significant reliance on informatics to achieve a meaningful and reportable result. As a consequence, clinical laboratories require personnel knowledgeable in bioinformatics or pathology/laboratory informatics to design and manage the bioinformatics analysis.

While CLIA regulations apply to clinical NGS testing, there is a lack of clarity regarding how the general CLIA quality system and personnel requirements should be specifically implemented for the NGS bioinformatics components. In April 2019, CLIAC made eight recommendations regarding CLIA's application to NGS-based technologies. This request for information is soliciting comments from the public for more information on topic areas mentioned in two of the recommendations, specifically, the qualifications of personnel performing bioinformatics activities; storage and retention of NGS data files; and maintenance of sequence analysis software. The April 2019 CLIAC summary is available in the docket under the Supporting Materials tab and at *https://www.cdc.gov/cliac/past-meetings.html.*

The qualifications and responsibilities of personnel performing the informatics component of the testing process are not addressed in the CLIA regulations. For the purpose of this request for information, the informatics component of NGS includes the analysis of NGS machine-generated data and subsequent computational processes. Therefore, CDC is asking the public to describe different responsibilities of personnel providing bioinformatics or pathology/laboratory informatics expertise such as validating and assuring that the informatics pipeline meets documented performance specifications.

CDC is also interested in learning the skills, training, and education of personnel who will fill bioinformatics or pathology/laboratory informatics positions, and how clinical and public health laboratories can recruit and retain personnel with these identified skills.

Lastly, the NGS testing process generates large amounts of data and requires multiple file types. CLIA regulations specify at 42 CFR 493.1105(a)(3) that all analytic systems records must be kept for at least two years, but the regulations do not specify the types of data to be captured or the retention time for a given data type. The regulations do not address the capability to access and reanalyze the data after the test is performed. This capability may require retention of the version of software used in the original analysis. CDC requests comment from the public on this topic.

Dated: May 12, 2020.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2020–10461 Filed 5–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19BHC]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Evaluation of the DP18–1815 Cooperative Agreement Program: Category A, Diabetes Management and Type 2 Diabetes Prevention to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 5, 2019, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Evaluation of the DP18–1815 Cooperative Agreement Program: Category A, Diabetes Management and Type 2 Diabetes Prevention—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Division of Diabetes Translation (DDT) and Division for Heart Disease and Stroke Prevention (DHDSP) are submitting this new information collection request (ICR) for an evaluation of the recently launched five-year Cooperative Agreement program CDC–RFA–DP18–1815PPHF18: Improving the Health of Americans Through Prevention and Management of Diabetes and Heart Disease and Stroke, hereafter referred to as ''1815''. This cooperative agreement funds all 50 State Health Departments and the Washington, DC health department (hereafter referred to as ''HD recipients'') to support investments in implementing evidence-based strategies to prevent and manage cardiovascular disease (CVD) and diabetes in high-burden populations/communities within each state and the District of Columbia. High burden populations/communities are those affected disproportionately by high blood pressure, high blood cholesterol, diabetes, or prediabetes due to socioeconomic or other characteristics, including access to care, poor quality of care, or low income. The 1815 program is a collaboration between DDT and DHDSP and is structured into two program categories aligning with each

Division: Category A focuses on diabetes management and type 2 diabetes prevention; Category B focuses on CVD prevention and management. This information request package focuses on data collection activities for the Category A diabetes assessment.

This cooperative agreement is a substantial investment of federal funds. DDT and DHDSP are responsible for the stewardship of these funds, and they must be able to demonstrate the types of interventions being implemented and what is being accomplished through the use of these funds. Thus, throughout the five-year cooperative agreement period, CDC will work with HD recipients to track the implementation of the cooperative agreement strategies and evaluate program processes and outcomes. In order to collect this information for Category A, CDC has designed two overarching components: (1) Category A rapid evaluation of DSMES and National DPP partner sites and (2) Category A recipient-led evaluations. Each component consists of data collection mechanisms and tools that are designed to capture the most relevant information needed to inform the evaluation effort while placing minimum burden on respondents. Respondents will include HD recipients, as well as select HD recipient partner sites, which are organizations that HD recipients are partnering with in the implementation of the 1815 strategies.

The evaluation of cooperative agreement strategies and activities conducted by DDT will determine the efficiency, effectiveness, impact and sustainability of 1815-funded strategies in the promotion, prevention, and management of diabetes and heart disease and help identify promising practices that can be replicated and scaled to better improve health outcomes. In addition, evaluation plays a critical role in organizational learning, program planning, decision-making, and measurement of the 1815 strategies. As an action-oriented process, the evaluation will serve to identify programs that have positive outcomes, identify those that may need additional technical assistance support, and highlight the specific activities that make the biggest contribution to improving diabetes and cardiovascular disease prevention and management efforts. Without collection of new evaluative data, CDC will not be able to capture critical information needed to continuously improve programmatic efforts and clearly demonstrate the use of federal funds.

OMB approval is requested for three years. Participation is required for cooperative agreement awardees and voluntary for partner sites. The total estimated annualized burden hours are 1,084.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Department (1815 Recipient).	Evaluation and Performance Measurement Plan (EPMP)	17	1	8
	Recipient-Led Evaluation Reporting Template	51	1	8
	DSMES Partner Site-Level Rapid Evaluation Rapid Evaluation Form.	17	1	0.5
	National DPP Partner Site-Level Rapid Evaluation Nomination Form.	17	1	0.5
DSMES Partner Site	DSMES Partner Site-Level Rapid Evaluation Survey Questionnaire.	340	1	0.5
	Program Coordinator Interview Guide	14	1	2
	Professional Team Member Interview Guide	28	1	2
	Paraprofessional Team Member Interview Guide	28	1	2
National DPP Partner Site	National DPP Partner Site-Level Rapid Evaluation Survey Questionnaire.	340	1	0.5
	Program Coordinator Interview Guide	14	1	1
	Lifestyle Coach Interview Guide	28	1	1

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Head Start Act, notice is hereby given of three 1-day tribal consultation sessions to be held between HHS/ACF OHS leadership and the leadership of tribal governments operating Head Start and Early Head Start programs. The purpose of these consultation sessions is to discuss ways to better meet the needs of American Indian and Alaska Native (AIAN) children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Three tribal consultations will be held as part of HHS/ACF or ACF Tribal Consultation Sessions. Please note the planned tribal consultation dates may be impacted by COVID–19 travel restrictions. OHS will consider virtual means of facilitating tribal consultations and/or the postponing of tribal consultations should travel restrictions and group meeting limitations remain in effect.

DATES: July 9–10, 2020, 1 to 3 p.m.
July 14–16, 2020, 1 to 3 p.m.
Aug. 3, 2020, 1 to 5 p.m.

ADDRESSES:

- July 9–10, 2020—Glendale, AZ (Location TBD)
- July 14–16, 2020—Denver, CO (Location TBD)
- Aug. 3, 2020—Spokane, WA (Northern Quest Resort)

FOR FURTHER INFORMATION CONTACT: Todd Lertjuntharangool, regional program manager, Region XI/AIAN, Office of Head Start, email