LIFEGIFT

North Region
1000 12th Ave.
Fort Worth, TX 76104
817-870-0060

Southeast Region
2510 Westridge St.
Houston, TX 77054
713-523-4438

West Region
5812 64th St.
Lubbock, TX 79424
806-798-5568

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,

LifeGift, the organ procurement organization (OPO) based in Houston, Texas and serving Fort Worth and West Texas appreciates the opportunity to comment on the proposed rule addressing Organ Procurement Organizations (OPOs) conditions for coverage and outcome measure requirements (Proposed Rule). LifeGift firmly supports the Proposed Rule's stated objectives to increase donation opportunities for transplantation, increase organ utilization and ultimately save more lives. It is important to first point out that this entire discussion is predicated on generosity of donors and their families. LifeGift acknowledges and is grateful for all donors and donor families who make transplantation possible. CMS should highlight this fact first in future correspondence about donation and transplantation system performance.

BACKGROUND

LifeGift strongly supports the intent of the American Kidney Health Initiative announced by President Trump to reduce the burden of kidney disease on individuals, families and our nation. We support the Administration's pledge and the stated goals in the Proposed Rule to increase organ donation and transplantation.

We agree that revisions to the OPO conditions for coverage (CfCs) are needed to stimulate and continue further increases in donation and transplantation.

I. GENERAL POINTS

LifeGift supports the following principles:

- We agree that improvement is essential and that the rate of improvement needs to accelerate.
- It is important to create transparent and verifiable measures which advance performance improvement.
- We suggest that performance metrics are rarely perfect, and that CMS should consider an evolving approach to those suggested so far based on the effects of how they are applied in actual practice.
- As highlighted by the Institute for Healthcare Improvement (http://www.ihi.org/resources/Pages/Tools/ResourcesforPublicHealth.aspx), multi-stakeholder collaboration with the goal of implementing shared effective practices is vital to

overall performance improvement. OPOs, Transplant Centers, Acute Care Hospitals and Social-Cultural Change Non-Profits should be encouraged to engage in organ and tissue donation improvement collaboratives.

- Clarifying the potential number of organ donors (Donor Potential) in detail is an important but not primary objective of the revised metrics, as the revised metrics should be aimed at comparative performance across the spectrum of OPOs as well as individual OPO performance over time (OPO compared to other OPOs over time AND OPO compared to self over time).
- Attention to revision (make the change) of performance monitoring and restructuring the organ procurement transplant system is critically needed. Attention to the process of transition and the subsequent impact (see the change through and make sure it is sustainable and impactful) on the system of organ and tissue donation and transplantation is even more important to ensure a robust and sustained impact.

II. COMMENTS ON SPECIFIC PROPOSALS

- CMS should approach the suggested first outcome measure with awareness of well-documented data inaccuracy issues around the use of death certificates. Potential donor criteria should include both inclusion and exclusion criteria by specific ICD-10 codes. Methodology for estimation is already developed in the 2012 Deceased Donor Potential Study funded by HRSA/HHS (OPTN Deceased Donor Potential Study (DDPS), Task 6).
- We support requiring electronic health record vendors to develop capability to provide direct transmission of patient level data to an independent reporting center such as the SRTR or the OPTN as it is preferable and possible.
- CMS should continue the use of the current SRTR provided Observed: Expected (O:E) organs transplanted metric because it is in use, has been validated, is independent of OPO reporting and is a known entity. We support continuing the use of this "2nd Outcome Measure" rather than replacing it with the metric proposed by CMS.
- An organ donor with zero organs transplanted should be included in the Definition of "Donor" because it is impossible to predict organs transplanted prior to the intraoperative recovery when managing any type of donor, especially those that are older and medically complex.
- Clarification of the timing of the application of a revised performance management system is needed. LifeGift supports the use of available data for application of results in a timely manner to prevent further delay of system improvement.
- Action is needed to increase the utilization of all organs, particularly organs from older and medically complex donors, including those recovered via the DCD approach.
    - Disincentives should be removed from willing transplant programs to accept these medically complex organs via:
        - Remove financial disincentives by increasing reimbursement for the increased expense of using kidneys, for example, that have net transplant benefit but require longer hospital stays.
        - Remove or smooth the impact of regulatory outcome measures for transplant programs to create incentives to utilize medically complex organs. Isolating OPO performance from transplant system utilization patterns is important for OPO improvement but misses the opportunity to create system change to increasing transplantation. The challenge at hand involves both supply and demand of a limited and lifesaving resource.
- CMS should incentivize accelerated biomedical innovation to improve organ preservation that will improve outcomes, extend preservation times and allow for broader allocation.

- OPOs that participate in approved innovative research practices (Project Hope, for example) supporting the above should be encouraged and incentivized to use their unique positions to broaden the impact of medical research, including deceased donor research.
- CMS should increase incentives and require practices at all applicable hospitals to facilitate donation after circulatory death (DCD). No hospital should be allowed to defer its obligation to collaborate in the use of this well-accepted method of organ recovery.
- Every OPO should be required to evaluate and recover organs from HIV-positive organ donors.
- CMS should provide OPOs under review or risk of decertification the opportunity to develop and submit a system improvement application (SIA) with detailed QAPI plans that can be monitored for a period of one year.
    - If the evaluation period is one year, the SIA could address the potential for the impact of rare but significant events such as major weather disruption, large donor hospital service interruption and subsequent lowering of donor potential with impact on performance in such a short evaluation period.
- CMS should proceed with the proposed changes while examining specific risk adjustment approaches, but should not delay implementation of improvement efforts while expending time and resources on the typical risk adjustment verification and validation processes.
- If an OPO is decertified, it should have the ability to demonstrate its concerns about particular issues with its service area population demographics in its SIA. LifeGift believes multicultural diversity in a service area is an opportunity rather than a challenge for increasing donation with expertise, effort and education. LifeGift is fortunate to serve the most culturally diverse city in the United States and is ranked as a high performing OPO per the proposed metrics based on 2017-2018 data.
- LifeGift also encourages CMS to consider strengthening requirements for OPOs to promote inclusion and workforce diversity to enable OPOs to better understand and relate to communities served and thus influence improvement of donation rates.

III. DECERTIFICATION PROCESS COMMENTS

- An SIA process should be required of any OPO under consideration of decertification unless that OPO declines to submit a plan.
- The potential for system disruption is real and extends not only to organ supply chain issues but also to critical medical resources via tissue donation. Impact on the acquisition and supply of donated products of human origin needs to be considered as transition plans are developed.
- Board Governance issues in non-profits are present and need attention in any OPO transition process. Use of academic resources in non-profit governance and social innovation is highly recommended as resources needed to smooth potential unintended consequence in restructuring OPOs.
- We do not support the concept of "open territory" across all OPOs over time as we believe creating continuous competition for other OPOs would be disruptive and distract OPOs from meeting their core mission. Furthermore, such open competition would likely create a reduction in collaborative, effective practice sharing that is needed for larger scale improvement.

IV. SPECIAL COMMENTS

- LifeGift supports a requirement that any organization recovering tissue should achieve or already hold accreditation by the American Association of Tissue Banks (AATB). Such a requirement allows for the provision of tissue safe for transplantation and is in the interest of public health. Additionally, AATB accreditation strengthens assurances of appropriate and

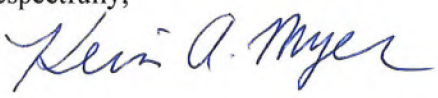
transparent business practices for tissue recovery agencies, the vast majority of which are OPOs, in parallel to the assurances afforded by accreditation by the Association of Organ Procurement Organizations (AOPO).

- LifeGift suggests that CMS use its influence and expertise in providing needed support for improved and better coordinated air traffic transportation systems. Welcomed increases in donation and transplantation have also stressed the limits of access to and availability of air transportation services across the U.S. This is an opportunity for the Federal government to use its resources and authority to encourage increased cooperation and support from commercial air providers and the FAA, TSA, etc.
- Costs of OPO consolidation are frankly unknown and even best case estimates are difficult to produce. Academic expertise in mergers & acquisitions in the non-profit ecosystem may be important resources for providing information on costs of transition leading to consolidation or organizational downsizing/segmentation.

V. CONCLUSION

LifeGift appreciates the opportunity to provide comments about the Proposed Rule and we appreciate the interest of CMS in these matters. We welcome the opportunity to share our experience, including the opportunities and challenges of an improving and growing OPO, to improve organ donation and transplantation in the United States.

Respectfully,



Kevin A. Myer, MSHA
President & Chief Executive Officer