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Nonprofit Kidney Care Alliance

September 4,2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1732-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program Proposed Rule (CMS-1732-P).

Dear Administrator Verma:

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations regarding the Centers for Medicare & Medicaid Services (CMS) 2021 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Payment for Renal Dialysis Services to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program Proposed Rule (CMS-1732-P). The NKCA represents six nonprofit dialysis providers: Centers for Dialysis Care; Dialysis Center of Lincoln; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 21,000 ESRD patients at more than 300 facilities in 30 states.

To keep patients *off* dialysis, we also serve more than 5,700 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of ESRD. To that end, many of our member companies participate in value-based care arrangements such as the Comprehensive ESRD Care (CEC) model and will likely continue to expand their participation in such arrangements under new models as part of the Administration's Advancing American Kidney Health Initiative. Through the CEC model, many of our member companies are pursuing partnerships with various providers and suppliers, not only in nephrology, but across the care continuum, from primary care to hospice.

Our goal in caring for dialysis patients and those with CKD is to provide the best care possible by improving patients' quality of life, reducing the risk of kidney failure, and increasing the number of kidney disease patients who can benefit from transplant. We believe that, on balance, the ESRD prospective payment bundle has allowed us to provide better care to our patients while achieving efficiencies in our delivery of care. It has also removed financial incentives that were not aligned with patient care. At the same time, we believe that it is critical that CMS "go upstream" to address CKD in a more comprehensive manner. Accordingly, we are very pleased that the Administration has launched

Advancing American Kidney Health. Through this initiative, more patients will benefit from transplant; fewer beneficiaries will start dialysis; and those who do start dialysis will be better prepared and more aware of their options, including home dialysis.

We appreciate the opportunity to provide comments on the following provisions of the Proposed Rule.

Comments Regarding Specific Sections of the ESRD PPS Proposed Rule

Inclusion of Calcimimetics in the ESRD PPS Bundled Payment

Following approval of the Food and Drug Administration (FDA) of an injectable calcimimetic in 2017, CMS began, as of January 1, 2018, to pay for it under its transitional drug add-on payment adjustment (TDAPA). This payment will continue through 2020, at which time CMS proposes to fold it into the ESRD PPS bundled payment with an additional adjustment to the base of $12.06 (after accounting for the outlier set-aside). In calculating the per treatment amount to add to the ESRD base rate, CMS looks to two primary factors: utilization in 2018 and 2019 as reflected in *adjudicated* claims and ASP data (for both oral and injectables) from the most recently available quarter in 2020. In the case of utilization data for 2019, adjudicated claims only run through January 31, 2020. CMS states that for the final rule, it will update utilization for adjudicated 2019 claims for 2019 through June 30, 2020. With respect to ASP data, CMS states that in the final rule, it will utilize the most recent ASP data available, expected to be 2nd quarter of 2020 data, for both oral and injectable calcimimetics.

In the main, we support CMS' proposal to add $12.06 to the base, in the manner it proposes, recognizing that the amount may vary due to updated data. We do, however, recommend that CMS consider dropping the first and second quarter of 2018 utilization data as it may not be representative due to slow take-up. Some dialysis providers were slow to adopt the injectable calcimimetic after their experience with another injectable only a few years prior, which turned out to be very problematic after it was marketed—and ultimately withdrawn. With the addition of more 2019 adjudicated claims expected for the final rule, this would still provide a robust, and likely more representative, set of utilization data. If that is insufficient, Q1 2020 claims, assuming they are adjudicated, could be included, as they would largely be unaffected by COVID-19, which CMS noted as not wanting to incorporate 2020 claims.

Transitional Add-On Payment for New and Innovative Equipment and Supplies (TPNIES)

In our comments on the 2020 ESRD Proposed rule we expressed our support for CMS' proposal, subsequently adopted, to incorporate both "newness" and "substantial clinical improvement" as necessary to qualify for the TPNIES. In particular, we concurred with CMS's proposal to apply a test of substantial clinical improvement similar to that used in the Inpatient Prospective Payment System (IPPS) to spur innovation for products that do more than offer minor, if any, real clinical improvement. In such a system, developers and manufacturers know up front by what criteria a new product will be judged. At the same time, we noted that new equipment and supplies *need not* be blockbusters to qualify. Rather, they may:

> (i) offer a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

(ii) offer the ability to diagnose a medical condition in a patient population where that condition is currently undetectable or diagnose a medical condition earlier in a patient population than allowed by currently available methods; or

(iii) significantly improve clinical outcomes for a patient population as compared to currently available treatments.

We believe that by setting the bar higher than only "newness", CMS can help ensure that increased Medicare expenditures and beneficiary copayments are better justified.

Notwithstanding our support for CMS overall policy with respect to "newness" and substantial clinical improvement, we do have concerns with how CMS proposes to apply that policy: first, in terms of how CMS, in determining substantial clinical improvement (SCI), accounts for the nature of dialysis care and the patient profiles and their impact on the conduct of clinical trials; and second, how CMS seems to be conflating its determination of whether a supply or equipment meets the twin test of newness and SCI, with the question of how to pay and where to pay.

With respect to our first concern, which goes to the determination of SCI, we urge CMS to calibrate its policy to take into account that, as the dominant payer in the dialysis field, CMS is in effect the sole gatekeeper on whether new equipment and supplies will be incentivized and come to market to improve patient care. In the ESRD field, this can be particularly challenging. Large clinical trials, over multiple years—while perhaps the gold standard—can be particularly challenging due to the nature of the ESRD population. With most ESRD patients covered through Medicare and/or Medicaid, payment rules play a dominant role in any assessment of return-on investment by developers and manufacturers. We recognize that there is a "judgement call" here, but in setting the bar high, it should not be so high as to be viewed impractical.

Our second concern revolves around CMS' proposal to add capital-related assets, but only for in-home dialysis and for a single patient, and only if purchased outright, and not under a lease arrangement. Here it seems that CMS is conflating two separate and distinct issues: does a supply or equipment meet the test of "newness," and does it represent a substantial clinical improvement. The second step—not unlike how CMS makes coverage and pricing decisions—is first, is something covered and then, by what methodology to pay for it and then how much. While we understand CMS' point about ownership and depreciation, this is more appropriately addressed in the payment methodology and level than by outright exclusion. Not all dialysis facilities have the ability to purchase new devices and may use operating leases in order to provide the benefit of new equipment for their patients. It is our understanding that the lease agreements typically account for depreciation and maintenance. Implementation of the TPNIES payment should not only impact patients of those providers with the capital to purchase the latest equipment, but should enable all providers, regardless of size, to use innovative and beneficial equipment for patient care.

In a similar vein, CMS proposes to include capital-related assets when intended to be used for home dialysis by a single patient, though not in-center use, largely on the grounds that it seeks to promote home dialysis. While we strongly support increasing home dialysis—and several of our members already exceed the national average—we believe that the TPNIES policy should be focused on transition payment for new equipment that represents a substantial clinical improvement, and not

skewed by site of service. Indeed, to combine the bar for SCI with an in-home only requirement would likely discourage investment in new technology—undercutting the entire TPNIES policy. Simply put, if CMS wants to promote innovation and improve patient care, both stated goals in prior rulemaking, then limitations based on site of service should not be employed.

CMS proposes a number of refinements to the TPNIES system to better align it with the new Healthcare Common Procedure Coding System (HCPCS) bi-annual process (as well as FDA market authorization). While this creates a three-year window on what is "new", it resolves what can otherwise be a "Catch 22" for new supplies and equipment. This can also help promote developer/manufacturer confidence by enabling them to better navigate multiple processes across two agencies, both critical to bringing a product to market.

Outlier Threshold

We propose, as we have before, that CMS reduce the outlier threshold from 1 percent to 0.5 percent. When the ESRD PPS bundle was adopted in 2007 and implemented in 2011, certain factors were included to better ensure appropriate payment, particularly for sicker, higher-cost patients. To account for the cost of these higher outlier payments, providers do not receive the full base rate for each treatment. Since 2011, the program has never reached the 1 percent threshold established in the implementing regulations. From 2011 through 2013, actual program experience fell *well short* of the 1 percent outlier target threshold (reaching only 0.3 to 0.5 percent). The closest the program came to the 1 percent threshold was 0.8 percent in 2017. In 2018, as the proposed 2020 rule acknowledges, outlier payments fell to 0.5 percent again. And, in this 2021 proposed rule, CMS reports that the outlier payments in 2019 only hit the 0.5 level yet again. This is a cumulative real loss to ESRD clinics and ultimately to their patients, resulting from an unnecessary and persistent loss to the base rate.

As we have advocated in each of the last several years, we urge CMS to reconsider the 1 percent outlier policy. While an outlier adjustment is required under the statute, it does not specify a particular value. We believe that a 0.5 percent outlier threshold would reduce the offset to the base payment, reducing the continued "leakage" from the base, and still provide for payment in the case of extraordinary costs. Moreover, CMS should address the operation of the outlier policy as part of its ongoing work with its contractors to review the overall functioning of the ESRD PPS and take administrative action to address its shortcomings.

Low Volume Payment Adjustment (LVPA) for COVID-19

Recognizing that COVID-19 may affect patient treatment counts, CMS proposes to hold dialysis facilities harmless in determining qualification for LVPA status. CMS proposes a two-part policy in which as part of the three-year lookback, a facility attests that its excess treatments, above the current 4,000 treatments threshold in 2020, was due to COVID-19. We concur in CMS stated policy goal and thank CMS for recognizing that ESRD facilities may have put their LVPA status at risk to help patients receive care in the middle of a pandemic.

However, we are puzzled by the two-part standard CMS proposes to which a provider would attest. Specifically, a provider would attest that it had exceeded the 4,000 treatment limit in 2020 due to COVID-19; and, as evidence, attest to its compliance with a 2,000 treatment limit in *any* combination of six months over the prior three years, whether consecutive or non-consecutive. In our view, if the effect, at least for purposes of 2021 is due to COVID-19, then any adjustment to the look-back should

be focused on 2020 without regard to any other years. As CMS points out in its discussion of its proposal, “there are between 50-60 ESRD facilities that typically lose their LVPA status because their patient population grew for reasons other than the COVID-19 PHE.” Arguably, a provider could accurately attest to a COVID effect on its 2020 experience and at the same time mask failure to comply with one or both of the prior two years, which would otherwise have disqualified them from LVPA status for 2021, whether COVID-19 had occurred or not.

Conclusion

Thank you for the opportunity to comment on the 2021 ESRD PPS Proposed Rule. The NKCA appreciates the opportunity to provide input to ensure that the system continues to support quality of care to the patients we serve. As nonprofit providers, some proposed changes to the ESRD PPS can affect us much differently than others. We would be pleased to discuss these comments and suggestions in greater detail at any time. If you have any questions, please feel free to contact Martin Corry at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,

Martin Corry
Executive Director