

March 4, 2021

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Elizabeth Richter
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Kyle Herber, Nebraska
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Kelly Ranum, Louisiana
Immediate Past-President

Steve Miller, CAE, Virginia
Chief Executive Officer

Re: CMS-3380-F2: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date

Dear Acting Secretary Cochran and Acting Administrator Richter:

On behalf of the Association of Organ Procurement Organizations (AOPO) and our Organ Procurement Organization (OPO) members, we appreciate HHS opening for additional comment on the above-referenced rule, particularly given major changes that were not included in the proposed rule, such as the new tiering system. We would also like to direct you to our [comments](#) previously submitted on the Proposed Rule.

[AOPO](#) is a nonprofit member association recognized as the national voice of the 57 federally designated OPOs serving more than 300 million Americans. Every day, OPO professionals work around the clock to ensure more American lives are saved through organ donation and transplant. This is especially important in our communities of color and diversity, which represent a majority of those awaiting the gift of transplantation. AOPO advances organ donation and transplantation by collaborating with stakeholders and sharing best practices with our member OPOs. Our goal is to continually improve so we can save as many lives as possible through our work. In 2020, organ donation from deceased donors in the United States set a record for the tenth year in a row. Notably, 36,548 organs from 12,588 deceased donors were transplanted, either individually or in multi-organ combinations. This resulted in 33,309 lifesaving transplants from deceased donors in 2020 and an overall total of 39,034 transplants performed in the United States from both living and deceased donors. These are world-leading rates of transplantation that have helped shrink the transplant waitlist and save more lives.

OPOs are already on pace to surpass CMS' prediction for the 2026 performance of 41,000 organ transplants by 4,785. To further maximize every possible donation opportunity, AOPO is committed to supporting OPOs to exceed expectations and achieve 50,000 annual transplants by 2026. Reaching this goal will necessitate improved coordination with this Agency and other stakeholders mutually working

toward improved organ donation and transplantation performance. As part of this objective, we aim to improve organ donation rates, address racial disparities in organ donation and transplantation, and leverage performance and accountability measures. More on this initiative may be found [here](#). We welcome an opportunity to discuss what AOPO is doing and will do to innovate and improve the organ donation and transplantation system. We would very much appreciate HHS' support of these important, groundbreaking efforts.

AOPO notes that our progress to date is only achieved through maximum care of potential heroic organ donors and their courageous families of all backgrounds. Equally important is the necessary collaboration with donor hospitals, transplant centers, healthcare professionals, and a host of other partners all working towards shared goals. We welcome opportunities to continue working collaboratively, and we support reform to the system. OPOs are integral to the complex organ donation and transplantation system. OPOs collaborate with hospitals to identify potential organ donors, obtain authorization from families of donors, allocate organs to transplant recipients in accordance with national policy, and coordinate transportation of organs to transplanting hospitals. We take this responsibility seriously. At the same time, it is important to recognize that we are one piece of a much larger system with interdependent components.¹ Transplant programs, for example, make the ultimate decision whether to utilize the organs that OPOs make available and are directly responsible for the care of organ failure patients. To achieve success, CMS needs to address alignment and accountability for all components of the system, not only OPOs. Unfortunately, we believe the policies promulgated by CMS in the last stretch of the Trump Administration miss an opportunity for alignment and oversimplify an incredibly complex system based on misguided data.

Throughout the rule, CMS relies heavily on a non-peer-reviewed study by the Bridgespan Group, leading to misleading assumptions about OPO performance. The report asserts that approximately 28,000 extra organs are readily available each year that do not get procured or transplanted because of OPO performance breakdowns. To reach the 28,000 number, the report assumes that every person eligible for donation would choose to donate or have their family authorize donation upon their death. The U.S. leads the world in donation rates at an impressive 70 percent of the eligible donors. However, to assume 100 percent of the population will authorize donation is unreasonable.

Additionally, the report assumes that 100 percent of all eight organs from every single donor will be medically suitable for transplantation (the current average is 3.45) and that 100 percent of organs offered by OPOs will be accepted by the transplant centers and recipient candidates to which they are offered. The current rate at which transplant programs or their candidates turn down available kidneys is around 20 percent. While we recognize opportunities for improvement, basing the regulation on the assumption of 100 percent success rates in each of these areas is unrealistic, if not impossible. These assumptions set up an expectation for system performance that is unsupported by facts.

Moreover, under the new regulations, CMS advances a forced competition model into a field designed to be run by community-based nonprofits that, up until now, have depended on collaboration for their mutual success. Keeping OPOs "striving for organizational survival" as referenced in the final rule would be detrimental to continuous system improvement, which requires long-term strategic planning, resources for innovation, and engaged staff. If OPOs are suddenly competing for donation service areas

¹ [https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20\(003\).pdf](https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20(003).pdf)

(DSAs), this will hinder the type of information and best practice sharing critical to driving improvement, particularly improving health equity in the organ procurement and transplantation mission. AOPO supports evidence-based standards to ensure performance. However, the self-described “aggressive” tiered strategy that by CMS’ estimates may lead to as many as 33 OPOs being decertified in the first cycle alone has the serious potential to dismantle the organ procurement supply chain and lead to a significant loss of institutional knowledge and relationships specific to local regions, which takes years, decades in most cases, to cultivate. At the end of the day, this competition-style approach could do more harm than good to the system and would be unlikely to benefit the complex and interdependent ecosystem, least of all the patients whose lives depend on it.

To be clear, AOPO agrees that revisions to the OPO conditions for coverage (CfCs) should be pursued and can be a meaningful way to drive improvement in the donation and transplantation community to save more lives. To be effective, performance metrics must be: 1) of sound methodology; 2) measure performance of processes that are within an OPO's ability to influence, and 3) enacted in coordination with other system-wide changes. Meaningful progress will require a coordinated, industry-wide effort to boost collaboration, improve and align performance metrics, and deploy targeted interventions to address our current system's most acute failures. This includes utilizing the thousands of organs per year being recovered from complex and older donors but declined for transplantation by transplant programs and addressing racial equity gaps in donation and transplantation (see Appendix III). AOPO is confident that together, we can continue to build on existing progress and work towards building the fairest, most effective, and most efficient organ donation and transplant system possible to diminish, if not end, mortalities on the waitlist. We appreciate CMS pausing and reopening this rule for input from stakeholders. We are hopeful it indicates the Agency’s willingness to move forward with a more collaborative, effective approach that builds on past progress.

In the spirit of advancing towards these shared goals, AOPO offers four practical recommendations that would drive meaningful improvement in organ donation and transplantation without disrupting patient access to lifesaving organ transplants. These are summarized below and detailed in Appendix I.

Executive Summary of AOPO High Priority Recommendations

Recommendation 1: AOPO agrees it is important to hold all parties to high standards to ensure the system is working efficiently and effectively. Unfortunately, the self-described “aggressive” competition-style tiering system for OPOs finalized in this rule threatens to upend the organ procurement system, which will ultimately harm patients. AOPO recommends CMS instead work collaboratively with stakeholders to recalibrate its approach, reserving decertification for the lowest performers and incentivizing other OPOs to consistently improve while moving toward objective, evidence-based performance thresholds.

- Under the final rule, OPOs performing at or above average (but below the top quartile) must compete for their service area rather than be recertified. It could also open the area up for competition by other OPOs under the rule. This approach would be detrimental to continuous system improvement, which requires institutional knowledge, long-term strategic planning, and engaged staff. Competition for above-average performing organizations will divert critical staff time and resources away from the OPO’s primary mission of procuring organs.

- CMS should instead use the normal curve, which identifies outliers by design. Specifically, CMS should set the cutoff for “Tier 1” OPOs no higher than the median. The cutoff for “Tier 3” OPOs no higher than 1.5 standard deviations below the mean, which would mirror the current performance parameter and represent the bottom 6.68 percent of OPOs every cycle.
- Meanwhile, CMS should actively pursue predictable, objective performance targets grounded in the best available scientific and medical evidence, not linked to relative peer performance.
- Using a weighted average in which the final year would be worth more than the years prior would strike a more appropriate balance between valuing performance improvement and consistent, high performance over time.

Recommendation 2: Work towards improving the accuracy of both outcome measures by refining the donor pool to exclude deaths with no donation potential while actively working toward identifying a more reliable data sources in the future, such as hospital inpatient deaths previously on a ventilator.

- While we appreciate CMS’ point that it must work with the data it has available, AOPO continues to have concerns with the factual accuracy of death certificate data. We believe there are several ways that CMS could immediately improve on this data by refining the donor eligibility pool and improving risk adjustment to account for causes of death.
- Meanwhile, we implore CMS to work toward securing a more accurate data source. Patient deaths of those on a ventilator at or near the time of death, for example, are a more accurate pool of potential donors for the metric denominator. This is because all organ donors must have been on a ventilator at or near the time of organ procurement. Some OPOs are already collecting this data, and these efforts could be easily expanded. AOPO stands ready and willing to partner with CMS to make this happen. Alternatively, hospitals could report inpatient death data and simply include a new ventilator status data point which would be a minor modification to data already being collected and reported by the hospitals served by OPOs.
- To uphold transparency, credibility, and integrity in the system, CMS should make the data and methodologies used to calculate the outcomes measures accurate, transparent, and publicly accessible without submitting a formal request for data.

Recommendation 3: Ideally, CMS should replace the organ transplantation rate outcome measure with the more accurate, dynamic, and non-duplicative Observed to Expected Yield (O/E) measure.

- The O/E measure is more accurate because it adjusts for factors outside the control of an OPO that affect the success or failure of placing an available organ for transplant. In this way, it also incentivizes the pursuit and placement of all donor types.
- The O/E measures are consistently monitored and adjusted by the Scientific Registry of Transplant Recipients (SRTR), which maintains their accuracy over time.
- The current transplantation rate measure is largely duplicative with the donation rate measure, while the O/E measure meaningfully differs from the donation rate measure and would

therefore help fulfill the National Organ Transplant Act's statutory requirement that OPOs be evaluated on multiple metrics.

Recommendation 4: CMS should work with AOPO, the Organ Procurement and Transplantation Network (OPTN), SRTR, and other members of the transplantation community to enact coordinated, system-wide changes that incentivize all parties to work together to maximize every donation opportunity, including from complex, aged, and minority donors, for the focused goal of transplanting more organs.

- Improving OPO performance metrics must be one piece in a larger system of reforms to align incentives and cultivate a community of partnership and collaboration towards common goals. CMS metrics for OPOs, OPTN, and SRTR metrics for transplant programs should be aligned in such a way that eliminates disincentives to accept and transplant organs from medically complex, aged, or otherwise imperfect donors.
- CMS should consider new, creative ways to better account for age, co-morbidities, and other factors that may render someone an imperfect, though not excluded, donor. For example, CMS should reverse its policy to remove "zero organ donors" from the definition of eligible donors since this may discourage the pursuit of medically complex donors.
- CMS should support AOPO, the United Network for Organ Sharing (UNOS), and other stakeholders in the important strides we are making to collect data, identify and share successful practices, and elevate total system performance, including closing racial equity gaps in the organ donation and recipient chain. Public-private partnerships have been highly successful in the organ donation and transplantation space in the past and are an area we encourage CMS to explore for the future.

AOPO's top priority has always been the thousands of organ donors and recipients we help connect with every year, as well as their courageous families. Any policy changes and their resulting impact on the organ donation and transplantation system must be carefully considered before implementation; real patient lives hang in the balance. As the nation's leading voice for OPOs, we represent the thousands of dedicated OPO professionals on the front lines making the most they can of every organ donated. We welcome future opportunities to work collaboratively with CMS and other stakeholders toward our shared goal of increasing the number of available organs and successful transplants to ultimately save more lives. Once again, we appreciate this opportunity to provide feedback and look forward to continuing this dialogue in the spirit of inclusion, transparency, and accountability for continuous improvement. To further discuss the content of this letter, please contact Mark Cribben at mcribбен@aopo.org.

Sincerely,



Joe Ferreira
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Appendix I: AOPO High Priority Recommendations in Detail

Recommendation 1: AOPO agrees it is important to hold all parties to high standards to ensure the system is working efficiently and effectively. Unfortunately, the so-described “aggressive” competition-style tiering system for OPOs finalized in this rule threatens to upend the organ procurement market, which will ultimately harm patients. AOPO recommends CMS instead work collaboratively with stakeholders to recalibrate its approach, reserving decertification for the lowest performers and incentivizing other OPOs to consistently improve while moving toward objective, evidence-based performance thresholds.

Final Rule Provision: Under the final rule, CMS established a new tiering system whereby at the end of each four-year recertification cycle, each OPO will be ranked based on its performance on 1) the donation rate measure; 2) the transplantation rate measure, and 3) recertification survey. Those ranked in the top quartile will be considered “Tier 1,” keep their DSA, and be automatically recertified for another four years. Those not in the top quartile but whose performance on both measures exceed the median will be considered “Tier 2” and subject to compete with other Tier 1 and 2 OPOs for their DSA. They will have to describe any barriers in its DSA, how that affected organ donation, what steps it took to overcome them, and the results. If a Tier 2 OPO does not win the competition for its or any other DSA, CMS will not renew its certification and the decision is final. The remaining OPOs, i.e., those with one or both measures below the median, will be deemed “Tier 3,” automatically decertified and disqualified from competing for any DSA, including their own, which would be opened to competition for Tier 1 and 2 OPOs.

Notably, this policy was not included in the proposed rule, which calls into question the fundamental fairness principles underlying the Administrative Procedure Act (APA), assuring a reasonable opportunity to review and comment on new government action.

AOPO Comments: The competition-style approach finalized in this rule would be detrimental to continuous system improvement, which requires institutional knowledge, long-term strategic planning, and engaged staff. Competition for above-average performing organizations will divert critical staff time and resources away from the OPO’s primary mission of procuring organs. Because the threshold is an ever-moving target based on peer performance, over time, the bottom performers will be weeded out based on increasingly smaller differences in performance which drives the median and upper quartile continuously upward. CMS acknowledges this in the rule when it states that “there may be a rate at which OPOs cannot improve anymore, and rates may cluster at the top” but that it nevertheless “intends to incentivize increases in the threshold rates for the top 25 percent and median as it would indicate that OPOs are procuring more organs for transplantation.” While we commend CMS for constantly striving to improve the number of organs procured, and share the same goal, holding certification in the balance for high performers is neither mathematically nor strategically sound, particularly in the long-term as OPOs all “cluster” around top performance. Most importantly, it is not in the best interest of patients because over half of OPOs could turn over every four-year cycle, losing critical institutional knowledge and longstanding relationships that are specific to the region and important to the functioning of the complex, multi-player system of organ donation, procurement, and transplant system.

The confidence interval does help to some degree, as CMS notes. Instead of 15 out of 57 OPOs falling in Tier 1, for example, it would be 24 (extrapolated from 2018 data). Despite this, according to CMS’ estimation in the rule, “it would be possible that approximately 7 to 33 OPOs could be decertified.” This means every four-year recertification cycle, more than half of OPOs would be subject to competition

and potential loss of certification. CMS acknowledges in the rule that its “aggressive threshold rate” could result in “too many OPOs being decertified, particularly in the first recertification cycle.” We support holding OPOs accountable to reasonable performance targets but disagree that potentially decertifying more than half of all OPOs in the first cycle strikes an appropriate balance. If the consequence is as severe as losing certification, CMS should reserve this only for the true outliers. Falling below the median, much less the top 25 percent of a performance measure, hardly constitutes “failing.”

Opening potentially more than half of DSAs for a resource-intensive bidding process every four years is an unproductive use of OPO staff time and resources that should be devoted to procuring organs. CMS estimates in the rule that every application would require approximately 104 staff hours, which CMS extrapolates to 7,592 hours and \$644,152 that could be devoted to OPO’s primary objective of procuring organs. We suspect this estimate is a significant under-estimation. Beyond the bidding process itself, transferring a DSA to a new OPO is another incredibly resource and time-intensive legal and administrative process for all parties, including CMS, that requires fiduciary decision-makers, state regulatory authorities, state filings, time, due diligence, and careful up-front planning to be accomplished successfully and without service disruption. In certain states, the Attorney General’s approval may be required because OPOs are privately held charitable nonprofit organizations.² Given all of these complicating factors, we find CMS’ expectation of “no costs for disruption of actual organ procurement at any OPOs” to be highly unrealistic.

For high-performing OPOs, there is a substantial financial and operational burden of expanding into a new service area and no clear incentive to jeopardize their ranking by taking on a new DSA, particularly one that historically underperformed. Even if an existing OPO were willing to absorb a new DSA, this opens a host of complex logistical and regulatory oversight complexities in its own right, particularly in non-contiguous geographic regions, as acknowledged in the rule. When the Massachusetts and Connecticut OPOs merged on January 1, 2021, the process took three years. The timeframe CMS lays out in the rule is unrealistic, particularly given the potential scope of DSA takeovers. Large swaths of the country have a single or no OPOs that would meet both new outcomes measure thresholds, threatening widespread disruptions and a genuine possibility of a region having no willing OPO after an existing OPO is decertified. CMS notes in the rule that its “aggressive” approach may leave the system “without enough OPOs with organizational capacity and interest to assume responsibility for those open DSAs.” This level of disruption cannot be an effective strategy for improving the system.

CMS should instead use the normal curve, which identifies outliers by design. Specifically, CMS should set the cutoff for “Tier 1” OPOs no higher than the median and the cutoff for “Tier 3” OPOs no higher than 1.5 standard deviations below the mean. This would mirror the current performance parameter and represent the bottom 6.68 percent of OPOs every cycle. Importantly, this approach would incentive continual performance improvement without destabilizing the system. CMS rejected the standard deviation approach in the final rule based on the logic that “there will always be an OPO below the targeted standard deviation from the mean, meaning that not all OPOs would have the opportunity to be a top-performing OPO; unless they all had identical rates.” However, the same is true for the median. CMS could simply apply the same confidence interval approach- and instead of using the median - it could use 1.5 standard deviations below the mean as the threshold. CMS also states the mean is problematic because “lower-performing OPOs could skew [it].” However, this problem would be virtually rectified after the first cycle in which the lowest-performing OPOs would be removed.

² See e.g. California Corp. Code, §§ 5913; Massachusetts G.L. ch. 180.

Meanwhile, CMS should actively pursue predictable, objective performance targets grounded in the best available scientific and medical evidence, not linked to peer performance. This approach would effectively target under-performing OPOs without causing wide-scale disruptions. It also serves as a successful long-term strategy that would allow CMS to drive continued, meaningful performance improvement without issues like “clustering.” Performance thresholds could be recalibrated over time to encourage continued improvement, as CMS does with a host of other federal programs, including the Merit-based Incentive System. Importantly, this approach would also continue to encourage sharing data and best practices to drive further improvement in the system, which OPOs may be less inclined to do under the finalized competition-based tiering system in which sharing proprietary data with your competitors would be strongly disincentivized. AOPO encourages CMS to develop low-performance thresholds based on objective data for best practices and would welcome an opportunity to share its own data and work with CMS towards this goal.

We appreciate CMS’ intent behind using only the last 12 months of data to calculate outcomes metrics performance in the hopes of driving consistent improvement. We share this same goal. However, we worry that in certain circumstances, this risks decertifying generally well-performing OPOs that experience a temporary drop in performance for a multitude of potential reasons. **Using a weighted average in which the final year would be worth more than the years prior would strike a more appropriate balance between valuing performance improvement and consistent, high performance over time.** This also aligns with policies for other CMS programs, such as the Medicare Shared Savings Program.

Finally, to uphold transparency, credibility, and integrity in the system, CMS should make the data and methodologies used for calculating the outcomes measures accurate, transparent, and publicly accessible without having to submit a formal request for data, so OPOs and other stakeholders are free to replicate the data and use it to drive further improvement.

Recommendation 2: Work towards improving the accuracy of both outcome measures by refining the donor pool to exclude deaths with no donation potential while working toward identifying an alternative, more reliable data sources in the future, such as hospital inpatient deaths.

Final Rule Provision: An OPO is evaluated by two outcomes measures: one that captures the donation rate and another that captures the transplantation rate. Both are calculated as percentages based on donor potential, measured as the total number of inpatient deaths in the DSA among patients 75 years of age or younger with a primary cause of death that is consistent with organ donation. This data is collected based on death certificates obtained from the Centers for Disease Control and Prevention (CDC). With one limited exception for International Classification of Diseases (ICD-10) codes that are absolute contraindications to organ donation, CMS will generally not risk-adjust either outcomes measure. The rule also clarifies that all transplanted organs count toward the organ transplantation rate, regardless of whether they are part of clinical practice or research purposes.

AOPO comments: While AOPO appreciates CMS’s point that it must work with the data it has available, AOPO continues to have concerns with the factual accuracy of death certificate data. As CMS acknowledges in the rule, one prominent study found that thirty to sixty percent of death certificates inaccurately reported the cause of death.³ In a recent interview, Bob Anderson, chief of the

³ <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf> page 38

mortality statistics branch at the National Center for Health Statistics, stated that death certifications' error rate was believed to be 20-30 percent.⁴ Moreover, we are concerned with the two-year lag between performance and feedback/measurement. To effectively drive improvement, data should be as current as possible.

We believe there are several ways that CMS could immediately improve on this data by refining the donor eligibility pool and improving risk adjustment to account for causes of death. We appreciate CMS seeking comments in the proposed rule regarding whether additional risk adjustments are necessary. We implore CMS to risk adjust for the primary cause of death, which has a proven impact on transplant outcomes⁵ and an OPO's likelihood of ending up in Tier 1, 2, or 3. In Appendix II, you can see that heart disease, external causes of mortality, and cerebrovascular disease are correlated with an OPO's tier. We provide the results based on 2018 data but have found the same trend across multiple years' worth of data. Regardless of the data source, CMS should risk adjust for the cause of death.

Similarly, the ratio of potential brain-dead donors to DCD donors is known to vary significantly between DSAs.⁶ Failing to properly risk adjust risks decertifying OPOs based on factors that are beyond their control. Moreover, if CMS did risk adjust for the cause of death, this would also drive OPOs to seek out these organs because they would not be penalized for procuring organs from riskier donors. Of course, it would be important for CMS to address transplant program metrics as well (see Recommendation 4).

Because death certificates do not require reporting secondary diagnoses that are unrelated to the cause of death, the donor pool against which OPOs are measured includes donors who would appear eligible but are appropriately ruled out for medical reasons, which unjustly diminishes an OPO's performance for both existing metrics. For example, death due to head trauma from an accident would be included in the calculation for the donation rate measure, despite the patient having a history of cancer, making them medically unacceptable for donation. These types of secondary diagnoses may rule out thousands of possible donors every year⁷ and do not appear in death certificate data. The transplantation rate measure likewise counts several types of donor organs that are ineligible, such as those from patients on the OPTN waiting list. The donation also rate measure includes patients who appear brain dead and are not declared and donated after cardiac death (DCD). Finally, AOPO appreciates CMS' statutory limitations regarding pancreata procured and used for islet cell transplantation or research. However, we continue to have concerns about including organs used for research purposes towards the outcomes measures' numerator. The utilization of pancreata for research is driven by local research demand, which is widely varied across DSAs and entirely out of an OPO's control. Including this data towards the existing outcomes measures will skew comparisons of OPOs, as evidenced by CMS' stating in the rule that "a particular OPO may move up or down 1-3 ranking spots based on the inclusion of this data." As a result of these numerous variables, published estimates of eligible donors are widely variant and inaccurate, ranging from 10,500⁸ to a staggering 272,000.⁹

⁴ <https://www.usatoday.com/story/news/investigations/2020/04/25/coronavirus-death-toll-hard-track-1-3-death-certificates-wrong/3020778001/>

⁵ <https://pubmed.ncbi.nlm.nih.gov/19917340/>

⁶ <https://iasn.asnjournals.org/content/28/12/3647>

⁷ <https://data.cdc.gov/NCHS/Weekly-Counts-of-Deaths-by-State-and-Select-Causes/muzy-jte6>

⁸ 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.

⁹ 84 Fed. Reg. at 70648.

For these reasons, we implore CMS to actively work toward securing a more accurate data source, such as ventilated inpatient deaths. A potential donor must be on a ventilator in a hospital at or near the time of death for organ donation to occur, making using the number of deaths among ventilated patients in an inpatient setting a better means of identifying actual potential donors. This data source would provide unparalleled complete and detailed information on multiple causes of death, procedures performed, hospitalization status at death, ventilator status, and co-morbidities. CMS states in the rule that “part of ensuring reliability is moving away from self-reported data as much as is feasible and using data that can be easily verified” adding “it would require an extraordinary effort for CMS to verify the zero organ donors as frequently as needed to calculate the annual assessments of OPO outcome measures.” Self-reported data is standard for a host of other federal performance programs, so it is unclear why CMS finds this data source acceptable and reasonably burdensome in those cases, but not for ventilated inpatient deaths. We also disagree that verifying the data on an annual basis would require an “extraordinary effort” on behalf of CMS. CMS currently is responsible for ensuring the validity of data reported for countless other federal programs with thousands of participating practices and hospitals, compared to 57 OPOs. Moreover, several independent bodies could serve in this capacity, such as AOPO or the SRTR.

We respectfully disagree with CMS that inpatient ventilated deaths “could not be obtained by reasonable efforts.” **Some OPOs have already begun collecting this data, and these efforts could be easily expanded to a national scale.** According to New England Donor Services, New England hospitals currently provide the regional OPO with a defined electronic data set for every inpatient death every month, including codes for ventilated status. This same electronic reporting process could be scaled nationwide for donor hospitals to directly report inpatient death data to CMS to calculate a denominator for OPO performance metrics. **AOPO stands ready and willing to partner with CMS to make this happen. Alternatively, hospitals could report inpatient death data and simply include a new ventilator status data point.** While we acknowledge CMS’ point that “not all hospitals have electronic health records that can transmit data or be shared; not all OPOs can receive electronic health record transmissions,” hospitals currently report data through EHRs for a host of other federal programs, including the Hospital Quality Assessment Performance Improvement Program and the Medicare Promoting Interoperability Program.

Recommendation 3: Ideally, CMS should replace the organ transplantation rate outcome measure with the more accurate, dynamic, and non-duplicative Observed to Expected Yield measure.

Final Rule Provision: Aside from a limited exception for the Hawaii DSA, the numerator for the organ transplantation rate is the number of organs transplanted from donors in the DSA. A fundamental change from the previous transplantation outcome measure is that a donor is now defined as a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted, not just procured for transplant or an individual from whom a pancreas is procured and is used for research or islet cell transplantation.

AOPO Comments: The O/E measure is more accurate because it adjusts for factors outside the control of an OPO that affect the success or failure of placing an available organ for transplant. In this way, it also incentivizes pursuit and placement of all donor types, including cases where the expected transplant rate is fewer than the optimal rate of 1.0 organs per donor. It thus better aligns with the stated CMS objective of successfully placing all possible organs for transplantation. In contrast, the finalized organ transplantation measure is based largely on transplant organizations and surgeons’ medical decisions completely out of the OPO’s control.

The O/E measures are consistently monitored, verified, and adjusted by the SRTR, which helps maintain its accuracy over time and makes it administratively simple to seamlessly and quickly incorporate into the planned OPO metrics.

The current transplantation rate measure is largely duplicative with the donation rate measure to the point that the two are confounding variables, as evidenced by the fact that both use the same denominator. While CMS states the two measures are “somewhat correlated,” an independent SRTR analysis found that only one of 32 OPOs who failed on the first measure would pass the second measure.¹⁰ The Goldberg report, which CMS cites to support the organ transplantation rate measure, notes the critical limitation that the two measures are “highly correlated” with a correlation coefficient of 0.88.¹¹ **The O/E measure in contrast meaningfully differs from the donation rate measure and would therefore help fulfill the National Organ Transplant Act's statutory requirement that OPOs be evaluated on multiple metrics.**

Recommendation 4: CMS should work with AOPO, the Organ Procurement and Transplantation Network (OPTN), SRTR, and other members of the transplant community to enact coordinated, system-wide changes that incentivize all parties to work together to maximize every donation opportunity, including from complex, aged, and minority donors and recipients, for the focused goal of transplanting more organs.

Final Rule Provisions. In the rule, CMS finalized changes to the definition of an eligible donor as a deceased individual from whom at least one vascularized organ is transplanted, not just procured for transplant, or an individual from whom a pancreas is procured and is used for research or islet cell transplantation. In the rule, CMS does not address metrics used to evaluate transplant organizations, such as performance standards used by the OPTN to evaluate transplant centers for continued OPTN membership and SRTR-calculated public “star ratings” used by private payers to determine transplant center participation in payer networks, which stand in conflict with OPO metrics.

AOPO Comments: AOPO welcomes increased accountability and improved measuring of the aspects of the transplantation process OPOs can control. Because the entire organ procurement and transplantation system has so many stakeholders and is so interconnected, **improvements to OPO performance metrics must be one piece in a more extensive system of reforms to align incentives and cultivate a community of partnership and collaboration towards common goals. As part of this, CMS metrics for OPOs, OPTN, and SRTR metrics for transplant programs should be aligned in such a way that eliminates disincentives to accept and transplant organs from medically complex, aged, or otherwise imperfect donors.** On average, candidates who die waiting for a kidney have received 16 organ offers from an OPO declined on the candidate's behalf by the transplant program.¹² Transplant centers use ineligible donors at vastly different rates, as demonstrated in the donor eligibility rate. This leads to large discrepancies across OPO transplant rates that are out of OPOs’ control. CMS eliminated outcomes metrics as a condition of recertification of transplant centers to remove disincentives to utilize organs at risk of discard, which AOPO applauds. However, performance standards used by the OPTN to evaluate transplant centers for continued OPTN membership and SRTR-calculated public “star ratings” used by private payers to determine transplant center participation in payer networks, unfortunately, both continue to disincentivize increased organ acceptance or risk-taking for expanded criteria donors.

¹⁰ www.srtr.org/reports-tools/opos/ accessed February 2, 2020

¹¹ See Goldberg *supra* at n. 8 (page 3187)

¹² 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).

As a result, despite CMS' efforts, the rates of non-utilization of kidneys offered by OPOs continue to climb.¹³ Ultimately, organ placement, acceptance, and transplantation are joint responsibilities of the OPO and transplant center communities within the same transplant ecosystem. Achieving the best outcomes will require joint efforts and mutual accountabilities to regulatory agencies and increased coordination among various regulatory agencies, the OPTN, and SRTR.

CMS will be unable to create an efficient system if the current disincentives to transplant organs at risk of discard from OPTN and SRTR are still in place. Using consistent definitions of eligibility and metrics to measure success across OPOs, transplant organizations, and regulatory agencies would expand the donor pool by reducing incentives to turn down organs, aligning shared goals, fostering data sharing and collaboration, and allowing CMS to glean additional insights into success factors to drive continuous process improvement. Moving the needle for OPOs alone won't work. It has to be orchestrated in a set of aligned system-wide changes.¹⁴ For example, CMS says that it kept the age of an eligible donor at 75 in part because "OPOs who are successful with the donation and transplantation of organs from deceased individuals greater than 75... may count the donors and organs transplanted in the numerator of our outcome measures without having the death counted in the denominator." While this may be true- it is of little value if existing OPTN and SRTR metrics actively discourage transplant organizations from accepting organs from patients over age 75. One recent report cited "implementation of new system-wide initiatives to drive the increase in acceptance and transplantation by transplant programs of more kidneys recovered and offered by OPOs" as critical to meaningfully accelerating the current rate of annual improvement in deceased donor kidney recovery and transplantation, particularly calling out that utilization of organs by transplant programs "must improve."¹⁵

CMS should consider new, creative ways to better account for age, co-morbidities, and other factors that may render someone an imperfect, though not excluded, donor. This would remove perverse incentives to reject organs from donors deemed imperfect and align with incentives for OPOs to procure as many usable, safe organs as possible to save more lives. In addition to risk adjusting, CMS could pursue other creative approaches, such as pairing similarly aged donors and recipients without penalizing transplant programs for the lower success rates that inevitably result, a concept that has been rolled out in multiple European countries, as CMS points out in the rule.¹⁶

As part of this strategy, **CMS should reverse its policy to remove "zero organ donors" from the definition of eligible donors because it may discourage the pursuit of medically complex donors** because the OPO is required to perform all work related to the donor and incur all costs associated with coordination, regardless of whether any organs offered by the OPO are accepted by transplant programs and transplanted. OPTN data shows that in 2018, there were 1,255 organs procured from these zero organ donors but never transplanted. This is because the way transplant organizations are evaluated inherently disincentivizes them from accepting organs from complex donors. AOPO appreciates CMS' offer to continue the dialogue with OPOs toward a more refined reporting process to capture information about zero organ donors and why the organs not being retrieved or transplanted and being open to further modifications in the future based on further analysis of data. We urge the Agency to approach this issue with a broader lens to include transplant organizations in

¹³ [https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20\(003\).pdf](https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20(003).pdf)

¹⁴ <https://www.oliverwyman.com/our-expertise/insights/2021/feb/organ-donation-and-transplantation.html>

¹⁵ [https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20\(003\).pdf](https://www.oliverwyman.com/content/dam/oliver-wyman/v2/publications/2021/feb/Organ%20donation_Feb9%20(003).pdf)

¹⁶ Olivier Aubert, et al

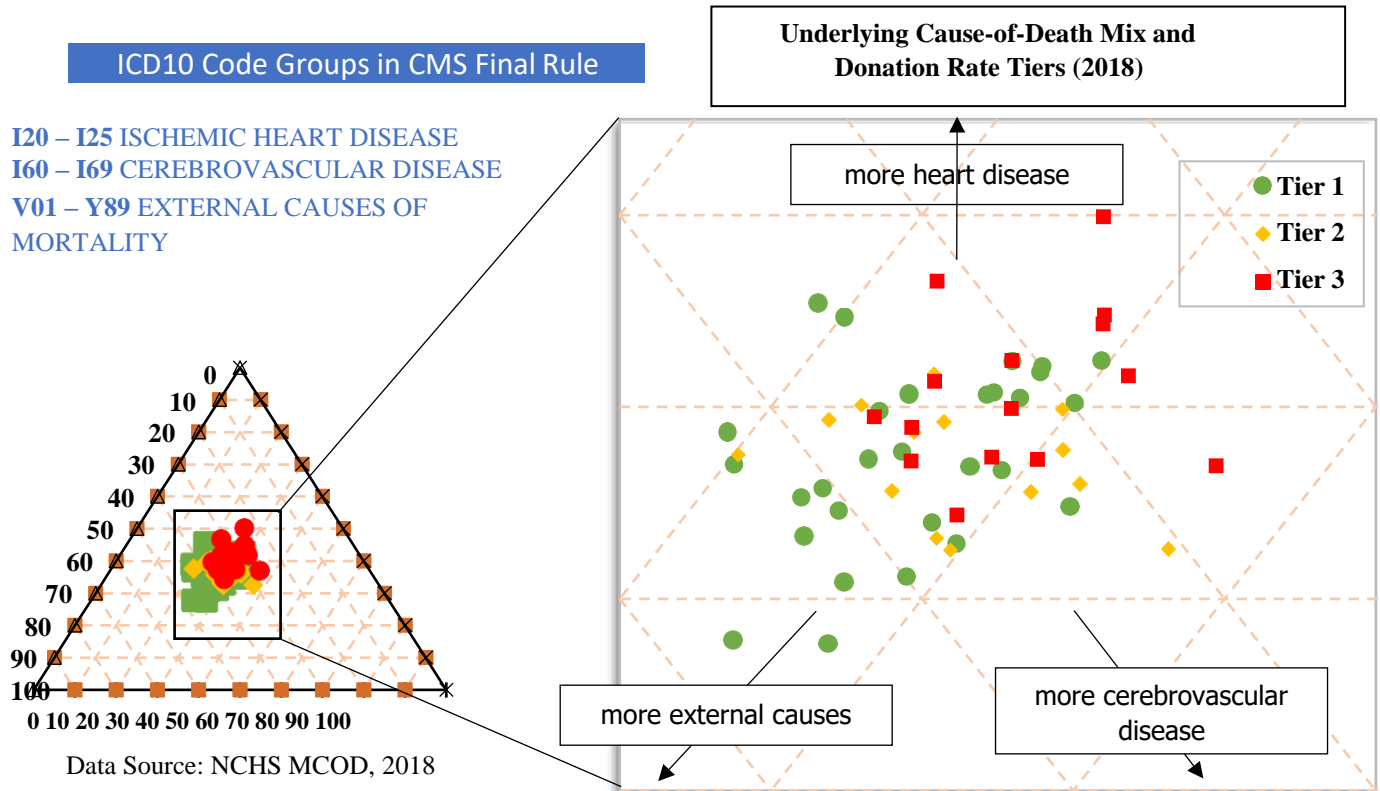
the conversations and align their incentives to encourage them to work collaboratively with OPOs towards procuring and using as many organs as possible, including from zero organ donors.

CMS should support AOPO, UNOS, and other stakeholders in the important strides we are making to collect data, identify and share "best practices," and elevate total system performance, such as AOPO's bold new 50,000 transplants by 2026 initiative. OPOs currently track information for the Quality Assurance and Performance Improvement (QAPI) Program to improve the affiliated hospital's donation process. We would be pleased to work with CMS to better leverage this to drive system-wide improvements.

Of course, CMS cannot improve the organ procurement and transplantation system's efficiency and effectiveness without addressing racial disparities, which is critical to both addressing health equity and increasing the overall number of available organs and successful transplants (see Appendix III). This is why AOPO has made this one of the four central tenants of our new 50,000 transplant initiative. CMS likewise needs to make this a strategic priority by **partnering with OPOs and other system participants to make strides to close gaps in racial equity in the organ donation chain.** There are multiple approaches CMS could take, including creating bonus points within the outcomes measures for improving racial disparities in organ procurement and transplantation or establishing a new, dedicated measures altogether. We encourage CMS to devote resources towards developing data-driven policies and research to advance health equity in organ donation and transplantation. Further, we encourage CMS to partner with AOPO and other stakeholders to establish national outreach efforts for communities of color to promote organ donation and address organ donation and broader health system concerns.

Appendix II: Risk Adjusting for the Underlying Cause of Death

CMS should consider risk-adjusting for the underlying cause of death. DSAs have different mixes for the underlying cause of death in their CMS Potential denominator. Below are the distributions of causes of death in the CMS Final Rule for each OPO. The different markers identify Donation Rate Tier 1, 2, and 3 OPOs. Notice the relationship between Tier 1 and more external causes of death and Tier 3 with fewer external causes of death.



CORS vs NYRT

Age Band	I20-I25	I60-I69	V01-Y89	
0_17	+0.0%	+0.2%	+2.9%	+3.1%
18_39	-0.3%	+0.4%	+8.1%	+8.2%
40_54	-2.2%	+0.9%	+3.4%	+2.1%
55_64	-6.5%	-0.9%	+4.1%	-3.3%
65_75	-13.0%	-1.8%	+4.8%	-10.0%
Total	-22.1%	-1.2%	+23.3%	

As an example of some of the extreme values above: CORS has +23.3% more CMS Potential in the external cause category than NYRT. CORS also has CMS Potential concentrated in younger age bands. CORS is in Tier 1; NYRT in Tier 3.

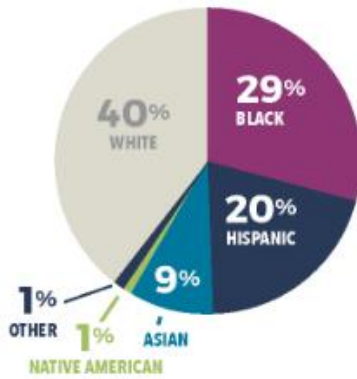
Challenges: The ICD-10-CM grouping of each organ donor is needed.

Considerations: The correlation between age and the cause of death (e.g.) younger individuals are more likely to die of external causes).

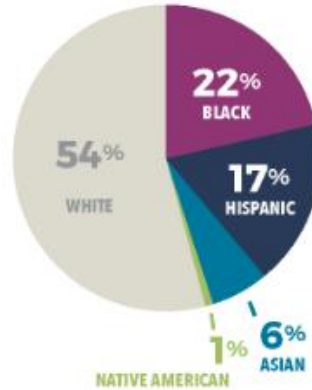
Appendix III: Minority Organ Donor Statistics

MINORITY ORGAN DONOR STATISTICS

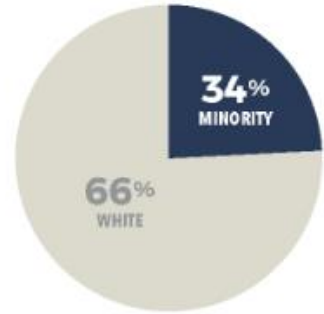
U.S. TRANSPLANT WAITING LIST 2020



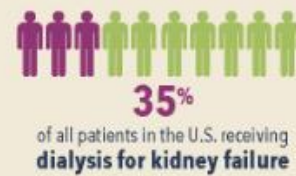
ORGAN TRANSPLANT RECIPIENTS 2020



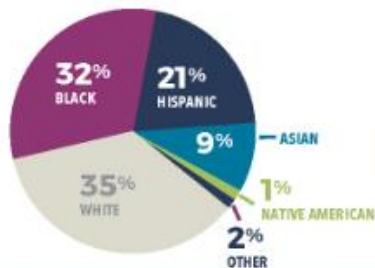
ORGAN DONORS 2020



AFRICAN AMERICANS/BLACKS REPRESENT

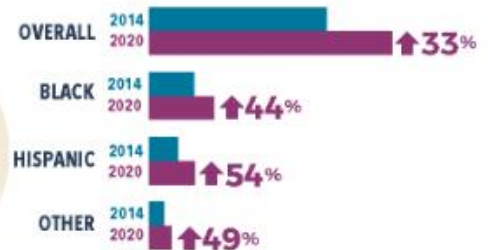


U.S. KIDNEY ORGAN WAITING LIST



65% OF THOSE WAITING FOR A KIDNEY TRANSPLANT ARE MINORITIES

MINORITY KIDNEY TRANSPLANTS



MINORITY KIDNEY TRANSPLANT IS INCREASING