LIFEGIFT

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September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard
Baltimore, MD 21244

RE: [CMS-1717-P] Medicare Program, Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc.

Dear Administrator Verma:

LifeGift, the Organ Procurement Organization (OPO) based in Houston, Texas appreciates the opportunity to submit its brief comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2020 (CMS-1717-P).

LifeGift serves a population of nearly 11 million people across 200+ hospitals and 9 transplant centers. The OPO provides organ and tissue recovery services and participates in multiple deceased donor research projects, including the HOPE Project involving HIV positive organ donors.

LifeGift strongly supports the intent of the American Kidney Health Initiative announced by President Trump to reduce the toll of kidney disease on individuals and to incentivize the use of transplantable organs currently discarded or never recovered. We strongly support the intent and the search for actionable recommendations which CMS may enact to drive performance improvement, remove disincentives in our transplantation system and discover needed performance monitoring methods to help our field serve its mission more fully.

Proposed Revision of the Definition of "Expected Donation Rate"

LifeGift supports the alignment of the definition to correspond with the Scientific Registry of Transplant Recipients' (SRTR) definition, details extensively described elsewhere.

We do not support limiting the evaluation period as proposed at 12 months but rather suggest a reasonable evaluation period of 18 months. This additional 6 months may help smooth normal system variation and at the same time aid CMS in seeking a more comprehensive evaluation period.

RFI Questions:

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.

We support the development of improved outcome measures that are independently collected, reported and evaluated. OPO performance ideally can be measured on the 1) effectiveness of recovering deceased donors from a measure of a potential donor population and 2) the effectiveness of recovered organ utilization. It is critical to note that organ utilization is dependent upon transplant program acceptance of

offered organs, and the continued measurement of these two interdependent practices in isolation drive disincentives to increasing transplantation across our entire transplant ecosystem.

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

The current metrics are used for performance comparisons and year over year benchmarking.

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

First, the certification process does drive OPO improvement efforts, quality systems approaches and creates a set of standards that OPO's utilize to develop their operational framework. Second, decertification impact is an unknown as it has not occurred in years, although the lack of a formal pathway designed to allow OPO's an opportunity to improve if it has not met performance outcome expectations has led to confusion and instability in the system. If an OPO fails to meet determined performance metrics, LifeGift also requests the development of a Systems Improvement Agreement (SIA) process described in detail by others. A critical addition to what others have suggested is the inclusion of an OPO's work and commitment to research and development, deceased donor research and forward-looking practices such as participation in the HOPE Project, Donor Hypothermia Study, Stanford Donor Heart Study, etc.

Are there any potential, empirically based outcome measures, other than those currently at § 486.318, that could be used either in addition to, or instead of, the current outcome measures for OPOs? If recommending another outcome measure, what is the empirical evidence for that recommended measure?

We believe use of directly reported hospital mortality data to use in the denominator of a donation performance metric would move the current approaches from estimation to determination. Recovered donors with any organ transplanted / in-hospital deaths with potential for donation (ventilated, cause of death consistent with donation and excluding cause of death preventing donation, using a sample size through age 75 years) would be ideal. We suggest proof of concept development and if possible, and inclusion in interoperability regulations.

In addition to the outcome measures, are there other indicators of quality that could be used for OPOs in the CfCs? If recommending another quality indicator, why should that indicator be used in the OPOs CfCs and what is the supporting evidence for this indicator?

No recommendation, needs study.

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

- LifeGift applauds CMS for following through with its decision of September 26, 2019 to remove barriers to use of medically complex organs for transplant: "*Therefore, we propose to remove the requirements at § 482.82 that require transplant centers to submit data (including, but not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant beneficiary registration and follow-up, and living donor registration and follow-up), clinical experience, and outcome requirements for Medicare re-approval, and make conforming changes to*

§482.102(a)(5) "Condition of participation, Patient and living donor rights" and § 488.61 "Special Procedures for Approval and Re-Approval of Organ Transplant Centers."

- LifeGift encourages CMS and other applicable regulatory agencies to support more projects such as the UNOS/OPTN COIIN Project that created an environment of clinical innovation to help increase understanding and utilization of medically complex organs such as higher KDPI kidneys.

Comments on the potential measure that 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 using the CDC Detailed Mortality File and the National Center for Health Statistic's National Vital Statistics Report.

LifeGift supports the proposed potential measure using CDC Detailed Mortality File while noting that this approach is a more refined estimation of donor potential which meets the need for independently reported data. Others have raised the concerns about the precision of such an approach which we believe are important, but to delay the implementation of this measure would be counterproductive to the goal of moving towards better defined metrics. LifeGift encourages CMS to adopt this proposed measure and continue seeking a more refined, next generation of determining donor potential through direct hospital reporting to an independent agency with expertise in health systems evaluation.

Comments on the potential measure is the actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation.

LifeGift supports the continued use of the current O/E risk adjusted metric as developed and produced by SRTR.

Thank you for the opportunity to comment. Please feel free to contact me for clarification of these comments or with any questions.

Respectfully,

Kevin A. Myer, MSHA
President & Chief Executive Officer