September 17, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1717-P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

VIA ELECTRONIC DELIVERY

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs [CMS-1717-P]; Comments on Organ Procurement Organization Issues

Dear Administrator Verma:

The Organ Donation Advocacy Group (ODAG) is pleased to submit comments on CMS-1717-P (Proposed Rule). Our comments focus on the Organ Procurement Organization (OPO) conditions for coverage (CfC) issues – the proposed revision of the definition of "expected donation rate" and the request for information (RFI) on changes to OPO and transplant center regulations. As explained in more detail below, ODAG makes the following recommendations to the Centers for Medicare & Medicaid Services (CMS) on these topics:

- **While CMS should revise the definition of "expected donation rate" as proposed, it should not implement the proposed time frames associated with the implementation of the change.**
- **ODAG supports making changes to the metrics to evaluate OPO performance.**
- **ODAG agrees with the identified concept of a donation rate metric, and recommends that CMS obtain patient level medical record data for such a metric.**
- **The second identified potential outcome measure is problematic, will not advance performance improvement and should not be developed further.**
- **CMS should implement its previous proposal to remove the aspects of 42 C.F.R. § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval.**

BACKGROUND

ODAG is a coalition of nine organ procurement organizations (OPOs) collectively serving 90.3 million in population, 1,655 hospitals and 77 transplant programs in 22 states. The ODAG members are committed to serving families and patients through organ donation and transplantation. ODAG members have increased organ donation in their service areas by 42% since 2012 (with over two-thirds of that growth independent of donors who died from drug overdose). As is true of all OPOs, the members know their life saving work is never done. ODAG was formed to jointly pursue meaningful changes to enhance organ donation and transplantation. As organizations that have successfully increased organ donation and

transplantation in urban and rural areas throughout the country, they provide significant real time experience and data to this critical debate.

DISCUSSION

In the Proposed Rule, CMS proposes a specific change to the OPO CfCs and makes a broad request for information on OPO and transplant regulations. As explained below, while ODAG generally agrees with the proposed change to the definition of expected donation rate, it does have a concern about the implementation of that change. As to both the OPO and transplant regulations, ODAG supports the need to modify these regulations to improve the regulatory framework and to better increase performance accountability and remove existing barriers to growth. ODAG generally agrees with the proposed donation rate metric with a specific request for CMS to consider obtaining patient level medical record data directly from hospitals as an independent source for the donation rate denominator to support the best and most accurate assessment of donation potential and OPO donation rate performance. ODAG has significant concerns with the second identified OPO performance measure.

I. Revision to Definition of Expected Donation Rate in 42 C.F.R. § 486.302

CMS proposes to revise the definition of "expected donation rate" in 42 C.F.R. § 486.302 so that it is more in line with the definition of that phrase by the Scientific Registry of Transplant Recipients (SRTR).[1] As CMS notes, the SRTR modified the definition of expected donation rate in 2009 to provide for a more precise method to calculate an OPO's expected donation rate, taking into account the fact that the eligible donor population varies from donor service area (DSA) to DSA in terms of age, sex, race, and cause of death. According to the Proposed Rule, the "updated SRTR's definition states: '[t]he expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and DSAs. This rate is adjusted for the distributions of age, sex, race, and cause of death among eligible deaths.'"[2] Due to an oversight, CMS did not make this corresponding change to the definition of the CfCs for OPOs when the SRTR originally made this change.[3]

ODAG supports the proposal to revise the definition of expected donation rate to reflect the change made by the SRTR in 2009. However, in the Proposed Rule, CMS also said the following:

> we also are proposing to revise § 486.318(a)(2), (b)(2), and (c)(1) to reduce the time period for this outcome measure. We are proposing to calculate the expected donation rate using 12 of the 24 months of data following the effective date of the final rule with comment period (using data from January 1, 2020 through December 31, 2020). After the 2022 recertification cycle, and if there are no other changes to the OPO outcome measures, we would assess OPO performance based on 36 months of data.[4]

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1 84 Fed. Reg. 39398, 39696-97 (Aug. 9, 2019).
2 Id. at 39596.
3 Id. at 39597.
4 Id.

ODAG objects to the timeframes in this proposal and urges CMS not to finalize them. Reducing the time period for calculating the expected donation rate for this outcome measure from 36 months to 12 months (1/1/20 through 12/31/20) does not provide an adequate time period for meaningful review and may have serious unintended consequences. Specifically the shortened time period might distort (positively or negatively) an OPO's performance. This is particularly a concern for those OPOs in the lowest quartile of eligible death volume because small numbers may represent a substantial fraction of the OPO's total activity. Additionally, twelve months is not an adequate or appropriate length of time to evaluate OPO performance on this or any other measure as it represents only 25% of the duration of each recertification cycle (48 months) as defined in the National Organ Transplant Act (NOTA).

In conclusion, while ODAG recommends that CMS finalize the proposal to revise the definition of expected donation rate to reflect the change made by the SRTR in 2009, it opposes the proposed change in the length of the observation period for the current recertification cycle. Rather, ODAG supports completing the current recertification cycle before revising the definition of expected donation rate, and then using the revised and more precise methodology for calculating an OPO's expected donation rate starting with the next recertification cycle, measuring the observed to expected donation rate over a period of 36 months.

II. Response to RFI on OPO and Transplant Regulations

In the Proposed Rule, CMS notes that it has received substantial feedback recommending modifications to the CfCs for OPOs and the conditions of participation (CoPs) for transplant centers. While CMS does not make specific proposed changes to either set of regulations, it seeks input on certain key areas and solicits comments on two potential OPO outcome measures.[5] Below, we offer perspectives on the key areas and the potential outcome measures.

A. Key Areas

1. Do the current OPO outcome measures that are set forth at 42 CFR 486.318 accurately and reliably reflect an OPO's performance? If not, please explain.

ODAG believes that OPOs metrics should be both an accurate assessment of performance and a tool for accountability and improvement. The current donation rate metric does not adequately meet either goal. As many have noted, the self- reported data used to calculate the current donation rate measure injects some level of interpretation by each OPO which is problematic to assure consistent assessment. Further, the denominator ("eligible death") currently used in the donation rate is too narrow to capture the pool of potential donors thus constricting the ability for this metric to identify underperforming OPOs for critical areas of growth (such as older donors and donation after cardiac death (DCD)) or to serve as a tool to drive process improvement**. ODAG agrees that the current donation rate metric can be improved and should be revised.**

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[5] Id.

2. What are the impacts or consequences of the current outcome measures on (1) an OPO's performance; and (2) the availability of transplantable organs?

Taken as a whole, the regulatory framework under which OPOs work has successfully supported significant growth and overall performance of the U.S. organ donation network compared to the rest of the world.[6] ODAG believes that there are many drivers impacting OPO performance, including a need to ensure on-going performance and accountability (such as outcome measures). OPOs use a wide variety of metrics and data internally to seek improvement, including benchmarking with other OPOs, using trending metrics, analyzing much more granular metrics like, number of referrals, family approaches, and authorizations at both DSA and individual hospital and staff team levels. These types of metrics are available in real time to inform operational strategies and have a direct correlation to performance for an OPO and ultimately in increasing the availability of organs for transplantation. It is important to highlight that any regulatory metric that is developed primarily to identify underperformers in any field (typically a small minority) will not likely have a significant isolated impact on those that perform at an average or above average level (typically the majority). It is the on-going evaluation of many performance measures and the implementation of responsive strategies that drives change and continual improvement. A single regulatory metric will certainly contribute to accountability, however in isolation it should not be expected to drive innovation and improvement for the entire system.

3. What impact, if any, do the certification and decertification processes for OPOs have on organ procurement and transplantation?

OPOs are surveyed every four years. Decertification is the only action available to CMS under existing regulations when an OPO does not meet the outcome measures in the CfCs. Decertification of an OPO failing to meet the CfCs without any interim step is a very blunt tool for improvement and may disrupt and destabilize donation in the immediate local service area as well as the national system which requires significant continuous and ongoing coordination between the 58 OPOs. This is particularly true as organ allocation policies require broader geographic distribution. Also, while failure to meet the performance metrics may be due to significant organizational underperformance, it may also be attributable to validated mitigating factors (e.g., donor demographics, surgeon acceptance practices, or even data that are not contemporary to an OPO's current performance).

ODAG proposes that CMS no longer be constrained by only having decertification as a tool to address underperformance. Instead, CMS should have the authority and option to move forward with systems improvement initiatives for an OPO that has fallen out of compliance. Similar to what is in the transplant center CoPs – and designed to support rapid performance improvement and minimize disruption to the system and patients waiting for transplantation – CMS should establish a process for OPOs that would include: (i) review of mitigating factors; and (ii) formal systems improvement agreement (SIA) as an alternative to decertification.

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[6] Glazier A, Mone T. Success of Opt-In Organ Donation Policy in the United States. Journal of the American Medical Association, Aug. 27, 2109.

CMS should develop a process for an OPO to request consideration of mitigating factors if the OPO has not met the outcome measures. Potential mitigating factors could include by way of example:

- Whether the OPO meets any outcome measure.
- The extent to which outcome measures are not met.
- Whether the most current data cycle reflects performance that meets outcome measures.
- Recent performance and trends reflecting year over year growth and improvement.
- Performance improvement initiatives implemented to address performance shortfall.
- Adoption of processes and practices that have supported improvement in other OPOs.
- Extenuating circumstances that impact performance (e.g., non-contiguous area, other external factors impacting eligible donors or ability to place organs).

Upon review of mitigating factors, CMS could either: (i) recertify; or (ii) provide opportunity for a SIA.

If, following a review of mitigating factors, CMS denies recertification, CMS and the OPO could choose to enter into a SIA that:

- Extends the OPO's certification and provides time for the OPO to implement long term sustainable performance improvements.
- Similar to a transplant center SIA, would be a legally binding agreement and:
    - Require the OPO to engage in a series of quality and performance improvement activities to address deficiencies in CfC compliance;
    - Require the OPO to engage an independent peer monitor/consultant approved by CMS to perform a gap analysis and assist in implementation of quality and performance improvement activities.
    - Provide for ongoing periodic monitoring (more frequently than the 4 year recertification cycle) by CMS of the OPO's compliance with the SIA and progress toward CfC compliance.

To best support continuous performance improvement and OPO outcomes that meet the metric, ODAG recommends that an OPTN process be established to identify OPOs with declining outcome measures and to work with these OPOs to improve performance before falling out of compliance with the OPO outcome measure requirements. Oversight of the process would be through the OPTN Membership and Professional Standards Committee (MPSC). The MPSC has already established a methodology for identifying OPOs with declining performance and is set-up to provide peer-review support, tools for improvement and ongoing monitoring. More explicit coordination between this existing performance improvement mechanism and any new CMS OPO performance measures would benefit the system.

Collectively, these recommendations would provide a more meaningful certification and decertification process by providing the means to facilitate improved performance that could lead to the desired improvement and avoid the disruption and destabilization that is associated with a decertification that may not be necessary.

4. Are there any transplant center CoPs that conflict with or should be harmonized with OPO CfCs? If yes, identify the specific requirements and how they would harmonize or otherwise modify the requirements.

The current metrics used by CMS to assess performance and certify transplant centers are structured in a manner that discourages the use of the full range of available organs. Specifically, the outcomes requirements in the transplant center CoP regulations result in underuse of medically complex, but transplantable organs, decreasing the yield from this pool of available organs. In short, the transplant center CoPs are hindering increased organ transplantation.

The outcomes requirements of Medicare transplant center CoP regulations (42 C.F.R. §§ 482.80, 482.82) do not promote the use of all available organs, including those from "medically complex donors" (organ donors over aged 60 and donors after circulatory death). The outcomes requirements in the transplant center CoP regulations require a comparison of observed patient deaths and transplant failures (observed events) to the expected number of patient deaths and transplant failures (expected events). This measure provides a disincentive to utilize any organ that comes with a higher risk of failure, even if that risk is marginal at best. Stated differently, the current outcomes requirements penalize transplant centers for using organs from medically complex donors, resulting in the wasting of transplantable organs to the detriment of the very patients the measure is designed to protect.

The U.S. discard rate for kidneys recovered for transplant stands at 20%, twice the rate experienced in the E.U. This represents 2,000 transplantable kidneys per year that are currently being discarded that should have been utilized. Additionally, studies consistently identify medically complex donors as the most significant areas for growth in increasing the number of organ transplantations, but this growth is hampered by the underutilization of these types of organs due to misaligned regulatory incentives. CMS recently noted that there has been an increased percentage of unused kidneys, and correctly noted that this "creates an imperative to action, given the lifesaving benefits of organ transplantation."[7] Acknowledging these concerns, CMS proposed and finalized a change to the CoP regulations aimed at addressing the increased percentage of unused kidneys. In May 2016, CMS raised the observed to expected outcome ratio threshold for a "condition" level deficiency from 1.5 to 1.85 in an effort to incentivize the use of organs while mitigating the risks of losing Medicare reimbursement based solely on these outcome measures.[8] However, this change was insufficient to alter transplant center organ acceptance practices to increase utilization of organs from medically complex donors.

Rather than making another attempt to revise the outcomes requirements in the CoP regulations to address this concern, **ODAG urges CMS to implement its previous proposal "to remove the requirements at § 482.82 that require transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval."[9] This proposal has yet to be finalized and ODAG believes that CMS should finalize it.**

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[7] 81 Fed. Reg. 79562, 79828 (Nov. 14, 2016).

[8] See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-24.pdf.

[9] 83 Fed. Reg. 47686, 47689 (Sept. 20, 2018).

B. Potential OPO Outcome Measures and Related Parameters

As part of the RFI, CMS asks for comments on the two potential OPO outcome measures. The first potential measure would be "the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation."[10] The data on inpatient deaths to calculate the denominator on this proposed donation rate would come from the Center for Disease Control and Prevention (CDC) Detailed Mortality File and the National Center for Health Statistics (NCHS) National Vital Statistics Report (collectively the "CDC Data Sets"). The second potential measure would be "the actual organs transplanted as a percentage on inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation."[11] In addition to seeking comments on the potential outcome measures, CMS seeks comments on parameters for the measures (e.g., how to determine the percentage that indicates successful performance, and if not a percentage, how should CMS determine what the parameters for the measures should be).[12] As discussed below, ODAG generally agrees with the concept of a donation rate metric using the appropriate data, but has significant concerns with the other OPO organs transplanted performance measure.

1. First Potential Measure (Donation Rate Metric)

The first potential outcome measure CMS identifies seeks to evaluate effectiveness in converting each potential organ donor who has died with conditions predictive of organ donation potential in each OPO's DSA. While ODAG supports this donation rate metric, it has concerns regarding the source of accurate data for the denominator – inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation. **As explained below, ODAG does not believe the CDC Data Sets to be appropriate to calculate this denominator. ODAG proposes an alternative independent data source for the denominator that it believes will be more accurate and also a significantly better tool to advance future OPO performance.**

a. Inpatient Deaths Among Patients 75 Years or Younger with a Cause of Death Consistent with Organ Donation as a Denominator of an OPO Outcome Measure

NOTA requires that OPOs be evaluated on "outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations."[13] Thus, the challenge with calculating "organ donor potential" as required for the performance measures has been the lack of a uniformly available data source for the denominator that incorporates the widely varying underlying population demographics and disease incidence across states and OPOs and their respective DSAs. This challenge was first recognized when

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10 84 Fed. Reg. at 39597.

11 Id.

12 Id.

13 42 U.S.C. § 273(b)(D)(II)(ii) (emphasis added).

CMS revised the previous metric, donors per million population, given that death rates and donor potential vary as much as 250% across the states.[14] The concept CMS identifies in the RFI would utilize data for the denominator from the CDC Mortality Tables which are produced from NCHS National Death Index data (the CDC Data Sets). There are a number of inherent limitations within the CDC Data Sets that compromise the proposed use of that data as an accurate means to hold OPOs accountable and advance donation performance. Concerns with the CDC Data Sets as a consistent and accurate source for the denominator include (1) granularity; (2) timeliness; (3) availability for regulatory use; and (4) adequate adjustment:

- Granularity: In-Hospital Deaths as calculated using the CDC Data Sets is insufficiently granular to accurately approximate donor potential. One of the concerns with using this broad cut of data as "donor potential" in the denominator is that most hospital deaths occur outside of intensive care units (ICUs) where ventilation – a necessary condition for organ donation – occurs. Per the Dartmouth Atlas, ICU deaths as a percentage of in-hospital deaths across the country range from a low of 7.5% to a high of 42.2%, a 5.6 fold difference.[15] This appears far too variable to constitute a statistically uniform denominator of "donor potential" to accurate assess OPO performance. Even within the subset of in-hospital deaths that occur within the ICU, there are a number of specific variables directly relevant to assessing donor potential. It is believed that 98% of ICU deaths are ineligible to be potential donors for the reasons cited below. Not taking these factors into account undermines the proposed use of the data.
    - Patient ventilator supported status (an intervention that is essential for organ donation) is not captured in the CDC data set, and varies 3.6 fold, from 14.1% to 50.8% of ICU patients in hospitals across the country.[16]
    - Patients with active cancer (a rule-out for organ donation) is not captured and this varies from a death rate frequency low of 120.3 in Utah to a high of 185.7 in Kentucky (54% higher than Utah).[17]
    - Organs from patients in organ failure are not medically suitable for transplantation and regional rates of patients suffering from organ failure, as determined from organ failure mortality rates as a cause of death, varies significantly by region.[18] The CDC Data Sets would need to include information on patients with organ failure to appropriately adjust for this variable.
- Timeliness of the Data: ODAG understands that the CDC Data Sets proposed for use are available 18 months after the reporting period (6 months after the end of each calendar year). This is not sufficiently contemporaneous to assure accurate assessment of current OPO performance and may delay identification of downward OPO performance trends.

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[14] Ojo AO, Wolfe RA, Leichtman AB et al. A practical approach to evaluate the potential donor pool and trends in cadaveric kidney donation. Transplantation 1999, Luskin R, Delmonico FL. Assessing organ donation from the dead should not be done by reporting a census of the living. Am J Transplant 2003.

[15] The Dartmouth Atlas of Healthcare Statistics http://archive.dartmouthatlas.org/data/table.aspx?ind=15.

[16] "ICU Occupancy and Mechanical Ventilator Use in the United States," ICU Occupancy and mechanical ventilator use in the United States" CCM Journal.org, December 2013 • Volume 41 • Number 12.

[17] *See* https://www.cdc.gov/nchs/pressroom/stats_of_the_states.htm.

[18] *See* id. For example, these data show mortality from kidney failure ranges from a high of 21.7/100,000 in Mississippi to a low of 3.3 in Vermont, a 6.6 fold difference; mortality from liver failure ranges from a high of 26.8 in New Mexico to a low of 6.6 in Maryland, a fourfold difference; and mortality from heart failure ranges from a high of 237.2 in Oklahoma to a low of 119.1 in Minnesota, a twofold difference.

CMS should clarify if this data set could be made available in more current time frames to address this concern.

- Availability & Use of the CDC Data Sets for Regulatory Purposes: It is unclear under the Public Health Services Act and the state contracts with the CDC for the data to create the CDC Mortality Tables and NCHS National Death Index, whether these data can be used for purposes beyond research and instead for the intended evaluation of OPO performance for regulatory recertification purposes. It is requested that CMS clarify whether this is a legally permissible use before further considering it.
- Adequate Adjustment for Demographics: The variation in authorization rates among different demographic groups is well documented. Accurate assessment and comparison of demographic variations in donor potential and authorization performance is an important factor in evaluating OPO performance. CMS should verify that the proposed data sets have timely and accurate information with regard to ethnicity, disease incidence and other documented demographic factors which would impact the statistical predictability and reliability of the CDC Data Sets when used to measure OPO performance.

For the reasons identified above, the CDC Data Sets are inadequate and will not enable more rigorous CMS monitoring and intervention to promote improvements in OPO performance.

b. Alternative Independent Data Source for the Donation Rate Denominator

Given these many challenges with CDC/NCHS/NDI Mortality data, ODAG proposes an alternate data source to establish **independently reported data to calculate the denominator** to better calculate donor potential as required by NOTA and more accurately assess and advance OPO performance.

CMS currently requires hospitals to report all "individuals whose death is imminent or who have died in the hospital" to OPOs and requires hospitals to allow OPOs to review death records to assess donation potential and referral effectiveness. [19] This hospital CoP regulation is the basis of the current 150,000+ organ donor referrals from hospitals. **CMS can leverage this current regulation and data reporting by requiring hospitals to periodically report, on a retrospective basis, a specified data set for all hospital patient deaths to CMS, OPTN, SRTR, and OPOs**. This could be accomplished through an electronic process with automated reporting on a routine basis (monthly). Several of the ODAG members currently receive such an automated electronic report to perform death record reviews. Using this patient-level medical record information directly from hospitals would enable the denominator of an OPO donation rate measure to be calculated (i) from information that is independent of OPOs, and (ii) both granular and timely enabling development of a donation rate metric with a denominator of donor potential consistent with requirements of NOTA. This data sourcing would support an accurate assessment of performance and serve a tool for improvement.

As noted, this hospital reported data set **would not** be determined by OPOs. CMS would establish a definition consistent with the concept in the RFI of patients 75 years or younger with a cause of death consistent with organ donation. This definition could easily rely on current

[19] 42 C.F.R. § 482.45(a)(1).

hospital medical record coding systems, and incorporate standard diagnosis and procedure codes, specifically those to capture:

- Neurologic Injury
- Ventilator Dependence
- Age
- Active Cancers
- Infectious Diseases
- Organ Systems in Failure
- Brain Death Testing Results

This regulatory refinement builds on existing CMS authority under the hospital CoPs, and would best support the goal of accurately evaluating OPO donation rate performance.

2. Second Potential Measure (Organs Transplanted Metric)

CMS has included a proposed second measure in the RFI to assess utilization or transplant yield. ODAG does not support this particular measure because it not independent of the proposed donation metric. By using the same denominator as the proposed donation rate metric, this contemplated measure is highly dependent on factors related to donation rate (timely identification of potential donors and authorization) which is a separate and distinct part of the operational process from the OPO's performance on organ utilization (donor management, surgical recovery, placement, preservation, and transportation of organs). As a result, an OPO's performance on the second identified measure (organs transplanted) would be almost entirely dependent on its performance on the first CMS identified measure (donation rate).

The Goldberg 2017 study in fact highlights that the two identified measures are highly correlated (Spearman correlation coefficient = .88). The organs transplanted measure is also dependent on factors that an OPO has limited control over such as mix of DCD donors. Without adjustment for DCD potential, where the expected number of organs an OPO can place for transplant is lower than in the setting of brain dead (BD) donation, the organs transplanted measure penalizes an OPO that has a larger percentage of potential DCD donors. Conversely, an OPO that has a lower percentage of potential DCD donors/higher percentage of potential BD donors would appear to perform better on this measure even if that OPO may not in fact perform as well placing organs per donor relative to other OPOs. NOTA specifically requires "multiple measures" for OPO certification[20] and so we believe it is important to ensure the identified measures in fact measure OPO performance on different and distinct parts of the donation process – conversion of potential donors and placement of organs for transplant. Having metrics that isolate OPO performance on these separate components of the donation process will also provide better tools for performance improvement. The best way to do that is to use a denominator in the utilization rate that is actual donors, not possible donors. It is unclear what the concern with the current O:E (observed to expected) yield measure (CMS just implemented in 2017 with broad support from the donation and transplant community) that this organs transplanted measure would solve. For these reasons, ODAG urges CMS to maintain the current O:E yield measure and to not pursue further the second proposed measure (related to transplant utilization) set forth in the RFI.

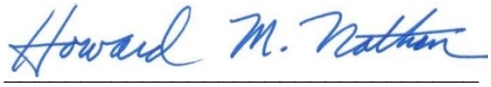
[20] 42 U.S.C. § 273(b)(1)(D)(ii)(III).

CONCLUSION

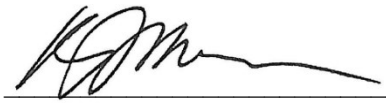
ODAG appreciates CMS's consideration of ways to improve the OPO CfCs and the transplant center CoPs. ODAG believes that revisions to both are needed in order to improve organ donation and transplantation. The proposed revision to the definition of expected donation rate is an advancement, yet, as noted above, it must be implemented in the right manner (not as CMS proposes with regard to time frames). Similarly, CMS should implement a revised donation rate metric, though we strongly encourage CMS to use the best data available (patient level medical record data) to do so. Finally, CMS should not pursue further the second identified measure because it is not an independent measure of OPO organ utilization performance. Thank you for your consideration of our comments.

Sincerely,

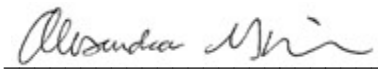
Kevin Cmunt, President/CEO
Gift of Hope Organ &
Tissue Donor Network



Howard Nathan, President & CEO
Gift of Life Donor Program



Kevin O'Connor, President & CEO
LifeCenter Northwest



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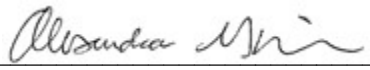
LifeChoice Donor Services

Kevin A. Myer, President & CEO
LifeGift

Susan Gunderson, CEO
LifeSource



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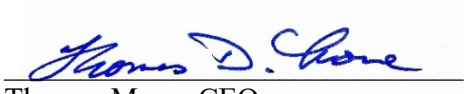
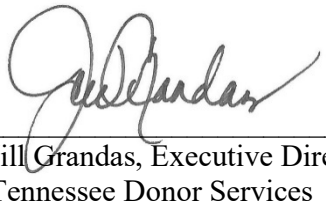
New England Organ Bank



Thomas Mone, CEO
OneLegacy



Jill Grandas, Executive Director
Tennessee Donor Services