Date: July 8, 2024

To: Centers for Medicare and Medicaid Services (CMS), HHS

From: LifeGift, Houston, Texas (Organ Procurement Organization)
Contact Lauren Quinn, VP for External Relations lquinn@lifegift.org for further information

Re: CMS-5535-P: Increasing Organ Transplant Access Model; Request for Public Comment

LifeGift Organ Donation Center (LifeGift), the organ and tissue procurement organization (OPO) based in Houston, Texas appreciates the opportunity to provide public comment in response to the proposed rule CMS-5535-P (Proposed Rule). LifeGift is one of the largest OPOs in the United States both in terms of service area size (geography) and in death referrals. In 2023, we coordinated 38,585 death referrals, 658 authorized organ donors and 469 donors with organs recovered (1,802), and organs transplanted (1,443, 4th highest in the U.S.). LifeGift also provided kidney perfusion services (600+ kidneys perfused/pumped in 2023) and recovered tissue as an AATB accredited and FDA approved recovery agency. Below is a snapshot of LifeGift:

LifeGift Organ Donation Center (TXGC)
From SRTR OPO Report based on April 2024 data
Population Served: 11,276,748
Population Rank: 7th among the 56 DSAs
Land Area Served: 105,325 square miles
Land Area Rank: 9th among the 56 DSAs
Deaths: 83,736 (10th among 56 DSAs)
Deaths per 1,000: 7.43
Deaths Rank: 54th among the 56 DSAs

We appreciate the opportunity to provide comment to the CMS-5535-P as follows:

This Proposed Rule describes a new mandatory Medicare payment model, the Increasing Organ Transplant Access Model (IOTA Model), that would test whether performance-based incentive payments paid to or owed by participating kidney transplant hospitals increase access to kidney transplants for patients with end-stage renal disease (ESRD) while preserving or enhancing the quality of care and reducing Medicare expenditures. This Proposed Rule also includes standard provisions that would apply to Innovation Center models whose first performance period begins on or after January 1, 2025. The Proposed Rule would also apply, in whole or part, to any Innovation Center model whose first performance period begins prior to January 1, 2025, should such model's governing documentation incorporate the provisions by reference in whole or in part. The proposed standard provisions relating to beneficiary protections; cooperation in model evaluation and monitoring; audits and records retention; rights in data and intellectual property; monitoring and compliance; remedial action; model termination by CMS; limitations on review; miscellaneous provisions on bankruptcy and other notifications; and the reconsideration review process.

LifeGift applauds CMS through CMMI for developing incentives to increase kidney utilization and transplantation and to advance health equity by improving equitable access to the transplantation ecosystem through design features such as a proposed health equity plan requirement to address health outcome disparities and a health equity performance adjustment.

LifeGift appreciates the intent of the innovation model using a control group consisting of half of the Donation Service Area ("DSA") kidney transplant programs to be compared to the intervention group of the other half of DSA kidney transplant programs for purposes of testing the proposed interventions for assessing the effect of payment model and quality incentives on kidney transplant program behaviors. **However, LifeGift believes that it would be more effective to expand this program across all kidney transplant programs from the start to avoid disadvantaging patients in need of transplant at centers not enrolled in the program. Practically, it will be as effective to mandate this intervention across all programs and (1) use performance over the previous 24-36 months as the comparison cohort, and (2) use risk adjustment methods to address any confounding factors in these prior periods. The current disadvantage for patients in the control group is exacerbated by the six-year length of the innovation model.**

In addition, LifeGift observes that the proposed innovation model applicable to transplant programs raises several inconsistencies in the methods proposed as well as time periods and risk adjustments as compared to the current CMS performance measurement system rules applicable to organ procurement organizations in **CMS-3064-F** (OPO Performance Measurement Model). The below summarizes concerns raised by the obvious inconsistencies in the two approaches to transplant centers and OPOs that highlight serious flaws in the OPO Performance Measurement Model:

1) **CMS's proposed policy for transplant programs under the Proposed Rule conflicts with its policy for OPOs under the OPO Performance Measurement Model.**

Although transplant programs and OPOs are interdependent parts of the same system, CMS proposes to use a substantially different policy approach in the Proposed Rule applicable to transplant centers relative to the OPO regulations without a rational basis:

• The Proposed Rule includes multiple performance measures that would provide for risk adjustment *for transplant programs unlike the OPO Performance Measurement Model which does not provide for risk adjustment except for age in certain circumstances.*
• Transplant volume expectations under the Proposed Rule would be based on the transplant programs' past performance *unlike the OPO Performance Measurement Model which does not take into account OPO past performance.*
• The Proposed Rule would offer transplant programs incentives for high performance and neutrality for median performance compared to CMS regulations applicable to OPOs which subject Tier 2 OPOs to competitive bidding.
• The Proposed Rule introduces a thorough scoring system for transplant programs, evaluating them based on benchmark performance without applying percentage threshold cutoffs, which contrasts with the approach for OPOs under CMS regulations.
• Unlike OPOs, transplant programs have no risk of losing CMS designation.
• While the Proposed Rule explicitly recognizes that *transplant program behavior drives organ utilization, the OPO Performance Measurement Model uses a transplant rate to decertify OPOs despite OPOs' lack of control over transplant program behavior.*

2) **Measurement group comparison between the Proposed Rule and the OPO Performance Measurement Model is arbitrary and inconsistent.**

   All OPOs are included in the single year evaluation period (2024) under CMS regulations while only half of kidney transplant programs would be selected by CMS under the Proposed Rule based on DSA location. Both small volume and pediatric transplant programs are excluded from the evaluation period for six (6) years.

3) **Domains/Measures Comparison between the Proposed Rule and OPO Performance Measurement Model is inconsistent.**

   OPOs are being evaluated based on only two (2) non-empirically based performance metrics: donation rate and transplantation rate. Under the Proposed Rule, transplant programs would instead be evaluated based on 3 domains (achievement, efficiency and quality) and 3 sub-metrics:
   ◦ Number of transplants performed relative to target developed using past performance of the transplant program
   ◦ Organ offer acceptance rate, which is a risk adjusted ratio of observed versus expected organ offer acceptances
   ◦ Composite post-transplant outcome measure

4) **Use of Risk Adjustment for Proposed Rule and not for OPOs under the OPO Performance Measurement Model is vastly inconsistent.**

   Under the OPO Performance Measurement Model, OPO performance is evaluated using two measures: donation rate and transplant rate. The model does not apply risk adjustment to the donation rate and only includes minimal age band adjustment for the transplant rate. The mortality estimate used in the denominator does not exclude factual medical or clinical comorbidities, nor does it require utilization coding for intubated or ventilated patients.
   In contrast, under the Proposed Rule, the applicable kidney transplant programs would have their Achievement domain risk adjusted for past volume of each individual transplant program and health equity population served; Offer-acceptance ratios risk adjusted for medical factors;

and Transplant outcome measures risk adjusted for medical factors.

5) **Proposed Rule and OPO Scoring Systems under the Proposed Rule and OPO Performance Measurement Model, respectively, are vastly inconsistent.**

OPO approach:

3 Tiers
◦ Tier 1 – Both measures in the top 25%
◦ Tier 2 – Both measures are above the median but one or both measures do not reach the Tier 1 threshold
◦ Tier 3 – One or both measures below the median
• Lower of the 2 measures defines an OPO's performance category
• A comparative measure using percentile cutoffs based on prior year

Kidney Transplant Program approach:

3 Zones:
◦ Total score above the threshold
◦Neutral zone at the threshold
◦ Bottom zone below the threshold
• Total scorecard based on composite calculation
• Thresholds set for achievement measure using individual program's past performance

6) **Financial Incentives and Penalties Comparison are unilaterally applicable to only kidney transplant programs while OPOs are held accountable for both donation rate and transplantation rate, the latter are systemic measurements that do not reflect OPO specific performance, and out of their control:**

OPO approach:

Tier 1: No incentive/ neutral for top performance by OPO
Tier 2: At risk for median performance - DSA opens up for competition and possible OPO decertification
Tier 3: Automatic decertification for one of two metrics below median

Kidney Transplant Program approach:

•100 points possible

◦ Achievement – 60 points possible
◦ Efficiency – 20 points possible
◦ Quality – 20 points possible

•60-100 pts: Upside Risk Eligible
•41-59 pts: No Up/Downside Risk
•0-40 pts: Downside Risk Payment but retain CMS participation/designation

7) **Assessment period, consideration of year-over-year performance improvement, and data sets for OPO Performance Measurement Model and Proposed Rule are vastly different and**

highlight an arbitrary choice of only one year for OPOs:

OPO Approach:

OPOs' assessment period is 12 months (CY 2024) out of a 4-year cycle (2022-2026)
◦ Year-over-year performance improvement not considered
◦ Tier thresholds not published by CMS until after the assessment year
(performance requirements to achieve tier 1/recertification are not provided to OPOs in advance of the performance year)

Kidney transplant program approach:

Transplant programs will have a 72-month (CY 2025 – CY 2030) performance period under the Proposed Rule

◦Phase-in downside risk beginning in CY 2 (2026)

Summary Table of Approaches:

Comparison Table of CMS Policy Approach Differences

	OPOs	Transplant Centers
Who	All OPOs	Selected kidney transplant hospitals (approx. 90 / 50%)
What	Kidneys, Liver, Heart, Lungs, Intestines, Pancreas (incl. research)	Kidneys only
#Measures	2 Donation Rate Transplantation Rate	5 Achievement Efficiency Quality - 3 sub-metrics
Risk-adjusted	No - other than transplant rate is age adjusted	Yes
Scoring	Lower of the two rates determinative % cut off based on comparison	Total points scorecard No % thresholds based on comparative component
Max Reward	None	Upside risk payment from CMS
Neutral zone	Only for top 25th%	Median performance and above
Max Penalty	Decertification	Downside risk payment to CMS

In summary, while OPOs, including LifeGift, are on pace for record level organ donation performance in 2024 (and in 2023 before that), a significant percentage of OPOs are facing the possibility of automatic decertification under current regulations. Based on current projections, CMS's OPO Performance Measurement Model will result in CMS simultaneously decertifying or not renewing agreements with 30-70% of the OPOs in 2026 with reassignment of DSAs taking place effective 2027 (all tier 3 OPOs plus tier 2 OPOs that lose in an undefined competitive process). ***This is true for ALL three (3) OPOs in Texas, according to mid-year projections for 2026, creating a potential total***

removal of all existing OPOs in Texas beginning in 2027 with an impacted service population of at least 30 million residents.

OPOs subject to potential decertification will include OPOs that have demonstrated performance improvement every year of the 4-year cycle and OPOs that perform highly in the SRTR risk adjusted measurements.

When reviewing the above comparison of approaches between transplant programs under the Proposed Rule and OPOs under existing regulations, across multiple domains, there are huge and arbitrary contrasts in application of performance improvement initiatives. The OPO approach under the performance regulations is punitive and not solution-focused in that it is not based on metrics that will identify the OPOs that are actually under-performing in their DSAs, which is in direct contrast to CMS Quality Program principles. Although the Kidney transplant program approach under the Proposed Rule also contains flaws, it would, with some notable refinements in approach, focus on performance improvement with appropriate quality measures and performance incentives over a time period that is reasonable for reaching established goals.

LifeGift appreciates the opportunity to comment. We are happy to provide further information upon request.

Respectfully,

Kevin Myer (Jul 9, 2024 06:38 EDT)
Kevin A. Myer, MSHA
President & Chief Executive Officer

cc: Lauren Quinn, Vice President of External Relations
Yolanda Becker, MD, FACS, FAST, Vice President & Chief Medical Officer