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September 27, 2019

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

Re: CMS-1713-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

Dear Administrator Verma,

The National Kidney Foundation (NKF) appreciates the opportunity to provide comments on the proposed changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and the ESRD Quality Incentive Program (QIP). We are grateful for Administration's commitment to payment policies for the ESRD PPS that "focus on patient care, support innovation, reduce burdens, and lower costs."[1] NKF welcomes the opportunity to work with CMS to refine the PPS and the ESRD QIP to achieve these stated goals on behalf of the patients we represent.

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).

I. Calendar Year (CY) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

a) Eligibility Criteria for the Transitional Drug Add-on Payment Adjustment

[1] The Office of the Assistant Secretary for Planning and Evaluation; US Department of Health and Human Services. (2019). *Advancing American Kidney Health . Advancing American Kidney Health* . Retrieved from https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health

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NKF believes that encouraging innovation in the ESRD space is of the utmost importance. We strongly support the goal of the ESRD PPS to "…encourag[e] competition through support of innovative drugs that would become optimal choices for ESRD patients and advance their care through improved treatment choices."[2] The dearth of new products available to ESRD patients reflects the need for a path to market access through the TDAPA followed by the evaluation of whether new money additions to the bundle may be appropriate. NKF has generally supported broad TDAPA eligibility for products both inside and outside the functional categories other than generics and biosimilar products. We are sympathetic to the concerns that broad TDAPA eligibility has the potential to inappropriately direct Medicare dollars to line-extensions and follow-on products, but believe these theoretical consequences, though important to consider, may be not immediately materialize given relatively small overall investment in renal drug and medical device development. We believe it is important, particularly at this moment of the Administration's commitment to kidney health, to direct resources towards fostering a rich environment for ESRD drug development. As the market expands and patients have access to a greater range of drug treatments, it may be appropriate to reevaluate the unintended effects of policies intended to drive innovation. As such, we are concerned about any proposal that constrains TDAPA eligibility, though we do support and thank CMS for proposing to exclude generic drugs from TDAPA eligibility, which we believe is appropriate. We encourage CMS to similarly exclude biosimilar products from TDAPA eligibility. In reference to CMS' assertion that restricting TDAPA eligibility would reduce CY2020 Medicare expenditures, which would have a favorable downstream impact on beneficiary coinsurance, we note that patients are willing to accept higher cost sharing in exchange for any innovation in the ESRD space.

NKF also reiterates our concerns with the policy, finalized in the CY2019 ESRD PPS final rule, of TDAPA payments based on Average Sales Price (ASP)+0. We believe this pricing policy creates a disincentive for some small and medium sized dialysis organizations to acquire the products and provide it in their facilities. We are concerned that under-reimbursement may threaten patient access if practitioners hesitate to prescribe a new therapy that they know the dialysis facility is not stocking. We believe it is important to prioritize innovation over the need to cost constrain the system. We concerned that the ASP+0 methodology will not encourage innovation despite CMS' intent and recommend instead that CMS leverage the ASP+6% methodology for TDAPA products.

Finally, NKF restates our recommendation that all drugs eligible for TDAPA be evaluated for additional money added to the bundle, regardless of whether the drug falls into a functional

[2] Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements, Federal Register. (August 6, 2019). (To be codified at 42 C.F.R. pts. 405, 410, 413, 414).

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category or not. We are greatly concerned that CMS' no new money policy is stymying desperately needed innovation to improve the outcomes and quality of life of ESRD patients.

b) New and Innovative Renal Dialysis Equipment and Supplies Under the ESRD PPS

NKF welcomes the creation of the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES). The proposed policy is well aligned with the goals of KidneyX and the Advancing American Kidney Health Initiative. We are grateful to CMS for taking action to activate investment in medical devices and are hopeful that TPNIES will help realize our shared goal of improving the lives of ESRD patients.

NKF supports the substantial clinical improvement (SCI) criteria as the basis of TPNIES eligibility. We agree that products that qualify for the payment adjustment should be "truly innovative." We do, however, emphasize the need to include an additional eligibility criterion based on patient preferences, patient-reported outcomes, and other patient-centered data. Improvements in the "diagnosis and treatment" of Medicare beneficiaries are not the only innovations that matter to patients. New products that enhance patients' experiences with dialysis can be important innovations that meaningfully improve patients' health-related quality of life (HRQoL). We strongly recommend that CMS use the SCI criteria as revised by the IPPS final rule for fiscal year (FY) 2020, which account for these considerations.[3] As codified at 42 CFR § 412.87, these criteria recognize substantial improvements in clinical outcomes relative to equipment or supplies previously available, as demonstrated by one or more of the following: "A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance."[4]

NKF would be pleased to work with CMS to define a process for evaluating improvements in one or more activities of daily living and improved quality of life. Such a process is especially important because patient preference and patient reported outcome data are not always available at the time that marketing authorization is granted by FDA. We want to ensure that equipment or supplies that represent a meaningful advance for patients in a HRQoL domain, but where the patient's preferences have not yet been formally evaluated at the time of FDA approval, would be eligible for TPNIES.

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[3] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals, 84 Fed. Reg. 42,044 (Aug. 16, 2019) (to be codified at 42 CFR pts. 412, 413, and 495).

[4] *Id.* at 42,292.

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We further urge CMS to clarify that different types of equipment and supplies may be eligible for TPNIES, regardless of the pathway by which they are approved. We believe products that represent substantial improvements for patients can be medical devices without predicates, or modifications to 510(k)s and should be eligible for TPNIES regardless. Our primary concern is that these products are truly innovative and represent a meaningful advance for patients.

Finally, NKF strongly recommends that CMS devise a methodology that would allow for capital-related assets, including dialysis machines that are both leased and owned, to qualify for TPNIES. As currently proposed, TPNIES would exclude dialysis machines and water purification systems, both of which are critical components of ESRD care where innovation can produce meaningful improvements in clinical outcomes and the patient experience. While we appreciate the complexity involved in establishing a cost per-treatment basis, we believe it is critically important to implement incentives that may result in lighter and easier to use home dialysis machines, especially given the Administration's efforts to increase the uptake of home dialysis. Home dialysis machines are both leased and purchased by facilities, so we believe both types of machines should ultimately be eligible for TPNIES, though we support CMS' efforts to begin with considering leased equipment for eligibility. NKF would welcome the opportunity to work with CMS on a definition of leased and owned products that would enable broadening the eligibility criteria for TPNIES.

c) Comment Solicitation on Payment for Renal Dialysis Humanitarian Use Devices (HUD)

NKF supports incorporating Humanitarian Use Devices (HUD) into the ESRD PPS. We believe the PPS should provide coverage and payment for these devices under the ESRD benefit if such devices are required to be used in the dialysis facility, whether they are for the treatment of ESRD or for the treatment of other conditions related to renal dialysis.

d) Proposed CY2020 ESRD PPS Update

i. Outlier Payment Adjustment

NKF continues to support the outlier payment adjuster as an appropriate protection for patients who utilize significantly more services than the average patient. We do not support the outlier payment as a mechanism to roll higher costs drugs into the bundle without the addition of new money. We further recommend that when outlier payments are less than 1 percent, that the remaining dollars are paid back to the dialysis facility to be invested in patient care.

ii. Low Volume Payment Adjuster (LVPA)

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NKF continues to support removing the rural payment adjuster and instead tiering the low volume patient adjuster (LVPA) to ensure it applies the most dollars to facilities that are serving a critical patient need, but also likely operating at a loss. The 2018 MedPAC report that distinguishes rural facilities adjacent to an urban area from rural non-urban adjacent facilities may provide an opportunity to target a tiered approach to the LVPA and ensure those facilities not adjacent to an urban area are receiving the higher adjuster.

iii. Patient Case Mix Adjuster

NKF requests that CMS ensure the patient case mix adjusters are serving their intended purpose. We are concerned that using cost reports as the data source for the age, BSA, and BMI case mix adjusters are neither reliable nor reflecting the patient characteristics that clinicians believe are drivers of higher costs. We recommend that CMS work quickly with clinicians to revise the patient adjusters to ensure they serve their purpose of accounting for higher cost patients.

II. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

In this section, NKF offers comments on proposed changes to the scoring methodology previously finalized for the PY2022 ESRD QIP, followed by comments on the continuing measures for the PY2023 ESRD QIP.

Proposed Changes to the Scoring Methodology Previously Finalized for the PY2022 ESRD QIP

a) Proposed Update to the Scoring Methodology for the NHSN Dialysis Event Reporting Measure

NKF recommends that CMS not proceed with the proposed update to assess successful reporting based on the number of months facilities are eligible to report the measure. Our recommendation is specific to new facilities and does not necessarily apply to facilities granted an ECE. NKF appreciates CMS' concern that many facilities, by nature of being new or of having been granted an ECE, are not reporting on dialysis events for twelve months, however we believe that the full year period is necessary for new facilities to successfully set up a reporting structure. Setting up the reporting process is a complex process. It takes over 4 months to gain clearance to access the system and begin reporting data and a much longer time for independent and isolated facilities.

In addition, NKF has longstanding concerns about the value of the reporting measure. We do not believe that the inclusion of a reporting measure in the patient safety domain can overcome the fundamental challenge with the clinical measure, which results from the failure of hospitals to report BSIs to dialysis facilities.

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b) Proposal to Convert the STrR Clinical Measure to a Reporting Measure

NKF appreciates CMS' attention to the community's concern regarding the validity of the STrR measure and we support converting the STrR measure to a reporting measure until such time as the validity of the clinical measure can be assured. In conducting its analyses, we encourage CMS to consider that transfusions do occur in settings outside the hospital including outpatient centers.

Continuing Measures for the PY2023 ESRD QIP

NKF acknowledges that CMS is not proposing to adopt any new measure beginning with the PY2023 ESRD QIP, however would like to reiterate our positions on the existing QIP measures if there are future opportunities to work together on improving the measure set. In addition to modifying the measures in the ESRD QIP, we additionally recommend that CMS consider revisions to the Performance Score Certificate (PSC) and Dialysis Facility Compare (DFC) to improve the ability of patients to meaningfully use these tools. At minimum, we ask CMS to consider that patients find the two separate scoring systems for the PSC and DFC confusing. We recommend that CMS either use the QIP measures and scores on DFC or substantially differentiate DFC by including indicators of quality that patients value most (safety/infections, cleanliness, patients' satisfaction with the care received, staff attentiveness). It is critical that patients understand and can use information on QIP performance in order to achieve the Administration's goal of providing transparent information to assist beneficiaries in making decisions about where they receive care.

a) In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)

NKF supports the ICH CAHPS survey measure, as it reflects an important premise that dialysis patients, many of whom spend a considerable amount of time in the dialysis facility, are satisfied with the attention they receive from facility staff and feel safe and comfortable in their surroundings. NKF remains concerned that the frequency with which ICH CAHPS is administered may preclude facilities from learning about and acting in response to feedback offered by patients prior to the survey being administered again. We recommend that administering ICH CAHPS every nine months, rather than every six months, may provide a more reasonable lag time during which facilities can analyze survey feedback and implement new interventions. We also note that many facilities are unable to report on the measure due to less than 30 patients completing and returning the survey. We ask CMS to consider that facilities are acting on the measure, but not according to the outcome action levels.

We also note ICH CAHPS is not suitable for home dialysis patients. This is an especially important consideration as the Administration seeks to improve uptake of home dialysis. NKF would welcome the opportunity to partner with CMS to develop a standardized survey to assess home patients' experience of care.

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b) Standardized Readmission Ratio (SRR)

NKF supports the SRR measure, though we encourage CMS to carefully consider the potential for the measure to affect patient access to care. We further note that for the SRR measure to be actionable by facilities, hospitals must be required to share key discharge information directly with facilities. Facilities report challenges in accessing hospital discharge data as it relates to medication changes and plans of care post discharge.

c) Standardized Transfusion Ratio (STrR)

NKF is concerned that the STrR measure may lead to undertreatment of anemia. We agree that avoiding transfusions is an important goal, particularly among patients waiting for a kidney transplant, however a transfusion avoidance measure does not consider patients' quality of life or the cardiovascular risks associated with low hemoglobin levels. We encourage CMS to include a measure in the QIP that incentivizes facilities to adequately manage anemia. We note the KDOQI Anemia Management guidelines recommend a low hemoglobin range of 9.0g/dL-10.0g/dL.[5]

d) Kt/V Dialysis Adequacy Comprehensive

NKF strongly opposes the use of a pooled dialysis adequacy measurement. We encourage CMS to return to individual adequacy measures or to construct a composite measure where each individual measure is evaluated and then rolled up into a single score. As currently implemented, the pooled measurement is distorted and no longer aligns with the KDOQI Guidelines, which recommend separate adequacy targets for hemodialysis and peritoneal dialysis.[6] [7]

e) Hemodialysis Vascular Access: Standardized Fistula Rate

NKF is concerned that a measure based on autogenous arteriovenous fistula (AVF) as the sole means of vascular access is not sufficiently patient-centered. There are numerous reasons, some clinical and some based on patient preferences, that lead to patients choosing not to go through the process of evaluation or maturation of an AV fistula or of pursuing an AV access. We believe that it would be appropriate to exclude patients from the measure who have severe steal syndrome affecting the partial or complete use of a limb, severe congestive heart failure, severe

[5] Kliger, A. S., Foley, R. N., Goldfarb, D. S., Goldstein, S. L., Johansen , K., Singh, A., & Szczech, L. (2013). KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for Anemia in CKD. American Journal of Kidney Diseases, 62(5), 849–859. doi: https://doi.org/10.1053/j.ajkd.2013.06.008

[6] National Kidney Foundation . (n.d.). 2006 Updates Clinical Practice Guidelines and Recommendations. 2006 Updates Clinical Practice Guidelines and Recommendations (pp. 1–193).

[7] National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015;66(5):884-930

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psychiatric illness, or other conditions in which the risk of surgery to place AV access, or use of AV access on dialysis, is deemed to be unacceptable by their physician. We note that further vascular surgery may not align with patients' preferences for care, for example for patients who have been on dialysis for many years and have had multiple vascular access surgeries. We believe it would be appropriate to exclude patients who have exhausted all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF or AVG placement, as well as patients that refuse consideration of AVF or AVG placement or use, despite greater than two attempts at education on the risks of catheters and benefits of AVF or AVG by their provider. We do believe that, in conjunction, facilities should be required to continue to attempt education on the risks of catheters and the benefits of AVF or AVG at least annually. The exclusions we recommend could be captured by modifying CROWNWeb to add checkboxes for facility reporting of patients who are not suitable for AVF or AVG placement, or who have declined to pursue it.

Our recommendations align with the updated KDOQI Vascular Access Guideline, which emphasizes that a patient's access needs stem from the creation of an individualized ESKD life-plan.[8] Rather than a "fistula-first, catheter-last" approach, the guideline reflects that the "right" vascular access is different for every patient. NKF would welcome the opportunity to discuss incorporation of the ESKD life-plan in the ESRD QIP.

f) Hemodialysis Vascular Access: Long-Term Catheter Rate

NKF continues to support this measure.

g) Hypercalcemia

NKK recommends removing hypercalcemia as a clinical measure and replacing it as a reporting measure. While hypercalcemia is a potentially important marker associated with mortality, the measure is not likely to drive improvements in patient outcomes. We believe changing the hypercalcemia measure from a clinical to reporting measure is the most feasible approach to fulfilling the statutory requirements of the Protecting Access to Medicare Act of 2014 (PAMA) to include quality measures related to conditions treated with oral-only medications with the need for the QIP to more highly value measures that drive improvements in patient outcomes.

h) Standardized Hospitalization Ratio (SHR)

NKF supports the SHR measure. While we agree that a measure that holds dialysis facilities accountable for preventing hospitalizations is appropriate, we believe that the measure should be better risk stratified for causes that are actionable by the nephrology care team.

[8] Current KDOQI Projects. (2019, May 24). Retrieved from https://www.kidney.org/professionals/guidelines/current-KDOQI-projects.

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i) Clinical Depression Screening and Follow-Up

NKF would be pleased to work with CMS on an improved Clinical Depression Screening and Follow-Up clinical, rather than reporting, measure. We are concerned that the current reporting measure is not adequately incentivizing appropriate follow-up within the facility. We acknowledge that patients with persistent or severe depression may need to be referred to a mental health practitioner outside the facility and note that it would not be appropriate to hold the dialysis facility or nephrologist accountable for counseling or prescribing anti-depressant medications to these patients. For many patients, however, behavioral health interventions can successfully be provided by dialysis facility social workers. We believe that a clinical measure is more appropriate, given the high proportion of depressive symptoms reported in the dialysis population and the potential for care to be provided within the facility. NKF and the Council of Nephrology Social Workers (CNSW) would welcome the opportunity to collaborate with CMS on developing a more adequate measure of clinical depression screening and follow-up.

j) Ultrafiltration Rate

NKF does not support the Ultrafiltration Reporting Measure, failing to see its value when there is an NQF endorsed clinical measure that, if implemented, would more meaningfully advance patient outcomes. We encourage CMS to implement NQF#2701: Avoidance of Utilization of High Ultrafiltration Rate (>/=13mg/kg/hour), which has been supported for endorsement by the NQF renal standing committee. There is limited evidence for a specific ultrafiltration target. The KDOQI Hemodialysis Adequacy Guideline does not include a target for UFR, recommending instead the minimization of UFR as best possible to maximize hemodynamic stability and tolerability of the hemodialysis procedure.[9] While UFR targets remain an area of active investigation and debate, NFK recommends using NQF#2701 in the QIP. We do acknowledge that successfully meeting the measure will require patient participation and adherence to the dialysis prescription and fluid restriction. This is a challenge that will require efforts from dialysis providers, dialysis facility staff, physicians, and patients to overcome.

k) NHSN Bloodstream Infections in Hemodialysis Patients

NKF continues to have concerns with maintaining both the NHSN Bloodstream Infection (BSI) clinical measure and the NHSN Dialysis Event Reporting measure in the QIP. We believe that the reporting measure serves to dilute the value of the clinical measure. The underlying problem with the clinical measure is the failure of hospitals to report BSIs to dialysis facilities. We do not believe that including the reporting measure in the patient safety domain will address this problem. We urge CMS to institute a system where hospitals are required to report BSIs either to NHSN or directly to dialysis facilities so that they can appropriately report on the measure.

[9] National Kidney Foundation. KDOQI clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015;66(5):884-930

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l) NHSN Dialysis Event Reporting Measure

Please see the above. NKF's comments on the proposed updates to the NHSN Dialysis Event Reporting Measure scoring methodology are in the next section.

m) Percentage of Prevalent Patients Waitlisted

Although NKF strongly supports efforts to improve patient access to transplants and although we believe facilities have instrumental roles in helping patients receive transplants, NKF maintains our opposition to the Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure. Transplant centers are the ultimate decision-makers regarding whether patients are waitlisted, considering varying criteria, including financial criteria, into which dialysis facilities do not necessarily have visibility. NKF recommends that CMS work with the kidney community to develop a transplant measure that is more actionable by the dialysis facility.

We recommend that the PPPW measure may more appropriately apply to a nephrologist participating in the Merit Based Incentive Payment System (MIPS), as the nephrologist has accountability for managing ESRD patients and coordinating care, and has a leading role in evaluating patients for referral to a transplant center and assisting patients in getting on the waitlist. We do note, however, that exclusions would need to account for circumstances affecting a patient's ability to be wait-listed that are beyond the nephrologist's control.

n) Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

NKF continues to support the addition of the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure to the QIP. Ensuring that dialysis facilities have the most accurate record of a patient's medications, including prescription, over the counter, and herbal supplementals, is critical for assuring patient safety and outcomes. We believe the MedRec measure is adequate to achieve these goals. NKF supports the proposed updates to the MedRec reporting measure scoring methodology.

The National Kidney Foundation thanks CMS for its attention to the concerns raised in this letter. We would be pleased to discuss our recommendations further. Please contact Kerry Willis, Chief Scientific Officer at kerryw@kidney.org and Miriam Godwin, Health Policy Analyst, at Miriam.godwin@kidney.org.

Sincerely,

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