

2C- Comments in Response to the Federal Register Notice and Efforts to Consult Outside of the Agency

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<p>Participant Eligibility: BMI requirement</p>	<p>CDC proposed to continue the eligibility requirement that all participants must have a body mass index (BMI) of ≥ 25 kg/m² (≥ 23 kg/m², if Asian American).</p>	<p>a) Two commenters (#17 and #18) stated that BMI should be removed as a program eligibility criterion because it perpetuates weight stigma for individuals classified as overweight or obese who may never develop diabetes. They further stated that removal of the BMI requirement would make the National Diabetes Prevention Program (National DPP) more accessible for individuals diagnosed with prediabetes who are classified as normal or underweight.</p>	<p>a) CDC does not agree to remove BMI from its eligibility criteria. Weight loss was the primary predictor of reduction in diabetes risk in the 2002 Diabetes Prevention Program (DPP) randomized control trial. For every kilogram of weight loss, there was a 16% risk reduction in development of type 2 diabetes among lifestyle intervention participants. Based on evidence from the DPP, this program is not optimal for normal or underweight persons, and they would not be eligible. The newly-revised, evidence-based CDC/American Diabetes Association (ADA) Prediabetes Risk Test found here, https://www.cdc.gov/prediabetes/takethetest/, continues to utilize BMI as a measurement for assessing risk.</p>

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<p>Participant Eligibility: Blood test requirements</p>	<p>CDC proposed to continue the eligibility requirement for a blood test within one year of participant enrollment and to allow blood test results to be self-reported. CDC also proposed to continue to use a fasting glucose range of 100 to 125 mg/dl.</p> <p>Note: For the Medicare Diabetes Prevention Program (MDPP) Expanded Model, CMS does not allow self-reported blood tests and uses a fasting glucose range of 110 to 125 mg/dl.</p>	<p>a) Commenter #24 stated they reviewed the MDPP final rule and found “it does not require the beneficiary to provide the DPP program with a report or paper result from a physician. MDPP allows for self-reported lab results as long as the test was performed within 12 months of the first class. When referencing the MDPP, CDC DPRP Standards should include the same language and directives.”</p> <p>b) Commenter #24 is also concerned about the eligibility differences between CDC’s National DPP and MDPP regarding the fasting glucose ranges. They feel they are confusing for clinicians when making the referral order, and they should</p>	<p>a) With respect to the reporting of blood test results, the Centers for Medicare and Medicaid Services (CMS) has a stricter requirement than CDC. CMS requires that the MDPP beneficiary record must contain evidence that each beneficiary met the required blood glucose levels within 12 months of the first core session. MDPP regulations do not specify the source from which a blood test result must come; MDPP suppliers may accept any lab tests which follow applicable federal and state regulations. MDPP regulations also do not require that the MDPP supplier obtain the blood results directly from the lab; participants may submit the required paperwork directly to the MDPP supplier. For CDC recognition purposes, a paper trail is not required. Organizations may accept a verbal confirmation from a participant that they have a lab result within the last 12 months prior to enrollment that indicates a lab value within the prediabetes range. Since CDC is looking at eligibility from an organizational perspective for recognition (35% of participants must be eligible for the program on the basis of a blood test), there is less need for strict documentation. Payers such as Medicare may set their own eligibility and documentation requirements regarding eligibility of individuals for coverage.</p> <p>b) CDC does not agree to align its fasting glucose ranges with CMS’, as the MDPP-related criteria are stricter. We recognize that there are</p>

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		align.	different fasting glucose ranges for the MDPP and CDC eligibility requirements for the National DPP lifestyle change program (LCP). CMS utilizes the World Health Organization (WHO) fasting glucose ranges to determine beneficiary eligibility. The WHO fasting glucose ranges more closely align with CMS MDPP Expanded Model cost savings needs. CDC uses the American Diabetes Association ranges.
Delivery Mode: Application	CDC proposed to continue the existing policy which allows a single organization to offer the program through any of four delivery modes, as long as the organization submits a separate application and obtains a separate ORGCODE for each delivery mode offered.	<p>a) Commenters #4 and #30 requested that, in the wake of the COVID-19 public health emergency (PHE), CDC allow organizations to change their delivery mode without resubmission of a new application.</p> <p>b) Commenter #14 recommended that CDC allow organizations to have one organization code not based on delivery mode, and to let payers determine how to identify delivery mode for reimbursement purposes.</p>	<p>a) CDC does not agree to let organizations change their delivery mode permanently without submission of an application. CDC sent guidance to recognized organizations allowing a temporary delivery mode change without submitting a new application due to the PHE. CDC agrees to add a statement to the Standards that gives us the ability to temporarily waive any of the existing Standards requirements during a PHE.</p> <p>b-c) CDC does not agree to this change, as we are required to assign separate organization codes for each delivery mode in order to accommodate CMS's requirement that only in-person organizations can apply to become MDPP suppliers. However, we will investigate the possibility of making system changes to accommodate handling multiple delivery modes on a single application as resources permit.</p>

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		<p>c) Commenters #5, #21, #27, #29, and #30 asked CDC to strongly reconsider the requirement for multiple applications per delivery mode. Commenter #30 specifically stated that submitting a separate application for each delivery mode is burdensome for organizations with data systems.</p>	
<p>Delivery Mode: Online</p>	<p>CDC proposed to continue the requirement that all delivery modes, including online, include live coach interaction. Further, CDC proposed to not allow emails and text messages to count as live coach interaction. Emails and texts would still be allowed for session content reminders, encouragement, weight collection where an automated system (such as a Bluetooth scale) is not available, and/or other logistical information.</p>	<p>a) Commenters #28, #29, and #30 asked that CDC reconsider including text messaging and emails as live coach interaction. Commenter #26 asked that CDC remove the requirement that interaction between a lifestyle coach and a participant be entirely “live”, as this would require synchronous communication which is the definition of distance learning. The commenters noted that these forms of</p>	<p>a-b) CDC agrees to specify that e-mails and texts can count toward the requirement for live coach interaction as long as there is bi-directional communication (i.e., organizations do not simply send out an announcement via text or e-mail and count that as live coach interaction; the participant must have the ability to respond to and get support from the live coach).</p>

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		communication are necessary for modern program delivery.	
Delivery Mode: Combination Definition	<p>CDC proposed to clarify the definition of a Combination delivery mode as the yearlong National DPP LCP delivered as a combination of any of the previously defined delivery modes (in-person, online, or distance learning) for an individual participant by a trained Lifestyle Coach. For example, a combination modality can include the use of one modality such as in-person in the core phase of the National DPP LCP and the use of a different modality such as online in the core maintenance phase. It is a consistent delivery of two modalities across all participants within a given cohort. As another example, a combination modality can include a consistent delivery approach of two modalities for each participant within the National DPP LCP in a</p>	<p>a) Commenter #7 requested confirmation that the definition applies to all cohorts offered under the combination delivery mode, even if each specific cohort uses a different combination of delivery modes.</p> <p>b) Two commenters (#11 and #14) asked whether the combination delivery mode accommodates a mixed modality class (participants can choose a different delivery mode for each session).</p> <p>c) Commenter #5 stated that the new combination definition appears overly restrictive and prefers the broader 2018 definition.</p>	<p>a) CDC agrees that each cohort may use a different combination of delivery modes (i.e., one cohort may use in-person and online and another cohort may use in-person and distance learning).</p> <p>b) CDC agrees that combination delivery mode accommodates mixed modalities where each participant can choose a different delivery mode for each session as long as participants are not selecting a single delivery mode for all sessions).</p> <p>c) CDC does not agree to revert to the 2018 definition, as the previous definition allowed organizations to avoid the requirement that they get a separate ORGCODE for each delivery mode. Under the previous definition, some organizations were offering multiple cohorts, each by a single delivery mode. This approach restricts the ability of MDPP participants attending an in-person cohort delivered by an organization with a combination delivery code from qualifying for the MDPP, since only in-person delivery organizations are allowed to become MDPP suppliers.</p>

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	<p>rotating manner (e.g., one session online and the next session in person; or one session in person and the next via distance learning). The combination delivery mode is not an option for organizations that wish to deliver entire cohorts by different delivery modes (one cohort in-person and another cohort online) and then aggregate data from all cohorts under one ORGCODE. In this situation, organizations should obtain separate org codes for each delivery mode.</p>		
<p>Application: Organization Type (variable)</p>	<p>CDC proposed that organizations choose one primary organization type: Local or community YMCAs; Universities/Schools; State/Local Health Departments; Hospitals/Healthcare Systems/Medical Groups/Physician Practices; Community-Based Organizations/Community Health Centers/Federally Qualified Health Centers; Pharmacies/Drug Stores/Compoundi</p>	<p>a) Commenter #28 stated that CDC left off the option of “privately-held companies” (i.e. for-profit business) from the Organization Type variable list and requested that it be added.</p>	<p>a) CDC agrees to edit the following option to “worksites/employees wellness programs/private business”.</p>

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	<p>ng Pharmacies; Indian Health Service/Tribal/Urban Indian Health Systems; Cooperative Extension Sites; Worksites/Employee Wellness Programs; Senior/Aging/Elder Centers; Health Plans/Insurers; Faith-Based Organizations/Churches; Other (please specify).</p>		
<p>Training</p>	<p>CDC proposed to continue the requirement that all Lifestyle Coaches meet the requirement for 12 hours of basic training, regardless of their existing credentials.</p> <p>CDC proposed that all Lifestyle Coaches and Program Coordinators should complete at least two hours of advanced coach training each year. Advanced coach training is 1) training beyond the required formal training for Lifestyle Coaches that builds on the foundational skills necessary for helping participants make effective lifestyle change, and 2) limited to trainings</p>	<p>a) Commenter #1 requested that CDC accept other coaching credentials in lieu of the required basic training (i.e., certification from the National Board for Health & Wellness Coaching).</p> <p>b) Both commenters #5 and #27 asked that CDC allow both basic and advanced coach training to be provided by entities other than those holding an MOU with CDC, noting that there were less expensive alternatives.</p> <p>c) Commenter #8 asked what documentation would be</p>	<p>a) CDC does not agree to change this requirement because the required basic Lifestyle Coach training includes critical content on the program delivery aspects of the lifestyle change program, such as the CDC-approved curriculum, Diabetes Prevention Recognition Program (DPRP) Standards, and information required for data submissions. This 2-day/12-hour formal training minimum applies to anyone who wants to be a National DPP Lifestyle Coach, regardless of background, to ensure all coaches have this foundational knowledge of program delivery.</p> <p>b) CDC does not agree to allow training for new Lifestyle Coaches or to Master Trainers outside of an MOU-holding training entity and will continue to prioritize training from training entities holding an MOU with CDC, as this is the only way we can ensure that training meets quality standards.</p> <p>c) CDC will continue to utilize a drop-down box (as it currently</p>

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	<p>provided by training entities that are listed on the National DPP Customer Service Center.</p>	<p>required to indicate the coach training entity.</p> <p>d) Commenter #28 asked if organizations are expected to report on advanced coach training attendance, and, if so, what that would entail.</p>	<p>exists in the 2018 DPRP Standards) on its application to indicate choice of training entity.</p> <p>d) CDC will not be collecting data on advanced lifestyle coach training. This is an organizational-level responsibility. CDC reserves the right to audit organizations on this requirement.</p>
<p>Required Curriculum Content</p>	<p>CDC proposed to continue using the yearlong lifestyle change program curriculum sessions that are contained within both the CDC-approved 2012 National DPP curriculum and the CDC-developed PreventT2 curriculum. It also proposed to continue the process for submitting an alternate, CDC-recognized organization-developed curriculum or materials to CDC for review and approval.</p>	<p>a) Three commenters (#5, #17, and #18) recommended that CDC update its curriculum to include modules that address social determinants of health, limited access to food, limited access to healthcare, and the impact of these factors on glycemic control.</p>	<p>a) CDC agrees and has already initiated a process to revise certain dietary information, and its impact on health, found in the PreventT2 curriculum. The PreventT2 curriculum was originally developed in 2015. New studies, research, and dietary guidelines that occurred since 2015 will be included in the revisions. The newly-developed curriculum information will be available around the end of 2021/beginning of 2022 for public use, at no charge. Additionally, any organization wishing to utilize such information to either augment a current curriculum, or to develop a new yearlong curriculum, can do so per guidance in the 2021 DPRP Standards. CDC is happy to work with organizations to review alternate curricula and materials for approval within a 4-6 week timeline. CDC encourages program delivery organizations to partner with community-based organizations and funders to help address social determinants of health</p>

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			(e.g., access to healthy food) as they are able.
Make-up Sessions	CDC proposed guidelines for the use of make-up sessions.	<p>a) Commenters #21 and #22 requested clarification regarding the number of make-up sessions allowed in a given week and the required days between make-up sessions.</p> <p>b) Commenter #21 also suggested that CDC add explicit guidance on which week to include physical activity minutes for a make-up session held in advance of the missed session.</p> <p>c) Commenter #22 suggested that CDC clarify how physical activity minutes should be recorded for a make-up session.</p>	<p>a) CDC agrees to clarify the guidance on make-up sessions. Sessions should not be delivered more than once per week unless a make-up session is being delivered in addition to a regular session. Further, there must be at least 5 days between make-up sessions to maintain the intensity of the program (weekly for the first 16 weeks). Delivering sessions on consecutive days that fall in two different weeks (Saturday/Sunday) does not meet the intensity requirement.</p> <p>b) CDC agrees to clarify that, for make-up sessions, a participant should report the number of physical activity minutes they were planning to report on the day of the session that was missed.</p> <p>c) CDC agrees to clarify that physical activity minutes for a make-up session must reflect the number of minutes performed during the week leading up to the session that was missed. If this information is not available, the organization should record 0.</p>
Umbrella Arrangements	CDC proposed allowing umbrella arrangements to let an organization with full or preliminary CDC recognition serve	a) Commenter #14 recommended adding language that makes it clear	<p>a) CDC agrees to add language specifying that umbrella organizations must submit applications to the DPRP.</p> <p>b) CDC does not agree to allow subsidiaries to maintain</p>

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	<p>as the sponsoring hub for a group of organizations (subsidiaries) that have CDC pending, preliminary, or full recognition.</p>	<p>that umbrella organizations must submit applications to the DPRP.</p> <p>b) Commenter #27 encouraged CDC to allow subsidiaries to maintain their recognition status independent of the umbrella organization.</p> <p>c) Commenter #27 also asked CDC to allow non-delivery organizations to serve as hubs, noting their potential to provide greater support through their resources and networks.</p> <p>d) Commenter #30 had several questions regarding umbrella arrangements, including potential disincentives to joining an umbrella arrangement, the types of support hubs would provide, and recourses available to both hubs and subsidiaries if</p>	<p>recognition status independent of the umbrella arrangement. Organizations that voluntarily choose to join umbrella arrangements generally do so because they are unable to maintain independent recognition status due to low numbers of enrollees. The main purpose for establishing umbrella arrangements is to allow smaller organizations to partner together to maximize enrollment and share the administrative and billing infrastructure costs necessary to become sustainable over the long-term. Organizations should carefully analyze the costs and benefits of this arrangement, as umbrella arrangements will not meet the needs of all organizations.</p> <p>c) CDC is in the second year of a two-year demonstration project to look at the feasibility of letting non-delivery organizations serve as umbrella organizations. Through the demonstration project, we are attempting to address the potential legal issues that can arise when non-delivery organizations attempt to bill public and private payers on behalf of delivery organizations participating in the umbrella arrangement. When the demonstration concludes, CDC will issue revised program guidance on this issue.</p> <p>d) There are both costs and benefits to joining an umbrella arrangement. Since we are in a learning phase, we are holding umbrella hub organizations harmless for the first two years of the arrangement, and they</p>

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		<p>the umbrella arrangement is not working.</p> <p>e) Commenter #28 strongly recommended that CDC establish a robust set of standards and an enforcement mechanism for umbrella arrangements to ensure that subsidiaries are meeting quality standards. They also asked a question regarding the ability of subsidiaries to bill Medicare if the umbrella hub is an approved MDPP supplier.</p>	<p>will not be at risk of losing CDC recognition during that time period. Current guidance requires both hubs and subsidiaries to sign agreements specifying any support services that will be provided by the hub and the recourses available if the arrangement is not working either during or after the initial two-year period. The guidance document may be obtained from the National DPP Customer Service Center.</p> <p>e) CDC assures the commenter that the hub and the subsidiaries participating in an umbrella arrangement must meet the current DPRP Standards. CDC does not propose to impose additional requirements on these organizations. All organizations, including those participating in an umbrella arrangement, are subject to the Quality Review requirements of the Standards. As part of a Quality Review, CDC can investigate any allegations of substandard performance.</p> <p>An umbrella hub may submit an application to become an MDPP supplier. Billing arrangements for subsidiaries will vary depending on how the MDPP supplier application is configured. Specific questions regarding MDPP supplier applications and MDPP billing must be submitted to CMS for response.</p>
<p>Requirements for Pending, Preliminary, and Full Recognition:</p>	<p>CDC proposed evaluating organizations that retain at least 5 completers in the evaluation cohort.</p>	<p>a) Commenter #5 requested that CDC also provide organizations with an</p>	<p>a) CDC does not agree to this change. While CDC encourages organizations to review data on all participants, at the current time we do not have the resources to generate</p>

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<p>9-month attendance required across all recognition categories for at least 5 participants</p>	<p>(Completers are eligible participants who attended at least 8 sessions in months 1-6 and whose time from the first session held by the cohort to the last session attended by the participant is at least 9 months). Cohorts are evaluated after 12 months.</p>	<p>evaluation of outcomes for the participants attending <9 months.</p> <p>b) Commenter #5 also expressed concern that specifying a minimum of 5 completers would contribute to gaps in access in rural communities and asked that CDC consider further reducing this minimum.</p> <p>c) Commenter #14 recommended changing the definition of completer to include participants who attended at least 9 sessions over a period of 9 months, noting that it could be simply explained by the expression "9 in 9." The commenter also suggested adding a requirement that participants start no later than session 4.</p> <p>d) Commenter #16</p>	<p>reports not directly related to recognition. We will continue to investigate the possibility of making additional reports available as resources permit.</p> <p>b) CDC is not able to change this requirement, as it was developed to support CMS's implementation of the MDPP Expanded Model. Organizations that are not able to retain the minimum number of completers are encouraged to explore the possibility of joining an umbrella arrangement to help provide access to participants in rural communities.</p> <p>c) While CDC appreciates the commenter's objective to simplify the definition, we do not accept this change, as it does not differ significantly from the current definition which has already been vetted with CMS and other stakeholders. In terms of starting no later than session 4, CDC stated in Appendix F that we "strongly recommend that organizations do not enroll participants who begin attending the class later than 14 days of the first scheduled session for the group cohort. Organizations will have the option of defining cohorts or allowing each participant to serve as their own cohort." We feel this meets the commenter's needs.</p> <p>d) CDC does not agree to shorten or otherwise redefine the terms of completion for the National DPP LCP. The evidence for the yearlong intervention is based on studies cited in Supporting Statement A of this ICR which continue to</p>

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		<p>recommended that the program be shortened to nine months and/or that completer status be based on sustained weight loss and minutes of physical activity at five consecutive sessions.</p> <p>e) Commenter #12 asked if CDC would grant “grandfathered” full CDC recognition status to existing Special Diabetes Program for Indians (SDPI) programs.</p> <p>f) Commenter #12 also asked if CDC would eliminate cohort size minimums (minimum of five participants) for tribal programs, as tribal programs are generally small, and this is a barrier to participation.</p>	<p>show a ‘dose response’ (i.e., more exposure over time results in greater type 2 diabetes risk reduction). Payers have agreed to provide coverage for the program on the basis of the existing evidence.</p> <p>e) In recognition of the expertise of tribes and tribal organizations that participated in the successful SDPI Diabetes Prevention Demonstration Project or Initiative (2004-2016), the CDC, with input from the Indian Health Service (IHS), initiated a ‘grandfathering’ opportunity in 2019, enabling these Tribal, Urban, and IHS programs to advance automatically from the initial “pending” level of recognition to “preliminary” upon application to the CDC DPRP. Preliminary recognition can expedite a program’s ability to apply as an MDPP supplier. Thirteen alumni SDPI Diabetes Prevention Demonstration Project or Initiative programs were grandfathered in 2019 and 2020, if there are others, CDC can grandfather them as well.</p> <p>We appreciate the suggestion to expand the grand-fathering opportunity to all SDPI programs, and we have given this request careful consideration. We agree to extend preliminary recognition to SDPI programs with previous experience offering a yearlong type 2 diabetes prevention lifestyle change program. This prior experience is critical to help ensure these organizations have the best chance at success in the National DPP.</p>

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			<p>Organizations will need to submit applications to the DPRP indicating the CDC-approved type 2 diabetes prevention curriculum they will use. The 2021 Standards propose allowing these organizations to remain in preliminary recognition status indefinitely if they make data submissions at the approved intervals (every 6 months) and are able to meet the requirements for preliminary recognition within 3 years of first achieving it, and then at least every 3 years thereafter. CDC will reach out to these organizations to inform them of this change and encourage their application.</p> <p>f) By allowing SDPI-funded tribes to enter the DPRP in preliminary recognition, CDC is waiving the initial requirement of having 5 participants who meet the criteria for completion. For tribal organizations that are never able to achieve the 5-participant minimum, the CDC offers the umbrella arrangement. Under this model, organizations can partner together to maximize enrollment and share the administrative and billing infrastructure costs necessary to become sustainable over the long-term.</p>
<p>Requirements for Pending, Preliminary, and Full Recognition: Preliminary</p>	<p>CDC proposed that an organization may remain in preliminary recognition indefinitely if it continues to submit the required data</p>	<p>a) Commenter #14 recommended that CDC limit preliminary recognition to 4 years and return organizations to</p>	<p>a) CDC does not agree to place time restrictions on preliminary recognition. We worked with CMS on this requirement to ensure continuity and access to the MDPP Expanded Model for Medicare beneficiaries. Preliminary recognition ensures that organizations are offering</p>

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	every 6 months.	<p>pending recognition after that time. The commenter also recommended that organizations be moved to preliminary recognition so as not to disrupt MDPP supplier status and payment.</p> <p>b) Commenter #21 asked CDC to clarify if subsequent evaluation cohorts need to meet the requirements for preliminary, or if a one-time achievement plus ongoing data submissions is sufficient for indefinite preliminary status.</p>	<p>the program with fidelity to the scientific evidence. Even if they are not achieving the outcomes at an organizational level required for full recognition, individual participants may be meeting payer outcome requirements. Extending preliminary recognition indefinitely does not jeopardize quality and does expand access. CDC has further clarified its preliminary timeline in b) below.</p> <p>b) CDC agrees to clarify that once an organization meets the requirements for preliminary, the organization may remain in preliminary recognition indefinitely if it continues to submit the required data every 6 months and is able to meet the requirements for preliminary within 3 years of first achieving it, and then at least every 3 years thereafter.</p>
Requirements for Pending, Preliminary, and Full Recognition: Time in Full	<p>CDC proposed that an organization may remain in full recognition for 3 years if it continues to submit the required data every 6 months. CDC further proposed that organizations that do not meet the requirements for full recognition at</p>	<p>a) Seven commenters (#5, #15, #21, #22, #27, #29, and #30) asked that CDC remove the requirement that organizations wait for 6-months before reapplying after not re-achieving full</p>	<p>a) CDC agrees to allow those organizations still active and submitting data that do not re-achieve full recognition status after 36 months to return to preliminary.</p> <p>b) CDC clarifies that, once an organization meets the requirements for full recognition, it will be allowed to remain in full for 3 years despite not meeting the requirements, as long as it continues to make data submissions in every</p>

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	<p>the 36-month mark will lose recognition and will be required to wait 6 months before reapplying.</p>	<p>recognition within the 36-month period. In lieu of the waiting period, all commenters suggested that organizations return to preliminary recognition.</p> <p>b) Commenter #21 asked whether CDC would continue to evaluate participant data for cohorts enrolled after an organization achieves full recognition and, if so, what actions would be taken if the organization did not continue to meet the requirements for full recognition on the basis of those evaluations.</p>	<p>submission due month.</p>
<p>Requirements for Pending, Preliminary, and Full Recognition: Full, Requirement 6</p>	<p>CDC proposed three different participant outcomes that organizations could use to show a reduction in risk of developing type 2 diabetes among completers in the evaluation cohort. The proposed requirement is that at least 60% of all</p>	<p>a) Commenter #29 asked CDC to consider evidence showing that weight loss at levels below 5% still reduces the risk of developing type 2 diabetes.</p> <p>b) Commenter</p>	<p>a) While CDC agrees that weight loss percentages less than 5% can reduce the risk of developing type 2 diabetes, we acknowledge they will not lead to the same risk reduction as the current 5%. Many payers, including CMS, have based their coverage decisions on the risk reductions associated with 5% weight loss. In developing the two new outcome metrics, we attempted to approximate a</p>

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	<p>completers achieve one of the following outcomes:</p> <ul style="list-style-type: none"> a. at least 5% weight loss 12 months after the cohort began, or b. at least 4% weight loss and at least 150 minutes/week on average of physical activity 12 months after the cohort began, or c. at least a 0.3% reduction in HbA1C. 	<p>#24 asked how CDC arrived at the requirement that 60% of participants must achieve one of the three outcome metrics.</p> <p>c) Commenters #24, #26, and #30 asked how CDC arrived at option b (combination of 4% weight loss and 150 minutes/week of physical activity) and requested that CDC produce the evidence supporting this recommendation. Similarly, Commenter #27 analyzed their own organization's participant data (N=3,918) against the proposed outcome measures for full recognition. They support the inclusion of optional variables but encourage CDC to mine its own data to determine if there is much difference among options, particularly by</p>	<p>risk reduction of 5%. Thus, we are allowing a weight loss of 4% when combined with an average of 150 minutes/week of physical activity. Physical activity has an independent, although not equal, impact on reducing type 2 diabetes risk. Similarly, the 0.2% reduction in HbA1C (as an agreed change, please refer to Submitting Evaluation Data: HbA1C, below) also approximates risk reduction equal to a 5% weight loss. Please also see the response to item e) below.</p> <p>b) CDC's decision to keep the 60% requirement for evaluation cohorts meeting one of the three proposed outcome measures is a programmatic decision based on review of DPRP data. We wanted organizations to demonstrate that a majority of their completers achieved evidence-based outcomes. Since the minimum number of completers required is only 5, and 50% of 5 is 2.5 participants, we rounded up to 3 participants (or 60% of completers). This requirement is carried over from previous iterations of the DPRP Standards.</p> <p>c) CDC will keep optional outcome variable b, as many stakeholders have commented that it will be helpful. Also, a CDC meta-analysis of recent literature showed that interventions offering only physical activity were independent predictors of reduced type 2 diabetes risk (X. Zhang et al., Effect of lifestyle interventions on glucose regulation among adults without</p>

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		<p>race/ethnicity.</p> <p>d) Commenter #26 supported a weight loss outcome of at least 3% and cited a report from the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Obesity Society (2013). Similarly, Commenter #12 asked for the weight loss to be lowered to 3%.</p> <p>e) Commenter #30 asked if option a (5% weight loss) could be reduced to 4%, citing a study by Ely et al. showing that only 35.5% of National DPP participants achieved 5% weight loss, even with median attendance of 14 sessions.</p> <p>f) Commenter #12 encouraged the utilization of IHS Diabetes Audit measures,</p>	<p>impaired glucose tolerance or diabetes: A systematic review and meta-analysis. Diabetes Research and Clinical Practice Volume 123, January 2017, Pages 149-164). Delahanty et al. also summarized literature on the impact of regular physical activity and the prevention of type 2 diabetes (L.M. Delahanty, J Am Diet Assoc. 2006 May; 106(5): 698–705).</p> <p>d) CDC does not agree to lower the weight loss outcome from a minimum of 5% to a minimum of 3%, as this does not reflect the evidence cited in Supporting Statement A. Also, CMS, participating state Medicaid programs, and many private insurers require a minimum weight loss of 5% for reimbursement.</p> <p>e) CDC does not agree to lower the 5% weight loss goal for several reasons. We do not expect all participants to achieve 5% weight loss. For quality assurance purposes, we look at weight loss at the organizational level, not at the participant level. We are seeing an increase in the number of organizations that meet the outcome requirements for full recognition, and, with the changes we have proposed, we expect to see an even greater number of organizations achieve full recognition. Recognition requirements do not reflect payer requirements, and we expect many payers will continue to reimburse on the basis of a 5% weight loss.</p> <p>f) Three data elements in the CDC DPRP Standards are also</p>

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		<p>which have been successful variables in the SDPI. These measures include reductions in blood sugar levels, reduced hypertension risk, lower BMI levels, increased intake of healthy foods, and increased rate of physical activity.</p> <p>Commenter #12 suggested that harm reduction and other risk-related factors be used instead of weight loss, and noted that use of these types of measures would provide a holistic approach to assist in addressing issues or disparities amongst different groups.</p> <p>g) Commenter #12 also recommended that CDC include a mental health measurement as part of</p>	<p>included in the IHS Diabetes Audit (weight, physical activity minutes, and HbA1C as a proposed optional DPRP data point). It should be noted that the IHS Diabetes Audit monitors data on people with diagnosed diabetes, while the National DPP lifestyle change program serves people with prediabetes or at high risk for type 2 diabetes.</p> <p>g) CDC recognizes the importance of addressing participants' mental health as a key to programmatic success. While mental health measurement is not part of the evidence-based curriculum, stress management, coping with triggers, and taking charge of your thoughts are all addressed to help participants maintain healthy lifestyle changes achieved through the program.</p>

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		<p>integrated care. Behavioral health plays a significant role in lifestyle/behavior change as well as weight loss. The commenter noted that this is especially vital in Indian Country where communities also face the reality of historical trauma.</p>	
<p>Requirements for Pending, Preliminary, and Full Recognition: Table 3</p>	<p>CDC proposed to measure recognition requirements 12 months after the cohort began. CDC provided an example of how it evaluates organizational performance over the course of the 12-month intervention in Table 3.</p>	<p>a) Commenter #5 requested that CDC consider measuring results from the last session participants attended rather than 12 months after the cohort began.</p>	<p>a) CDC does not agree to this change because we do not evaluate cohorts until 365 days (12 months) have lapsed since the first session was held. However, per the complete definition, any eligible participant attending after month 9 (and attending at least 8 sessions in the first 6 months) would have their data included within the overall cohort weight loss calculation.</p>
<p>Submitting Evaluation Data- General concerns regarding making data system changes to accommodate the new data collection requirements</p>	<p>While CDC proposed new data collection requirements, the proposed Standards do not address transition issues, especially as they relate to making major system upgrades.</p>	<p>a) Commenter #22 pointed out that many CDC-recognized organizations use programmed platforms to collect, track, and submit their data, and requested that CDC allow transition time for system upgrades to</p>	<p>a) CDC agrees to provide transition guidance before the release of the 2021 DPRP Standards and to permit enough time for system upgrades.</p> <p>b) CDC does not agree to eliminate the new variables collected during enrollment (i.e., gender, enrollment motivation, Coach ID). While there is an additional burden associated with the new items, it is a one-time only collection. These data are important for generating additional information to assist</p>

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		<p>align with the new 2021 DPRP Standards.</p> <p>b) Commenter #26 noted that adding data collection variables as part of the enrollment process could discourage participant enrollment and asked CDC to reconsider the need for the new items.</p> <p>c) Commenter #12 asked CDC to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses). OMB has determined that it takes 2 hours to collect and report the information for each participant.</p>	<p>CDC in better understanding and informing efforts to strengthen participant recruitment and program delivery.</p> <p>c) Additionally, CDC anticipates that its transition to a DPRP data submission portal will streamline the data submission process and reduce organizational data management burden.</p>

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<p>Submitting Evaluation Data: HbA1C</p>	<p>CDC proposed a 0.3% reduction in HbA1C as an optional outcome variable and provided guidance on collection and submission timelines:</p> <ul style="list-style-type: none"> The initial HbA1C value should be taken within a year prior to enrollment and reported at the first session of the program. The final HbA1C value must be recorded as part of the last session record in months 10-12. 	<p>a) Several commenters from national organizations applauded CDC for the inclusion of this new optional variable for recognition.</p> <p>b) Commenter #5 provided published 2020 research studies that CDC did not have access to when conducting the initial literature review. They also highlighted forthcoming (currently non-published) program research in support of a lower than 0.3% reduction in HbA1C and requested consideration of a 0.1% reduction. Commenters #24 and #30 also asked for further justification for the 0.3% reduction in HbA1C.</p> <p>c) Commenter #10 did not support using HbA1C as an outcome variable due to potentially high additional costs</p>	<p>a) With each new revision of the DPRP Standards, CDC strives to examine new research, mine DPRP data, and listen to the needs of its stakeholders. Thank you for your support of this new variable inclusion.</p> <p>b) Based on a review of the additional evidence submitted, CDC agrees to lower the reduction in HbA1C to 0.2%. We concluded that the current evidence on the relationship between body weight reduction via lifestyle intervention and HbA1C changes is mixed and depends on many factors such as the initial HbA1C level, program intensity, and a person's status on the prediabetes/diabetes spectrum. Using a regression model and the new evidence provided, CDC estimates a 5% bodyweight reduction is associated with a 0.2% HbA1C reduction in persons with prediabetes, which was calculated as $-0.21\% [y=0.0448*(-0.05)+0.0001]$.</p> <p>The following 18 studies were included in this model and serve as justification: Ackermann et al. (2008); Aldana et al. (2005); Ashra et al. (2015); Balk et al. (2015); Daftarian et al. (2020); Galaviz et al. (2018); Gummesson et al. (2017); Knowler et al. (2002); Kramer et al. (2018); Marrero et al. (2016); Moin et al. (2017); Mudaliar et al. (2016); Pi-Sunyer et al. (2007); Roumen et al. (2008); Sauder (2020); Sepah (2014); Toro-Ramos (2020); and Tuomilehto et al. (2001).</p> <p>c) CDC does not agree to eliminate this option. The use of</p>

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		<p>for healthcare providers, the possibility of lab testing errors, and the lack of evidence that use of this variable will impact social determinants of health.</p> <p>d) Commenter #8 asked whether CDC would be providing funding support, noting that Medicare does not cover HbA1C testing.</p> <p>e) Commenters #13 and #30 asked if these data could be self-reported, or if they need to come from a lab or other source.</p> <p>f) Commenter #15 asked if a point of care (PoC) HbA1C test could be used.</p> <p>g) Commenters #21 and #30 asked CDC to consider changing the requirement that the initial HbA1C test be recorded at the first session to allow recording by the fourth session or within the first</p>	<p>pre- and post-intervention HbA1C is entirely optional as a program outcome variable and is supported by the literature listed in b) above.</p> <p>d) CDC does not have the resources to provide funding support for HbA1C testing. This is an optional variable that many current organizations have the capacity to implement. There are two other outcome variables that organizations can use for recognition purposes that have no associated costs.</p> <p>e) CDC agrees to allow participant self-report of HbA1C levels for both eligibility purposes and as an outcome variable for determining recognition status. But payers, such as CMS, may require additional documentation from the participant such as a report from a lab or physician's office.</p> <p>f) CDC agrees to allow PoC HbA1C tests when FDA devices approved specifically for this purpose are used. (See the resources below). CDC will not monitor the devices used. This will be the CDC-recognized organization's responsibility. CDC will add this information to the 2021 DPRP Standards.</p> <ul style="list-style-type: none"> • https://pubmed.ncbi.nlm.nih.gov/30236830/ • https://abbott.mediaroom.com/2019-06-17-Abbott-Launches-First-ever-Rapid-Point-of-Care-HbA1c-Test-to-Aid-in-the-Diagnosis-of-Diabetes <p>g) CDC agrees to permit recording of the initial HbA1C test result within the first 14 days of the program. We do not agree to permit recording within</p>

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		<p>few weeks of the program. Commenter #27 also asked if HbA1C could be recorded within the first 4 sessions.</p> <p>h) Commenter #30 asked if all participants in an organization's program need to use HbA1C as the outcome metric, or whether CDC would accept a hybrid model of HbA1C and weight data. Commenter #28 asked whether any one of the 3 outcome metrics would count towards the 60% requirement, and how participants would be evaluated if they met multiple outcome metrics. Commenter #8 asked if HbA1C could be used per cohort and asked for clarification on how to operationalize this.</p>	<p>the first 4 sessions, since this could extend more than a month. If organizations plan to use HbA1C test results as a potential outcome measure, they should plan to obtain this information within the first 14 days to establish a baseline and allow sufficient time to demonstrate a contributory HbA1C reduction. We will add this language to the 2021 DPRP Standards.</p> <p>h) Participants within a given cohort may meet one or more of the outcome metrics (i.e., an organization does not need to select one metric for use by all participants). For example, if there are 10 completers in a cohort, as long as 6 of them (60%) meet one of the three criteria for risk reduction, the organization will meet that requirement. (i.e., there could be 4 participants who meet the 5% weight loss requirement, 2 who meet the 4% weight loss/150 physical activity minutes requirement, and 0 meeting the HbA1C reduction requirement.) If a single person meets more than one criterion, it still counts as one. To further clarify, if a completer meets any one of the three criteria detailed in Requirement 6, they count towards the 60%; however, if they meet more than one, they only count once.</p>
Submitting Evaluation Data: 5%	CDC proposed to continue the use of a 5% weight	a) Two commenters (#17 and #18)	a) CDC does not agree to remove this requirement.

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<p>weight loss</p>	<p>loss variable as one of three possible outcome variables required for full CDC recognition.</p>	<p>recommended that the requirement for 5% weight loss be removed from the 2021 DPRP Standards as a means for organizations to achieve full CDC recognition. They stated that weight it is a barrier to program participation because it can be viewed as stigmatizing.</p>	<p>Weight loss is based on findings from the original 2002 DPP randomized control trial and follow-up efficacy studies and has been used in successful program replication in other countries. These studies demonstrated that a moderate weight loss of 5-7% achieved through an evidence-based lifestyle change program over a year-long period of time that led to a 58% reduction in conversion to type 2 diabetes in adults with prediabetes aged 20-59, and a 71% risk reduction in adults aged 60+ (studies cited in Supporting Statement: Part A of OMB No. 0920-0909). Weight loss was the primary predictor of type 2 diabetes risk reduction in the DPP. For every kilogram of weight loss, there was a 16% risk reduction among lifestyle intervention participants. Weight loss as an outcome variable is widely supported by National DPP stakeholders, as it is an easy metric to obtain and/or to have participants self-report. Also, CMS and other insurers recognize the weight loss goal of 5% as an evidence-based outcome for reimbursement. This coverage helps with program sustainability.</p>
<p>Table 4. Data Dictionary: Evaluation Data Elements—Adding elements/outcome measures</p>	<p>CDC proposed outcome variables related to weight loss, physical activity minutes, and reduction in HbA1C.</p>	<p>a) Commenter #16 recommended adding additional evaluation/outcome variables based on literature reviews, including reduced blood pressure,</p>	<p>a) CDC does not agree to add additional evaluation/outcome variables, as the current variables are linked to a strong body of evidence as cited in Supporting Statement A accompanying this ICR. The addition of evaluation/outcome variables would increase the data collection burden on CDC-recognized organizations. The goal of the current variables is</p>

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		lowered cholesterol levels, increased consumption of fruits and vegetables, and smoking cessation.	to meet evidence-based outcomes for program recognition purposes with minimal burden to organizations.
<p>Table 4. Data Dictionary: Evaluation Data Elements—COHORTID</p>	<p>CDC proposed a new variable called Cohort ID to help organizations identify and monitor participants who enroll in the same class offering. CDC also provided organizations with the option of entering the participant ID as the cohort ID if the organization opts to let each participant serve as their own cohort (this is most commonly the case for organizations offering online delivery). Cohort IDs must be uniquely assigned and maintained by the applicant organization and must not contain any personally identifiable information (PII).</p>	<p>a) Commenter #27 asked for further clarification about the Cohort ID variable. Specifically, they asked how to handle changes associated with participants changing cohorts.</p> <p>b) Commenter #19 asked if CDC is able to provide additional analysis to help organizations better understand cohort characteristics.</p>	<p>a) CDC agrees to add language explaining how to handle participants who change cohorts. If a participant changes to a new cohort, it is strongly recommended that the new cohort be on the same timeline as the initial cohort, because the participant will now be evaluated on the timeline of the new cohort. If a participant joins a cohort that is not on the same timeline, the organization can use the Participant ID as the Cohort ID to indicate the person will be on an individual timeline.</p> <p>b) CDC does not provide analyses by cohort.</p>
<p>Table 4. Data Dictionary: Evaluation Data Elements—COACHID and Class ID</p>	<p>CDC proposed adding a Coach ID variable for each cohort to help both CDC and program delivery organizations better understand</p>	<p>a) Commenter #2 asked that CDC make changes to accommodate situations where multiple coaches lead</p>	<p>a) CDC does not agree to revise the Coach ID variable to allow reporting of more than one coach per cohort. We ask that the organization simply pick one coach per cohort. Please see d) below for more information.</p>

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	<p>the impact of coaches on participant outcomes. For example, organizations could improve program quality by assessing the types of advanced coach training that lead to higher participant retention and achievement of outcomes.</p>	<p>the same cohort.</p> <p>b) Commenter #8 asked if CDC would be providing evaluation report feedback for Coach ID and Class ID and requested further justification for this data collection if there were no plans to provide this feedback. Similarly, commenters #27 and #30 were concerned about the increased burden of tracking and reporting these IDs, as coaches may vary from session to session. Commenter #8 also asked that CDC consider eliminating this variable due to the data collection burden.</p> <p>c) Commenter #13 wanted to know if CDC would also be collecting data on where coaches received their education and training and what</p>	<p>b) While CDC will not be able to provide feedback to individual organizations, we could provide aggregate feedback to help organizations provide support to coaches; this will be considered. Based on lessons learned from CDC's 1705 grantees, tracking data by cohort allows for better monitoring and improved outcomes.</p> <p>c) CDC will not be collecting information about coaches that goes beyond the scope of the National DPP-specific training offered by MOU-holding Lifestyle Coach training entities or beyond CDC's needs for evaluation data. However, CDC does encourage organizations to seriously consider the recommendations provided in APPENDIX C. STAFFING GUIDELINES, ROLES, AND RESPONSIBILITIES; AND SAMPLE POSITION DESCRIPTIONS within the 2021 DPRP Standards. Organizations should keep coaches' previous education and experience relevant to their target audiences in mind during hiring decisions.</p> <p>d) CDC will not use Coach ID as a means of evaluating an organization for recognition status. CDC has always aggregated participant data for recognition purposes. CDC has never analyzed data per participant and reported data back to organizations in that manner. Organizations can examine their own data in such a way as to help individual participants where needed. As a public health agency, CDC recognizes successful organizations that deliver the yearlong LCP to a cohort</p>

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		<p>experiences they had before becoming National DPP Lifestyle Coaches.</p> <p>d) Commenters #13 and #30 expressed concern about Class ID and Cohort ID analyses “removing the individuality of the program participants.”</p> <p>e) Commenter #21 asked which coach information will need to be supplied and updated by CDC-recognized organizations.</p> <p>f) Commenter #26 urged CDC to allow flexibility for organizations with approved (data) models that may find implementation of the Coach ID variable challenging.</p> <p>g) Commenter #28 asked how information should be reported to CDC if a substitute coach is used for a session(s).</p>	<p>(group) of participants. This information is being collected for program improvement purposes and in response to grantee feedback/lessons learned.</p> <p>e) CDC-recognized organizations will provide Coach ID on the data spreadsheet they submit to the DPRP and coach training information on their initial (one-time) application.</p> <p>f) CDC agrees to work with organizations that find this challenging.</p> <p>g) Coach ID represents the coach assigned to lead the cohort. CDC reiterates that any substitute coach should be trained as specified under the DPRP Standards. Long-term substitute coaches should be reflected on the data (CSV) file, whereas a one-time substitute coach does not need to be reflected on the data file.</p>

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<p>Table 4. Data Dictionary: Evaluation Data Elements—Removal of SESSID</p>	<p>CDC proposed removing the Session ID variable (SESSID). SESSID was the variable that numbered the order of sessions delivered within the yearlong LCP.</p>	<p>a) Several commenters thanked CDC for removing this variable.</p> <p>b) Commenters #8 and #19 asked that SESSID not be removed due to a concern about CDC's ability to calculate a retention rate if SESSID is removed.</p> <p>c) Commenter #10 asked that CDC keep the SESSID variable, noting that clinical outcomes correlate to the number of sessions attended. They further noted that being able to link sessions attended with other variables such as physical activity minutes and participant engagement is helpful in monitoring the program.</p>	<p>a) CDC is attempting to minimize data collection burden on CDC-recognized organizations wherever possible.</p> <p>b) CDC does not agree to reinstate the SESSID variable. The removal of SESSID does not impact CDC's ability to calculate retention rates or any other performance-related measure.</p> <p>c) CDC does not agree to keep SESSID for these reasons, as participant data such as weight and physical activity minutes will still be recorded for each session and will be available for analysis. Removing the SESSID variable only results in removing the numbering identification for each session (session 1, session 2, etc.).</p>
<p>Table 4. Data Dictionary: Evaluation Data Elements—</p>	<p>CDC proposed splitting the 2018 ENROLL variable into two separate variables, ENROLL-HC (i.e.,</p>	<p>a) Commenter #20 suggested re-combining ENROLL-HC and ENOLL-MOT and using</p>	<p>a-b) CDC does not agree to re-combine the ENROLL-MOT and ENROLL-HC variables, as DPRP data indicated that organizations and participants did not understand the previous</p>

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<p>ENROLL-HC and ENROLL-MOT</p>	<p>enrollment source) and ENROLL-MOT (i.e., enrollment motivation) to capture information on two distinct concepts. For example, two people may have both been referred by a physician but may have totally different personal motivations for acting/not acting on that referral.</p>	<p>a larger dropdown menu to present a wider range of response options. Similarly, Commenter #27 recommended re-combining the ENROLL-HC and ENROLL-MOT variables into one as per the 2018 DPRP Standards.</p> <p>b) Commenter #28 recommended making ENROLL-MOT optional and eliminating ENROLL-HC. They indicated that, because they are a large online provider, collection of this information for thousands of participants will be difficult.</p>	<p>collapsed variable. CDC also does not agree to eliminate either variable or to make either variable optional. The 2018 ENROLL variable included <i>both</i> people who had referred participants to the intervention and participants' motivations for having enrolled in the intervention, making it difficult to draw appropriate conclusions from these data. Information on healthcare provider referrals (ENROLL-HC) is needed by key National DPP stakeholders and is also used as a metric for an agency-wide priority under CDC's Strategic Framework.</p>
<p>Table 4. Data Dictionary: Evaluation Data Elements—Sex and Gender</p>	<p>CDC proposed separate variables for sex and gender. For the sex variable, participants should indicate their sex at birth as male, female, other, or not reported. For the gender variable,</p>	<p>a) Commenter #21 asked that CDC provide clarification on how to handle the new sex and gender variables in their transition plan for the 2021</p>	<p>a) CDC agrees to provide guidance on how to handle the new variables for already enrolled participants in the form of a transition plan for organizations before 3/1/2021.</p> <p>b-c) CDC agrees to follow the OMB guidance recently distributed on the collection of sex and gender information</p>

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	<p>participants should indicate the gender with which they identify as male, female, other, or not reported.</p>	<p>Standards.</p> <p>b) Commenter #25 encouraged CDC to align its sex and gender categories with other Federal reporting systems, such as HRSA.</p> <p>c) Commenter #28 asked CDC to consider a non-disclosed option for privacy purposes.</p>	<p>(when self-reported), which is as follows: SEX 1 = male, 2 = female, 9 = not reported; GENDER 1 = male, 2 = female, 3 = transgender, 9 = not reported (will be provided).</p>
<p>Table 4. Data Dictionary: Evaluation Data Elements—Physical Activity (PA) Minutes</p>	<p>CDC proposed to continue the collection of PA minutes per participant per each session attended.</p>	<p>a) Commenter #21 requested that CDC discontinue the option of using 997 as a cap on PA minutes.</p>	<p>a) CDC agrees that participants who enroll on/after 3/1/2021 will not have the option of using 997 as a cap on PA minutes.</p>
<p>Appendix C. Staffing Guidelines, Roles and Responsibilities; and Sample Position Descriptions</p>	<p>CDC provided guidance and sample job descriptions for Lifestyle Coaches and Program Coordinators.</p>	<p>a) Commenter #27 stated that CDC should take into consideration that staff have other responsibilities such as updating marketing materials and websites.</p>	<p>a) CDC assures the commenter that other staff roles and responsibilities regarding marketing have been taken into consideration and are reflected: “Program Coordinators may engage in other key functions such as publicity and marketing of the National DPP LCP, which may require assistance from senior leadership in the organization.”</p>
<p>Miscellaneous – Collection of additional information within the 2021 DPRP Standards</p>	<p>CDC proposed to collect additional information as part of the online application, including Coach IDs, names of training entities</p>	<p>a) Commenters #7 and #8 asked if CDC was going to collect this additional information from both new</p>	<p>a) CDC has already collected these data previously from existing organizations by e-mailing the organizations upon each application submission. They do not have to take any action. The proposed process will formalize this data</p>

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<p data-bbox="240 1377 394 1556">Miscellaneous – Targeting of programs and mapping</p> <p data-bbox="240 1866 394 1892">Miscellaneous</p>	<p data-bbox="477 548 699 768">used to train coaches, and the availability of live coach interaction provided as part of virtual delivery modes.</p>	<p data-bbox="773 264 963 779">and existing organizations. If the requirement will apply to existing organizations, the commenter asked CDC to explain how the information would be collected, since applications for existing organizations have already been approved.</p> <p data-bbox="773 810 954 989">b) Commenter #7 further inquired as to what the actual questions would be.</p>	<p data-bbox="1039 369 1409 457">collection within the automated application moving forward with new organizations.</p> <p data-bbox="1039 489 1409 978">b) CDC will provide the questions in the online application. They are very similar to the questions asked via follow-up e-mail to organizations after they applied under the 2018 DPRP Standards. They are summarized as follows in Attachment 5: intensity of live coach interaction per session; how curriculum is delivered; how/when weight and PA minutes are collected via virtual programs; and participant module delivery options.</p>
	<p data-bbox="477 1171 699 1791">CDC proposed that, upon application approval, organizations will provide CDC with any public class locations and other pertinent organization/recognition information. Organizations would also provide six-month updates on class locations to the DPRP for program location mapping purposes.</p>	<p data-bbox="773 1241 954 1692">a) Commenter #3 requested that CDC include(s) prospective areas/cities within the U.S. where the programs will take place to ensure target areas and populations are accordingly met.</p> <p data-bbox="773 1866 954 1892">a) Commenters</p>	<p data-bbox="1039 1272 1409 1665">a) CDC maps and displays the locations of program delivery organizations in its new National DPP Operations Center. We expect to make modules within the Operations Center available to external partners in 2021. Additionally, CDC supports grantees whose work includes targeting areas where those at highest risk for type 2 diabetes are, including areas currently underserved.</p> <p data-bbox="1039 1866 1390 1892">a) CDC agrees to explore this</p>

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<p>us – DPRP Data Submission Portal</p>		<p>#20, #29, and #30 asked that CDC consider revising its DPRP data submission portal to eliminate the need to enter participant-level static variables for each session. They noted that this would minimize both the data reporting burden and the likelihood of data submission errors.</p>	<p>possibility internally.</p>
<p>Miscellaneous – CDC use of the acronym National DPP LCP</p>	<p>Throughout the proposed 2021 DPRP Standards, CDC uses the acronym National DPP LCP for National Diabetes Prevention Program (National DPP) lifestyle change program (LCP).</p>	<p>a) Commenter #5 noted that this acronym is repetitive and hard to use, and suggested that CDC consider using something simple such as diabetes prevention program.</p>	<p>a) CDC does not agree to use “diabetes prevention program” as the acronym for this program. The term “Diabetes Prevention Program”, or “DPP”, historically refers to the DPP randomized control trial. CDC has been careful and deliberate over the past decade to brand its evidence-based, yearlong intervention as the National DPP lifestyle change program (LCP). This includes branding on web pages, policy documents, internal and external stakeholder documents and web pages; and with the MDPP, Congress, Medicaid, private insurers, and other stakeholder groups. Conversely, the term “National DPP” refers to the larger partnership of public and private organizations working collectively to build a nationwide delivery system for this lifestyle change program in the U.S.</p>
<p>Miscellaneous – Data</p>	<p>CDC has historically issued</p>	<p>a) Commenter</p>	<p>a) CDC agrees that a transition period is needed and will email</p>

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<p>transition guidance from 2018 to 2021 DPRP Standards</p>	<p>guidance to assist organizations in transitioning to the current version of the DPRP Standards and plans to do the same this year as soon as OMB approves the ICR package.</p>	<p>#21 asked if CDC plans to analyze data against the 2018 Standards, the 2021 Standards, or both during the transition to the 2021 Standards. Similarly, Commenters #27 and #30 agreed that a transition period is needed.</p>	<p>guidance to all CDC-recognized organizations prior to the anticipated March 1, 2021 go-live date for the 2021 DPRP Standards. All submissions made after that date will be evaluated under the 2021 Standards. Submissions for February 2021, due in March, will likely be delayed to allow transition time for both CDC and the organizations.</p>
<p>Miscellaneous— Anticipated impact of the COVID-19 PHE on 2021 DPRP Standards implementation</p>	<p>CDC provided program implementation and data coding guidance in March 2020 regarding the PHE; see Delivery Mode: Application, item a) within this table above.</p>	<p>a) Commenter #21 asked how the 2021 Standards would be impacted if the PHE declaration has not been lifted by June/July 2021. Specifically, they asked if in-person delivery organizations could continue to offer virtual sessions using their in-person org code. Similarly, Commenter #22 asked that CDC continue to apply the PHE guidance in 2021 with emphasis on allowance of virtual options for coaches and participants.</p>	<p>a) CDC agrees to extend current PHE guidance and distribute it closer to the release of the 2021 DPRP Standards.</p> <p>b) CDC agrees to address transition guidance and practices in the least burdensome way possible, including enhancing the data submission portal for organization-level data.</p>

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		b) Commenter #21 requested that CDC, during this transition, incorporate guidance on, "inclusive, non-burdensome delivery practices that will support organizations in capturing participant-level data."	