



May 30, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

Thank you for your outstanding and thoughtful leadership of the Centers for Medicare and Medicaid Services (CMS).

The Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American healthcare and serves as 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. Members of HLC – the nation's leading hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies – advocate measures to increase the quality and efficiency of healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine. We also strongly believe in the use of consumer choice and competition to enhance value.

HLC supports value-based payment systems which seek to better align incentives and improve care quality. As the healthcare delivery system transitions to more bundled payment systems, it is important that such payment systems include mechanisms that allow the adoption of clinical innovations that benefit patients through improved outcomes. When the End Stage Renal Disease (ESRD) bundle was implemented in 2011 without a mechanism to recognize newly approved therapies, we were concerned that such a bundled payment system would discourage innovation. We sent a letter to CMS on August 24, 2015 regarding the ESRD Prospective Payment System (PPS) proposed rule [CMS-1628-P], recommending that the agency adopt a new mechanism in a way that would promote future innovation in ESRD medical therapies and set a precedent of supporting the adoption of clinical innovations in future Medicare payment bundles. Therefore, we were encouraged when CMS finalized a policy, the Transitional Drug Add-On Payment Adjustment (TDAPA) in 2015 that established a framework for considering new and innovative treatments in dialysis care and provided a process to promote investment in innovations that improve patient care.

More recently in our ongoing dialogue with the agency, we have prioritized and highlighted inefficiencies that serve as roadblocks to improving quality and access to healthcare. In particular, we have identified the assignment of Healthcare Common

Procedure Coding System (HCPCS) codes on an annual basis as an operational hurdle that unnecessarily delays patient access to new drugs. Instead, we believe CMS should issue codes more frequently, on a quarterly basis, to ensure Medicare patients have quick access to innovative treatments.

The Food and Drug Administration (FDA) recently approved the first new treatment in more than a decade for adults with Secondary Hyperparathyroidism on hemodialysis. However, there is no mechanism for Medicare reimbursement of this new therapy until CMS assigns a product specific HCPCS code. CMS should assign a temporary code as soon as possible to ensure Medicare patients have access to new innovations, which is vital to promoting future innovation and ensuring that the agency is working efficiently for America's seniors and patients with chronic debilitating diseases such as ESRD.

Thank you for your consideration of this important issue. HLC looks forward to continuing to work with you. If you have any questions, please do not hesitate to contact Debbie Witchev at (202) 449-3435.

Sincerely,

A handwritten signature in cursive script, reading "Mary R. Grealy". The signature is fluid and elegant, with a prominent initial "M" and a long, sweeping tail on the "y".

Mary R. Grealy
President