BENJAMIN L. CARDIN
MARYLAND

www.cardin.senate.gov

509 HART BUILDING
WASHINGTON, DC 20510–2004
(202) 224–4524

TOWER 1, SUITE 1710
100 S. CHARLES STREET
BALTIMORE, MD 21201
(410) 962–4436

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April 19, 2019

The Honorable Alex Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Azar and Administrator Verma:

We are writing to begin a dialogue with you regarding the Medicare End-Stage Renal Disease (ESRD) program and the need for administrative actions to maintain its long-term stability for patients and providers.

We encourage the Centers for Medicare and Medicaid Services (CMS) to take administrative steps to ensure that the ESRD Prospective Payment System (PPS) promotes innovation, quality, and care coordination. We feel strongly that CMS must take additional steps to ensure that policies designed to promote the development and availability of innovative ESRD drug and biological therapies achieve those goals. Consistent with the Department of Health and Human Services' December 2018 Request for Information (RFI) on care coordination improvements, CMS should adopt policies to facilitate the exchange of information between hospitals and providers involved in an ESRD patient's care. Finally, in keeping with the Administration's commitment to reducing administrative burden on providers, we recommend that CMS better align requirements under its ESRD quality improvement initiatives. Each of these issues is described in greater detail below.

Defer most patient-level case-mix adjusters until methodological issues are addressed. With the exception of the onset of the renal dialysis adjuster, persistent methodological issues have diminished the case-mix adjusters' validity and reduced reimbursement under the ESRD PPS. In addition to MedPAC, numerous stakeholders have on multiple occasions raised concerns about the case-mix adjusters. We urge CMS to adopt recommendations that ensure valid and appropriate methodology, consistent with the provisions introduced in legislation last session and that we plan to reintroduce this year.

Adjust the base rate when truly innovative drugs and biologicals are added to the ESRD bundle, if the base rate does not already cover the cost of the product. One concern we have heard from stakeholders is whether adequate incentives are in place to promote the development and inclusion of truly innovative drugs and biologicals in the ESRD bundle. While we expect CMS to incorporate new drugs or biologicals into the ESRD bundle over time, we also urge CMS to make sure that when new drugs or biologicals are added to the bundle, the costs of such items are appropriately incorporated into the bundled payment rate. CMS should also ensure that

the dollars added to the PPS for such drugs or biological "follow the patient" to make sure the incentives are structured to protect patient access. Such a policy is particularly important if the drug or biological is used for a small subset of patients. We urge CMS to consider these concerns and engage with stakeholders to make sure appropriate incentives are in place to protect patient access.

Establish clear rules that facilitate hospitals' sharing of clinical and other data with providers involved in an ESRD patient's care. It has come to our attention that dialysis facilities often face challenges in obtaining clinical and other data from hospitals necessary to ensure effective post-hospitalization care for ESRD patients. This data sharing appears to work well when ESRD patients provide hospitals with the names of their dialysis facilities and nephrologists. Unfortunately, this exchange of contact information does not always occur, resulting in the delayed transfer of crucial discharge summaries, laboratory results, and other post-hospitalization instructions. We encourage CMS to clarify that hospitals must share information with providers involved in an ESRD patient's care by sending them appropriate data to enhance care coordination.

Achieve Better Alignment Between ESRD Quality Improvement Initiatives. There is no doubt that quality improvement initiatives such as the ESRD Quality Incentive Program (QIP) and Dialysis Facility Compare (DFC) have enhanced care value and outcomes. Unfortunately, achieving their full potential has been hindered by overlap and inconsistencies between the initiatives. Similar to the case-mix adjusters, various stakeholders, including MedPAC, dialysis providers, and patient and caregiver groups have conveyed their concerns that the quality improvement initiatives' structures have undermined patients' trust in the information and resulted in unnecessary burden and inefficient use of dialysis facility resources. To rectify these issues, CMS should encourage the use of meaningful, uniform, outcome-based measures.

ESRD is a challenging condition physically, emotionally, and financially. With all they must endure, ESRD patients and their families deserve to know that Medicare will be there for them in their time of need. We encourage CMS's swift action to update the ESRD PPS to keep pace with innovative clinical developments and patient need, and we hope to continue this dialogue with you and your staff.

Sincerely,

Benjamin L. Cardin
United States Senator

Roy Blunt
United States Senator