

personal information about all individuals accessing the LRN website. Since CDC must be able to contact all laboratory personnel during an event, each laboratory staff member who obtains access to the restricted LRN website must provide his or her contact information to the LRN Program Office.

As a requirement of membership, LRN laboratories must report all biological and chemical testing results to the LRN Program using a CDC developed software tool called the LRN Results Messenger, or through the laboratory information management system (LIMS) which CDC refers to as Data Integration. CDC supplies this software to LRN laboratories at no charge. This information obtained from LRN laboratories is essential for surveillance of anomalies, to support response to an event that may involve multiple agencies, and to manage limited resources.

LRN laboratories are also required to participate in Proficiency Testing Challenges or Validation Studies and report their results to CDC. LRN laboratories participate in multiple Proficiency Testing Challenges, Exercises and/or Validation Studies every year. These activities consist of 5–500 simulated samples provided by CDC. These challenges are necessary to verify the testing capability of the LRN laboratories. Because biological or chemical agents perceived to be of bioterrorism concern can occur rarely, some LRN laboratories may not be maintaining proficiency in certain

testing methods as a result of day-to-day testing. Thus, simulated samples are distributed to ensure proficiency across LRN member laboratories. LRN laboratories also enter the results of these simulated samples into the LRN Results Messenger or through Data Integration for evaluation by CDC.

During a surge event resulting from a bioterrorism or chemical terrorism attack, or during an emerging infectious disease outbreak, LRN Laboratories must submit all testing results using LRN Results Messenger or through Data Integration. CDC uses these results in order to track the progression of a bioterrorism event, responds in the most efficient and effective way possible, and shares this data with other Federal partners involved in the response.

Data is collected via two primary avenues, the program LRN Results Messenger or through Data Integration and the LRN website. Laboratories belonging to the Laboratory Response Network utilize the CDC developed software tool LRN Results Messenger to submit testing results to CDC. Data Integration is an effort parallel to the LRN Results Messenger which will ultimately allow laboratories to submit data to CDC using their own data collection systems. Results include details about the type and source of samples as well as the tests performed and the numerical and empirical results of those tests. The LRN website is used by laboratories to provide their complete testing capabilities to CDC. All individuals who use the LRN website

must provide their contact information to the LRN Program Office during registration.

An LRN laboratory must provide its testing capabilities, physical and shipping addresses, United States Department of Agriculture (USDA) and Select Agent Permits, and specified responsible individuals' names, phone numbers and email addresses. After registering with the LRN website, a user must provide his/her first and last name, work phone number, alternate phone number, email address, and month and day of birth.

During reporting of results, sample details, tests performed, results obtained, and conclusions of tests are required. Accomplishments during the last three years include the requalification of labs. The requalification occurred between November 7, 2016 and December 12, 2016. We had 130 domestic LRN labs tasked with completing the requalification, and had a 96% response rate. The LRN website has remained the same, and has only undergone routine maintenance since 2015 to keep it in working order.

This data collection is authorized under the Public Health Service Act, (42 U.S.C. 241) Section 301. CDC has estimated the annualized burden for this project to be 2,064,660 hours, a decrease of 317,640 hours per year. There is no cost to respondents other than the time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public health laboratories	Biennial Requalification	130	1	2
	General Surveillance Testing Results	130	25	24
	Proficiency Testing/Validation Testing Results.	130	5	56
	Surge Event Testing Results	130	625	24

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

Centers for Disease Control and Prevention

[30 Day–19–1090]

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 Formative and

Summative Evaluation of Scaling the National Diabetes Prevention Program (National DPP) in Underserved Areas 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 October 4, 2018 to obtain comments from the public and affected agencies. CDC received and responded to five sets of unique public 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 agency's 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 or send an email to omb@cdc.gov. 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

Formative and Summative Evaluation of Scaling the National Diabetes Prevention Program (National DPP) in Underserved Areas (OMB No. 0920-1090, exp. 12/31/2018)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC-led National Diabetes Prevention Program (DPP) is a partnership of public and private organizations working collectively to build the infrastructure for nationwide delivery of an evidence-based lifestyle change program to prevent or delay type 2 diabetes among adults with prediabetes. The National DPP lifestyle change program is founded on the science of the Diabetes Prevention

Program research study and several translation studies that followed, which showed that making modest behavior changes helped people with prediabetes lose 5% to 7% of their body weight and reduce their risk of developing type 2 diabetes by 58% (71% for people over 60 years old). From 2012 to 2017, CDC funded six national organizations through a cooperative agreement to establish and expand multistate networks of over 200 program delivery organizations that were able to meet national standards and achieve the outcomes proven to prevent or delay onset of type 2 diabetes. CDC has conducted a formative and summative evaluation of this program and used the evaluation findings and lessons learned to provide data-driven technical assistance to the grantees and other organizations delivering the National DPP lifestyle change program. The data and lessons learned from DP12-1212 were also used to inform decision-making and policy, including the development of the Centers for Medicare & Medicaid Services (CMS) Medicare Diabetes Prevention Program (MDPP). As of April 1, 2018, the MDPP Expanded Model provides coverage for the National DPP lifestyle change program for eligible Medicare beneficiaries.

Despite the fact that over 1,700 CDC-recognized organizations in 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and other U.S.-affiliated island jurisdictions/territories offer the National DPP lifestyle change program, there are still many geographic areas with few, or no, in-person delivery programs. In addition, some populations, including Medicare beneficiaries, men, African-Americans, Asian-Americans, Hispanics, American Indians, Alaska Natives, Pacific Islanders, and people with visual impairment or physical disabilities, are under-enrolled relative to their estimated numbers and disease burden. To address these gaps, CDC funded a new, five-year cooperative agreement with ten new national organizations in September 2017, "Scaling the National DPP in Underserved Areas" (DP17-1705). CDC funded 10 national organizations with affiliate program delivery sites in at least three states, each to start new CDC-recognized organizations in underserved areas and to enroll both general and priority populations in new or existing CDC-recognized organizations. The DP17-1705 grantees will work on activities designed to accomplish three main goals:

(1) Build the infrastructure in underserved areas necessary to deliver

the National DPP lifestyle change program to the general population and to priority populations, including Medicare beneficiaries, men, African-Americans, Asian-Americans, Hispanics, American Indians, Alaska Natives, Pacific Islanders, and non-institutionalized people with visual or physical disabilities;

(2) Tailor and adapt the program to address the unique needs and challenges of the enrolled participants; and

(3) Provide participants with specialized support needed to successfully complete the program and achieve 5-7% weight loss. Through this new cooperative agreement, it is anticipated that enrollment, retention, and achievement of 5-7% weight loss in the targeted populations will increase.

At this time, CDC requests an additional three years of OMB approval to continue collecting information needed to evaluate the effectiveness of CDC's funding for the new grantees. The data collection will allow CDC to continue to provide data-driven, tailored programmatic technical assistance to ensure continuous quality improvement for each year of the cooperative agreement. A number of additional changes to the evaluation forms are proposed based on the public comments received from the previously published notice on October 4, 2018 to reduce burden on respondents. Evaluation data elements have been modified accordingly to ensure that reporting and evaluation requirements are consistent with the aims of the new cooperative agreement and reflect lessons learned from the original funded national organizations and their affiliate delivery sites. Also, the method of data collection has changed from an Excel spreadsheet to a web-based data system to allow for real-time feedback and technical assistance. The estimated reporting burden has increased and is expected to vary between three and five hours with an average of four hours per grantee response (increased from average of three hours in the previous notice), and between five and seven hours with an average of six hours per affiliate delivery site response (increased from an average of five hours in the previous notice). These estimated burden hours include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and entering data in the web-based data system. The number of respondents will increase with the increased number of grantees. These changes result in a net increase of 478 annualized burden

hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
National DPP Affiliate Delivery Sites	Evaluation Form for Sites	100	1	6
National DPP Grantees	Evaluation Form for Grantees	10	1	4

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

Centers for Disease Control and Prevention

[30Day-19-1050]

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 *Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery* 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 March 23, 2018 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 or send an email to omb@cdc.gov. 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

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB 0920-1050, Expiration 6/30/2019)—Revision—Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that our programs are effective and meet our customers’ needs, Centers for Disease Control and Prevention (CDC) seeks to obtain OMB approval of a generic clearance to collect qualitative feedback on our service delivery on collections. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be

generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on March 23, 2018 (vol. 83, No. 57, pages 12766–12768). OMB approval is requested for three years. The estimated annualized burden hours are 22,250.