NATIONAL KIDNEY FOUNDATION®

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The Honorable Seema Verma
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

July 10, 2020

Re: File Code CMS-1735-P – Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma:

The National Kidney Foundation (NKF) greatly appreciates the opportunity to offer our perspective on the proposed Fiscal Year (FY) 2021 inpatient rule. Our comments are limited to the proposals pertaining to the transplantation of kidneys, section 8. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). We are pleased that CMS has proposed to create three new MS-DRGs: Pre-MDC MS-DRG 019 (simultaneous pancreas/kidney transplant with hemodialysis), MS-DRG 650 (kidney transplant with hemodialysis with MCC) and MS-DRG 651 (kidney transplant with hemodialysis without MCC). We cannot overstate how much we value CMS' willingness to examine and modify the GROUPER logic for DRG 652 in order to best implement the Administration's Advancing American Kidney Health initiative and give more patients access to the life changing benefits that transplantation provides. Our most significant concern is that CMS will extract money from DRGs 652 and 008 to pay for the proposed MS-DRGs. We implore CMS to examine the costs in the context of total Part A and Part B expenditures on end-stage kidney disease (ESKD), analyzing Medicare spend on kidney transplantation in light of the marked reduction in cost that transplantation affords when compared with of dialysis expenditures.

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 NKF has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the NKF Kidney Disease Outcomes Quality Initiative (KDOQI). NKF is committed to providing treatment choice to patients who have chronic kidney disease, whether that choice is dialysis in the home, dialysis in a center, conservative management, or a kidney transplant. NKF has long supported differential payment for kidney transplants as a mechanism to increase organ utilization and provide more opportunities for patients who desire it access to transplantation. In May 2017, NKF convened a consensus conference to discuss the challenges associated with improving organ utilization and decreasing kidney discards.

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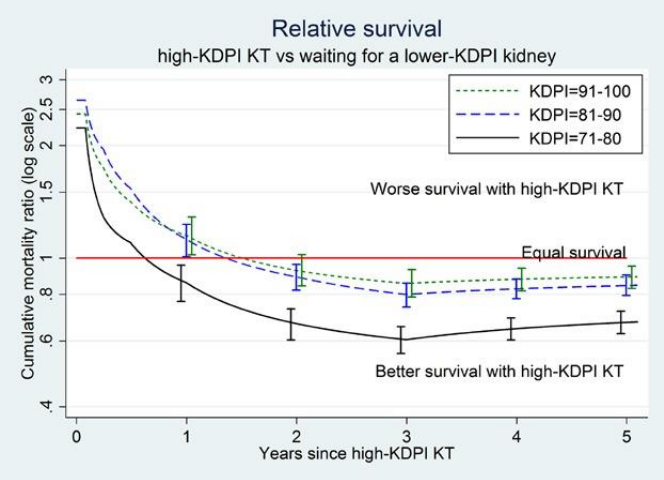
The summary of the discussions and findings from the conference, "Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards" was published in Clinical Transplantation in 2018. The findings recognize that the additional costs of transplanting less than perfect organs into patients with lower Expected Post Transplant Survival (EPTS) compound one another and contribute to kidney discards. The authors note, "the development of risk-adjusted payment systems is needed to ensure that organs that are clinically and economically beneficial in the long term are not declined due to the financial challenges in the short term."[1] This statement reflects the discontinuity between the higher costs faced by transplant programs and the overall cost savings which accrue to the Medicare program through transplantation. Successful transplantation is not only less expensive, it allows the successful transition from Medicare to other insurance coverage after three years further reducing the economic burden to the Medicare program as a patient who continues on Medicare beyond three years reverts to their employer insurance as the primary payer.

As stated, NKF supports the proposal to create differential payments for kidney transplants. This policy change is a vital first step in increasing transplantation through use of complex donors, including high Kidney Donor Profile Index (KDPI) kidneys. While high KDPI kidneys are associated with a shorter expected posttransplant kidney survival, acceptance of these organs increases access to kidney transplant and therefore reduced mortality for appropriate patients compared to their colleagues who remain on dialysis (Figure 1). There are many factors that go into determining which treatment option is best for a given person, both from the individual's and health care team's perspectives including personal preference as well as medical or psychosocial contraindications to transplant. For those who are interested in pursuing moderate-to-high KDPI kidneys, the wait time can be shortened and there is a significant survival benefit compared to remaining on dialysis. Most current USRDS data show that people who are transplanted can expect to live 2-3 times as long as their dialysis counterparts.[2]

Figure 1. Survival with high KDPI (Kidney Donor Profile Index) versus waiting for a lower-KDPI kidney



Unfortunately, transplantation is not available to all patients who want it due in part to the dramatic gap between the supply of deceased donor organs and the demand for them. Moderate-to-high KDPI kidneys can help to bolster supply, but **up to 50% of high KDPI kidneys**

[1] https://onlinelibrary.wiley.com/doi/epdf/10.1111/ctr.13419

[2] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

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recovered with the intent to transplant go unused because no transplant center is willing to accept them for their patients.

Broader use of these moderate-to-high KDPI organs provides a patient-centered approach, allowing more kidney transplant candidates to derive the benefit of this life changing procedure. These candidates are disproportionately Medicare beneficiaries, who frequently are not offered these organs under the current payment system, as they are associated with substantially greater cost. While a significant cause of the higher cost is associated with the need for inpatient, post-transplant dialysis, these recipients also have longer lengths of stay and higher pharmaceutical spend necessary to prevent complications. Thus, the creation of novel MS-DRG payments can, and should, incentivize the use of these organs.

However, adequately reimbursing transplant centers for the increased cost of high KPDI transplants must not come at the expense of non-high-risk transplant procedures. We ask CMS not to reduce the Part A reimbursement for kidney and simultaneous kidney-pancreas transplants that do not require inpatient hemodialysis in order to fund them.

All types of kidney transplant have been demonstrated to reduce the overall cost of ESKD, however many require substantial resources at the time of transplant, not all of which are based on the need for dialysis. Acute tubular necrosis (ATN) causing delayed graft function (DGF) that requires hemodialysis is not the only factor that drives transplantation costs. Other factors include high levels of donor specific antibodies; cardiac care and monitoring in older transplant recipients; and the use of expensive, but highly effective biologic agents to reduce the risk of rejection. Potential unintended consequences of decreasing the DRG for non-dialysis requiring transplants include adversely impacting centers that provide care to Medicare beneficiaries, reducing access to transplantation, and increasing ESKD related mortality.

As CMS itself pointed out in its recent proposed rule on Organ Procurement Organization (OPO) metrics, OPOs and transplant centers are closely interrelated. Transplant centers are hesitant to accept a deceased donor organ that is expected to incur costs higher than the MS-DRG payment or that is associated with an MCC other than hemodialysis, resulting in programmatic losses and contributing to the excessive discard of these organs. This impacts OPOs' ability to successfully place recovered organs and creates a practice pattern in which OPOs are discouraged from seeking out deceased donors on the margins. As CMS notes in its OPO proposed rule, these donors represent the greatest opportunity for increasing the organ supply. Furthermore, lowering the DRG payments for kidney and simultaneous kidney-pancreas transplants without hemodialysis penalizes transplant centers transplanting organs with complexities that are being accounted for neither in the existing MS-DRG payment nor the proposed MS-DRGs, for example transplant centers transplanting highly sensitized patients. Further and most concerningly, it creates an incentive for OPOs and transplant centers not to procure and utilize organs. This fails to maximize the opportunity for transplant and the cost savings of transplantation overall.

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NKF strongly favors policies that incentivize the procurement and utilization of every kidney possible, both high and low KDPI and other organs at high risk for discard. This is because **kidney transplants are preferable in outcomes, quality of life, and costs when compared to dialysis**. Even acknowledging that transplanting more organs of mixed quality may increase total CMS expenditures on transplantation, those expenditures are unlikely to reach the $91,000 PPPY spend on hemodialysis and $76,000 PPPY spend on peritoneal dialysis (PD). Spending on dialysis is only expected to increase, despite the bundled ESRD payment, due to increasing ESKD prevalence, growing Medicare Advantage enrollment and increasing Part D costs.[3]

Figure 2: Total Medicare ESRD expenditures per person per year, by modality, 2004-2016

NKF thanks CMS for taking this important step towards achieving the goal of the Advancing American Kidney Health initiative to double the number of kidney transplants by 2030. While any policy change that increases organ utilization and decreases kidney discards is favorable, our community must recognize that transplantation and dialysis are typically not equivalent treatment modalities and the costs of transplantation must not be evaluated in a vacuum.

We ask CMS to look to the examples of the HHS Office of the Assistant Secretary for Planning and Evaluation and the Congressional Budget Office, both of whom have found substantial cost savings to the Medicare program of extending immunosuppressive coverage for ESRD beneficiaries whose coverage would otherwise end at 36 months post-transplant by evaluating both Part A and Part B costs. The ESRD benefit is a unique case in this way, as it incurs substantial costs in both the Part A and Part B programs which are reduced by greater access to transplant. Without acknowledging these circumstances, we will not be able to achieve the improvements to kidney care quality we expect for patients suffering from chronic kidney disease. We would welcome the opportunity to partner with CMS to make transplantation available to more patients. Please contact Miriam Godwin at miriam.godwin@kidney.org.

Sincerely,

[3] United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

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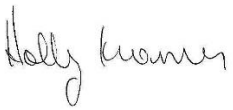

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