

funding, but not all Part A/B grantees will have Part C programs. Therefore, there are likely to be 295 unique respondents, but only 250 will have to

complete all three portions of the application. This application covers all three parts of Title VI.

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Title VI Application Part A/B .....	295	1	2.75	270.4
Title VI Application Part C .....	250	1	1.5	125
Total .....	.....	.....	4.25	395.4

The number of burden hours associated with the Title VI, Part C, data collection was calculated as 811.25.

However, since this instrument is used only once every three years results in an annualized number of 270.4 hours. Similarly, the total hours associated with the Title VI, Part C, application is 375.

Dated: September 23, 2022.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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**BILLING CODE 4154-01-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 (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 November 28, 2022.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to 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 Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443-9094.

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

*Information Collection Request Title:* Data System for Organ Procurement and Transplantation Network (OPTN), OMB No. 0915-0157—Revision.

*Abstract:* Section 372 of the Public Health Service Act requires that the Secretary of HHS, by contract, provide for the establishment and operation of a private, non-profit entity the OPTN, which on behalf of HRSA, oversees the U.S. donation and transplantation system. The OPTN Board of Directors (BOD) determines what data must be collected to appropriately fulfill their responsibilities pursuant to their regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, on behalf of the OPTN BOD and in alignment with the Paperwork Reduction Act of 1995, submits OPTN BOD-approved data elements for collection to OMB for official federal approval.

*Need and Proposed Use of the Information:* HRSA and the OPTN BOD use data 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. In addition, the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, HHS, and members of the public for evaluation,

research, patient information, and other important purposes.

This is a request to revise the current OPTN data collection which includes time-sensitive, life-critical data on transplant candidates and donors, the organ matching process, histocompatibility results, organ labeling and packaging, and pre- and post-transplantation data on recipients and donors. This revision also includes OPTN BOD-approved changes to the existing OMB data collection forms. The OPTN collects these specific data elements from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The OPTN uses this information 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, and (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is requesting to make the following OPTN BOD-approved changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements:

(1) Adding data collection forms from the OPTN donor management and organ matching system to the existing OMB-approved information collection. The system allows an organ procurement organization to add donors, run the donor/potential transplant recipients matches, and place a donated organ(s) with a computer-matched potential transplant recipient. Transplant centers will access the system to view posted donor information to assist them with accepting decisions, along with other donor/potential transplant recipient functions such as entering offer responses and verifying organ offer refusals. The OPTN donor management and organ matching system is comprised of eight data collection forms:

initial donor registration, organ procurement organization notification limit administration, potential transplant recipient, death notification registration, deceased donor death referral, donor hospital registration, donor organ disposition, and transplant center contact management.

(2) The OPTN BOD-approved additional revisions to existing data collection forms to improve organ matching, allocation, and OPTN policy compliance.

(3) Existing OPTN data collection forms that collect a single race and ethnicity variable will be revised to collect separate race and ethnicity variables, following the minimum standards for collecting and presenting data on race and ethnicity for all federal reporting found within *Revisions of Standards for the Classification of Federal Data on Race and Ethnicity*, OMB Statistical Policy Directive No. 15 in **Federal Register**, 62 FR 58782 (Oct. 30, 1997). Improving data collection around race and ethnicity information of donors and candidates aligns with Executive Order 13985, which calls on agencies to advance equity through identifying and addressing barriers to equal opportunity that underserved communities

may face due to government policies and programs.

*Likely Respondents:* Transplant programs, organ procurement organizations (OPO), 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 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 estimated total estimated burden hours for this collection increased by 213,662 hours from the currently approved ICR package. This increase is due to the addition of eight collection forms from the OPTN donor management and organ matching system to this data collection package, specifically the burden increase from the Potential Transplant Recipient form. While the data fields collected on the Potential Transplant Recipient form are limited, the volume of organ offer responses is significant due to the large number of potential transplant recipients shown on the organ match run results. The organ match run results produce thousands of potential transplant recipients that require responses from OPOs and transplant hospitals. This volume of candidates significantly impacts the total burden hours for this form.

*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	243.560	13,883	1.09	15,132
Living Donor Registration .....	216	28.106	6,071	2.19	13,295
Living Donor Follow-up .....	216	90.550	19,559	1.52	29,730
Donor Histocompatibility .....	141	149.184	21,035	0.20	4,207
Recipient Histocompatibility .....	141	264.950	37,358	0.40	14,943
Heart Transplant Candidate Registration .....	145	34.586	5,015	0.90	4,514
Heart Transplant Recipient Registration .....	145	26.324	3,817	1.40	5,344
Heart Transplant Recipient Follow-Up (6 Months) .....	145	24.400	3,538	0.40	1,415
Heart Transplant Recipient Follow-Up (1–5 Years) .....	145	104.140	15,100	0.90	13,590
Heart Transplant Recipient Follow-Up (Post 5 Year) .....	145	171.100	24,810	0.50	12,405
Heart Post-Transplant Malignancy Form .....	145	13.170	1,910	0.90	1,719
Lung Transplant Candidate Registration .....	72	42.970	3,094	0.90	2,785
Lung Transplant Recipient Registration .....	72	35.010	2,521	1.20	3,025
Lung Transplant Recipient Follow-Up (6 Months) .....	72	33.630	2,421	0.50	1,211
Lung Transplant Recipient Follow-Up (1–5 Years) .....	72	139.940	10,076	1.10	11,084
Lung Transplant Recipient Follow-Up (Post 5 Year) .....	72	136.280	9,812	0.60	5,887
Lung Post-Transplant Malignancy Form .....	72	22.630	1,629	0.40	652
Heart/Lung Transplant Candidate Registration .....	70	0.960	67	1.10	74
Heart/Lung Transplant Recipient Registration .....	70	0.640	45	1.30	59
Heart/Lung Transplant Recipient Follow-Up (6 Months) ....	70	0.600	42	0.80	34
Heart/Lung Transplant Recipient Follow-Up (1–5 Years) ...	70	2.100	147	1.10	162
Heart/Lung Transplant Recipient Follow-Up (Post 5 Year) .....	70	3.360	235	0.60	141
Heart/Lung Post-Transplant Malignancy Form .....	70	0.290	20	0.40	8
Liver Transplant Candidate Registration .....	143	96.920	13,860	0.80	11,088
Liver Transplant Recipient Registration .....	143	64.580	9,235	1.20	11,082
Liver Transplant Recipient Follow-Up (6 Month–5 Year) ....	143	320.266	45,798	1.00	45,798
Liver Transplant Recipient Follow-Up (Post 5 Year) .....	143	384.320	54,958	0.50	27,479
Liver Recipient Explant Pathology Form .....	143	7.300	1,044	0.60	626
Liver Post-Transplant Malignancy .....	143	19.060	2,726	0.80	2,181
Intestine Transplant Candidate Registration .....	21	6.860	144	1.30	187
Intestine Transplant Recipient Registration .....	21	4.570	96	1.80	173
Intestine Transplant Recipient Follow-Up (6 Month–5 Year) .....	21	20.050	421	1.50	632
Intestine Transplant Recipient Follow-Up (Post 5 Year) ....	21	40.190	844	0.40	338
Intestine Post-Transplant Malignancy Form .....	21	0.620	13	1.00	13
Kidney Transplant Candidate Registration .....	234	177.000	41,418	0.80	33,134
Kidney Transplant Recipient Registration .....	234	105.397	24,663	1.20	29,596
Kidney Transplant Recipient Follow-Up (6 Month–5 Year) .....	234	517.124	121,007	0.90	108,906
Kidney Transplant Recipient Follow-Up (Post 5 Year) .....	234	525.103	122,874	0.50	61,437
Kidney Post-Transplant Malignancy Form .....	234	24.474	5,727	0.80	4,582
Pancreas Transplant Candidate Registration .....	120	2.650	318	0.60	191
Pancreas Transplant Recipient Registration .....	120	1.190	143	1.20	172

Form name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Pancreas Transplant Recipient Follow-Up (6 Month–5 Year) .....	120	6.680	802	0.50	401
Pancreas Transplant Recipient Follow-Up (Post 5 Year) ...	120	17.820	2138	0.50	1,069
Pancreas Post-Transplant Malignancy Form .....	120	1.060	127	0.60	76
Kidney/Pancreas Transplant Candidate Registration .....	120	12.450	1,494	0.60	896
Kidney/Pancreas Transplant Recipient Registration .....	120	6.840	821	1.20	985
Kidney/Pancreas Transplant Recipient Follow-Up (6 Month–5 Year) .....	120	39.440	4,733	0.50	2,367
Kidney/Pancreas Transplant Recipient Follow-Up (Post 5 Year) .....	120	69.410	8,329	0.60	4,997
Kidney/Pancreas Post-Transplant Malignancy Form .....	120	2.490	299	0.40	120
VCA Transplant Candidate Registration .....	21	0.330	7	0.40	3
VCA Transplant Recipient Registration .....	21	0.190	4	1.36	5
VCA Transplant Recipient Follow Up .....	21	1.000	21	1.31	28
Organ Labeling and Packaging .....	57	247.720	14,120	0.18	2,542
Organ Tracking and Validating .....	308	19.487	6,002	0.08	480
Kidney Paired Donation Candidate Registration .....	159	1.200	191	0.29	55
Kidney Paired Donation Donor Registration .....	159	1.560	248	1.08	268
Kidney Paired Donation Match Offer Management .....	159	1.520	242	0.67	162
Disease Transmission Event .....	308	1.810	557	0.62	345
Living Donor Event .....	251	0.155	39	0.56	22
Safety Situation .....	449	0.600	269	0.56	151
Potential Disease Transmission .....	57	8.720	497	1.27	631
Request to Unlock Form .....	449	42.399	19,037	0.02	381
Initial Donor Registration .....	57	335.720	19,136	3.00	57,408
OPO Notification Limit Administration .....	57	0.490	28	0.17	5
Potential Transplant Recipient .....	308	4,718.480	1,453,292	0.05	72,665
Death Notification Registration .....	57	185.770	10,589	0.42	4,447
Deceased Donor Death Referral .....	57	53.840	3,069	0.50	1,535
Donor Hospital Registration .....	57	0.040	2	0.08	0
Donor Organ Disposition .....	57	335.720	19,136	0.17	3,253
Transplant Center Contact Management .....	251	637.500	160,013	0.06	9,601
Total = 70 forms .....	9,146	.....	2,352,736	.....	643,929

\* The numbers of respondents and the numbers of total responses in the burden table were updated with 2021 OPTN data and reflect increases in the number of organ transplants and changes in the number of respondents (Transplant Hospitals, OPO, and Histocompatibility Labs).

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's and the OPTN'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

### Health Resources and Services Administration

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

This notice amends Part R of the Statement of Organization, Functions

and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 87 FR 229–230 dated January 4, 2022). This reorganization updates the functions of the Provider Relief Bureau (RD).

#### Chapter RD—Provider Relief Bureau

##### Section RD.10 Organization

Delete the organization for the Provider Relief Bureau (RD) in its entirety and replace with the following:

The Provider Relief Bureau (RD) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Provider Relief Bureau includes the following components:

- (1) Office of the Associate Administrator (RD);
  - (2) Division of Customer Support (RD2);
  - (3) Division of Program Operations (RD4);
  - (4) Division of Data Analytics (RD5);
- and

(5) Division of Program Integrity (RD6).

##### Section RD.20 Function

Delete the functional statement for the Provider Relief Bureau (RD) in its entirety and replace with the following:

##### Provider Relief Bureau (RD)

The Provider Relief Bureau (PRB) ensures resiliency of the nation's health care systems and infrastructure by supporting health care entities in the United States to prevent, prepare for, and respond to coronavirus. PRB reimburses health care providers for health care-related expenses or lost revenues attributable to coronavirus and provides claims reimbursement for health care entities for COVID–19 testing, treatment, and vaccine administration for uninsured and under insured individuals.

##### Office of the Associate Administrator (RD)

The Office of the Associate Administrator (OAA) provides overall leadership, direction, coordination, and planning in support of the programs