KIDNEY CARE PARTNERS

September 11, 2018

Mr. Ross Bowling, Ph.D.
KidneyX
200 Independence Avenue SW
Room 624D
Washington, D.C., 20201

Re: Kidney X Request for Information #1

Kidney Care Partners (KCP) appreciates the opportunity to provide a response to the request for information regarding how the Kidney Accelerator (KidneyX) project can best spur innovation in preventing, diagnosing, and/or treating kidney diseases. KCP is an alliance of members of the kidney care community that includes patient advocates, kidney care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.[1]

KCP supports the efforts to incentivize innovation in the treatment of ESRD and commends the commitment by Department of Health and Human Services (HHS) to this goal, as evidenced by the launch of the KidneyX project. When HHS launched it, Bruce Greenstein, then HHS Chief Technology Officer, indicated that "KidneyX will create a sense of urgency in the innovator community by spotlighting the immediate needs of patients and their families."[2] He further noted that:

> KidneyX is designed to accelerate the development of drugs, devices, biologics and digital health tools spanning **prevention, diagnostics, and treatment** with the aim of giving patients with renal failure better treatment options and ultimately, to reduce the need for dialysis.[3]

Most importantly, he promised that HHS would prioritize patients' access to clinical innovation. He recognized that for those living with kidney failure and relying upon dialysis treatment the innovations seen in other areas of health care had passed them by. "Some 30 million Americans suffer from kidney disease, yet the solutions are nearly identical to what they were decades ago."[4]

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[1] A list of KCP members is provided in Appendix A.
[2] Bruce D. Greenstein, "KidneyX: A new wave of innovation to treat kidney disease," HHS Blog (April 26, 2018) (*available at: https://www.hhs.gov/blog/2018/04/26/kidneyx-new-wave-innovation-treat-kidney-disease.html).*
[3] *Id.*
[4] Bruce D. Greenstein, "Putting patients at the center of KidneyX," HHS Blog (May 16, 2018) (*available at: https://www.hhs.gov/blog/2018/05/16/putting-patients-at-the-center-of-kidneyx.html*).

KCP agrees and is pleased that HHS has launched this effort to promote innovation. Our members have been supporting and advocating for federal policies that would address this problem. While these efforts have included advocating for early detection, increased patient education through the Chronic Kidney Disease (CKD) Education Benefit, and developing innovative payment models that support care coordination, the root of the lack of innovation in this space is the fact that the current payment system stifles innovation. The lack of the potential for new money for new technology within the ESRD PPS bundle for advances in this area keeps investors from investing and companies from innovating in this space. To ensure the success of KidneyX , it is crucial that sensible payment policies be implemented. The comments that follow reflect this shared goal.

CMS has an opportunity in this rulemaking, as it refines the drug designation process, to support the Department's efforts and incentivize the development and integration of new technology for the care of dialysis patients. KCP asks CMS to balance the pressures of reducing drug costs with the desperate need for innovative treatment options in this population to ensure patients with kidney failure who rely on dialysis – and Medicare – to stay alive are not left out of the future that medical innovation promises.

In addition to responding to the four questions outlined in the RFI, KCP asks that HHS not only consider ways to accelerate innovation, but also to be sure that once the innovation happens the Medicare payment policies are structured in a way that supports its adoption. If payment policies do not support innovation, the efforts of KidneyX will not become a practical reality. One of the biggest challenges we hear from innovators is that investors will not invest in any product that would be used primarily in the ESRD space because the Medicare program payment policies stifle innovation.

I. Current unmet needs

KCP is excited about the opportunities that KidneyX may provide to innovators. We believe that innovation should focus on those areas of drug, device, and service (including diagnostics) that will improve the outcomes and quality of life for patients with kidney disease. The specific areas include for kidney failure patients relying upon dialysis:

- Fluid removal
- Vascular access
- Renal replacement technology

We also recommend focusing on potential interventions that could be used with patients with chronic kidney disease (CKD). The specific areas for CKD patient should include slowing the progression of renal disease.

II. Obtaining a broad range of innovators participating in KidneyX

The Medicare payment system needs to be improved. The current policies disincentivize the development of new products because there is no pathway for truly innovative drugs that fall within existing "functional categories" to be adequately reimbursed. This lack of a payment pathway is particularly problematic when it comes to attracting innovators who are not familiar with the kidney care space. Innovators not only need seed money and support to develop products, but almost more importantly a clear pathway for adoption of the product.

In our August 10, 2018, letter, KCP provided detailed comments about how the ESRD PPS payment needs to be modified to support this commitment to innovation. In that letter, we support applying Transitional Drug Add-on Payment Adjustment (TDAPA) to new renal dialysis drugs and biologicals that are not defined as generics or biosimilars (using the FDA definition of those terms). We also recommended that CMS learn from the problems experienced in the hospital outpatient setting and rely upon the Average Sales Price (ASP)+6 percent for the TDAPA rate and that CMS obtain two full calendar years of claims data before determining whether to fold a new renal dialysis drug into the ESRD PPS.

KCP members continue to experience difficulties with the implementation of TDAPA, particularly related to the transition of oral drugs from payment under Medicare Part D to Medicare Part B and ask that CMS assist in resolving these problems given that calcimimetics remain under TDAPA for at least one more year. Problems like these should be eliminated as quickly as possible to provide confidence to innovators to provide confidence that there will be a clear payment pathway that supports adoption of the product.

In the August 10, 2018 letter, KCP recommends a modified approach to how CMS evaluates new renal dialysis drugs and biologicals for purposes of including them in the ESRD PPS bundle. These recommendations seek to create incentives for truly innovative products and not reward only minimal changes in products. We believe that without changes to the drug designation process, there will be extremely limited interest by investors and manufacturers in developing truly innovative products for patients who must rely on dialysis treatments.

In sum, KCP recommends the following methodology for evaluating renal dialysis drugs and biologicals:

- First, consistent with KCP's recommendations around TDAPA, generics and biosimilars (as defined using the FDA's definition) should be folded into the existing functional categories without new money.

- Second, CMS should assess, based upon the utilization and prescribing data collected during the TDAPA period, whether the drug is provided to the average patient, which CMS uses to define the scope of the bundle.[5] If only a small portion of patients use the product, then it should not be added to the bundle. Incorporating such products into the bundle would create the wrong incentives. Providers who use the product will always be reimbursed less than it costs to provide and providers who do not use the product will receive a windfall (albeit a small one). Bundling a product that is medically necessary for only a small percentage of patients only disincentivizes its use.

- If the utilization is such that the renal dialysis drug or biological should be bundled, KCP supports adding new money to the bundle when a new renal dialysis drug or biological that is not in an existing functional category is incorporated.

- However, KCP outlines in the August 10, 2018, letter, that it is not appropriate to assume that the bundled base rate is sufficient to support adding new renal dialysis drugs and biologicals if CMS determines they are in existing functional categories. New money should be added to the bundle for new drugs and biologicals that CMS determines are in existing functional categories,[6] when the new products can be differentiated – shown to be truly innovative – from existing therapies. KCP recommends that CMS look at the following factors to determine when a new renal dialysis drug or biological is differentiated from existing products to warrant new money be added to the ESRD PPS base rate. Specifically, the renal dialysis drug or biological achieves one of the following priorities:

    - Fills a treatment gap (addresses an unmet medical need) for renal dialysis patients.
        - CMS could solicit input from the kidney care community to identify these gaps and use that as a guardrail to ensure the appropriate application of this factor.

        - A subcategory of this factor are drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug's label. There is clearly a treatment gap when the FDA has not approved a product for a specific CKD/ESRD/dialysis-related condition.

[5] 83 *Fed. Reg.* at 34314.
[6] As described below, part of this analysis should include an evaluation of whether the utilization during the TDAPA period supports adding the product to the bundle.

- Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material (including within the clinical pharmacology and study portion of the FDA label, sections 11 and 14 or any other section of product labeling) and that do not fit within a single existing functional category. These drugs and biologicals may offer multiple advantages over existing products.

- Drugs and biologicals that demonstrate a significant improvement in safety over products currently available in the bundle.

- Drugs and biologicals, that based on FDA labeling that, have demonstrated clinical superiority to existing products in the bundle.

- Drugs and biologicals that improve priority outcomes, such as:
  - Decreasing hospitalizations;
  - Reducing mortality;
  - Improving quality of life (based on a valid and reliable tool);
  - Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);
  - Addressing patient-centered objectives (including patient reported outcomes once they are developed and used by the FDA in its review of drugs and biologicals); or
  - Reducing side effects or complications.[7]

In making these recommendations, KCP seeks to help CMS establish clear guardrails that support truly innovative products while protecting the integrity of the bundle.

As noted our August 10, 2018 comment letter, KCP has raised concerns about the functional categories. While we appreciate that they have been part of the ESRD PPS since its inception, the current categories, if applied in a manner that does not acknowledge the development of new products, will stifle innovation to treat the core conditions that dialysis patients experience. Any policy that locks the bundled payment amount at current levels removes any incentive for developers, manufacturers, and investors to innovate in this area. The bundle should be defined, in-line with its original intent, around products that are "associated with the dialytic treatment" to align with this intent. Eliminating the broader scope of the functional categories by further narrowing them and centering the bundle on services and items associated with the dialytic treatment align the ESRD PPS more closely into line with the policies in other Medicare prospective payment systems that do not use functional categories for drugs and biologicals and define the bundle in a manner consistent with the services provided in the dialysis facility under the PPS.

[7]Current legislation being considered by the Congress includes criteria such as these. *See* H.R. 5997 "Ensuring Patient Access to Critical Breakthrough Products Act of 2018" introduced by Reps. DelBene (D-WA), Walorksi (R-IN), Sewell (D-AL), Bilirakis (R-FL), and Cardenas (D-CA).

Additionally, KCP supports developing a policy to provide clarity as to the payment policies related to new renal dialysis drugs. We ask that CMS also provide clarity on how it will incentivize the development of new device that it may determine come within the ESRD PPS. To the extent there is such a device, KCP asks that at a minimum, CMS apply a pass-through payment to new devices when they are determined to be within the bundle and then evaluate them based on the data obtained during that period to determine whether it is appropriate to add them into the bundle and if so whether new money should be added as well. We welcome the opportunity to engage with CMS to develop a more detailed policy. In the short-term, we ask that CMS indicate in the final rule that it will provide such a pathway and work with stakeholders in future-rulemakings to further define it.

Having a clear pathway as outlined above would be an important part of a set of policies that would encourage innovators to bring advances in clinical care in the CKD and ESRD areas.

III. What information could assist innovators not familiar with kidney disease

CMS needs to be clear as to the reimbursement pathway for new drugs, biologicals, devices, and services. A lack of clear requirements that are consistently applied will create uncertainty and drive innovation dollars and talent to other areas of health care where their work has a clear reimbursement pathway. Thus, we recommend that HHS work with CMS to clearly set out the reimbursement pathway and remove barriers to innovation. This information will address any mis-conceptions and eliminate any historic concerns about innovating in this area.

IV. Conclusion

We are grateful for the commitment to innovation in the kidney space made by HHS through KidneyX, and we look forward to working with HHS on policies that can optimize the likelihood of changing the kidney failure treatment paradigm for the better. If you have questions or comments, please contact Kathy Lester at klester@lesterhealthlaw.com or (202) 534-1773. Thank you again for considering our recommendations.

Sincerely,

Allen Nissenson, M.D.
Chairman
Kidney Care Partners

Appendix A: KCP Members

Akebia Therapeutics, Inc.
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Keryx Biopharmaceuticals, Inc.
Kidney Care Council
Medtronic
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Otsuka
Relypsa
Renal Physicians Association
Renal Support Network
Rogosin Institute
Satellite Healthcare
U.S. Renal Care