



September 27, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1713-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1713-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) 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; Proposed Rule

Dear Administrator Verma:

The Renal Physicians Association (RPA) is the professional organization for nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. Part of RPA's mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA is writing to offer comments on specific provisions of the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule addressing the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and other ESRD-related policies for calendar year 2020 (CY 2020 Proposed Rule). RPA greatly appreciates CMS' ongoing efforts to improve kidney care in the U.S., and we share the Agency's belief that the need to do so is urgent. However, RPA is concerned that certain policies under the CY 2020 Proposed Rule, if finalized, would have the unintended negative consequence of adversely affecting the care and treatment of patients with kidney disease. Specifically, we have concerns regarding the Proposed Rule's provisions relating to the transitional drug add-on payment adjustment (TDAPA). Our concerns are described below.

The proposed changes to the TDAPA criteria, if finalized, would exclude several types of new and innovative drugs from eligibility for the TDAPA, which, in turn, could lead to unintended negative consequences for patients and would hinder healthcare providers' ability to evaluate and incorporate new medicines into their care plans and treatment protocols for patients. We strongly urge CMS not to finalize the proposed reliance on FDA's "NDA classification codes" as a basis for making TDAPA determinations for new drugs. Such reliance on the NDA classification codes for TDAPA eligibility purposes would be misplaced, as it would be

inconsistent with the stated purpose and meaning of the NDA classification codes themselves, and would run contrary to the purposes of TDAPA as stated in the CY 2020 Proposed Rule (and other CMS rulemakings). We also are concerned that the proposed reliance on NDA classification codes for TDAPA determination purposes would significantly undermine the important goals for kidney care that are reflected in the Administration's Advancing American Kidney Health Initiative (AAKHI).

As stated in the CY 2020 Proposed Rule, the TDAPA is important in order to "help ESRD facilities transition or test new drugs and biological products in their businesses under the ESRD PPS." Under the CY 2020 Proposed Rule's TDAPA provisions, the TDAPA eligibility criteria would be excessively and inappropriately narrowed (and the payment rate significantly reduced). As a result, ESRD facilities would not have the opportunity—for many new and innovative drugs—to incorporate the new treatments into their care plans and to make appropriate changes in their businesses to adopt such products. That result would run directly counter to the stated goals and purposes of the TDAPA as described by CMS in the CY 2020 Proposed Rule. Accordingly, while we understand CMS' desire to ensure that only new innovative therapies are eligible for TDAPA, we respectfully disagree with and do not support the proposal to use the "NDA classification codes" to determine TDAPA eligibility for new drugs since this is not an appropriate or well-suited "proxy" for determining TDAPA eligibility.

The proposed changes to the TDAPA criteria reflect significant differences compared to the TDAPA criteria finalized under the CY 2019 ESRD Final Rule. Stakeholders have been expecting, planning, and preparing since November 2018 for the TDAPA provisions under the CY 2019 ESRD Final Rule; those provisions currently are scheduled to take effect on January 1, 2020. We are concerned that the CY 2020 Proposed Rule would make substantial changes to the previously finalized provisions, and that CMS has proposed to make such changes effective on January 1, 2020. Doing so would provide stakeholders with very little time between issuance of a final rule and the proposed effective date to plan for or adapt to any changes. We urge CMS to re-evaluate and revise both the substance of the proposed changes, as well as the proposed effective date for any changes that may be finalized.

RPA urges CMS not to finalize the proposed changes to the TDAPA criteria under the CY 2020 Proposed Rule, and to instead maintain the CY 2019 Final Rule's eligibility criteria for TDAPA, with an effective date of January 1, 2020.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its continued work on policies relating to the ESRD PPS and other initiatives relating to the payment, quality, and delivery of care of patients with kidney disease. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Robert Blaser at 301-468-3515 or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jeffrey A. Perlmutter" followed by a stylized flourish.

Jeffrey A. Perlmutter, MD
President