transmission, and allows for the possibility of hepatitis C elimination [Falade-Nwulia O, Ann Intern Med 2017].

Testing is the first step to accessing life-saving treatment; however, about one-third of people with hepatitis C in the United States are unaware of their infection [Lewis KC, CID 2024]. The Centers for Disease Control and Prevention (CDC) recommends hepatitis C screening for all adults at least once, all pregnant women during every pregnancy, and all persons with risk for HCV infection, including periodic testing if risk persists [Schillie S, MMWR Recomm Rep 2020]. Current testing guidance for clinicians and laboratorians begins with a hepatitis C antibody (anti-HCV) test followed, when reactive, by a nucleic acid test to detect HCV RNA to diagnose current infection [CDC MMWR 2013]. Updated operational guidance was provided to ensure completion of the two-step approach using specimens collected during a single patient encounter. (Cartwright EJ, MMWR 2023)

A limitation of the antibody-first hepatitis C testing approach is that it takes an average of 7 to 8 weeks after HCV infection to develop a reactive HCV antibody (Abdel-Hamid M, Clin Micro 2002). Therefore, the current testing sequence fails to diagnose HCV infection in the window-phase/early acute phase, within the initial months following infection, and among immunocompromised people who may have delayed seroconversion. Fortunately, advancements in the diagnostic and regulatory landscape have created an opportunity to improve hepatitis C testing. Currently, there are two tests for viral markers that identify current HCV infection: (1) real-time (RT) polymerase chain reaction (PCR) testing of HCV ribonucleic acid (RNA) detects virus within 1 to 2 weeks of infection (Gowda C, Clin Infect Dis 2020); and (2) HCV core antigen (HCVcAg) testing, currently approved outside of the United States, that uses an immunoassay to detect HCV core antigen within 2 to 3 weeks of infection (Sepulveda-Crespo D, Rev Med Virol 2023). Such virologic tests have become faster to perform and more accessible in a variety of care settings including closer to the point-of-care.

With CDC support, the Association of Public Health Laboratories (APHL) held a 2-day convening of key stakeholders and subject matter experts in October 2021 to identify high-priority diagnostic tools needed to advance diagnosis of current HCV infection and linkage to treatment in a range of clinical and nonclinical settings. The published meeting report called for the U.S. Food and Drug Administration (FDA) to reclassify HCV diagnostic tests from class III to class II, supported the availability of an FDA-cleared rapid CLIA-waived point-of-care (POC) HCV viral detection test, and encouraged CDC to review and update recommendations for HCV testing to identify current HCV infection, including testing sequences that detect HCV viral markers in the first step. (*https://www.aphl.org/aboutAPHL/publications/Documents/ID-HCV-2021-Meeting-Report.pdf*).

Subsequent to the APHL-led meeting:

In November 2021, the FDA reclassified hepatitis C diagnostic tests from class III devices to class II devices with special controls (510k). This action provided a new, lower-barrier opportunity for manufacturers to introduce new hepatitis C diagnostic tools for FDA review, including tests that were available at that time outside of the United States, such as a nucleic acid test for HCV RNA detection in a point-of-care format and an assay for HCVcAg.

In January 2024, CDC affirmed existing viral-first testing recommendations among people with recent HCV exposure ( ).

In January 2024, CDC began the process of updating HCV testing guidance for clinicians and laboratorians, including evaluating testing strategies for the general population that include tests for viral markers in the first testing step (*e.g.,* ''viral-first'').

In June 2024, the FDA authorized an HCV RNA CLIA-waived near point-of-care test for the diagnosis of current HCV infection.

Public Participation

Public engagement will entail listen-only observation of information shared on day 1 and day 2. If members of the public have input on the questions asked during the meeting, those public comments can be submitted through *regulations.gov* using docket CDC–2025–0321 on or before September 24, 2025, and will be included in the final meeting report.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov*. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2025–15859 Filed 8–19–25; 8:45 am]

BILLING CODE 4163–18–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 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 20, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14NWH04, 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 ICR title for reference.

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915–0184—Revision.

Abstract: The purpose of this ICR is to renew and revise membership application materials for the Organ Procurement and Transplantation Network (OPTN). Membership in the OPTN is determined by submission of application materials to the OPTN 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, 42 CFR part 121, OPTN Policies, and OPTN Management and Membership Policies. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8, requires that hospitals in which transplants are performed by members of the OPTN 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 the information necessary to confirm and demonstrate that applicants meet OPTN membership application requirements and create a record of the application review process and resulting actions for consideration by the Secretary of HHS in the event an applicant subsequently appeals a membership rejection by the OPTN.

Transplant hospitals, organ procurement organizations, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals complete the appropriate application materials to meet or sustain requirements for OPTN membership. The revisions include the addition of a new data collection form for Information Security Contact Management, a required role for accessing the OPTN Computer System; additional updates to align the membership applications for histocompatibility laboratories and businesses with new requirements, as well as non-substantive changes to the existing OMB data collection forms to improve clarity and efficiency for both members and OPTN.

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 estimated burden hours for this collection decreased by 2,091 hours from the currently approved ICR package. The decrease in burden can be attributed to members becoming more familiar with the revised 2022 application forms and from consultation with the appropriate OPTN committees to estimate the burden. Specifically, OPTN based its burden hour estimates on input from a representative sample of potential respondents. Accordingly, the estimates were developed through consultation with the Transplant Administrator, Histocompatibility, Organ Procurement Organization, and Vascularized Composite Allograft committees. These committees reviewed the forms and instructions and determined the estimates through consensus during their meetings. In preparation for these discussions, some committee members also sought input from subject matter experts within their respective organizations.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS:

Form	Form name	Number of respondents [1]	Number of responses per respondent	Total responses [2]	Average burden per response (in hours)	Total burden hours [3]
1	OPTN Membership Application for Transplant Hospitals and Programs.	250	0.14	35	12.17	426
2	OPTN Membership Application for Kidney Transplant Programs.	235	0.34	80	6.85	548
3	OPTN Membership Application for Liver Transplant Programs.	144	0.46	66	5.79	382
4	OPTN Membership Application for Pancreas Transplant Programs.	135	0.22	30	5.79	174
5	OPTN Membership Application for Heart Transplant Programs.	155	0.25	39	16.82	656
6	OPTN Membership Application for Lung Transplant Programs.	81	0.20	16	5.79	93
7	OPTN Membership Application for Islet Transplant Programs.	22	0.09	2	8	16
8	OPTN Membership Application for Vascularized Composite Allograft Transplant Programs.	48	0.27	13	23.79	309
9	OPTN Membership Application for Intestine Transplant Programs.	19	0.16	3	11	33
10	OPTN Membership Application for Histocompatibility Laboratories.	138	0.22	30	3.7	111
11	OPTN Membership Application for Organ Procurement Organizations.	55	0.18	10	18.33	183

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS:—Continued

Form	Form name	Number of respondents [1]	Number of responses per respondent	Total responses [2]	Average burden per response (in hours)	Total burden hours [3]
12	OPTN Medical/Scientific Membership Application.	11	0.18	2	1.42	3
13	OPTN Public Organization Membership Application.	10	0.40	4	2	8
14	OPTN Business Membership Application.	19	0.47	9	1.61	14
15	OPTN Individual Membership Application.	16	0.625	10	1.53	15
16	OPTN Representative Form	499	0.27	135	0.43	58
17	Primary Data Coordinator Form	1,032	0.09	93	0.43	40
18	Primary Program Administrator Form	839	0.12	101	0.45	45
19	Additional Surgeon and Physician Request Form.	839	0.37	310	0.84	260
20	HOPE Act Variance Request Form	56	0.02	1	0.50	1
21	Kidney Paired Donation Pilot Program contact update form.	160	0.18	29	0.56	16
22	OPTN Membership Application Surgeon or Physician Log [4].	0	0	0	0	0
23	Information Security Contact Management Form [5].	462	1.46	675	0.19	128
		5,225		1,693		3,519

1. The numbers of respondents were updated with OPTN membership data as of December 2, 2024, and reflect the number of current OPTN members.
2. The numbers of total responses were calculated with data from December 1, 2023, through December 31, 2023. "Total Responses" are rounded to the nearest whole number.
3. "Total Burden Hours" are rounded to the nearest whole number.
4. 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 of completing the application is included in the organ-specific application form.
5. The Information Security Contact Management Form is new, added to the Membership ICR in 2025.

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. 2025–15830 Filed 8–19–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Early Childhood Developmental Health Systems: Evidence to Impact

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing additional award funds of $440,000 in fiscal year (FY) 2025 to ZERO TO THREE National Center for Infant, Toddler, and Families, Inc., the current recipient of the Early Childhood Developmental Health Systems (ECDHS) Program cooperative agreement (HRSA–22–091), to support the continuation of existing activities relating to early childhood development health services.

FOR FURTHER INFORMATION CONTACT: Ekaterina Zoubak, Early Childhood Systems Analyst, Division of Home Visiting and Early Childhood Systems, HRSA, at *ezoubak@hrsa.gov* or 240–475–8014.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: ZERO TO THREE National Center for Infant, Toddler, and Families, Inc.

Amount of Non-Competitive Award: $440,000.

Project Period: September 30, 2025, to September 29, 2026.

Assistance Listing Number: 93.110.

Award Instrument: Non-competitive supplemental funding to the existing Cooperative Agreement.

Authority: 42 U.S.C. 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act).

TABLE 1—RECIPIENT(S) AND AWARD AMOUNT(S)

Grant No.	Award recipient name	City, state	Award amount
UK2MC46349	ZERO TO THREE National Center for Infant, Toddler and Families, Inc	Washington, DC	$440,000

Justification: In FY 2022, under the authority for Special Projects of Regional and National Significance (42 U.S.C. 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act)), HRSA awarded funds for the ECDHS Program to ZERO TO THREE National Center for Infant, Toddler, and Families, Inc. (HRSA–22–091). This award included