

Information Collection Request

CDC's National Diabetes Prevention Program (National DPP) Diabetes Prevention Recognition Program

Revision

OMB No. 0920-0909; Exp. Date: 02/28/2021

Supporting Statement: Part A

Program official/project officer: Stephanie Gruss, PhD, MSW (NCCDPHP/DDT/PIB)
Centers for Disease Control and Prevention
Division of Diabetes Translation
Atlanta, Georgia
Telephone number: 770-488-8173
Fax number: 770-488-8634
Email address: inf6@cdc.gov

November 19, 2020

TABLE OF CONTENTS

A. JUSTIFICATION

- A-1 Circumstances Making the Collection of Information Necessary
- A-2 Purpose and Use of Information Collection
- A-3 Use of Improved Information Technology and Burden Reduction
- A-4 Efforts to Identify Duplication and Use of Similar Information
- A-5 Impact on Small Businesses or Other Small Entities
- A-6 Consequences of Collecting the Data Less Frequently
- A-7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A-8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- A-9 Explanation of Any Payment or Gift to Respondents
- A-10 Protection of the Privacy and Confidentiality of Information Provided to Respondents
- A-11 Institutional Review Board (IRB) and Justification for Sensitive Questions
- A-12 Estimates of Annualized Burden Hours and Costs
- A-13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
- A-14 Annualized Cost to the Government
- A-15 Explanation for Program Changes or Adjustments
- A-16 Plans for Tabulation and Publication and Project Time Schedule
- A-17 Reason(s) Display of OMB Expiration Date is Inappropriate
- A-18 Exceptions to Certification for Paperwork Reduction Act Submissions

REFERENCES

ATTACHMENT

- 1 Authorizing Legislation PHSA
- 2A 60-Day Federal Register Notice
- 2B Summary of Public Comments Received
- 2C Comments in Response to the Federal Register Notice and Efforts to Consult Outside of the Agency
- 3 DPRP Standards 2021
- 4A DPRP Application Form and Instructions (screenshot)
- 4B DPRP Evaluation Data Collection Form (screenshot)
- 5 Table of Changes
- 6 IRB Exemption from Human Subjects Research

Summary Table

- Goal of the study. The goal of this information collection is to allow the Centers for Disease Control and Prevention (CDC) an additional three years of OMB approval to continue collecting the information needed to administer the Diabetes Prevention Recognition Program (DPRP) and information needed by the Centers for Medicare & Medicaid Services (CMS) to support the Medicare Expanded Model (Medicare Diabetes Prevention Program [MDPP]). Based on experience with the DPRP from 2012–2020, and feedback from applicant organizations and internal and external partners, CDC proposes to revise the DPRP Standards and the associated information collection.
- Intended use of the resulting data. Data will be used to evaluate the performance of organizations offering the National Diabetes Prevention Program (National DPP) lifestyle change program (LCP). High performing organizations that meet CDC standards specified in this data collection package are awarded either preliminary or full CDC recognition. Recognition is pivotal to an organization's ability to ensure effective program delivery and bill private and public health insurers, and for MDPP implementation. Data will also be shared in aggregate form to inform technical assistance and enhance overall program outcomes.
- Methods to be used to collect information. CDC will collect participant-level, de-identified data directly from organizations via a comma separated value (CSV) Excel spreadsheet or a matching data system such as Data Reporting for Evaluation and Monitoring (DREM) (ICR PIA-201807-0095 1705 DREM; approved 03/21/2019) twice per year. CDC calculates averages across participant cohorts to determine organizational-level performance. Participant-level performance is not assessed by CDC.
- The subpopulation to be studied. The subpopulations for this data collection include CDC Division of Diabetes Translation (DDT) recipients and MDPP suppliers. Final responsibility for MDPP suppliers is that of CMS and not CDC.
- How data will be analyzed. Data analysis will include thematic and aggregate analysis of de-identified quantitative, and organizational qualitative, data using descriptive statistics (e.g., counts, means, range, standard deviation) for organizational-level recognition assessment. Aggregate findings will be provided to organizations via evaluation reports and could be used for annual reports or articles, in which case regression analyses would be used.

Overview

CDC's Division of Diabetes Translation collects information needed to administer the National DPP's quality assurance program, the DPRP (OMB No. 0920-0909, exp. 02/28/2021). Through the DPRP, CDC recognizes organizations that successfully deliver the evidence-based National DPP LCP to participants who have prediabetes or are at high risk for type 2 diabetes. The National DPP LCP is based on a structured yearlong lifestyle intervention shown to be effective in a clinical research trial and in subsequent translation studies which demonstrated the program's effectiveness in communities and other real world settings. The DPRP Standards, initially approved in 2011 and revised in 2015 and again in 2018, specify criteria for the program and describe how organizations can achieve CDC recognition. Information currently submitted to CDC for recognition includes a one-time application form followed by biannual (every 6 months) transmission of evaluation data that allow CDC to assess each organization's fidelity to the DPRP's national quality standards and the progress achieved by participant cohorts. Full CDC recognition is awarded to qualifying organizations when program participants, in aggregate, achieve outcomes aligned to the comprehensive body of research studies.

The 2015 revision described changes in the DPRP Standards and information collection that allowed CDC to recognize organizations that used virtual technologies such as web-based tools and distance learning platforms to deliver the LCP. The 2015 revision also outlined corresponding changes to the information collection plan that allowed CDC to ensure that uniform evaluation criteria are applied to both in-person and virtual programs. Additional changes were made to clarify forms/instructions and to accommodate more user-friendly methods of transmitting required information to CDC.

The 2018 revision described changes that affect the annualized burden estimates. In the initial three-year approval period (OMB No. 0920-0909, exp. 11/30/2014), CDC collected DPRP evaluation data elements semi-annually (once every 6 months). In the second approval period, organizations submitted this information annually (once every 12 months), and the evaluation elements were more rigorous than in the 2011 PRA package. In the 2018 revision, CDC returned to semi-annual data collection to align with the CMS MDPP benefit to cover CDC-recognized organizations serving eligible Medicare beneficiaries beginning January 1, 2018. Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh §424.59) authorized CDC-recognized organizations to prepare for enrollment as MDPP suppliers in order to bill CMS. The current revision continues to be directly linked to the CMS MDPP Expanded Model; both are now working in tandem in order to more broadly scale the National DPP LCP. CMS continues to rely on CDC's DPRP for quality assurance and data monitoring necessary to implement and evaluate the MDPP Expanded Model and to reimburse MDPP suppliers.

In 2011, CDC received OMB approval to collect organizational and de-identified participant information needed to administer the DPRP (OMB No. 0920–0909, exp. 11/30/2014). In 2015, CDC renewed these Standards for 3 years (OMB No. 0920-0909, exp. 12/31/2017) to continue collecting information needed to manage the DPRP. As a result of the MDPP Expanded Model being authorized through the Social Security Act (42 U.S.C. 1302 and 1395hh §424.59) specifying that only organizations in good standing with the CDC’s DPRP are eligible as MDPP suppliers,^{1b} MDPP reimbursement is directly tied to CDC preliminary or full recognition status. The 2018 Standards revision (OMB No. 0920–0909, exp. 02/28/2021) aligned with the CMS MDPP Expanded Model that became effective on January 1, 2018. The MDPP Expanded Model continues to scale the National DPP LCP to a high risk population of Medicare beneficiaries ages 65 and over.

In the current revision of the DPRP Standards, the following changes were made to better assist CDC-recognized organizations in achieving both preliminary and full CDC recognition. Based on these changes, CDC will:

- Collect additional organizational information from applicant organizations to better understand their delivery/intervention models and the intensity of their Lifestyle Coach training efforts (Delivery mode questions; Coach Identifier - ID; Coach training entity).
- Collect Sex and Gender information of participants, one time at program enrollment, to allow for inclusivity and due to research showing greater odds of being diagnosed with type 2 diabetes based on gender identity:³²
 - Sex (described as sex at birth) – Male/Female/Other/Not reported
 - Gender (described as how a participant self-identifies) – Male/Female/Other/Not reported
- Collect cohort information to evaluate outcomes by annual participant cohorts (Class ID).
- Remove session-level, per participant ID to reduce organizational data collection burden.
- Collect and analyze an optional outcome variable to provide organizations an alternative to weight loss as a means of achieving full CDC recognition:
 - Hemoglobin A1C (HbA1C) collected pre-intervention (within one year before first session enrollment and reported at Session 1) and post-intervention (collected in months 10-12) to assess improvement in HbA1C value as one alternative to the original 5% average cohort weight loss. This is an optional variable, as not all organizations will have the capacity to collect and report it.
- Analyze already-collected weight loss and physical activity (PA) minutes in combination to achieve full CDC recognition (i.e., 4% weight loss combined with 150 minutes of PA/week on average). This would be a second alternative to the original 5% average cohort weight loss.

OMB approval is requested for three years to continue to align with the CMS MDPP Expanded Model and to allow organizations an opportunity to further institutionalize and scale the

evidence-based National DPP LCP. The seminal literature around lifestyle change for the prevention of type 2 diabetes has remained fairly consistent, and current literature, DPRP data analyses, and key stakeholder feedback support this current revision. Thus, CDC anticipates no need to fully revise the DPRP Standards for another three years.

Section A. Justification

1. Circumstances Making the Collection of Information Necessary

According to CDC's 2020 National Diabetes Statistics Report, more than 34 million adult Americans (13.0%) are living with type 2 diabetes, and 88 million have prediabetes (34.5%).^{1a} Diabetes is a disease in which blood glucose levels are above normal. Diabetes can cause serious health complications including heart disease, blindness, kidney failure, and lower-extremity amputations. Prediabetes is a condition in which blood sugar is elevated but not high enough for a diagnosis of diabetes.^{1a} People with prediabetes have an increased risk of developing type 2 diabetes, heart disease, and stroke. In 2017, the direct and indirect cost of the management and treatment of type 2 diabetes and its related complications in the U.S. was estimated to be \$327 billion^{1b}. Type 2 diabetes affects more than 25 percent of Americans aged 65 or older, and its prevalence is projected to increase approximately two fold for all U.S. adults (ages 18-79) by 2050 if current trends continue.^{1c} CMS estimated that Medicare spent \$42 billion more in the single year of 2016 on fee-for-service, non-dual eligible, over age 65 beneficiaries with diabetes than it would have spent if those beneficiaries did not have diabetes.^{1b} Providing a cost-effective way to prevent or delay the progression of prediabetes to type 2 diabetes can help improve quality of life for Americans and contain health care costs.^{17,18}

Fortunately, type 2 diabetes can be prevented. In 2001, results from the Diabetes Prevention Program (DPP), a research study led by the National Institutes of Health (NIH), showed a structured lifestyle intervention to be effective in preventing or delaying the onset of type 2 diabetes in participants with prediabetes when delivered on a one-on-one basis. In the DPP research trial, participants losing 5-7% body weight in the lifestyle intervention experienced a 58% lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention.² Follow-up to the DPP and other international studies showed that reduced type 2 diabetes incidence could be sustained for 15 or more years.³⁻⁵ Effectiveness research demonstrated that the DPP curriculum, when modified slightly for delivery in a group setting by community-based organizations, helped program participants achieve the 5-7% weight loss needed to prevent or delay type 2 diabetes in individuals with prediabetes, and that such a program can be cost effective and cost saving.^{6-10,23} Medicare actuarial analyses determined the program to be cost-saving as well.^{1b} Other studies where the lifestyle change program was delivered via the internet, with and without behavioral e-counseling, demonstrated effectiveness.^{11,26-28,30}

CDC established the National DPP, administered by DDT, to make the lifestyle intervention broadly available to individuals at high risk for type 2 diabetes. Key features of the evidence-based intervention that are known to be successful include: weight loss (5-7% of body weight), documentation of physical activity minutes (with a goal of ≥ 150 minutes per week), and attendance throughout the 12-month program (with two required phases, a minimum of 16 weekly sessions in months 1-6 and a minimum of 6 monthly sessions in months 7-12). The quality assurance arm of the National DPP, the DPRP, has shown—via analyses of its own dataset—that there is a dose/response relationship between attendance and weight loss, especially when attendance is maintained throughout the yearlong program.^{19-22,31}

The National DPP is authorized under Sections 301(a) and 1703(a) of the Public Health Service Act (**Attachment 1**). The National DPP was to include a program “to determine eligibility of entities to deliver community-based diabetes prevention services” and provide “evaluation, monitoring, and technical assistance” to those entities. In 2011, CDC established the DPRP as the evaluation and quality assurance arm of the National DPP.²⁻¹¹ The DPRP was created to recognize organizations that deliver the evidence-based National DPP LCP, via a 12-month in-person program, to individuals with prediabetes or at high risk for type 2 diabetes. Based on later promising scientific evidence from published studies, virtual programs were added in 2015.^{12-15,26-27} Key objectives of the DPRP include:

- Assure program quality, fidelity to scientific evidence, and broad use of the National DPP LCP throughout the United States.
- Monitor, evaluate, and provide technical assistance to entities that offer the program to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition.
- Develop and maintain a registry of organizations recognized for their ability to effectively deliver the National DPP LCP to people at high risk for type 2 diabetes.

Criteria for achieving recognition are outlined in the **CDC Diabetes Prevention and Recognition Program: Standards and Operating Procedures** (DPRP Standards) (**Attachment 3**) throughout this ICR. The DPRP Standards describe how an organization may apply for, achieve, and maintain recognition. To achieve full CDC recognition, all programs, regardless of delivery mode, must meet all of the requirements outlined in the DPRP Standards. The requirements reflect the lifestyle change program elements proven effective for the prevention or delay of type 2 diabetes, including participant eligibility requirements, program intensity and duration, participant weight loss, recording of physical activity minutes, reduction in HbA1C value and documentation of required attendance throughout the entire 12-month program.

As authorized by the Public Health Service Act (**Attachment 1**), CDC is currently approved to collect information from organizations seeking recognition through the DPRP (OMB No. 0920-0909, exp. 02/28/2021). CDC is seeking a fourth revision for three years (March 1, 2021 through February 28, 2024). Two types of information have been and will continue to be collected from applicant organizations: a one-time DPRP Application Form (**Attachment 4A**), followed by the DPRP Evaluation Data Collection Form (**Attachment 4B**). The DPRP Application Form allows CDC to assess the applicant organization's readiness to achieve CDC recognition and to maintain pertinent contact and organizational information. Organizations that have the capacity to deliver a the National DPP LCP and agree to adhere to the DPRP Standards proceed to "pending" recognition status. Once in pending, an organization agrees to submit evaluation data twice per year to CDC for review. The evaluation data elements consist of de-identified information about participants and the educational/coaching sessions delivered by the applicant organization. Collection of evaluation information allows CDC to assess the organization's fidelity to the DPRP Standards and to provide technical assistance, as needed, for program improvement. "Full" recognition is awarded to organizations that fully meet the requirements described in the DPRP Standards within a specified time frame. In this fourth revision, collection of evaluation information will continue to permit CDC-recognized organizations that are also MDPP suppliers to bill CMS for their services once either preliminary (meeting pending recognition requirements and retaining at least 5 completers in the yearlong evaluation cohort) or full recognition status is achieved.

CDC seeks to extend OMB approval for DPRP data collection for three years, with revisions. Importantly, the DPRP Standards are being revised to remove the previous 2018 DPRP Standards requirement to record Session ID, which will reduce the 2021 DPRP Standards reporting burden. This revision will also strengthen information pertaining to sex/gender, delivery mode, and Lifestyle Coach training, and will offer optional outcome variables for achieving full CDC recognition. It will also strengthen CDC's ability to analyze data by organization-level cohorts.

The revised 2021 DPRP Standards and data collection requirements will be effective for all new applicant organizations immediately upon receipt of OMB approval of this revision (estimated February 2021 to March 1, 2021). In order to provide current CDC-recognized organizations an orderly transition from the 2018 DPRP Standards to the revised 2021 DPRP Standards, CDC will develop a transition plan, as program guidance, in early 2021 that will allow organizations to adapt their reporting systems without unduly interrupting progress toward achievement of CDC recognition. A transition e-mail will be sent to organizations to inform them of the changes that will affect them and of the allowances that will be made made for existing organizations during the first 6 months of 2021. CDC will offer technical assistance during this process to ease the burden.

CDC anticipates that information collection will continue throughout the lifetime of the DPRP. At this time, CDC requests an additional three years of OMB approval (March 1, 2021 through February 28, 2024) to collect the information needed to administer the DPRP and to continue to align with the MDPP Expanded Model.

2. Purpose and Use of the Data

The DPRP is a quality assurance program for organizations offering the National DPP LCP. The DPRP helps generate awareness of and demand for the program among people at high risk for developing type 2 diabetes, health care providers, and public and private payers, including CMS. CDC recognition assures physicians, other health care providers, and employers and insurers that they are referring people with prediabetes or at high risk for type 2 diabetes to organizations that are implementing the program with fidelity to the evidence.

DPRP information collected by CDC and aggregated at the organizational, state, regional, or national level is used for multiple purposes, including:

- To promote the dissemination and use of effective strategies for preventing type 2 diabetes;
- To assess applicant organizations' compliance with the DPRP Standards, their progression from "pending" and "preliminary" to "full" recognition status, and their need for technical assistance to help strengthen delivery of the program;
- To enhance public health intervention strategies at the organizational, state, regional, and/or national level;
- To help potential participants, health care providers, and payers identify CDC-recognized organizations, including their locations.

Organizations applying for **Pending Recognition** must submit an application for each delivery modality and agree to deliver a yearlong evidence-based program using a CDC-approved curriculum. They must also agree to submit evaluation data semi-annually to allow the DPRP to monitor fidelity of program delivery and program effectiveness, and to provide technical assistance.

Organizations achieve **Preliminary Recognition** when they meet the following criteria:

1. The requirements for pending recognition.
2. Requirement 5: Organizations must retain at least 5 completers in the evaluation cohort (eligible participants in the evaluation cohort who attended at least 8 sessions in months 1-6 and whose time from the first session held by the cohort to the last session attended by the participant is at least 9 months).

Once an organization meets the requirements for preliminary, the organization may remain in preliminary recognition indefinitely if it continues to submit the required data every 6 months and is able to meet the requirements for preliminary within 3 years of first achieving it, and then at least every 3 years thereafter.

- **Temporary Preliminary Recognition**

If an organization has preliminary or full recognition for one delivery mode and subsequently applies to deliver the National DPP LCP through an additional delivery mode, the DPRP will convey temporary preliminary recognition to the new delivery mode. This is a special designation that will only last until the organization has its first evaluation for the new delivery mode. At that time, the organization will achieve recognition based only on data submitted for the new delivery mode. If the organization is unable to meet the requirements for preliminary or full recognition based on that evaluation, the DPRP will place it in pending recognition status.

Full Recognition

Organizations may receive full recognition for a period of either three years or five years. See additional requirements below for an organization to qualify for full recognition for five years. An organization may remain in full recognition for 3 years if it continues to submit the required data every 6 months. Those organizations still active and submitting data that do not re-achieve full recognition status after 36 months will return to preliminary. MDPP suppliers that lose full recognition will be able to continue as an MDPP supplier with preliminary recognition. Once an organization meets the requirements for full recognition, it will be allowed to remain in full for 3 years despite not meeting the requirements, as long as it continues to make data submissions in every submission due month. Organizations will achieve full recognition when they meet the following criteria:

1. The requirements for pending recognition.
2. The requirement for preliminary recognition.
3. Requirement 6: Organizations must show that there has been a reduction of risk of developing type 2 diabetes among completers in the evaluation cohort by showing that at least 60% of all completers achieved at least **one** of the following outcomes:
 - a. at least 5% weight loss 12 months after the cohort began or
 - b. at least 4% weight loss and at least 150 minutes/week on average of physical activity 12 months after the cohort began or
 - c. at least a 0.2% reduction in HbA1C
4. Requirement 7: Organizations must show that at least 35% of completers in the evaluation cohort are eligible for the yearlong National DPP LCP based on either a blood test indicating prediabetes or a history of GDM.

Organizations will be granted an additional 2 years of full recognition (for a total of 5 years) if, at the time full recognition is achieved, the following retention criterion is met:

Eligible participants in the evaluation cohort must have been retained at the following percentages:

- A minimum of 50% at the beginning of the fourth month since the cohorts held their first sessions.
- A minimum of 40% at the beginning of the seventh month since the cohorts held their first sessions.
- A minimum of 30% at the beginning of the tenth month since the cohorts held their first sessions.

Application data: CDC uses the data elements from the DPRP application to communicate with the applicant organization. A limited amount of information about the applicant organization [organization name, organization code, telephone number, location, web address (if provided and approved), program delivery mode, organization class locations for mapping purposes, and level of recognition] is made publicly available on the National DPP web site or through other directories. This information helps consumers, health care providers, and payers such as CMS identify organizations that are delivering the National DPP LCP with fidelity to the evidence.

Evaluation data: The evaluation data elements provide the basis for the recognition process. Using the elements and objective criteria, CDC monitors the fidelity of program delivery and effectiveness and provides timely feedback and technical assistance. The evaluation data elements address both fidelity of program delivery and participant outcomes. However, CDC's primary objective is to assess the effectiveness of organizations rather than the success or failure of the individual program participants. A secondary objective is to assist organizations in meeting requirements to secure reimbursement from CMS and other public and private payers.

CDC provides technical assistance to help organizations identify opportunities for improving program delivery and/or for providing additional support to participants. For example, technical assistance may include, but is not limited to, discussing optimal intervention strategies for each delivery mode and implementing strategies to encourage program participants to make and maintain behavioral changes. In 2018, CDC developed a National DPP Customer Service Center. Through this federal agency Gears of Government award-winning Center, CDC is able to provide a wide range of technical assistance to numerous partners.

Without the ongoing collection of evaluation information, CDC could not verify program eligibility or effectiveness, and there would be no way to monitor and evaluate program

quality on a national level. In addition, CMS would not be able to implement the MDPP Expanded Model, since CDC recognition is a requirement for organizations offering the MDPP to Medicare beneficiaries. CMS continues to depend on the DPRP to assure the quality of the National DPP LCP for Medicare beneficiaries ages 65+ who are at high risk for type 2 diabetes.^{1b}

Privacy Impact Assessment Information

Application data: Each organization seeking recognition must submit contact information, including the organization's name, mailing address, telephone and fax numbers, and web url (if applicable); as well as the names, job titles, and e-mail addresses of employees designated to serve as the organization's primary and secondary contacts and designated data preparer. Organizations must also submit training entity information to ensure adequate and proper training of Lifestyle Coaches. Although the application includes personnel-related Personally Identifiable Information (PII) (e.g., names), the information is not considered personal or private in nature. CDC maintains the PII in password-protected files in a secure facility. A directory of recognized programs is publicly available. However, the directory lists only the name, address, telephone number, web address (if provided and approved), type of organization, and recognition status of each organization; it does not include the name of the organization's contact person or any other person's name.

Evaluation data: CDC analyzes the evaluation data submitted by organizations to objectively assess adherence to the DPRP Standards and recognition criteria. The method of determining prediabetes status is collected to assess compliance with program eligibility standards. Participant-level identification codes and session attendance elements (session date, session type, weight, physical activity minutes, and optional pre- and post-intervention HbA1Cs) are used to evaluate recognition criteria. The elements are aggregated across participants to indicate whether an organization met the required percentage of overall recognition outcome goals.

Collection of demographic information about program participants is necessary to ensure program effectiveness across sex/gender, ages (18+), socioeconomic status (SES) groups (measured by education level), and racial/ethnic groups. Participant process and outcome data include site-specific information (organization code). The organizations generate, assign, and maintain a coded identification number for each participant. Only de-identified, coded, participant-level information is transmitted to CDC. CDC recognizes that some of the participant-specific information (state of residence, ethnicity, race, age, sex/gender, insurance status, method of determining prediabetes status) when coupled with other data (organization code) might be considered PII. However, CDC does not receive or store specific names of persons and will not attempt to identify individuals by data linkages involving demographic,

geographic, or outcome information. CDC will also not contact individual participants or disclose any participant-level data.

As stated above, the required data elements are essential for monitoring the fidelity and effectiveness of the National DPP LCP; providing targeted technical assistance to the CDC-recognized organizations; assisting CMS with implementation of the MDPP Expanded Model; and helping consumers, health care providers, and public and private payers identify quality organizations.

We believe that the proposed procedures are appropriately scaled to ensure low likelihood of disclosure and low likelihood of harm that could result from inadvertent disclosure of individual participant information.

To elaborate, in the DPRP data system, participant-level evaluation data are linked to organization-level application data through the organization code, which is assigned to the organization by CDC at the time of acceptance into the program and subsequently appended to all participant-level records by the organization before it sends data to CDC. Hence, the only linkage of participant records within the DPRP data system is to the organization's contact information (e.g., organization name, address, phone number, contact person). The organizations assign and maintain participant IDs, and CDC does not have access to the keys for these codes or to the applicants' data systems.

No PII- directly or indirectly identifiable- about participants is transmitted to CDC. All identifiers (except the organization code, which is provided by CDC) are assigned and maintained by the applicant organization. Data are submitted in a precisely defined format. The DPRP data system incorporates standard procedures for checking the format and for validating the content of evaluation data submissions upon receipt. Evaluation data sent to CDC that does not conform to the specified format, or includes any PII, is not accepted and is returned immediately and never stored by the DPRP.

CDC is concerned with national program, regional, state, organizational, and aggregated cohort performance, not the performance of individual participants. CDC reports recognition status for each participating organization, and may produce summary reports that include data on the performance of all or some recognized organizations, but will not report on individual participant performance. CDC summary reports may link aggregate program data to geographic area-level variables (e.g., state or county-level demographics), or to organizations for the purpose of providing technical assistance, but we do not believe that such reports could be used to identify an individual participant.

In summary, we believe the risk for identification or disclosure of PII is very low for several reasons:

1. CDC does not accept PII about participants. This is ensured by requiring that evaluation data be submitted in a specific format and having procedures to check format and content before data are accepted.
2. IF PII is sent to CDC, CDC immediately returns, then destroys, any participant-level PII submitted by an organization.
3. The only direct linkage of participant-level data in the DPRP data system is to each organization's contact information via the organization code.
4. CDC does not have access to the keys to any codes, other than the organization code, or to the applicant organizations' data systems.
5. CDC does not attempt to identify individuals by data linkages involving demographic, geographic, or outcome information.
6. CDC does not report on the performance of individual participants and will not disclose any participant-level data.

CDC uses the data only as described and safeguards and secures the data to the full extent required by law. The DPRP Standards clearly assign the principal responsibility for maintaining participant privacy to the participating organizations.

3. Use of Improved Information Technology and Burden Reduction

CDC designed this information collection to minimize the burden to respondents and to the government, to maximize convenience and flexibility, and to ensure the quality and utility of the information collected. One hundred percent of the information submitted to the DPRP is submitted electronically, as specified in the DPRP Standards.

4. Efforts to Identify Duplication and Use of Similar Information

The National DPP, including the DPRP, is authorized under Sections 301(a) and 1703(a) of the Public Health Service Act (**Attachment 1**).

CDC originally examined credentialing, accreditation, or recognition of its National DPP program delivery organizations by the National Committee for Quality Assurance (NCQA), a not-for-profit organization dedicated to improving health care quality. NCQA does not have any efforts for specific monitoring of type 2 diabetes prevention programs. The closest is an accreditation for Wellness and Health Promotion Programs, focused on general risk reduction, primarily for programs offered by employers and health plans. This NCQA offering would not provide the data needed to monitor type 2 diabetes prevention programs.

Since no other federal agency or nonfederal organization monitors lifestyle change programs for the prevention of type 2 diabetes, and CMS now relies on the DPRP for data monitoring

in order to implement and reimburse for the MDPP Expanded Model; the information collected by the DPRP is not available from other sources. CMS proposed the MDPP in Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh §424.59), authorizing CDC-recognized organizations to enroll as MDPP suppliers in order to bill CMS for these services since early 2018. This benefit specifies that only CDC-recognized organizations in good standing with the DPRP are eligible as MDPP suppliers.^{1b} Thus, it is imperative that CDC continue the administration of the DPRP and the accompanying information collection.

5. Impact on Small Businesses or Other Small Entities

This data collection, while not specifically aimed at small business entities, does include organizations that are smaller businesses. Any organization— public, private, non-profit, government, academic, healthcare, etc.—can apply for CDC recognition if they have the capacity to offer the National DPP LCP. Thus far, approximately 25% of applicants are large business entities, and 75% are small business entities. Approximately 70% of applicants are from the private sector, and 30% are from the public sector. We anticipate that programmatic changes (e.g., participant eligibility for the MDPP Expanded Model, virtual program delivery) will attract more large businesses and thus change the distribution among future participating organizations. When a small business offering the National DPP LCP applies for CDC recognition through the DPRP, the small business is required to meet all the eligibility and evaluation requirements outlined in the DPRP Standards. CDC provides technical assistance on an as-needed basis. A small business may need, and receive, more technical assistance than a large business.

6. Consequences of Collecting the Data Less Frequently

The lifestyle change program is 12 months long (with two required phases, a minimum of 16 weekly sessions in months 1-6 and a minimum of 6 monthly sessions in months 7-12). Organizations seeking recognition through the DPRP currently submit evaluation data to CDC every 6 months under the 2018 DPRP Standards. CDC uses these data to monitor program effectiveness. This allows CDC to provide timely technical assistance to organizations having difficulty meeting minimum DPRP performance goals, and gives organizations time to improve performance and achieve or maintain preliminary or full recognition. CDC will continue collecting data biannually and will continue to align with the CMS MDPP Expanded Model. Experience to date has demonstrated that splitting the annual data into two reporting periods permits more frequent organizational feedback and provides CMS critical information on program integrity which is required for payment.

Less frequent reporting would delay the provision of technical assistance and limit opportunities for organizations to implement corrective action. Ineffective programs have

potential negative consequences, including but not limited to, inefficient use of health care dollars, harm to participants and the reputation of the National DPP, and reluctance of public and private payers to reimburse.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside of the Agency

A 60-day Federal Register Notice (60Day-20-0909) was published in the *Federal Register* on June 15, 2020, Docket No. CDC-2020-0070, Document Citation 85 FR 36214, pages 36214-36215 (2 pages). CDC received and responded to 30 sets of unique public comments that were related to this notice from both individuals and organizations outside of CDC. Within those 30 unique sets of comments, there were 126 unique questions/comments answered by CDC in reference to this proposed data collection plan, instrument/variables, and methods (Attachment 2C). Two commenters (#6 and #9) wrote a solely positive response to this Information Collection Review (ICR); thus, their comments are not addressed below, but were noted and appreciated. CDC is not required to respond to questions or comments outside the scope of this ICR.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be offered to organizations that seek CDC recognition through the DPRP.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

- A. This submission has been reviewed by the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) Privacy Officer and it was determined that the Privacy Act does not apply.
- B. Application form information and evaluation data are submitted to CDC via online forms. These transmission methods were reviewed and determined to be secure by CDC's Information Systems Security Officer; they align to Privacy Impact Assessment information approved by OMB in ICR No. 0920-1090: Formative and Summative Evaluation of Scaling the National Diabetes Prevention Program (National DPP) in Underserved Areas. Data are maintained on a password protected computer in secure CDC facilities and accessible only to DPRP staff (CDC personnel and onsite contractors) for approved analyses. CDC protects the data to the extent required by law. CDC does not collect, release, publish, or disclose PII relating to individual program participants.

CDC publishes only aggregated data. At the discretion of DDT or National DPP leadership, aggregated data at the organizational, state, regional, or national level may be shared with external partners for the purpose of preparing reports, or manuscripts, or providing targeted technical assistance.

- C. Consent: Respondents are organizational entities, not individuals. Organizational consent is established by submission of the DPRP application form and evaluation data.
- D. Nature of Response: Participation by organizations is strictly voluntary. Organizations may withdraw from the DPRP at any time by not transmitting evaluation data or for reasons specific to the organization. No additional withdrawal notification is required.

Privacy Impact Assessment

Overview of the Data Collection

Respondents are organizational entities that deliver the National DPP LCP and seek CDC recognition through the DPRP. Two types of information are being collected: application data and evaluation data. The currently approved online DPRP application form (Attachment 4A) is being revised and is located on the National DPP web site (https://nccd.cdc.gov/DDT_DPRP/applicationForm.aspx). The new application form (Attachment 4A) will replace the current form and may be submitted at any time beginning March 1, 2021. The information contained in the application is needed to communicate with the organization and provide technical assistance. Evaluation data are transmitted to the DPRP by the organization every 6 months in accordance with the DPRP Standards. These data are needed to assess recognition status according to objective criteria, assure fidelity to DPRP Standards, identify opportunities for quality improvement or technical assistance, and align with the MDPP Expanded Model to allow organizations to apply as MDPP suppliers and bill CMS for Medicare beneficiaries who participate in the program. To minimize the burden on organizations and ensure the quality and utility of the data, evaluation data are submitted to CDC using the DPRP's interactive web application (Attachment 4A, Attachment 4B).

Items of Information to Be Collected

A. **Application data elements:** Applicants for recognition are organizational entities, not individuals. The data elements collected on the DPRP application include some information in identifiable form (PII); however, the identifiable information is only that needed to enable communication with the organization's designated contact person(s). The application form (Attachment 4A-screenshot) includes all the following elements. There are no new data elements, but there are some updated descriptions/follow-up questions for some of the elements.

Below are the application data elements as described in this revision of the DPRP Standards:

1. **Type of Application.** Select *Initial* if this is the first application being submitted. Select *Reapplying* if this is a subsequent application due to previous withdrawal or loss of recognition. If an organization chooses to change its curriculum to another CDC-approved curriculum, a notification to CDC through the National DPP Customer Service Center at <https://nationaldppcsc.cdc.gov/s> is required, and no further steps are needed involving the application.

Organization Code. This code is assigned by the DPRP. Choose *Not applicable* if this is an initial application. For organizations reapplying, enter the previously assigned organization code.

2. **Organization Name.** Upon application approval, the organization name will be published in the DPRP registry on the CDC website and/or in a publicly available program locator.
3. **Organization Physical Address.** Provide the main organization's business office or headquarters address. Upon application approval, this will be published in the DPRP registry on the CDC website and/or in a publicly available program locator.
4. **Organization Web Address or URL.** Optional. Upon application approval, this will be published on the DPRP Registry and/or in a publicly available program locator. All web addresses must link directly to a location where participants can find information about the organization's CDC-recognized National DPP LCP and enroll in the program. CDC will not accept or host any other web addresses.
5. **Organization Phone Number.** Provide the number that participants, payers, and others should call to obtain information about the program. Organizations should not provide a 1-800 number unless a live operator is available. Upon application approval, this will be published in the DPRP registry on the CDC website and/or in a publicly available program locator.
6. **Organization Type.** Choose the option that best describes the organization type. This refers to an organization's main headquarters location or main office: Local or community YMCAs; Universities/Schools; State/Local Health Departments; Hospitals/Healthcare Systems/Medical Groups/Physician Practices; Community-Based Organizations; HRSA-funded Federally Qualified Health Centers (FQHC), Community Health Centers, or Lookalike; Pharmacies/Drug Stores/Compounding Pharmacies; Indian Health Service/Tribal/Urban Indian Health Systems; Cooperative Extension Sites; Worksites/Employee Wellness Programs/Private Businesses; Senior/Aging/Elder Centers; Health Plans/Insurers; Faith-Based Organizations/Churches.

7. **Delivery Mode.** An applicant organization can select one delivery mode per each application submitted (either in-person only, online only, distance learning, or combination). Delivery modes will be published in the DPRP registry on the CDC website and/or in a publicly available program locator. For definitions, see the Standards and Requirements for Recognition, Delivery Mode section.
8. **Program Coordinator Name.** Provide the name of the individual who will be the applicant organization's Program Coordinator. Provide a salutation [e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify)], last name, first name, and middle initial]. The Program Coordinator's name will not be included in the DPRP registry and/or public program locator.
9. **Program Coordinator Contact Information.** Provide the phone number and email address for the organization's Program Coordinator. DPRP staff will use this information to communicate with the organization. All DPRP-related documents, reports, and emails will go to the Program Coordinator. The Program Coordinator's contact information will not be included in the DPRP registry and/or public program locator.
10. **Secondary Contact Name.** Provide the name of the individual who will be the applicant organization's Secondary Contact, if applicable. This person would be contacted in the event an organization's Program Coordinator cannot be reached for routine communication. Provide a salutation [e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify)], last name, first name, and middle initial]. The Secondary Contact's name will not be included in the DPRP registry and/or public program locator.
11. **Secondary Contact Information.** Provide the phone number and email address of the organization's Secondary Contact, if applicable. The Secondary Contact's contact information will not be included in the DPRP registry and/or public program locator.
12. **Data Preparer Name.** Provide the name of the individual who will be the organization's Data Preparer. This can be either the Program Coordinator or the Lifestyle Coach if a third person is not designated at this time. Provide a salutation [(e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify))], last name, first name, middle initial, and academic credentials, if applicable [(e.g., MD, RN, MPH, MPA, PhD, other (please specify))]. The Data Preparer's name will not be included in the DPRP registry and/or public program locator.
13. **Data Preparer Contact Information.** Provide the **phone number and** email address of the organization's Data Preparer. DPRP staff will use this information to communicate with the organization about data submission issues, if required. The Data Preparer's contact information will not be included in the DPRP registry and/or public program locator.
14. **Class Type.** Select all applicable class types offered: **public** (open to anyone who qualifies for the National DPP LCP without further restrictions), **employee** (open only to employees

of the organization or the host organization), **member-only** (open only to member insureds; membership required) or **other** (write in target audience served such as American Indians/Alaska Natives, patients, clients, etc.). Organizations offering classes/sessions to the public are required to provide/update the physical addresses of the sessions in the manner that CDC specifies with their six-month data submissions. Upon application approval, the class type as well as public class information (addresses, if insurance is accepted- optional, or program costs- optional), will be published in the DPRP registry on the CDC website and/or in a publicly available program locator. CDC anticipates launching a new, publicly available program locator in 2020. When this locator is available, CDC-recognized organizations will be expected to update their public class location information regularly.

15. **Lifestyle Coach Training Entity.** Provide the name of the training entity the applicant organization will use or has used to train their main Lifestyle Coaches. Choose from 1) a training entity that has an MOU with CDC and is listed on the CDC website (found here: <https://nationaldppCustomerServiceCenter.cdc.gov/s/article/Training-for-your-Lifestyle-Coaches>); 2) a private organization with a national network of program sites; 3) a CDC-recognized virtual organization with national reach; or 4) a Master Trainer who has completed at least 12 hours of formal training as a Lifestyle Coach, successfully offered the National DPP lifestyle change program for at least one year, and completed a Master Trainer program offered by a training entity listed on the CDC website.

16. **Curriculum.** Select either a CDC-approved curriculum (one that CDC has either developed or previously approved for use by your or another organization) or ‘Other Curriculum’ if the applicant organization is submitting an alternate curriculum for review and approval. If selecting Other Curriculum, provide the completed yearlong curriculum with any supplemental materials, handouts, or web-based content together with the application.

B. Evaluation data elements: Each CDC-recognized organization (pending, preliminary, or full) transmits evaluation data (Attachment 4B) to CDC every 6 months, beginning 6 months from the organization’s effective date. Evaluation data are submitted to CDC via an online web application form. Data from all of the lifestyle change program sessions conducted by the organization during the preceding 6 months must be included in this transmission.

No PII is transmitted to CDC during evaluation data submissions. All identifiers (except the organization code that is provided by CDC) are assigned and maintained by the CDC-recognized organizations. Any MDPP-related PII is stored at the organization level only, and not transmitted to CDC. MDPP suppliers will work directly with CMS to bill for qualifying Medicare participants based on any rule, law, or policy governing data storage and communication from CMS. All participants in CDC-recognized lifestyle change programs are 18 years of age or older.

Below are the evaluation data elements included as described in this revision of the DPRP Standards. New elements for this fourth revision are marked accordingly as “new”:

- 1) Enrollment Motivation (**new**): Organizations will identify the main motivation which led the participant to enroll in the yearlong program.
- 2) Enrollment Source (**revised**): Organizations will identify whether a healthcare professional was the source which led the participant to enroll in the yearlong program.
- 3) Payer Type: Organizations will identify one main payment method that participants are using to pay for their participation in the yearlong program.
- 4) Participant State: Organizations will record the state in which a participant resides at enrollment and included on all session attendance records generated for that participant. The two-letter postal abbreviation for the U.S. state or territory should be used. Organizations choosing to deliver the lifestyle program to U.S. citizen participants residing outside of the U.S. or its territories should default to the participant's U.S. resident state or U.S. Army Post Office (APO) address state.
- 5) Participant's Prediabetes Determination: Organizations should record this information at enrollment and include it on all session attendance records generated for an individual participant. This indicates whether a participant's prediabetes status was determined by a blood test, a previous diagnosis of GDM, or by screening positive on the CDC Prediabetes Risk Test (see guidance titled CDC/ADA Prediabetes Risk Test). Multiple responses are allowed and may be added. For example, if a participant was originally enrolled on the basis of a risk test and then subsequently received a blood test indicating prediabetes, the risk test value remains the same, and the blood test value is changed to a positive.
- 6) HbA1C Value (**new**): Organizations can use this option to record HbA1C values only on participants who enter the program with a GLUCTEST value of 1. The initial HbA1C value should be taken within a year before entering the program, and reported at the first 14 days of the program. HbA1C values, if used, per participant must be collected and submitted prior to final data submission for that LCP year. If used, it must be included in last session record and recorded in months 10-12.
- 7) Participant's Age: Organizations should record age at enrollment and use that recorded age throughout all records regardless of a birthday occurring during the yearlong program. If the participant's age is incorrectly recorded at enrollment (or at the first session), then the age should be corrected on all records. If an organization's recordkeeping system automatically adjusts the age on a participant's birthday, then the two recordings of age are acceptable.
- 8) Participant's Ethnicity: Organizations should record ethnicity at enrollment and include it on all session attendance records generated for an individual participant. Organizations

should ask the participant to self-identify and choose one of the following: Hispanic/Latino, not Hispanic/Latino, or not reported.

9) Participant's Race: Organizations should record race at enrollment and include it on all session attendance records generated for an individual participant. Organizations should ask the participant to self-identify and choose one or more of the following: American Indian or Alaska Native, Asian or Asian American, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Multiple responses are allowed. This element requires responses for five fields, and each field includes a response for not reported.

10) Participant's Sex: Organizations should record sex at enrollment and include it on all session attendance records generated for an individual participant. Organizations should ask the participant to indicate their sex at birth. The data record should indicate male, female, other, or not reported.

11) Participant's Gender (**new**): Organizations should record gender, only once upon enrollment, and include it on all session attendance records generated for an individual participant. Organizations should ask the participant to indicate the gender by which they identify. The data record should indicate male, female, other, or not reported.

12) Participant's Height: Organizations should record height at enrollment and include it on all session attendance records generated for an individual participant. Organizations are instructed that height may be self-reported, and that it is not necessary to measure the participant's height; the participant may simply be asked, "What is your height?" or "How tall are you?". Organizations should record the participant's height to the nearest whole inch.

13) Education: Organizations should record education as the highest grade or year of school the participant states they completed. Organizations should record this information, only once upon enrollment, and include it on all session attendance records generated for an individual participant.

14) Delivery Mode: Organizations should use this variable to identify the delivery mode for the specific participant and session (i.e., in-person, online, distance learning). Organizations are informed that, since this is a session level variable, combination mode does not apply.

15) Session Type: Organizations should use this variable to identify the core sessions attended in months 1-6 as "C", the core maintenance sessions attended in months 7-12 as "CM", and the ongoing maintenance sessions in months 13-24 as "OM." Ongoing maintenance sessions are mandatory for MDPP suppliers and optional for other organizations. MDPP suppliers must collect and report data for ongoing maintenance sessions in the same way they do for core and core maintenance sessions, including recording

participant weights. CDC will collect these data for CMS to assist with the implementation and evaluation of the MDPP Expanded Model. Organizations will identify make-up sessions as “MU-C” if the participant is making up a session that was regularly scheduled in months 1-6. Organizations will identify make-up sessions as “MU-CM” if the participant is making up a session that was regularly scheduled in months 7-12, and will identify them as “MU-OM” if the participant is making up a session scheduled in months 13-24.

16) Session Date: Organizations should record a session date each time a participant attends a session, and the actual date of the session should be recorded. The date should be recorded in mm/dd/yyyy format. Organizations should not record more than one record (line of data) per each participant for any specific session date, except for make-up sessions. Organizations may hold one make-up session per week on the same date as a regularly scheduled session for the convenience of the participant. For online sessions, organizations should record the date each session is completed.

17) Participant’s Weight: Organizations should record weight each time a participant attends a session, and his or her body weight should be measured and recorded to the nearest whole pound. Organizations are instructed that weight should be included on the record for that participant and session. For online programs, organizations should record the weight associated with the session completion date.

18) Participant’s Physical Activity (PA) Minutes: Organizations should record the number of minutes of moderate or brisk PA completed by each participant during the preceding week. Organizations should include PA minutes on the record for that participant and session. If a participant reports doing no activity during the preceding week, organizations should record zero (0) minutes.

CDC uses evaluation data to assess each organization’s progress toward meeting or maintaining CDC recognition standards. Organizations may not achieve recognition or may lose recognition if they do not:

- meet or maintain either the requirements for preliminary or full recognition for three consecutive years,
- submit complete and acceptable data within the month it is due, or
- report attendance twice during any 12-month intervention period.

CDC will grant extensions and exceptions to data submission requirements on a case-by-case basis due to extenuating circumstances including, but not limited to, natural disasters, public health emergencies, or unexpected staff losses. However, organizations must communicate these occurrences to CDC as soon as possible so that proper guidance can be given.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The research determination for this project is public health practice, thus IRB approval is not required.

Justification for Sensitive Questions

Although all data submitted are de-identified, some data elements such as prediabetes status, weight, education, HbA1C values, and attendance might be considered sensitive information. It is essential that this information be provided to the DPRP. Without this information, the DPRP would not be able to support CMS in implementing and evaluating the MDPP Expanded Model, monitor program delivery to ensure that quality programs are being delivered to individuals with prediabetes or at high risk for type 2 diabetes, or evaluate program effectiveness to ensure that participant cohorts are meeting attendance requirements and achieving weight loss outcomes proven to prevent or delay type 2 diabetes. In order to monitor program effectiveness and assure that CDC-recognized organizations are delivering science-based, effective programs to all participants regardless of race/ethnicity, age, gender, and SES status (i.e., education), organizations transmit de-identified, coded information about participant demographics, prediabetes status, weight loss, HbA1C values, and session attendance.

It is important to emphasize that CDC does not collect or receive directly identifiable information about participants.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

Application Data (Attachment 4A). Respondents are organizational entities that seek CDC recognition through the DPRP. Each respondent will submit a brief one-time application form to the DPRP for each delivery mode. The application form and instructions are posted on the National DPP web site, and the application must be completed online (applications may not be submitted by mail or by fax). There is no submission deadline, and respondents may apply whenever it is convenient for them to do so. CDC estimates that 300 organizations per year, on average, will seek CDC recognition over the 3 years of the requested OMB approval period. The total estimated average annualized application burden to respondents is 300 hours (1 hour per response). This includes an estimate of the time needed to read the application instructions, review the DPRP Standards document describing organizational capacity and data transmission requirements, fill out and submit the application form, and submit curriculum materials, if required.

CDC estimates that 70% of applicant organizations (210 per year) will be private sector entities, and 30% of applicant organizations (90 per year) will be public sector entities. Table

A.12-1. estimates the annualized burden to respondents by private and public entities by both application and evaluation burden.

Evaluation Data (Attachment 4B). Each respondent will submit evaluation data to the DPRP every 6 months. The due dates for each organization’s submission will be determined by its effective date (the 1st day of the month following DPRP approval of the application). The evaluation data are submitted to CDC via an online web application form in accordance with the DPRP Standards (4A). During the OMB approval period, the DPRP anticipates that 900 organizations (annualized to 300 per year) will apply for recognition, and that the number of organizations submitting data will increase from 1,800 by the end of the first year to 2,400 in the third year. The total estimated average annualized evaluation burden to respondents is 8,700 hours. This includes an estimate of the time needed to extract and compile the required data records and fields from an existing electronic database, review the data, create or enter a data file in the required format (i.e., an electronic CSV file), and submit the data file via the National DPP web site for automated upload into the DPRP Data Portal. Table A.12-1 provides a summary of the total annualized evaluation burden to respondents (in gray).

Table A.12-1. Estimated Annualized Burden to Respondents (public and private)

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response	Total Burden
				(in hours)	(in hours)
Public sector organizations that deliver the National DPP LCP	DPRP Application Form	90	1	1	90
	DPRP Evaluation Data	630	2	2	2,520
Private sector organizations that deliver the National DPP LCP	DPRP Application Form	210	1	1	210
	DPRP Evaluation Data	1,470	2	2	5,880
				Total	8,700

B. Cost to Respondents

We anticipate that respondents will use paid staff to provide the requested information to the DPRP, and we used two times the federal minimum wage as our basis for estimating the cost to respondents.

Table A.12-2. Estimated Annualized Cost to Respondents (public and private)

Type of Respondent	Form name	No. of respondents	No. of responses per respondent	Hourly wage rate	Total burden (in hours)	Total Cost
Public sector organizations that deliver the National DPP LCP	DPRP Application Form	90	1	\$28.20	90	\$2,538
	DPRP Evaluation Data	630	2	\$28.20	2,520	\$71,064
Private sector organizations that deliver the National DPP LCP	DPRP Application Form	210	1	\$28.20	210	\$5,922
	DPRP Evaluation Data	1,470	2	\$28.20	5,880	\$165,816
					Total	\$245,340

1. Source: National DPP Funding Opportunity Announcement, DP-12-1212, Grantee Evaluation, average Lifestyle Coach hourly salary, 2016.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

We anticipate that, for most respondents, the majority of application data elements will be a subset of the program data elements already being collected and maintained at the organization level (including the organizational contacts listed once on the one-time application). It should be noted that ENROLL-HC and ENROLL-MOT represent the splitting of one previous 2018 data element (ENROLL). Thus, significant additional time and resources will not be needed for data collection. Since many DPRP data elements are directly tied to CMS reimbursement, it is anticipated that respondents will be willing to collect and report such data.

CDC's DPRP is also removing a 2018 data element (SESSION ID) and adding COHORT ID, which will be easier to collect and report. As a result of the new data elements, it is possible that some future applicant organizations and/or currently recognized organizations

using third party administrators to assist with data collection may need to make modifications to their systems and may incur additional costs in doing so. CDC offers an easy-to-use, no-cost comma separated variable spreadsheet that will link with the DPRP data portal for easy data upload and validation. Also, no-cost webinars and technical assistance on use of the data portal will be routinely offered in an effort to minimize data collection and reporting burden. Healthcare organizations that offer the program may also be able to report the optional HbA1C value, which will allow them multiple ways to successfully achieve CDC full recognition. This will be seen as an advantage to such organizations, and not an additional burden, based on stakeholder feedback.

14. Annualized Cost to the Government

Labor Costs include personnel for oversight, communication, evaluation, development of the Information Collection Request for OMB, report writing, presentations, publications, and technical assistance; and contract labor for monitoring, data collection, analysis, evaluation, and assistance with report writing.

The total estimated annualized cost to the government is \$2,787,740 as summarized in the table below.

<u>Personnel</u>	<u>Base salary</u>	<u>Fringe</u>	<u>Total cost</u>
FTE*	\$503,600	\$184,150	\$687,740
<u>Contract support**</u>			<u>\$2,100,000</u>
TOTAL COSTS:			\$2,787,740

* FTE cost includes percentages of time for approximately 2 FTEs (100%); 1 FTE (60%); 2 FTEs (70%).

**Contract support includes partial costs from 3 contracts support the DPRP – Northrop Grumman (\$1,000,000), Cyberdata (\$850,000), and Deloitte Consulting (\$250,000)

15. Explanation of Program Changes or Adjustments

The estimated burden per response for each information collection is 1.0 hour for application completion (including reading the DPRP Standards and Capacity Assessment). The actual completion of the automated, online application involves drop-down boxes and is not estimated to be time-consuming. The estimated information collection burden per response for each evaluation data submission is 2.0 hours. A few changes are proposed for each information collection instrument (the DPRP Application Form and the DPRP Evaluation Data), as outlined in **Attachment 5- Table of Changes**. The proposed changes to the

estimated number of respondents, the types of respondents, and the frequency of responses are described below.

In 2018, CDC estimated that 500 organizations per year would apply for CDC recognition through the DPRP. At that time, CDC estimated that 70% (350) of the applicants would be private sector organizations, and 30% (150) of the applicants would be from the public sector (state, local, or tribal government organizations). Each applicant organization would be required to submit a one-time DPRP application form, followed by biannual submissions of evaluation data.

For this three-year period, CDC is revising the total estimated annualized number of applicant organizations to 300, as the previous number was not realized during the three-year revision process in 2018. The distribution of those applicants is still predicted to be 70% (210) from the private sector and 30% (90) from the public sector, based on current DPRP data and projections. Trends indicate we will see a smaller number of organizations with capacity to enroll larger numbers of participants successfully.

The DPRP application form will continue to be a one-time submission for each delivery mode. CDC is also increasing the estimated number of organizations submitting DPRP evaluation data from a little over 1,500 currently to 900 more in the upcoming three-year period (a rate of an additional 300 per year for three years). The revised estimate maintains the evaluation data burden hours of 2.0 hours biannually from the 2018 revision. The inclusion of new variables is minimal, and the removal of the previous SESSION ID variable will be time-saving, as will the new DPRP Data Portal organizations will use to upload and submit data to CDC. CDC will continue to collect data every six months to align with the MDPP Expanded Model. Data submission every six months also provides more frequent opportunities for organizations to review their own data, address areas of concern, receive technical assistance, and make early programmatic corrections to ensure success.

These changes result in a net decrease of 1,000 annualized burden hours. The distribution of these changes is summarized in Table A.12-3. below.

Table A.12-3 Estimated Annual Data Collection Burden Hours by Respondent, 2018 to 2021

Type of Respondent and Form Name		2018			2021			Change from 2018-2021
Type of Respondent	Form Name	No. Respondents	No. Responses per	Total Burden	No. Respondents	No. Responses per	Total Burden	Total Burden

			Responde nt	Hours *		Responde nt	Hours	Hours
Public sector organizatio ns that deliver the National DPP LCP	DPRP Applicati on Form	150	1	150	90	1	90	-60
	DPRP Evaluatio n Data	350	2	1400	290	2	1160	-240
Private sector organizatio ns that deliver the National DPP LCP	DPRP Applicati on Form	350	1	350	210	1	210	-140
	DPRP Evaluatio n Data	1444	2	5776	1304	2	5216	-560
	Total			7,676			6,676	-1,000

*Burden per Response = 1 hr. per application and 2.0 hrs. per evaluation data submission

16. Plans for Tabulation and Publication and Project Time Schedule

Task

Date

Application process (ongoing)	ongoing since January 2012
Applicants transmit data (ongoing)	ongoing since January 2012
Data analyses	ongoing since July 2012
CDC recognition status renewed	ongoing since January 2013
OMB approval of revision request	February 28, 2021 (estimated)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to this certification.

References

Current Diabetes/Prediabetes Statistics in Overview/Justification:

1a. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2020. Atlanta, GA: US Department of Health and Human Services; 2020; <https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>.

MDPP Report which the 2018 *DPRP Standards* helped support:

1b. American Diabetes Association, Economic Costs of Diabetes in the U.S. in 2017, *Diabetes Care* 2018 Mar; dci180007; <https://doi.org/10.2337/dci18-0007>.

1c. Centers for Medicare and Medicaid. Medicare Diabetes Prevention Program (MDPP) Expanded Model, 2017. Baltimore, MD: US Department of Health and Human Services; 2017; <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/index.html>.

Efficacy and Effectiveness Studies upon which the 2011 *DPRP Standards* were based:

2. Knowler, W.C., Barrett-Connor, E., Fowler, S.E., Hamman, R.F., Lachin, J.M., Walker, E.A., et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New Engl J Med* 2002; 346:393–403.
3. Diabetes Prevention Program Research Group. Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program Outcomes Study. *Lancet Diabetes Endocrinology*, 2015 Nov;3(11):866-75. doi: 10.1016/S2213-8587(15)00291-0.
4. Lindstrom, J., Ilanne-Parikka, P., Peltonen, M., Aunola, S., Eriksson, J.G., Hemiö, K., et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: Follow-up of the Finnish Diabetes Prevention Study. *Lancet* 2006; 368:1673–79.
5. Li, G., Zhang, P., Wang, J., Gregg, E.W., Yang, W., Gong, Q., et al. The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing Diabetes Prevention Study: A 20-year follow-up study. *Lancet* 2008; 371:1783–89.
6. Ackermann, R.T., Finch, E.A., Brizendine, E., Zhou, H., Marrero, D.G. Translating the Diabetes Prevention Program into the community: The DEPLOY pilot study. *Am J Prev Med*. 2008; 35(4):357–63.

7. Ackermann, R.T., Marrero, D.G. Adapting the diabetes prevention program lifestyle intervention for delivery in the community: The YMCA model. *Diabetes Educ.* 2007; 33:1–6.
8. Amundson, H.A., Butcher, M.K., Gohdes, D., Hall, T.O., Harwell, T.S., Helgerson, S.D., et al. Translating the diabetes prevention program into practice in the general community: Findings from the Montana Cardiovascular Disease and Diabetes Prevention Program. *Diabetes Educ.* 2009; 35:209. doi: 10.1177/0145721709333269.
9. Williamson, D.F., Marrero, D.G. Scaling up type 2 diabetes prevention programs for high risk persons: Progress and challenges in the United States (chapter). *Diabetes prevention in practice.* pp 69-81 Schwarz P, Reddy P, Greaves C, Dunbar J, Schwarz J, eds. World Congress on Prevention of Diabetes. Dresden, Germany 2010. TUMAINI Institute for Prevention Management. ISBN 978-3-00-03070765-2.
10. Abelson, R. An insurer’s new approach to diabetes. *New York Times.* April 13, 2010. <http://www.nytimes.com/2010/04/14/health/14diabetes.html>.
11. Tate, D.F., Jackvony, E.H., Wing, R.R. Effects of internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. *JAMA.* 2003;289(14):1833-1836.

Additional translational studies upon which the 2015 *DPRP Standards* were based:

12. Ackermann, R.T., Sandy, L.G., Beauregard, T., Coblitz, M., Norton, K.L., and Vojta, D. (2014), A randomized comparative effectiveness trial of using cable television to deliver diabetes prevention programming. *Obesity.* 22(7):1601-1607.
13. Sepah, C.S., Jiang, L., Peters, A.L. (2104). Translating the diabetes prevention program into an online social network: Validation against CDC standards. *The Diabetes Educator.* 40(4):435-443.
14. Marrero, D., Palmer, K., Rost, S., Frederick, A., Miller-Kovach, K., Saha, C. Using Weight Watchers approach to lifestyle modification to reduce risk for type 2 diabetes. [abstract] International Diabetes Federation. Melbourne, Australia 2013. Available at: <http://conference2.idf.org/MEL2013/World%20Diabetes%20Congress%202013/data/HtmlApp/main.html#open-sessions> (IDF conference abstract website, search topic “Weight Watchers” to go directly to the abstract) (See also: <http://clinicaltrials.gov/show/NCT02000024> for study description)

15. Ross, K., Kaufman, N.D. Automating coaching: Technology delivers proven weight loss intervention at affordable cost while minimizing personnel time. Presented at the Care Continuum Alliance conference, Oct. 2013.

Additional studies and evaluation research upon which the 2018 and current revision of the *DPRP Standards* are based:

Attrition/Retention:

16. Gray, L.J., et al. (2016). "Engagement, Retention, and Progression to Type 2 Diabetes: A Retrospective Analysis of the Cluster-Randomised "Let's Prevent Diabetes" Trial." *PLoS Med* 13(7): e1002078.

Cost-effectiveness/Economic evaluation:

17. Alouki, K., et al. (2016). "Lifestyle Interventions to Prevent Type 2 Diabetes: A Systematic Review of Economic Evaluation Studies." *Journal of Diabetes Research* 2016.
18. Li, R., et al. (2015). "Economic Evaluation of Combined Diet and Physical Activity Promotion Programs to Prevent Type 2 Diabetes Among Persons at Increased Risk: A Systematic Review for the Community Preventive Services Task Force." *Annals of Internal Medicine* 163(6): 452-460.

Duration and intensity

19. Mudaliar, U., et al. (2016). "Cardiometabolic Risk Factor Changes Observed in Diabetes Prevention Programs in US Settings: A Systematic Review and Meta-analysis." *PLoS Med* 13(7): e1002095.
20. Aziz, Z., et al. (2015). "A systematic review of real-world diabetes prevention programs: learnings from the last 15 years." *Implementation science : IS* 10: 172.
21. Brokaw, S. M., et al. (2015). "Effectiveness of an Adapted Diabetes Prevention Program Lifestyle Intervention in Older and Younger Adults." *J Am Geriatr Soc* 63(6): 1067-1074.
22. Ackermann, R. T., et al. (2015). "A Randomized Comparative Effectiveness Trial for Preventing Type 2 Diabetes." *American Journal of Public Health* 105(11): 2328-2334.

Group size

23. Brokaw, S. M., et al. (2014). "Intensive lifestyle intervention goals can be achieved as effectively with large groups as with small groups." *Primary care diabetes* 8(4): 295-300.

Evidence to support additional collection on education level

24. O'Brien, M. J., et al. (2015). "The comparative efficacy of lifestyle intervention and metformin by educational attainment in the Diabetes Prevention Program." *Preventive Medicine* 77: 125-130.

Physical activity

25. Eaglehouse, Y. L., et al. (2015). "Evaluation of physical activity reporting in community Diabetes Prevention Program lifestyle intervention efforts: A systematic review." *Prev Med* 77: 191-199.

Virtual programs

26. Michaelides, A., et al. (2016). "Weight loss efficacy of a novel mobile Diabetes Prevention Program delivery platform with human coaching." *BMJ Open Diabetes Res Care* 4(1): e000264.
27. Fischer, H. H., et al. (2016). "Text Message Support for Weight Loss in Patients With Prediabetes: A Randomized Clinical Trial." *Diabetes Care* 39(8): 1364-1370.
28. Sepah, S.C, Jiang L., & Peters, A.L. "Long-Term Outcomes of a Web-Based Diabetes Prevention Program: 2-Year Results of a Single-Arm Longitudinal Study." *Journal of Medical Internet Research* 2015;17(4):e92; doi:10.2196/jmir.4052.

Weight loss achievement

29. DiBenedetto, J. C., et al. (2016). "Achievement of Weight Loss and Other Requirements of the Diabetes Prevention and Recognition Program: A National Diabetes Prevention Program Network Based on Nationally Certified Diabetes Self-management Education Programs." *Diabetes Educ.*
30. Franz, M. J., et al. (2015). "Lifestyle weight-loss intervention outcomes in overweight and obese adults with type 2 diabetes: a systematic review and meta-analysis of randomized clinical trials." *Journal of the Academy of Nutrition & Dietetics* 115(9): 1447-1463.

31. Klem M.L., Wing R.R., McGuire M.T., Seagle H.M., Hill J.O. A descriptive study of individuals successful at long-term maintenance of substantial weight loss. *Am J Clin Nutr.* 1997 Aug;66(2):239-46. PubMed PMID: 9250100.

Gender differences

32. Caceres, B.A., Jackman. K.B., Edmondson, D., Bockting, W. O. “Assessing gender identity differences in cardiovascular disease in US adults: an analysis of data from the 2014–2017 BRFSS.” *J Behav Med* (2020) 43:329–338.

New HbA1C Evidence (added based on public comments)

33. Toro-Ramos, T., Michaelides, A., Anton, M., Karim, Z., Kang-Oh, L., Argyrou, C., Loukaidou, E., Charitou, M., Sze, W., Miller, J. “Mobile Delivery of the Diabetes Prevention Program in People With Prediabetes: Randomized Controlled Trial.” *JMIR mHealth and uHealth* (<http://mhealth.jmir.org>), 08.07.2020.

34. Daftarian, Z., Bowen, P. “Improving outcomes in patients with prediabetes through a lifestyle modification program.” *Journal of the American Association of Nurse Practitioners*: March 2020 - Volume 32 - Issue 3 - p 244-25.