

CDC Diabetes Prevention Recognition Program

Revision
OMB No. 0920-0909

Supporting Statement: Part A

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Table of Contents

Section A

- A-1 Circumstances Making the Collection of Information Necessary
- A-2 Purpose and Use of the Data
- 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 Assurance of Confidentiality Provided to Respondents
- A-11 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

Attachments

- 1A Authorizing Legislation Public Law 111-148
- 1B Authorizing Legislation PHSA
- 2A Federal Register Notice
- 2B Summary of Public Comments
- 2B American Association of Diabetes Educators
- 2B America's Health Insurance Plans
- 2B American Medical Association
- 2B Healthcare Leadership Council
- 2B San Juan Regional Medical Center
- 2B Weight Watchers International, Inc.
- 2B Wisconsin Division of Public Health
- 2B YMCA of the USA
- 3 DPRP Standards 2014
- 4A DPRP Application Form and Instructions (screenshot)
- 4B DPRP Homepage (screenshot)
- 4C DPRP Confirmation Page (screenshot)
- 4D DPRP Confirmation Email
- 4E DPRP Application Acceptance Email
- 4F DPRP Application Rejection Email
- 5A Data Dictionary: Evaluation Data Elements (updated 2014)
- 5B Data Dictionary: Evaluation Data Elements (previously approved by OMB 2011)
- 5C DPRP Data Web Application (screenshot)
- 5D(1) Data Reminder Email (4 weeks prior to due date)
- 5B(2) Data Reminder Email (2 weeks past due)

5D(3) Loss of Recognition Email (Failure to Send in any Data at 18 Months)

5D(4) Progress Report

5D(5) Evaluation report

5D(5) Evaluation Report (Determination of Full Recogniton)

5D(6) Loss of Recognition Email (Failure to Meet Standards)

5D(7) Notification of Achievement of Full Recognition

6 Overview of Changes

Overview

The Centers for Disease Control and Prevention (CDC) collects information needed to administer the Diabetes Prevention Recognition Program (DPRP) (OMB No. 0920-0909, exp. 11/30/2014). Through the DPRP, CDC recognizes organizations that successfully deliver an evidence-based lifestyle change program to participants who have pre-diabetes. The lifestyle 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, specified criteria for such programs and how organizations could attain recognition through the DPRP. Information submitted to CDC for DPRP recognition includes a one-time application form, followed by semi-annual 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 recognition has been awarded to qualifying organizations when program participants achieved outcomes predicted by the original clinical studies.

This Revision request describes changes in the *DPRP Standards* and information collection that will allow CDC to recognize organizations that offer "virtual" lifestyle change programs, i.e., programs that employ Web-based tools and other distance learning technologies. It also outlines corresponding changes to the information collection plan that will allow CDC to identify virtual programs and ensure that uniform evaluation criteria are applied to both traditional and virtual programs. Additional changes are proposed to clarify forms/instructions, and to accommodate more user-friendly methods of transmitting required information to CDC. 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.

This Revision request also describes changes that affect the annualized burden estimates. In the initial three-year approval period, CDC collected DPRP Evaluation Data Elements semi-annually. In the next approval period, organizations will submit this information once per year. Finally, CDC will increase the estimated number of organizations expected to apply for recognition through the DPRP. This adjustment reflects increased demand from organizations that offer virtual programs. There is a net increase in estimated annualized burden hours.

OMB approval is requested for 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 diabetes.¹ 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 diabetes and diabetes-related complications in the U. S. was estimated to be \$245 billion. 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. People with prediabetes have an increased risk of developing type 2 diabetes, heart disease, and stroke. Without lifestyle changes to improve their health, 15% to 30% of people with prediabetes will develop type 2 diabetes within five years. 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.

Fortunately, research has shown that lifestyle intervention can prevent or delay 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 results 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.⁶⁻¹⁰ One study delivered the lifestyle program via the internet with and without behavioral e-counseling.¹¹

CDC established the National Diabetes Prevention Program (NDPP), administered through the Division of Diabetes Translation (DDT), to make strategies 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 include: weight loss (5-7% of body weight), documentation of physical activity minutes (with a goal of ≥ 150 minutes per week), attendance throughout the 12-month intervention (there is somewhat of a dose/response relationship between attendance and weight loss/maintaining weight loss although the exact “dose” has not been determined). The NDPP is authorized and funded in part through Section 399-V of P.L. 111-148, the Patient Protection and Affordable Care Act (**Attachment 1A**). The NDPP 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, based on the available scientific evidence, CDC established the Diabetes Prevention Recognition Program (DPRP) as one arm of the NDPP. The DPRP was created to recognize

organizations that deliver effective evidence-based lifestyle change curricula via a 12-month in-person intervention, to individuals with pre-diabetes. Key objectives of the DPRP include:

- Assure program quality, fidelity to scientific evidence, and broad use of effective type 2 diabetes prevention lifestyle interventions 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 interventions 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 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 intervention. As authorized by the Public Health Service Act (**Attachment 1B**), CDC is currently approved to collect information from organizations seeking recognition through the DPRP (CDC Diabetes Recognition Prevention Program, OMB No. 0920-0909, exp. 11/30/2014). Two types of information are collected from applicant organizations: a one-time DPRP Application Form, followed by DPRP Evaluation Data Elements. The DPRP Application Form allows CDC to assess the applicant organization's readiness to achieve recognition through the DPRP. Organizations that have the capacity to deliver a DPRP-approved lifestyle intervention and agree to the *DPRP Standards* proceed to "pending" recognition status. During the next one to two years, in which the organization's DPRP recognition status remains "pending," the organization submits 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.

CDC seeks to extend OMB approval for DPRP data collection for three years, with changes. Importantly, the *DPRP Standards* are being revised to incorporate findings from studies which show that effective health education and coaching can be delivered through distance

learning modes of program delivery. Initially, the DPRP did not recognize organizations that offered virtual programs because of the limited evidence of virtual program efficacy provided by a single study.¹¹ However, since the DPRP's inception in 2011, additional translational research has shown that evidence-based curricula delivered outside of the typical classroom setting (e.g., virtual delivery) can produce results similar to those shown in early efficacy and effectiveness trials.¹²⁻¹⁵ As a result, CDC plans to allow organizations that deliver "virtual" programs (e.g., Web-based programs) to apply for and receive recognition through the DPRP if virtual program participants achieve outcomes that are comparable to outcomes achieved by participants who attend in-person education and coaching sessions. 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 (traditional or virtual). Data items that are only applicable to in-person programs (e.g., in-person session ID) will be eliminated and one new data item will be added that allow CDC to describe the reach of virtual programs (participant's state of residence). This Revision request also describes a number of changes that are based on experience administering the DPRP (e.g., changes to clarify instructions for applicant organizations). Finally, a group of changes relate to burden estimates. The number of organizations applying for DPRP recognition will be adjusted to accommodate increased demand for DPRP services and recognition, but the frequency of reporting for DPRP Evaluation Data Elements will be reduced from semi-annual to annual. 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 2014 *DPRP Standards* and data collection requirements will be effective for all new applicants organizations immediately upon receipt of OMB approval of this Revision (estimated December 2014). CDC anticipates that some applicants will be in "pending" recognition status at this time. To provide for orderly transition from the initial 2011 *DPRP Standards* to the revised 2014 *DPRP Standards*, CDC will allow programs that initiated their applications under the 2011 *DPRP Standards* the option of submitting one additional Evaluation Data Elements report in the 2011 format. Thereafter, these programs will transition to the 2014 *DPRP Standards*. The transition plan will allow organizations to adapt their reporting systems without unduly interrupting progress toward achievement of DPRP recognition.

CDC anticipates that information collection will continue throughout the lifetime of DPRP. At this time CDC requests an additional three years of OMB approval to collect the information needed to administer the DPRP. However, ongoing discussions with recognized programs and potential applicants, along with results from ongoing studies, may necessitate additional changes to the *DPRP Standards* making another revision request possible before the end of the three-year period. For example, the CDC-preferred curriculum is currently

being revised. The new curriculum will be identified more closely with the CDC and, although it will remain faithful to the science, should allow programs more flexibility in content and delivery.

Privacy Impact Assessment

Overview of the Data Collection

Respondents are organizational entities that deliver type 2 diabetes prevention lifestyle interventions and seek recognition through 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 DPRP Web site (www.cdc.gov/diabetes/prevention/recognition) (**Attachment 4B**), and may be submitted at any time. The information contained in the application is needed to communicate with the applicant organization and provide technical assistance. Evaluation data is transmitted to DPRP by the applicant organization every 12 months in accordance with *DPRP Standards*. These data are needed to assess recognition status according to objective criteria, assure fidelity to *DPRP Standards*, and identify opportunities for quality improvement or technical assistance. To minimize the burden on applicant organizations and ensure the quality and utility of the data, evaluation data are submitted to CDC using DPRP's interactive web application (**Attachment 5A, Attachment 5C**).

Items of Information to Be Collected

Application data elements. Applicants for recognition through DPRP are organizational entities, not individuals. The data elements collected on the DPRP application include 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).

The application form (**Attachment 4A**) includes the following elements:

- Type of Application (initial or reapplying)
- Organization Code (unique identifier assigned by DPRP)
- Organization Name, Organization Physical Address, Organization Web Address or URL, and Organization Phone Number (will be included in the DPRP registry and published on the DPRP Web site)
- Contact Person Name, Contact Person Title, Contact Email Address, Contact Phone Number, Contact Fax Number, and Organization Mailing Address (will be used by DPRP staff to communicate with the applicant organization; no contact person information will be included in the registry)

- **New elements** - (if applicable) Secondary Contact Person Name, Secondary Contract Person Title, Secondary Contact Email Address, Secondary Contact Phone Number, Secondary Contact Fax Number
- **New elements** – (if applicable) Data Preparer Name, Data Preparer Title, Data Preparer Email Address, Data Preparer Phone Number, Data Preparer Fax Number (if applicable)
- Curriculum - The CDC-preferred curriculum or other curriculum; if other curriculum is selected, the curriculum must be submitted with the application
- **New element** – Intended Mode of Delivery (in-person only, virtual-only, other [specify]) (this is a new data element and will be used evaluate alternative modes of delivery and will be noted in the organization’s entry in the DPRP registry and published on the DPRP Web site)
- Electronic signature asserting that the organization has read *DPRP Standards* and agrees to the recognition criteria

Evaluation data elements. Each DPRP recognized organization (pending or full) transmits evaluation data (**Attachment 5A**) to CDC every 12 months, beginning 12 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 sessions conducted by the organization during the preceding 12 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 DPRP-recognized organization. All participants in DPRP-recognized lifestyle interventions are 18 years of age or older.

The evaluation data includes the following elements:

- Organization Code (unique identifier assigned by DPRP)
- Participant ID (assigned and maintained by the DPRP-recognized organization, used to uniquely identify and track participants across sessions; should not be based on social security number or other personally identifiable information)
- Participant information recorded at program enrollment and used to establish eligibility: Participant’s Prediabetes Determination (used to assure that participants come from high risk groups in which diabetes prevention has been shown to be effective; the coding on this element has been simplified so that organizations no longer need to indicate the type of blood test performed), Participant’s Age (used to monitor program reach), Participant’s Height (used to determine body mass index for participant eligibility)
- Participant information recorded at enrollment and used to provide technical assistance: Participant’s Ethnicity, Participant’s Race, Participant’s Sex (these four elements are used to monitor program reach and effectiveness across population)

- groups)
- Participant- and session-specific information used to evaluate program outcomes and provide technical assistance: Session Date (to monitor/evaluate the 12-month intervention), Participant’s State (new code) (to monitor program reach and enable reporting by state), Participant’s Weight (to determine if individual participants’ lose the 5-7% of body weight shown to prevent or delay diabetes), and Participant’s Physical Activity Minutes (to monitor programs to ensure recording of physical activity minutes and to determine if participants are achieving the CDC-recommended 150 minutes of activity per week)

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

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

Identification of Web Site(s) and Web Site Content Directed at Children Under 13 Years of Age

The online application form and instructions (**Attachment 4A**), and *DPRP Standards* (**Attachment 3**), which include complete specifications for the evaluation data elements and instructions for their transmission, are posted on the DPRP Web site (www.cdc.gov/diabetes/prevention/recognition) (**Attachment 4B**). There is no Web site content directed at children under 13 years old.

2. Purpose and Use of the Data

Information collected by CDC for DPRP administration is used

- By the federal government to promote the dissemination and use of effective strategies for preventing diabetes
- By CDC to assess applicant organizations’ compliance with *DPRP Standards*, their progression from “pending” recognition status 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.

The DPRP is a recognition program for lifestyle 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. DPRP recognition of a lifestyle program is an assurance of program quality that encourages physicians and other health care providers to refer their patients with prediabetes to the recognized programs.

For an organization's lifestyle program to receive pending recognition, the organization must agree to deliver an evidenced-based program using a DPRP-approved curriculum and submit evaluation data annually to allow the DPRP to monitor fidelity of program delivery and program effectiveness and to provide technical assistance. Full recognition is awarded after organizations meet all of the effectiveness criteria specified in the DPRP standards. Recongized programs continue to submit data annually thus allowing program effectiveness to be reassessed for as long as the organization participates in the recognition program. DPRP collects two types of data: 1) application data (contact information and curriculum to be used) and evaluation data (to monitor program quality and effectiveness).

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, telephone number, location, Web address [if provided], program delivery mode and level of recognition) is made publicly available on the DPRP Web site or through other directories. This information helps providers and consumers identify organizations recognized for delivering effective lifestyle interventions 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 intervention programs, not the success or failure of the individual program participants. 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 the organization to meet the DPRP requirements and the participants to prevent diabetes and continue to lead healthy lifestyles).

Without the ongoing collection of evaluation information, DPRP could not exist because CDC could not verify program eligibility or effectiveness and there would be no way to monitor and evaluate program quality on a national level.

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, as well as the name, job title, and e-mail address of an employee designated to serve as the organization's primary contact person and, if applicable, a secondary contact person and designated data preparer. Although the application includes IIF, 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, address, and telephone number (and Web address, if provided); 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 DPRP 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 and weight) are used to evaluate recognition criteria relating to attendance and weight loss (which are aggregated across participants to indicate whether or not the program met its percentage of overall weight loss goal). Collection of demographic information about program participants is necessary for analyses that ensure program effectiveness in both genders, across all ages (18+) and in all racial/ethnic groups. The participant process and outcome data includes 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, method of determining prediabetes status) when coupled with other data (organization code) might be considered IIF. CDC does not 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 intervention programs and for providing targeted technical assistance.

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, the participant-level evaluation data is linked to the 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 DPRP

applicant organizations assign and maintain the participant ID, and CDC does not have access to the keys for this code or to the applicants' data systems.

No 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 is submitted in a precisely defined format. The DPRP data system incorporates standard procedures for checking the format and content of evaluation data submissions upon receipt. Any 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 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.

In addition, we would point out that CDC provides the critical assurance to participating organizations that CDC uses the data only as described and safeguards and secures the data to the full extent allowable by law. On the organization side, the *DPRP Standards* clearly assign the principal responsibility for maintaining participant privacy to the participating organization.

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

Section 399V–3 of Public Law 111-148 (**Attachment 1A**), authorized CDC to establish a national diabetes prevention program for prevention of type 2 diabetes in high risk adults. As a part of this program, CDC was tasked “to determine eligibility of entities to deliver community-based type 2 diabetes prevention services” and to monitor, evaluate, and provide technical assistance to these entities.

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, the information needed to administer DPRP is not available from other sources.

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 60% of applicants are from the private sector and 40% are from the public sector. We anticipate that programmatic changes (e.g., participant eligibility via additional blood tests, virtual program delivery) will attract more large businesses and thus change the distribution among future participants. When a small business offering type 2 diabetes prevention programs applies for recognition through 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 interventions. 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 intervention is 12 months long (with two phases, months 1-6 and months 7-12). Organizations seeking recognition through DPRP submit evaluation data to CDC every 12 months. 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.

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 DPRP, and undermine efforts to encourage payers to reimburse 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

A Notice was published in the *Federal Register* on April 11, 2014 (**Attachment 2A**). During the 60-day comment period, comments were received from eight organizations: the American Association of Diabetes Educators, America's Health Insurance Plans, American Medical Association, Healthcare Leadership Council, San Juan Regional Medical Center, Weight Watchers International, Inc., Wisconsin Division of Public Health, and the Y-USA. The Y-USA provided extensive comments which included some topics also raised by one or more of the other responding organizations (e.g., virtual delivery). Thus, the comments from the Y-USA were chosen to represent comments from all eight organizations. The comments from the Y-USA, and CDC's response, are included verbatim below. All comments were carefully considered and some resulted in changes or additions to the program (e.g., the transition plan for existing organizations). For additional information on the public comments, as well as the complete comments/responses of all eight organizations, see **Attachment 2B**.

Note: (C) indicates the beginning of a comment, suggestion or request for clarification from the Y-USA; (R) indicates a response from CDC (CDC's responses are indented).

(C) General Comment

From the outset of efforts to disseminate the YMCA's DPP, the potential of formal CDC recognition has been one of the strongest motivators for YMCAs and their partners. Thus, we have been enthusiastically supportive of the creation of the DPRP, and have been glad to inform its development. Many Ys have applied for DPRP recognition under the DPRP, and many more will. It is our goal to have more than 300 YMCAs running the YMCA's DPP, and seeking DPRP recognition, by 2017. Our goal has been and continues to be to leverage the DPRP as a means of documenting the quality of the YMCA's DPP. By doing so, we aim to increase the number of insurance plans covering this intervention to reduce barriers to entry, control costs for participants, the long-term sustainability of the program, and the greatest possible benefit to society.

However, we have some significant concerns about the practical utility of the information being proposed to be collected through a revised set of standards for the DPRP. We also have concerns about the accuracy of the agency's estimate of the burden of the newly proposed requirements for the collection of information. We believe, and have data to demonstrate, that the proposed changes to the DPRP will potentially be counter-productive. This letter outlines all our concerns, which have been established after a thorough review of the DPRP data collection plans and instruments, and the generation of significant real-world experience in documenting the implementation of the YMCA's DPP.

(C) Overview of Y-USA's Comments

We believe that prior to adopting the proposed changes to the DPRP, current providers should be consulted and the proposed changes should be reviewed to:

A. Ensure the practical utility of the DPRP by holding program providers to clear, evidence-informed, and equitable standards regarding

1. the mode of DPP delivery,
2. risk assessment practices,
3. eligibility verification requirements,
4. reporting processes; and

B. Assess more accurately the additional time and costs that will be incurred by the majority of current successful DPP providers, who have made significant investments to conform to existing standards, and who will have to make changes to current operations, training

practices, and technologies that currently allow for efficient and high-quality DPRP reporting.

Upon completion of the review of our concerns, we would hope that the proposed revisions to the DPRP reporting processes would be further amended to minimize the time and material costs associated with making changes to reporting systems, and to not put current providers at a financial and operational disadvantage when delivering recognition-worthy programs and reporting our successes.

(R) Regarding point A above, a notice of our intent to revise the DPRP Standards was published in the Federal Register on April 11, 2014. This notice outlined our proposed revisions and opened a 60-day public comment period. This 60-day comment period served as the DPRP's official solicitation for comments on the DPRP Standards and during that period anyone wishing to do so, including the CDC-recognized organizations, could submit comments. Also, since the program's inception in November 2011, any potential applicant or recognized organization could contact the DPRP with questions, concerns or suggestions to improve the program. The revisions to the standards were precipitated by feedback from recognized and/or partnering organizations, including the Y-USA.

Regarding point B above, to ensure the success of a national diabetes prevention program the reach of current prevention efforts must be expanded. After consultation with several national partners, the DPRP decided to allow programs more flexibility in the structure of the curriculum (e.g., the order in which sessions occur) and to allow virtual delivery of the lifestyle program. With these revisions, some data elements will no longer be meaningful for all organizations. To evaluate the national program, it is essential that the DPRP collect a uniform set of data elements from all participating organizations. Changes in the DPRP's data elements were made to ensure the practical utility and comparability of the data. To lessen the burden associated with modifying the data, the DPRP kept changes to a minimum. Organizations may continue to collect all or part of the former dataset for internal use, but should send the DPRP only the required data fields. The DPRP added one new element, the participant's state of residence. Virtual delivery makes this element essential for state or regional reporting purposes. We do not believe changing the dataset will be excessively burdensome for the majority of our recognized organizations. However, to help minimize the burden for all recognized organizations, the DPRP has developed a transition plan for organizations awarded pending or full recognized prior to 12/1/14 (pending OMB approval). The plan should help ease the transition to the new standards and data elements. Technical assistance will also be available.

A. Specific Concerns Regarding the Practical Utility of DPRP Data Requirements

(C) There are many changes being proposed to the DPRP which will have limited practical utility—and potentially even unhelpful effects—if greater clarity and consistency are not included in the revised standards. Areas of concern in this regard include:

1. In Section II. Standards and Requirements for Recognition, the subsection on Participant Eligibility includes (in item #2) a description of options for verifying eligibility of participants using values from screening tests. For DPP providers that offer in-person interventions, these values have been and will be required to be documented lab test values; but proposed changes would allow virtual providers to provide self-reported data from their participants. It is unclear and impractical that a difference should be allowed in the documentation practices for recording blood tests between in-person delivery and virtual delivery modes. A great deal of work is involved in documenting of blood screening test results, and for good reason. The evidence behind all DPP interventions is based on the effectiveness of these interventions on a group of individuals with a specific range of blood test values. The lack of a consistent standard in eligibility verification sets up a very real risk that the data submitted by providers offering different forms of DPPs will not be comparable, because the quality of self-reported data cannot reasonably be expected to be as valid or reliable as the quality of documented results. It is impractical and unequitable to hold in-person providers to a higher standard than virtual providers. At the very least, standards for documenting the eligibility of participants in recognizable programs should be consistent. Without consistency, the DPRP standards will produce data with less practical utility. Perhaps worse, the providers of the most proven and reliable form of the DPP (i.e., in-person) will essentially be subject to a “quality tax” by having to work harder to enroll participants than providers of less-proven modalities. If any inequalities are to be established by the DPRP, one would think that the efforts to prove the quality of less-proven modalities would have to reach a higher standard.

(R) Programs have always had the ability to accept participants who self-report that an acceptable blood test performed in the last year indicated prediabetes. We did not mean to imply that only virtual programs could accept participants based on a self-reported blood test and should have been clearer in addressing this standard. The text has been modified as follows:

“A minimum of 50% of a program’s participants must have had a recent (within the past year) blood test (blood test may be self-reported) or claim code . . .”

2. The same section and subsection referred to in the previous point includes new language regarding the utilization of claims-based coding data to identify potentially eligible participants (in bullet point #2) and new language regarding the use of claims-based risk tests (in bullet point #3). However, there are no concrete or detailed standards established for these tests and methods of eligibility verification. Additionally, there is not any language provided on how DPRP will track the use of these codes. This lack of clarity makes it difficult to

determine what, if any, operational changes would be required by YMCAs that benefit from the use of a claims-based data mining system to establish eligibility. Further, the developers of any such methodology will have no clear understanding of whether the potentially eligible participants identified in future coding analysis systems would actually meet the eligibility criteria. Thus the data are likely of minimal practical utility and more thought and detail should be added to the proposed DPRP standards to ensure that innovations in data mining produce meaningful and actionable information for DPP providers and the CDC.

(R) The specific codes or risk tests will not be reported to, or tracked, by the DPRP. The data will be coded, as has the data for all previous eligibility criteria, to demonstrate eligibility by blood test, history of gestational diabetes (GDM) or risk test. This data will be analyzed to determine if an organization meets the DPRP eligibility requirement. Claims-based codes were added to provide recognized organizations an additional option through which high-risk individuals might be deemed eligible to participate. The use of claims-based codes is voluntary.

3. In the subsection titled Required Curriculum Content, the language around Intervention Intensity has changed substantially and has raised several concerns. This section under the current standards used to reflect the science behind the vast majority of DPP translations. The lifestyle intervention currently begins with an initial core phase during which a minimum of 16 one-hour, in-person, group-based sessions are offered to all participants over a period lasting at least 16 weeks and not more than 26 weeks. The proposed revisions now say the lifestyle intervention must begin with an initial six-month phase during which a minimum of 16 sessions are offered over a period lasting 16 weeks and not more than 26 weeks. Each session must be of sufficient duration to convey the session content – or approximately one hour in length. It is unclear how increasingly flexible standards will affect the utility of data collected on DPPs, but it is difficult to imagine that the utility of the data will be increased by allowing for more variability in the delivery of curriculum content.

(R) The requirements for recognition (e.g., percent weight loss, reporting of physical activity minutes, a minimum number of sessions attended during both the first and second six months of the program) have not changed. All recognized organizations submit the same data elements. To reach full recognition an organization, regardless of the mode of delivery or rigidity of program structure, must meet all of the minimum requirements in the DPRP Standards. Also, though reworded (e.g., by changing at least 16 to a minimum of 16), the requirement for a minimum number of sessions (16) to be delivered in no more than a set number of weeks (16-26) has not changed. The changes in this section, the addition of virtual delivery and the flexibility in duration of each session, are the direct result of feedback from partners and recognized organizations. Virtual delivery will expand the reach of the program. Sessions may still be one hour in length. However, flexibility in session duration will allow organizations to devote more or less time to

curriculum areas based on participant need. Neither virtual delivery nor session duration affects the utility of the data as these are not included in the data analysis. As noted earlier, all recognized organizations submit the same data elements and must meet all of the minimum requirements to achieve recognition.

4. In Section II's subsection on Additional Requirements for Full Recognition Status, the changes being proposed in point #5 are very significant. The practical utility of the data to be collected under this new approach must be questioned, because the standards have essentially changed to capture data on participants in ways that do not reflect well-established program delivery methods in previously approved curricula and the result will be that some providers will be reporting only core session data at the six-month point while others will be submitting data on both core and maintenance sessions. This will be problematic for data collection related to attendance, and will make analyses of potentially incomparable data less practically useful to the CDC, DPP providers, the public, etc.

(R) Although we no longer use the terms “core” and “post-core,” the required length of the two distinct parts of the lifestyle program, as specified in the 2014 DPRP Standards, has not changed. During the first six months of the program, a minimum of 16 sessions must be delivered over a period of not less than 16 weeks and not more than 26 weeks. During the second six months of the program, there must be a minimum of one session delivered in each of the six months (for a minimum of six sessions). Organizations wishing to provide more sessions during the second six months of the program may do so (and it may be wise to do so as participants may have difficulty transitioning to less frequent sessions). The frequency and timing of sessions delivered during phase one, which is an organizational choice, determines the length of time that programs use to deliver phase two. Programs choosing to complete the first phase of the program in 26 weeks, rather than in 16 weeks, could potentially move on to phase 2 of the lifestyle program later in time. However, no organization will have less than six months to complete the second half of the program. Participant engagement throughout the year-long program should be strongly encouraged.

5. The next item in this same subsection (i.e., #6) includes changes to the DPRP standards that have essentially reduced weight loss data reporting requirements. On one hand, this could be seen as an attempt to make an allowance for efficiencies in program delivery. However, the concern is that changing the standards (i.e., to allow for weight data to be captured in at least 80% attended classes for all people who attend at least four sessions) will in effect remove any requirement to collect weight loss data during the maintenance phase (now called Phase II) of program delivery. This new section should be tied to all weight data collected across the entire year of the intervention, but it's not clearly called out by the revised requirements.

(R) Requirement 6 in the updated DPRP Standards states that “Documentation of body weights will be based on all participants who attended a minimum of four or more sessions. Body weight must have been recorded at 80% or more of all sessions attended.” Calculation of this measure will be based on all sessions attended by participants during the entire 12 months following their start dates.

6. Another item in this same subsection (#8) describes how weight loss data will be averaged across all participants attending a minimum of four sessions. In the existing standards, this requirement was specific to just core sessions but because of changes referenced above this will now include data on both core and maintenance sessions. There are purposefully designed differences in approved curricula between core and maintenance sessions. By removing the distinction between weight lost in core and maintenance phases the utility of the data reported to DPRP will likely be reduced as the effectiveness of distinct coaching strategies will not be discernable. Additional lack of clarity on how this standards will actually be applied comes from the relationship of an earlier standard (i.e., in #5, the average number of sessions attended must be a minimum of 9) to this standard. Why would DPRP anchor on that number for attendance but not for weight loss reporting? Consistency in the approach to data collection across attendance and weight loss data would likely increase the utility and efficiency of data reporting.

(R) Months 1-6 (first half of the intervention year) describes the timeframe during which “core” content is to be delivered in an intensive manner, with sessions offered approximately once per week. Months 7-12 (second half of the intervention year) describes the period during which participants are to be supported with monthly “post-core” or maintenance sessions to assist them in internalizing lessons learned so they can continue and maintain their lifestyle change beyond the end of the intervention. The change from “core” and “post-core” to first six months and second six months is largely semantic. By describing these phases in terms of time, DPRP will be able to accommodate minor, permissible variations in program delivery and still apply the evaluation criteria uniformly to all recognized organizations.

Session attendance is averaged over participants who attended a minimum of four sessions over the course of 12 months. Weight loss is also averaged over these same participants (those who attended a minimum of four sessions). Nine is the performance standard for average attendance in the first six months. Three is the performance standard for average attendance in the second six months. 5% is the performance standard for average weight loss, and is calculated at 6 and 12 months, with the first recorded weight as the baseline. We believe that these measures are consistent with one another, and also with the measures used in the 2011 version of the DPRP Standards.

To help organizations understand exactly how all performance measures will be calculated, we are providing a detailed example as an appendix to the 2014 DPRP Standards.

7. Changes to the very next bullet point (#9) have essentially just removed language around post core session attendance, and shifted to language describing session attendance for months 7-12 as Phase II. The metric for success is still the same (i.e., average number of sessions attended during months 7-12 must be 3 sessions attended). The anticipated result is a decrease in the time available for achieving success in this metric. This is probably an unintended consequence of trying to build more flexibility into the core session phase (i.e., Phase I). With an expected diminished rate of success in this aspect of DPP delivery, the utility of collecting data on this phase of the program under the proposed changes should be evaluated and explained.

(R) As stated above, although we no longer use the terms “core” and “post-core,” the required length of the two distinct parts of the lifestyle program, as specified in the 2014 DPRP Standards, has not changed. During the first six months of the program, a minimum of 16 sessions must be delivered over a period of not less than 16 weeks and not more than 26 weeks. During the second six months of the program, there must be a minimum of one session delivered in each of the six months (for a minimum of six sessions). Organizations wishing to provide more sessions during the second six months of the program may do so (and it may be wise to do so as participants may have difficulty transitioning to less frequent sessions). The frequency and timing of sessions delivered during phase one, which is an organizational choice, determines the length of time that programs use to deliver phase two. Programs choosing to complete the first phase of the program in 26 weeks, rather than in 16 weeks, could potentially move on to phase 2 of the lifestyle program later in time. However, no organization will have less than six months to complete the second half of the program. Participant engagement throughout the year-long program should be strongly encouraged.

8. In Section III, Applying for Recognition, point #14 states that organizations can now select various modes of delivery from all that apply. Options are in-person, virtual or “other”. It would be useful to define or clarify what is meant by “other”. Without greater clarity, this vague standard will reduce the value of collecting any data on the mode of delivery.

(R) Thank you for pointing out the need for additional clarification in this section. Organizations will now choose one of the following: 1) in-person only; 2) online/virtual only; 3) Other (hybrid/multiple modes) please specify _____.

9. In Section IV, Submitting Evaluation Data to DPRP, the subsection on Evaluation Data Elements includes a list of data elements that have been re-ordered from the previous version

of DPRP standards. This seems to indicate that the packaging of data to CDC will now be required to be submitted in a revised format. If this is the intent of the CDC, then it would be beneficial to clarify this as an expected change.

(R) The data dictionary in the 2014 DPRP Standards includes changes to the variables and format of the data submission. Data must be submitted in the specified format. Variables (columns) in the data submission file should have the same names (column headings) as in the data dictionary. We have added a sentence to the data submission instructions to clarify. With the exception of “Participant State,” which is a new data element, the data elements required by the revised DPRP Standards are a subset of the previously required data. Thus, we do not anticipate that costs associated with re-ordering the variables will be prohibitive for the majority of the DPRP’s currently recognized organizations. The DPRP has developed a transition plan for organizations recognized prior to 12/1/14 (pending OMB approval). The plan should help ease the transition from the old (2011) standards to the new (2014) standards. Technical assistance will also be available.

10. In this same section and subsection, one of the points (#2) has been changed to “class code”. We think the existing “group code” field will map to this new field, but it has previously been allowable for participants to switch between groups if they must (e.g., when participants might start the year-long program in a community where they spend their winters, but end the program in a community where they live in the summer). It is unclear if CDC will allow more than one class code now per participant.

(R) After additional internal discussion, we decided not to change the Core Group Code to Class Code. The Core Group Code will be discontinued. For the purpose of data analysis to assess criteria for full recognition, each participant will be considered to be his/her own “class” and tracked via the organization-assigned participant ID. This will facilitate reporting for organizations where participants may move from one group to another.

11. CDC has also eliminated data that had to be reported on the “session type” (e.g., core vs. maintenance). We are concerned about this for many practical reasons mentioned above. With the transition to a system of recognition that is built on two 6 month phases, the concepts of ‘core’ and ‘maintenance’ which have proven useful and effective will be diminished in relevance to DPP providers and DPRP data will not distinctively discern the effectiveness of these independently valuable concepts.

(R) As under the 2011 standards, there are still two program phases. The curriculum topics and goals covered during the first six months (in at least 16 weeks but no more than 26 weeks) and the second six months of the program are exactly the same in the

2011 and 2014 standards. The goals in the first six months focus on moderate changes in both diet and physical activity to achieve modest weight loss in the range of 5% to 7% of baseline body weight. The second six months of the program focus on topics that reinforce and build on the content delivered during the first six months of the intervention, including topics that proved challenging for participants. Under the 2011 standards, program phases were defined by a session code number. Under the 2014 standards, program phases are defined by time (months 1-6 and months 7-12). We do not anticipate that this change will be problematic for the programs or for data analysis.

B. Specific Concerns Regarding Efforts Required for DPRP Data Submission

Y-USA has several concerns about the estimates of time (and other associated costs) related to the preparing and submission of DPRP data. In each of the sections referenced below, changes have been made to the DPRP standards which will result in the need for significant time and treasure to be spent adapting current systems and technology to the new requirements. Past experience has shown that these adjustments may take a year or more to complete, and require significant investment of resources. Disruption in data reporting for programs that are in the midst of program delivery will come with additional costs and challenges.

1. In section II's subsection on Required Curriculum Content, changes to the way DPRP is recognizing the structure of any DPP (i.e., to Phase I and Phase II) will create a need for changes in the timing of reporting and our delivery cycle for the program, and there will be time and costs associated with adapting our reporting platform to these new requirements. Because Y-USA does not own this system, it is unclear what the exact costs or timeline for adjustments might be. We simply do not have knowledge of how other CDC partners, such as the Diabetes Prevention and Control Alliance, will adapt to these new requirements. As they are the owner of the reporting system used by all YMCA's we cannot precisely define the change in time and effort required for reporting.

(R) The data collection, storage and submission process is potentially unique to each organization. The DPRP has no knowledge of, or control over, this process. Thus, we are unable to address your comments, numbered 1-6 and 8, regarding changes to specific data elements relative to the Y-USA. All recognized organizations will submit the same data elements. With the exception of "Participant State," which is a new data element, the data elements required by the 2014 DPRP Standards are a subset of the previously required data. Thus, we do not anticipate that costs for adapting these processes, if necessary, will be prohibitive for the majority of the DPRP's currently recognized organizations. The DPRP has developed a transition plan for organizations recognized prior to 12/1/14 (pending OMB approval). Under the plan, organizations will submit data

one time per 12-month period and data due between 12/1/2014 and 11/30/15 may be submitted using either the 2011 or 2014 data elements. This additional time should help ease the transition from the 2011 standards to the 2014 standards. Technical assistance will also be available.

2. Point #4 in this section, discussed previously, includes language around Intervention Intensity. Changes in language related to the collection of weight loss data reporting requirements will result in the same types of increases in time and resources to rebuild our current reporting system.

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

3. In the subsection Additional Requirements for Full Recognition Status, point #5 refers to the same changes outlined above, and our concerns about increases in time and resource requirements are the same.

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

4. In the same subsection, point #9 highlights data reporting requirements specific to both Phase I and Phase II. This is an appropriate part of the document to cite to make the point that many changes to one side of our reporting systems (i.e., core) will automatically trigger changes to the programming related to the other side of our reporting systems (i.e, maintenance). This may help to again establish our concerns about the lack of estimated time and resources required for current and successful providers to come in line with new standards. Again, the result is a perception that these early and experienced providers of DPP are paying an inequitably high cost for the transition to a new system, when compared to others (e.g., future providers of DPPs which may use more or less evidence-based modes of delivery).

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

5. The next bullet point (#10) provides one more example of how changes in the way weight loss data are to be reported will require an investment of time and resources to adapt to new reporting requirements.

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

6. Changes to the way claims-based risk tests will be reported (#11) again will require report changes and increased time and costs of reporting for many current DPP providers and their partners.

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

7. If there are indeed changes to the order in which data are to be reported to CDC, as might be implied by changes to Section IV. Submitting Evaluation Data to DPRP, then it is worth pointing out that even these superficial changes will require programming and resources to be accommodated (and the time to produce these changes).

(R) There has been a re-ordering of the data elements in the data dictionary due to the deletion, modification, or addition of some data elements. The re-ordering was not arbitrary, but is the result of efforts to streamline and improve data collection for all organizations. Data must be submitted in the specified format. Variables (columns) in the data submission file should have the same names (column headings) as in the data dictionary. We have added a sentence to the data submission instructions to clarify. With the exception of “Participant State,” which is a new data element, the data elements required by the revised DPRP Standards are a subset of the previously required data. Thus, we do not anticipate that costs associated with re-ordering the variables will be prohibitive for the majority of the DPRP’s currently recognized organizations.

8. In bullet point #4 of this section, a new category of data is required. We understand the use of these data; CDC can’t currently give States’ Department of Health any of the DPRP data specific to their population at this time. This change would allow them to do so and we are supportive of the change. Y-USA’s data system already collects these data. Again, however, time and resources will be involved in making changes to our reporting system aligned with these new requirements.

(R) See response to section B. Specific Concerns Regarding Efforts Required for DPRP Data Submission, item number 1 above.

Comments on the Strategic Value of the Proposed Changes

In addition to concerns about the practical utility of and assumptions about the time required to implement the proposed changes to the DPRP, we also have questions about the strategic value of the proposed changes. Generally, it appears as though the intent behind many of the proposed changes to DPRP standards is to attempt to speed the dissemination of “DPPs” and to reach more people with prediabetes via new and relatively less tested modes of delivery.

These are laudable goals in principle; and the Y shares them... But our data and experience suggest the proposed changes would likely produce undesirable unintended effects.

Due to an approximate one-year lag between the training of any YMCA's DPP program provider and their first submission of data to the DPRP, Y-USA has internal data which come from a much larger data set than the CDC currently has access to via the DPRP. These data are all collected using methods that are entirely consistent with current DPRP standards. They just simply include many data points that haven't been submitted to CDC by Ys in their 12-18 months of delivering the YMCA's DPP. This is because our internal data show that Ys get better at program delivery in these first months. Thus, it has been Y-USA's policy to discourage the application of local YMCAs to the DPRP until they have delivered the program for a year or more, or until they have had four classes of participants complete the program. Using these data, we have modelled what the effects will be of revising the DPRP standards as is currently being proposed by the CDC. The results of our analyses (Table 1A-C) show the proposed changes will actually reduce the ability for the CDC to report successes from DPPs.

Merely by applying the newly proposed standards to existing data on more than 20,000 participants served since 2010, the average weight loss at the end of the program that would be reported by the YMCA's DPP to the DPRP would fall from 6.06% to 4.33%. To be clear: the first 20,000+ participants in the YMCA's DPP would have lost no more or less weight under the new method of DPRP reporting; the new lower weight loss values reported to the DPRP would be only due to a difference in the reporting methodology (i.e., reporting %WL on participants with a minimum of 4 phase I sessions attended vs. the current requirement of reporting %WL on participants with a minimum of 4 core and 1 maintenance session attended). Studies done by the CDC, such as the meta-analysis of 28 community-based translations of DPPs that was published by Ali et. al. in the journal Health Affairs in 2012, have demonstrated that the "dose" of the DPP is what drives success. By removing the requirement for at least one maintenance session to be included, dose is reduced. Additionally, the effect on the %WL average is likely increased because the session that is being removed from consideration is a maintenance session that comes later in the most widely recognized program model. People attending maintenance sessions have by definition "kept with the program", and eliminating even one data point has a clear effect on the average %WL of all participants.

Moving to the newly proposed DPRP reporting requirements would also likely create a decrease in reported average maintenance session attendance (i.e., Phase II attendance in the new DPRP reporting system). This is troubling because, again, this would likely just be an effect of changing reporting requirements. Assuming the actual attendance patterns do not change, Ys would likely report decreased attendance at the proposed 6 month time-point vs. the 20 week time-point used in the current system simply due to routine attrition between the 20 week and 6 month time-points. In addition to the reasons outlined above (cost,

consistency, clarity) Y-USA would recommend requiring attendance reports to be synchronized with weight loss reports. In that scenario, attendance standards would be modified to consider a ‘completer’ to be someone who has attended (a) at least 4 core sessions attended and (b) at least 1 maintenance session. If this were the definition, then the average number of maintenance sessions attended by completers across all 880 program sites run by YMCAs to date would be a very successful 3.35.

(R) We performed an analysis of the data received to date, comparing outcomes using criteria described in both the 2011 and 2014 DPRP Standards. As of July 2014, CDC had accepted data submissions that included information on participants in completed year-long intervention. These data submissions included attendance records for participants who had the opportunity to complete the 12 month intervention and who attended at least 4 core sessions.

Performance measures of particular importance are those concerning weight loss (requirements 8 and 11 under the 2011 standards and requirements 8 and 10 under the 2014 standards). An organization’s average weight loss is to be at least 5%; in our analysis average weight loss across all participants was 4.6% at the end of the core (2011 standards) and 4.9% at the end of 6 months (2014 standards). At the end of the post core/12 months, average weight loss was 6.1% (2011 standards) and 4.9% (2014 standards).

The attendance measures (requirements 5 and 9 under both the 2011 and 2014 standards) are also very important. Average attendance during the core/first six months is to be at least 9 sessions; in our analysis average attendance was 13.7 (2011 standards) and 14.9 (2014 standards). Average attendance during the post-core/second six months is to be at least 3; in our analysis average attendance was 3.1 (2011 standards) and 1.9 (2014 standards).

These data demonstrate that, although some of the organizations in this early and preliminary analysis have not yet attained the standards for full recognition, key outcomes are attainable under the updated as well as the current standards. The results of our analysis indicate that many recognized organizations need to focus their efforts on participant retention and attendance during the maintenance phase of the lifestyle intervention.

When we looked at retention for the participants in our data analysis, using the 2011 standards and defining core completion as attending 4 or more core sessions and overall completion as attending an additional 1 or more post-core sessions, we observed low retention from the core to the post core phase. Among eligible participants, 92%

completed the core phase, but only 63% completed 4 core sessions plus 1 post-core session.

Low retention from the core (first six months) to the post-core or maintenance phase (second six months) had an unintended impact on the evaluation measures used in the 2011 DPRP Standards. The 2011 evaluation criteria included measures based on the performance of participants who attended a minimum of 4 core sessions plus 1 post core session. This meant that (1) an organization's 12-month average weight loss was based on the (sometimes greatly diminished) subset of participants who did not drop out of the program before the maintenance phase, and (2) an organization's post-core attendance did not include participants who attended zero post-core sessions. Because these two measures did not include outcomes (or lack thereof) for a large proportion of participants, they did not accurately reflect the overall performance of many recognized programs. In effect, these evaluation measures were often made artificially large by the exclusion of participants who dropped out after attending 4 or more core sessions, but before attending any post-core or maintenance sessions. The 2014 evaluation measures correct this problem, as they include data on all participants who attended 4 or more sessions over the course of the entire intervention.

The 2014 standards address the importance of program retention and completion, and help insure that recognized organizations deliver a program of sufficient intensity and duration to effectively reduce the risk for developing type 2 diabetes in their participants.

The concerns we have about sacrificing the perception of quality results for a potential increase in the quantity of participants served are also being created by numerous proposed changes in the DPRP's requirements which clearly distance the DPRP standards from the best available science. Examples of the changes where we've seen a clear change in the commitment to holding DPP providers accountable to high-fidelity implementation of the evidence based DPP methods include:

1. In Section II's subsection on "Location" heading, Organizations may now choose to deliver the lifestyle intervention virtually or via one or more distance-learning modalities or approaches (e.g. online, remote classroom). We are not aware of published results of any large-scale online or distance-learning modes of DPP delivery and question whether there is sufficient science to allow for these modalities to be seen as equivalent to in-person delivery models.

(R) Innovative strategies for deploying effective diabetes prevention interventions are critical if we are to achieve significant reach and health impact. As a result, the DPRP is proposing to include some innovative strategies for delivering the lifestyle program based on translational research, feedback from stakeholder organizations, and expert opinion. A summary of this input is provided in the subsequent paragraphs.

Shortly after publication of the DPP research study results, Tate et al. conducted a randomized controlled trial of 92 overweight adults (mean BMI 33.1) at risk for type 2 diabetes to compare the effects of an internet weight loss program alone vs. with the addition of behavioral counseling via email provided for one year.¹ The results showed that the group that received e-behavioral counseling in addition to the internet weight loss program lost 4.8% of original body weight compared to 2.2% in those receiving the internet program only. This study demonstrates that provision of virtual counseling as part of an internet-based program significantly improves weight loss in adults at risk of diabetes.

In a recently published study of 306 individuals in two U.S. cities, sponsored by UnitedHealth Group and Comcast Cable, Ackermann (et.al), found that “In-home delivery of evidence-based diabetes prevention programming (using the curriculum that is available on the CDC website) in a reality television format, offered with or without online behavioral support tools, can achieve modest weight losses consistent with past implementation studies of face-to-face programs using similar content.”² Those who participated in 9 or more of the 16 intervention sessions (which is consistent with the DPRP standard) achieved a mean weight loss of 4.9%. While outside of this particular study, UnitedHealth Group and Comcast noted that between May 2012 and May 2013 49,953 customers in the two participating cities viewed or streamed the program content 102,326 times. This occurred without any marketing or incentive strategies to promote the program to nonparticipants. It has been said that this program is “at the intersection of innovation, science and impact” and the United-Health Group is “committed to making NOT ME (name of online program) diabetes prevention available to more people across our country with convenient and cost effective models.”³ This research was sponsored by a large insurer, and based on the results, that insurer plans to offer the intervention as a program.

Omada Health recently conducted a study to “evaluate the efficacy of Prevent, an online social network-based translation of the diabetes prevention program (DPP) lifestyle intervention, against CDC Diabetes Prevention and Recognition Program (DPRP) outcome standards and weight loss outcomes of other DPP translations.”⁴ The curriculum used in this online program is available on the CDC website. The participants who completed the core phase of the program (n=187) achieved 5% and 4.8% weight loss at 16 weeks and 12 months. The participants who also completed the post-core phase of the program (n=144) achieved 5.4% and 5.2% weight loss at 16 weeks and 12 months. This study successfully demonstrated the ability of an online program to deliver the lifestyle intervention.

Weight Watchers is currently conducting a clinical trial in 226 adults with prediabetes who were randomized to an experimental intervention using a version of the Weight Watchers program modified specifically for persons with prediabetes or a control intervention which consisting of a educational materials and brief counseling about weight and diabetes risk, strategies for starting a weight loss program, goal setting, tracking food intake and increasing physical activity. 5 Intervention subjects attended an initial activation session that explained prediabetes, appropriate weight loss goal for reducing risk of diabetes, and how to use Weight Watchers sessions to achieve goals and were then “mainstreamed” into Weight Watchers programs in their communities and/or online. Preliminary results presented at the 2013 International Diabetes Federation meeting showed that the intervention group lost an average of 6.2% of baseline weight compared to 1.0% in the control group.⁶

DPS Health has evaluated delivery of a year-long an online version of the DPP called Virtual Lifestyle Management (VLM) in 385 Government Employees Health Association (GEHA) insurance plan members with a BMI > 27.5 and obesity-related comorbidity (e.g. abnormal glycemia, sleep apnea) or obese (BMI > 30) with or without comorbidity.⁷ Mean weight loss for the group was 3.7% of original body weight, 30% lost greater than 5% and 12.5% lost greater than 10% of original body weight. DPS Health and GEHA conducted an analysis of the impact of VLM on health care utilization and health care expenditures as measured through processed insurance claims. The analysis showed that VLM reduced GEHA paid claims by a cumulative \$1,049 in 2011 and 2012 and total claims by \$2,945. Cost savings was significantly in excess of program costs. GEHA offered the program to 5,000 members in 2013 and is now offering it to an additional 5,400 members in 2014.

Waiting for additional evidence would delay getting these innovative strategies into the field - innovative strategies that could provide the capacity to reach the 86 million Americans who have prediabetes now.⁸It is important to note that the DPRP will continue to assure program quality and results, including assessment of curriculum content. All recognized programs will be accountable to the same standards and any program not meeting all of the DPRP Standards will not achieve full recognition.

¹ Tate DF, Jackvony EH, Wing RR. 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

² 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.

³<http://ceshealth.com/2013/12/not-me-an-in-depth-look-at-unitedhealth-groups-ces-innovations-award-winning-diabetes-prevention-program/>

⁴ Sepah CS, Jiang L, Peters AL. (2104). Translating the diabetes prevention program into an online social network: Validation against CDC standards. *The Diabetes Educator*. 40(4):435-443.

⁵ <http://clinicaltrials.gov/show/NCT02000024>

⁶ Marrero 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)

⁷ Ross K, Kaufman ND. Automating coaching: Technology delivers proven weight loss intervention at affordable cost while minimizing personnel time. Presented at the Care Continuum Alliance conference, Oct. 2013. Provided by DPS Health

⁸ Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: US Department of Health and Human Services; 2014.

2. We noted in Section II’s subsection on “Requirements for Pending Recognition Status” several changes to Required Curriculum Content (#2). Previously existing language requiring the use of curriculum with ‘direct’ connections to the curriculum that was proven in the DPP Trial has been removed. How many deviations from proven methodology will be allowed before anyone rightly questions the fidelity of less “direct” translations of the original curriculum?

(R) See response to section Comments on the Strategic Value of the Proposed Changes, item 1 above. The majority of the studies described above, utilizing virtual program delivery, used either the DPP curriculum or CDC’s preferred curriculum. We believe that some future DPRP applicants, including virtual and in-person programs, will use these curricula. However, other applicants will want to use alternative curricula. Regardless of the theory upon which a curriculum is based, alternative curricula (i.e., any curriculum other than the CDC preferred curriculum) must be reviewed and approved by the DPRP prior to being used. The required curriculum content (i.e., the topic areas that must be covered during each phase of the 12-month lifestyle program) is identical in the 2011 and 2014 DPRP Standards and reflects the content delivered in the DPP.

3. In Section II’s subsection on “Requirements for Pending Recognition Status” we were concerned by change to Intervention Intensity (#4) to delete group based delivery, hour long class sessions, and in-person program delivery requirements. Obviously, we understand the original DPP Trial showed the effectiveness of one-on-one program delivery. Our main concern is with the other deletions and modifications. We are not aware of published results of any large-scale online or distance-learning modes of DPP delivery, or of DPP delivery that

occurs in sessions that last less than an hour. These deletions seem to be significant changes to the DPRP, which are not yet supported by sufficient science to be seen as comparable to in-person delivery methods.

(R) See response to section Comments on the Strategic Value of the Proposed Changes, item 1 above. Virtual programs are often self-paced. As such, to require that an individual session be exactly one hour is not practicable. However, the decision to eliminate the one-hour requirement was not done solely for virtual programs. We received feedback from in-person programs desiring to adjust session length based on participant need. The 2014 DPRP Standards require sessions to be “of a sufficient duration to convey the session content – or approximately one hour in length.”

4. In Section II’s subsection on “Requirements for Pending Recognition Status” we were concerned by the assumption (in #4; intervention intensity) that self-reported weights provided by participants of online or distance-learning versions of the program would be considered valid, or somehow equivalent to data collected and reported by in-person Lifestyle Coaches. The lack of validity of self-reported weights as a measure has been well established in the public health literature. Allowing these data to be seen as equivalent to data obtained by a trained data collector will only make all weight loss data suspect.

(R) The DPRP standards represent the minimum standards a program must meet to achieve recognition. Virtual programs are required to collect and report weights and, to meet the minimum requirement, weight may be self-reported since it is not possible for staff in virtual program to see the participant step on the scale and verify the weight. Programs may certainly go beyond this minimum requirement and utilize other means of collecting/transmitting weights such as electronic scales with wireless transmission. Use of this technology for collecting/transmitting weight, however, does not guarantee that weights will be accurate or not falsified. A participant could place anything on the scale and this weight would be transmitted. All other requirements are the same for in-person or virtual programs.

Although participants’ weights must still be obtained and reported at in-person sessions, the DPRP Standards have been revised to allow these weights to be measured by either the lifestyle coach or the participant. Thus, participants of in-person programs may also, at the organization’s discretion, self-report weights by reporting the objectively obtained weights to the coach. To help ensure that all programs report consistent weights over time, there is an appendix to the DPRP Standards (“Recommended Standards for Measuring Weight”).

5. In Section II’s subsection on “Additional Requirements Additional Requirements for Full Recognition Status” we noted a change to how weight loss is to be reported at the end of the year (#10). The proposed standard says that average weight loss achieved over the entire

intervention period by participants attending at least 4 sessions must be a minimum of 5% of “starting” body weight. Under the current standards the requirement is that average weight loss achieved over the entire intervention period by participants attending at least 4 core sessions and 1 post-core session must be a minimum of 5%. This new language is at least inconsistent with recent science, and can be expected to result in lower reported weight loss averages. Studies done by the CDC, such as the meta-analysis of 28 community-based translations of DPPs that was published by Ali et. al. in the journal Health Affairs in 2012, have demonstrated that the “dose” of the DPP is what drives success.

(R) Under the 2014 DPRP Standards, average weight loss will be evaluated at 6 and 12 months, based on the same set of participants (those who attended four or more sessions over the course of a year). Similarly, average attendance in the first and second six months will be based on these same participants. We believe this will provide a more informative and accurate picture of program performance for at least two reasons. First, the 12 month average weight loss will not be biased by the exclusion of possibly significant numbers of participants who dropped out before the maintenance phase, Second, the average number of sessions attended in the second six months will include those who did not attend any sessions. Calculating the performance measures in this way places appropriate and needed emphasis on attendance during the second half of what is intended to be a year-long program.

6. In Section IV’s subsection on “Evaluation Data Elements” we noted a change to no longer require the reporting of a session ID. Until now, this measure was used to demonstrate fidelity to the proven curriculum. We can understand why DPP providers might want to deliver different sessions of a DPP model in a different order, and thus why eliminating the need to report this variable would be desirable, but behavioral science was used to design the original curriculum and we believe the science clearly supports fidelity to the order of the sessions (i.e., nutrition topics are covered well in advance of physical activity topics for a reason).

(R) The DPRP received feedback from organizations wishing to deliver the curriculum topics in a slightly different order. We know of no randomized control trial to determine the best order in which to deliver the content the DPP curriculum. Thus, we proposed to allow some flexibility in the content delivery. However, all of the content areas must be delivered by trained lifestyle coaches. The required curriculum content (i.e., the topic areas that must be covered during each phase of the 12-month lifestyle program) is identical in the 2011 and 2014 DPRP Standards and reflects the content delivered in the DPP.

The allowance for less- proven methods of DPP program delivery (i.e., via “virtual, online or other” delivery modes) also leads us to question the strategic value of adopting the new

DPRP standards. We are only aware of two peer-reviewed studies of these types of delivery modes—and one was just published this month! There is thus a seemingly large divide between the evidence base behind “virtual, online or other” forms of DPP delivery and the evidence behind the in-person delivery of DPPs. Including these versions of DPPs as equivalents of the in-person program modes (or even making the reporting requirements under the DPRP more lax for these new modes) may undermine confidence in the overall science behind, and value of, one of the most well-researched prevention strategies ever developed by the National Institutes of Health or the CDC.

We are especially nervous that the early successes we are having in the engagement of payors, health care providers, and employers—who all invariably state the evidence behind the in-person DPP model is what sets it apart from all the other interventions that they do not support—will be potentially diminished by a general loosening of the existing DPRP standards and the perception that the science behind the CDC’s National DPP is being watered-down. Our enrollment data have consistently shown that payor, provider, and employer involvement in recruitment is what drives sustainable levels of enrollment and implementation. Supporters of the current DPP model, such as the American Medical Association, are often having to convince others of the science behind the DPP. In health care circles, the DPP intervention has not completely taken hold because, in part, of the ‘newness’ of the science behind the DPP. Clinicians are looking for longer-term data on program outcomes. Without these partners’ confidence in the intervention, DPP providers will need to spend much more time per capita in recruitment efforts. Thus there is a real risk, in our view, that without credible DPRP standards, DPRP recognition will be meaningless to providers such as the YMCA.

(R) The Y-USA has been a valued partner since before the DPRP’s inception. We appreciate your continued involvement and commitment to the ongoing success of the program and to the prevention of type 2 diabetes. We understand and appreciate your desire that the DPRP remain faithful to science. When the DPRP was established in 2011, it was based on the available science, primarily the DPP. Since 2011, the science has evolved with additional translational studies adding to the research base. There have also been some important “lessons learned” from partners, including the Y-USA, participating in the DPRP and delivering the lifestyle program. The 2014 DPRP Standards were revised to include the additional scientific evidence as well as what we learned from our recognized programs and other stakeholders. As such, we believe that our revisions to the DPRP Standards balance fidelity to science with practical implementation. We sought to keep the changes to the DPRP Standards to a minimum, particularly those that might require changes in the data systems of our currently recognized organizations. We understand that changes to data system will take some time, effort and resources. We have attempted to minimize the burden by frequency of data submissions and by the transition plan that will allow organizations to submit data under the 2011 standards through 11/30/2015.

We eagerly await the approval and adoption of the 2014 DPRP Standards. With these standards, we anticipate an increase in the number of recognized organizations, lifestyle programs participants, and ultimately an increase in the number of cases of type 2 diabetes prevented or delayed. We look forward to having more Y-USA sites join the DPRP and to many more years of partnering with the Y.

- B. Prior to receiving OMB approval in 2011, CDC established a DPRP workgroup consisting of CDC and DPRP staff and non-federal partners, including some potential applicant organizations like the Y (formerly the YMCA). This workgroup developed the *DPRP Standards*. CDC also met with other other federal entities such as the Health Resources and Services Administration, the Center for Medicare and Medicaid Services, and the Diabetes Mellitus Interagency Coordinating Committee.

In the fall of 2013, DPRP sought feedback internally and externally on issues related to participant eligibility criteria, program delivery and the role of state diabetes control programs. This feedback resulted in programmatic changes intended to increase participant access to, and organizational acceptance of, the DPRP by allowing the use of additional blood tests to determine participant eligibility and allowing organizations to delivery the lifestyle program virtually, captured via the addition of the program delivery mode code in the application form. Continuing discussions with these and other entities, along with results from ongoing studies, may lead to further revisions of the standards and data elements in 2015 or beyond.

9. Explanation of Any Payment or Gift to Respondents

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

10. Assurance of Confidentiality Provided to Respondents

IRB Approval

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

Privacy Impact Assessment Information

- A. This submission has been reviewed by CDC's Information Collection Review Office, which 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, secondary contact 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 include a participant code. The organizational entity requesting recognition through DPRP (applicant organization) assigns and maintains the participant code.

- 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's Information Systems Security Officer. Data is 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 allowed 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 project officer or DDT 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 DPRP at any time by not transmitting evaluation data or for reasons specific to the organization. No additional withdrawal notification is required.

11. Justification for Sensitive Questions

In order to monitor program effectiveness and assure that recognized programs are delivering science-based, effective lifestyle programs, organizations transmit de-identified, coded information about participant prediabetes status, weight loss, and session attendance. Prediabetes status, weight, and attendance might be considered sensitive information. It is essential that this information be provided to DDT. Without this information, DDT would not be able to monitor program delivery to ensure that programs are being delivered to individuals with or at risk for prediabetes (where science indicates that such programs are effective), evaluate program effectiveness to ensure that participants are achieving the amount of weight loss proven to prevent type 2 diabetes, or be sure that individuals are attending enough classes to benefit from the information conveyed. It is important to emphasize CDC does not collect or receive directly identifiable information about participants. However, CDC recognizes that some of the participant-specific information (ethnicity, race, age, gender, method of determining prediabetes status) when coupled with other data (organization code) might be considered IIF. CDC does not attempt to identify

individuals by data linkages involving demographic, geographic or outcome information; contact individual participants; or disclose any participant-level data.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

Application Data (Attachment 4A). Respondents are organizational entities that seek recognition through DPRP. Each respondent will submit a brief one-time application form to DPRP. The application form and instructions are posted on the DPRP Web site, and the application must be completed on-line (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 350 organizations per year will seek recognition through DPRP over the 3 years of the requested OMB approval period. The total estimated average annualized burden to respondents is 350 hours (1 hour per response). This includes an estimate of the time needed to read the application instructions, review the *DPRP Standards* document and data transmission requirements, fill out and submit the application form, and submit curriculum materials, if appropriate.

CDC estimates that 60% of DPRP applicants will be private sector entities and 40% of DPRP applicants will be public sector entities.

Evaluation Data (Attachment 5A). Each respondent will transmit evaluation data to DDT every 12 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 online web application form in accordance with *DPRP Standards (Attachment 3)*. During this entire OMB approval period, DDT anticipates that 1050 organizations (annualized to 350 per year) will apply for recognition and that the number of organizations submitting data will increase from 850 in the first year to 1,550 in the third year (annualized to 1,200 organizations per year). The total estimated average annualized burden to respondents is 1,200 hours (1,200 organizations x 1 hour per response x 1 response 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 a data file in the required format, and submit the data file via the DPRP Web site.

Table A.12-1 provides a summary of the total annualized burden to respondents.

Table A.12-1. Estimated annualized burden to respondents

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	140	1	1	140
	DPRP Evaluation Data	480	1	1	480
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	210	1	1	210
	DPRP Evaluation Data	720	1	1	720
				Total	1,550

B. Cost to Respondents

We anticipate that respondents will use paid staff to provide the requested information to DDT, 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

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	140	1	\$14.50	140	\$2,030
	DPRP Evaluation Data	480	1	\$14.50	480	\$6,960
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	210	1	\$14.50	210	\$3,045
	DPRP Evaluation Data	720	1	\$14.50	720	\$10,440
					Total	\$22,475

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

We anticipate that for most respondents the evaluation data elements are a subset of the lifestyle program data elements they are already collecting and maintaining, so we do not anticipate that organizations will incur significant additional burden hours or costs. However it is possible that some future DPRP applicants and/or currently recognized organizations may need to make modifications to their systems for collecting and managing lifestyle program data, and may incur additional costs in doing so.

14. Annualized Cost to the Government

Labor Costs include personnel for oversight, communications, 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 \$1,828,502, as summarized in the table below.

Personnel	Base salary	Fringe	Total cost
FTE*	\$732,903	\$197,883	\$930,786
Contract support**			\$787,716
Travel			\$25,000
Other direct costs			
Copies, binding, presentation materials			\$5000
		Communications	\$10,000
Data system maintenance and improvements			\$70,000

* FTE cost include percentages of time of approximately 4.5 FTEs and 3.5 contractors

** Contract support 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 one hour. Minor changes are proposed for each information collection instrument (the DPRP Application Form and the DPRP Evaluation Data), as outlined in **Attachment 6**, but these changes do not

alter the estimated burden per response. The proposed changes to the estimated number of respondents, the types of respondents, and the frequency of response are described below.

In 2011, CDC estimated that 120 organizations per year would apply for recognition through the DPRP. At that time, CDC estimated that 90% (108) of the applicants would be private sector organizations, and 10% (12) of the applicants would be from the public sector (state, local, or tribal government organizations). Each DPRP applicant submitted a one-time DPRP application form, followed by semi-annual submissions of DPRP Evaluation Data.

In the next three-year clearance period, CDC is increasing the total annualized number of applicants to 350, and the distribution of those applicants to 60% (210) from the private sector, and 40% (140) from the public sector. The DPRP application form will continue to be a one-time submission. CDC is also increasing the estimated number of organizations submitting DPRP Evaluation Data from 240 to 1,200. The revised estimate includes a mix of approximately 500 organizations that have a current DPRP classification status of “full” or “pending” recognition, and new applicant organizations. The frequency of reporting for DPRP Evaluation Data will be reduced from semi-annual to annual.

These changes result in a net increase of 950 annualized burden hours. The distribution of these changes is summarized in the table below.

Type of Respondent and Form Name		2011			2014			Change from 2011-2014
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	12	1	12	140	1	140	+ 128
	DPRP Evaluation Data	24	2	48	480	1	480	+ 432
Private sector organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	108	1	108	210	1	210	+ 102
	DPRP Evaluation Data	216	2	432	720	1	720	+ 288
Total				600			1,550	+ 950

*Burden per Response = 1 hour; therefore, Total Burden Hours = Total Number of Responses

16. Plans for Tabulation and Publication and Project Time Schedule

<u>Task</u>	<u>Date</u>
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	November 2014 (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.

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Diabetes/Prediabetes Statistics

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Additional translational studies upon which the 2014 changes are based:

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13. Sepah CS, Jiang L, Peters AL. (2104). Translating the diabetes prevention program into an online social network: Validation against CDC standards. The Diabetes Educator. 40(4):435-443.
14. Marrero 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 ND. Automating coaching: Technology delivers proven weight loss intervention at affordable cost while minimizing personnel time. Presented at the Care Continuum Alliance conference, Oct. 2013.