National Kidney Foundation®

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

February 21, 2020

Dear Administrator Verma,

The National Kidney Foundation appreciates the opportunity to offer comments on the proposed rule, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations." As an organization committed to increasing the number of transplants, NKF largely supports the proposed accountability framework for Organ Procurement Organizations (OPOs) based on the donation rate and transplant rate measures under consideration. However, given that OPOs would be responsible for ensuring procured organs are successfully transplanted, we believe it is inappropriate to incorporate no additional accountability for transplant centers. In addition to voicing our strong support for greater accountability for OPOs, the recommendations we provide in this letter seek to strike the balance between increasing the number of organs available for transplantation and acknowledging transplant centers' responsibility for improving utilization.

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 U.S. 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).

On the whole, NKF supports CMS' effort to break down silos in the transplant system by driving the entities involved to achieve the outcome that matters most to kidney patients: greater numbers of transplants. We agree with CMS that the right approaches to achieving more transplants are to encourage OPOs to procure more organs from deceased donors and to reduce the number of organs that are currently being discarded. As leaders on the issue of kidney discards, however, we do not believe that the responsibility for reducing discards belongs solely to OPOs. In May 2017, NKF convened a group of 75 multidisciplinary experts on transplantation to discuss the high rate of organ discard at the Consensus Conference to Decrease Kidney Discards. The paper that resulted from that conference outlined a set of

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actionable steps to improve utilization and reduce discards. The recommendations acknowledge the interdependent relationship between OPOs and transplant centers and emphasize that reducing discards will be most successfully achieved by holding both entities accountable for improving patient access to transplantation. However, NKF agrees that OPOs have some responsibility for ensuring organs are successfully transplanted and not discarded. While our preference is that both the transplant and donation rate measures are paired with an organ offer acceptance rate measure for transplant centers, we would support the transplant rate measure as proposed. As to the donation rate measure, we do not support revising the definition of "donor" to require that the organ be transplanted until such time as the donation rate measure is paired with an organ offer acceptance rate measure. We disagree with CMS' rationale that a donation rate measure for OPOs should be targeted at discouraging the discard of procured donors and we note that an organ offer acceptance rate measure for transplant centers would be a more effective means of encouraging transplantation of single organs from older donors or donors after cardiac death. Aside from the proposed changes to the definition of donor, NKF supports the donation rate measure.

In addition to our concerns regarding holding OPOs accountable for reducing organ discards, we note that the current proposal rests on the strength of the relationship between OPOs and transplant centers and the expectation that OPOs can leverage that relationship to influence transplant centers' organ acceptance practices. NKF agrees that improvements can be achieved through close relationships that engender collaboration and dissemination of best practices and, in fact, also, that OPOs should be incentivized to do more to ensure successful placement of organs. However, holding OPOs entirely accountable for transplantation may serve only to fracture the relationships between OPOs and transplant centers as transplant surgeons face greater pressure to transplant more marginal organs in an environment where transplant centers are currently rewarded for risk aversion. In addition, the recent elimination of the DSA in favor of a 250 NM circle around the donor hospital means that OPOs must maintain close relationships with more donor hospitals and transplant centers distributed across a larger area, decreasing the likelihood that any single relationship can transform transplant center practice. Of even greater consequence is the probability that OPOs are simply unable to meaningfully influence transplant center behavior. To our knowledge, there is no evidence that the transplant centers that are using "less than perfect" organs are doing so because of influence from the OPO. If CMS is overestimating the clout of the OPO, the result will be the decertification of multiple OPOs, disrupting the transplant system without providing any additional access to transplant for patients.

NKF appreciates the Administration's commitment to giving more patients the opportunity to benefit from a kidney transplant. As proposed, however, the regulation is unlikely to achieve its intent without the potential for significant unintended effect. It is imperative that CMS pairs the new OPO measures with the development and implementation of a new accountability framework for transplant centers. Transplant centers are currently evaluated by CMS and the Organ Procurement and Transplantation Network (OPTN) based on measures of one-year post-transplant patient and graft survival. These measures fail to capture patient's preferences and values for transplant, cause risk aversion, do not incentivize transplant centers to perform higher cost transplants and do nothing to address the crisis of transplant centers declining many

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potentially clinical valuable organs on behalf of the patient without her or his knowledge.[1] It is essential that the proposed OPO performance measures be paired with a performance measure for transplant centers based on organ offer acceptance rate. An organ offer acceptance rate measure would dramatically improve the success of the proposed rule by encouraging transplant centers to accept more of the organs that OPOs are expected to procure, creating a positive feedback loop that will result in more patients receiving transplants. A recent report by Mohan et al. found that transplant recipients who received a deceased donor kidney received a median of 17 offers over 422 days.[2] Clearly, there is much to be gained by holding transplant centers accountable for improving their acceptance practices. An organ offer acceptance rate would also provide the transparency that patients demand into organs being declined on their behalf. More generally, NKF believes that an organ offer acceptance rate measure is a first step toward implementing an accountability framework for transplant centers that is patient-centered, improves access to transplant, and enables a holistic evaluation of transplant center performance.

NKF applauds the Administration for its goal of doubling the number of kidneys available for transplant within the next decade. We agree that procuring more organs from deceased donors while significantly reducing the numbers of kidneys that are discarded are straightforward ways to transplant significantly more patients, keeping more people off of dialysis for longer and savings more lives. We are eager to partner with the Administration and CMS to achieve these goals. We offer the following comments in the spirit of making the proposed rule as effective as possible on behalf of the patients we represent.

Summary Recommendations

- NKF supports replacing the three current outcome measures for OPOs with two: the donation rate and transplantation rate measures.
- NKF strongly recommends pairing the proposed measures with an organ offer acceptance rate measure for transplant centers.
- NKF supports a denominator for both measures of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation.
- NKF supports the revised definition of "donor" only if the proposed rule is paired with a performance measure of organ offer acceptance rate for transplant centers.
- NKF does not believe any additional risk adjustment to the denominator of donation rate measure is required.
- NKF believes a risk adjustment methodology for statistically significant factors affecting transplantation rates could be appropriate.
- NKF supports holding OPOs operating in noncontiguous States, Commonwealths, and Territories accountable for the 25 percent threshold performance standard only if an organ offer acceptance rate measure is implemented for transplant centers.
- NKF supports evaluating OPO performance based on the lowest rate among the top 25 percent of donation rate and organ transplantation rate.

[1] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2749266
[2] *Ibid.*

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- NKF would be concerned about assessing OPO performance every 12 months. NKF recommends that a QAPI be mandated for an underperforming OPO less often than annually, but at least once during the 4-year recertification cycle. NKF supports making the results of the performance assessments public.
- NKF believes that CMS must include a mechanism to decertify OPOs prior to the 2022 recertification cycle, when the new accountability framework would go into effect.
- NKF supports the existing requirements for an OPO seeking to take over the service area of a decertified OPO or an OPO selected by CMS to take over a service area.
- NKF recommends that CMS proactively develop a robust process for how an existing OPO will promptly and effectively take over operations for an open service area in order to minimize disruptions to organ procurement.
- NKF recommends developing a learning collaborative for OPOs to facilitate communication between OPOs and the dissemination of best practices from high performers.

II. A. Proposed Changes to Outcome Requirements (§486.318)

Proposed Donation Rate and Transplantation Rate Measures

NKF has had longstanding concerns that the current OPO donation and yield metrics are not maximizing the recovery and utilization of kidneys and have failed to enable evaluation of OPO performance due to the reliance on unverified self-reported data. NKF supports replacing the three existing outcome measures based on the donation and yield metrics with the proposed donation rate and transplantation rate measures. We agree with CMS that there is value in having two measures that incentivize two similar, but distinct activities: pursuing every possible donor and procuring as many organs as possible from each donor. NKF has historically been agnostic with regards to the alternative OPO denominators as long as the denominator does not rely on unverified self-reported data and does not exclude potential donors. We believe that the proposed denominator of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation achieves both these goals.

NKF supports revising the definition of "donor" only if an organ offer acceptance rate measure is implemented for transplant centers. In response to CMS' concern that without a donation rate measure based on actual transplantation, there will be fewer incentives to procure and transplant single organs from older donors or donors after cardiac death, we have the following response. First, under this proposal, OPOs' organ procurement costs may not be paid for acquiring these organs unless they are transplanted. Organs from older donors or donors after cardiac death are already at higher risk of discard.[3] Second, as we have noted, we are concerned about the ability of OPOs to transform transplant center acceptance practices nationwide. NKF believes that these compounded disincentives will not result

[3] https://journals.lww.com/transplantjournal/fulltext/2017/07000/Predictors_of_Deceased_Donor_Kidney_Discard_in_the.30.aspx

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in OPOs seeking donors at the outskirts of donor potential, as CMS suggests, unless more s done to drive transplant centers to use higher risk organs.

Role of OPOs in Reducing Discards

NKF strongly disagrees with CMS' assertion that it is the OPOs' responsibility to ensure that "less than perfect" organs are transplanted instead of discarded. The recommendations from NKF's Consensus Conference to Decrease Kidney Discards are rooted in collaboration between OPOs, transplant centers, UNOS, CMS, and insurance companies. The conference paper advises that OPOs and transplant centers have a shared responsibility to reduce discards by strengthening OPO and transplant center cooperative QAPI efforts, improving communication between OPO and the accepting transplant surgeon, disseminating best practices, identifying local backups, and improving the process by which the surgeon is informed of the condition of the organ.[4] None of these recommended activities, and none of the recommendations put forth in the paper, fall to the OPO alone. Conversely, transplant centers are responsible for educating patients about accepting higher risk organs and engaging transplant nephrologists and renal pathologists to improve decision-making on organ offers. OPOs have neither the expertise nor the capacity to influence these endeavors on a large scale.[5]

Risk Adjustment

NKF agrees with CMS that the proposed denominator of the donation and transplantation rate measures of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation accounts for the clinical characteristics affecting donor potential and that no further risk adjustment is needed.

As this letter highlights, NKF believes there are numerous factors affecting transplantation practice that are beyond the control of OPOs. We agree that a risk adjustment methodology for factors that have a statistically significant impact on transplantation rates could be appropriate. We believe our shared goal, however, is not to accept current transplantation rates as they are, but to use the levers at our disposal to encourage OPOs and transplant centers to seek out and transplant every clinically valuable organ. In short, we do not believe that risk adjusting for factors affecting transplantation rates should come before other approaches to incentivizing more progressive organ acceptance practices by transplant centers.

Incentivizing High Performance

NKF agrees that OPOs have a critically important role in the transplantation system and should be held to the highest possible standards. We believe that establishing threshold donation and organ transplantation rates based on the lowest rate among the top 25 percent of donation rates and transplantation rates is appropriate and will help address the wide variation in OPO performance that is currently limiting

[4] https://onlinelibrary.wiley.com/doi/10.1111/ctr.13419
[5] *Ibid.*

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patients' ability to benefit from a transplant. NKF strongly affirms CMS' strategy to incentivize the system to continually achieve the highest donation and transplantation rates possible rather than relying on expected or average OPO performance. We do have reservations about conducting the outcome measure assessment every 12 months, which we believe constitutes a moving target that lower performing OPOs may not be able to reasonably reach. We are concerned this would lead to OPOs being decertified when they may be able to improve their performance given a fixed target and sufficient time to meet it. Assessing OPO performance on 18 or 36 months of data would give OPOs more time to improve their performance relative to a fixed benchmark. NKF applauds CMS for striving to leverage the proposed approach in order to make almost 5000 more organs available annually. It is these types of bold goals that will radically change kidney patients' clinical outcomes and quality of life. CMS' analyses demonstrate that these gains will come primarily from reducing discards. We would point out again that while we resolutely support the goal of "eliminating all inappropriate organ discards," we do not believe that realigning the incentives for OPOs can or should be the only approach.

NKF believes that it would only be appropriate to hold OPOs operating in noncontiguous States, Commonwealths and Territories to the same standard of performing at least as well as the top 25 percent of performers in the presence of an organ offer acceptance measure for transplant centers. Given the challenges that OPOs in these DSAs already face in placing organs within their DSA and the failures of the supply chain in transporting organs outside the DSA, there must be an expectation that the nearest transplant centers will accept less than perfect organs. Otherwise, these OPOs will not be able to meet the performance threshold and will be decertified. It is reasonable to expect that the challenges of expanding the boundaries of an existing OPO in the noncontiguous States, Commonwealths, and Territories would be exacerbated and the potential to disrupt organ procurement and transplantation especially high. NKF recommends exercising caution with regards to holding these OPOs to the 25 percent performance threshold.

II. B. Proposed Changes to Definitions and Re-Certification and Competition Processes (§486.316)

NKF supports continuing to rely on the language at §486.316 outlining the requirements that an OPO must meet in order to compete for an open service area and the criteria for selection of an OPO for an open service area. We have no objection to removing the requirement that an OPO being designated to a service area be contiguous to the open service area so long as the OPO can demonstrate that it can successfully educate and work with donor hospitals remotely.

We agree with CMS that the goal must be to ensure continuous coverage of a service area in the event an OPO is decertified. We are extremely concerned about the potential for disruption given that CMS estimates that between 7 and 33 OPOs could be decertified under the proposed rule. No OPO has ever been decertified and there is an according lack experience with the process. We strongly recommend that CMS work in collaboration with OPOs and other stakeholders to proactively identify how an existing OPO will rapidly add the staff, resources, and processes needed to take over operations for an entire additional service area. A period of transition where the decertified OPO phases out operations and the new OPO

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phases in operations may be appropriate. Additional resources from CMS to support the takeover of the service area may also be appropriate.

II C. Proposed Changes to the Re-Certification Cycle (§486.302 and §486.318) and Proposed Change to the Quality Assessment and Performance Improvement Requirement (§486.348)

NKF agrees with CMS that an OPO's outcome measure assessment should be performed and made public periodically, however we are concerned that a requirement that an OPO evaluate its program and include processes to address poor performance in its Quality Assessment and Performance Improvement (QAPI) every 12 months that it falls below the 25 percent threshold may interfere with the OPO actually working to improve its performance. An 18-month QAPI cycle could strike the right balance between identifying OPOs that need to improve and providing them with an opportunity to do so. We agree that failure to meet the outcome measures in the final period, whether 12, 18, or 36 months, should result in decertification.

We emphasize the importance of including in the final rule a mechanism to decertify the lowest performing OPOs in the country prior to the 2022 recertification cycle. OPOs that have continually failed to meet their obligations to CMS are exacerbating the severity of the organ shortage and contributing to patient deaths on the waitlist. The majority of OPOs deserve the opportunity to improve their performance. Those that skirt their responsibilities to CMS, OPTN, and especially patients, do not.

NKF does believe that CMS has an obligation to help OPOs become high performers to the extent possible. The most effective way to do this is to hold both OPOs and transplant centers accountable for higher rates of transplantation. In addition, CMS should support OPOs in identifying opportunities for improvement and implementing changes. We additionally recommend that CMS develop a learning collaborative in order to improve relationships and communication between OPOs and to facilitate the dissemination of best practices from high performers.

NKF is grateful to CMS for its diligence in realizing the goals of the Advancing American Kidney Health initiative, particularly as they pertain to transplantation and the nearly 95,000 patients waiting for kidneys around the country. These kidneys, which will provide the gift of life to a waiting patient, are a national resource whose stewardship requires shared partnership, collaboration, and accountability. 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 Miriam Godwin, Health Policy Analyst, at miriam.godwin@kidney.org.

Sincerely,

Kevin Longino
Kevin Longino
CEO and transplant patient

Holly Mattix Kramer
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President

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