



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: Membership Forms for Organ Procurement and

Transplantation Network OMB No. 0915-0184 – 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 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 or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

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

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network

OMB No. 0915-0184 – Revision

Abstract: This is a request for OMB approval for revisions of the application documents used to collect information for determining if the interested party is compliant with membership requirements contained in the final rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN), (42 CFR part 121) “the OPTN final rule.”

Need and Proposed Use of the Information: 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 be 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. Section 1138 contains a similar provision for the organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its rules and requirements (that have been approved by the HHS Secretary), including those relating to data collection, mandatory for all transplant programs and OPOs.

Proposed Revisions to OPTN Membership Applications: Changes to the forms are proposed to make application requirements more clear and organized, and thus less cumbersome for applicants to complete. Proposed revisions include changes to wording to

make questions more consistent with the language of the OPTN Bylaws (Bylaws). In addition, the applications have been revised so that the sequence of questions is parallel to that of the Bylaws. Using the Bylaws as a baseline, the revamped applications have been constructed in parallel order of the Bylaws so that an applicant can have the application and Bylaws side-by-side for easy reference. Additional proposed changes to the application include:

- A few major changes were made to the application order of documentation and attachments. The embedded transplant logs were revised in the form of a ‘universal’ surgeon and physician log that will be provided as a separate attachment to the application. This new log will provide applicants with all OPTN Bylaws requirements. We hope the added technology utilized in the log will help applicants complete the log with limited errors.
- Also within the applications, “checkboxes”—fillable tables that were not checkboxes at all—were removed and working checkboxes were inserted. The “narrative” section was replaced by checkbox attestations, which will serve the same purpose - understanding relevant and recent surgeon and physician applicant experience.
- The previous membership applications had several places for the applicants to sign. The new application requests only one signature from each individual member applicant involved.
- Additional changes to the application process include streamlining previous application attachments for key personnel and living donor components into one form for the respective organ application.

- Pediatric Bylaw Requirements, where applicable, were also given their own sections within the organ applications. Conversely, the Certificate of Assessment (formerly known as Certificate of Investigation) and the Primary Coverage Plan Checklist were pulled out of the previous organ specific applications and given their own, separate attachment. These changes will allow OPTN application reviewers to give these application components to applicants in as few attachments as possible. These changes will also allow the United Network for Organ Sharing Membership Team to give these important application components to applicants in as few attachments as possible, but are inclusive of all possible changes within a program.
- Further changes have been made to the Vascularized Composite Allograft (VCA) Transplant program applications, which were previously submitted as separate applications for OMB approval based on body part transplanted. These forms have been revised into one single application with sections for each VCA organ type.
- Personnel changes for Organ Procurement Organizations (OPOs) and Histocompatibility Laboratories have also been consolidated into organization applications. OPO and Lab applicants will be able to use one respective application for new and/or personnel changes.
- Given these changes, the overall burden has decreased significantly from an estimated 7,016 total burden hours to 4,755 hours in this current proposed revision package, although some forms have been combined into one more comprehensive form resulting in increased burden hours for a particular form.

Likely Respondents: Parties seeking initial OPTN membership approval and then maintenance of existing OPTN approval. Applicants include the following: hospitals seeking to perform organ transplants, non-profit organizations seeking to become an organ procurement organization, and medical laboratories seeking to become an OPTN-approved histocompatibility laboratory. In addition, there are other OPTN membership categories for organizations and individuals who want to participate in the organ transplant system, and they are also required to fill out an appropriate application.

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.

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
OPTN Membership Application for Transplant Hospitals	2	1	2	3	6
OPTN Certificate of Assessment and Program Coverage Plan Membership Application	2	1	2	3	6

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
OPTN Membership Application for Kidney Transplant Programs	189	2	378	3	1,134
OPTN Membership Application for Liver Transplant Programs	110	2	220	3	660
OPTN Membership Application for Pancreas Transplant Programs	120	2	240	3	720
OPTN Membership Application for Heart Transplant Programs	142	2	284	3	852
OPTN Membership Application for Lung Transplant Programs	60	2	120	3	360
OPTN Membership Application for Islet Transplant Programs	4	2	8	2	16
OPTN Membership Application for Vascularized Composite Allograft (VCA) Transplant Programs	53	2	106	2	212
OPTN Membership Application for Intestine Transplant Programs	90	2	180	3	540
OPTN Membership Application for Organ Procurement Organizations (OPOs)	10	1	10	3	30
OPTN Membership Application for Histocompatibility Laboratories	27	2	54	3	162
OPTN Representative Form	20	2	40	1	40
OPTN Medical/Scientific Membership Application	7	1	7	1	7

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
OPTN Public Organization Membership Application	4	1	4	1	4
OPTN Business Membership Application	2	1	2	1	2
OPTN Individual Membership Application	4	1	4	1	4
OPTN Membership Application Surgeon or Physician Log*	-	-	-	-	-
Total = 18 forms	846	1,661	4,755

*The OPTN Membership Application Surgeon or Physician Log accompanies every individual organ application. The burden to complete is built into the organ application data.

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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