National Kidney Foundation®

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The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

September 27, 2019

Re: File Code CMS-1717-P; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage

Dear Administrator Verma,

The National Kidney Foundation strongly supports CMS' efforts to comprehensively update the Conditions for Coverage (CfCs) for Organ Procurement Organizations (OPOs). NKF has serious concerns that the current donation and yield metrics by which OPO performance are judged are not maximizing the recovery and utilization of organs. We support CMS' goals to implement metrics that "maximize total organ procurement and efforts to improve placements of all procured organs."

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI). Increasing the size of the pool of kidneys available for transplant is an NKF priority. The status quo, wherein 94,649 patients are currently waitlisted for kidneys, is unacceptable. The reasons for the organ shortage are multifactorial, stemming from factors related to donors, recipients, OPOs, transplant centers, payors and regulators. We agree with CMS' assessment that OPOs and transplant centers are closely linked. Accordingly, we believe that strong partnerships between OPOs, donor hospitals, and transplant centers are necessary to maximize organ procurement and utilization. While NKF does not believe that any single player in the system can be held entirely responsible for these goals, we acknowledge that OPOs have an integral role in ensuring that as many organs as possible are identified and procured from deceased donors. NKF supports revisions to the OPO CfCs that would result in OPOs evaluating and procuring organs from a larger pool of potential deceased donors, allow for patients to better understand and benchmark OPO performance, and hold transplant centers accountable for their role in ensuring as many organs as possible, including less than perfect organs, are recovered and successfully transplanted.

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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.

NKF does not believe that the current OPO outcome measures accurately and reliably reflect OPO performance. We are concerned that the metrics upon which the outcome measures are based, the donation and yield metrics, are flawed. We are concerned that the current donation metric excludes a subset of actual and potential deceased donors, resulting in a loss of potential lifesaving organs for transplantation. We are additionally concerned that data on "eligible deaths", a self-reported metric by OPOs, leads to a failure to understand OPO performance. NKF supports a revised OPO donation metric that would not rely on unaudited data that are self-reported by OPOs, would accurately account for the pool of potential donors, as well as provide data that can be used to benchmark and compare OPOs across DSAs of varying demographic and population densities. While we are less concerned that the yield metric is disincentivizing single organ donors, we do believe that even a revised OPOs yield metric should ultimately be replaced and or supplemented by a combined OPO and transplant center metric that reflects the symbiotic roles that OPOs and transplant centers play in maximizing the number of transplants.

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

NKF believes that the current decertification process for OPOs may not be achieving its intent of holding low performing OPOs accountable. There are two gaps in OPO performance accountability. The first is the problematic metrics by which OPO performance is judged. The second is a lack of a suitable organization able to perform an OPO's pivotal function when an OPO is identified as a low performer. We believe the inability to institute performance improvement processes, and, in extreme cases, withdraw CMS support, is limiting CMS' ability to hold OPOs accountable. However, we do caution CMS that shutting down an OPO should be a measure of last resort. NKF supports a lengthy probationary period for low performing OPOs during which an intense improvement process, and in some cases, management change, would be instituted. During this time, we believe it would be appropriate for a neighboring OPO to assume the donor coverage in the DSA. We note that supplementary funding may be necessary to support the OPO's expanded operations.

Overall, however, we reiterate that decertifying OPOs is not an appropriate solution in most cases. A revised donation metric that enables better understanding of OPO performance would allow for dissemination of best practices and a better understanding of the resources necessary for OPOs to be successful. We believe these solutions are also important contributors to bringing all OPO performance up to a more consistent level.

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?

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NKF supports replacing, at minimum, the existing donation metric. NKF has historically believed that many proposed, alternative donation metrics could be suitable and would be preferable, provided they do not exclude potential deceased donors and prohibit self-reported data. We note that there is often a tradeoff in proposed alternative donation metrics between an overly broad denominator and one that captures a narrower, but more likely, subset of potential donors. NKF has no objection to CMS considering the broader donation metric of actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger, which we agree with CMS likely includes "potential donors in the denominator who would never clinically qualify as organ donors." We agree that a donation metric that produces reliable comparative performance data across all OPO donation coverage areas is a priority. We do appreciate that one tradeoff of a potential larger donor pool is that a metric that incentivizes the pursuit of a smaller, but more likely population of potential donors, may better serve OPOs in targeting outreach and education to donor hospitals.

NKF views even a revised yield metric as an interim step toward the ideal solution of a series of combined OPO and transplant center metrics based on overall number of transplanted organs. While CMS' proposed yield metric of actual organs transplanted as a percentage of inpatient deaths among patients 75 years of age or younger does reflect the role of the transplant center, only OPOs are held accountable for their performance on the metric. Transplant centers, though responsible for transplanting the organs, are not held accountable by the metric. We are concerned that any metric that holds only OPOs accountable for "actual organs transplanted" will disincentivize OPOs from pursuing organs they believe transplant centers are likely to discard. Even a revision that links a revised OPO yield metric to a transplant center metric based on organ offer acceptance rate would require that these two metrics be reconciled. NKF supports combined OPO and transplant center metrics as part of a broader and more transparent evaluation process based on an expected transplant rate. An improved evaluation process should not rely only on new, combined metrics, but should also include efforts to understand how many and what types of organs are not being pursued by OPOs and being rejected by transplant centers. We believe that combined metrics, alongside increased transparency, will support the necessary multi-disciplinary efforts needed to understand where expected donors are being missed and how we can work in collaboration to stem these gaps. We encourage CMS to engage with HRSA and OPTN, both of which have initiated work to develop these combined metrics.

In conjunction with the development of combined OPO and transplant center metrics, we recommend that CMS work with OPOs and transplant centers to reduce the rate of kidney discards. The National Kidney Foundation's Consensus Conference to Decrease Kidney Discards developed numerous recommendations to increase organ utilization that reflect the close association between OPOs and transplant centers. We would be pleased to discuss these recommendations with CMS at CMS' convenience.

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NKF is grateful for CMS' efforts to update the OPO Conditions for Coverage (CfCs). We believe that holding OPOs accountable for maximizing organ procurement and implementing metrics that will allow for a better understanding of how OPOs are performing will generate meaningful improvements in the number of organs available for transplant. We note, however, that organs are a national resource whose stewardship requires partnership and collaboration. We encourage CMS to continue to consider multi-stakeholder solutions that reflect the interdependent nature of the transplant system. NKF would welcome the opportunity to partner with CMS on this urgently important work. Please contact Kerry Willis, Chief Scientific Officer, at kerryw@kidney.org and Miriam Godwin, Health Policy Analyst, at miriam.godwin@kidney.org.

Sincerely,

Kevin Longino
Kevin Longino
CEO and transplant patient

Holly Mattix Kramer
Holly Mattix Kramer, MD, MPH
President