organs for transplant at a rate consistent with national performance with organs from similar donors. If the O/E ratio is less than or greater than 1.0, then the OPO has lower or higher rates, respectively, of successfully placing organs for transplant. For example, an O/E ratio of 1.2 for liver yield suggests that the OPO successfully places livers for transplant 20% more frequently than expected based on national experience with livers from similar donors, and an O/E ratio of 0.85 suggests that the OPO successfully places livers for transplant 15% less often than expected based on national experience."[23]

This measure has a statistically high accuracy level and is dynamic and adjusted over time comparing current performance to a significant sized, but relatively recent data cohort. Moreover, it incentivizes pursuit and placement of all donor types, including cases where the expected transplant rate is <1.0 organs per donor. Thus, AOPO believes that the O:E Yield outcome measure is more suitable than the proposed organ transplantation rate outcome measure because it better aligns with the stated CMS objective of successfully placing all possible organs for transplantation. The current measure of compliance used by the OPTN is not necessarily appropriate for CMS's stated purpose of driving improvement through the decertification process. Rather, CMS should utilize a statistical analysis to determine what an appropriate O:E cutoff would be for action by CMS.

D. Zero Organ Donors Should Not Be Excluded from the Definition of "Donors"

An appropriate goal of the Proposed Rule is to maximize the number of donor organs OPOs make available for transplant, with the ultimate system goal of having those organs transplanted to benefit patients. In the Proposed Rule, CMS expresses concern existing outcome measures might encourage "OPOs to walk away from cases in which the donor only has one viable organ for transplant (such as for older patients)" and that "potentially transplantable organs may be wasted, exacerbating the organ shortage problem."[24] CMS seeks to encourage the "pursuit of single-organ donors because we believe that these donors are the greatest opportunity for growth."[25] However, these are the donors who most often are older or DCD donors. Excluding these individuals from whom an OPO recovered at least one organ with the intention of transplant (but no organs were transplanted) from the definition of "donors" - referred to as "Zero organ donors" - is in direct conflict with these important goals. AOPO recommends that CMS not exclude Zero organ donors

[23] See "Measuring Donor Yield", available at https://www.srtr.org/about-the-data/guide-to-key-opo-metrics/opoguidearticles/donor-yield/.

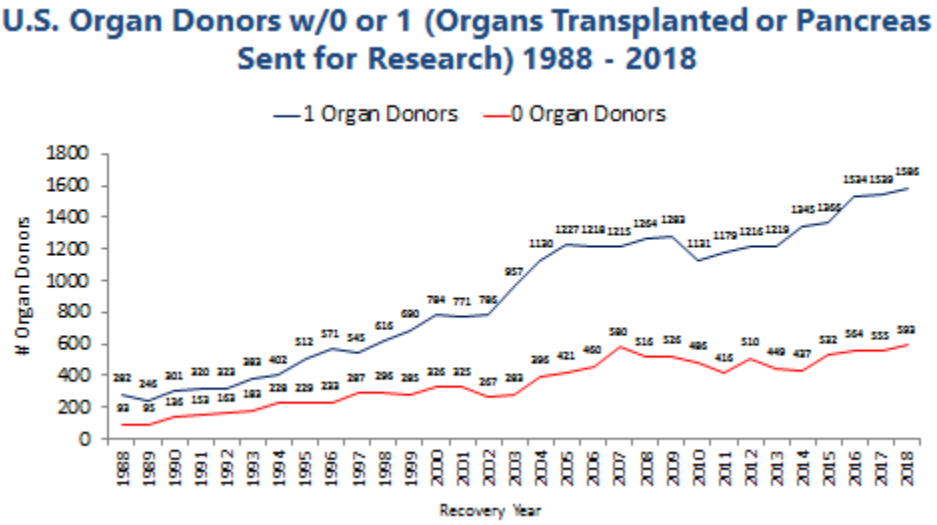
[24] 84 Fed. Reg. at 70630.

[25] 84 Fed. Reg. at 70631.

from the definition of "donor" because inclusion will ultimately facilitate increased organ procurement and potentially transplantation.

Exclusion of Zero organ donors would have the unintended consequence of discouraging, rather than encouraging, the pursuit of organs. Zero organ donors only include patients that were: (1) referred to the OPO; (2) preliminarily determined by the OPO to be medically suitable; (3) authorized for donation by the OPO; (4) allocated for transplant for at least one organ and had that offer preliminarily accepted by a transplant center; and (5) taken to an operating room where the OPO coordinated the surgical removal of the organ and at least one was removed from the patient with the intent to transplant. It is only after the OPO has successfully performed all of these critical donation process steps when a transplant surgeon may discover new information regarding the organ or donor or recipient which precludes the transplantation. This can occur for a variety of reasons, such as biopsy findings or organ preservation parameters only discovered following the organ removal.

Including Zero organ donors in the definition of "donor" as calculated in the numerator for a donation rate incentivizes OPOs to actively pursue more complex donors (the exact behavior CMS wants to incentivize) and future improvements in organ preservation technologies may aid in allowing more of these organs to be transplanted. Indeed, organs from complex donors represent a significant opportunity for growth in donor organs which should be incentivized. The data shows that as the number of donors with a single organ transplanted has increased so has the number of Zero organ donors.



E. The Outcome Measures Should be Risk Adjusted

In the Proposed Rule, with one exception, CMS indicates that it would not risk adjust any of the proposed outcome measures.[26] We believe that this undermines the effectiveness of the new measures. AOPO strongly supports inclusion of additional risk adjustments to calculations of the donor pool that are objective and available in the CDC data set. These factors are known to significantly impact actual donation opportunity and are beyond the control of the OPO.

[26] 84 Fed. Reg. at 70634 (proposing only the exclusion of ICD-10 codes that are absolute contraindications to organ donation, the age of 75 and younger, and the requirement that the death occurred as a hospital inpatient).

The concept of risk adjustment for objective, known, and meaningful variables that influence outcomes is well established in organ donation and transplantation, and the breadth of standardized data collected is unique in healthcare. To be able to produce the most accurate estimate of the number of potential organ donors a data source would need to include complete and detailed information on multiple causes of death, all procedures performed, the hospitalization status at death, ventilatory status, and all co-morbidities for every death in the United States. Such a source independent of the OPOs does not currently exist.

AOPO advocates additional risk adjustments based on underlying characteristics that are objective, calculated to be significant, and beyond the control of OPO influence. This is particularly important in light of the proposed consequences of an OPO not meeting the performance threshold under the Proposed Rule (i.e., decertification without ability to present mitigating factors or enter into a structured improvement plan). Without appropriate risk adjustment, the system cannot be assured an accurate measurement of OPO performance and could result in decertification decisions based on underlying factors beyond the OPOs control rather than performance.

In the proposed rule CMS acknowledges the limitations of the CDC data set. This includes the absence of co-morbidities not related to the cause of death which significantly impacts the donor pool and documentation of mechanical ventilatory support, a known requirement for organ donation potential.[27] The OPTN Deceased Donor Potential Study (DDPS) analyzing the same data source concluded: "As a result, there may be deaths in the analysis that are considered to have donation potential but should have been excluded from consideration if complete clinical information had been available. Thus, any estimates based solely on NCHS data may overestimate the true number of potential deceased organ donors. It is not possible to quantify the degree to which donor potential is overestimated strictly from the NCHS data."[28] This is consistent with research using administrative data sets, similar to those in the Proposed Rule, by Caren Rose, PhD, which shows that only 50.4 percent of "estimated possible donors" were found to be medically suitable organ donors following medical chart review.[29] Given this discrepancy between the estimated and actual donor pools assessed through patient-level medical records (the recognized gold standard),[30] it is crucial for the data to be risk adjusted to ensure accurate measurement of OPO performance.

Accordingly, AOPO supports risk adjustment of the proposed donor potential calculation to include objective factors available in the data set such as age, cause of death and gender. The evaluation measures should adjust for underlying characteristics that significantly affect the probability of the donor pool becoming actual donors. These factors also impact transplant center acceptance of an organ for transplantation. The SRTR currently maintains 43 risk adjustment models for assessing post-transplant patient and graft survival.[31] For example, advanced age is known to have a significant effect on organ yield. The most recent SRTR report, depicted in the graphic below, demonstrates the strong association between the age of the donor and the odds of acceptance, with odds of acceptance approaching zero above age 60.[32] Data for other organs is available on the SRTR website and shows similar correlations.

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[27] Organ Procurement and Transplantation Network. OPTN Deceased Donor Potential Study (DDPS), Task 6, DHHS Contract 234-2005-37011C/0023, available at https://optn.transplant.hrsa.gov/media/1161/ddps_03-2015.pdf.

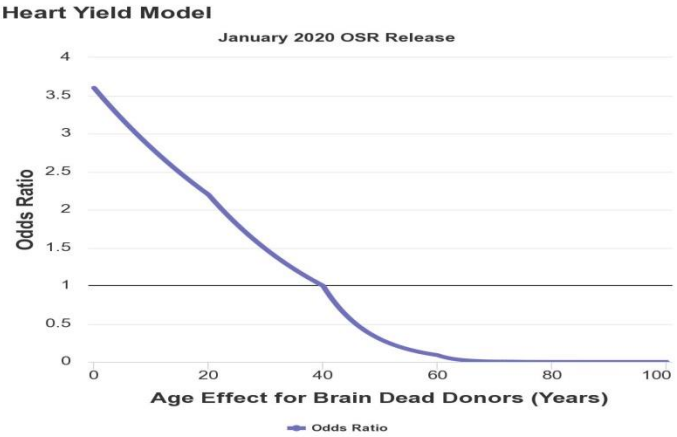
[28] Id. at pp. 18-19.

[29] Rose C, Nickerson P, Delmonico F, Randhawa G, Gill J, Gill JS. "Estimation of potential deceased organ donors in Canada." Transplantation, 2016; 100: 1558–1563.

[30] *See* Goldberg, *supra* at n. 8.

[31] Snyder J, Salkowski N, Kim SJ, Zaun D, Xiong H, Israni AK, Kasiske BL. "Developing Statistical Models to Assess Transplant Outcomes Using National Registries: The Process in the United States." Transplantation 2016; 200(2); 288-294.

[32] Scientific Registry of Transplant Recipients. www.srtr.org/reports-tools/opos/ accessed February 2, 2020.



CMS seeks input on an alternative model using diagnostic inclusionary criteria, the so called CALC measure as proposed by Goldberg, et al. AOPO supports the CALC model as it measures greater precision and consistency in reporting OPO level donation potential. This model brings additional refinement by identifying deaths that are consistent with donation potential.

F. Revisions to Outcome Measures Should First be Implemented in the 2022-2026 Recertification Cycle

The benefits of an improved outcome measure will be immediate in that all OPOs will be able to more accurately assess their performance against their peers and thus seek improvement through benchmarking and sharing of best practices. AOPO's understanding is CMS will begin using the new measures for recertification evaluation in 2026. Please confirm this to be the case.

AOPO also asks for clarity on certain additional points related to implementation of the new measures. For a year assessed under the new measures, from which year will the data be drawn? In addition, AOPO seeks clarity on the year in the recertification cycle to be considered in a decertification decision and which year the data will be calculated from – will the numerator and the denominator be calculated from the same time period? Finally, does CMS expect to use multiple years of data and, if so, will it use a weighted average? AOPO would appreciate CMS providing more specific information on these issues.

We recommend that multiple years be used in the calculation which will be more indicative of OPO performance over time. This will eliminate the disparity of data sets across OPOs and help balance year-to-year variation.

G. More Needs to be Done by All Entities Within the Donation/Transplantation Eco-System to Increase the Utilization of Organs, Particularly Complex Organs

The organ donation process involves distinct and regulated entities such as OPOs, transplant centers, and donor hospitals. OPOs have been charged in their performance measures to recover as many organ donors and transplantable organs as possible. Transplant center performance has been measured with the charge of transplanting patients who will survive one year or longer with their graft. Donor hospitals have standards of performance that are set out in the CoPs. While the Proposed Rule is focused on OPO CfCs, in order to effect system-wide improvement, AOPO believes a wider lens should be adopted to reach the stated goal.

Donor hospital CoPs require them to maintain supportive measures to allow for donation and make a timely referral (defined in the OPO affiliation agreements with these hospitals and usually stipulated as being within 1 hour of a mutually-agreed-upon clinical trigger) for every death and imminent death. In addition, under the CoPs, donor hospitals must preserve the option of donation for the family decision and have a designated requestor – the OPO or someone at the hospital trained by the OPO – to discuss the option of donation with the family.

The donor hospital CoPs target donor hospital performance, but currently only the OPO is tracking information for usage in a quality assurance and performance improvement (QAPI) program to improve the donation process at the affiliated hospital. CMS does not currently track or report this information which AOPO believes is a missed opportunity. By collecting and reviewing this data, CMS would be able to identify "best practices" to share with the donation community – possibly through a national collaborative activity - to elevate system performance.

In the President's Executive Order "Advancing American Kidney Health", it was noted not only is there a need to improve the OPO outcome measures, but also reduce delayed acceptance of organs by transplant centers and invest in improved technologies.[33] CMS likewise recognizes the equally important role played by transplant centers, having noted "the inextricable connection between transplant centers and OPOs."[34] It also stated its "goal for this rule and the organ transplantation rate measure is to incentivize the 'system' to establish efficiencies that will result in substantial improvement of organ placement and transplantation".[35]

Researchers studying organ donation and transplantation issues similarly stated that it "is important to recognize that the responsibility of maximizing organ utilization rests not only with the OPO but the transplant centers who decide to accept or decline the organs procured by the OPOs."[36] AOPO fully agrees with these statements and believes improvements to the OPO outcome measures are important steps to increase availability of organs. However, it is important to consider the role that all participates in the donation/transplantation eco-system play in increasing the transplantation of organs to the benefit of patients.

CMS should acknowledge and address the two different paradigms in organ donation and transplantation. The common refrain is that there is a shortage of organs for transplant. In fact, the U.S. surpasses the expected rate of donation from the pool of younger, healthier donors.[37] Equally true, but less acknowledged, there is not enough transplant program demand for organs from older, medically complex and DCD donors as evidenced by the high turndown and discard rates in the U.S. The increase in donation CMS anticipates will be derived in large part from complex, older, or DCD donors. Failure to address the current barriers will result in significant increases in the already high discard rate and will thwart efforts to meet the shared goal of increased transplant rates.

An area that deserves particular attention is the removal of obstacles for transplant program acceptance of organs, especially from complex, older, or DCD donors. Evidence shows that many organs offered by OPOs are not being accepted by transplant programs. From 2016-2018, over 14,600 recovered organs offered by OPOs were declined by all programs to which offers were made, and ultimately discarded. This includes over 10,900 kidneys discarded over three years, which is 20 percent of the total

33 84 Fed. Reg. 33817 (Jul. 15, 2019).
34 84 Fed. Reg. 39398, 39597 (Aug. 9, 2019).
35 84 Fed. Reg. at 70632.
36 *See* Goldberg, *supra* at n. 87 (page 3190).
37 "OPOs exceed expectations when collecting organs from young brain-dead donors" Lives Lost, Organs Wasted, Washington Post, December 20, 2018.

number of deceased donor kidneys recovered.[38] Studies have shown that on average, candidates that die waiting for a kidney have received 16 organ offers from an OPO that were declined on the candidate's behalf by the transplant program where the candidate was listed.[39]

Further, CMS's mention of the study comparing French and American organ utilization from 2004 to 2014 points to the use of organs from older donors in France contributing significantly to their higher transplantation rate.[40] The authors of the study state their findings "strongly suggest that patients wait-listed for kidney transplantation would benefit if U.S. transplant programs were more willing to accept lower quality kidneys, particularly from older deceased donors. Notably, the higher KDRI (Kidney Disease Risk Index) scores of kidneys transplanted in France vs the United States was primarily owing to older donor age and not to the wider use of kidneys from donors with other specific characteristics that may negatively impact allograft quality, such as hepatitis C seropositivity or cardiac death."[41]

In light of these findings, there are other steps that CMS can take to eradicate disincentives for transplant centers to accept organs from complex, older, or DCD donors. If measures applicable to OPOs or transplant centers reward the acceptance of only the more desirable organs, the United States will continue to lag behind other countries. As CMS noted there is an important policy difference between here and France and other European countries, where "organs from older donors are systematically matched for use by older patients, without penalizing transplant programs for the lower success rates that inevitably result."[42] That is precisely what CMS needs to do here to complement its revisions to the OPO outcome measures.

In the Proposed Rule, CMS states that OPOs have influence on transplant hospital practice through OPO advisory boards. The level of influence this affords, if any, should not be overstated. Most transplant hospitals have multiple transplant programs representing different organs, and only one of these programs from each hospital is required to be on the OPO advisory board. As such, the majority of transplant programs do not have surgeons on these OPO advisory boards. Further, with the introduction of broader distribution policies, the historical relationship between OPOs and their affiliated transplant programs has fundamentally changed. In fact, for the first six months of 2019, 43 percent of all transplanted organs went to transplant programs outside of the donor DSA.[43] In some OPO service areas the percentage of organs transplanted outside of the DSA is over 90 percent.[44] Organ acceptance practices have not changed significantly despite more than a decade of transplant surgeon representation on Advisory Boards.

In summary, AOPO encourages CMS to remove disincentives and incentivize transplant programs to be more diligent in their organ acceptance and utilization decisions. Many of these strategies are described in detail in the recent paper: Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards (Cooper M, Formica R, Friedewald J, et al, Clin Transplant. 2019 Jan;33(1):e13419.

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38 This information comes from the OPTN DSA dashboard, released in January of 2020 and available at www.optn.org.

39 Husein A, King K, Pastan S. "Association Between Decline Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates." JAMA Network Open 2019; 2(8).

40 84 Fed. Reg. at 70654-55.

41 Aubert O, Reese PP, et al, "Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance." JAMA Intern Med 2019: 2322.

42 84 Fed. Reg. at 70654-55.

43 This information comes from the OPTN DSA dashboard, released in January of 2020 and available at www.optn.org.

44 Scientific Registry of Transplant Recipients, available at https://www.srtr.org/reports-tools/opos/.

AOPO recognizes OPOs can work in collaboration with the donation/transplantation partners to impact and enhance the probability organs are utilized. This can be accomplished by implementing strategies related to the donation process in collaboration with our hospital partners. While OPOs currently focus on continual improvement, more can be done along these lines to optimize the likelihood viable organs will be transplanted. AOPO wants CMS to know that it is committed to improving the aspects within an OPO's control while working collaboratively with transplant center partners to maximize the outcomes of this process. We welcome increased accountability and improved measuring of the aspects of the transplantation process OPOs can control. The ultimate decision of whether an organ is transplanted into a recipient is within the practice of medicine and ultimately rests with the transplant surgeon.

H. Incorporate Mitigating Factors and Implement a Performance Improvement Plan Prior to Decertification

The Proposed Rule outlines revised outcome measures for evaluating OPO performance and consequences for OPOs which fall below the performance threshold established by these measures. While the limitations of the measures have been addressed elsewhere in this document (Sections II(A), (B) and (C) above), under any measure, it is expected that some OPOs may fall below the required performance threshold.

AOPO has significant concerns the Proposed Rule does not provide OPOs that do not meet both outcome measures an alternative to decertification. Rather, the Proposed Rule creates a pass/fail "cliff" system specifically based on the last 12 months of performance. This would create a unique situation in the healthcare system where a provider or entity has no opportunity for improvement, appeals, or remediation. The proposal could lead to the decertification of high performing OPOs that had previously met performance measures during the first three years of the certification cycle, yet simply missed the performance threshold of one measure by a small margin during the last year. OPOs that implemented process changes through their QAPI plans resulting in continuous, substantial and sustained improvements over the four-year certification cycle, and still only met one of the two outcome measures, could also be decertified. This undermines the incentives to improve. As noted above, an OPO may fail to meet outcome measures based on the limitations of the measures themselves and the lack of risk-adjustments.

CMS notes that the Proposed Rule has the potential to decertify between 7 and 33 OPOs.[45] Decertification of such a large number of OPOs will create disruption and instability in the organ donation system. The consequences of such destabilization are discussed in detail in Section II(H) below. With the development of a systematic appeals process for OPOs, stability can be added to the system and prevent OPOs from being decertified unnecessarily. Such a process would further provide structure and guidance for both CMS and the OPO community, as well as transparency to other interested parties.

As part of the appeal process, AOPO strongly advocates for allowing OPOs that do not meet the outcome measures to request consideration of mitigating factors relative to performance. Potential mitigating factors could include (though not limited to): (1) the extent to which outcome measures are met, (2) recent performance or trends reflecting continuous improvement, (3) adoption of processes and practices that have supported improvement in other OPOs, (4) demonstrated disproportionate demographic variances that result in the decertification of the OPO, or (5)

[45] 84 Fed. Reg. at 70639.

extenuating circumstances, such as a natural disaster may have a temporary effect on meeting outcome measures.

Upon review of mitigating factors, CMS could either: (1) recertify the OPO or (2) provide the opportunity for a Performance Improvement Plan. AOPO's suggestions are in line with processes afforded to other entities subject to Conditions of Participation (CoPs) or Conditions for Coverage (CfCs). Transplant centers were provided the opportunity to submit mitigating factors or enter into a systems improvement agreement (SIA) upon Medicare re-approval until recently when key outcome measures were removed from their CoPs, negating the needs for mitigating factors or SIA. Even so, "transplant programs are still afforded the opportunity to submit mitigating factors or enter into systems improvement agreements for the initial Medicare approval."[46] AOPO simply requests the same considerations be provided to OPOs.

I. Decertification Process Concerns

The decertification process CMS proposes raises a number of concerns and questions. Without the opportunity to present mitigating factors or enter into a Performance Improvement Plan (discussed in Section II(G) above), the automatic decertification of OPOs that do not achieve the proposed threshold could cause significant destabilization of the system resulting in a drop in donation rates. There are large areas of the country where an entire region has either no or only one smaller OPO that appears to meet the proposed measures. For example, the Proposed Rule identifies only one OPO in the entire Northeast which meets the proposed threshold and that OPO coordinated 50 donors in 2017, whereas the OPOs in the surrounding area (Connecticut, Maine, Massachusetts, New Hampshire, New York, New Jersey, Rhode Island and Vermont) that do not meet the proposed measures coordinated over 1,000 donors total in 2017. With the goal of continuing to improve the availability of organs for donation, nationwide destabilization of the organ donation process will in fact stall progress, potentially resulting in lives lost. Continuous coverage can only be achieved with collaboration, cooperation and a stepwise transition, which does not appear attainable with multiple decertifications in play.

While CMS solicits "comment on the costs associated with an OPO entering a new DSA after a decertification, including retraining, leadership, relationship building and implementation of other best practices"[47] and on the "transition costs associated with the disruptive process of decertification",[48] as detailed below there are legal and institutional issues that CMS should consider with regard to decertification.

- Financial, Operational and Legal Considerations: The required capital investment for an OPO to expand into a new service area previously served by a decertified OPO (e.g., 24/7 staffing, buildings, equipment, information technology, vehicles) would likely be high. The level of that investment is likely to reduce, if not prevent, the competition for open DSAs as a result of decertification. OPOs are required by federal statute to be privately held charitable non-profit organizations and are subject to state-based corporate laws restricting the use of their funds and their corporate restructuring.[49] OPOs decertified by CMS would remain nonprofit organizations. The OPO's assets, as a nonprofit organization, are therefore subject to state Attorney General oversight[50]. It is unclear to AOPO how the assets of a decertified OPO, which is still an existing entity, will be transferred to another OPO.

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46 84 Fed. Reg. at 51732, 51750 (Sept. 30, 2019).
47 84 Fed. Reg. at 70661.
48 84 Fed. Reg. at 70660.
49 42 U.S.C. § 273(b)(1)(A).
50 *See* https://www.stateag.org/policy-areas/charities.

Because non-profit governing boards have fiduciary responsibility of financial and corporate stewardship, OPO Board approval is legally required for any consolidation, merger or transfer of the organization or its assets. In addition, Attorney General approval may be required dependent upon state law.[51] Some OPOs are hospital-based which means they are not independent nonprofit organizations but rather subject to the Hospital's Governing Board.

The processes of merger or consolidation require fiduciary decision-makers, state regulatory authorities, state filings, time, diligence and careful up-front planning to be accomplished successfully and without service disruption. A decertified OPO may remain a fully operational nonprofit organization functioning as a tissue recovery agency or other organ donation-related work through public education or fundraising. This is an important consideration as CMS contemplates automatic decertification of OPOs. The state legal requirements regarding nonprofit corporate actions, together with the financial and operational burden of start-up costs for an OPO to expand into new service areas may create the real possibility of an area having no OPO at all after an existing OPO is decertified.

- OPO Evaluation of Applying for a Decertified OPO's DSA: An OPO that has a higher donation and transplant rate under the Proposed Rule has no incentive or regulatory relief in taking on a low performing OPO's service area. The Proposed Rule proposes that CMS would not evaluate an OPO that takes on a decertified OPO's service area until twelve months of data is available. However, twelve months is not an adequate timeframe to ensure sufficiently increased performance to not jeopardize the OPO's ranking moving forward. AOPO suggests that more significant regulatory relief and financial incentives be provided to ensure that OPOs can maintain current performance while focused on intense performance improvement of a new service area. Finally, as noted above, consolidation, merging or expanding service area requires Board action.

- Destabilization of the System: The best practices that support performance at a small OPO or a hospital based OPO may not in fact be successful at a larger OPO or a different area of the country. It is important to appreciate organizational scale and infrastructure necessary to support continual performance improvement. The incorporation of the larger OPO program into a smaller OPO may for example delay, halt or even reverse progress on donation performance for both OPOs. The time necessary to staff with trained donation professionals, forge donor hospital and transplant program relationships, and establish goals for the integrated entity, could cause a decline in local donation rates. Simultaneous decertification of multiple OPOs will likely cause significant short-term expense to the system without any certainty of long-term benefit. The goal of system improvement is better served through regulatory incentives and removal of existing regulatory barriers to OPO consolidation.

J. Special Issues for Non-Contiguous OPOs

The Proposed Rule specifically requests comment regarding the burden and unique challenges faced by non-contiguous OPOs.[52] These challenges have been well documented by CMS and other governmental bodies, acknowledging the differences in these service areas with appropriate alternatives designated to measure performance. These alternative measures, risk adjusted to reflect

[51] See e.g. California Corp. Code, §§ 5913; Massachusetts G.L. ch. 180.
[52] 84 Fed. Reg. at 70636.

the population and potential, should continue to exist for the two current non-contiguous OPOs (Hawaii and Puerto Rico).

In the CMS 2006 OPO final rule, the agency recognized that "OPOs operating exclusively in non-contiguous locales have fewer options for placing organs because they have fewer transplant centers (particularly extra-renal transplant centers) and may be located too far from the continental United States for the viability of extra-renal organs (including pancreata used for islet cell transplantation or research) to be maintained until transplantation can take place."[53]

More recently, the OPTN Liver Committee acknowledged the importance of the differences in the non-contiguous service areas and supported modification to OPTN policy language to ensure these populations were not disadvantaged due to their unique service areas noting: "The Liver Committee is now proposing changes to this variance that were recommended by the Minority Affairs Committee (MAC). The MAC reviewed the similarities between Hawaii and Puerto Rico, in terms of their geographic isolation and ethnic populations and recommended that Puerto Rico be added to this variance. A version of this variance has been in place since 1994."[54]

While perfusion technologies are being developed and may have an impact on reducing geographic isolation, many of these technologies for non-renal organs are still under Food and Drug Administration review and are limited to investigational use in the U.S.[55]

Methodologies developed through the SRTR to measure and ensure higher organ transplant yields show non-contiguous states have significantly lower odds of transplanting extra-renal organs (excluding pancreata) as compared to contiguous states. For example, the odds of successfully transplanting a heart is 192 percent higher if the donor is within the contiguous 48 states. Other organs, as noted using the SRTR models, have different estimates.[56] These measures have been previously adopted by both CMS and OPTN to predict yield and measure performance.

AOPO supports and encourages continued use of an alternative measure for non-contiguous states and territories, specifically the kidney utilization rate through the SRTR yield models. Evidence that this is a fair measure is documented in the SRTR model, which demonstrates the odds of a kidney transplant from a contiguous OPO is only 2.5 percent higher than that of a non-contiguous OPO.[57] The risk adjustment accounts for the unique factors of these predominantly minority populations and the effects of organ suitability for transplant.

K. Concerns Regarding Opening the Service Area of Every OPO at the Conclusion of Each Recertification Cycle

AOPO is opposed to all OPO service areas being opened for competitive bidding even if the DSA met or exceeded performance criteria. OPOs have historically worked together to collaborate and spread best practices, allowing for collective improvement of the national system. Opening every service area for competition at the conclusion of each cycle, regardless of performance, will create a disincentive to collaborate and could have the effect of changing the system into a marketplace, where OPOs compete for other high-performing DSAs. Further, this could create an atmosphere of

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53 71 Fed. Reg. 30982, 31005 (May 31, 2006).

54 Liver and Intestine Distribution Using Distance from Donor Hospital Briefing Paper OPTN/UNOS Liver and Intestine Transplantation Committee, available at https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf.

55 Transmedics OCS Lung, OCS Heart and OCS Liver devices, available at https://www.transmedics.com/patents/.

56 Scientific Registry of Transplant Recipients (SRTR), available at https://www.srtr.org/reports-tools/opos/.

57 Id.

distrust thereby stifling sharing of ideas, innovations, and improvements. Any process that encourages competition and discourages collaboration would be contrary to CMS' goals of increasing organ utilization and saving lives. This concept can also perpetuate myths and misconceptions about organ donation and transplantation.

III. CONCLUSION

AOPO is grateful for the opportunity to provide comments on the Proposed Rule. AOPO members are dedicated to advancing improvement strategies to increase the number of lives saved through organ donation with that goal in mind. AOPO stands ready to continue to collaborate on ways to improve organ donation and transplantation with all stakeholders of this life-saving process.

Sincerely,

Kelly Ranum
AOPO President