National Kidney Foundation®

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August 15, 2018

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

RE: CMS-1691-P: 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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Dear Administrator Verma:

The National Kidney Foundation appreciates the opportunity to comment on the proposed changes to the end-stage renal disease (ESRD) prospective payment system (PPS), including policies that will govern coverage and payment for renal dialysis services delivered to individuals with acute kidney injury (AKI), and the quality incentive program (QIP) for payment years 2021-2024. The National Kidney Foundation 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). This year we are dividing our comments into three separate letters in hopes to make it easier to review our recommendation on each section of the rule. This letter responds to payment changes within the ESRD PPS. Two additional letters will reflect our comments regarding proposed changes to the QIP and the request for comment on questions regarding home dialysis and transplantation. Our recommendations on the proposed payment update include the following:

- Transitional Drug Add on Payment Adjuster (TDAPA)
    - Should be paid at the Average Sales Price (ASP) plus 6%
    - Should not apply to generics or biosimilars

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  - Should be continued beyond two years if sufficient claims data is not available to account for utilization and costs
  - At the end of the TDAPA period CMS should establish a process to consider adding new dollars to the bundle for the drug even if it falls within an existing functional category
- Payment Adjusters
  - The Outlier Payment Adjuster should not be used as an alternative to including new money into the PPS for higher costing medications
  - CMS should return money withheld from the ESRD PPS to pay for patient care when the full 1% of outlier payments was not distributed.
  - CMS should eliminate the rural payment adjuster and instead revisit additional policies related to the Low Volume Facility Adjuster (LVPA) to ensure the adjuster adequately provides funds to support facilities that serve a critical access need
  - CMS should revisit the patient case-mix adjusters of age body mass index (BMI) and body surface area (BSA) to ensure they are achieving their stated purpose of accounting for higher costing patients

Proposed Changes to the 2019 ESRD PPS

The National Kidney Foundation frames our comments on the proposed payment updates using the following patient-centric questions:

1) Does the payment policy affect patient access to care?
2) Does the payment policy affect choice in care?
3) Does the payment policy affect patient outcomes?
4)Does the payment policy affect patient out-pocket costs?

A. <u>The National Kidney Foundation recommends modifications to TDAPA and that additional money be added to the bundle for new treatments under certain factors.</u>

The National Kidney Foundation is pleased that CMS has recognized the lack of innovation in new treatments for individuals with ESRD. We support that TDAPA should apply to all drugs and biologics approved by the FDA as new. However, we do not believe TDAPA should apply to generics or biosimilars and request that CMS make that clarification. Unfortunately, CMS is proposing paying only 100% of ASP or 100% of the Wholesale Acquisition Costs (WAC) and we believe this creates a disincentive for some, particularly medium and small dialysis organizations, to acquire the product and provide it in their facilities because they may be under-reimbursed. This could lead to patient access issues in obtaining the drug as clinicians may be hesitant to prescribe a new therapy if they know the dialysis facilities are not stocking it. Other payment systems rely on the ASP plus 6% methodology and while we appreciate CMS working to reduce

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drug pricing, we are concerned the trade-off is that this proposed TDAPA policy will not encourage innovation despite CMS's intent. Given that there has been little innovation in new ESRD therapies in over two decades we request that CMS not apply this untested new pricing policy to the ESRD PPS TDAPA. Instead, we request that CMS ensure patients have access to treatments that may improve their outcomes and have choice in treatment options by reimbursing FDA approved new treatments at ASP plus 6%.

While we recognize that patient's out-of-pocket costs may be higher with an ASP plus 6% TDAPA than under the ASP plus 0% proposal, we believe the trade-off of spurring innovation in new treatments warrants the cost. While our preference is that coinsurance would not be applied to TDAPA given this is a facility-level adjuster to the PPS, we recognize that CMS has stated it does not have the authority to waive the coinsurance. We understand this will be a barrier to patient choice and access, but likely not as great as a proposal to reimburse at ASP+0 would be.

The National Kidney Foundation requests that for all TDAPA drugs that CMS apply the policy for a minimum of 2 years to allow the agency time to have enough data on utilization and costs to determine appropriate changes to the per-treatment ESRD PPS base rate before TDAPA ends. CMS has proposed that it will limit TDAPA for drugs that fall into an existing functional category

The National Kidney Foundation also believes that for significant innovation in ESRD treatments to occur CMS needs to ensure that all drugs qualifying for TDAPA be evaluated for additional money added to the bundle before TDAPA ends. Given that new drugs for dialysis patients are expected in 2019, we encourage CMS to develop a final rule, with comment period, that describes the process and criteria it will use to evaluate drugs for functional category consideration and for when additional money will be added to the bundle. Evaluating adding new money to the bundle should occur regardless whether CMS determines the new treatment falls into a functional category. In addition to stymieing innovation there is also the potential that drug prices could be set high during the TDAPA period to account for big losses once the new drug is bundled in.

Yet, we understand the need to ensure that the payment system does not simply create incentives for the development of new drugs that may have little to no added benefit for patients. Therefore, in addition to adding new money to the bundle when a new drug is used for the treatment of the average dialysis patient and does not fall into an existing functional category, we also support the following factors for CMS to consider for additional money when a new drug is determined to fall into a functional category. These factors were developed and recommended by Kidney Care Partners.

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- *Drugs and biologicals that fill a treatment gap (address an unmet medical need) in an existing functional category; or*
- *Drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug's label; or Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material (including within the clinical pharmacology and study portion of the FDA label, sections 11 and 14); or*
- *Drugs and biologicals that based on the FDA labels (if appropriate to add to a functional category) that have demonstrated clinical superiority to existing products in the bundle; or*
- *Drugs and biologicals that improve priority outcomes, such as:*
    - *Decreasing hospitalizations;*
    - *Reducing mortality;*
    - *Improving quality of life (based on a valid and reliable tool);*
    - *Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);*
    - *Addressing patient-centered objectives (including patient reported outcomes once they are developed and used by the FDA in its review of drugs and biologicals); or*
    - *Reducing in side effects or complications;*[1] *or*
- *Drugs and biologicals that have a significantly better safety profile than existing products.*

In addition, to these factors we request CMS monitor outcomes associated with drugs pre and post TDAPA through the agency's ESRD PPS claims-based monitoring program. For example, in our comments on the 2018 ESRD PPS we asked CMS to monitor parathyroidectomies to be able to compare pre and post TDAPA for calcimimetics. We believe this monitoring is an important component to ensuring that new payment policies do not unintentionally restrict patient access to care.

B. Outlier Payment Adjuster

NKF continues to support the outlier payment adjuster as an appropriate protection for patients who utilize significantly more services that the average patient. However, we do not support the outlier payment as a mechanism for higher cost drugs rolled into the bundle without an additional money added. We also encourage CMS to ensure that when outlier payments are less than the 1% set aside that the remaining dollars are paid back to dialysis

[1]Current legislation being considered by the Congress includes criteria such as these. *See* H.R. 5997 "Ensuring Patient Access to Critical Breakthrough Products Act of 2018" introduced by Reps. DelBene (D-WA), Walorksi (R-IN), Sewell (D-AL), Bilirakis (R-FL), and Cardenas (D-CA).

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facilities to be invested into patient care.

C. Low Volume Payment Adjuster (LVPA)
As CMS is proposing changes to the LVPA, we reiterate our past requests to remove the rural payment adjuster and instead tier the LVPA to ensure it more applies the most dollars to facilities that are serving a critical patient need, but also likely operating at a loss. NKF remains concerned that facilities in isolated areas serving predominately Medicare and Medicaid beneficiaries would be the first to be targeted for closure even with a rural payment adjuster. We point to the March 2018 MedPAC report that distinguishes rural facilities adjacent to an urban area from rural non-adjacent facilities. This may provide an opportunity for CMS to target a tiered approach to the LVPA and ensure those facilities not adjacent to an urban area are receiving a higher adjuster.

D. Patient Case Mix Adjuster
The National Kidney Foundation also requests that CMS revisit our requests from the 2018 ESRD PPS to ensure that the patient case mix adjusters are serving their intended policy purposes. It appears that the cost reports as the data source for the age, BSA and BMI case mix adjusters are not reliable or reflecting the patient characteristics that clinicians believe are actual drivers of higher costs. As a result, payments are not reflecting the policy intent of these adjusters and we recommend that CMS quickly work with clinicians to revise the patient adjusters to ensure they serve their purpose of accounting for higher cost patients.

The National Kidney Foundation appreciates the opportunity to comment on upcoming changes to the payment system and opportunities to encourage innovation in new therapies. We would be happy to meet with CMS to further discuss our recommendations. For questions, please contact Tonya Saffer, Vice President for Health Policy at tonya.saffer@kidney.org or 202.244.7900 x 717.

Sincerely,

Kevin Longino *Michael Choi*

Kevin Longino
CEO and Kidney Patient

Michael Choi, MD
President