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Nonprofit Kidney Care Alliance

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1713-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-1713-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) 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Payment for Renal Dialysis Services to Individuals with Acute Kidney Injury, and ESRD Quality Incentive Program Proposed Rule (CMS-1713-P). 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 patients at more than 300 facilities in 30 states. In an effort 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. Four of our members are also participating in the Center for Medicare and Medicaid Innovation (CMMI) alternative payment model, the Comprehensive ESRD Care (CEC) model.

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 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 Aspects of the ESRD PPS Proposed Rule

Transitional Drug Add-on Payment Adjustment (TDAPA)

We are pleased that the 2020 Proposed Rule addresses our prior concerns with changes to TDAPA policies, but we have several concerns with CMS's proposed changes.

In the 2019 ESRD Proposed Rule, CMS proposed changes to TDAPA policies in the ESRD PPS to promote access to new therapies and give dialysis providers the ability to test new therapies during an initial uptake period. The proposed expansion of TDAPA encompassed *all* (except "oral only") drugs—including generics—not just intravenous and injectable, regardless of whether a new drug falls within the current ESRD functional categories, which were established in the 2016 Final Rule. In the 2019 ESRD Final Rule, CMS adopted its proposals but wisely delayed implementation until program year 2020. CMS noted at the time that this new policy would increase not only Medicare expenditures but also beneficiary cost sharing.

We agreed with CMS's concern that the then-extant TDAPA policy, based on the existing functional categories, might discourage development of innovative therapies and thwart adoption by ESRD providers. But we were concerned that the proposed policy went too far and would encourage "me too" drugs and higher launch prices, even if moderated after two years. We urged CMS to consider a new-drug policy more in line with policies in other parts of the Medicare program for new drugs and devices, such as the new technology add-on payment for the inpatient prospective payment system (IPPS). (See NKCA's 2019 ESRD PPS Proposed Rule comment, September 10, 2018.)

In the 2020 ESRD PPS Proposed Rule, CMS proposes to significantly revise its policy, limiting the number and type of new drugs that will be eligible for TDAPA based on the Food and Drug Administration's (FDA) New Drug Classification (NDA) Classification Codes. CMS thoughtfully reviews the merits of drugs in each of the FDA categories, narrowing the type and number of drugs that would be eligible for TDAPA. We agree with the net result of CMS's review—a more focused approach rather than the all-inclusive approach in the 2019 Final Rule. For example, it should be clear on its face that generic drugs, as well as so-called line extension drugs, should be excluded from TDAPA. The proposed approach will provide a clearer roadmap for drug developers and manufacturers, as well as ESRD providers, without adding additional administrative burdens.

We commend CMS for reconsidering its policy and proposing a new approach, as it will better use patient, provider, and Medicare dollars while also promoting innovation. By "piggybacking" on the FDA's NDA classifications, CMS goes a long way toward addressing concerns raised by stakeholders regarding the 2019 Final Rule.

However, the proposed policy could go further by also addressing whether new drugs for renal care represent a "substantial clinical improvement." In this, the proposed policy—welcome as it is—stands in contrast to the more robust policy (discussed below) that CMS proposes for new equipment and supplies based on the Medicare IPPS new technology add-on payment. While it is expected that some drugs with a new molecular entity or new active ingredient will represent a substantial clinical improvement, not all will. CMS should also consider whether a new drug/biologic addresses the needs of a patient population unresponsive to, or ineligible for, currently available treatments, or significantly

improves clinical outcomes for a patient population compared to currently available treatments. CMS's TDAPA policy should spur innovation by targeting products that do more than offer minor, if any, clinical improvement. Such an improvement need not be "blockbuster" in nature. For example, a drug that significantly improves compliance because it is not accompanied by complications such as gastrointestinal effects, which can deter patient compliance, might warrant TDAPA status and higher payment.

Additionally, we have some concern regarding CMS's proposal with respect to biosimilars, which CMS would make eligible for TDAPA. While we understand CMS's position that this will help promote development and introduction of biosimilars, thereby spurring competition and lower prices, we question whether this warrants a new-drug add-on payment. We recommend that CMS revisit its assumptions and conclusions about biosimilars, either in the Final Rule or in future rulemaking with the benefit of more experience.

Finally, we agree with CMS that a manufacturer's withholding ASP data should exclude a drug from that manufacturer on TDAPA—and, further, we urge CMS to consider whether a pattern of withholding ASP data by a manufacturer should result in CMS's excluding all drugs from the noncompliant manufacturer.

Transitional Add-On Payment for New and Innovative Equipment and Supplies

We support the CMS proposal, modeled on IPPS policy, which incorporates both "newness" and a "substantial clinical improvement" threshold for the add-on payment.

CMS proposes to add a new pathway to support the use of new renal dialysis equipment and supplies, both to provide an incentive for dialysis providers to adopt new technologies and to spur innovation such as the Kidney Innovation Accelerator (Kidney X) initiative. The process and criteria CMS proposes are similar to the new technology add-on payment currently used in the IPPS. In contrast with its proposal for new drugs, CMS would employ criteria that address both newness and substantial clinical improvement in determining whether new dialysis equipment and supplies would qualify for a two-year add-on payment.

We concur with CMS's proposal to apply a test of substantial clinical improvement for the add-on payment similar to that used in the IPPS. In that system, developers and manufacturers know up front by what criteria a new product will be judged. This policy is intended to spur innovation for products that do more than offer minor, if any, real clinical improvement. At the same time 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.

CMS proposes that new equipment and supplies—both for in-clinic and home use—for which FDA approves authority to market on or after January 1, 2020, would be eligible for consideration. We agree that a prospective, rather than retrospective, date is appropriate, since part of the basis for providing additional payment is to spur innovation, which industry stakeholders have said has been thwarted.

CMS proposes to exclude from the new add-on payment "at this time" capital-related assets, as defined in the Provider Reimbursement Manual (Chapter 1, Section 104.1)—that is, assets in which a provider has an economic interest through ownership, irrespective of how the asset may have been acquired—on the grounds that the cost of such assets are reflected in cost reports, depreciated over time, and used for multiple patients. CMS cites dialysis machines and water purification systems as examples of capital-related assets. While we understand CMS's concern that such costs need to be accounted for so as not to double pay, we recommend that CMS reconsider the proposed policy, as such equipment represents a large upfront cost, even if depreciated over time.

Outlier Threshold

We propose 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. 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.

Accordingly, based on its review of 2017 data, CMS proposes to reduce both the fixed-dollar loss amount and the Medicare allowable payment for 2020 for adult patients in order to reach the 1 percent outlier threshold. 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 ESRD PPS and take administrative action to address its shortcomings.

Conclusion

Thank you for the opportunity to comment on the 2020 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, we are affected by changes to the ESRD PPS

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