Billing Code 4165-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation OMB No. 0906-0034 – Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Submit your comments to paperwork@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation

OMB No. 0906-0034 – Revision

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency of HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living donations (42 U.S.C. §273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. §273b). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living donors who provide informed consent to participate in the pilot registry. The SRTR's authority to collect information concerning potential living organ donors is set forth in the HHS organ procurement and transplantation network regulation, 42 CFR part 121, requiring organ procurement organizations and transplant hospitals to submit to the SRTR, as appropriate, information regarding "donors of organs" and "other information that the Secretary deems appropriate" (42 CFR 121.11(b)(2)). In 2018, an updated version of the data collection instrument was approved. The data collection modifications improve the quality of the data and reduce the administrative burden for respondents.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information

to transplant programs in their future donor selection process and aid potential living organ donors in their decision to pursue living donation.

There were minor revisions to the burden per response as it has decreased from the current amount due to improvements to the efficiency of the processes used by programs for data submission, as well as the tools provided for program use by SRTR

Likely Respondents: Potential living donors, transplant programs, medical and scientific organizations, and public organizations.

Burden Statement: Burden, in this context, means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. 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. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Average Number of Responses per Respondent	Total Number of Responses	Average Burden per Response (in hours)	Total Burden Hours
Potential Living Donor Registration form	16 [a]	112	1,792	.27	484
Potential Living Donor Follow-up form	754 [b]	1	754	.50	377
Reasons Did not Donate form (liver or kidney)	16 [a]	106	1,696	.23	390
Total	786		4,245		1,251

[a] Number of respondents is based on the current number of transplant programs and is likely to increase as additional programs decide to participate.

[b] Number of living organ donor candidates submitting follow-up forms in 2019.

HRSA specifically requests comments on (1) the necessity and utility of the proposed

information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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