Congress of the United States

Washington, DC 20515

October 2, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

As co-chairs of the Congressional Kidney and Health Care Innovation Caucuses, we share your goal of improving care and expanding access to innovative drugs and devices for patients with kidney diseases. To that end, we are encouraged that the Centers for Medicare & Medicaid Services (CMS) calendar year 2024 end-stage renal disease (ESRD) prospective payment system rule includes new payments for innovative drugs. However, as you work to finalize the rule, we wish to highlight concerns from across the kidney stakeholder community—including patients, providers, and innovators—that the proposal does not sufficiently reimburse for new, innovative products.

More than one in seven Americans live with kidney diseases, including over 800,000 people with kidney failure, for which there is no cure. For over 50 years, Congress has recognized the unique needs of these patients by allowing them to enroll in Medicare regardless of age, resulting in life-saving treatment for millions of people across the country.

Because Medicare is the primary payer for ESRD care, how it pays for kidney drugs, devices, and other medical products for ESRD patients has a significant impact on innovation and the extent to which investors, researchers, and companies pursue development of new, cutting-edge treatments. As Congress and successive administrations have recognized through the bipartisan KidneyX initiative, there has not been sufficient innovation when it comes to treating individuals with kidney diseases. KidneyX seeks to stimulate and accelerate innovation in this area. If Medicare does not pay for innovation, it will undermine the long-term goals of improving care and reducing Medicare costs.

CMS has rightly acknowledged that there may be insufficient funding in the current bundled payment to support long-term adoption of innovative products and has, as a result, taken action to impose two-year temporary add-on payments for drugs (TDAPA) and devices (TPNIES) to address this problem. Furthermore, CMS' most recent proposal includes three years of additional payments for drugs following the end of the TDAPA period to "support Medicare ESRD beneficiaries' continued access to new renal dialysis drugs and biological products."

We support CMS' efforts to construct a sustainable, long-term reimbursement for innovative treatments for ESRD patients. As CMS works to finalize its proposal, we urge you to consider concerns from patients, providers, and companies who have received TDAPA or TPNIES payments. These concerns include:

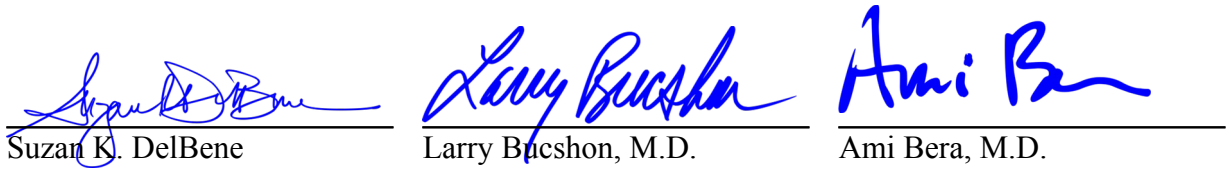
- Time Period: Ending additional payments for drugs after five years and devices after two years may create disincentives for providers to incur the costs of the new product. The Medicare Payment Advisory Commission now estimates that dialysis facilities will have negative margins for 2023, and it is unclear how these current programs or the proposed post-TDAPA add-on payment could support the permanent adoption of a product given low and sometimes negative Medicare margins. Without certainty that new products will be accessible to patients once reimbursement drops, providers may hesitate to adopt new products and investors may prioritize other areas with higher potential financial returns. We would also appreciate more information on why additional add-on payments were proposed for drugs but not devices.

- Sufficient Payment: While we appreciate the importance of the current bundled payment system to promote high-quality and efficient care, we are skeptical that the proposed post-TDAPA add-on payments would, in many cases, sufficiently reimburse for new, innovative products. For example, the proposed rule indicates that using available data for the current TDAPA product, CMS' methodology would result in a nine-cent increase to the base rate for all dialysis patient claims, regardless of whether they use the product or not. Although we are not suggesting a specific reimbursement amount for a particular product, we share concerns that such a low add-on payment, paired with low or negative Medicare margins, may not support access to new drugs. This is especially true in cases when only a small portion of ESRD patients medically require a given treatment.

- Implementation: We have heard concerns from drug and device makers that are currently participating in TDAPA and TPNIES that implementation challenges may have reduced product adoption. For example, the maker of the current TPNIES product shared with us that the Medicare Administrative Contractors (MACs) continued to deny or not process claims nine months into the program, which in part led to much lower adoption than CMS anticipated in the product's first TPNIES year. The early success of participants in these programs is critical to ensure we do not discourage future participation.

We request a briefing for our staff on the status of and proposed changes to TDAPA and TPNIES as soon as is practicable. Thank you for your consideration.

Sincerely,



Suzan K. DelBene
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Ami Bera, M.D.
Member of Congress