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with
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President & Chief Executive Officer
LifeGift

Remarks

Good morning. My name is Kevin Myer and I serve as President & Chief Executive Officer for LifeGift, the organ procurement organization based in Houston Texas serving the areas of greater Houston, Fort Worth, Lubbock and Amarillo. (see www.lifegift.org)

Thank you for the opportunity to share our thoughts, references and evidence concerning the proposed rulemaking for **42 CFR 486.** Joining me on the call are Lauren Quinn, VP for External Relations, LifeGift; Kristine Browning, VP for Quality and Regulatory Compliance, LifeGift; Christie Cardon, Esq, King & Spalding and Adam Robison, Esq, King & Spalding.

Recognition and Respect for Generous Donors and Donor Families

We are grateful for all the donors and donor families who have made such a difference in the lives of so many others. None of these comments nor this entire topic would be possible without the generosity of those giving the gift of life.

Recognition of Hospital and Transplant Center Personnel

We are grateful for the 1000s of hospital and transplant center professionals who do this lifesaving work day in and day out. We respect their expertise and dedication to this work and we are privileged to work side by side with our colleagues in this endeavor.

Overview of What We Want to Cover

Today, I will:

1. introduce LifeGift and highlight its unique characteristics as an OPO;
2. note our support for continuous reforms to improve the system;
3. identify at a high level our concerns with revised performance metrics;
4. propose refinements in the new metrics that would further the ultimate goal, which is to increase organ transplants

About LifeGift

LifeGift is the 7th largest OPO by population (11.3 million), 9th largest by land mass at over 105,000 square miles, 10th for total deaths per year at around 83,700 yet with a one of the lowest death rates across OPOs at 54th of 56 (2023) among all OPOs. (https://srtr.org/reports/opo-specific-reports/interactive-report?center=txgc&type=OPO)

In 2023, we coordinated 37,082 death referrals, recovered 468 organ donors of which 143 were via the DCD approach and 325 were following brain death. 49.6 % of our donors were non-white compared to the U.S. at 34.5% reflecting the immense diversity of the communities we serve. All of this contributed to transplanting 1,437 organs for patients at 123 transplant centers across the United States illustrating the broad geographic impact that we have. This number does NOT include any research pancreata or islet cell transplants.

The take-home message from all of these numbers is that we are a large organ procurement organization serving a very diverse population and widespread geography with significant impact in our communities and widespread impact on patients in need of transplantation anywhere in the United States. In fact, for 2023, we had the 12th highest volume of organ donors among the 56 OPOs; however, we helped coordinate the transplantation of the 4th highest number of organs. Being 4th highest in organs transplanted in the U.S. in 2023 reflects our documented expertise in organ placement and allocation; even though we have no control over transplant program acceptance behaviors.

CMS Performance Metrics:

Our Public Comment Track Record

LifeGift has consistently submitted thorough and thoughtful public comment on the matter of the CMS Rule for OPO Performance (November 20, 2020: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F) since 2019. We were early in supporting the need for performance improvement, but we made relevant comments about our concerns and recommendations for a better measurement system. Each of these public comments has been submitted for your reference. *(See References #1 - #4, #6)*

Pancreas for Research

Of note is our most recent comment (See Reference #15)) on the matter of counting pancreas for research as transplantable organs leading to pancreas-only donors counting as actual organ donors. The revised organ donation rate measure is dependent on a definition of donor that includes an individual "from whom a pancreas is procured and is used for research or islet cell transplantation." The imprecise definition of what pancreata count for purposes of the donation rate has led to variations in OPO approaches to recovering and reporting pancreata for use in determining the donor numerator in the donation rate metric. We maintain that this approach is not consistent with the original intent to support research for pancreas islet cell transplantation, not basic science of general islet cell cryopreservation research. As acknowledged by CMS (See Reference #12-#13), the wording in the Final Rule has created significant consequences for the accuracy of any ranking or tier system. We strongly object to the inclusion of pancreas for research [other than for research for islet cell transplantation] in any measurement of OPO performance around actual organ transplantation.

Geographic Differences in Mortality

It is well documented and accepted as a fact in the public health discipline and across all branches of medicine that mortality varies by geography. Location matters as highlighted in the Dartmouth Atlas in 1000's of examples using Medicare covered populations. Geographic variation, for example, is clearly articulated by Jayme Locke, MD, PhD (incoming HRSA Division of Transplantation Director) in her 2020 publication (Reference #5: https://journals.lww.com/transplantjournal/fulltext/2020/02000/Geographic_Differences_in_Population_Health_and.33.aspx# showing that the unique

demographics and comorbidities of the U.S. Gulf Coast region create a lower organ supply especially for kidneys, contributing to lower donor potential. CMS's position that such variation would "average" out over the various OPO populations is not supported anywhere in the literature and contradicts standard accepted principles of public health. Established approaches in health system assessment for performance and/or for reimbursement by HSA, HRR or census division, for example, are highly applicable and should be used for risk adjustment. One example in mortality risk adjustment as described by CMS in CSM AUS 2022 Report is here: https://www.cms.gov/files/document/2022-condition-specific-mortality-measures-updates-and-specifications-report.pdf

Donation Rate & Transplant Rate Essentially Same Metric and Never Validated

The two metrics being used for Tier Ranking are problematic. Donation Rate includes pancreas for research only donors and is based on a seriously flawed denominator. This same severely flawed denominator is used for the Transplant Rate. Moreover, OPOs are being held accountable for behaviors and practices of transplant programs, transplant clinicians and transplant systems over which we have zero control. For example, in our donation service area, the variation in organ acceptance rate for kidneys is widely different by center (data available at srtr.org, Organ Offer Acceptant Rate). Neither of these metrics have ever been validated although some authors (Doby, Lynch, Goldberg) have asserted that this is the best available set of metrics to use because any other approach such as that used by the HRSA OPTN Deceased Donor Potential Study is "too difficult to perform…" We assert that "good enough" is not acceptable. Furthermore, NOTA requires that the regulations "rely 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."

Denominator Is Only a Crude Estimate of Mortality From Which a Small Number of Deaths May Be Organ Donors

The denominator is not "donor potential." The method used to collate in-hospital deaths under age 76 with death certificates indicating cause of death in three extremely broad ICD-10 codes is merely an estimate of mortality with no correlation to actual organ donor potential. There is no requirement for

consideration of ventilation in these deaths which is required for perfusion and oxygenation of transplantable organs and there are no exclusion criteria for conditions totally incompatible with any organ donation such as lymphoma or widespread metastatic cancer. This is why the denominator creates only a crude estimate of deaths that may be in a category typical of organ donation. As pointed out above, these death patterns vary by region and the denominator has no adjustment for the wide variation of these deaths by county, DSA or any other larger geographic region.

No Quality or Patient Safety Consideration in Performance Unlike All Other Health System Measurement

Unlike CMS Performance measurement systems for all other health systems in CMS, this OPO Tier approach does not include any consideration of quality or patient safety and could easily lead to a Tier 1 OPO being severely out of compliance with OPTN Policy and HHS/HRSA regulations. Once again, this approach is also not consistent with the National Organ Transplant Act (NOTA). NOTA requires that the regulations "rely 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."

Only One Year for Comparison (2024)

This evaluation period is for only one year of the current 4-year certification period 2022-2026. 2024 is the year of evaluation in isolation from trend, improvement year over year, etc. In contrast, the proposed CMS system designed by CMS, not others, known as IOTA, proposes a six-year evaluation period for transplant centers. This widely divergent approach is puzzling and non-sensical, particularly given the historical wide swings OPOs have encountered in OPO placement among Tiers 1-3 each year during the 2022-2026 measurement period. (See LifeGift Public Comment CMS-5535-P: Increasing Organ Transplant Access Model; Request for Public Comment, see attached labeled as Reference #16)

No Risk Adjustment Unlike All Other Health System Measures

We have included numerous references (See references #7, #8, #11) in our submitted materials on the need for risk adjustment and the consequences for decertifying OPOs that actually would be in different Tiers with proper risk adjustment. This approach should extend to geography, mortality patterns, demographics, ADI, for example.

Established Statistical Bias Against Larger Size OPOs

Numerous references (See Reference #9-#10) highlight the statistical bias against larger sized OPOs like LifeGift. This is very evident when reviewing the most recent Tier rankings when the vast majority of apparent Tier 1 OPOs are smaller such as the OPOs in Iowa, Utah, Nevada and Nebraska. Under the Final Rule's competitive bidding process, this could also lead to smaller OPOs assuming the donor service areas of larger OPOs without the resources, infrastructure, or experience necessary to operate larger and more complex donor service areas.

LifeGift & System Performance:

Year over Year Improvement

LifeGift has demonstrated year over year improvement in both organ donor volume and organs transplanted with the exception of the Covid period, which was especially significant for the Houston based Texas Medical Center.

Innovative Practices

Within the existing framework of HRSA and CMS, LifeGift has made and continues to make significant contributions to organ donation science and transplantation research. The Deceased Donor Hypothermia Study (machine perfusion for kidneys), the Hope Project (use of HIV positive donor organs for transplantation), the Stanford Donor Heart study (evaluation of donor hearts leading to more transplants), numerous NIH and NSF funded projects and many others centered on medical devices for machine perfusion have contributed to overall system improvement and more transplants. There should be inclusion of consideration of these contributions in evaluating OPOs.

What's a Better Approach?

Refine Denominator to Include a More Specific Donor Potential

We suggest there is a better way first to change the current denominator from a crude estimate to a more refined donor potential by including ventilator status, applying exclusion criteria using ICD-10 codes and requiring hospitals to use standard electronic referral systems that can start the documentation of a potential donor from recognition to referral to evaluation, authorization, recovery and outcome. This electronic journey would remove the need for many of the previous suggestions for risk adjustment because measurement would be direct, not a crude estimate and would be at the hospital and patient level.

Risk adjustment for variation in OPO size, demographics and mortality by region would still be necessary to make valid comparison between the unique characteristics of the Nebraska OPO, for example, as LifeGift with a dramatically different population demographic as well as size.

Evaluation Period Should Be Longer Consistent with Current CMS Practices

The evaluation period of one year needs to be extended to three years (2023-2026). This is aligned with the current certification period and more closely aligns with the proposed IOTA model and excludes 2022 because of lagging impacts of the Covid pandemic.

Evaluate and Hold Hospitals Accountable for Existent Conditions of Coverage

OPOs routinely experience direct and indirect challenges with accessing support for organ donor cases at a variety of hospitals. These challenges range from lack of access to operating suites for recoveries, refusal to provide physicians to declare when appropriate DCD donors, late referrals, limited access or seriously delayed access to OPTN required testing such as cardiac catheterization and evaluation for organ donor management. CMS has done well to promulgate these requirements 42 CFR Parts 413, 441, 486 and 498, Conditions for Coverage for Organ Procurement Organizations (OPOs); Final Rule but evaluation and direct feedback to non-compliant hospitals is rarely if ever provided, even as it has a direct and consequential impact on the number of organs transplanted. We acknowledge and

are grateful for the 1000s of highly stressed physicians and nurses and critical care staff who work tirelessly to support donation where possible in the service of families losing loved ones and patients in need of transplantation.

Thank you and I am happy to answer your questions.