DEPARTMENT OF HEALTH AND HUMAN SERVICES

- 2 Office of the Chief Technology Officer (OCTO)
- 3 Announcement of Requirements and Registration for the "KidneyX: Patient Innovator
- 4 Challenge"
- 5 Authority: 15 U.S.C. 3719

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- The Kidney Innovation Accelerator (KidneyX) is a partnership between the U.S. Department of
- 8 Health and Human Services (HHS) and the American Society of Nephrology (ASN). This
- 9 document announces the requirements and registration for a prize competition: the KidneyX
- 10 Patient Innovator Challenge, funded by the National Kidney Foundation (NKF). Prize
- 11 competitions challenge individuals, communities, businesses, institutions, and non-profit
- 12 organizations, among others, to achieve defined goals in a defined timeframe. The Patient
- 13 Innovator Challenge seeks ideas and fixes that people living with kidney diseases have
- 14 developed through their own everyday experiences and ingenuity.

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Patient Innovator Challenge dates:

- 17 Submission Period Begins: August 1, 2019
- 18 Submission Deadline: 5:00 pm EDT, September 16, 2019
- 19 Winners Announced By: March 26, 2020

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- A. Background
 - B. Subject and Scope of Prize Competition
 - C. Prize Competition Structure
 - D. Submission Requirements, Judging Criteria, Eligibility, and Intellectual Property Rights

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A. Background:

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- HHS, ASN, and NKF believe that people living with kidney diseases have important knowledge
- and experience that can help us find better ways to prevent, diagnose, and treat kidney
- diseases. Many patients, across a wide range of diseases and conditions, have invented their
- own fixes that have then been more widely adopted by the patient community. For example,
- 34 innovations created by patients have led to a better method for cystic fibrosis patients to clear
- 35 their lungs; a way for breast cancer patients to shower without the risk of infection; and a
- 36 better way for celiac disease patients to record, monitor, and manage their symptoms.
- 37 Similarly, care partners¹ have developed important solutions, such as a parent who designed a
- 38 harness allowing a child with cerebral palsy to walk with adult assistance or a grandchild who
- 39 developed a wearable sensor to track the movements of his grandfather who has Alzheimer's
- 40 disease.

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¹ By this term we mean anyone who helps another with health, wellness, and caring—including but not limited to families, friends, and formal and informal caregivers.

Unfortunately, our healthcare system generally cannot easily test, validate, and scale patient-designed innovations. Thus, it is likely that many ideas from patients and care partners are missed, or at least not spread and shared as widely as they should be. With this prize competition, funded by NKF, KidneyX hopes to recognize innovative ideas and solutions that people living with kidney diseases can create.

B. Subject and Scope of Prize Competition:

The Patient Innovator Challenge asks patients and care partners for ideas on how to improve therapeutic options and quality of life for people living with kidney diseases. The goal of the prize is to gather and share new approaches and possibilities with the nephrology community. HHS, ASN, and NKF are asking participants for both solutions that they have already developed and for their ideas for possible solutions. We use the term "solution" broadly here: this competition seeks any method or fix that will help people living with kidney diseases. In general terms, this could include (but is not limited to) ways to improve health and relieve symptoms, ways to make daily life easier, ways to reduce the cost of care. Potential areas to consider include:

- Managing side effects of treatment (e.g., fatigue, insomnia, cramping)
- o Tweaks or fixes that helped promote independence
- A diet/fluid regimen that worked particularly well
- Approaches/methods that have successfully sustained family and social life
- Techniques/behaviors that have increased physical activity
- Approaches to improve quality of life

C. Prize Competition Structure

Prize submissions will be submitted and judged based on two categories:

<u>Category 2</u>: "New Ideas," which are solutions that have not yet been created or tried.

<u>Category 1</u>: "Solutions in Practice," which are solutions already tried or put into practice.

Submissions will be judged in comparison to the other submissions in their category (i.e., a Category 1 solution will only be compared with other Category 1 solutions, not Category 2 solutions). Participants may submit more than one solution in either or both Categories for this competition.

The submission period for this prize competition opens **August 1, 2019**, and closes at 5:00 pm EDT on **September 16, 2019**. Submission requirements and judging criteria are discussed in

Section D, below. At the end of the submission period, judges will review submissions and an authorized official will select up to 25 winners: up to 10 winners in Category 1 will receive \$4,000 each, while up to 15 winners in Category 2 will receive \$2,000 each. The total prize pool for the KidneyX Patient Innovator Challenge is \$70,000, and prize money will be paid by NKF.

Winners may also be invited to speak or share solutions and ideas at events like the KidneyX Summit. Winning ideas, as appropriate, will be shared on the KidneyX.org website. Information deemed proprietary will not be shared.

D. Submission Requirements, Judging Criteria, Eligibility, and Intellectual Property Rights

Submission Requirements

Complete instructions for submission can be found at kidneyx.org/compete.

Submissions, which will be used to determine winners, will be submitted in written format and submitted through the submission site at kidneyx.org/competes. Submissions should be no more than 2 pages, 8.5 x 11 inch page, 10-point font or greater and one inch margins. Although not required, participants may indicate whether they believe their solution should be in Category 1 (Solutions in Practice) or Category 2 (New Ideas). HHS and ASN reserve the right to re-categorize entries. Submissions will be considered in only one category; a submission will not be considered in both categories.

Submissions must include a publicly shareable abstract limited to 100 words. By submitting an abstract, all Patient Innovator Challenge participants automatically agree to allow this abstract to be published on the KidneyX.org website. No proprietary information should be included in the abstract.

Participants may, but are not required to, submit supplemental documents as part of their submission—such supplements must be visual in nature (e.g., diagrams, pictures, and links to videos).

All reviewers and judges, as well as all HHS, ASN and NKF staff involved in the review of submissions will be required to sign a Non-Disclosure Agreement prior to receiving access to the submissions. However, submissions should also clearly delineate any Intellectual Property (IP) and/or confidential commercial information contained in a submission that the participant wishes to protect as proprietary data.

Judging Criteria

A multi-disciplinary panel will select winners for this prize competition. Judges will review submissions in two categories: Category 1 (Solutions in Practice) and Category 2 (New Ideas). Submissions will be judged only against the other submissions in their category.

- 124 Evaluation criteria that judges will use:
 - Creativity and novelty of the solution
 - How feasible it would for patients and/or care partners to use this solution
 - How much impact the solution would have for patients and/or care partners
 - Significance of the problem being addressed
 - [Solutions in Practice category only] Level of impact the solution has had on the participant's life

Amount and Payment of the Prize

For the Patient Innovator Challenge prize competition, the National Kidney Foundation is offering \$70,000 in total prize money. ASN, HHS and NKF will select up to 25 winners: up to 10 winners in Category 1 will receive \$4,000 each, and up to 15 winners in Category 2 will receive \$2,000. Prize money will be paid by NKF. All funding will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Eligibility Rules

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- To be eligible to win a prize under the KidneyX: Patient Innovator Challenge prize competition, an individual or entity—
- 142 (1) Shall have registered to participate in the prize competition;
- 143 (2) Shall have complied with all the requirements set forth in this announcement for participation in this prize competition;
- 145 (3) For 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,
- 147 whether participating singly or in a group, shall be a citizen or permanent resident of the
- 148 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;
- 152 (4) May 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 the acceptance of a KidneyX prize);
- 156 (5) Shall not be an HHS employee;
- 157 (6) Federal grantees may not use Federal funds to develop submissions unless consistent with
- 158 the purpose of their grant award; and
- 159 (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.
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Additional Requirements

- An individual or entity shall not be deemed ineligible because the individual or entity used
- 165 Federal facilities or consulted with Federal employees during a competition if the facilities and
- 166 employees are made available to all individuals and entities participating in the competition on
- 167 an equitable basis.

Each individual (whether participating singly or in a group) or entity agrees to follow all applicable federal, state, and local laws, regulations, and policies.

Participants must also agree to assume any and all risks and waive all claims against the Federal Government, ASN, NKF and their related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants are not required to obtain liability insurance or demonstrate financial responsibility in any specified amount for claims by a third party for death, bodily injury, or property damage or loss resulting from an activity carried out in connection with participation in a prize competition, but are encouraged to consult with their advisors with respect to the level of insurance that is prudent for each participant. Registered participants agree to indemnify the Federal Government, ASN, and NKF against third party claims for damages arising from or related to prize competition activities, and further indemnify the Federal Government, ASN, and NKF for damage or loss to Government, ASN, and NKF property, respectively resulting from such activities.

HHS reserves the right to cancel, suspend, and/or modify this prize competition, or any part of it, for any reason, at HHS's sole discretion. HHS reserves the right not to award any prizes if no entries are deemed worthy. ASN and NKF may also discontinue their participation in the prize competition at their discretion. If ASN and/or NKF elects to discontinue participation, every effort will be made to announce that decision promptly on the KidneyX.org website.

Intellectual Property (IP) Rights

- Participants are free to discuss their submission and the ideas or technologies that it contains with other parties, are encouraged to share ideas/technologies publicly, are encouraged to collaborate or combine with other teams to strengthen their solutions, and are free to contract with any third parties. Participants should be aware that any agreement signed or obligation undertaken in regard to their participation in this prize competition that conflicts with the prize competition rules, terms, and conditions may result in disqualification of the participant's submission.
- By participating in this prize competition, each participant (whether participating singly or in a group) warrants that he or she is the sole author or owner of, or has the right to use, any copyrightable works that the submission comprises, that the works are wholly original with the participant (or is an improved version of an existing work that the participant has sufficient rights to use and improve), and that the submission does not infringe any copyright or any other rights of any third party of which participant is aware. In addition, each participant (whether participating singly or in a group) and each entity grants to HHS an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly (e.g., on websites)

212 the abstracts on the web or elsewhere. Each participant will retain all other intellectual 213 property rights in their submissions, as applicable. To participate in the prize 214 competition, each participant must warrant that there are no legal obstacles to 215 providing the above-referenced nonexclusive licenses of participant rights to the federal 216 government. To receive an award, winners will retain ownership of their intellectual 217 property rights in the solution, but must grant to the federal government the nonexclusive, nontransferable, irrevocable, paid up license to practice, or have practiced 218 219 for or on its behalf, the solution throughout the world for federal purposes. Each 220 participant also warrants that the work is free of security threats and/or malware.

- Each participant must clearly delineate any Intellectual Property (IP) and/or confidential commercial information contained in a submission that the participant wishes to protect as proprietary data.
- All materials submitted to the kidneyx.org/competes website as part of a submission become HHS, ASN and NKF records. Any confidential commercial or financial information contained in a submission must be clearly designated at the time of submission.
- If the submission includes any third party works (such as third party content or open source code), the participant must be able to provide, upon request, documentation of all appropriate licenses and releases for use of such third party works. If the participant cannot provide documentation of all required licenses and releases, HHS, ASN, and NKF reserve the right, at their sole discretion, to disqualify the submission.

For Further Information Contact: Ross Bowling; ross.bowling@hhs.gov; 202-260-7158.

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