DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Chief Technology Officer (OCTO)
Plans for the Artificial Kidney Prize; Request for Information
Authority: 15 U.S.C. 3719

REQUEST FOR INPUT

This Request for Information (RFI) from the Office of the Chief Technology Officer (CTO) at the U.S. Department of Health and Human Services (HHS) asks for your feedback on the intent to issue a new KidneyX prize competition, to fulfill goals set forth by KidneyX and Section 6 of Executive Order 13879 'Advancing American Kidney Health' (84 FR 33817) signed by the President on July 10, 2019. KidneyX, established in April 2018, is a public-private partnership between HHS and the American Society of Nephrology (ASN). HHS and ASN are holding a series of KidneyX prize competitions to advance development of innovative solutions to better prevent, diagnose, and treat kidney diseases. KidneyX's goal is to improve quality of life for people living with kidney diseases.

HHS, in partnership with ASN, intends to launch the Artificial Kidney Prize (hereafter referred to as "the Prize") in April 2020, subject to the availability of funds and final agency approval. The Artificial Kidney Prize is designed to build on the goals of Redesign Dialysis and further advance the development of an artificial kidney that can replace enough physiological kidney function to sustain life and improve patient quality of life. The competition is anticipated to run for up to four years and offer substantial financial rewards for meeting the goals.

The Prize will be separated into two tracks. The first 'moonshot track' will offer a substantial reward for completion of ambitious milestones for integrated devices, with the goal to advance more solutions into human trials.

The second 'modular track' will seek solutions to specific and discrete problems whose solution would benefit multiple approaches. The intent is to offer concurrent challenges, as needs arise and whose duration will vary according to the complexity of the problem.

We are particularly interested in your input on the following questions. Additionally, any other relevant comments are appreciated.

1. How would you prioritize the modular challenges described in section I.C, Scope of the Prize Competition? Are there additional challenges that should be considered?
2. For patients and care partners: What criteria should the Artificial Kidney Prize use for judging a solution's ability to improve the quality of life for patients?

3. What criteria would you propose for award of the moonshot prize, to both ensure that all promising approaches are considered on their merits and that the field advances beyond the current state towards human testing of an artificial kidney?
4. What forms of technical or operational support would enable you to participate, or accelerate your development timeline, in either track of the Artificial Kidney Prize?
5. If you entered the Artificial Kidney Prize, would you be more interested in participating in the moonshot track or modular track? What would you consider in deciding which track to enter?

Solutions for the challenges in the modular track will be judged separately from solutions for the moonshot track. This is designed to encourage participation from adjacent and outside domains and create greater levels of collaboration across domains.

See Section I of this RFI for details on the intent of the Artificial Kidney Prize. HHS will take comments into consideration as it continues to develop the scope, rules, and budget for this competition.

Section II provides current summaries of the FDA and CMS regulatory, coverage, and payment landscape, highlighting in particular recent changes that may impact the development of, investment in, and adoption of an artificial kidney. We have provided this information as reference to better inform responses to the design and specifications of the Artificial Kidney Prize.

DATES

The period for comments begins with the publication of this document. Submissions must be received on or before 12/13/19, to be considered.

SUBMISSIONS

You may submit comments, identified by the title, "KidneyX Prize Comment" by:

E-Mail: please send responses to KidneyX@hhs.gov.
Mail: please send mail to KidneyX, c/o Office of the Chief Technology Officer, 200 Independence Avenue SW, Room 624D, Washington, D.C., 20201
Please submit comments by one of these methods.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the

preparation of any information submitted or for its use of that information.
Responses may be compiled and shared publicly in an unedited version after the close of the comment period. Please do not include any proprietary, classified, confidential, or sensitive information in your response. The Government reserves the right to use any non-proprietary technical information in summaries of the state of the science, and any resultant solicitation(s). HHS may use information gathered by this RFI to inform development of future guidance and policy directions.

We look forward to your input and hope you will share this RFI with your colleagues. We invite everyone to respond but are particularly interested in hearing input from people living with kidney disease, potential participants to this challenge, clinicians and others in the dialysis community.

FOR FURTHER INFORMATION
Contact Sandeep Patel, PhD; KidneyX@hhs.gov; 202-205-0355.

SECTION I. ARTIFICIAL KIDNEY PRIZE NOTICE OF INTENT

A. Background
KidneyX is a public-private partnership between HHS and ASN formed to catalyze innovation in the prevention, diagnosis, and treatment of kidney diseases. HHS and ASN are running a series of KidneyX prize competitions to support companies, teams, or individual innovators that have promising solutions or technologies that can prevent, diagnose, and/or treat kidney diseases. Information about the first, completed KidneyX prize competition, Redesign Dialysis Phase 1, can be found on the KidneyX website. The website also contains information about the current ongoing prize competition, Redesign Dialysis Phase 2, which is accepting submissions through January 31, 2020.

KidneyX is an integral component of the larger HHS commitment to reduce the number of people developing kidney failure, increase patient choice regarding treatment alternatives, and also increase the number of kidneys available for transplant, in support of the Administration's focus on advancing kidney health.

B. Overview of the Proposed Artificial Kidney Prize
HHS and ASN plan to launch the KidneyX Artificial Kidney prize competition in April 2020 (subject to availability of funds and final agency approval), divided into two distinct but interrelated tracks. The first, the 'moonshot track,' will aim to demonstrate a wearable or

implantable solution that replicates those physiological kidney functions necessary to sustain life while increasing the quality of life for people experiencing kidney failure. Another way of expressing the aim is to produce artificial equivalents to a kidney transplant without the need for immunologic suppression and with minimized use of anti-coagulation. This competition is anticipated to run up to 4 years; it is intended to catalyze efforts to create an artificial kidney by setting clear targets and providing substantial funding to winners.

In addition to establishing long-range targets for developing an artificial kidney through a moonshot track, this prize competition will seek to solve more discrete, cross-cutting scientific and engineering problems whose solutions may originate from either within or beyond the kidney disease research and development community and will likely benefit the development of an artificial kidney through the moonshot track. These smaller independent challenges will be administered concurrently over the course of the moonshot track. Their duration will vary according to the complexity of the problem, but are anticipated to be shorter than the moonshot track, with each challenge being judged at its completion and awards being distributed after winners are selected.

These modular challenges are also intended to encourage experts and entrepreneurs from multiple domains and disciplines to become involved in this important work, leading to a more dynamic, robust, and collaborative environment in the care of people living with kidney diseases. HHS and ASN will encourage participants and winners of the modular challenges to collaborate with participants in the moonshot track, to expand information flows with the intent to accelerate development of artificial kidney technologies.

C. Scope of the Prize Competition

This proposed KidneyX prize competition will have a primary 'moonshot track' for developing a functional wearable or implantable artificial kidney, and a secondary 'modular track' identifying additional technical challenges whose solution will advance the development of multiple approaches.

For the moonshot track, winning submissions are anticipated to replicate enough of the following kidney functions to sustain life and improve the quality of that life for patients. Kidney functions are as follows, referenced from the KHI '[Technology Roadmap for Innovative Approaches to Renal Replacement Therapy.](#)'

- **Blood Filtration** (filtering blood to remove waste and excess fluid)
- **Electrolyte Homeostasis** (maintaining appropriate levels of key minerals in the blood)
- **Fluid Regulation** (regulating the amount of and/or removing excess fluid)

- **Toxin Removal and Secretion** (limiting or preventing toxins in the bloodstream)
- **Filtrate Drainage and Connectivity** (removing excess filtrate after processing; connectivity issues for filtration, processing, and exterior drainage)
- **Endocrine Functions** (secretion of hormones and humoral factors, including local autocrine and paracrine molecules)

Specific criteria for patient quality of life will be determined by patient input (as well as by patient and care partner feedback to this RFI); they will likely align with the priorities identified in the Kidney Health Initiative's Patient Edition of the Renal Replacement Therapy Roadmap, including:

- Minimized impact on family and social life
- Ability to be more physically active
- More freedom to work and travel
- More treatment choices and options based on lifestyle or life stage
- A less restrictive diet, with greater freedom to eat and drink what you want
- Fewer pill to take
- Fewer side effects or complications like fatigue, nausea, dizziness, infection, cramping, and depression or other mental health issues
- Less time spent in the hospital or undergoing procedures
- Reduced financial impact

The posting and scope of the modular challenges will vary by the complexity of each problem. They will be identified based on current technical gaps facing the medical product development community, needs or functions desired by patients, or otherwise identified as areas of need by HHS and ASN. The following are some of the currently known and long-standing engineering challenges creating barriers to the development of an artificial kidney. This RFI seeks input on how to prioritize the following list, keeping in the mind the ultimate goal is to create an artificial kidney that improves quality of life. HHS and ASN intend to run at least four modular challenges as part of the initial launch of the Artificial Kidney Prize.

- Develop vascular access with internal connection to the native vasculature that maintains patency without the need for systemic anticoagulation, maintains acceptable infection risk, and minimizes bleeding risk
- Develop technologies to detect and proactively mitigate clotting
- Develop "smart" filters, mixed-matrix membranes, or blood sorbents capable of binding/adsorbing uremic toxins
- Develop integrated renal tubular replacement units that performs active ion transport activities

- Develop a size-selective, non-clotting filter that is capable of 40L/day filtrate with 12–24 months of continuous performance
- Develop integrated systems that use sensor input to adjust fluid removal as part of a closed-loop system
- Develop toxin removal and secretory functionality of implanted cell-based systems in vivo
- Develop solutions for handling removed fluid and solutes
- Develop solutions for removing microbubbles or gases
- Develop solutions for plumbing of an artificial kidney to the urinary tract
- Develop solutions to reduce or eliminate water utilization

D. Anticipated Rules for the Prize Competition

Anticipated Prizes:
Currently, it is anticipated that the total prize purse for the Artificial Kidney Prize competition will be substantially higher than previous efforts under KidneyX, the majority of which will be dedicated to the moonshot track winners, with 50% dedicated to the first place winner, 30% to the second place winner, 10% to a third place winner, and the remaining 10% dedicated for modular track challenges. HHS and ASN anticipate the availability of additional funds toward new modular track challenges as needs arise.

Anticipated Submission Requirements:
For the moonshot track, HHS and ASN will announce submission requirements before submissions open. For each modular challenge, it is anticipated that HHS and ASN will seek demonstration that a prototype can perform the stated function, an explanation for assessing the prototypes' safety, a description of what scientific and/or engineering advancements led to that solution, and a description of how this technology can be integrated with others towards the goals for the moonshot track. Specific submission requirements are anticipated to vary; these requirements will be determined ahead of each challenge's launch.

All competitions run under the Artificial Kidney Prize are anticipated to be open to the public, in accordance with the America COMPETES Act prize authority.

Anticipated basis upon which winners will be selected:
For each challenge run as part of this prize competition, a multi-disciplinary judging panel will review submissions, and an authorized official will select the winners from the submissions received. If submissions require specific subject matter expertise not represented by the

judging panel, then the panel will invite additional experts to provide input as necessary.

Judging criteria for the moonshot are to be determined, but are anticipated to be drawn from the *Kidney Health Initiative's Technology Roadmap for Innovative Approaches to Renal Replacement Therapy*. Specific judging criteria for each modular challenge will be determined ahead of that challenge's launch.

Anticipated Eligibility Rules:
To be eligible to win a prize in the Artificial Kidney Prize competition, an individual or entity—
(1) Shall have registered to participate in the prize competition;
(2) Shall have complied with all the requirements set forth in this announcement for participation in this prize competition;
(3) For any prize money from HHS - In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. Note: Non-U.S. citizens and nonpermanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria but will not be eligible to win a monetary prize (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized when results are announced. For any prize money from ASN, which is jointly sponsoring this prize competition, non-U.S. citizens and nonpermanent residents may be eligible to win a monetary prize – ASN would be responsible for determinations of eligibility for prizes that it awards directly;
(5) Shall not be an HHS employee;
(4) Shall not be a Federal entity or Federal employee acting within the scope of their employment (all non-HHS federal employees must consult with their agency Ethics Official to determine whether the federal ethics rules will limit or prohibit acceptance of a KidneyX prize);
(6) Federal grantees may not use Federal funds to develop submissions unless consistent with the purpose of their grant award; and
(7) Federal contractors may not use Federal funds from a contract to develop KidneyX prize competition applications or to fund efforts in support of a KidneyX prize competition submission.

SECTION II. CURRENT FEDERAL REGULATORY, COVERAGE, AND PAYMENT LANDSCAPE

There have been a number of recent changes to the regulatory, coverage, and payment provisions at the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) that will likely impact the development of, investment in, and adoption of an artificial kidney. The following highlights and summarizes these provisions for the benefit of the entire community.

FDA Breakthrough Device Program

The U.S. Food and Drug Administration (FDA) has reviewed its Breakthrough Device Program criteria in regard to its applicability to devices that replicate kidney functions. This review is particularly relevant to participants in KidneyX prize competitions: FDA believes that all products focused on the development of a wearable or implantable artificial kidney will likely qualify for breakthrough designation. Benefits of this breakthrough designation include:

- Interactive and timely communications with FDA experts
- Efficient and flexible clinical study design consideration
- Review team support
- Engagement with senior management
- Priority review

FDA encourages sponsors with innovative technologies to engage with FDA early in their product development through FDA's pre-submission programs. The Breakthrough Device program focuses on devices that treat or diagnose a life-threatening or irreversibly debilitating condition, as well as meeting other criteria, and offers sponsors/manufacturers an opportunity to interact with FDA experts and to work collaboratively on design and premarket issues. Open dialogue and the ability to provide valuable feedback to the sponsors in a timely manner will streamline the regulatory paradigm with the goal of allowing alternative innovative technologies to reach patients sooner.

FDA Expedited Programs for Regenerative Medicine Products

Regenerative medicine products include cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, with some exceptions. FDA has in place a number of expedited programs to assist sponsors in the development and review of promising regenerative medicine products to treat patients with serious conditions. These include Fast Track Designation, Breakthrough Therapy Designation, Regenerative Medicine Advanced Therapy Designation, Priority Review Designation and Accelerated Approval, which are summarized in guidance for industry (Expedited Programs for Regenerative Medicine Therapies for Serious Conditions).

FDA also has two programs within the Center for Biologics Evaluation and Research (CBER) that could provide early advice and interaction to participants in KidneyX prize competitions. The first is the INTERACT Program (INitial Targeted Engagement for Regulatory Advice on CBER producTs), which enables product developers to obtain informal consultation with the agency at an early stage of development prior to a pre-IND (investigational new drug application) meeting. The second is the CATT (CBER Advanced Technologies Team) Program, which provides an interactive mechanism for prospective innovators/developers of advanced manufacturing and testing technologies to discuss with agency staff issues related to the implementation of these technologies in the development of FDA-regulated products.

CMS Innovation Center Proposed New Kidney Payment Models

The development of an artificial kidney would also be supported by the proposed payment models from the Center for Medicare and Medicaid Innovation (CMMI) announced as a part of President Trump's Advancing American Kidney Health Executive Order. CMS issued a proposed rule to implement the ESRD Treatment Choices (ETC) Model, which proposes, in relevant part, to assess participating Managing Clinicians and ESRD facilities on their rates of kidney and kidney-pancreas transplants received by their attributed beneficiaries during each Measurement Year and to adjust certain of their Medicare payments upward or downward based on their transplant rate. This would include kidney transplants from existing deceased donor and live donor mechanisms and would include new kidney technologies such as mechanical or biological wearable or implantable artificial kidneys developed through the KidneyX program in the future. CMS also announced the new Kidney Care Choices (KCC) Model, which contains financial incentives for the nephrologists and other providers managing the care of patients with kidney disease to support beneficiaries through the transplant process. These incentives would be given to the entity coordinating care if the transplant occurs through existing mechanisms or from new kidney technologies such as wearable or implantable artificial kidneys developed through the KidneyX program.

New Technology Add-On Payment Policy

The FDA Breakthrough Devices Program can help expedite the development and review of new devices that meet expedited program criteria (e.g., devices intended to treat serious or life-threatening diseases or conditions for which no approved or cleared alternatives exist). CMS believes it is appropriate to facilitate patient access to new technology by providing New Technology Add-on Payments for these transformative technologies for Medicare beneficiaries. Marketing authorization (e.g., approval or clearance) of a medical device that is subject to this Breakthrough program could lead to situations where the evidence base for demonstrating substantial clinical improvement in accordance with CMS's current new technology add-on payment policy has not fully developed at the time of FDA market authorization. To address this, CMS finalized an alternative new technology add-on payment pathway for a medical

device that receives FDA marketing authorization and is part of the Breakthrough Devices Program.

Under the FY 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) final rule, if a medical device subject to the FDA's Breakthrough Devices Program has received marketing authorization from the FDA, CMS considers that product new and not substantially similar to an existing technology for purposes of the IPPS new technology add-on payment, and it is not subject to the substantial clinical improvement criterion. Under finalized policy, the medical device will need to meet the cost criterion to receive the add-on payment. This change begins with applications received for new technology add-on payments for FY 2021.

CMS Coverage Options

CMS is committed to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to new cures and technologies that improve beneficiary health outcomes. CMS continues to explore ways to incentivize innovative device development and beneficiary access. There are coverage pathways currently available that may be helpful covering new devices.

National Coverage Determinations (NCDs): The evidence-based NCD pathway can be used for national coverage of devices and is initiated after a formal request is received by CMS. The NCD process can include a decision of Coverage with Evidence Development (CED). CED decisions provide coverage for items and services within the context of a clinical study, which can be a registry based prospective observational study, a randomized controlled trial, or other study designs.

Local Coverage Determinations (LCDs): Using a modernized, transparent process, the MACs may develop evidence-based Local Coverage Determinations (LCDs) that apply only within the jurisdiction of the individual MAC. Innovators can request a coverage decision through the LCD pathway at any time.

Claim-by-claim Adjudication: Medicare Administrative Contractor (MACs) have the discretion to cover a technology on a claim-by-claim basis.

In addition to the coverage options described above, CMS has the authority to cover devices that are not FDA market authorized (i.e., pre-market devices) as Investigational Device Exemption (IDE) devices in an FDA-approved study. The centralized IDE process was introduced in 2015 to permit national coverage of Category B devices that, among other things, meet Medicare IDE coverage criteria.

2020 End-stage Renal Disease (ESRD) Payment Rules

Beginning January 1, 2020, CMS has proposed that certain FDA-approved new renal dialysis drugs and biological products will receive a transitional drug add-on payment adjustment

(TDAPA) under the ESRD PPS for two years if the product fits into one of the End-stage Renal Disease Prospective Payment System (ESRD PPS) functional categories. Under current policy, if it does not, and the product is determined to be a renal dialysis service product, an existing functional category is revised or a new functional category is created (through notice and comment rulemaking) and the product will receive TDAPA or for at least two years so utilization can be determined. Data analysis will determine if and how much will be added to the ESRD PPS base rate after the TDAPA period only for a product in a new functional category.