

oversight, coordination, and logistical support for the Medical Expert Panel, as well as Clinical Reviewer contracts; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine and Countermeasures Injury Tables; (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; and (12) providing guidance in using the results and decisions of the Medical Claims Review Panel to HHS Operating Divisions to improve the quality of health care in its facilities and by its practitioners.

*Division of National Hansen's Disease Program (RRH)*

The National Hansen's Disease Program, in accordance with regulations and the Public Health Service (PHS) Act, Sec. 320 as amended by Public Law 105–78, Sec. 211, (1) provides care and treatment for persons with Hansen's Disease (leprosy), including managing a national short-term and outpatient health care delivery program providing specialized services to persons with Hansen's Disease; (2) conducts and promotes the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases; (3) conducts training in the diagnosis and management of Hansen's disease and related complications; (4) provides education and training to staff from the outpatient Hansen's Disease Clinics and to private physicians; (5) operates and oversees the National Hansen's Disease Museum and Cemetery; (6) consults on the coordination of activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in Hansen's Disease activities; and (7) manages a network of contracted outpatient clinics providing care to persons with Hansen's Disease; and (8) manages and coordinates the National Hansen's Disease Program's administrative and operational activities with HRSA and HHS; other federal agencies, state and local governments; and other public and private organizations involved in Hansen's Disease activities.

*Section R.30 Delegation of Authority*

All prior delegations of authority and re-delegations of authority consistent with this reorganization are in effect. I affirm and ratify any actions taken by

HHS officials that involved the exercise of those authorities prior to the effective date of this reorganization.

(Authority: 44 U.S.C. 3101)

Dated: August 6, 2021.

**Xavier Becerra,**  
*Secretary.*

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**BILLING CODE 4165–15–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: 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.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for the 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 November 1, 2021.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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](mailto: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:* Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision.

**Abstract:** Section 372 of the Public Health Service Act requires that the Secretary, by contract, provide for the establishment and operation of a private, non-profit entity: The Organ Procurement and Transplantation Network (OPTN). The data collected pursuant to the OPTN's regulatory authority in 42 CFR 121.11 of the OPTN Final Rule is collected through OMB approved data collection forms. Therefore, data approved for collection by the OPTN Board of Directors are submitted by HRSA for OMB approval under the Paperwork Reduction Act of 1995.

This is a request for revising the current OPTN data collection associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant to include data collection forms in the OPTN Organ Labeling, Packaging, and Tracking System, the OPTN Kidney Paired Donation Pilot Program (KPDPP), and the OPTN Patient Safety Reporting Portal (PSRP). This revision also includes OPTN Board of Directors approved changes to the existing OMB data collection forms. These specific data elements of the OPTN data system are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The information is used to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is submitting the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements. All of these proposed changes have been approved by the OPTN Board of Directors.

(1) Adding two data collection forms for the OPTN Organ Labeling, Packaging, and Tracking System to the existing OMB approved Data System for Organ Procurement and Transplantation Network. The system has two forms that are used through mobile and web-based applications to ensure the correct organ is transplanted into the correct patient, minimize labeling and transport errors, accelerate organ information transfer,

and capture data regarding organ procurement. OPTN Organ Labeling, Packaging, and Tracking System is comprised of two data collection forms: Organ labeling and packaging, and organ tracking and validating.

(2) Adding data collection forms for the OPTN KPDPP to the existing OMB approved Data System for Organ Procurement and Transplantation Network. Kidney paired donation is a transplant option for those patients waiting for a kidney transplant who have a willing living donor who is medically able but cannot donate a kidney to their intended candidate because they are incompatible. OPTN KPDPP matches living donors, and their intended candidates with other living donors or intended candidate pairs when the living donors cannot donate to the person(s) they initially hoped would receive their kidney. OPTN KPDPP is comprised of three data collection forms: Candidate registration, donor registration, and match offer management.

(3) Adding data collection forms in the OPTN PSRP to the existing OMB approved Data System for Organ

Procurement and Transplantation Network. OPTN PSRP allows the OPTN to collect reports on any event or process variance that could cause concerns from transplantation, donation, safety, or quality perspective. OPTN PSRP is comprised of four data collection forms: Disease transmission event, living donor event, safety situation, and potential disease transmission.

(4) Additional revisions to existing data collection forms were made based on the OPTN Board of Directors-approved changes to improve organ matching, allocation, and OPTN policy compliance.

*Need and Proposed Use of the Information:* 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, and Histocompatibility Laboratories.

*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 to collect, validate, and verify information, process and maintain information, and disclose and provide information; to train personnel and 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	Number of responses per respondent *	Total responses	Average burden per response (in hours)	Total burden hours
Deceased Donor Registration .....	57	188.26	10,731	1.10	11,804
Living Donor Registration .....	300	22.85	6,855	2.19	<sup>a</sup> 15,012
Living Donor Follow-up .....	300	62.23	18,669	1.53	<sup>b</sup> 28,564
Donor Histocompatibility .....	147	123.99	18,227	0.20	3,645
Recipient Histocompatibility .....	147	225.10	33,090	0.40	13,236
Heart Transplant Candidate Registration .....	140	33.69	4,717	0.90	4,245
Heart Recipient Registration .....	140	24.33	3,406	1.20	4,087
Heart Follow Up (6 Month) .....	140	22.01	3,081	0.40	1,233
Heart Transplant Recipient Follow Up 1–5 Year .....	140	90.61	12,685	0.90	11,417
Heart Transplant Recipient Follow Up Post 5 Year .....	140	153.97	21,556	0.50	10,778
Heart Post-Transplant Malignancy Form .....	140	12.77	1,788	0.90	1,609
Lung Transplant Candidate Registration .....	71	45.21	3,210	0.90	2,889
Lung Transplant Recipient Registration .....	71	35.66	2,532	1.20	3,038
Lung Transplant Recipient Follow Up 6 Month .....	71	32.35	2,297	0.50	1,148
Lung Transplant Recipient Follow Up 1–5 Year .....	71	118.85	8,438	1.10	9,282
Lung Transplant Recipient Follow Up Post 5 Year .....	71	116.49	8,271	0.60	4,962
Lung- Post-Transplant Malignancy Form .....	71	19.72	1,400	0.40	560
Heart/Lung Transplant Candidate Registration .....	69	0.97	67	1.10	74
Heart/Lung Recipient Registration .....	69	0.46	32	1.30	41
Heart/Lung Transplant Recipient Follow Up 6 Month .....	69	0.45	31	0.80	25
Heart/Lung Transplant Recipient Follow Up 1–5 Year .....	69	1.14	79	1.10	87
Heart/Lung Transplant Recipient Follow Up Post 5 Year ...	69	3.30	228	0.60	137
Heart/Lung Post-Transplant Malignancy Form .....	69	0.30	21	0.40	8
Liver Transplant Candidate Registration .....	146	90.29	13,182	0.80	10,546
Liver Transplant Recipient Registration .....	146	56.55	8,256	1.20	9,908
Liver Transplant Recipient Follow-Up 6 Month—5 Year ....	146	266.57	38,919	1.00	38,919
Liver Transplant Recipient Follow-up Post 5 Year .....	146	316.61	46,225	0.50	23,113
Liver Recipient Explant Pathology Form .....	146	10.58	1,545	0.60	927
Liver Post-Transplant Malignancy .....	146	16.35	2,387	0.80	1,910
Intestine Transplant Candidate Registration .....	20	6.95	139	1.30	181
Intestine Transplant Recipient Registration .....	20	5.20	104	1.80	187
Intestine Transplant Recipient Follow Up 6 Month—5 Year .....	20	26.20	524	1.50	786
Intestine Transplant Recipient Follow Up Post 5 Year .....	20	37.20	744	0.40	298
Intestine Post-Transplant Malignancy Form .....	20	2.10	42	1.00	42
Kidney Transplant Candidate Registration .....	237	168.77	39,998	0.80	31,999

## 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
Kidney Transplant Recipient Registration .....	237	89.43	21,195	1.20	25,434
Kidney Transplant Recipient Follow-Up 6 Month—5 Year ..	237	431.86	102,351	0.90	92,116
Kidney Transplant Recipient Follow-Up Post 5 Year .....	237	449.40	106,508	0.50	53,254
Kidney Post-Transplant Malignancy Form .....	237	22.64	5,366	0.80	4,293
Pancreas Transplant Candidate Registration .....	133	2.77	368	0.60	221
Pancreas Transplant Recipient Registration .....	133	1.46	194	1.20	233
Pancreas Transplant Recipient Follow-Up 6 Month—5 Year .....	133	7.87	1,047	0.50	523
Pancreas Transplant Recipient Follow-Up Post 5 Year .....	133	15.93	2,119	0.50	1,059
Pancreas Post-Transplant Malignancy Form .....	133	0.73	97	0.60	58
Kidney/Pancreas Transplant Candidate Registration .....	133	9.75	1,297	0.60	778
Kidney/Pancreas Transplant Recipient Registration .....	133	7.73	1,028	1.20	1,234
Kidney/Pancreas Transplant Recipient Follow-Up 6 Month—5 Year .....	133	32.80	4,362	0.50	2,181
Kidney/Pancreas Transplant Recipient Follow-Up Post 5 Year .....	133	57.80	7,687	0.60	4,612
Kidney/Pancreas Post-Transplant Malignancy Form .....	133	2.20	293	0.40	117
VCA Transplant Candidate Registration .....	27	0.89	24	0.40	11
VCA Transplant Recipient Registration .....	27	1.59	43	1.36	<sup>c</sup> 58
VCA Transplant Recipient Follow Up .....	27	0.67	18	1.31	<sup>d</sup> 24
Organ Labeling and Packaging .....	57	208.25	11,870	0.18	2,137
Organ Tracking and Validating .....	34	169.06	5,748	0.08	460
Kidney Paired Donation Candidate Registration .....	160	1.38	221	0.29	64
Kidney Paired Donation Donor Registration .....	160	1.46	234	1.07	250
Kidney Paired Donation Match Offer Management .....	160	1.51	242	0.67	162
Disease Transmission Event .....	308	1.44	444	0.62	275
Living Donor Event .....	251	0.12	30	0.56	17
Safety Situation .....	450	0.48	216	0.56	121
Potential Disease Transmission .....	57	6.88	392	1.27	498
Request to Unlock .....	450	39.22	17,649	0.02	353
<b>Total .....</b>	<b>8,290</b>	<b>.....</b>	<b>604,519</b>	<b>.....</b>	<b>437,240</b>

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

<sup>a</sup> Total burden increased due to the approval of the “Modify Data Collection on VCA Living Donors” proposal approved by the OPTN Board of Directors (BOD) in December of 2020. The proposal required adding 54 new data fields onto this form and removing 1 data field from this form.

<sup>b</sup> Total burden increased due to the approval of the “Modify Data Collection on VCA Living Donors” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 17 new data fields onto this form.

<sup>c</sup> Total burden increased due to the approval of the “Programming VCA Allocation in UNet” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 16 new data fields onto this form and removing 10 data fields from this form.

<sup>d</sup> Total burden increased due to the approval of the “Programming VCA Allocation in UNet” proposal approved by the OPTN BOD in December of 2020. The proposal required adding 54 new data fields onto this form and removing 5 data fields from this 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.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Establishment of the Office of Climate Change and Health Equity

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

### Statement of Organization, Functions, and Delegations of Authority

Part A, Office of the Secretary, Statement of Organization, Function, and Delegation of Authority for the U.S. Department of Health and Human Services (HHS) is being amended at Chapter AC, Office of the Assistant Secretary for Health (OASH), as last amended at 75 FR 53304, dated August 31, 2010, and 72 FR 58095–96, dated

October 12, 2007. Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad*, section 222(d), directs the Secretary of Health and Human Services to establish an Office of Climate Change and Health Equity to address the impact of climate change on the health of the American people. This amendment reflects the establishment of an office to address the impact of climate change on the health of the American people and to empower individuals through information, data, and scientific approaches to pursue environmental justice. Specifically, this notice establishes the Office of Climate Change and Health Equity in the OASH. The changes are as follows:

A. Under Part A, Chapter AC, under the Office of the Assistant Secretary for Health, add the following:

1. The Office of Climate Change and Health Equity (OCCHE), is headed by a