

section 564 of the FD&C Act (88 FR 8874). Termination of the February 6, 2015, declaration automatically terminated the CDC EV–D68 EUA, which was the only EUA issued under the declaration.

III. Electronic Access

An electronic version of this document is available on the internet at <https://www.regulations.gov>.

IV. Notice of EUA Termination

Based on the Secretary of HHS's February 6, 2023, termination of the February 6, 2015, declaration that circumstances exist justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68, FDA is issuing, under section 564(h)(1) of the FD&C Act, this notice of termination of the May 12, 2015, CDC EV–D68 EUA. Section 564(h)(1) of the FD&C Act requires FDA to provide notice of each termination of an authorization under section 564 of the FD&C Act, and an explanation of the reasons therefor.

Dated: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03373 Filed 2–16–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement, OMB No. 0915–0338—Revision.

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

ACTION: Notice.

SUMMARY: In compliance with of 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 March 20, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to 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 301–594–4394.

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

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement OMB No. 0915–0338—Revision.

Abstract: The National Healthy Start Program, authorized by 42 U.S.C. 254c–8 (section 330H of the Public Health Service Act), and funded through HRSA, has the goal to improve health outcomes before, during, and after pregnancy, and reduce racial/ethnic differences in rates of infant death and adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and has expanded since then to 101 grantees across 35 states; Puerto Rico; and Washington, DC. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average and high rates for other adverse perinatal outcomes. These communities are often low-income and located in geographically, racially, ethnically, and linguistically diverse areas. Healthy Start offers services during the perinatal period (before, during, after pregnancy) and the program works with women, men, and infants/children through the first 18 months after birth. The Healthy Start program pursues four goals: (1) improve women's health, (2) improve family health and wellness, (3) promote systems change, and (4) assure impact and effectiveness. Over the past few years, HRSA has sought to implement a uniform set of data elements for monitoring and conducting an evaluation to assess grantees' progress towards these program goals. Under the current OMB approval, the data collection instruments for the program's reporting requirements include three

participant-level screening tools: (1) Background, (2) Prenatal, and (3) Parenting Information.

In this proposed revision, HRSA plans to retain the participant-level tools as approved by OMB in 2020; however, HRSA did introduce minor changes to the forms. These changes included only the following: correction of typos, addition of response options (e.g., “don't know,” “declined to answer”), and clarification of instructions. The purpose of these minor changes is to improve the quality of the instruments and make it easier for the respondents to complete the forms. The improved instructions should reduce confusion in completing the forms. Adding additional response options will eliminate forced responses that do not represent the participant's intent and will increase response accuracy.

A 60-day notice published in the **Federal Register**, Vol. 87, No. 203, FR 64065–64066 (Friday, October 21, 2022). There were no public comments.

Need and Proposed Use of the Information: The purpose of the revised data collection instruments will be to assess grantee and participant-level progress towards meeting Healthy Start program performance measures. The data will be used to conduct ongoing performance monitoring of the program, thus meeting program needs for accountability, programmatic decision-making, and ongoing quality assurance.

Likely Respondents: For the General Background, Prenatal, and Parenting Information participant-level forms, respondents include pregnant women, women of reproductive age, and men who are served by the Healthy Start program.

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 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
General Background Form	* 45,700	1	45,700	.30	13,710
Prenatal	* 30,300	1	30,300	.10	3,030
Parenting	* 30,300	1	30,300	.25	7,575
Total	106,300	106,300	24,315

* All adult participants (45,700) complete the General Background form, and a subset of these same individuals (30,300) also complete the Prenatal or Parenting forms for total of 106,300 responses.

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 and utility 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

Indian Health Service

The Special Diabetes Program for Indians Nashville Area Technical Assistance and Support Program

Announcement Type: New Single Source.

Funding Announcement Number: HHS-2023-IHS-SDPI-0002.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.237.

Key Dates

Application Deadline Date: April 3, 2023.

Earliest Anticipated Start Date: April 18, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting an application for a single source cooperative agreement with United South and Eastern Tribes, Inc. (USET) to continue the Special Diabetes Program for Indians (SDPI) Nashville Area technical assistance and support. These services are authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and Section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c-3. This program is described in the Assistance

Listings located at <https://sam.gov/content/home/> (formerly known as the CFDA) under 93.237.

Background

Diabetes is a complex and costly chronic disease that requires tremendous long-term efforts to prevent and treat. Although diabetes is a nationwide public health problem, American Indian and Alaska Native (AI/AN) people are disproportionately affected. In 2019, 14.5 percent of AI/AN people aged 18 years or older had diagnosed diabetes, compared to 7.4 percent of non-Hispanic white people [CDC, 2021. <https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html>]. In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population [O'Connell, 2010 (<https://diabetesjournals.org/care/article/33/7/1463/39326/Racial-Disparities-in-Health-StatusA-comparison-of>); Cho, 2014 (<https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2014.301968>)]. Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

In response to the burgeoning diabetes epidemic among AI/AN people, Congress established the SDPI through the Balanced Budget Act of 1997. This grant program was developed to provide diabetes treatment and/or prevention activities and/or services (also referred to as "activities/services") for AI/AN communities. There are currently 302 SDPI grant programs that are dispersed throughout each of the 12 IHS Areas. Each of the IHS Areas contain SDPI programs (primary grantees or subgrantees) that implement the mandatory requirements of the grant management process, including, but not limited to, the grant application, budgetary requirements, data collection/analysis, reporting, training, etc. Of the 12 IHS Areas, 9 of them have elected to fund a mechanism to provide technical support for their SDPI programs within their Area. Since the inception of SDPI, the Nashville Area, IHS, has received

technical assistance and SDPI program support from USET via an SDPI grant mechanism. It has been determined that in 2023, support for the Nashville Area SDPI programs would need to be supported by USET via an IHS cooperative agreement.

Purpose

The purpose of this program is to allow USET to continue to provide technical assistance and SDPI program support for the SDPI grant programs in the Nashville Area. The focus of this assistance and support would be in the areas of grant management, program capacity building, budget development, and grant reporting to ensure the Nashville Area SDPI programs are meeting all of the grant requirements and deliverables in a timely manner. To do this, USET must meet the following objectives:

- Provide culturally-appropriate training and technical assistance to Nashville SDPI programs using diabetes-specific tools, the Resource and Patient Management System (RPMS), and other electronic health record (EHR) systems.
- Continue to refine and provide practical and innovative diabetes project tools.
- Build partnerships and collaboration for the expansion of resources and services to Tribal diabetes programs.
- Demonstrate and provide culturally appropriate training to Tribal programs on various Best Practices and topics, such as tobacco cessation, nutrition, physical activity, eye exams, motivational interviewing, Healthy Heart and Diabetes Prevention Program curricula, traditional foods/gardens, and motivational interviewing.

Required, Optional, and Allowable Activities

(1) Complete a needs assessment survey to help plan program activities and prioritize site visits throughout the Nashville Area, IHS.

(2) The project contracts diabetes program coordinators to offer technical assistance and training and discuss the site's needs.