KIDNEY CARE PARTNERS

April 27, 2022

The Honorable Meena Seshamani, M.D., Ph.D
Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Deputy Administrator Seshamani,

Thank you again for meeting with representatives from Kidney Care Partners to discuss the members' priorities for the CY 2023 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule. As we discussed, these include:

- Recognizing the limitations in the ESRD PPS bundle for innovative products in functional categories;
- Addressing the practical problem that current market basket proxies are not capturing the exponential increase in labor costs; and
- Addressing the 2025 timeline for inclusion of oral-only drugs in the ESRD PPS.

During our conversation, your asked for our thoughts about the authority CMS has to create an adjuster to address the increasing labor costs that the current proxies do not capture. This letter provides a summary of our analysis. We would welcome the opportunity to discuss it with you, if that would be helpful. The focus of this letter is on CMS's ability to create an adjuster to address rising labor costs; however we also wanted to expand on our comments related to the potential inclusion of oral only drugs, such as phosphate binders, in base rate.

I. Overview of CMS Authority to Address the Workforce Crisis

CMS has used its existing authority to create two temporary drug add-on payments that add new money to the base rate and without applying a budget neutrality factor. Of the temporary drug add-ons, the first add-on was the calcimimetic add-on. The second is the transitional drug add-on payment adjustment (TDAPA) for new drugs that do not fall within a functional category. CMS also pays the home dialysis training add-on that is not budget neutral and which CMS has adjusted several times to meet policy goals.

CMS has relied on language not only from the Protecting Access to Medicare Act of 2014 (PAMA) for the drug add-ons, but also the original adjuster authority from the Medicare Improvement for Patients and Providers Act (MIPPA) for these adjusters. The MIPPA language reads:

> (iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment —
> (I) for pediatric providers of services and renal dialysis facilities;
> (II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and
> (III) for providers of services or renal dialysis facilities located in rural areas.
> The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

This language from the Social Security Act (SSA) provides CMS with the authority to adopt a temporary adjuster to address the unprecedent increase in the cost of labor that the ESRD proxies do not address. The authorizing statute states that the ESRD PPS "may include such other payment adjustments as the Secretary determines appropriate." CMS cited this authority when it established the TDAPA policy and decision to add dollars to the base rate for calcimimetics and drugs/biologicals not within existing functional categories. While there are examples of other types of adjusters outlined in the statute, the authority is permissive and not limited to these examples. Adjustments do not have to be case-mix or facility-level adjustments.

Nothing in this section requires that the adjustments be budget neutral or otherwise limited. In fact, the statute specifically established a budget neutrality requirement when adopting the transitional phase-in of the ESRD PPS, but only for the years of the phase-in:

> The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

If the Congress had intended payments to be budget neutral on an ongoing and permanent basis, it would not have limited the budget neutrality requirement to the phase-in years and would have instead included language similar to the acute inpatient hospital PPS.

Some might counter that the more specific language of the provision related to the ESRD PPS annual update mechanisms suggests that the Congress did not intend for permanent adjustments beyond the update mechanism, but that conclusion does not seem reasonable. The language that those who oppose an adjustment might reference is the phrase "the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services." Clearly, this language is very specific, but it does not eliminate the authority to establish "other

adjustments" as the preceding paragraph indicates. And, while the annual update provision speaks in terms of an annual increase based on the ESRD market basket to the base rate, it is a mandatory adjustment. The mandatory nature of the adjustment results in a construction that differs from the construction that is used for the permissive nature of the adjustments in the preceding paragraph.

Thus, it seems appropriate to conclude that the Congress would allow CMS to establish additional adjustments beyond those enumerated in the statute. These adjustments do not have to be budget neutral; and the adjustments could be incorporated into the ESRD PPS base rate on a permanent basis. In sum, CMS has sufficient authority to create a temporary adjustment to the base rate that adds new money to address the unanticipated skyrocketing labor costs facilities face.

There is also a strong policy argument to support a temporary labor adjuster to increase the base rate. As we have discussed previously, it is important to provide sufficient resources so that facilities have the staff they need to provide treatments to individuals receiving in-center or home dialysis. An adjustment is necessary to protect this access. KCP members and others in the health care field are already sharing anecdotal evidence of facilities eliminating shifts, closing early, or not being available on certain days of the week because they cannot find the nurses and technicians they need to safely operate. The market-basket update alone will not address these issue. As a result, KCP has asked that CMS establish a temporary adjustment to support facilities as they bear the additional costs that the workforce shortage has required them to incur to protect beneficiary access to dialysis.

II. Addressing the 2025 Timeline for Inclusion of Oral-Only Drugs in the ESRD PPS

KCP members continue to have practical implementation concerns about adding oral-only products to the ESRD PPS. Phosphate binders, which are not administered in the facility, could come into the bundle January 1, 2025. We believe the same concerns that have kept these products out of the bundle continue to exist and because of them, we ask that CMS exercise its existing authority to further delay the inclusion of oral-only drugs that are furnished for the treatment of ESRD or permanently exclude them from the bundle. The statute does not mandate their inclusion in 2025. It only prohibits CMS from including them prior to 2025. We believe further delay or permanent exclusion of these products will benefit beneficiaries who require these drugs, relieve burden on providers, and benefit the Medicare program.

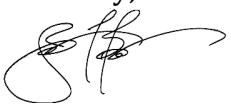
If CMS were to decide to include phosphate binders in the base rate for 2025, KCP asks CMS to seek comments in the CY 2023 proposed rule about adopting a transitional add-on adjustment period to assess the utilization and cost of these products before adding them to the bundle with new money. CMS did not include the cost for oral drugs in the ESRD PPS base rate when it created the bundled rate. As KCP has articulated in the past,

Part D data is incomplete. To ensure adequate payment for the phosphate binder class, a full TDAPA period should be provided during which dialysis facilities can test the efficacy and safety of alternative treatments within their patient population, develop clinical protocols, train staff, negotiate contracts with manufacturers, and establish distribution or dispensing systems. This period would also allow CMS to collect the pricing and utilization data necessary to make the adjustment to the ESRD PPS base rate that reflects the additional costs of the products when bundled.

III. Conclusion

KCP hopes that this analysis is helpful and responsive in addressing the questions you asked. Again, please do not hesitate to let us know if you have any questions or would like to continue our discussion.

Sincerely,



John Butler
Chairman

cc: Elizabeth Richter, Deputy Director
Jason Bennett, Director, Technology, Coding, and Pricing Group
Ing Jye Cheng, Director, Chronic Care Policy Group

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Pediatric Nephrology
American Society of Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Healthcare Association
Renal Support Network
Rockwell Medical
Rogosin Institute
U.S. Renal Care
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma