Information Collection Request

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

Revision
OMB No. 0920-0909; Exp. 12/30/2020

Supporting Statement: Part A

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Summary Table

- Goal of the study. The goal of this information collection is to allow 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 CMS to support the Medicare Expanded Model. Based on experience with the DPRP from 2011–2017, and feedback from applicant organizations and internal and external partners, in order for CDC to revise the DPRP Standards and the associated information collection.
- Intended use of the resulting data. For program implementation monitoring and evaluating of organization-level performance around evidence-based diabetes prevention programs. High performing organizations that meet CDC standards specified in this data collection package are awarded either preliminary or full CDC recognition. Recognition is pivotal for an organization's ability to ensure effective program delivery and for billing of programs with both private and public health insurers.
- 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 twice per year. CDC calculates averages across cohorts to determine organizational-level performance. Paticipant-level performance is not assessed by CDC.
- The subpopulation to be studied. The subpopulations for this data collection include CDC Division of Diabetes Translation grantees such as 1705, 1305, 1422, and 1421 and Medicare Diabetes Prevention Program (MDPP) suppliers. Final responsibility for MDPP suppliers is that of the Centers for Medicare and Medicaid Services (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 or average findings will be presented to orgnizations via evaluation reports and could be used, in aggregate, for annual reports or articles; in which case, regression analyses would be used.

Overview

The Centers for Disease Control and Prevention’s (CDC’s) National Diabetes Prevention Program (National DPP) collects information needed to administer the National DPP’s quality assurance program, the Diabetes Prevention Recognition Program (DPRP) (OMB No. 0920-

0909, exp. 1/31/2018). Through the DPRP, CDC recognizes organizations that successfully deliver an evidence-based lifestyle change program to participants who have prediabetes or are at high risk for type 2 diabetes. The lifestyle change program recommended by the DPRP is based on diabetes prevention strategies that were shown to be effective in a clinical setting and translates these strategies to a 12-month educational and coaching curriculum delivered in a group or community setting. The *DPRP Standards*, initially approved in 2011, and revised and approved in 2014, specified criteria for such programs and how organizations could attain recognition through the DPRP. Information currently submitted to CDC for recognition includes a one-time application form, followed by annual (every 12 months) transmission of evaluation data elements that allow CDC to assess the organization's fidelity to DPRP program standards and the progress of program participants. Full CDC recognition has been awarded to qualifying organizations when program participants achieved outcomes predicted by the comprehensive body of research studies.

The second 2015 revision, approved in 2014, described changes in the *DPRP Standards* and information collection that allowed CDC to recognize organizations that began offering "virtual" lifestyle change programs in 2015, i.e., programs that employ web-based tools and other distance learning technologies. The 2015 revision also outlined corresponding changes to the information collection plan that allowed CDC to identify virtual programs and 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.

This current revision request describes changes that affect the annualized burden estimates. In the initial three-year approval period (OMB No. 0920-0909, exp. November 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 this revision, CDC is returning to semi-annual data collection to align with the Centers for Medicare and Medicaid's (CMS's) proposed expanded Medicare Diabetes Prevention Program (MDPP) benefit to cover CDC-recognized National DPP organizations serving qualified Medicare beneficiaries beginning January 1, 2018. On January 1, 2018, the MDPP expanded model was established through rulemaking. The preamble discussions establishing the MDPP expansion are located in the CY 2017 and CY 2018 Physician Fee Schedule final rules, 81 FR 80459-80483 and 82 FR 53234-53339, respectively. The regulation text sections pertaining to the MDPP expanded model are located at: 42 CFR §§ 410.79, 414.84, 424.200, 424.205, 424.210, 424.518, and 424.55. Thus, this current revision is directly linked to the CMS MDPP Expanded Model; both are now working in tandem in order to more broadly scale the National DPP. Since no other federal agency or nonfederal organization monitors lifestyle programs for the prevention of type 2 diabetes, and CMS will now rely on CDC's DPRP for data monitoring

in order to implement and reimburse for the MDPP Expanded Model, the information needed to administer the DPRP is in this third revision is critical to joint success of the National DPP and the MDPP.

Previously, 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. Date 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] the MDPP reimbursement is directly tied to CDC Preliminary and Full statuses. The intent of this current Standards revision is to align with the CMS MDPP that will be finalized in 2017 and in effect January 1, 2018, and to account for new evidence in the diabetes prevention literature. The MDPP Expanded Model will scale type 2 diabetes prevention programs to a high risk population of Medicare beneficiaries ages 65 and over.

Accordingly, CDC has increased the estimated number of organizations expected to apply for recognition through the DPRP. This adjustment reflects increased demand from organizations that offer MDPP programs. Also, this current revision liberalizes the evaluation of data requirements based on key stakeholder feedback on the 2015 *DPRP Standards* gathered through multiple listening sessions in December 2016 (e.g., basing evaluation for the requirements on participants who attended at least 3 sessions in moths 1-6 and whose time from first sessions to last session was at least 9 months; and amending the blood test-based eligibility requirement to 35%). This liberalization is to allow more inclusion in a cohort for final data analyses, but does not relax the science around the program nor impact the quality of the program. This is being proposed in an effort to ensure that organizations serving low Socioeconomic Status (SES) and racial/ethnic minority populations can succeed per new studies assessing National DPP implementation and outcomes in vulnerable populations.[30,31] There is a net increase in estimated annualized burden hours, both to the application and the evaluation data elements. A major contributor to the increased burden hours is the significant increase in the number of applicant organizations expected due to the CMS MDPP Expanded Model. An overview of proposed changes to the DPRP Standards, the DPRP Application Form, and the DPRP Evaluation Data Elements is provided, along with revised versions of these materials.

OMB approval is requested for three years to align with the CMS MDPP Expanded Model and to allow organizations an opportunity to further institutionalize evidence-based and data-informed type 2 diabetes prevention programs without having to make changes to data systems and programming every three years as they did previously. The seminal literature around lifestyle change for the prevention of type 2 diabetes has remained fairly consistent, and the current literature review (see References) supports 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 the CDC's 2014 National Diabetes Statistics Report, 29.1 million people or 9.3% of the U.S. population have type 2 diabetes.[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. In 2012, 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 $245 billion. 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.[1b] CMS estimates that Medicare will spend $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 spend if those beneficiaries did not have diabetes.[1b] The percentage of Americans with diabetes has more than tripled in the past two decades, and an estimated 86 million Americans (ages 20 and over) have prediabetes, 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. 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, research has shown that lifestyle interventions can prevent or delay type 2 diabetes in individuals at high risk of the disease. In 2001, results from the Diabetes Prevention Program (DPP), an efficacy 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 10 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 Diabetes Prevention Program (National DPP), administered through the Division of Diabetes Translation (DDT), to make the lifestyle intervention for preventing type 2 diabetes broadly available to individuals at high risk of developing diabetes. Key features of interventions that are known to be successful based on scientific evidence 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 CDC's National DPP, the DPRP, has shown—via analyses of their own dataset—that there is a dose/response relationship between attendance and weight loss, especially when attendance is maintained throughout the yearlong program. Although the exact "dose" has not been determined, there are promising studies examining the yearlong duration of programming on weight loss.[19-22,32]

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. To that end, in 2011, based on the available scientific evidence, 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 effective evidence-based lifestyle change curricula, 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 effective type 2 diabetes prevention lifestyle change programs throughout the United States.
- Monitor, evaluate, and provide technical assistance to entities that offer these programs to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition status.
- Develop and maintain a registry of organizations recognized for their ability to deliver effective type 2 diabetes prevention lifestyle change programs to people at high risk.

Criteria for achieving recognition are outlined in the *CDC Diabetes Prevention and Recognition Program: Standards and Operating Procedures*, referred to as *DPRP Standards* (**Attachment 3**) throughout this ICR. The *DPRP Standards* describe how an organization may apply for, earn, and maintain recognition. To maintain recognition, all programs, regardless of mode or method of delivery, must meet all of the requirements outlined in the standards. The requirements reflect the lifestyle program elements proven effective for the

prevention or delay of type 2 diabetes, including participant eligibility requirements, program intensity and duration, participant weight loss (at least 5% of body weight), documentation of physical activity minutes (with a goal of 150 minutes per week), 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 (CDC Diabetes Recognition Prevention Program, OMB No. 0920-0909, exp. 12/31/2017). CDC is seeking a third revision for three years (January 1, 2018 through December 31, 2020). 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 DPRP Evaluation Data Elements (**Attachment 5A**). The DPRP Application Form allows CDC to assess the applicant organization's readiness to achieve recognition through the DPRP and to maintain pertinent contact and organizational information. Organizations that have the capacity to deliver a CDC-approved lifestyle change program and agree to the *DPRP Standards* proceed to "pending" recognition status. During the next one to two years, in which the organization's CDC recognition status remains "pending" or moves to the new CMS designation of "preliminary" status (explained herein; **Attachment 5Da**), the organization will submit semi-annual evaluation data 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 programs that fully meet the requirements and participant outcomes described in the DPRP Standards within a specified time frame. In this third revision, collection of evaluation information will permit CDC-recognized organizations that are also MDPP suppliers to bill CMS for their services once either preliminary 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 incorporate data elements needed for the MDPP Expanded Model (Attachment 6) and for participating CDC-recognized organizations to be able to bill CMS. CDC's DPRP anticipates that the majority of current CDC-recognized organizations and most new CDC-recognized organizations after January 1, 2018 will participate in the MDPP Expanded Model as MDPP suppliers as authorized by Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh §424.59). It should be noted that CMS will be responsible for training such organizations on becoming MDPP suppliers and billing CMS for MDPP services. CDC's DPRP will continue to monitor organizations solely against data elements contained within the *DPRP Standards*.

A number of changes to DPRP data collection are proposed to ensure that reporting and evaluation requirements are consistent for all DPRP applicants, regardless of mode of

program delivery (in-person only, online only, disatance learning, and/or combination thereof), both for the DPRP and for CMS. This revision request also describes a number of changes that are based on experience administering the DPRP (e.g., changes to applicant organization information collected for CMS MDPP Expanded Model implementation and learned by the DPRP to streamline program administration). Evaluation data elements are added accordingly as well. Finally, some changes relate to burden estimates. The number of organizations applying for CDC recognition will be adjusted to accommodate increased demand for MDPP services and recognition, and the frequency of reporting for DPRP evaluation data elements will be increased from annual to semi-annual to accommodate CMS and to allow for more frequent program assessment and technical assistance delivery. An overview of all changes is provided in **Attachment 6**. The overview clarifies how key changes in DPRP administration are reflected in the revised *DPRP Standards* (**Attachment 3)**, the revised DPRP Application Form (**Attachment 4A)**, and the revised DPRP Evaluation Data Elements (**Attachment 5A**).

The revised 2018 *DPRP Standards* and data collection requirements will be effective for all new applicant organizations immediately upon receipt of OMB approval of this revision (estimated December 2017). In order to provide current CDC-recognized organizations an orderly transition from the previously-approved 2015 *DPRP Standards* Evaluation Data Elements (**Attachment 5B**) to the revised 2018 *DPRP Standards*, CDC will allow programs that initiated their applications under the 2015 *DPRP Standards* the option of submitting the 2015 data elements or submitting the 2018 data elements, up to June 30, 2018. Thereafter, these programs will be required to transition to the 2018 *DPRP Standards*. The transition plan will allow organizations to adapt their reporting systems without unduly interrupting progress toward achievement of CDC recognition. A transition letter (**Attachment 7**) will be sent to organizations to inform them of the changes that will affect them and of the allowances being made to existing organizations during the first 6 months of 2018.

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 (January 1, 2018 thorugh December 31, 2020) to collect the information needed to administer the DPRP and to align with the MDPP Expanded Model.

2. Purpose and Use of the Data

The DPRP is a recognition program for lifestyle change programs for the prevention of type 2 diabetes. The DPRP generates awareness of and demand for recognized diabetes prevention programs among people at high risk for developing type 2 diabetes, health care providers, and payers, including insurance providers such as CMS. CDC recognition of a

lifestyle change program is an assurance of program quality that encourages physicians, other health care providers, and employers to refer persons with prediabetes to CDC-recognized programs.

Information collected by CDC for DPRP administration is used:

- By the federal government to promote the dissemination and use of effective strategies for preventing type 2 diabetes;
- By CDC to assess applicant organizations' compliance with *DPRP Standards*, their progression from "pending" and "preliminary" to "full" recognition status, and to provide technical assistance that helps applicant organizations strengthen program delivery;
- By the public to identify organizations that have achieved full recognition or are in the process of seeking recognition so that they may enroll in quality type 2 diabetes prevention programs.

For organizations to receive pending recognition, they must agree to deliver an evidenced-based program using a CDC-approved curriculum and submit evaluation data semi-annually to allow the DPRP to monitor fidelity of program delivery and program effectiveness and to provide technical assistance. For organizations to be awarded preliminary recognition, they must meet the following criteria:

1. The 12 month data submission must include at least 5 participants who attended at least 3 sessions in the first six months and whose time from first session attended to last session of the lifestyle change program was at least 9 months; and
2. Of the participants eligible for evaluation in #1 above, at least 60% must have attended at least 9 sessions in months 1-6, and at least 60% must have attended at least 3 sessions in months 7-12. This is an attendance-based requirement necessary to begin billing CMS for MDPP services. CDC's DPRP data set analyses show a direct link between attendance and weight loss.

Full recognition is awarded after organizations meet all of the effectiveness criteria specified in the *DPRP Standards*. Recognized organizations continue to submit data semi-annually, thus allowing program effectiveness to be reassessed for as long as the organization participates in the recognition program. The DPRP collects two types of data: 1) application data (contact information, other organizational information, and curriculum to be used) and evaluation data (to monitor program quality and effectiveness and, beginning January 1, 2018, to permit CDC-recognized organizations that are also MDPP suppliers to bill CMS for their services).

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, and level of recognition] is made publicly available on the National DPP web site or through other directories. This information helps health care providers and consumers, including CMS, identify organizations recognized for delivering effective lifestyle change programs as well as entities that are working to achieve full recognition.

Evaluation data. The evaluation data elements are used to assess recognition status using objective criteria, monitor fidelity of program delivery and effectiveness, and provide timely feedback and technical assistance. The evaluation data elements include elements that are related to the fidelity of program delivery as well as participant outcomes. CDC's objective is to assess the effectiveness of lifestyle change programs, not the success or failure of the individual program participants. With this revision, CDC also wants to help successful organizations choosing to provide MDPP services to become MDPP suppliers eligible to bill CMS for those services.

CDC provides technical assistance to help applicant organizations identify opportunities for improving program delivery and/or areas where participants may need additional support. For example, technical assistance may encompass not only the modes and methods of delivery but strategies to engage and encourage program participants to make and maintain behavioral changes, thus enabling organizations to meet the DPRP requirements and their participants to prevent type 2 diabetes and continue to lead healthy lifestyles.

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, implementation of the CMS Expanded Medicare Coverage benefit could not occur, since CDC recognition is a requirement for organizations offering the program to Medicare beneficiaries. CMS is depending on CDC's DPRP to assure quality of the lifestyle change program for Medicare beneficiaries. Thus, without the ongoing collection and evaluation of information, the DPRP could not assist CMS with their provision of valuable insurance coverage to 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, web url (if applicable), as well as the name, job title, and e-mail addresses of employees designated to

serve as the organization's primary and secondary contact person, and designated data preparer. Although the application includes personnel-related IIF (e.g., names), the information is not considered personal or private in nature. CDC maintains the IIF in password-protected files in a secure facility. A directory of recognized programs is publically available. However, the directory lists only the organization name and code, address, and telephone number (and web address, if provided and approved); 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 applicant organizations to objectively assess adherence to *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, and weight) are used to evaluate recognition criteria relating to attendance and weight loss (which are aggregated across participants to indicate whether the program met its percentage of overall weight loss and attendance goals). Collection of demographic information about program participants is necessary to ensure program effectiveness in both genders, across all ages (18+), in all SES groups (measured by education level), and in all 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, and only de-identified, coded, participant-level information is transmitted to CDC. However, CDC recognizes that some of the participant-specific information (state of residence, ethnicity, race, age, gender, insurance status, method of determining prediabetes status) when coupled with other data (organization code) might be considered IIF. 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; 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 type 2 diabetes lifestyle change programs and for providing targeted technical assistance to the CDC-recognized organization, and to assist CMS with implementation of the MDPP Expanded Model.

We believe that the proposed procedures are appropriately scaled to the low likelihood of disclosure and the 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 sending to CDC. Hence, the only linkage of participant records within the DPRP data system is to the organization contact information (e.g., organization name, address, phone number, contact person). The applicant

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 Individually Identifiable Information (IIF)- 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 IIF, is not accepted and is returned or destroyed immediately.

CDC is concerned with program 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-produced summary reports may link aggregate program data to geographic area-level variables (e.g., state or county-level demographics), 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 IIF is very low for several reasons:

1. CDC does not accept IIF 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. The only direct linkage of participant-level data in the DPRP data system is to the organization contact information via the organization code.
3. CDC does not have access to the keys to any codes, other than the organization code, or to the applicant organizations' data systems.
4. CDC does not attempt to identify individuals by data linkages involving demographic, geographic, or outcome information.
5. 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 DPRP is submitted electronically, as specified in *DPRP Standards*.

4. Efforts to Identify Duplication and Use of Similar Information

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

CDC examined credentialing, accreditation, or recognition of programs 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 programs for the prevention of type 2 diabetes, and CMS will now rely on CDC's DPRP for data monitoring in order to implement and reimburse for the MDPP Expanded Model, the information needed to administer 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 prepare for enrollment as MDPP suppliers in order to bill CMS for these services beginning in 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 is not specifically aimed at small business entities. Thus far, approximately 25% of applicants are large entities, and 75% are small 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 participanting organizations. When a small business offering type 2 diabetes prevention programs applies for CDC recognition through the DPRP, the small business is required to meet all the eligibility and evaluation requirements outlined in *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.

The DPRP evaluation data elements are typically collected by organizations that deliver lifestyle change programs. Thus, the impact of DPRP data collection on respondents—including small businesses—is expected to be minimal.

6. Consequences of Collecting the Data Less Frequently

The lifestyle change program is 12 months long (with two required phases, a minimum of weekly sessions in months 1-6 and a minimum of monthly sessions in months 7-12). Organizations seeking recognition through the DPRP currently submit evaluation data to CDC every 12 months under the 2015 *DPRP Standards*. CDC uses these data to monitor program effectiveness. This allows CDC to provide timely technical assistance to programs having difficulty meeting minimum DPRP performance goals, thus giving programs time to improve performance and achieve or maintain full recognition. Thus, CDC will return to collecting the same program-related annual data, biannually, with a few new elements that align with the CMS MDPP Expanded Model; essentially, splitting the annual data into two reporting periods to permit regular organizational feedback and CMS program integrity monitoring required for payment.

Less frequent reporting would delay the provision of technical assistance and limit opportunities for applicant organizations to implement corrective action. Ineffective programs are an inefficient use of health care dollars, could potentially be harmful to the participants and the reputation of the National DPP, and undermine efforts to encourage payers, including Medicare, to reimburse for the cost of lifestyle interventions.

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 (see Attachment 2B Summary of Public Comments)

A 60-day Federal Register Notice was published in the *Federal Register* on July 14, 2017, Docket No. CDC-2017-0053, Document Citation 82 FR 32549, pages 32549-32551 (3 pages). CDC received and responded to 33 unique public comments that were related to this notice from both individuals and organizations that are outside of CDC. Within those 33 comments, there were 119 unique questions/comments that CDC answered. The table contained within "Attachment 2B Summary of Public Comments" summarizes the public comments and how CDC plans to address them.

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 eviewed by CDC's Information System Security Office, as well as the Division of Diabetes Translation's program office, and both determined that the Privacy Act does not apply. Although the DPRP Application Form includes IIF (the name and contact information for each organizational entity's contact person and data preparer), the contact information only provides information relating to designated roles in the organization. The contacts do not provide personal information to CDC. The data submitted to CDC for evaluation purposes is identifiable by organizational entity. The participant-level evaluation data submitted to CDC does not include participant names, but includes participant codes. The organizational entity requesting CDC recognition through the DPRP (applicant organization) assigns and maintains participant codes.

B. Application form information and evaluation data are submitted to CDC via online web application forms. These transmission methods were reviewed and recommended by CDC'Added s Information Systems Security Officer. 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 IIF relating to individual program participants. CDC publishes only aggregated data. At the discretion of the DPRP Manager or DDT Division Director, aggregated data may be shared with external partners for the purpose of preparing reports or manuscripts.

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 type 2 diabetes prevention lifestyle change programs 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 from (Attachment 4B) will replace the current form and may be submitted at any time beginning January 1, 2018. The information contained in the application is needed to communicate with the applicant organization and provide technical assistance. Evaluation data are transmitted to the DPRP by the applicant organization (currently every 12 months; proposed 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, beginning January 1, 2018, to align with the MDPP Expanded Model to allow organizations to bill for diabetes prevention services for Medicare beneficiaries. To minimize the burden on applicant organizations and ensure the quality and utility of the data, evaluation data are submitted to CDC using the DPRP's interactive web application (Attachment 5A, Attachment 5C).

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 (IIF); however, the identifiable information is only that needed to enable communication with the applicant entity's designated contact person(s). New elements for this third revision are marked accordingly as "new".

The application form (Attachment 4A-screenshot) will be updated to include all the following elements; new elements are marked as "new":

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.

2) Organization Code. This code is assigned by the DPRP. Choose Not applicable if this is an initial application. For re-applicants, enter the previously assigned organization code. Organization codes will be published in the DPRP registry corresponding to the organization name on the CDC website here: https://nccd.cdc.gov/DDT_DPRP/Registry.aspx.

3) Organization Name. Upon application approval, the organization name will be published in the DPRP registry on the CDC website.

4) Delivery Mode (new in terms of one mode per application). 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. For definitions, see the Standards and Requirements for Recognition, Delivery Mode section.

5) Class Type (new). Select all applicable class types offered: public (open to anyone who qualifies for the lifestyle change program 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/Alaskan Natives, patients, clients, etc.). Organizations offering classes to the public should provide the physical addresses of the classes, or online link to class offerings, to DPRPApply@cdc.gov. Upon application approval, the class type as well as public class locations will be published in the DPRP registry on the CDC website. If public classes are added, deleted, or changed, organizations should email updated public class location addresses at least every 6 months to DPRPAsk@cdc.gov.

6) Organization Physical Address. Provide the main organization's business office or headquarters address. Upon application approval, this will be published in the DPRP registry and on the CDC website.

7) Organization Mailing Address. Include if different from the Organization Physical Address. DPRP staff will use this address to communicate by mail with the organization (i.e., mailing the certificate of achievement of full recognition if/when achieved).

8) Organization Web Address or URL. Optional. Upon application approval, this will be published in the DPRP registry and on the CDC website. All web addresses must link directly to a location where participants can find information about the organization's CDC-recognized lifestyle change program and enroll in the program. CDC will not accept or host any other web addresses.

9) 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.

10) Organization Type (new). 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/Community Health Centers/Federally Qualified Health Centers; Pharmacies/Drug Stores/Compounding Pharmacies; Indian Health Service/Tribal/Urban Indian Health Systems; Business Coalitions on Health/Cooperative Extension Sites; Worksites/Employee Wellness Programs;

Senior/Aging/Elder Centers; Health Plans/Insurers; Faith-Based Organizations/Churches; For-profit Private Businesses; Other (please specify).

11) 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, middle initial, and academic credentials, if applicable [e.g., MD, RN, MPH, MPA, PhD, other (please specify)]. The Program Coordinator's information will not be included in the DPRP registry.

12) Program Coordinator Contact Information. Provide an email address, phone number, and fax number (if applicable) of 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.

13) 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, middle initial, and academic credentials, if applicable [e.g., MD, RN, MPH, MPA, PhD, other (please specify)]. The Secondary Contact's information will not be included in the DPRP registry.

14) Secondary Contact Information. Provide the email address, phone number, and fax number of the organization's Secondary Contact, if applicable. DPRP staff will use this information to communicate with the organization in the event an organization's Program Coordinator cannot be reached for routine communication, including data-related communication.

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://www.cdc.gov/diabetes/prevention/lifestyle program/staffing training.html), 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 (has completed at least 12 hours of formal training as a Lifestyle Coach, has successfully offered the National DPP lifestyle change program for at least one year, and has completed a Master Trainer program offered by a training entity listed on the CDC website).

16) 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 contact information will not be included in the DPRP registry.

17) Data Preparer Contact Information. Provide the email address, phone number, and fax number of the organization's Data Preparer. (This can be either the Program Coordinator or Lifestyle Coach if a third person is not designated at this time.) DPRP staff will use this information to communicate with the organization about data submission issues, if required.

18) Curriculum. Select either a CDC-approved curriculum (one that CDC has either developed or previously approved for use by your 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 5A) 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 (Attachment 5C). 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 IIF about lifestyle program coaches or participants is transmitted to CDC. All identifiers (except the organization code that is provided by CDC) are assigned and maintained by the CDC-recognized organization. Any MDPP-related IIF is stored at the organization level only, and not transmitted to CDC. MDPP supplier organizations 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.

The evaluation data includes the following elements. New elements for this third revision are marked accordingly as "new" or "reinstated" and justifications are specified for each new data element:

1) Organization Code. Will be assigned by the DPRP when the organization's application is approved. Each applicant will have a unique organization code. This code must be included by the applicant organization on all data records submitted.

2) Participant ID. Will be assigned by the organization to uniquely identify and track participants across sessions. The participant ID must be included on all session attendance records generated for an individual participant. The participant ID should not be based on social security number or other PII. If a participant re-enrolls in a new class, the organization should assign this participant a new participant ID.

3) Enrollment Source (new—This variable is required so that CDC and CMS can evaluate the most effective means to reach participants with prediabetes or at high risk for type 2 diabetes, including Medicare beneficiaries. In particular, CDC and CMS want to evaluate the outcomes of their work with the American Medical Association to encourage physicians to refer eligible people to the lifestyle change program). Will identify the source (person, place, or thing) which led the participant to enroll in the yearlong program (see data dictionary for the appropriate code).

4) Payer Type (new—This variable is required by CMS to identify Medicare beneficiaries participating in the National DPP lifestyle change program). Will identify one, main payment method that participants are using to pay for their participation in the yearlong program (see data dictionary for the appropriate code).

5) Participant State. The state in which a participant resides should be recorded 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.

6-8) Participant's Prediabetes Determination. Should be recorded at enrollment and included 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 Screening Test (see guidance titled CDC Prediabetes Screening Test) or the ADA Type 2 Diabetes 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.

9) Participant's Age. Should be recorded at enrollment and the recorded age used 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 okay.

10) Participant's Ethnicity. Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self- identify and have the opportunity to choose one of the following: Hispanic/Latino, Not Hispanic/ Latino, or not reported.

11–15) Participant's Race. Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to 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 (refer to Table 2, the data dictionary).

16) Participant's Sex. Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The data record should indicate male, female, or not reported.

17) Participant's Height. Should be recorded at enrollment and included on all session attendance records generated for an individual participant. Height may be self-reported (i.e., 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?"). The participant's height should be recorded to the nearest whole inch.

18) Education (new—This variable serves as a proxy for Socioeconomic Status (SES) and will allow CDC to monitor and evaluate the participation and outcomes of vulnerable populations. The intent is to ensure that the program does not unintentionally increase health-related disparities). Will identify the highest grade or year of school the participant completed. This information should be recorded at enrollment and included on all session attendance records generated for an individual participant.

19) Delivery Mode (new—This variable is required by CMS as the MDPP Expanded Model will only reimburse for in-person programs). Will identify the delivery mode, as defined in the Applying for Recognition section, for this specific participant and session (i.e., in-person, online, distance learning).Please note that since this is a session level variable, combination mode does not apply.

20) Session ID (reinstated—This is a reinstated data element from CDC's original 2011 DPRP Standards package. This variable is required by CMS to align specific sessions with the value-based payments in the Expanded Model (i.e. payment after 4 sessions, 9 sessions, etc.)) Will identify weekly sessions offered throughout the yearlong program. Session IDs in months 1-6 could be numbered 1 through 26 depending on the frequency of weekly offerings. Session IDs in months 7-12 will all be numbered as 99, and sessions in ongoing maintenance months (for Medicare DPP supplier organizations or other organizations that choose to offer ongoing maintenance sessions) will all be numbered as 88. If a 7-12 month curriculum module (such as one from PreventT2) is used in months 1-6, it should be coded as 1 through 26, since it is being delivered during that timeframe. If a 1-6 month curriculum module is used in months 7-12, it should be coded as 99, since it is being delivered during that timeframe.

21) Session Type [(reinstated—This is a reinstated data element from CDC's original 2011 DPRP Standards package. This variable is also required by CMS to implement the value-based payments in the Expanded Model (i.e. payments are tied to completion of specific session types.) Will identify the session attended within months 1-6 (scheduled core sessions) as "C", core maintenance sessions attended within months 7-12 as "CM", or ongoing maintenance sessions as "OM" in the second year (post-yearlong lifestyle change program)] for Medicare DPP suppliers or other organizations that choose to offer ongoing maintenance sessions. Medicare DPP 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 Medicare to assist with their continued implementation and assessment of the Medicare DPP expanded model.

Make-up sessions will be identified as "MU" and should be used with the corresponding Session ID that was previously missed by the participant (i.e., the session they are making up). If a 7-12 month curriculum module (such as one from PreventT2) is used in months 1-6, it should be coded as a "C", since it is being utilized as a core session. If a 1-6 month curriculum module is used in months 7-12, it should be coded as a "CM", since it is being utilized as a core maintenance session.

22) Session Date. Each time a participant attends a session, the actual date of the session should be recorded. The date should be recorded in mm/dd/yyyy format. A participant should not have more than one record (line of data) for any specific session date, with the exception of make-up sessions. One make-up session per week may be held 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.

23) Participant's Weight. Each time a participant attends a session, his or her body weight should be measured and recorded to the nearest whole pound. The 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.

24) Participant's Physical Activity Minutes. Once physical activity monitoring has begun in the curriculum, participants will be asked to report the number of minutes of moderate or brisk physical activity completed during the preceding week. This information should be included on the record for that participant and session. If a participant reports doing no activity during the preceding week, then zero (0) minutes should be recorded. Note: Zero (0) minutes reported will not count as documented physical activity minutes.

CDC uses evaluation data to assess the applicant organization's progress toward meeting ormaintaining CDC recognition standards. Organizations may not achieve recognition, or lose recognition, if they do not:

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

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

IRB Approval

The DPRP was initially reviewed by human subjects contacts in CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) in 2011, and the Center determined the DPRP's function to be public health practice which does not involve any research involving human subjects (**Attachment 8**). Therefore, review by an Institutional Review Board is not required.

Justification for Sensitive Questions

Prediabetes status, weight, education, 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 enact the CMS MDPP Expanded Model jointly with CMS, monitor program delivery to ensure that programs are being delivered to individuals with prediabetes or at high risk for type 2 diabetes (where science indicates that such programs are effective), evaluate program effectiveness to ensure thatparticipants are achieving the amount of weight loss proven to prevent or delay type 2 diabetes, or attending enough classes to benefit from the information conveyed. In order to monitor program effectiveness and assure that CDC-recognized organizations are delivering science-based, effective lifestyle change programs to all races/ethnicities, adult age groups, genders, and SES statuses (i.e., education), organizations transmit de-identified, coded information about participant demographics, prediabetes status, weight loss, 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 per each of their delivery modes. 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 500 organizations per year, on average, will seek CDC recognition through the DPRP over the 3

years of the requested OMB approval period. The basis for this increase is from an actuarial estimate that CMS and CDC conducted anticipating the uptake of new organizations applying for CDC recognition in order to eventually apply as MDPP suppliers. Only CDC-recognized organizations can apply as MDPP supplier organizations. CMS is solely offering reimbursement for Medciare beneficiaries for participation in CDC-recognized diabetes prevention programs. Thus, there is an anticipated increase in program enrollment.

The total estimated average annualized application burden to respondents is 500 hours (1 hour per response). This includes an estimate of the time needed to read the application instructions, review the *DPRP Standards* document describing organization capacity and data transmission requirements, fill out and submit the application form, and submit curriculum materials, if appropriate.

CDC estimates that 70% of applicant organizations will be private sector entities, and 30% of applicant organizations 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 5A**). Each respondent will transmit evaluation data to the DPRP every 6 months. The due dates for each organization's evaluation data transmissions will be determined by the organization's effective date (the 1st day of the month following the DPRP's approval of the application). The evaluation data are submitted to CDC via an online web application form in accordance with the *DPRP Standards* (**Attachment 3**). During this entire OMB approval period, the DPRP anticipates that 1,500 organizations (annualized to 500 per year) will apply for recognition, and that the number of organizations submitting data will increase from 1,794 by the end of the first year to 2,794 in the third year (annualized to 2,294 organizations per year). The total estimated average annualized evaluation burden to respondents is 9,176 hours (2,294 organizations x 2 hour per response x 2 responses per organization). 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 electonric CSV file), and submit the data file via the National DPP web site. 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 (in hours)	Total Burden (in hours)

Public sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	150	1	1	150
	DPRP Evaluation Data	350	2	2	1400
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	350	1	1	350
	DPRP Evaluation Data	1444	2	2	5776
				Total	7,676

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 type 2 diabetes prevention programs	DPRP Application Form	150	1	$28.20	150	$4,230
	DPRP Evaluation Data	350	2	$28.20	1400	$39,480
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	350	1	$28.20	350	$9,870
	DPRP Evaluation Data	1,444	2	$28.20	5776	$162,883
					Total	$216,463

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 are a subset of the program data elements already being collected and maintained at the organization level; even those not previously required to be reported to the DPRP prior to the 2018 Standards (i.e., organization type, session type). For most respondents, additional evaluation data elements such as session type, delivery mode (by session), and participants' payer type (i.e., health insurance status), which are required by CMS of all MDPP suppliers, are new data elements, and additional time and resources will be needed for collection. Since such 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 also added a new evaluation data element, participant education, as a proxy for SES for surveillance and programmatic purposes (i.e., how to implement successful programs to individuals with low SES). As a result of these new data elements, it is possible that some future applicant organizations and/or currently recognized organizations using third party administrators to assit with data collection may need to make modifications to their systems, and may incur additional costs in doing so. CDC does offer an easy-to-use Comma Separated Variable spreadsheet, as well as, webinars and technical assistance on its use in an effort to minimize data collection burden. However, some organizations still choose to enter into data agreements with other entities and this could impact those systems.

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 $2,031,300 as summarized in the table below.

Personnel	Base salary	Fringe	Total cost
FTE*	$450,700	$135,600	$586,300
Contract support**			$1,300,000
Travel			$25,000
Other direct costs			
Copies, binding, presentation materials			$10,000
Communications			$10,000

Data system maintenance and improvements	$100,000
Total costs	**$2,031,300**

* FTE cost includes percentages of time for approximately 5 FTEs.

** Contract support includes percentages of time for approximately 8 contractors. Contract support also includes program management, data management software/support, administrative support, and development of other DPRP-related web site(s).

15. Explanation for Program Changes or Adjustments

The estimated burden per response for each information collection is 1 hour for application completion (including reading the DPRP Standards and Capacity Assessment). The actual filling out of the automated, online application simply involves drop-down boxes and is not estimated to be very time-consuming. The estimated information collection burden per response for each evaluation data submission is 2 hours. A few changes are proposed for each information collection instrument (the DPRP Application Form and the DPRP Evaluation Data), as outlined in **Attachment 6**. The proposed changes to the estimated number of respondents, the types of respondents, and the frequency of responses are described below.

In 2015, CDC estimated that 350 organizations per year would apply for CDC recognition through the DPRP. At that time, CDC estimated that 60% (210) of the applicants would be private sector organizations, and 40% (140) of the applicants would be from the public sector (state, local, or tribal government organizations). Each applicant organization submitted a one-time DPRP application form, followed by an annual submissions of evaluation data.

In this three-year revision period, CDC is increasing the total estimated annualized number of applicants to 500. The distribution of those applicants is predicted to be 70% (350) from the private sector and 30% (150) from the public sector, based on current DPRP data and projections. This change is based on an anticipated increase in the number of healthcare organizations applying for CDC recognition to deliver the lifestyle change program due to the MDPP Expanded Model and its promotion by CMS and the American Medical Association in healthcare settings. Again, the basis for this increase is from an actuarial estimate that CMS and CDC conducted anticipating the uptake of new organizations applying for CDC recognition in order to eventually apply as MDPP suppliers. Additionally, CDC conducted its own analyses of current DPRP organizations with at least one years' worth of data and learned that more than 80% of them would currently qualify as MDPP suppliers. Hence, confirming the liberalization of new data methods will permit more

promising organizations to become both CDC-recognized and MDPP suppliers. This is expected to lead to more applications for CDC recognition. Additionally, CDC has heard from large national partners that increased uptake in applications for CDC recognition is anticipated (e.g., American Medical Association, American Diabetes Association). Lastly, CDC has issued a Notice of Funding Opportunity Announcement that has funded ten large national organizations to further scale and sustain the National DPP. All 50 states and several US territories will be working in this area. An initial introductory webinar on the National DPP and MDPP expanded model had more than 5,000 interested participants.

The DPRP application form will continue to be a one-time submission, but per each delivery mode (e.g., one for in-person only programs and one for online-only programs, etc.). CDC is also increasing the estimated number of organizations submitting DPRP evaluation data from over 1,200 currently to 2,294 in the upcoming three-year period. The revised estimate includes a mix of current organizations with "full" or "pending" recognition and new applicant organizations. The frequency of reporting DPRP evaluation data will increase from annually to semi-annually, as it was in the 2011 initial OMB submission. The increase in data submission frequency also aligns with the MDPP Expanded Model and will help organizations that are Medicare suppliers bill CMS for their service. It will also allow organizations to submit half of their previous annual data for early evaluation of progress by the DPRP. This allows an organization more opportunities to review their own data, address areas of concern, receive CDC DPRP technical assistance, and make programmatic corrections sooner in order to ensure success. In other words, CDC is returning to the initial 2011 *DPRP Standards* data collection timeline; but, still collecting the same 12 months of program-related data, now biannually, with a few new elements that align with the CMS MDPP Expanded Model. Essentially, this will split the annual data into two 6-month reporting periods to permit regular organizational feedback and CMS MDPP billing.

These changes result in a net increase of 6,126 annualized burden hours. The distribution of these changes is summarized in Table A.12-3. below.

Table A.12-3 Estimated Data Collection Burden Hours by Respondent, 2015 to 2017

Type of Respondent and Form Name		2015			2017			Change from 2015-2017
Type of Respondent	Form Name	No. Respondents	No. Responses per Respondent	Total Burden Hours*	No. Respondents	No. Responses per Respondent	Total Burden Hours	Total Burden Hours

Public sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	140	1	140	150	1	150	10
	DPRP Evaluation Data	480	1	480	350	2	1,400	920
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	210	1	210	350	1	350	140
	DPRP Evaluation Data	720	1	720	1444	2	5,776	5,056
			Total	1,550			7,676	6,126

*Burden per Response = 1 hr. per application and 2 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
Recognition status renewed (ongoing, every 2 years)	ongoing since January 2013
OMB Approval of revision request	December 2017 (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

Diabetes/Prediabetes Statistics in Overview/Justification:

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