DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157, Revision

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

ACTION: Notice

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 15, 2017.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

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 a subset of the 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 transplant.

Need and Proposed Use of the Information: Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to facilitate organ placement and match donor organs with recipients, monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements, review and report periodically to the public on the status of organ donation and transplantation in the United States, provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation, and perform transplantation-related public health surveillance including possible transmission of donor disease. This request revises a subset of the current OPTN data forms associated with donor organ procurement and an individual's clinical characteristics at the time of registration, transplant, and follow up.

In 2015, the OPTN Board of Directors approved policies that necessitate the addition of new data elements to registration forms for heart, lung, heart/lung, liver, intestine, kidney, pancreas, and kidney/pancreas recipients. The OPTN also approved policies that impact the data collection for deceased donor registration, pancreas candidate registration, kidney/pancreas candidate registration, pancreas follow-up, and kidney/pancreas follow-up forms. The policy modifications necessitate changes to 17 of the 52 forms contained in this data collection. For example, the pancreas and kidney/pancreas transplant recipient registration and follow up forms were modified to be consistent with an OPTN policy change pertaining to data collected from pancreas programs for pancreas graft failure. Specifically, the ''graft status'' section of the pancreas forms was updated to be consistent with a new policy that helps transplant professionals identify when pancreas allograft failure has occurred and how to document the pancreas graft failure event. In addition, ''drop down'' menus were added to facilitate reporting of toxoplasma serology results and infectious diseases, consistent with revised scope of policy requirements for infectious disease testing and reporting. Finally, a policy modification to improve collection of information on lungs perfused prior to transplant resulted in the creation of easy-to-complete data fields on lung and heart/lung recipient registration forms. The modified forms allow transplant centers to easily provide information on lung perfusion, which contributes to improved accuracy in monitoring of lung allocation, recipient safety, and organ and patient outcomes.

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; 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. The burden will decrease by approximately 3,500 hours.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent *	Total responses	Average burden per response (in hours)	Total burden hours
Deceased Donor Registration	58	176.9	10,262	1.1	11,288.2
Living Donor Registration	304	19.5	5,936	1.8	10,684.8
Living Donor Follow-Up	304	58.2	17,686	1.3	22,991.8
Donor Histocompatibility	152	102.7	15,611	0.2	3,122.2
Recipient Histocompatibility	152	183.0	27,810	0.4	11,124.0
Heart Candidate Registration	137	32.4	4,439	0.9	3,995.1

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent*	Total responses	Average burden per response (in hours)	Total burden hours
Heart Recipient Registration	137	20.5	2.805	1.2	3,366.0
Heart Follow-Up (6 Months)	137	16.5	2,261	0.4	904.4
Heart Follow-Up (1–5 Years)	137	77.3	10,595	0.9	9,535.5
Heart Follow-Up (Post 5 Years)	137	117.4	16,085	0.5	8,042.5
Heart Post-Transplant Malignancy	137	11.8	1,623	0.9	1,460.7
Lung Candidate Registration	70	37.0	2,592	0.9	2,332.8
Lung Recipient Registration	70	29.4	2,058	1.2	2,469.6
Lung Follow-Up (6 Months)	70	25.8	1,809	0.5	904.5
Lung Follow-Up (1–5 Years)	70	99.1	6,939	1.1	7,632.9
Lung Follow-Up (Post 5 Years)	70	70.0	4,898	0.6	2,938.8
Lung Post-Transplant Malignancy	70	15.8	1,106	0.4	442.4
Heart/Lung Candidate Registration	68	0.7	46	1.1	50.6
Heart/Lung Recipient Registration	68	0.2	14	1.3	18.2
Heart/Lung Follow-Up (6 Months)	68	0.2	13	0.8	10.4
Heart/Lung Follow-Up (1–5 Years)	68	1.4	94	1.1	103.4
Heart/Lung Follow-Up (Post 5 Years)	68	2.9	199	0.6	119.4
Heart/Lung Post-Transplant Malignancy	68	0.3	21	0.4	8.4
Liver Candidate Registration	140	85.9	12,026	0.8	9,620.8
Liver Recipient Registration	140	50.9	7,125	1.2	8,550.0
Liver Follow-Up (6 Months–5 Years)	140	235.6	32,985	1	32,985.0
Liver Follow-Up (Post 5 Years)	140	279.3	39,108	0.5	19,554.0
Liver Recipient Explant Pathology	140	12.9	1,812	0.6	1,087.2
Liver Post-Transplant Malignancy	140	14.2	1,985	0.8	1,588.0
Intestine Candidate Registration	40	5.0	200	1.3	260.0
Intestine Recipient Registration	40	3.5	141	1.8	253.8
Intestine Follow-Up (6 Months–5 Years)	40	13.3	530	1.5	795.0
Intestine Follow-Up (Post 5 Years)	40	16.4	655	0.4	262.0
Intestine Post-Transplant Malignancy	40	0.6	24	1	24.0
Kidney Candidate Registration	238	151.6	36,076	0.8	28,860.8
Kidney Recipient Registration	238	75.2	17,899	1.2	21,478.8
Kidney Follow-Up (6 Months–5 Years)	238	383.3	91,234	0.9	82,110.6
Kidney Follow-Up (Post 5 Years)	238	375.9	89,453	0.5	44,726.5
Kidney Post-Transplant Malignancy	238	22.4	5,327	0.8	4,261.6
Pancreas Candidate Registration	133	2.9	389	0.6	233.4
Pancreas Recipient Registration	133	1.8	233	1.2	279.6
Pancreas Follow-Up (6 Months–5 Years)	133	9.4	1,252	0.5	626.0
Pancreas Follow-Up (Post 5 Years)	133	14.7	1,953	0.5	976.5
Pancreas Post-Transplant Malignancy	133	0.9	120	0.6	72.0
Kidney/Pancreas Candidate Registration	133	9.5	1,265	0.6	759.0
Kidney/Pancreas Recipient Registration	133	5.4	718	1.2	861.6
Kidney/Pancreas Follow-Up (6 Months–5 Years)	133	32.0	4,262	0.5	2,131.0
Kidney/Pancreas Follow-Up (Post 5 Years)	133	51.7	6,876	0.6	4,125.6
Kidney/Pancreas Post-Transplant Malignancy Form	133	2.1	283	0.4	113.2
VCA Candidate Registration	28	1.8	49	0.4	19.6
VCA Recipient Registration	28	1.8	49	1.3	63.7
VCA Recipient Follow-Up	28	1.8	49	1	49.0
Total	**463	.....	488,980	.....	370,274.9

*The Number of Responses per Respondent was calculated by dividing the Total Responses by the Number of Respondents and rounding to the nearest tenth.

**Total number of OPTN member institutions as of April 6, 2017. Number of respondents for transplant candidate or recipient forms based on the organ-specific programs associated with each form.

Amy McNulty,

Deputy Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket Number CDC–2016–0121; NIOSH–285]

Closed-Circuit Escape Respirators; Final Guidance for Industry; Availability

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of availability.

SUMMARY: On December 28, 2016, the National Institute for Occupational Safety and Health (NIOSH), within the Centers for Disease Control and Prevention, Department of Health and Human Services, published a notice in the **Federal Register** announcing the availability of an interim guidance document addressing the availability of closed-circuit escape respirators (CCERs) for purchase, and the readiness of respirator manufacturers to comply with the regulatory provisions