

Interim Public Meeting; Public Meeting; Interim Report; Availability; Request for Comments.” Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Sarah Ikenberry, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1128, Silver Spring, MD 20993–0002, 301–796–6893, BsUFARegSciProgram@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under BsUFA III, FDA committed to piloting a regulatory science program to facilitate biosimilar and interchangeable product development that focuses on: (1) advancing the development of interchangeable products; and (2) improving the efficiency of biosimilar product development. FDA also committed to publish an interim progress report and hold an interim public meeting by October 31, 2025, approximately midway through the pilot program.

FDA is hosting a hybrid public meeting on September 18, 2025, to meet the BsUFA III commitment to review the progress of the pilot program aims or demonstration projects, and to solicit input on future research priorities. FDA has published the interim progress report entitled “BsUFA III Regulatory Science Pilot Program Interim Report” at <https://www.fda.gov/media/187445/download?attachment>; this report provides a summary of activities that established the pilot program, an overview of research progress, and a brief discussion of future directions.

II. Topics for Discussion at the Public Meeting

In general, the public meeting’s format will include presentations by FDA and other interested parties, including scientific and academic experts participating in the BsUFA Regulatory Science pilot program and biosimilar industry representatives. The agenda includes an overview of the pilot program, awardee presentations on the progress of their research, lessons learned, and the role of regulatory science in biosimilar development. A draft agenda and other background information for the public is available at: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025>.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-public-meeting-bsufa-iii-regulatory-science-program-interim-public-meeting-09182025>. Please indicate either in-person or virtual attendance and provide complete contact information for each attendee, including name and email.

Registration is free for both in-person and virtual attendance. In-person attendance is based on space availability, with priority given to early

registrants. Persons interested in attending this public meeting must register by Thursday, September 18, 2025, at 9 a.m. Eastern Time for in-person registration. Virtual attendees can register and join at any time through the conclusion of the meeting. Early registration for in-person attendance is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8:30 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Ikenberry, 301–796–6893, BsUFARegSciProgram@fda.hhs.gov, no later than September 11, 2025.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: August 12, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15571 Filed 8–14–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Infant-Toddler Court Program—National Resource Center

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

ACTION: Notice of supplemental funding.

SUMMARY: HRSA is providing additional award funds of \$1,750,000 in federal fiscal year (FY) 2025 to ZERO TO THREE National Center for Infant, Toddler and Families, Inc., the current recipient of the Infant-Toddler Court Program (ITCP)—National Resource Center (NRC) cooperative agreement (HRSA–22–074), to support the continuation of existing activities, using the Infant Toddler Court (ITC) approach, to improve child welfare and early childhood systems and advance early developmental health and well-being. The supplemental funding would provide financial and technical support

to local infant-toddler court sites that previously received funding under HRSA–18–123, but that do not currently receive HRSA funding under HRSA–22–073/074, and expand technical assistance (TA) needed to support the continuation and expansion of State Award activities funded under HRSA–22–073/074.

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:
\$1,750,000.

Project Period: September 30, 2025–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
U2DMC32394	ZERO TO THREE National Center for Infant, Toddler and Families, Inc.	Washington, DC	\$1,750,000

Justification: In FY 2022, under the authority for Special Projects of Regional and National Significance (SPRANS) (42 U.S.C. 701(a)(2) (Title V, § 501(a)(2) of the Social Security Act)), HRSA awarded the ITCP National Resource Center to ZERO TO THREE National Center for Infant, Toddler and Families, Inc (HRSA–22–074). This award included expectations for the recipient to provide TA to the ITCP (HRSA–22–073) recipients and support the nationwide implementation and sustainability of the evidence-based ITC approach.

A Congressional Report accompanying the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) included funding to “to continue and expand research-based Infant-Toddler Court Teams to change child welfare practices to improve wellbeing for infants, toddlers, and their families,” (Senate Report 118–84). In addition, the Joint Explanatory Statement accompanying the FY 2024 appropriations act directed HRSA to “allocate funding to ensure continuation of existing grantees, technical assistance, and other activities.” In FY 2024, HRSA provided a supplement of \$1,750,000 in SPRANS to the NRC Program recipient to continue work initiated in FY 2023 (with an increased SPRANS appropriation), to expand TA to ITC teams, provide financial and technical support to local infant-toddler court sites that previously received funding under HRSA–18–123, and advance national-level reach and impact of the program.

Consistent with previous Congressional intent, HRSA, through its Maternal and Child Health Bureau, will provide a supplement of \$1,750,000 in SPRANS funding to the ITCP NRC Program recipient to continue to provide subawards and technical assistance to ITC teams, expand technical assistance to ITC teams

funded under HRSA–22–073/074 and advance the reach and impact of the program.

This supplement will improve access to evidence-based child welfare practices and improve the early developmental health and well-being of infants, toddlers, and their families. Supplemental funding for similar activities may be considered in future years, subject to the availability of funding for the activity and satisfactory performance.

Thomas J. Engels,

Administrator.

[FR Doc. 2025–15537 Filed 8–14–25; 8:45 am]

BILLING CODE 4615–15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Scholarships for Disadvantaged Students Program Specific Form, OMB No. 0906–0073—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day

comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 15, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Scholarships for Disadvantaged Students Program Specific Form, OMB No. 0906–0073—Revision.

Abstract: HRSA seeks to collect data on the Scholarships for Disadvantaged Students (SDS) Program Specific Form, which will assist the agency in making funding decisions for SDS program awards. The SDS Program Specific Form and another form, the Bureau of Health Workforce (BHW) Program Specific Data Form, are currently approved under OMB No. 0906–0073 with an expiration date of November 30, 2025. This clearance is for the approval of one form, the SDS Program Specific Form, and removal of the BHW Program Specific Data Form. For programmatic efficiency, HRSA will move the BHW Program Specific Data Form to another ICR that reports data outcomes post grant award. The information collection request has been renamed to the *Scholarships for Disadvantaged*