Congress of the United States
Washington, DC 20515

October 17, 2019

The Honorable Alex Azar
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 urge the Centers for Medicare & Medicaid Services Innovation Center (Innovation Center) to address several serious design issues before implementing its proposed ESRD Treatment Choices (ETC) mandatory demonstration.

We strongly support your efforts to finally address the dire need to change the delivery of kidney care and share your wishes to see the model succeed and have patient outcomes demonstrate that success. We agree that increasing the number of patients choosing home dialysis and receiving a kidney transplant are laudable goals but fear these goals will not be met unless meaningful changes to the model are made. We ask that the Innovation Center to address the following issues before implementation of the model:

1. **Recognize and support a patient's treatment modality propensity and personal decision**. The model seeks to incentivize nephrologists and facilities to place patients on home dialysis but has a flawed metric to determine a patient's propensity for home dialysis and does not account for patient choice. We recognize that historically uptake of home dialysis has been minimal in part due to the existing reimbursement structure of dialysis and understand the Innovation Center's attempt to correct this. The model as proposed uses the CMS hierarchical condition category (CMS-HCC) risk scores to determine a patient's propensity to use home dialysis. We recommend that CMS replace this risk score with a metric that accounts for a patient's clinical status, including activities of daily living, as well as their ability and willingness to use home dialysis. This metric should be designed in such a way to properly align payment incentives with the best modality for the patient.

2. **Align the demonstration's scope with testing a new payment model.** Congress has always been concerned with the scope of any Innovation Center demonstration project. We ask the Innovation Center to minimize the number of providers to as few needed as possible to

transplant rates separately or develop an alternative to ensure an adequate sample in a smaller segment of the country.

3. **Ensure that Medicare rules do not preclude providers from working together.** The Innovation Center already has the authority to grant waivers to Stark and anti-kickback laws. We ask that the Innovation Center offer these waivers, when appropriate, in the ETC model to allow for providers to meaningfully coordinate care and improve the patient experience.

4. **Address organ supply issues before holding providers financially accountable for transplant rates**. Under current law, many of the barriers to transplant cannot be overcome solely by dialysis facilities or nephrologists. Today, roughly 19,000 kidneys become available annually, while more than 100,000 patients are awaiting a kidney transplant. We ask that the Innovation Center develop metrics that would hold facilities accountable for their rates of referral for a transplant workup and patient waitlist status, which are steps the Innovation Center can take now to ensure providers are meeting their responsibility to prepare patients for transplant. Such metrics should recognize clinical eligibility for transplant and patient choice, including religious exemptions for patients. Holding providers accountable for their roles in the transplant process should be paired with holding the organ procurement organizations accountable with the new performance metric being proposed in the Hospital Outpatient Prospective Payment System for Calendar Year 2020. If the supply of transplantable organs doesn't increase, providers will be unable to improve their transplant rates.

5. **Patient Satisfaction.** Patient satisfaction is crucial to determine provider performance and we are concerned by the ETC model's lack of a formal measure of the beneficiary experience. We agree with Medicare Payment Advisory Committee's recommendation to establish a formal means to assess beneficiary experience and satisfaction, such as developing a home dialysis CAHPS instrument.

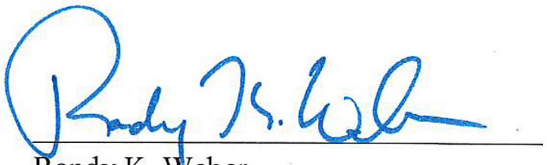
Again, we want to see the ETC model succeed and for kidney care to truly be revolutionized. We fear that without the changes presented above, the demonstration will not achieve its desired goals we all share. Prior to finalizing the model, we would appreciate a written response that outlines the Innovation Center's plan to address these design issues in a final rule and the plan's impact on the model's proposed implementation date. We look forward to working with the Innovation Center and kidney care stakeholders to protect ESRD patients' treatment modality choices while promoting home dialysis and transplants. Thank you for your consideration and thank you for your commitment to ESRD beneficiaries and Medicare's sustainability.

Sincerely,

Suzan K. DelBene
Member of Congress

Larry Bucshon, M.D.
Member of Congress

David P. Roe, M.D.
Member of Congress



Randy K. Weber
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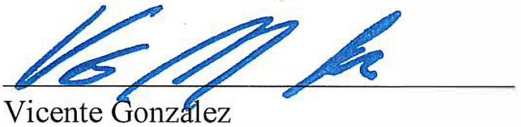

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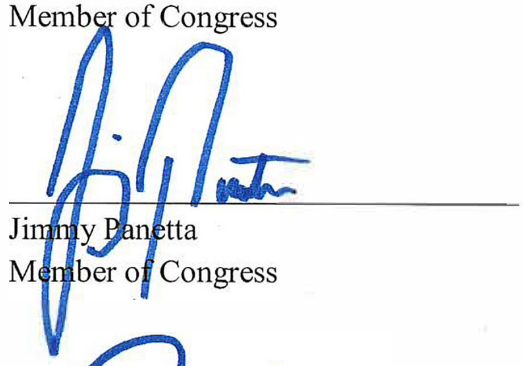

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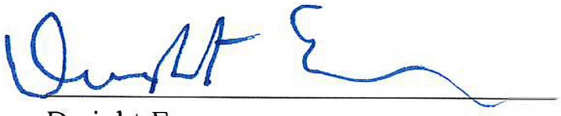

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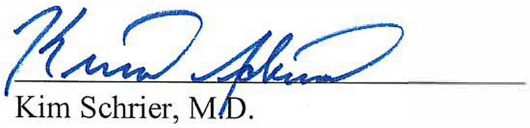

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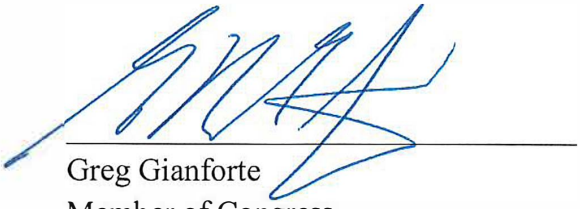

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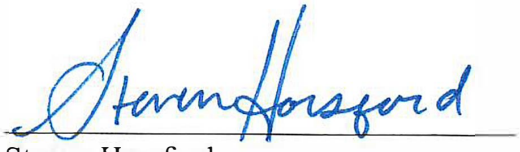

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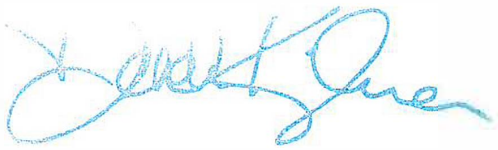

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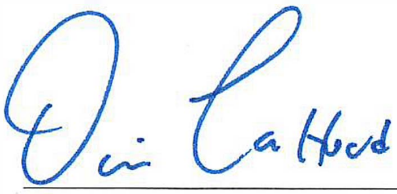

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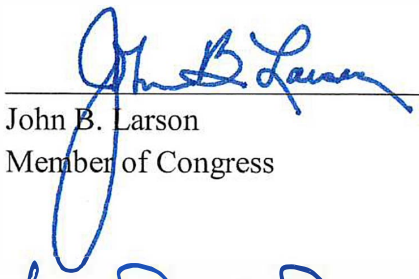

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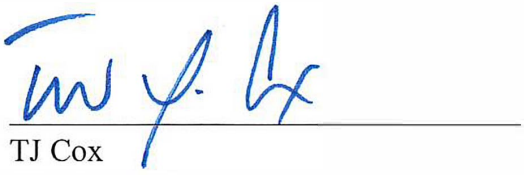

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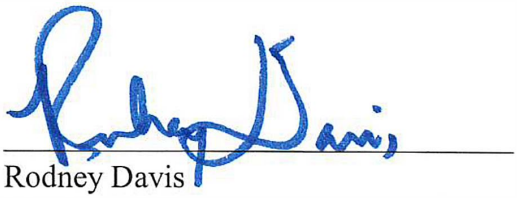

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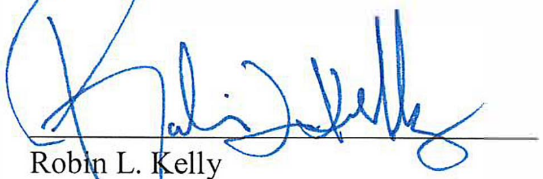

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