

HRSA to submit assessed data on the number of FTE residents trained by the children's hospitals participating in the CHGME Payment Program in an FTE resident assessment summary.

*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
Application Cover Letter (Initial and Reconciliation) .....	60	2	120	0.33	39.6
HRSA 99 (Initial and Reconciliation) .....	60	2	120	0.33	39.6
HRSA 99-1 (Initial) .....	60	1	60	26.5	1,590
HRSA 99-1 (Reconciliation) .....	60	1	60	6.5	390
HRSA 99-1 (Supplemental) (FTE Resident Assessment) ..	30	2	60	3.67	220.2
HRSA 99-2 (Initial) .....	60	1	60	11.33	679.8
HRSA 99-2 (Reconciliation) .....	60	1	60	3.67	220.2
HRSA 99-4 (Reconciliation) .....	60	1	60	12.5	750
HRSA 99-5 (Initial and Reconciliation) .....	60	2	120	1.55	186
CFO Form Letter (Initial and Reconciliation) .....	60	2	120	0.33	39.6
Exhibit 2 (Initial and Reconciliation) .....	60	2	120	0.33	39.6
Exhibit 3 (Initial and Reconciliation) .....	60	2	120	0.33	39.6
Exhibit 4 (Initial and Reconciliation) .....	60	2	120	0.33	39.6
FTE Resident Assessment Cover Letter (FTE Resident Assessment) .....	30	2	60	0.33	19.8
Conversation Record (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit C (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit F (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit N (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit O(1) (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit O(2) (FTE Resident Assessment) .....	30	2	60	26.5	1590
Exhibit P (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit P(2) (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit S (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit T (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit T(1) (FTE Resident Assessment) .....	30	2	60	3.67	220.2
Exhibit 1 (FTE Resident Assessment) .....	30	2	60	0.33	19.8
Exhibit 2 (FTE Resident Assessment) .....	30	2	60	0.33	19.8
Exhibit 3 (FTE Resident Assessment) .....	30	2	60	0.33	19.8
Exhibit 4 (FTE Resident Assessment) .....	30	2	60	0.33	19.8
<b>Total</b> .....	<b>*90</b>		<b>*90</b>		<b>8,164.80</b>

\* The total is 90 because the same hospitals and auditors are completing the forms.

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.

**Jason E. Bennett,**

*Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Organ Procurement and Transplantation Network

**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 (Section 3506(c)(2)(A) 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 Information Collection Request must be received no later than February 7, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to the HRSA Information Collection Clearance Officer, at 5600 Fishers Lane, Room 14N39, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain copies of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call 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:* Organ Procurement and Transplantation Network OMB No. 0915-0184—Revision.

*Abstract:* HRSA is proposing additions and revisions to the following documents used to collect information from existing or potential members of the Organ Procurement and Transplantation Network (OPTN). The documents under revision include: (1) Application forms for individuals or organizations interested in membership in OPTN, (2) application forms for OPTN members applying to have organ-specific transplant programs designated within their institutions, and (3) forms submitted by OPTN members to report certain personnel changes.

*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.* (NOTA), OPTN Final Rule, 42 CFR part 121, OPTN bylaws, and OPTN policies. 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 (as approved by the Secretary of HHS) of the OPTN, including those relating to data collection, as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision for organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its operating rules and

requirements, including those relating to data collection, mandatory for all OPOs. The membership application forms listed below enable prospective OPTN members to submit the information necessary for OPTN to make membership decisions. Likewise, the designated transplant program application forms listed below enable OPTN members to submit the information necessary for OPTN to make designation decisions.

New membership forms have been created for transplant centers seeking to perform Vascularized Composite Allograft (VCA) transplants, a new and emerging field. VCAs were added to the set of organs covered by NOTA and the OPTN final rule via regulation, effective July 3, 2014. The OPTN Board approved OPTN membership requirements for VCA programs in late 2015. Because a transplant center applying to be an OPTN-approved VCA transplant program must already have current OPTN approval as a designated transplant program for at least one other organ, the VCA membership forms were developed based on existing membership forms.

To keep pace with scientific and clinical advances in the field of transplantation, HRSA plans to submit a clearance package to OMB after reviewing comments to this notice. New forms and revisions to the current OPTN forms include the following:

- Organ-specific program and histocompatibility laboratory applications reflecting key personnel requirement revisions made to the OPTN bylaws (the bylaws revisions will be implemented upon approval of these forms).
- Program applications based on existing organ-specific application forms, for programs seeking intestinal and VCA transplantation approval OPTN-defined VCAs: VCA head and neck, VCA upper limb, VCA abdominal wall kidney, VCA abdominal wall liver,

VCA abdominal wall pancreas, VCA abdominal wall intestine, and VCA other.

- Intestine program applications, based on an existing organ-specific application form.
- Cover pages, based on existing cover pages for other organ types, have been created for VCA new transplant program, VCA key personnel change, VCA other new transplant program, and VCA other key personnel change.
- Questions and tables reflecting new ordering and numbering for improved flow on various forms.

The burden of completing the new and revised forms is expected to be minimal, as these forms are based on OPTN membership applications that organizations have completed in the past.

*Likely Respondents:* Likely respondents to this notice include the following: Hospitals performing or seeking to perform organ transplants, organ procurement organizations, and medical laboratories seeking to become OPTN-approved histocompatibility laboratories.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested, including the time needed to (1) review instructions; (2) develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and transmitting, disclosing, or providing information; (3) train personnel to respond to a collection of information; (4) search data sources; (5) complete and review the information collected; (6) and transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request 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
A. New Transplant Member Application—General .....	2	1	2	8	16
B Kidney (KI) Designated Program Application .....	118	2	236	4	944
B Liver (LI) Designated Program Application .....	59	2	118	4	472
B Pancreas (PA) Designated Program Application .....	60	2	120	4	480
B Heart (HR) Designated Program Application .....	92	2	184	4	736
B Lung (LU) Designated Program Application .....	30	2	60	4	240
B Islet (PI) Designated Program Application .....	2	2	4	3	12
B Living Donor (LD) Recovery Program Application .....	42	2	84	3	252
B VCA Head and Neck Designated Program Application ...	14	2	28	3	84
B VCA Upper Limb Designated Program Application .....	17	2	34	3	102
B VCA Abdominal Wall* Designated Program Application	13	2	26	3	78

## 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
VCA Abdominal Wall—Kidney					
VCA Abdominal Wall—Liver					
VCA Abdominal Wall—Pancreas					
VCA Abdominal Wall—Intestine					
B VCA Other ** Designated Program Application .....	9	2	18	2	36
B Intestine Designated Program Application .....	40	2	80	3	240
C OPO New Application .....	0	1	0	4	0
D Histocompatibility Lab Application .....	3	2	6	4	24
E Change in Transplant Program Key Personnel .....	395	2	790	4	3,160
F Change in Histocompatibility Lab Director .....	25	2	50	2	100
G Change in OPO Key Personnel .....	10	1	10	1	10
H Medical Scientific Org Application .....	7	1	7	2	14
I Public Org Application .....	4	1	4	2	8
J Business Member Application .....	2	1	2	2	4
K Individual Member Application .....	4	1	4	1	4
Total = 25 forms .....	948	.....	1,867	.....	7,016

\* VCA Abdominal Wall Designated Program qualification requirements require documentation on VCA Head and Neck, VCA Upper Limb, Kidney, Liver, Intestine, or Pancreas program requirements.

\*\* VCA Other Designated Program Application data based on four categories of "others" including genitourinary and lower limb as defined by the OPTN bylaws.

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.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

[Document Identifier: OS-0990-New-60D]

### Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans

to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate below or any other aspect of the ICR.

**DATES:** Comments on the ICR must be received on or before February 7, 2017.

**ADDRESSES:** Submit your comments to [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or by calling (202) 690-5683.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the document identifier OS-0990-New-60D for reference.

*Information Collection Request Title:* A Client-Centered Performance Measure for Contraceptive Services.

*Abstract:* The Office of the Assistant Secretary for Health/Office of Population Affairs is seeking an approval by the Office of Management and Budget on a new information collection. We propose to evaluate a scale previously developed by our collaborators at the University of California San Francisco (UCSF)—the 11-item Interpersonal Quality of Family Planning Care (IQFP) scale—among 3,000 female family planning clients. Initially informed by qualitative work around women's preferences for contraceptive counseling, the IQFP scale has already been shown to be a valid

and reliable scale in research settings but its use as a performance measure hasn't yet been evaluated. Family planning providers will also complete a short survey about provider characteristics (approximately 80 providers) and clinic demographics (approximately 10 clinics).

*Need and Proposed Use of the Information:* The proposed use of the information to be collected is to develop a patient-reported outcome performance measure (PRO-PM) on contraceptive counseling and assess its validity, reliability, feasibility, usability, and use. If we find that this measure has adequately met these criteria, UCSF and the Office of Population Affairs (OPA) will prepare it for submission to the National Quality Forum (NQF) for use in a variety of clinical settings where family planning care is provided. Measurement of the quality of contraceptive counseling can be used as part of quality improvement activities to increase awareness and use of client-centered counseling approaches. By improving client-centered services, women can choose the contraceptive method that works best for them, which can lead to reductions in rates of unintended pregnancy and other adverse reproductive outcomes.

*Likely Respondents:* Family planning providers and their patients.