

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**[Document Identifier: OS-0990-XXXX]**

**Agency Information Collection Request. 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** The purpose of this data collection is to support evaluation of the Kidney Innovation Accelerator (KidneyX) initiative organized by HHS. KidneyX was launched in October 2018, after nearly 2 years of discussion, as a joint effort among HHS, the American Society for Nephrology (ASN), and the Kidney Health Initiative (KHI) to spur new innovations in the prevention, diagnosis, treatment, and possibly cure of kidney disease. One motivation for the initiative is the poor quality of life (QoL) that patients with end-stage renal disease (ESRD) now experience. The two most common forms of current treatment, kidney transplantation and kidney dialysis, have substantial limitations and debilitating side effects. KidneyX seeks to improve dramatically the existing technologies addressing renal conditions and diseases and to foster new solutions providing improved outcomes for patients via less burdensome treatment options. This evaluation will generate, collect, and analyze data to measure changes in the rate and volume of innovative advances during the initial 5 years of KidneyX and the degree to which those changes are attributable to activities pursued under the initiative.

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-xxxx60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, Sherrette.funn@hhs.gov, or call 202-795-7714.

## **SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project: 0990-xxxxEvaluation of the Kidney Innovation Accelerator (KidneyX).

Abstract:

Section 401 of the Pandemic and All-Hazards Preparedness Act of 2006 authorized the Secretary of Health and Human Services to use prize payments to support and encourage biomedical innovation. The America COMPETES Reauthorization Act, as amended, requires annual reports to Congress on prize competitions administered by HHS and other agencies. The data collected under this submission will help HHS inform the required reports to Congress and also support departmental evidence-building activities required under the Foundations of Evidence-Based Policymaking Act of 2018.

The KidneyX evaluation involves a mixed-methods design for data collection and analysis. The evaluation integrates qualitative techniques, such as document analysis and stakeholder interviews, to capture the details and effects of processes and changes within the KidneyX initiative. We will apply quantitative methods, such as surveys and econometric analysis, in discrete situations in which we find sufficient certainty and coherence in environmental conditions to conduct rigorous analysis.

The evaluation will use a data-driven set of methodologies to address, to the extent possible, the central question of the effectiveness of KidneyX: the degree to which KidneyX contributed to any acceleration in the rate of innovation in the targeted area of kidney technology compared with how innovation would have progressed without KidneyX.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in min)	Total Burden (in hr)
Prize competition applicants	Applicant Interview Guide	12	1	45/60	9
Prize competition awardees	Awardee Interview Guide	6	1	45/60	4.5
Prize competition non-awardees	Non-awardee Interview Guide	6	1	45/60	4.5

Other Stakeholders	Other Stakeholder Interview Guide	6	1	45/60	4.5
Prize competition applicants	Pre-award Survey Instrument	300	1	30/60	150.00
Prize competition awardees and non-awardees	Post-award Survey Instrument	300	1	30/60	150.00
Total					322.5

Date:

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Enter Signer name:

Office of the Secretary

Paperwork Reduction Act Reports Clearance Officer