

Information Collection Request

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

Revision
OMB No. 0920-0909

Supporting Statement: Part B

Program official/project officer: Stephanie Gruss, PhD, MSW
Centers for Disease Control and Prevention
National Diabetes Prevention Program
Atlanta, Georgia
Telephone number: 770-488-8173
Fax number: 770-488-4639
Email address: Inf6@cdc.gov

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REFERENCES

ATTACHMENT

- 1 Authorizing Legislation PHSA
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- 3 DPRP Standards 2018
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Section B. Collections of Information Employing Statistical Methods

Statistical methods are not used to select respondents. Respondents (organizational entities offering a type 2 diabetes prevention lifestyle change program and seeking CDC recognition through the DPRP) self-select by applying for recognition.

1. Respondent Universe and Sampling Methods

The potential respondent universe is any organizational entity in the United States desiring CDC recognition of its type 2 diabetes prevention lifestyle change program. We anticipate 500 applicant organizations per year and 2,794 CDC-recognized organizations (annualized) submitting evaluation data during the 3-year OMB approval period (January 1, 2018 through December 31, 2020).

Calculating the Burden for Submitting Process/Evaluation Data

OMB Year	Previously Recognized Programs	Programs Recognized This Year	Total Recognized Programs	Burden Per Data Submission	Submissions Per Year	Burden Per Year
Year 1	1294	500	1794	2.0 hour	2	7,176 hours
Year 2	1794	500	2294	2.0 hour	2	9,176 hours
Year 3	2294	500	2794	2.0 hour	2	11,176 hours
Year 4	2794	500	3294	2.0 hour	2	13,176 hours
Year 5	3294	500	3794	2.0 hour	2	15,176 hours
Total for 5 years			13,970			55,880 hours
Annualized Total			2,794			11,176 hours

2. Procedures for the Collection of Information

For organizations applying on or after January 1, 2018 (pending OMB approval)

The DPRP administers the *CDC Diabetes Prevention Recognition Program Standards and Operating Procedures (DPRP Standards)* (**Attachment 3**). Any organization with the capacity to deliver a type 2

diabetes prevention lifestyle change program meeting *DPRP Standards* may apply for CDC recognition. Organizations seeking recognition must complete and submit an online application form (**Attachment 4A**) which includes organization contact information, information on the curriculum to be used, mode of delivery, and organization web URL. The DPRP application form is located on the National DPP web site (https://www.cdc.gov/diabetes/prevention/lifestyle-program/apply_recognition.html) (**Attachment 4B**) and may be submitted at any time.

After submitting the application form, the organization sees a confirmation web page (**Attachment 4C**) and receives a confirmation e-mail (**Attachment 4D**). When the applicant indicates that they are using the CDC-approved curriculum, DPRP staff will notify the applicant by e-mail of the results of the CDC review within 15 working days. When the applicant indicates that they are using an alternate curriculum, DPRP staff will review the alternate curriculum along with the application. In this case, DPRP staff will notify the applicant by e-mail of the results of the CDC review within 4-6 weeks.

When an organization's application has been reviewed and approved, the DPRP will send an e-mail to the organization's Program Coordinator indicating that the organization has been awarded pending recognition status (**Attachment 4E**). This e-mail includes the unique organization code assigned by the DPRP, the organization's effective date (the first day of the month immediately following CDC approval of its application) which determines the date the organization's evaluation data is due to the DPRP, and instructions for data submission. At the same time, the organization will be listed in the DPRP Registry and on the CDC website. This entire process takes approximately 15 working days. If an organization submits an alternate curriculum for review and approval by CDC, an initial email indicating receipt will be sent (**Attachment 4D**). Organizations should allow 4-6 weeks for review and approval of the application and curriculum and assignment of an organization code. If an alternate curriculum is not approved by CDC, the application will not be approved. CDC will delineate the reasons why a curriculum is not approved in writing and allow the organization an opportunity to address any issues and reapply for recognition once the curriculum is amended. When an organization's application is not accepted, the DPRP will notify the applicant by e-mail (**Attachment 4F**). These acceptance/rejection email messages are individualized to reflect specific issues associated with acceptance/rejection (curriculum used, reason(s) for rejection, etc.).

When an application for recognition is approved, the organization will have pending recognition status and may begin offering classes on or after the application approval date. An organization may begin offering classes immediately upon approval and is required to start offering classes no later than six months after its effective date.

Evaluation data are transmitted to the DPRP by the organization every 6 months in accordance with the *DPRP Standards* (**Attachment 3**). To minimize the burden on applicant organizations and to ensure the quality and utility of the data, each evaluation data transmission consists of a single data file submitted via a DPRP web application (**Attachment 5C**). Detailed specifications for the evaluation data file are contained in the *DPRP Standards* Data Dictionary: Evaluation Data Elements (**Attachment 5A**).

The 2018 DPRP Standards require organizations to submit evaluation data to the DPRP every 6 months from the organizations' effective dates (the first day of the month following the approval of an organization's application). There must be at least one session record per participant in the organization's submission at six months post effective date and at least six months of participant data in the organization's submission at 12 months post effective date. This will allow for timely data analysis and provide opportunities for the organization to receive interim feedback on its progress in meeting recognition requirements. Data may be submitted at any time during the month of the submission due date. Organizations failing to submit complete and acceptable data in the month in which it is due, or failing to report attendance in a 6-month period, will lose recognition and must wait 6 months before re-applying. This occurs only after multiple e-mail reminders (**Attachments 5D(1) and 5D(2)**), and outreach and technical assistance offers by CDC have occurred. Notification of loss of recognition is made by e-mail (**Attachment 5D(3)**).

Each data submission must include one record per participant for each session attended during the preceding 6 months. The first data submission (6 months post-effective date) must also include records for any sessions attended between the application approval date and the effective date. Subsequent data submissions should not include participant data previously submitted. After the first (6 month) data submission, CDC will provide the organization with an interim Progress Report (PR). Once a full 12 months of complete program data are available, CDC will prepare the first Evaluation Report (ER) that assesses whether the organization has met the requirements for preliminary (**Attachment 5-5a**) or full recognition; meaning, an organization can progress directly to full and bypass preliminary if all requirements for full are met. Either preliminary or full recognition statuses will permit an organization to bill Medicare for MDPP services. The evaluation will be based on data from participants who attended their first session at least one year but not more than 18 months before the submission due date.

Organizations will be evaluated for preliminary recognition only at the time of required data submissions. To be evaluated for preliminary recognition, organizations must have submitted a full 12 months of data on at least one completed cohort. A completed cohort is a set of participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time. Organizations will be awarded preliminary recognition when they meet Requirement 5 in **Table 3** of the *DPRP Standards* (**Attachment 3**). Organizations may remain in preliminary recognition status for four consecutive 6-month data submission periods (i.e., two years; 24 months), provided they continue to meet the requirements for preliminary recognition at the 12 month mark. The 24 month limit in preliminary recognition applies regardless of how many months the organization was in pending status. Organizations that either do not maintain preliminary recognition at 12 months or fail to achieve full recognition at 24 months will lose recognition and will need to wait 6 months before reapplying. Loss of preliminary recognition will preclude an organization from participation as a Medicare DPP supplier until preliminary recognition is reacheived.

Organizations will be evaluated for full recognition only at the time of required data submissions. To be evaluated for full recognition, organizations must have submitted a full 12 months of data on at least one completed cohort. Organizations will be awarded full recognition when they meet the requirements for pending and preliminary recognition, and also meet Requirements 6-9 in **Table 3** of the *DPRP Standards (Attachment 3)*. Organizations may remain in full recognition status for four consecutive 6-month data submission periods (i.e., two years). If organizations do not continue to meet full recognition at 24 months, but do meet the requirements for preliminary recognition, they can remain in full recognition status on a Corrective Action Plan for an additional 12 months. Organizations that do not re-achieve full recognition requirements at the 36 month mark will lose recognition and will need to wait 6 months before reapplying. Loss of full recognition will preclude an organization from participation as a Medicare DPP supplier until preliminary recognition is re-achieved. Re-achieving preliminary from pending status will not be permitted. Notification of loss of recognition is made by e-mail (**Attachment 5D(6)**).

If, after the first evaluation where an organization has at least one complete 12-month cohort, the organization has not achieved all of the requirements for preliminary or full recognition, it will continue in pending recognition status for an additional 6 months. During this period, the DPRP will offer technical assistance to the organization to help it achieve preliminary or full recognition. The DPRP will conduct evaluations for preliminary and full recognition every 6 months when data are submitted. These evaluations will be based on data from participants who attended their first session at least one year but not more than 18 months before the submission due date. If the organization is not successful in achieving preliminary or full recognition by the 36 month evaluation, it will lose pending recognition and must wait 6 months before reapplying. Notification of loss of recognition is made by e-mail (**Attachment 5D(6)**).

Each CDC-recognized organization (with pending, preliminary, or full recognition) must submit evaluation data to the DPRP every 6 months. This requirement begins 6 months from the organization's effective date. Four weeks prior to an organization's first data submission due date, the DPRP will send an email reminder to the organization's Program Coordinator and other contacts regarding the data submission requirement and data due date (**Attachment 5D(1)**). A second data submission reminder (if necessary) will be sent to the organization's Program Coordinator and other contacts, as a courtesy, approximately 2 weeks after the data submission due date (**Attachment 5D(2)**). If, after this second reminder, the DPRP still does not receive the first evaluation data submission within an additional 4 weeks, the organization will lose recognition and will be removed from the DPRP Registry. Notification of loss of recognition is made by e-mail (**Attachment 5D(3)**). Organizations receiving a loss of recognition must wait 6 months to reapply to the DPRP.

The DPRP will continue to send reminders four weeks before and two weeks after each subsequent data submission due date. Organizations are required to submit one data file every 6 months. If there is a gap in enrollment resulting in no classes being held, CDC allows a one-time 6-month period where data are not submitted. If after two 6-month periods a data submission is not received by the DPRP within 6

weeks of a data submission due date, the organization will lose recognition and will be removed from the DPRP Registry. Notification of loss of recognition is made by e-mail (**Attachment 5D(3)**).

For organizations approved prior to January 1, 2018 (pending OMB approval)

Organizations recognized prior to the effective date of the 2018 Standards, especially those that have already submitted evaluation data, cannot reasonably be expected to comply with the new Standards immediately, as doing so would be disruptive and detrimental to organizational operations and performance. Thus, a transition plan was developed to help facilitate the transition from the previously approved data elements in the 2015 DPRP Standards (OMB Control Number 0920-0909, expiration date: December 31, 2017) (**Attachment 5B**) to the revised data elements in the 2018 DPRP Standards (**Attachment 5A**). It should be noted that we expect the transition to be fairly easy due to the fact changes are minor. Furthermore, we are liberalizing the requirements for full recognition based on evidence and an evaluation of current DPRP data. This will continue to assure quality while increasing the number of programs that achieve either preliminary or full CDC recognition.

In order to provide current CDC-recognized organizations an orderly transition from the 2015 *DPRP Standards* to the revised 2018 *DPRP Standards*, CDC will allow programs that initiated their applications under the 2015 *DPRP Standards* the option of submitting the 2015 data elements or submitting the 2018 data elements, up to June 30, 2018. Thereafter, these programs will be required to transition to the 2018 *DPRP Standards*. The transition plan will allow organizations to adapt their reporting systems without unduly interrupting progress toward achievement of CDC recognition. A transition letter (**Attachment 7**) will be sent to organizations to inform them of the changes that will affect them and of the allowances being made to existing organizations during the first 6 months of 2018.

For more detailed information and an example of a data submission and evaluation timeline, see **Attachment 3 DPRP Standards: Appendix D: Description of the Data Submission and Evaluation Timeline with examples**.

DPRP correspondence related to receipt/non-receipt of data, data issues (missing or miscoded data), technical assistance and recognition/failure to achieve recognition is personalized, and the content must be individualized to address one or more specific issues or organizational needs. Thus, it is not feasible to include templates for every reason that an organization might be contacted by the DPRP. Sample correspondence is included for review as follows: first data reminder email (4 weeks prior to due date) (**Attachment 5D(1)**), second data reminder email (2 weeks past due date) (**Attachment 5D(2)**), loss of recognition for failure to submit data (**Attachment 5D(3)**), progress report (**Attachment 5D(4)**), evaluation report (**Attachment 5D(5)**), loss of recognition for failure to meet Standards (**Attachment 5D(6)**), letter of achievement of preliminary recognition (**Attachment 5-5a**), and achievement of full recognition (**Attachment 5D(8)**).

3. Methods to Maximize Response Rates and Deal with No Response

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. All information submitted to the DPRP is submitted electronically, as is specified in *DPRP Standards*.

CDC provides regular training to organizations that have questions or may be encountering challenges in providing CDC the required information within the required timeframes. Training includes two monthly webinars to review the Standards and data submission requirements. The DPRP also offers tailored technical assistance calls to organizations to help them achieve preliminary or full recognition. The frequency and nature of technical assistance are based on both demand and issues that emerge that are shared by multiple organizations. The DPRP is also developing quick, self-paced webinars and videos, to be released by January 1, 2018 concurrent with the new Standards. These will include a Welcome Kit, helpful hints for Lifestyle Coaches and organizations, and data submission assistance. A National DPP customer service center is also in development to further assist to organizations.

The online application form and instructions (**Attachment 4A**), complete specifications for the evaluation data elements and instructions for their transmission (**Attachment 5A**), and *DPRP Standards* are posted on the National DPP web site (<https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf>) (**Attachment 4B**). Potential applicants are encouraged to read and carefully review all of this information before applying for recognition.

Participation by organizations is strictly voluntary. Organizations may withdraw from the DPRP at any time by not transmitting evaluation data or by stating reasons specific to the organization. Regardless of the circumstances of the withdrawal, they must wait 6 months prior to reapplying for CDC recognition. No additional withdrawal notification is required. Organizations that do not transmit evaluation data as required do not achieve and maintain full recognition. As assistance to organizations, CDC sends e-mails to remind recognized organizations of data submission due dates four weeks before and two weeks after data are due (**Attachment 5D(1)**, **Attachment 5D(2)**).

4. Tests of Procedures or Methods to be Undertaken

Prior to receiving initial OMB approval in 2011, a DPRP workgroup comprised of internal and external stakeholders, which included representatives from academic and other organizations, met several times over the course of one year. During this time, the workgroup provided input on required data elements, frequency of data transmission to CDC, and on the application form and instructions. A hard copy of the DPRP application form was pilot tested with seven individuals (three CDC employees and four staff of potential applicant organizations). Feedback was reviewed by DPRP staff, and the *DPRP Standards* (**Attachment 3**) and the online application form (**Attachment 4A**) were revised as deemed appropriate. Subsequent feedback received after the 2015 *DPRP Standards* revision included several programmatic changes suggested by potential applicants and recognized organizations, as well as from CDC's DP-12-1212 grantees. In addition, in December 2016, four listening sessions were held with a variety of stakeholders to get input on the proposed revisions to the DPRP Standards. Stakeholders included

grantees; state health departments; large, private CDC-recognized organizations; smaller, successful CDC-recognized organizations; organizations that had achieved full recognition; and virtual organizations. Recommendations from stakeholder listening sessions directly informed the 2018 Standards revision.

The Medicare Diabetes Prevention Program (MDPP) expansion of CDC's National DPP was announced in early 2016, when the Secretary of Health and Human Services determined that the Diabetes Prevention Program met the statutory criteria for inclusion in Medicare's expanded list of healthcare services for beneficiaries (<https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>¹). This is the first time a preventive service model from the CMS Innovation (CMMI) Center has been expanded. After extensive testing of the DPP model in 17 sites across the US in 2014-2016, CMS proposed the MDPP in Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh §424.59), authorizing CDC-recognized organizations to prepare for enrollment as MDPP suppliers in order to bill CMS for these services beginning in January 2018¹. Only organizations in good standing with the DPRP will be eligible as MDPP suppliers.

CMS' MDPP allows for a new recognition status, preliminary, in addition to pending and full recognition. CMS determined that a new category was necessary in order to ensure that there would be a sufficient number of Medicare suppliers able to bill CMS when the benefit is effective on January 1, 2018. Most of the organizations currently in the DPRP Registry are new to the National DPP and have not had enough time to achieve full recognition. However, CMS also needed to ensure that MDPP suppliers had enough experience to deliver a quality program. The new category of preliminary recognition was created for organizations with at least 12 full months of experience offering the program who met program attendance requirements, as DPRP data strongly indicate that attendance leads to weight loss. Since CDC would not be able to include this new category until the Standards were revised, CMS included this definition in its proposed rule to cover the interim period between now and January 1, 2018. MDPP reimbursement will be dependent on organizations achieving either preliminary or full recognition status. Any organization with interim preliminary recognition based on the CMS rule will automatically move to preliminary recognition based on the CDC 2018 Standards on January 1, 2018, and the CMS authority for tracking preliminary recognition will revert to CDC.

The intent of the current Standards revision is to align with the CMS MDPP rule that will be finalized in 2017 and is expected to be in effect on January 1, 2018, and to account for new evidence in the diabetes prevention literature. The majority of the additional data elements included in the current Standards revision are the result of new CMS requirements for MDPP suppliers. In particular, CMS is requiring participant-level data submission every 6 months. While data submissions every 6 months are included to align with the CMS MDPP supplier requirements, this change will also benefit organizations that are not MDPP suppliers, as it will allow them to receive more feedback in an effort to make necessary mid-course corrections and successfully achieve either preliminary or full recognition status.

These new CMS requirements for MDPP resulted in the need for changes to the data elements being collected (**Attachment 5A**). These additional data and application elements have been added: Class Type- revised, Organization Type, Lifestyle Coach Training Entity, Participant's Education, Delivery Mode, Session ID, Session Type, Enrollment Source, and Payer Type.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Staff in CDC's Division of Diabetes Translation (DDT) (CDC personnel and contractors) have been consulted on the development and maintenance of the DPRP data collection processes and automated platforms, including the online application form, the online registry, and the web application [program] for data submission. All data management, analysis, and reporting are performed at CDC by DDT staff and on-site contractors. The individuals listed below were consulted on all statistical aspects of the DPRP. DDT staff will be responsible for DPRP data collection and data analysis.

Ann Albright, PhD, RD
Director
Division of Diabetes Translation
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Phone: 770-488-5000

Stephanie Gruss, PhD, MSW
Program Manager, Diabetes Prevention Recognition Program
Division of Diabetes Translation
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Phone: 770-488-8173
E-mail: Inf6@cdc.gov

Elizabeth Ely, MS
Mathematical Statistician
Division of Diabetes Translation
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Phone: 770 488-8086
Email: eke0@cdc.gov

Kunthea Nhim, DrPH, MPH
Epidemiologist
Division of Diabetes Translation
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
Phone: 770-488-0912
E-mail: xmh8@cdc.gov