Attachment 6: Overview of Changes to 2015 *Formative and Summative Evaluation of the National Diabetes Prevention Program* (OMB No. 0920-1090, exp.12/31/2018) for 2018 *Formative and Summative Evaluation of Scaling the National Diabetes Prevention Program in Underserved Areas* (Reinstatement with revisions)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
1. Programmatic changes	The newly funded grantees and affiliate sites under cooperative agreement DP17-1705 will submit evaluation data directly to CDC through a web-based data system called the Data Reporting for Evaluation and Monitoring of 1705 (1705 DREM) System, accessible using a web browser on a PC, MAC, or mobile device. The changes in the data collection instruments (Attachment 3A and 3B) were made to reflect changes in programmatic strategies (Attachment 7A: Program Logic Model for DP17-1705) outlined in the Notice Of Funding Opportunity (NOFO). This revision request also describes a number of changes that are based on experience from a previous NOFO (DP12-1212) and lessons learned from the funded national organizations and their affiliate sites that delivered the CDC-recognized lifestyle change program.	The web-based data system will allow real-time data entry by grantees and affiliate delivery sites and real-time feedback and technical assistance (TA) from CDC to facilitate continuous quality improvement by grantees and sites. The web-based data system will allow data entry directly by affiliate delivery sites instead of requiring the grantees to compile and submit a consolidated response based on each of their affiliate delivery sites. The changes to the evaluation forms will ensure that reporting and evaluation requirements are consistent with the successor NOFO (DP17-1705).	- *Evaluation Form for National DPP Grantees* (Attachment 3A) - *Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
2. Collect additional organizational information from grantees	Based on lessons learned from the evaluation of the previous DP12-1212 cooperative agreement, we propose to collect some additional information about the grantees to allow for a more robust and targeted evaluation of DP17-1705, the successor cooperative agreement. This is necessary as CDC attempts to scale and sustain the National DPP to reach priority populations in underserved areas. While the evaluation of DP12-1212 yielded valuable and critical information to help improve the work of grantees and affiliate delivery sites, CDC needs to further refine our TA to help reduce health-related disparities. As a result of the evaluation of DP12-1212, CDC learned that the quality of the TA provided by grantees to affiliate delivery sites was critical in improving outcomes at the delivery site level. Therefore, we are proposing to expand our collection of information about TA, with a specific focus on reaching priority populations.	We propose to add the following fields: - Types of TA provided by the grantees to their affiliate delivery sites including: obtaining CDC recognition for new sites; working effectively with specific priority populations; engaging health systems and healthcare providers to screen, test, and refer priority populations with prediabetes to a CDC-recognized organization, and implementing administrative systems required to bill and receive payment from payers. - Types of advanced skills training provided for lifestyle coaches. - Descriptors of key facilitators for: recruiting new affiliate delivery sites in underserved areas; securing agreements with health care providers/systems to screen, test, and refer priority populations; and obtaining coverage for the National DPP lifestyle change program. - Types of value-based payment methods used to reimburse affiliate sites for delivering the lifestyle change program. - Strategies used to increase retention of priority populations in the year-long lifestyle change program. - Descriptors of activities and tools developed and implemented to help obtain coverage for the National DPP lifestyle change program.	*Evaluation Form for National DPP Grantees* (Attachment 3A)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
3. Collect additional organizational information from sites	See #2 above. In addition to needing further information from the DP17-1705 grantees, we also need additional information from the affiliate delivery sites in order to learn more about how to effectively reach and retain priority populations in the CDC-recognized lifestyle change program. While grantees are responsible for developing and implementing overall strategies and for providing TA to affiliate delivery sites, the sites themselves are ultimately responsible for enrolling and serving the priority populations. Gathering additional information at the affiliate delivery site-level is critical as the National DPP supports over 1800 total delivery organizations and needs to develop general TA and training materials for dissemination through the National DPP Customer Service Center.	We propose to add the following fields: - Acknowledgement of completion of the DPRP Organizational Capacity Assessment as part of applying for CDC recognition. - Types of marketing activities/strategies, tools/resources, and facilitators to working with health systems or healthcare providers to screen, test, and refer priority populations with prediabetes to the affiliate delivery site. - Strategies or best practices to retain specific priority populations in the yearlong lifestyle change program. - Types of billing and coding systems used to submit claims to payers.	*Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
4. Collect additional information about lifestyle coaches	Based on the evaluation of DP12-1212 and other studies, CDC learned that lifestyle coaches are critical to participant success in achieving program outcomes. Participants must lose 5-7% of their baseline body weight to reduce their risk of progressing to type 2 diabetes. We are proposing to collect additional information about lifestyle coaches to learn more about how they can best reach and support priority populations and, thereby, help reduce health-related disparities. Also, as noted above, CDC will use this information to develop further TA and training for the 1800 CDC recognized organizations and over 8000 lifestyle coaches to further increase their effectiveness.	We propose to add the following fields: -A unique de-identified Coach ID or National Provider Identifier (NPI) for lifestyle coaches participating in the Medicare Diabetes Prevention Program (MDPP). - Description of coach activities over and above delivering the lifestyle change program. - Allocation of time for each activity. - Name of curriculum on which coaches were trained. - Description of training received by coaches.	*Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)
5. Collect additional information about class locations	Affiliate delivery sites offer the lifestyle change program at multiple class locations and through multiple delivery modes (in-person, online, distance-learning, or a combination of one or more modes.) In addition, classes at specific locations may be offered in a language other than English. We are proposing to collect additional information about class locations to better understand how delivery sites modify their offerings to reach priority populations.	We propose to add the following fields for each class location: - One unique de-identified class ID - In-person class address - Type of curriculum - Language used to deliver the curriculum - Delivery mode	*Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
6. Collect additional information about participants	As noted in the supporting statements, we will not be collecting any personally identifiable information for participants. The majority of the de-identified participant information for the evaluation of DP17-1705 will be collected by the DPRP (OMB No. 0920-0909, exp. Date 02/28/2021). However, there are a few items, which the DPRP does not collect and are required for DP17-1705. While the DPRP collects information on Medicare status, gender, and race/ethnicity, it does not collect information on disability status. As people with physical disabilities or visual impairment are one of the priority populations of DP17-1705, we need to collect that information as part of this ICR. Also, the DPRP only collects session data once sessions actually commence. We need to be able to evaluate efforts to recruit and enroll participants, which often involves an introductory session known as Session Zero. Also, we need to know additional information about how far participants are willing to travel to participate in the yearlong program. The DPRP collects addresses at a state level only. We need participant zip codes to be able to assess whether the infrastructure has been scaled sufficiently to reach priority populations.	We propose to add the following participant fields: - Physical disabilities or visual impairments - Attendance at a Session Zero or Introductory Session - Residence zip code	*Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
7. Increase estimated annualized number of respondents for grantees and estimated burden hours for sites	The respondents and burden hours have changed from those submitted for DP12-1212. First, there are 10 national grantees for DP17-1705 compared to six for DP12-1212. Second, we are instituting a web-based data entry system rather than the Excel-based system used in DP12-1212, which should reduce the reporting burden. Third, the reporting burden decreases at the grantee level, but increases at the site level, since under DP17-1705, sites will enter their own information directly into the web-based system rather than submitting it to the grantee for inclusion in a consolidated grantee submission. Based on the public comments received from the 60-day Federal Register Notice, we have added an hour to the estimated reporting burden for both the grantee and affiliate site respondents.	- In this three-year revision period for Years 1-3 of DP17-1705, CDC estimates that the ten new national organization grantees will establish approximately 100 new affiliate sites per year to offer the CDC-recognized lifestyle change program to priority populations in underserved areas. - The reporting burden of this collection of information is estimated to vary between 3 and 5 hours with an average of 4 hours per grantee response (decreased from 12 hours), and between 5 and 7 hours with an average of 6 hours per affiliate delivery site response (increased from an average of 45 minutes per response).	Estimated Data Collection Burden Hours by Respondent, 2015 to 2018 (Supporting Statement A; Table A.15-1)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
8. Decrease number of fields and streamline the information collection request	Based on the public comments received from the 60-day Federal Register Notice, we have further revised the Evaluation Form for Grantees to reduce and streamline the information collection request. We will also modify the structure of the CDC-developed, web-based system called "Data Reporting for Evaluation and Monitoring of 1705" (1705 DREM) system to facilitate data entry and submission to CDC.	To reduce the reporting burden, we propose to streamline and clarify the following fields: - Q4, Q6, and Q7: We will clarify that multiple organization codes can be selected for each response item and provide a drop down menu for the organization codes. - Q9, Q14, Q25: We will revise to reduce the number of facilitators from ALL to just the top 5. - Q10, Q15, Q26: We will revise to reduce the number of barriers from ALL to just the top 5 and reduce the reporting of strategies to address barriers by requesting this once for all barriers rather than for each barrier separately. - Q17, Q21: We will revise the question to require reporting strategies used for all priority populations of focus rather than requiring specific strategies to be reported for each individual priority population group. - Q18: We will revise the question to require reporting of coverage for only priority population participants who were covered by the payment method reported rather than for all participants. We will also streamline the drop down menu to align the response options between Q18 on the Evaluation Form for Grantees (Attachment 3A) and Q19 (formerly Q21) on the Evaluation Form for Sites (Attachment 3B). - Q22: We will require reporting on activities conducted to promote the lifestyle change program as a covered benefit only once for all payer types rather than for each individual payer type. - Q23: We will reduce the reporting burden by asking the respondents to provide a list of all tools used across all payers reported in Q22 rather than by each individual tool.	*Evaluation Form for National DPP Grantees* (Attachment 3A)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
9. Decrease number of fields and streamline the information collection request	Based on the public comments received from the 60-day Federal Register Notice, we have further revised the Evaluation Form for Affiliate Sites to reduce and streamline the amount of information collection request.	To reduce the reporting burden, we propose to streamline and clarify the following fields: - Q6: We will revise the field to ask for an overall description of why the class locations were selected instead of asking for this information for each individual class location. - Q7, Q8: We will reduce the reporting of TA and resources from ALL to the top 5. We will also ask for an overall description of how the resources were selected instead of asking for this information for each individual resource and reduce the number of drop down menu options from 15 to 8. - Q9 and Q11 were removed from the information collection request. - Q11 (formerly Q13), Q12 (formerly Q14): We will combine the fields for health care providers (HCPs) and health care systems. - Q13 (formerly Q15), Q14 (formerly Q16): We will remove an item asking for number of participants enrolled, and reduce the number of drop down menu options from 14 to 8. We will also provide clarification that this question is optional and only ask for mode of referral if respondents reported receiving referrals from HCPs/health care systems. - Q17 (formerly Q19): We will remove number of people reached by each marketing strategy and streamline the response options to clarify the distinction between marketing strategies and channels. To ensure consistency of reporting, we will also add the definitions and examples of “marketing strategies” and “marketing channels” in the “Glossary of Terms” (Attachment 3C). - Q18 (formerly Q20): We will clarify that respondents need to report frequency per marketing channel used only as they are able to report it.	*Evaluation Form for National DPP Affiliate Delivery Sites* (Attachment 3B)

Type of Change	Rationale	Detailed Description of Change(s)	Affected Form(s)
		- Q17 (formerly Q19), Q20 (formerly Q22), Q21 (formerly Q23), Q22 (formerly Q24): We will revise the questions to report strategies used for all priority populations of focus rather than for each individual priority population. - Q19 (formerly Q21): We will revise the question to ask for a brief description of how payment/reimbursement arrangements were made for all types of payment methods used, instead of for each individual payment method. We will also add the definition and examples of "pay for outcomes" in the "Glossary of Terms" (Attachment 3C). - Q22 (formerly Q24): We will revise the question to ask for a brief description of how and when the strategies or best practices were adopted for all strategies, instead of for each individual strategy. - Q23 (formerly Q25): We will revise the question to ask for the names of all payers (instead of for each individual payer type) and remove the field for payer markets. - Q24 (formerly Q26): We will revise the question to ask for types of billing and coding systems used across all payers (instead of for each individual type of payer) and remove "types of payers" from this question. - For Coach, Class, and Participant-level information, we will add detailed definitions and instructions to the headings of each field, and provide clarification on how multiple Coach IDs and Class IDs can be tracked in the CDC-developed, web-based system (1705 DREM) per each participant over the course of the reporting period.	

* None of these changes alter the critical elements of the lifestyle change program shown to prevent or delay type 2 diabetes in research studies – participant eligibility requirements, lifestyle 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.