

CDC Diabetes Prevention Recognition Program

New

Supporting Statement: Part A

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Section A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request (ICR) supporting activities authorized by Section 399-V of P.L. 111-148, the Patient Protection and Affordable Care Act (see **Attachment 1A**). The Act directs the Centers for Disease Control and Prevention (CDC) to establish a national diabetes prevention program. This program will be housed in CDC's Division of Diabetes Translation (DDT). One function of this program is to determine the eligibility of community-based entities to offer type 2 diabetes prevention services for high-risk adults, and to monitor, evaluate, and provide technical assistance to entities that offer these programs. CDC's authorization to collect information is provided by the Public Health Service Act (see **Attachment 1B**).

Diabetes is a serious disease involving complicated and costly treatment. Effective interventions need to be made broadly available to significantly reduce the incidence of type 2 diabetes in high-risk populations. Efficacy and effectiveness research on lifestyle interventions have demonstrated that prevention (or delay of onset) of type 2 diabetes is possible and that beneficial effects can continue 10 years or longer after the intervention. In 2001, results from the Diabetes Prevention Program (DPP), a research study led by 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.¹ In the DPP research trial, participants in the lifestyle intervention experienced a 58% lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention. A follow-up DPP study showed that benefits from the lifestyle intervention may persist for 10 or more years.²⁻⁴ More recently, effectiveness research has shown that the DPP curriculum, when modified slightly for delivery in a group setting by community-based organizations, helps program participants achieve the 5–7% weight loss needed to prevent or delay type 2 diabetes in individuals with prediabetes,

¹ Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New Engl J Med* 2002; 346:393–403.

² Diabetes Prevention Program Research Group. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. *Lancet*: Published Online October 29, 2009. DOI: 10.1016/S0140-6736(09)61457-4.

³ Lindstrom J, Ilanne-Parikka P, Peltonen M, Aunola S, Eriksson JG, Hemiö K, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: Follow-up of the Finnish Diabetes Prevention Study. *Lancet* 2006; 368:1673–79.

⁴ Li G, Zhang P, Wang J, Gregg EW, Yang W, Gong Q, et al. The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing Diabetes Prevention Study: A 20-year follow-up study. *Lancet* 2008; 371:1783–89.

and that such a program can be cost effective.⁵⁻⁹ In 2009, to begin the translation of this research into practice, CDC funded several Y sites (previously known as YMCA sites) to deliver a slightly modified DPP curriculum, hereafter referred to in this ICR as the *National Diabetes Prevention Program Curriculum*. However, the large-scale adoption of effective evidence-based lifestyle programs in local communities has yet to occur.

Barriers to the translation of effective interventions in community practice include:

- Lack of knowledge that type 2 diabetes can be prevented through lifestyle changes
- Lack of understanding about what constitutes an effective lifestyle program
- Shortage of individuals with the knowledge, skills and abilities to lead lifestyle programs
- Shortage of organizations willing to provide trained staff to conduct effective programs or to offer them in local settings
- Cost of programs, which is often not covered by the participants' health insurance

A variety of local organizations have begun to offer type 2 diabetes prevention programs, however, there are currently no minimum guidelines for the lifestyle programs and no entity charged with monitoring the programs to ensure effectiveness. As a result of the lack of standards and monitoring, these programs are not always led by qualified staff, do not always follow a science-based curriculum, and unfortunately, do not consistently achieve the outcomes known to prevent or delay type 2 diabetes.

⁵ Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community: The DEPLOY pilot study. *Am J Prev Med*. 2008; 35(4):357–63.

⁶ Ackermann RT, Marrero DG. Adapting the diabetes prevention program lifestyle intervention for delivery in the community: The YMCA model. *Diabetes Educ*. 2007; 33:1–6.

⁷ Amundson HA, Butcher MK, Gohdes D, Hall TO, Harwell TS, Helgerson SD, et al. Translating the diabetes prevention program into practice in the general community: Findings from the Montana Cardiovascular Disease and Diabetes Prevention Program. *Diabetes Educ*. 2009; 35:209. doi: 10.1177/0145721709333269.

⁸ Williamson DF, Marrero DG. Scaling up type 2 diabetes prevention programs for high risk persons: Progress and challenges in the United States (chapter). *Diabetes prevention in practice*. pp 69-81 Schwarz P, Reddy P, Greaves C, Dunbar J, Schwarz J, eds. World Congress on Prevention of Diabetes. Dresden, Germany 2010. TUMAINI Institute for Prevention Management. ISBN 978-3-00-03070765-2.

⁹ Abelson R. An insurer's new approach to diabetes. *New York Times*. April 13, 2010. <http://www.nytimes.com/2010/04/14/health/14diabetes.html>.

To help remedy this situation and to support the delivery of high quality, evidence-based diabetes prevention programs on a broad scale, CDC's DDT established the National Diabetes Prevention Program. The National Diabetes Prevention Program will build on results obtained through research on effective type 2 diabetes prevention strategies, such as the structured lifestyle intervention delivered and evaluated through the DPP research trial.

One of the main components of the National Diabetes Prevention Program is the Diabetes Prevention Recognition Program (DPRP), which will provide a means of identifying and acknowledging applicant organizations that deliver effective type 2 diabetes prevention lifestyle interventions.

DPRP has three key objectives:

- Assure program quality, fidelity to scientific evidence, and broad use of effective type 2 diabetes prevention lifestyle interventions throughout the United States
- Develop and maintain a registry of organizations that are recognized for their ability to deliver effective type 2 diabetes prevention lifestyle interventions to people at high risk
- Provide technical assistance to local type 2 diabetes prevention programs to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition status.

To support these objectives, as directed by Congress in the program's authorizing legislation, CDC has developed written standards for the recognition of organizations delivering type 2 diabetes prevention lifestyle interventions (see **Attachment 3**, *CDC Diabetes Prevention and Recognition Program: Standards and Operating Procedures*, referred to as *DPRP Standards* throughout this ICR). This document describes the DPRP standards for type 2 diabetes prevention lifestyle interventions in detail and explains how an organization may apply for, earn, and maintain recognition.

Briefly, "pending" and "full" recognition will be offered through DPRP. Any organization with the capacity to deliver a lifestyle intervention meeting DPRP standards may apply for recognition. After an organization has applied for recognition with DPRP, the organization will achieve pending recognition if it agrees to the curriculum, duration, and intensity requirements described in *DPRP Standards*.

In addition, the organization will be required to submit evaluation data to DPRP every 6 months from the date of the first lifestyle session offered after application acceptance. This will allow for timely data analysis and provide opportunities for the applicant organization to receive interim feedback on its progress in meeting recognition requirements.

Recognition status will be assessed 24 months after the first session, and the organization

will receive full recognition status if it has demonstrated program effectiveness by achieving *all* of the remaining requirements described in *DPRP Standards*. These recognition requirements will be assessed based on data from all of the lifestyle interventions (each having duration of 1 year) that were delivered in their entirety by the organization during the 24-month period.

If, after 24 months the applicant organization has not achieved all of the requirements for full recognition, it will continue in pending recognition status for an additional 12 months. During this period, DPRP will continue to provide technical assistance to the organization to help it achieve full recognition. If the organization is not successful in achieving full recognition at the end of this period (36 months after the first session), it will lose recognition and must wait 12 months before it may reapply for recognition.

Fully recognized organizations will continue to submit evaluation data every 6 months and will be reevaluated every 24 months, but will not need to reapply for recognition.

CDC requests OMB approval for 3 years to collect the information needed to administer DPRP. Information collection will consist of the initial application for recognition, followed by the semiannual transmission of the evaluation data needed to monitor performance and assess whether recognition criteria have been met. CDC anticipates that information collection will continue throughout the lifetime of DPRP.

Privacy Impact Assessment

Overview of the Data Collection

Respondents will be organizational entities that deliver type 2 diabetes prevention lifestyle interventions and seek recognition through DPRP. Two types of information will be collected, application data and evaluation data. The online DPRP application form (**Attachment 4A**) will be 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 will be transmitted to DPRP by the applicant organization every 6 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, each evaluation data transmission will consist of a single data file sent to DPRP as an e-mail attachment (**Attachment 5A**).

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.

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

- Type of Application (initial, change, or reapplying) and 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)
- Curriculum (*National Diabetes Prevention Program Curriculum* or other curriculum; if other curriculum is selected, the curriculum must be submitted with the application).
- 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) must transmit evaluation data (**Attachment 5A**) to CDC every 6 months, beginning 6 months from the date of the first lifestyle intervention session following the DPRP application acceptance date. Data from all of the lifestyle sessions conducted by the organization during the preceding 6 months must be included in this transmission.

No IIF about lifestyle program coaches or participants should be transmitted to CDC. All identifiers (except the organization code that is provided by CDC) will be assigned and maintained by the DPRP-recognized organization. All participants in DPRP-recognized lifestyle interventions will be 18 years of age or older.

The evaluation data includes the following elements:

- Organization Code (unique identifier assigned by DPRP)
- Codes assigned and maintained by the DPRP-recognized organization: Participant ID (used to uniquely identify and track participants across sessions; should not be based on social security number or other personally identifiable information), Location Code (used to uniquely identify each venue or location used to conduct the applicant's lifestyle intervention program sessions), Core Group Code (used to uniquely identify each set of core program sessions), and Lifestyle Coach ID (used to uniquely identify and track lifestyle coaches across all lifestyle intervention sessions conducted by the applicant; 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, Participant's Age, Participant's Height
- Participant information recorded at enrollment and used to provide technical assistance: Participant's Ethnicity, Participant's Race, Participant's Sex
- Participant- and session-specific information used to evaluate program outcomes and provide technical assistance: Session Date, Participant's Weight, Participant's Physical Activity Minutes, Session Type, and Session ID

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

Information about recognition through DPRP will be available on the DPRP Web site (www.cdc.gov/diabetes/prevention/recognition). There will be no Web site content directed at children under 13 years old.

2. Purpose and Use of the Data

CDC will use 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, and level of recognition) will be made publicly available on the DPRP Web site or through other directories. This information will help consumers identify organizations recognized for delivering effective lifestyle interventions as well as entities that are working to achieve full recognition.

The evaluation data elements will be 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 will be used to monitor the effectiveness of lifestyle intervention programs, not the success or failure of the individual people participating in those programs.

CDC anticipates that DPRP will generate 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. In 2009, UnitedHealthcare agreed to provide health insurance coverage for individual participation in type 2 diabetes prevention programs with proven effectiveness. Because the DPRP monitoring plan will include evaluating program data (attendance, weight loss, etc.) to assure program quality and effectiveness, CDC anticipates that additional payers, such as other insurance companies, Center for Medicare & Medicaid Services (CMS), and others will recognize the cost-effectiveness of prevention and begin to reimburse for the recognized lifestyle programs in community settings. Similarly, CDC hopes that DPRP's assurance of quality will encourage

physicians and other health care providers to refer their patients with prediabetes to the recognized programs.

The collection of this information is necessary to meet the legislative mandate for the DPRP. Without the ongoing collection of evaluation information, DPRP, one of the key elements of the National Diabetes Prevention Program authorized by Congress, 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 contact person. Although the application includes IIF, the information is not considered personal, private, or confidential in nature. CDC will maintain the IIF in password-protected files in a secure facility. A directory of recognized programs will be publically available. However, the directory will list only the organization name, address, and telephone number (and Web address, if provided); it will not include the name of the organization's contact person or any other person's name.

Evaluation data. CDC will analyze the evaluation data submitted by DPRP applicant organizations in order to objectively assess adherence to *DPRP Standards* and recognition criteria. The method of determining prediabetes status will be collected to assess compliance with program eligibility standards. Participant-level identification codes and session attendance elements (session date, weight, core group code, session type, and session identification number) will be used to evaluate recognition criteria relating to attendance and weight loss (which will be aggregated across participants to indicate whether or not the program met its percentage of overall weight loss goal). The lifestyle coach's identifier and location code will be used to provide feedback for quality improvement and targeted technical assistance. Collection of demographic information about program participants is necessary for analyses that will ensure program effectiveness in both genders, across all ages (18+) and in all racial/ethnic groups. The participant process and outcome data will include site-specific information (organization and location codes) and group-specific information (core-group code and lifestyle coach's identifier). The organization will generate, assign, and maintain a coded identification number for each participant, and only de-identified, coded, participant-level information will be transmitted to CDC. 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, location code and core group code) might be considered IIF. CDC 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 will be 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 will be to the organization contact information (e.g., organization name, address, phone number, contact person). The DPRP applicant organizations will assign and maintain all other codes, including the participant ID and lifestyle coach ID, and CDC will not have access to the keys for these codes or to the applicants' data systems.

No information in identifiable form (directly or indirectly identifiable) about lifestyle program coaches or participants should be transmitted to CDC. All identifiers (except the organization code, which is provided by CDC) will be assigned and maintained by the applicant organization. Data is to be submitted in a precisely defined format. The DPRP data system will incorporate standard procedures for checking the format and content of evaluation data submissions upon receipt. If evaluation data is sent to CDC that does not conform to the specified format, or includes any IIF, it will not be accepted and will be returned or destroyed immediately.

CDC is concerned with program performance, not the performance of individual participants. While CDC will report recognition status for each participating organization, and may produce summary reports that include data on the performance of all or some recognized organizations, CDC 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 will not accept IIF about lifestyle coaches or participants. This will be 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 will be to the organization contact information via the organization code.

3. CDC will not have access to the keys to any codes, other than the organization code, or to the applicant organizations' data systems.
4. CDC will not attempt to identify individuals by data linkages involving demographic, geographic or outcome information.
5. CDC will 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 will use the data only as described and will safeguard and secure the data to the full extent allowable by law. On the organization side, the DPRP Standards document clearly assigns 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. CDC anticipates that 100% of the information submitted to DPRP will be submitted electronically, as is specified in *DPRP Standards*.

The online application form and instructions (**Attachment 4A**), and *DPRP Standards* (**Attachment 3**), which includes complete specifications for the evaluation data elements and instructions for their transmission, will be posted on the DPRP Web site (www.cdc.gov/diabetes/prevention/recognition) (**Attachment 4B**).

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. CDC anticipates that approximately 85% of applicants will be large entities, and 15% will be small entities. CDC further anticipates that approximately 90% of applicants will be from the private sector and 10% will be from the public sector. If a small business offers type 2 diabetes prevention programs and wishes to apply for recognition through DPRP, the small business will be required to meet all the eligibility and evaluation requirements outlined in *DPRP Standards*. CDC will provide technical assistance on an as-needed basis. It is possible that a small business may need, and receive, more technical assistance than a large business.

To determine the least burdensome method of collecting the information needed to administer DPRP, CDC consulted with several community-based organizations currently offering lifestyle interventions (such as the Y). During these meetings, the organizations stated they routinely collect and/or record data about individuals participating in their programs. For example, organizations collect demographic information, process measures (how many sessions and which type of sessions were attended, and participant outcome measures) and, in many cases, a variety of additional data elements related to program administration and local evaluation (e.g., family histories, names of friends/relatives who might want to join a program, satisfaction). Organizations use these data for a variety of internal and external purposes such as billing, tracking participant progress, marketing, and others. 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 (divided between a core and post-core curriculum). Organizations that seek recognition through DPRP will submit evaluation data to CDC every 6 months. CDC will use these data to monitor program effectiveness. This will allow CDC to provide timely technical assistance to programs that have 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. A notice was published in the *Federal Register* on December 21, 2010, Vol. 75, No. 244, pp. 80057–80058 (**Attachment 2A**). During the 60-day comment period for *DPRP Standards*, comments were received from three organizations: YMCA (the Y), the New York City Department of Health and Hygiene, and the Minnesota Department of Health. Their comments can be grouped into three broad categories: *editorial comments*, *requests for clarification*, and *areas of concern or disagreement* with the *DPRP Standards*.

Editorial comments were primarily typographical errors, inconsistent use of terminology within and between *DPRP Standards* and the supporting statements, and suggestions for rewording specific clauses or sentences for readability or clarity. A writer-editor was engaged and has reviewed and edited the documents for clarity and consistency.

Requests for clarification focused primarily on the data elements which organizations must transmit to CDC every 6 months. The comments stated that the data elements were not clearly defined and expressed the concern that the data received by CDC would not be consistent in nature, limiting the usefulness of the data. CDC responded by clearly defining the terms used for the data elements and providing a data dictionary with specific response codes and parameters for the data ranges. In addition, rather than allow organizations to submit data to CDC in any software and format, as originally envisioned, CDC has decided to require organizations to submit data using the comma separated value (CSV) format and has provided specific instructions for the rows and fields. CDC believes these revisions provide the requested clarification and will result in the submission of data that satisfies DPRP analytic requirements and is of consistently high quality.

Commenting organizations also had *areas of concern or disagreement* with selected criteria, standards, or burden estimates in the *DPRP Standards* document or supporting statements. Examples of these areas included: the minimum number of sessions a participant must attend for their data to be included, the role of the community advisory boards, the burden/cost (wage rate) estimates, the required data elements, and the way in which weight loss was calculated. In the first three areas, CDC revised the *DPRP Standards* document to address the concerns expressed in the comments. The minimum number of sessions that participants must attend for their data to be included was increased from two to four and the requirement to have a community advisory board was dropped. The burden hours and wage rates (used to estimate cost of staff time) were

increased. Regarding the comments on the data elements, some organizations wanted more data elements and others wanted fewer data elements. In particular, the Y suggested that CDC is requiring more data elements than their organizations currently collect. CDC believes that, while all Ys may not be collecting all of the required data elements, the Y sites currently offering lifestyle programs to prevent type 2 diabetes (for example, the Y sites associated with the UnitedHealth Group) are routinely collecting all of the required data elements plus some additional elements. CDC believes that all of the required elements are needed to adequately monitor the effectiveness of the lifestyle programs. In response to the comment that CDC should change the way in which weight loss is calculated, CDC has revised the weight loss criteria and will calculate weight loss as the average per-participant percentage weight loss. For additional information see **Attachment 2B**.

- B. In response to Congressional authorization of National Diabetes Prevention Program, CDC convened a Program Recognition Workgroup to assist CDC in the development of *DPRP Standards*. The workgroup met six times, from February to September 2010, and was comprised of external partners and constituents representing academia, community-based organizations, state health departments, clinical practice, and health care delivery systems (**Attachment 6**). Representatives from these sectors were recruited to ensure that the workgroup's deliberations, and ultimately the *DPRP Standards* reflected the best available science, practical implementation experience, relevant infrastructures, and the perspectives of prospective participants in National Diabetes Prevention Program. Workgroup members from the Y and other organizations currently delivering lifestyle programs for preventing type 2 diabetes were essential partners. These organizations provided CDC with a list of participant data elements typically collected and maintained by their organizations for local program administration. From this existing organizational data, the workgroup then determined a subset of the data elements that would be necessary for administering DPRP. The frequency of data transmission to CDC was decided at the September 2010 meeting and the *DPRP Standards* were completed in October 2010. The Program Recognition Workgroup did not encounter any major problems that could not be resolved during the course of the Workgroup's deliberations.

Development of the National Diabetes Prevention Program and DPRP has been coordinated within HHS. The National Diabetes Prevention Program is one of the priority projects of the HHS Healthy Weight Task Force, which consists of all operating divisions within HHS. The director of CDC's DDT provided updates about the National Diabetes Prevention Program and answered questions from the Healthy Weight Task Force on two occasions during 2010. CDC has also provided specific information to the Healthy Weight Task Force about DPRP because evaluation data from DPRP-recognized programs will be one of the primary methods of evaluating the National Diabetes Prevention Program.

Additionally, discussions about the data elements required for administering DPRP were held with other federal entities. Type 2 diabetes prevention was the topic for discussion at the Diabetes Mellitus Interagency Coordinating Committee (DMICC) meeting on November 10, 2009 (**Attachment 7** is the meeting agenda). The DMICC is chaired by the NIH with representation from all HHS agencies, as well as the Department of Defense (DOD) and the U.S. Department of Agriculture (USDA). During this meeting we discussed the importance of monitoring program quality in order to assure fidelity to content and outcomes achieved in the DPP research study and subsequent translation studies.

DDT has had two follow-up phone calls with CMS and one conference call and one in-person meeting with key leadership at the Health Resources and Services Administration (HRSA) during 2010 to discuss the National Diabetes Prevention Program. The discussions with CMS focused on what would be necessary for them to provide reimbursement for the National Diabetes Prevention Program. Discussions with HRSA focused on increasing utilization of the National Diabetes Prevention Program and access points through HRSA's infrastructure. CMS and HRSA leadership acknowledged the importance of the role CDC will play in assuring program quality through DPRP. CMS and HRSA are represented on the Healthy Weight Task Force and DMICC.

Finally, DPRP has been discussed by CDC's DDT in presentations to other divisions in CDC's National Center for Chronic Disease Prevention and Health Promotion.

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 CDC human subjects contacts 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 will include IIF (the name and contact information for each organizational entity's contact person), the contact person will only provide information relating to his or her designated role in the organization. The contact person will not provide personal information to DDT. The data submitted to DDT for evaluation purposes will be identifiable by organizational entity. The participant-level evaluation data submitted to

DDT will not include participant names, but will include participant and lifestyle coach codes. The organizational entity requesting recognition through DPRP (applicant organization) will assign and maintain the participant and lifestyle coach codes.

- B. Application form information will be submitted to CDC via an e-mail generated by the online application form software. Evaluation data will be submitted to CDC as e-mail attachments. These transmission methods were reviewed and recommended by CDC's Information Systems Security Officer. Data will be maintained on a password secured computer in secure CDC facilities and accessible only to DPRP staff (CDC personnel and onsite contractors) for approved analyses. CDC will protect the data to the extent allowed by law. CDC will not collect, release, publish or disclose IIF relating to individual program participants. CDC will only publish 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 implied 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. No additional withdrawal notification is required.

11. Justification for Sensitive Questions

Prediabetes Status and Weight Loss

In order to monitor program effectiveness and assure that recognized programs are delivering science-based, effective lifestyle programs, organizations will 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 will 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, location code and core group code) might be considered IIF. CDC will 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. Respondents are organizational entities that seek recognition through DPRP. Each respondent will submit a brief one-time application form to DPRP (**Attachment 4A**). The application form and instructions will be 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 120 organizations per year will seek recognition through DPRP over the 3 years of the initial OMB approval period. The total estimated average annualized burden to respondents is 120 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.

Evaluation Data. Each respondent will transmit evaluation data (**Attachment 5A**) to DDT every 6 months. The due dates for each organization's evaluation data transmissions will be determined by the date of the first lifestyle intervention session it offers after the date of its application. The evaluation data must be submitted to DDT electronically (as data files attached to e-mails) in accordance with *DPRP Standards* (**Attachment 3**). DDT anticipates that the number of organizations submitting data will increase from approximately 120 in the first year to a total of 360 organizations in the third year of the OMB approval period. On an annualized basis, an average of 240 organizations will submit evaluation data to DDT during the 3-year OMB approval period. The total estimated average annualized burden to respondents is 240 hours (1 hour per response). 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.

CDC estimates that 90% of DPRP applicants will be private sector entities and 10% of DPRP applicants will be public sector entities.

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 hrs)	Total Burden (in hrs)
Organizations that deliver type 2 diabetes prevention programs	DPRP Application Form	120	1	1	120
	DPRP Evaluation Data	240	2	1	480
Total:					600

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 (based on burden hours)

Form name	No. of respondents per year	No. of responses per respondent per year	Hourly wage rate	Total burden (in hrs)	Annualized cost to respondent
DPRP Application Form	120	1	\$14.50	120	\$1,740.00
DPRP Evaluation Data	240	2	\$14.50	480	\$6,960.00
Total:					\$8,700.00

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

We anticipate that for most respondents the evaluation data elements will be 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 DPRP applicants will 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 \$1,011,510, as summarized in the table below.

<u>Personnel</u>	<u>Base salary</u>	<u>Fringe</u>	<u>Total cost</u>
FTE*	\$513,000	\$138,510	\$651,510
Contract support**			\$250,000
Travel			\$25,000
Other direct costs			
			\$5,000
			\$10,000
			\$70,000

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

** Contract support includes data management software/support, administrative support, and development of other DPRP-related Web site(s).

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

<u>Task</u>	<u>Date</u>
Data Management System Completed	September 2011
OMB Approval	October 2011
DPRP Web site completed	October 2011
Open application process (ongoing)	Upon OMB approval
Applicants transmit data (ongoing, every 6 months)	6 months after pending recognition
Recognition status renewed (ongoing, every 2 years)	2 years after pending recognition

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.