NATIONAL KIDNEY FOUNDATION®

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June 9, 2023

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services (CMS)
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership [CMS-1785-P]

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) is writing to provide our perspective to CMS on the proposed FY 2024 Hospital Inpatient Prospective Payment System (IPPS) rule. NKF commends Agency efforts to uphold safety and patient-centric quality measures in addition to the prioritization and evaluation of equitable payment models for innovative therapies for kidney patients. Our specific comments pertain to (1) the addition of the Hospital Harm – Acute Kidney Injury eCQM (CBE #3713e) to the Hospital IQR Program and (2) add-on payments for new services and technologies. 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.

Hospital Inpatient Quality Reporting Program (Hospital IQR Program)

NKF strongly supports the alignment of quality measures across federal programs and recognizes the nuanced care required for patients with Acute Kidney Injury (AKI) in the hospital setting. The integral endeavor to balance volume overload and the minimization of intradialytic changes in blood pressure is key. Patients that lose or gain dry weight during this balancing act require frequent patient reassessment by their care team. In addition to the association of chronic kidney disease (CKD) and progression to end-stage renal disease (ESRD) following AKI, hospital incentives to rapidly discharge patients can lead to unintended consequences. AKI patients may be committed to an AKI-ESRD diagnosis prematurely without allowing time for full recovery. While AKI is 10-20 percent in general hospitalized patients and up to 45-50 percent among critically ill patients, as stated in the proposed rule, variables outside of the overseeing physician's control within this patient population impact the rate in which AKI occurs in the hospital setting and should be evaluated carefully and adjusted for case mix. In consideration of these key issues, we do not support the adoption of Hospital Harm – Acute Kidney Injury eCQM (CBE #3713e) into the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination.

Possible alternative solutions for decreased hospitalization readmission and mortality rates for AKI patients rely in the standardization of quality improvement initiatives and multidisciplinary practices

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pre- and post-hospital discharge, as no evidence-based clinical practice guidelines currently exist.[1-2] Clinicians and health care systems at the community level can identify high-risk populations and implement coordinated preventative strategies. During a hospital encounter, programs can be launched to specifically focus on limiting the duration and severity of AKI. In a study examining three domains of care between nephrologists and primary care physicians (timing of follow-up laboratory monitoring of kidney function, medication and comorbidity management, and nephrology referral at the time of discharge), it was found that an educational opportunity exists regarding "the prognostic importance of proteinuria in the risk of progressive loss of kidney function following an AKI episode."[3] Perceived barriers by providers also impacted the disparate rates in which recommended follow-up laboratory monitoring of kidney function was ordered within 14 days after discharge, such as patient insurance coverage, physical access to facilities, and timely results.[4]

Lastly, we would like to highlight the importance of empowering all patients to have access to the dialysis modalities of their choice. Health-related quality of life (HRQOL) should not be lowered as a result of repeated hospital admissions and ongoing dialysis in the outpatient setting after hospital discharge. We recognize all AKI patients may not be eligible for home hemodialysis or peritoneal dialysis and we also recognize that all AKI patients are not able to access noteworthy resources within a dedicated AKI dialysis facility. We encourage efforts to decrease barriers for AKI patients who no longer require hospitalization, prefer home dialysis in lieu of outpatient hemodialysis, and have the assistance and guidance of their physician and care team as they attempt to recover kidney function.

Add-on Payments for New Services and Technologies

NKF supports the implementation of add-on payments for TERLIVAZ® (terlipressin) for the treatment of hepatorenal syndrome (HRS) with rapid reduction in kidney function. The dire consequences of HRS require significant consideration for patients who may benefit from this medication and fail to get relief from other treatments that are ineffective for them. Of note is the approval of this therapy in September 2022 within the U.S. and additional use for approval around the world. We support the assertion of the applicant that this therapy meets the substantial clinical improvement criterion and advocate for increased awareness and education on preemptive interventions for respiratory failure and acute respiratory failure associated with use of this therapy.

NKF supports the implementation of add-on payments for DefenCath™/Taurolidine/Heparin for the treatment of catheter-related bloodstream infections (CRBSI) from in-dwelling catheters in ESRD patients undergoing hemodialysis (HD) through a central venous catheter (CVC). In the event the applicant does not receive FDA marketing authorization in the required timeframe, CMS' proposal for conditional approval for new technology add-on payment is sound. The benefits of protection for patients against the ever-increasing development of antimicrobial-resistant microscopic organisms

[1] Kashani K, Rosner MH, Haase M, et al. Quality Improvement Goals for Acute Kidney Injury. Clin J Am Soc Nephrol. 2019; 14(6):941-953. https://doi.org/10.2215/CJN.01250119

[2] Lunyer J. Acute Kidney Injury Survivor Care Following Hospital Discharge: A Mixed-Methods Study of Nephrologists and Primary Care Providers. Kidney Medicine. 2023; 5(4):100619. https://doi.org/10.1016/j.xkme.2023.100619

[3] *Id*.

[4] *Id.*

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with specific modes of action exceed cost-savings benefits and are incomparable. Of note are the implications to impact as many as thirty-eight percent of patients with ESRD who learn of their diagnosis only after their kidneys have failed, requiring them to initiate dialysis in the emergency room in a "crash" start.

The National Kidney Foundation appreciates the opportunity to provide comments to CMS on the proposed FY 2024 inpatient rule. Patient-centric quality measures that improve the performance of critical aspects across the kidney care continuum are gravely significant. Timely access to innovative therapies remains crucial to the improvement of quality of life for individuals with kidney disease in the achievement of their life-goal preferences. We welcome the prospect of providing additional insight on future initiatives regarding these matters. Please contact Ivory Harding, Director of Quality and Regulatory Affairs, at Ivory.Harding@kidney.org with any questions or concerns.

Sincerely,

Kevin Longino
CEO and Transplant Recipient

Sylvia Rosas, MD
President