Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

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 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: Data System for Organ Procurement and Transplantation Network

OMB No. 0915-0157– Revision

Abstract: Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). This is a request for revisions to current OPTN data collection forms associated with donor organ procurement and an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant. Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used to develop transplant, donation, and allocation policies, to determine whether institutional members are complying with policy, to determine member-specific performance, to ensure patient safety and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and members of the public for evaluation, research, patient information, and other important purposes.

Likely Respondents: Transplant programs, organ procurement organizations, histocompatibility laboratories, 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; 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; train personnel to respond to a request for collection of information; search data sources; complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Section/Activity	**Number of Respondents**	**Average Number of Responses per Respondent**	**Total Number of Responses**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Deceased Donor Registration	58	158.2	9174	1.1	10091.4
Living Donor Registration	290	20.6	5984	1.8	10771.2
Living Donor Follow-up	290	60.7	17610	1.3	22893.0
Donor Histocompatibility	151	96.7	14598	0.2	2919.6
Recipient Histocompatibility	151	173.5	26199	0.4	10479.6
Heart Candidate Registration	131	30.5	3991	0.9	3591.9
Heart Recipient Registration	131	19.3	2525	1.4	3535.0
Heart Follow Up (6 Month)	131	17.0	2229	0.4	891.6
Heart Follow Up (1-5 Year)	131	73.9	9683	0.9	8714.7
Heart Follow Up (Post 5 Year)	131	115.2	15091	0.5	7545.5
Heart Post-Transplant Malignancy Form	131	11.0	1447	0.9	1302.3
Lung Candidate Registration	64	39.6	2534	0.9	2280.6
Lung Recipient Registration	64	30.0	1923	1.4	2692.2
Lung Follow Up (6 Month)	64	26.2	1677	0.5	838.5
Lung Follow Up (1-5 Year)	64	99.4	6364	1.1	7000.4
Lung Follow Up (Post 5 Year)	64	65.6	4201	0.6	2520.6
Lung Post-Transplant Malignancy Form	64	1.5	99	0.4	39.6
Heart/Lung Candidate Registration	63	0.7	46	1.1	50.6
Heart/Lung Recipient Registration	63	0.3	21	1.4	29.4
Heart/Lung Follow Up (6 Month)	63	0.3	20	0.8	16
Heart/Lung Follow Up (1-5 Year)	63	1.5	97	1.1	106.7
Heart/Lung Follow Up (Post 5 Year)	63	3.1	194	0.6	116.4
Heart/Lung Post-Transplant	63	0.2	12	0.4	4.8

Malignancy Form					
Liver Candidate Registration	135	89.2	12048	0.8	9638.4
Liver Recipient Registration	135	47.8	6457	1.3	8394.1
Liver Follow-up (6 Month – 5 Year)	135	231.1	31194	1	31194.0
Liver Follow-up (Post 5 Year)	135	256.5	34622	0.5	17311.0
Liver Recipient Explant Pathology Form	135	12.3	1665	0.6	999.0
Liver Post-Transplant Malignancy	135	13.2	1786	0.8	1428.8
Intestine Candidate Registration	41	4.4	182	1.3	236.6
Intestine Recipient Registration	41	2.7	109	1.8	196.2
Intestine Follow Up (6 Month – 5 Year)	41	13.3	547	1.5	820.5
Intestine Follow Up (Post 5 Year)	41	13.5	553	0.4	221.2
Intestine Post-Transplant Malignancy Form	41	0.6	25	1.0	25.0
Kidney Candidate Registration	233	162.6	37880	0.8	30304.0
Kidney Recipient Registration	233	72.5	16904	1.3	21975.2
Kidney Follow-Up (6 Month – 5 Year)	233	379.5	88422	0.9	79579.8
Kidney Follow-up (Post 5 Year)	233	346.7	80770	0.5	40385.0
Kidney Post-Transplant Malignancy Form	233	18.1	4213	0.8	3370.4
Pancreas Candidate Registration	134	3.6	479	0.9	431.1
Pancreas Recipient Registration	134	1.9	259	1.1	284.9
Pancreas Follow-up (6 Month – 5 Year)	134	10.4	1398	1.0	1398.0
Pancreas Follow-up (Post 5 Year)	134	13.5	1804	0.5	902.0
Pancreas Post-Transplant Malignancy Form	134	0.8	108	0.6	64.8
Kidney/Pancreas Candidate Registration	134	9.6	1280	0.9	1152.0
Kidney/Pancreas Recipient	134	5.7	760	1.1	836.0

Registration					
Kidney/Pancreas Follow-up (6 Month – 5 Year)	134	33.6	4509	1.0	4509.0
Kidney/Pancreas Follow-up (Post 5 Year)	134	48.2	6465	0.6	3879.0
Kidney/Pancreas Post-Transplant Malignancy Form	134	1.6	211	0.4	84.4
VCA Candidate Registration	9	1.7	15	0.4	6.0
VCA Recipient Registration	9	1.7	15	1.3	19.5
VCA Recipient Follow Up	9	1.7	15	1.0	15.0
Total	**453***		**460414**		**358092.5**

*Total number of OPTN member institutions as of 6/6/2014. Number of respondents for transplant candidate or recipient forms based on number of organ specific programs associated with each form.

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.

Dated: August 29, 2014

Jackie Painter

Acting Director, Division of Policy and Information Coordination

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