

intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device.

An alternative to obtaining written authorization from the foreign government is to accept a notarized

certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within

the jurisdiction of a department or Agency of the United States. Respondents to this collection of information are companies that seek to export medical devices.

In the **Federal Register** of January 28, 2022 (87 FR 4609) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity and FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—801(e)(2)	36	1	36	2	72	\$8,250

¹ There are no capital costs associated with this collection of information.

Our estimate of the reporting burden is based on our experience with the information collection and reflects an overall decrease of 27 hours and a corresponding increase of three responses. We attribute this adjustment to an increase in the number of submissions received.

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18326 Filed 8–24–22; 8:45 am]

BILLING CODE 4164–01–P

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 (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 October 24, 2022.

ADDRESSES: Submit your comments to 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 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: Membership Forms for Organ Procurement (OPTN) and Transplantation Network OMB No. 0915–0184 – Revision.

Abstract: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, *et seq.*, the OPTN final rule, OPTN Policies, and OPTN Bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 (section 1138) requires that hospitals in which transplants are performed by members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

Need and Proposed Use of the Information: The application materials

are needed to ensure that all members and prospective members of the OPTN submit evidence that they meet the required qualifications for membership. These materials provide the OPTN with information to permit the OPTN to confirm and demonstrate that applicants meet OPTN membership application requirements and to create a record of the application review process and resulting actions for consideration by the Secretary of HHS if an applicant subsequently appeals a membership rejection by the OPTN.

This is a request to revise the current OPTN data collection associated with transplant hospitals, organ procurement organizations, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals to meet or sustain requirements for OPTN membership to include data collection forms for OPTN member hospitals requesting HIV Organ Policy Equity (HOPE) Act Variances and Kidney Paired Donation Pilot Program (KPDPP) contact update form. This revision also includes changes to the existing OMB data collection forms. HRSA is submitting the following changes to the Membership forms to clarify requirements and eliminate redundancy while adding more explanatory language and instruction to the applications, which include:

(1) Adding two new data collection forms for HOPE Act Variance Request and KPDPP contact update form. The HOPE Act Variance Request is for any OPTN member transplant program that wishes to start a variance to receive HIV-positive organs for their HIV-positive patients. The KPDPP contact

update is a form that indicates contact information for programs participating in the KPDPP.

(2) Adding three standalone forms for revised data collection: Primary Program Administrator, Primary Data Coordinator, and Additional Surgeon and Physician. All three of these forms include data previously collected on other OMB- approved forms in this package but now will be standalone forms for greater ease of use for the applicant.

- The Primary Program Administrator data collection form includes data previously collected in each organ-specific application form. Users will only have to complete one form of the proposed Primary Program Administrator serves in that role for multiple programs.

- The Primary Data Coordinator collection form includes data previously collected in each organ-specific application form. This form will be used for organ procurement organizations, histocompatibility lab members, and organ transplant programs so that one

standalone form will serve all three member types.

- The Additional Surgeon and Physician data collection form includes data previously collected in the Certificate of Assessment and Program Coverage Plan (COA/PCP) Membership Application form. Users will only have to complete one form if the proposed Surgeon and Physician serve in that role for multiple programs.

The organ-specific application forms have been revised to include the information found in the Certificate of Assessment and Program Coverage Plan Membership Application (COA/PCP). The information found in the COA/PCP has been embedded into all of the organ-specific application forms, negating the need for an independent data collection form.

Likely Respondents: New and existing transplant hospitals, organ procurement organizations, histocompatibility laboratories, medical/scientific organizations, public organizations, businesses, and individual members.

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 total burden hours in the OMB inventory increased by 898 hours from the previously OMB-approved data collection package from August 20, 2020. This increase is due in part to including new membership forms.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents ¹	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
OPTN Membership Application for Transplant Hospitals	251	0.28	70	4	280
OPTN Membership Application for Kidney Transplant Programs	234	0.56	132	8	1,056
OPTN Membership Application for Liver Transplant Programs	143	0.59	85	13	1,105
OPTN Membership Application for Pancreas Transplant Programs	120	0.26	32	13	416
OPTN Membership Application for Heart Transplant Programs	145	0.34	50	20.5	1,025
OPTN Membership Application for Lung Transplant Programs	72	0.64	46	9	414
OPTN Membership Application for Islet Transplant Programs ²	19	0	0	5	0
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	43	0.98	42	15.5	651
OPTN Membership Application for Intestine Transplant Programs	21	0.19	4	11	44
OPTN Membership Application for Organ Procurement Organizations (OPOs)	57	0.14	8	40	320
OPTN Membership Application for Histocompatibility Laboratories	141	0.21	30	2.5	75
OPTN Representative Form	1,760	0.02	37	0.25	9
OPTN Medical/Scientific Membership Application	10	0.3	3	0.75	2
OPTN Public Organization Membership Application	7	0.57	4	0.5	2
OPTN Business Membership Application	11	0.55	6	0.88	5
OPTN Individual Membership Application	8	0.88	7	0.25	2
OPTN Membership Application Surgeon or Physician Log ³	0	0	0	0	0
Primary Program Administrator Form	1,562	0.047	74	0.25	19
Primary Data Coordinator Form	1,760	0.03	52	0.13	7
Additional Surgeon and Physician Request Form	1,562	0.0736	115	1.17	135
HOPE Act Variance Request Form ⁴	68	0	0	1.33	0
Kidney Paired Donation Pilot Program (KPDPP) contact update form	159	0.33	53	1.63	86
Total = 22 forms	8,153	850	5,653

¹ The numbers of respondents were updated with the data as of December 31, 2021, and reflect changes in members' statuses.

- ² There were no Islet applications processed in 2021, hence no responses.
- ³ The OPTN Membership Application Surgeon or Physician Log is an optional form. The information can also be submitted by the OPTN member using a different format. The burden to complete is built into the organ application data.
- ⁴ There were no HOPE Act Variance Request forms processed in 2021, hence no responses.

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.

[FR Doc. 2022–18356 Filed 8–24–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21).

Date: September 7, 2022.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Qingdi Quentin Li, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 858–3914, liquenti@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 22, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18345 Filed 8–24–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIDCR Special Grants Review Committee.

Date: October 20–21, 2022.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental & Craniofacial Research, 6701 Democracy Blvd. Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nisan Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental & Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 668, Bethesda, MD 20892, 301–451–2405, nisan.bhattacharyya@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 22, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18346 Filed 8–24–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2022–0035]

Commercial Customs Operations Advisory Committee

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee management; notice of federal advisory committee meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, September 14, 2022, in Chicago, Illinois. The meeting will be open for the public to attend in person or via webinar. Due to COVID–19 restrictions, the in-person capacity is limited to 75 persons for public attendees.

DATES: The COAC will meet on Wednesday, September 14, 2022, from 2:00 p.m. to 6:00 p.m. EDT/1:00 p.m. to 5:00 p.m. CDT. Please note that the meeting may close early if the committee has completed its business. Registration to attend and comments must be submitted no later than September 9, 2022.

ADDRESSES: The meeting will be held at the Hilton Chicago O'Hare Airport, International Ballroom, located on the Lower Level, 10000 W Balmoral Ave., Chicago, IL 60666. For virtual participants, the webinar link and conference number will be provided to all registrants by 9:00 a.m. EDT on September 13, 2022. For information or to request special assistance for the meeting, contact Mrs. Latoria Martin, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344–1440 as soon as possible.

Comments may be submitted by one of the following methods: