



September 3, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1732-P
7500 Security Boulevard
P.O. Box 8010, Baltimore, MD 21244
Mail Stop C4-26-05

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program

Dear Administrator Verma,

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the proposed rule by the Centers for Medicare and Medicaid Services (CMS) to update and revise the Medicare End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for FY21.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Chronic kidney disease affects millions of Americans¹ and if left untreated leads to ESRD, requiring patients to regularly receive dialysis treatment to ensure a functional kidney system. HLC is appreciative of CMS' effort to encourage innovative kidney treatment through new payment mechanisms such as the Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payments for New and Innovative Equipment and Supplies (TPNIES), but we have concerns about post-TDAPA payment policy and that some of the TPNIES requirements to obtain additional payment are too burdensome to meet. HLC offers the following thoughts on the proposed rule:

¹ *End Stage Renal Disease (ESRD)*, Johns Hopkins Medicine (2020), <https://www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-failure>.

Post-TDAPA Payment Policy

HLC supports efforts to create better treatments for the approximately 500,000 Medicare beneficiaries suffering from ESRD.² Providing adequate payment for innovative treatments, such as through the TDAPA, will help accomplish this goal. Equally important for supporting continued access to innovation is the policy that CMS will use to account for new treatments in the ESRD PPS bundled rate in the post-TDAPA period.

CMS is proposing how it will account for the first products (calcimimetics) to go through the TDAPA process. This sets important precedent for how future innovations for ESRD patients may be valued under the ESRD PPS. It is essential the CMS methodology accurately accounts for these therapies within the ESRD PPS after the TDAPA period ends.

CMS is proposing to use utilization data from CY 2018 and CY 2019 to account for calcimimetics in the ESRD PPS base rate, along with the most recent pricing data. CMS should not use CY 2018 utilization data as it fails to capture how innovation has been adopted. Given that new drugs take time to be integrated into clinical practice, CMS should use available utilization data from the most recent 12 months as that information more accurately accounts for the adoption of new innovations. HLC hopes that CMS makes the appropriate changes in this area as the proposed rule's current framework would set a negative standard in how CMS considers future innovation.

Transitional Add-on Payments for New and Innovative Equipment and Supplies (TPNIES)

HLC is concerned that the proposed rule's requirements to receive transitional add-on payments for innovative equipment and supplies is overly burdensome for manufacturers and other stakeholders. In order for TPNIES applications to receive the additional add-on payment, CMS proposes to require extensive data submission to show that the application in question would show a significant clinical improvement for patients. HLC agrees that all applications should show measurable benefits to receive add-on payments, but we are concerned that CMS' analysis does not properly consider the innovative impact of these applications.

HLC recognizes CMS' interest in only granting add-on payments to TPNIES applications that show significant clinical improvement, basing those determinations in part on the outcomes of randomized controlled trials (RCTs). Ensuring that a new therapy is effective before widespread implementation is important, but the difficulty in treating patients suffering from ESRD often prevents such robust RCTs. Allowing for additional information, such as real-world evidence to be considered in add-on payment determination will allow for new therapies to be developed while still maintaining strong protections for patients. HLC hopes that CMS will further clarify the types of data that can be submitted to receive a positive TPNIES application determination and recognize the benefit of diverse datasets.

HLC believes that providing traditional add-on payments will foster stakeholders to create additional innovative treatments. We encourage CMS to carefully examine pending TPNIES applications and approve those that have evidence pointing to significant clinical improvements so other stakeholders will decide to participate in the application process.

² *Medicare Advantage: What is Changing for Beneficiaries with End-Stage Renal Disease (ESRD) in 2021?*, America's Health Insurance Plans (March 12, 2020), https://www.ahip.org/wp-content/uploads/202003_AHIP-MA_ESRD-v03.pdf.

HLC appreciates CMS' commitment to supporting innovative treatments for patients suffering from ESRD. Ensuring that both the post-TDAPA payment policy and the TPNIES recognizes the value of innovation will ensure that manufacturers and other stakeholders participate in developing new treatments and create a sustainable reimbursement framework in the future. Should you have any questions please contact Tina Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" and last name "Grealy" being the most prominent parts.

Mary R. Grealy
President