BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15ANC; Docket No. CDC-2015-0044]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a newly proposed information collection entitled "Formative and Summative Evaluation of the

National Diabetes Prevention Program". Mixed methods will be used to describe program performance.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0044 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall

have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. 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.

Proposed Project

Formative and Summative Evaluation of the National Diabetes Prevention Program,- New - National Center for Chronic Disease

Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Diabetes takes a significant toll on the public's health and, subsequently, our nation's health care system. In addition to 29.1 million people in the US population diagnosed with diabetes, CDC estimates that 86 million adults aged 20 or older have prediabetes. Evidence-based lifestyle change programs have proven effective for preventing or delaying the onset of type 2 diabetes. However, several challenges must be addressed to achieve large-scale adoption and implementation of evidence-based lifestyle change programs. Implementation barriers include creating a shared vision among inherently different organizations, managing costs, managing variations in the quality of interventions, and training and appropriate referral of those at risk to lifestyle change programs.

In response to these challenges, CDC led the development of the National Diabetes Prevention Program (National DPP), a lifestyle change program aimed to increase knowledge and awareness of healthy eating and activities among people at-risk for diabetes. The National DPP funded six grantees to establish and expand "a network of structured, evidence-based lifestyle change programs designed to prevent type 2 diabetes among people

at high risk." Grantees are responsible for sustaining and scaling up the National DPP, which involves establishing evidence-based lifestyle change programs in multiple states and building a system to strategically recruit participants at high risk for diabetes.

As a central component of the National DPP, grantees promote sites' participation in the CDC's Diabetes Prevention Recognition Program (DPRP). The DPRP recognizes organizations that demonstrate effective delivery of proven type 2 diabetes prevention lifestyle interventions. To sustain the programs beyond the funding period, grantees are responsible for

- gaining concrete support for delivery sites from insurance companies in the form of reimbursement, and
- developping delivery sites' capacity to obtain and maintain DPRP recognition, and
- actively educating employers and insurance companies on the cost savings of including the lifestyle change program as a covered health benefit and reimbursing delivery sites on a pay-for-performance basis.

The National DPP has the potential for increasing the availability and reach of lifestyle change programs for those at risk for type 2 diabetes, improving the quality of programs and resources offered, and creating sustainable changes in how third-party payers offer and reimburse for programs to ensure

that they are available to individuals regardless of their ability to pay.

CDC plans to collect information needed to evaluate the role of program-level factors on the effectiveness of National DPP efforts and to identify best practices. The best practices will draw from many different implementation strategies and take into account the barriers that arise in a variety of different delivery settings. Specifically, this assessment will reveal the impact of recruitment strategies and delivery models on factors such as reaching targeted demographics and participant completion rates. As a result of the assessment, the successes and challenges experienced by all programs can be used by other organizations to sustain and increase the effectiveness of their own lifestyle change programs. This information is necessary for translating the National DPP into various settings nationwide.

CDC plans to distribute an assessment tool (spreadsheet) to all six grantees, who will, in turn, disseminate the tool to their partner organizations across 23 states and 2 tribes and tribal organizations. The spreadsheets are a means for grantees and intervention sites to report on program components and progress. Grantees are responsible for completing their specific data collection spreadsheet and for distributing the spreadsheets to their interventions sites. Each grantee will collect information from its intervention sites, collate the

site-specific spreadsheet reports into an aggregate grantee report, and submit the aggregate spreadsheet report to the CDC.

Program coordinators at each intervention site will be asked to describe their intervention, identify barriers and facilitators to implementation, and identify resources used to hold the lifestyle change classes. The estimated burden per response is 30 minutes. Project directors at the grantee level will be asked similar questions about resource use and implementation strategies, but will also be asked to discuss elements related to the reach of their National DPP programs. The estimated burden per response for a grantee is 8 hours.

CDC will use the information to investigate how to 1) expand the reach and sustainability of the National DPP program, 2) ensure the quality of the program as it is offered within communities, 3) increase referrals, and 4) secure sustained commitment among insurance providers to reimburse organizations providing the program so it is accessible to individuals most in need of this intervention. Finally, CDC will use the information to inform the development of data-driven technical assistance for National DPP grantees and their intervention sites.

OMB approval is requested for three years, in which there will be two waves of information collection. Wave one will include 110 NDPP Intervention Sites and 6 NDPP Grantees, and wave two will include 120 NDPP Intervention Sites and 6 NDPP

Grantees. Over the three-year clearance period, the total burden estimate is based on 73 annualized responses from NDPP Intervention Sites (110 + 120 / 3) and 4 annualized responses from NDPP Grantees (6 + 6 / 3).

Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
NDPP Intervention Sites	Spreadsheet for NDPP Intervention Sites	73	1	30/60	37
NDPP FOA Grantees	Spreadsheet for NDPP Grantees	4	1	8	32
Total					69

_____

Leroy A. Richardson,
Chief, Information Collection Review Office,

Office of Scientific Integrity,
Office of the Associate Director for Science,

Office of the Director,
Centers for Disease Control and Prevention.

[FR Doc. 2015-13955 Filed: 6/8/2015 08:45 am; Publication Date: 6/9/2015]