

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS:—Continued

| Form     | Form name   | Number of respondents <sup>1</sup> | Number of responses per respondent | Total responses <sup>2</sup> | Average burden per response (in hours) | Total burden hours <sup>3</sup> |
|----------|---|------------------------------------|------------------------------------|------------------------------|--|---------------------------------|
| 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 <sup>4</sup> . | 0                                  | 0                                  | 0                            | 0                                      | 0                               |
| 23 ..... | Information Security Contact Management Form <sup>5</sup> .         | 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.  
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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](mailto: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

expectations for the recipient to provide technical assistance to the Transforming Pediatrics in Early Childhood (TPEC) program (HRSA–22–141) recipients and a broad range of providers and stakeholders to support the integration of early childhood development expertise in pediatric care.

A Congressional Report accompanying the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) included funding to “expand placements of early childhood development experts in pediatrician offices with a high percentage of Medicaid and Children’s Health Insurance Program patients” (Senate Report 118–84), which led to the funding of four additional TPEC recipients in FY 2024, for a total of eight. Consistent with Congressional intent accompanying the FY 2024 appropriation, HRSA, through its Maternal and Child Health Bureau, will provide a supplement of \$440,000 in Special Projects of Regional and National Significance funding to the ECDHS Program recipient to continue their provision of technical assistance to these four additional TPEC recipients and for national dissemination of technical assistance to support early childhood development integration within comprehensive early childhood systems.

This supplement will improve access to early childhood development services that improve health outcomes and prevent the onset of chronic illness for families nationwide and will build the capacity of the health system to deliver high-quality pediatric services that address the holistic needs of children and families.

Thomas J. Engels,  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Declaration of Emergency Pursuant to the Federal Food, Drug, and Cosmetic Act for New World Screwworm

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On August 18, 2025, the Secretary

determined, pursuant to his authority under the FD&C Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World Screwworm (*Cochliomyia hominivorax*) (NWS).

**DATES:** The determination and declaration were effective August 18, 2025.

#### FOR FURTHER INFORMATION CONTACT:

Tristan Colonius, Chief Veterinary Officer, U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, [Tristan.colonius@fda.hhs.gov](mailto:Tristan.colonius@fda.hhs.gov), 301–796–2624.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), HHS has the ability to take certain steps to help facilitate the availability of medical countermeasures based on one of four determinations under section 564(b): (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of the Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a CBRN agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary [of HHS] that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may declare that circumstances exist

that justify Emergency Use Authorization (EUA), at which point the Commissioner of Food and Drugs of the U.S. Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product, if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The Commissioner of Food and Drugs requested that the Secretary issue the declaration to allow FDA to take measures based on information currently available about NWS. The determination that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves NWS (*Cochliomyia hominivorax*), and the declaration that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent NWS myiasis in animals by the Secretary, enable the Commissioner of Food and Drugs to issue EUAs for animal drugs for prevention or treatment of New World Screwworm myiasis.

##### II. Determination by the Secretary of Health and Human Services

On August 18, 2025, I determined, pursuant to my authority under section 564(b)(1)(C) of the FD&C Act, that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves New World Screwworm (*Cochliomyia hominivorax*).

##### III. Declaration of the Secretary of Health and Human Services

On August 18, 2025, pursuant to section 564(b)(1) of the FD&C Act and subject to the terms of any authorization issued under that section, I declare that circumstances exist justifying the authorization of emergency use of animal drugs to treat or prevent New World Screwworm myiasis in animals. This declaration remains in effect until the declaration is terminated in