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Submitter Info

Comment:	Thank you for putting on the very informative webinar, "Medicare Diabetes Prevention Program Model Expansion Listening Session" on 8/16/17. I do have two questions I am hoping you can help me with. 1) If our organization is currently in "Pending CDC Recognition" status and the next time we submit our data (Feb 2018), we remain in "Pending Recognition", does that have any bearing on our ability to achieve "Preliminary MDPP Recognition" as long as we meet the MDPP criteria? If not, how long can an organization have "Preliminary MDPP Recognition" status without having "Full CDC Recognition" status before it loses its ability to be reimbursed by Medicare? 2) Regarding the MDPP Ongoing Maintenance sessions for years 2 and 3, what are the expectations of suppliers? Is this just an opportunity for DPP graduates to attend a scheduled in-person session to report their body weight? Or do suppliers need to provide formal follow-up in-person classes with a curriculum and collect body weights? Thank you for your time. *
First Name:	Sheldon
Last Name:	Smith
ZIP/Postal Code:	84108
Email Address:	sheldon.smith@hsc.utah.edu
Organization Name:	
Cover Page:	HTML

American Association of Diabetes Educators
200 West Madison Suite 800
Chicago, IL 60622

Department of Health and Human Services
Leroy A. Richardson
Information Collection Review Office,
Centers for Disease Control and
Prevention, 1600 Clifton Road NE., MS–
D74, Atlanta, Georgia 30329.
Docket No. CDC–2017–0053

August 25, 2017

RE: CDC Diabetes Prevention Recognition Program (DPRP) (OMB Control Number 0920–0909, exp. 12/31/2017)— Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The American Association of Diabetes Educators (AADE) appreciates the opportunity to provide comments related to the Centers for Disease Control and Prevention (CDC) proposed 2018 Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures, published July 14, 2017.

AADE is one of six organizations in a cooperative agreement with the CDC to scale the National Diabetes Prevention Program nationwide and the only one to offer prevention education within Medicare certified diabetes self-management education programs. The "AADE DPP" model is a proven success for participants. In a recently published study of the original 25 AADE DPP programs revealing a more than 5% average weight loss, and a current average weight loss of more than 6%. AADE looks forward to continuing to support DPRP programs across the nation and contribute towards the overall sustainability of the National DPP.

AADE is pleased to see that the Centers for Medicare & Medicaid Services' (CMS) and CDC are working to align efforts with the 2018 Physician Fee Schedule Proposed rule, Medicare Diabetes Prevention Program (MDPP) and 2018 DPRP Standards and Operating Procedures. We urge CMS to maintain close alignment with the DPRP so suppliers are not troubled by to two different standards. To that end, the AADE provides the following comments on the proposed 2018 Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures.

Overarching Comments

Participant Eligibility

AADE appreciates that CMS has aligned with DPRP regarding the body mass index (BMI) requirement, program's participants must have a body mass index (BMI) of ≥25 kg/m2 (≥23 kg/m2, if Asian American). Identifying the eligibility qualifications for Medicare Diabetes Prevention Program (Medicare DPP) suppliers will eliminate potential confusion. AADE does encourage CDC to include verbiage stating that a health care professional referral would be needed for MDPP suppliers but not for DPRP recognition.

We appreciate the further clarification on participants who become pregnant during the program. However, if weight loss percent for women becoming pregnant can be calculated using data submitted prior to pregnancy, there is the potential for data to be skewed. We would encourage CDC to provide more information on whether a pregnant participant's last recorded weight will be what CDC analyzes or will they be eliminated from weight loss averages all together.

Guidance on Diabetes Self- Management Education and Support (DSMES)

AADE commends CDC for encouraging participants that develop type 2 diabetes while in the program be referred to a diabetes self-management education (DSME) program or continue in the CDC-recognized lifestyle change program while receiving DSME. However, to have accurate terminology, the National Standards uses Diabetes Self-Management Education and Support (DSMES). AADE encourages CDC to provide a definition on DSMES and the critical element of care for those people with diabetes.

Clarification should be provided if a program participants data has already been collected by DPRP and how a program can remove a participant that develops type 2 diabetes from there data or show that there was a diagnosis of type 2 diabetes. DPRP programs data may be negatively impacted by those that receive a type 2 diabetes diagnosis during the course of the program. It may appear that a program participant dropped out of program and affect program outcomes if they already attended 3 sessions or more.

We encourage CDC to develop a code where data will not be included when calculating average weight loss (similar to the pregnancy code). This will allow programs to still collect data on program participants but not be held responsible.

New Program Application

The standards suggest that any organization with the capacity to deliver an approved type 2 diabetes prevention lifestyle change program may apply for CDC recognition. We suggest CDC clearly define what an "organization" means.

Application Elements/Fields:

- **Class Type**. AADE is in support of the new application category "Class Type" but recommends that CDC's include more verbiage on how organizations can update DPRP if they identify future locations.

- **Organization Type.** For the category of "Organization Type", clarification on whether programs inputting information are to be referring to their main location or all the settings (which may differ) they may be delivering the program.

- **Program Coordinator Contact Information/ Data Preparer Contact Information.** More information on definition of program coordinator vs data preparer role and if they can be the same person. Additionally, AADE suggests CDC implement a change of status report to ensure accurate records and communication.

- **CDC Grantee.** AADE understands CDC wanting to improve the ability to assess an applicant organization's capacity in delivering the lifestyle change program but we suggest removing the "CDC Grantee" field/question to eliminate program confusion.

Delivery Mode

Clarification on individual program delivery modes will be beneficial to DPP providers and ensure accuracy in reporting. However, requiring programs to submit under multiple organizational codes for each delivery mode may cause confusion for DPP providers. AADE encourages CDC to take into consideration that programs may only delivery one type of mode upon initial application to become a DPRP recognized program but decide at a later date to deliver multiple modes of delivery. We encourage CDC to allow DPP program suppliers to only submit under one DPRP code but identify the delivery mode used by the coding value listed in the evaluation data elements.

Training

To effectively lead the lifestyle change program sessions and support and encourage participants, lifestyle coaches should be "required" to undergo a formal training. AADE suggests rewording to add "formal training" for LSC coaches (right now it only states formal training for Program Coordinator). AADE urges CDC to provide additional guidance on what is considered a formal training and the following verbiage, "In addition to the training entities listed on the CDC website, training may be provided by 1) a private organization with a national network of program sites, 2) a CDC-recognized virtual organization with national reach, or 3) a Master Trainer (a current or former National DPP Lifestyle Coach who has delivered at least one yearlong lifestyle change program)." In addition, clarification on what is considered a formal training for a MLSC and what organizations are approved to provide this training would be beneficial. AADE requests CDC provide additional guidance on how long after completing a training a lifestyle coach needs to begin facilitating sessions. We also encourage CDC to incorporate measures for continuing education such as ongoing training every two years to ensure lifestyle coaches are up to date and current.

Curricula Topics

AADE understands the importance of maintaining the evidence and fidelity of the program by using an approved curriculum that emphasizes self-monitoring, self-efficacy, and problem-solving that assist participants in achieving program goals.

We would appreciate further explanation on whether programs can add additional sessions beyond the required 16 sessions in month 1-6 and if yes, whether DPP suppliers are allowed to select from the following topic options in months 7-12 based on participants needs and interests.

Recognition Requirements/Status

AADE support the continuation of the recognition categories (pending; full) in addition to the newly listed category; preliminary. These categories ensure organizations are meeting a specific standard and effectively delivering a proven diabetes prevention lifestyle change program. We believe the requirement listed under preliminary recognition, specifically where it states, "of the participants eligible for evaluation in #1, at least 60% attended at least 9 sessions in months 1-6, and at least 60% attended at least 3 sessions in months 7-12" will be achievable of DPP programs but also evaluate their ability to deliver the program at this period in time.

On these sections, the AADE does have concerns about the requirement of a data submission including at least 5 participants who attended at least 3 sessions. AADE feels this will cause confusion for DPRP programs when the MDPP ruling is proposing to pay suppliers after 4 sessions. AADE recommends adding verbiage in regards to MDPP requirements or adjusting this to only include participants who attend 4 sessions or more.

We feel the requirements around remaining in recognition, returning to pending recognition, and re-achieving preliminary from pending status is complicated for DPRP programs and may veer them away from implementing the program. AADE is proposing to adjust this process to a more simplistic approach in achieving and/or re-achieving specific recognition statuses.

Submitting Data Evaluation to DPRP: Reapplying

We urge CDC to provide guidance on how programs can continue to deliver the National DPP (with as smooth of a transition as possible) if an organization loses its preliminary recognition status, fails to achieve full recognition status, goes out of business, or is otherwise unable to continue to deliver the benefit**.** The concern is programs will not risk delivering the program if they must wait a year to reapply and another year to obtain the preliminary recognition (a total of 2 years) before they can potentially be reimbursed. Programs simply cannot afford to stay in business without being reimbursed for the services they provide. AADE has witnessed this in DSMES programs and many of the DSMES programs have another income source.

Voluntary Withdraw

Organizations can voluntarily withdraw at any point in their timeline, but requiring programs to wait 12 months prior to reapplying may be of concern to programs seeking to apply for recognition. AADE will build awareness around this requirement to provide support to interested organizations, ensuring they are knowledgeable and prepared prior to applying for recognition.

Data Submission Date Range

AADE support CDC's change in submission requirements by requesting the transmission of data to CDC every 6 months from the CDC-assigned effective date and submission date versus the previous 12 month requirement. This will align with the CMS MDPP benefit's Physician Fee Schedule and provide an opportunity for more data-related and programmatic feedback to organizations.

Data Submission Requirements

To ensure high quality and impact, AADE is in agreement with CDC setting required standards for organizations that wish to offer an in-person or online lifestyle change program. Below are a list of comments on behalf of data submission requirements:

- **Submission Number.** We appreciate that CDC has provided guidance, if there is a gap in enrollment resulting in no classes being held and CDC allowing a one-time 6-month period where data are not submitted. However, AADE feels adding a more direct statement saying that an organization must implement at least one cohort per year would only reduce the potential for confusion. This will inform programs that they are required to submit data and reminds programs that data is needed for CDC to do a complete evaluation of their progress.

- **Make-up Sessions.** AADE supports the change to make-up sessions being allowed to occur on the same day as a regularly scheduled class session but only allowing one make-up session be held per week. We would appreciate clarification on how long a participant/program has to conduct a make-up session after the originally scheduled class. (For example, whether a core session needs to be made up within the first 6 months or if a core maintenance make up session needs to occur within a month of the regularly scheduled session.)

- **Attendance Percentages.** AADE supports the revisions to session attendance during months 1-6 and 7-12, requiring programs have at least 60% of its participants attending at least 9 sessions during months 1-6 and at least 60% of its participants attending at least 3 sessions in months 7-12. We feel this will allow programs more flexibility for attendance requirements.

- **Weight Loss Percentages.** The newly proposed weight loss standard, the average weight loss (mean percentage weight loss) achieved over the entire intervention period must be a minimum of 5% of starting body weight may confuse DPRP program because the MDPP expanded rule is proposing that participant must meet the 5% weight loss at both the 6 and 12 month marker. AADE recommends putting in additional information on MDPP supplier requirements and/or providing programs with figures on how a participant stands at 6 months but not requiring the 5% weight loss as a standard.

- **Inclusion/Exclusion**. The additional inclusion of only looking at participants that have attended 3 sessions in months 1-6 and whose time lapse from 1st session to last session is at least 9 months means the participant would have attended a session in months 7-12, bringing up the likelihood that this is a consistent participant. AADE is in agreement with this change.

- **Physical Activity Documentation.** We are in support of a yearlong cohort of participants being required to document physical activity during at least 60% of sessions. Includes all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. AADE feels this is a more realistic and attainable requirement for programs to achieve and is consistent with the inclusion criteria of other data elements. AADE does encourage CDC to provide more guidance for those that code physical activity as 0 minutes and whether this will be included in program outcome averages.

Evaluation Data Variables

AADE offers the following suggestions in regards to coding data into a form that can analyze program outcomes:

- **Session Type**. We recommend removing the variable code "OM" (Ongoing maintenance sessions (for Medicare DPP supplier organizations or other organizations that choose to offer ongoing maintenance sessions)) under evaluation data "Session Type". This will cause misunderstanding for DPP programs trying to analyze their data if it is being collected but not analyzed.

- **Lifestyle Coach NPI.** Collecting Lifestyle Coach Medicare-assigned NPI number for CMS may be confusing for programs that are DPRP but are not MDPP suppliers. AADE recommends completely removing the evaluation data variable.

- **Education.** We understand collecting educational information on program participants can potentially be a proxy for socioeconomic status (SES). However, we feel many programs will not be able to collect this information for all participants and will be an additional burden for programs to extend their intake forms.

- **Session Date.** AADE has concerns about the following verbiage, "A participant should not have more than one record (line of data) for any specific session date." We would appreciate further guidance on how programs would handle this if they conduct a make-up session on the same day. In the example situation, a participant could have the same make-up date recorded as another regularly scheduled session but the session type would be coded differently. AADE recommends removing this verbiage.

- **Other Data Variables.** AADE supports data elements including Session ID, Session Type, enrollment source, and payer type.

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Transitional Plan (existing DPRP programs)

We support the transitional phase for programs by adding a transition plan: existing organizations may submit data elements previously approved by OMB (2015) once between 01/01/18 and 06/30/18.

Key Terms and Definitions

The newly revised 2017 National Standards for Diabetes Self-management Education and Support added a definition of the National DPP. AADE suggests CDC add the definition of DSMES and DSMT (the Medicare definition) to the Key Terms and Definition section of the 2018 DPRP Standards and Operating Procedures.

Closing Remarks

AADE feels that the above suggested changes will not alter the critical elements of the lifestyle change program, shown to prevent or delay type 2 diabetes in research studies – the 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.

We thank you for the opportunity to provide comments on the proposed 2018 DPRP Standards and Operating Procedures and for considering our comments. If you have any questions or need additional information, please free to contact lkolb@aadenet.org.

Sincerely,

Natalie Blum, MPH and Leslie Kolb RN, BSN, MBA
The American Association of Diabetes Educators

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Title:	Comment from (Susan Anonymous) *
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Submitter Info

Comment: In the webinar on 8/23/17 about the Proposed 2018 Diabetes Prevention Recognition Program Standards, I noted where part of the requirement to meet Preliminary and Full recognition is that a minimum of 5 participants is needed. Would classes that start in 2017 with only 4 participants then not be able to obtain preliminary and full recognition? Or would the 5 participants per class only apply to classes started in 2018 and after? *

First Name: Susan

Last Name: Anonymous

ZIP/Postal Code: 45885

Email Address: sgerdemann@jtdmh.org

Organization Name:

Cover Page: 

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Submitter Info

Comment: We have one hospital that would like to offer their own NDPP within two separate departments. They have the capacity and numbers to do this. Is there any reason that they would both not be able to bill CMS if they each submit a separate application? *

First Name: Maria

Last Name: Hipp

ZIP/Postal Code:

Email Address:

Organization Name: Wyoming Department of Health

Cover Page: 

FOR YOUTH DEVELOPMENT®
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September 6, 2017

Leroy Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS D-74,
Atlanta, GA 30329

Submitted Electronically

Re: Docket No. CDC-2017-0053

Dear Mr. Richardson,

The National Council of Young Men's Christian Associations of the United States of America (Y-USA) appreciates the opportunity to provide comments with respect to the Centers for Disease Control and Prevention's (CDC) 2018 revision of Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures ("DPRP Standards"), published on July 14, 2017, 82 FR 32549. Y-USA is the national resource for nearly 900 independent YMCAs which work through more than 2,700 branches and more than 10,000 program sites to improve the health of their members and communities.

To advance a model of community integrated health and to achieve our vision of community where everyone has the opportunity to learn, grow, and thrive, Y-USA works to support local YMCAs, whose leaders view evidence-based health intervention delivery as a public health imperative given the financial, health, and emotional tools of diseases like type 2 diabetes. Since 2010, Y-USA has served as partner of the CDC's National Diabetes Prevention Program, supporting CDC's charge to curb the diabetes epidemic by way of an established infrastructure that facilitates the continued scaling and dissemination of the YMCA's Diabetes Prevention Program (one licensed, CDC-approved, curriculum among several approved Diabetes Prevention Program curricula) throughout the communities in the United States where YMCAs operate. In the last seven years, the network of Ys offering this intervention has grown from two providers to nearly 250, making us the largest in-person, single curriculum provider of the DPP in the nation. As of June 30, 2017, we have served over 54,000 individuals with prediabetes, and helped those who completed the program lose an average of more than 5% of their total body weight. We have nearly 1,700 program sites, and over 4,000 trained Lifestyle Coaches. We believe no other organization has the amount of cumulative experience in the successful implementation of an in-person DPP.

Private and public payor reimbursement enhances the ability of organizations like the Y to help address the burden of diabetes through programming that is more likely to be sustained over the long-term. Similarly, DPPs must maintain a high level of rigor to ensure fidelity to the original evidence base and achievement of outcomes that yield actual improvements to the health of our participants and communities. Because of this, Y-USA has been enthusiastically supportive of the creation of the DPRP, providing input to inform both its development and its evolution over the years – input that is based on years of experience operationalizing and tailoring program delivery to reach and engage program participants and help ensure their success. All local Ys delivering the YMCA's Diabetes Prevention Program (YMCA's DPP) are required to seek recognition; most have done so already and many more will seek recognition as they move through program implementation. Y-USA's goal is to leverage the DPRP as a mechanism for ensuring quality of the YMCA's DPP, and now to position the highest capacity Ys (in achievement, if not resources) to become Medicare DPP suppliers. This in turn supports our strategy of continuing to secure more health plan coverage of the program, thereby reducing barriers to program

entry, controlling costs for program participants and providers, and generating the greatest possible benefit to the populations being served.

The Notice published on July 14, 2017 in 82 FR 32549 invites comments on: a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; b) the accuracy of the agency's estimate of the burden of the proposed collection of information; c) ways to enhance the quality, utility, and clarity of the information to be collected; d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Y-USA is supportive of the direction DPRP is moving based on the proposed standards, and applauds changes and additions that may better enable organizations to achieve these standards and to seek reimbursement for Medicare. Y-USA has some concerns however, about the practical utility of some of the information CDC proposes to collect as well as feedback on ways to enhance the quality of information being collected. Y-USA also seeks clarity on some of the language included in the 2018 standards and how, and when, information will be collected on respondents. This response outlines all our concerns and feedback, which have been established after a thorough analysis of the proposed standards, and is written on behalf of all current and future providers of the YMCA's DPP. We are hopeful that with some additional clarification, these concerns can be addressed.

Specific Y-USA Comments

Participant Eligibility

The 2018 standards state that participants may be eligible based on "a recent (within the past year) blood test (may be self-reported; however, for Medicare DPP suppliers a self-reported blood test is not permitted for billing)." Y-USA requests additional information on what type of documentation is required to validate a qualifying blood value for Medicare participants and within that documentation, what specific data should suppliers capture to ensure these participants meet program eligibility criteria. Because self-report is acceptable for non-Medicare participants, it may be necessary to establish dual enrollment protocols with guidance on what intake information to capture on each participant type.

This section also indicates that "clinically diagnosed GDM during a previous pregnancy (may be self-reported); a previous history of GDM is not an eligibility qualification for Medicare DPP suppliers." However, the draft rules for the Medicare Diabetes Prevention Program published in the July 2017 physician fee schedule indicate that beneficiaries with a prior history of gestational diabetes will NOT be excluded (page 557). Y-USA requests clarification on whether or not gestational diabetes during one's lifetime will help to satisfy eligibility criteria for participants covered by Medicare.

Similar to the 2015 standards, CDC is allowing participants who may develop type 1 or type 2 diabetes while in the program to continue participation. Once the 2018 standards are in effect however, data on these participants should not be collected or if collected, should not be submitted to CDC. Y-USA requests that CDC consider offering guidance to organizations in the DPRP on how they may best capture information on conversion to diabetes and clarify whether this information can be self-reported by participants (including Medicare participants) or will it require documentation/confirmation from a health care provider. It would also be helpful to understand how these participants will be treated in any analysis. If data captured prior to developing type 1 or type 2 diabetes are included in analysis, will CDC establish a minimum number of sessions attended for these participants to avoid skewing any weight loss calculations? Additionally, Medicare has indicated participants who develop diabetes can continue to participate in the MDPP but if the data on MDPP participants is no longer provided to CDC for those who develop diabetes, how will CDC and Medicare (CMS) work together to compare data? CMS is asking all

Medicare Suppliers to provide a cross-walk file of participants so they can use DPRP data for continued analysis but there will be no data on individuals who develop diabetes.

Later this section refers to participants who become pregnant while in the program, with coding direction to ensure weights captured after pregnancy is known are removed from analyses. The section goes on to read, "weight loss percent for women becoming pregnant can be calculated using data submitted prior to pregnancy." It is not clear whether this is quality assurance guidance for the organization providing DPP or if this is an indication that CDC will use the last recorded weight prior to pregnancy as part of its data analysis. If the latter, organizations will need to reflect the date pregnancy status becomes known and tie this to a specific program session in its submissions to CDC. Y-USA seeks clarity on whether this is the case, and whether CDC intends to establish a minimum required number of sessions attended prior to becoming pregnant to include these participants in analysis. The point in the program at which pregnancy status becomes known will influence the amount of weight an individual could have lost, even if that individual meets the criteria of 3+ sessions attended in the first six months and at least 9 months between first and last session.

Makeup Sessions

Y-USA is supportive of CDC's proposal to allow a makeup session once again to occur the same day as a regularly scheduled session, as this aligns with operational practices used by program providers and imposes less of a drain on resources than ensuring these are scheduled for different days. This also makes it more feasible for participants to receive any program content they may have missed. Are there any length requirements for makeup sessions (i.e., must makeups be the same length as a regularly scheduled session)? In previous DPRP, makeup sessions had to be at least 15 minutes in length; we are hoping CDC can clarify whether this is still the case.

In addition, can CDC confirm makeups will be treated the same way as regularly scheduled sessions in data analysis? There is language in the section of the standards describing evaluation data elements that indicates "a participant should not have more than one record (line of data) for any specific session date." Does this mean the makeup session occurring on the same day as a regularly scheduled session will be excluded from analysis, or is it more accurate to assume that a participant should not have more than one record for any specific session date AND session ID?

Preliminary and Full Recognition

The proposed 2018 standards outline a new category of preliminary recognition - first mentioned in 2016 - in connection with the proposed MDPP rules. Organizations with "2017 CMS interim preliminary recognition will automatically move to CDC preliminary recognition on January 1, 2018." Y-USA seeks clarity on the 2017 CMS interim preliminary recognition designation and would like information on how an organization can determine whether they've been conferred this status. It is our understanding that 2017 CMS interim preliminary status is a safeguard to ensure "preliminary" status goes into effect on January 1, 2018 in the event that CDC's DPRP changes for 2018 are not ready for implementation at that point. Is this correct?

One of the requirements for preliminary or full recognition is that data submissions include at least five participants who attended 3+ sessions in the first six months and whose time from first to last session attended is 9+ months; among these, at least 60% must have attended 9+ sessions in the first six months and at least 60% must have attended 3+ sessions in the second six months. Y-USA would like clarification on when the attendance benchmark for the second six months is assessed – is it only once a full 12 months has passed from the date of the first session?

Organizations can remain in either preliminary or full status for four consecutive 6-month data submissions, after which they will be returned to either pending or preliminary status assuming they have

not met all of the required DPRP standards. Will an organization's status be assessed at each data submission timepoint? If so, must they meet the applicable standards at each of those timepoints, or only after the fourth data submission? It would be helpful to have more clarity on the timeline for data analysis and how this aligns with data submission deadlines.

Additionally, the proposed DPRP standards indicate that an organization would move from preliminary back to pending status after 24 months should full recognition not be achieved. While CDC allows another 12 months to improve outcomes to reach DPRP standards, Y-USA is concerned about the impact to MDPP participants if an organization moves from preliminary to pending status. We've asked CMS to clarify what happens to MDPP participants at that point and time. We encourage CDC and CMS to work together to ensure this transition from preliminary to pending status does not cause undue burden to MDPP beneficiaries, especially because CDC allows an organization an additional 12 months of data submission to allow for improvement. We encourage CMS to allow MDPP suppliers to continue serve existing MDPP participants during months 25-36 when CDC allows organizations to continue to strive towards full recognition.

Physical Activity

The transition letter document accompanying the 2018 proposed standards provides a summary of the changes from the 2015 standards, and indicates that "for the evaluation of documented PA minutes, reporting of '0' physical activity minutes will be excluded from analyses." Y-USA seeks clarity on whether fields with 0 recorded will be dropped when determining whether organizations meet the standard requiring that physical activity minutes are documented at a minimum of 60% of all sessions attended in addition to fields with 999 recorded. If so, we'd like more information on the rationale for the change in focus from documentation to achievement of physical activity, especially if CDC will accept fields with 0 in the first place. Although one of the goals of the program is for participants to complete at least 150 minutes of moderate physical activity each week, we also encourage and support any attempts at behavior change. The act of tracking in and of itself is an important milestone for participants. This may be the case for participants with physical limitations that influence when they can be active and how much physical activity they can complete.

Required Data Elements

Both the application and the six-month data submissions include data elements that were not required/collected as part of the 2015 standards. Y-USA has a few questions about some of these proposed elements related both to their utility and the recommended means of determination.

1. Class type, application – will there be an option to select multiple from the list of public, employee, member-only, or other? Type may be variable within one organization depending on both class and location.

2. CDC grantee, application – should organizations respond here with a "yes" if they have ever received CDC funding or if they are using CDC funding at the time of application?

3. Lifestyle Coach Medicare NPI, data submission – if a Lifestyle Coach obtains a NPI, should this be included on session attendance records for Medicare beneficiaries only, or on all participants in classes facilitated by this coach?

4. Payer type, data submission – in a future state, it could be theoretically possible for participants to be covered by multiple payer types (like dual eligible beneficiaries), so Y-USA would recommend an option to select all that apply. Given how this data element is defined in the data dictionary, it would be helpful to add clarity on whether and how grant funders should be classified, particularly those that are providing a grant to cover partial program fees or that are typically categorized as one of the

other payer types listed. Finally, Y-USA seeks clarity on whether this field should be captured at enrollment only, or updated if payer type should change while a class is underway.

5. Session ID, data submission – Y-USA requests additional information on the need for this specific element and how these data will be used. In addition, can CDC provide clarity on how participants who switch between classes will be treated? There may be scenarios where, due to scheduling limitations, an individual might repeat the same session with a new cohort.

6. Education, data submission - Y-USA applauds CDC in adding this data element, particularly to the extent that it serves as a proxy for socio economic status, a demographic detail that has not previously been captured in the standards, but one that will help to ensure this much-needed service is delivered to anyone who might benefit.

   Y-USA does have concerns, however, about the phrasing used to describe and justify changes to the 2015 DPRP standards. According to the *Overview of Changes to 2015 DPRP Standards (OMB No. 0920-0909, exp. 12/31/17)*, the proposed 2018 standards "liberalize data evaluation methods to ensure that organizations serving low SES and racial/ethnic minority populations can succeed (e.g., allowance for 60% of cohort to meet 12-month weight loss requirement vs. 80%)". Although technically true there is a lower attendance threshold in these new standards, and while this language is not included in the standards themselves, we need to be mindful of the potential for unintended consequences when we use messaging that assumes participants can expect different program gains based solely on their education level, race, or ethnicity – especially in the absence of health equity-related context. Though not included in the actual 2018 standards, this language could potentially be interpreted as a "greenlight" for organizations to cherry pick data submitted to CDC – only submitting weights for those participants with higher loss percentages since the requirement for weight capture is reduced from 80% to 60%.

   Y-USA and the local Ys believe it is our mission to support all individuals who qualify for the program regardless of their ability to pay, and work very intentionally to improve health equity in our communities by identifying and training staff who can deliver culturally relevant and competent messaging, and by addressing the access issues such as cost, transportation, child care, lack of social support, etc., that sometimes make it difficult for individuals to enroll and remain in the program. To prevent organizations from being dis-incented to serve low-income individuals or to include data only from specific participants in their data submissions, Y-USA urges CDC to regularly address health equity in its training and technical assistance.

   In addition, we encourage CDC, when working with payors or organizations focused on business development, to incorporate the concept of risk adjustment to payments to ensure sufficient resources are available to reach and enroll participants who face additional challenges, such as the ones listed above, in the DPP. For years, the health insurance market has used risk scoring and adjustment to account for the additional cost of insuring patients with conditions that carry greater severity and expense. Organizations need additional resources for outreach, behavior change support, and blood work to support low SES participants.

Transition to 2018 Standards

Both the proposed 2018 standards and the accompanying transition letter outline plans for transitioning organizations already in the DPRP to the new standards during the first half of 2018. Y-USA has a few clarifying questions related specifically to this transition, which are outlined in this section.

1. What is CDC's plan for capturing the additional application-level detail described above? Will there be guidance provided to existing organizations on when and how to share this data or will existing organizations be grandfathered into the 2018 application?

2. The 2018 standards reflect a return to the same data submission intervals first used in the 2012 standards – every six months. Per the standards, data are to be submitted to CDC every six months starting six months after the last submission prior to January 1, 2018. Based on this, it's clear that any organization that submitted its most recent set of data between July and December 2017 will need to submit again prior to June 2018. It would be helpful then to receive confirmation from CDC that organizations that last submitted between January and June 2017 will remain on a 12-month data submission cycle until after their next data submission. For example, is it accurate to state that an organization that last submitted data in April 2017 must submit data in 2018 twice: first in April 2018 and then in October 2018?

3. Between January and June 2018, does CDC plan to analyze data against the 2015 standards, the 2018 standards, or both? Or will that depend on which data elements are included in the data submission itself? Because preliminary recognition is a new status that was not previously designated, we are hoping to get clarity on whether organizations must provide the new data elements described previously to be considered for preliminary recognition, or will it be sufficient to include columns for these data elements that are populated with "9" since much of this data was not previously captured on participants? There are numerous local Ys in our network that are motivated by the potential for Medicare reimbursement and are eager to position themselves as early as possible as Medicare DPP suppliers, so understanding exactly how best to set them up for success vis a vis DPRP will be necessary. Similarly, Y-USA requests information on CDC's plan to map data submissions between the 2015 and 2018 standards. Is it safe to assume any 2018 submissions will be merged with previously submitted data (to the extent this will allow for a full complement of data) and then assessed against the 2018 standards?

4. Additionally, regarding timeline, although it is clear how an organization newly applying to the DPRP in 2018 will be treated, it is unclear how and whether maximum windows for pending, preliminary, and full recognition will be applied to organizations already in the DPRP. Assuming one achieves preliminary recognition, can that organization be allowed to maintain the status for up to two full years, even if it had already been in pending status for 18 months? Does the maximum 36-month window apply to an organization's original approval data (if determined prior to 2018) or will there be a reset? Clarity on windows is crucial as we support our network in preparing both for the new DPRP standards as well as the Medicare DPP.

Medicare DPP Suppliers

Y-USA supports the recommendation to ensure organizations billing Medicare for the DPP meet specific quality standards as these standards will increase the likelihood that the new Medicare coverage will have its intended societal impact. And because the 2018 DPRP standards were drafted to align with the CMS's proposed rule for the expansion of the Medicare DPP, there is quite a bit of content contained therein on what these standards will mean for Medicare DPP suppliers, or organizations approved to receive reimbursements for Medicare-eligible participants in the program. Some of the requirements around participant eligibility, for example, differ slightly depending on whether a participant is covered by Medicare. Y-USA's understanding is this will be distinguished at the individual participant level, rather than the organizational level. Due to the nuances of language, there may be some room for interpretation when, for example, the standards state that "for Medicare DPP suppliers a self-reported blood test is not permitted for billing". Y-USA requests confirmation from CDC that, because a Medicare DPP supplier may not serve Medicare participants exclusively, CDC's expectation is not that one set of requirements is extended to the supplier's entire participant population, but rather this organization may have marginally different types of data to submit for different types of participants.

Finally, because Medicare DPP supplier status is tied directly to DPRP recognition, and preliminary or full recognition status in particular, Y-USA requests more detail on 1) when and how status changes will be communicated by CDC to CMS, and 2) what impact these status changes will have on Medicare participants in classes that are underway and the ability of organizations to receive reimbursement for these individuals. Depending on the final design of the Medicare DPP, there is the potential for significant operational challenges on the ground, as organizations manage timing, expectations for benchmarks already achieved, decisions around converting participants to self-pay, communication with CDC and participants, changes to billing and coding procedures, and flags to program management systems.

Conclusion

Y-USA appreciates the opportunity to provide comment on the proposed 2018 DPRP standards and we do so with the best of intentions. The team at Y-USA along with our local Y colleagues share CDC's vision of a future state with increased awareness of diabetes risk and reduced incidence of diabetes, and are pleased with continued recognition of the value community-based providers offer in this arena. We are also grateful for this ongoing partnership that allows us to work in tandem with CDC to serve as many people with prediabetes as possible and to reduce access barriers to this proven intervention. If you have any questions or if we can provide any additional feedback as CDC finalizes the 2018 version of DPRP, please contact our national team by using the contact information for Jonathan Lever provided below.

Sincerely,

Jonathan Lever
Executive Vice President
YMCA of the USA
101 N. Wacker Drive
Chicago, IL 60606
jonathan.lever@ymca.net
312 419 8352

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Submitter Info

Comment:	Will there be an consideration for rural states and communities where recruiting for one class a year is already challenging? It may be exceedingly difficult for smaller communities to maintain two classes per year. Because gaining recognition will be more difficult, many smaller communities may lose motivation to apply for recognition. *
First Name:	Maria
Last Name:	Hipp
ZIP/Postal Code:	82002
Email Address:	maria.hipp@wyo.gov
Organization Name:	
Cover Page:	HTML

September 12, 2017

Secretary Tom Price
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

CDC Director Fitzgerald
Centers for Disease Prevention and Control
1600 Clifton Road Atlanta, GA 30329-4027

ELECTRONIC DELIVERY

RE: Docket No. CDC-2017-0053
Agency: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

Dear Secretary Price and CDC Director Brenda Fitzgerald, MD:

The National Association of Chronic Disease Directors (NACDD) and its more than 6,500 members seek to strengthen state-based leadership and expertise for chronic disease prevention and control in states and nationally. The Diabetes Council is NACDD's longest standing Council representing more than 300 public health professionals who work in diabetes prevention and control at state departments of health, District of Columbia and U.S. territories. NACDD respectfully is providing comments on the revision of the Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures.

General Comments
NACDD is pleased to see many positive changes in the 2018 DPRP Standards. However, the 2018 Standards includes detailed and nuanced information, especially around data collection and evaluation. We feel that this will deter many community-based organizations from offering the program due to data collection complexities. We are concerned this may shift the program delivery to major health systems and larger entities and unintentionally undermine access in community settings. We urge CDC to provide targeted technical assistance to organizations serving at risk-populations.

Voluntary withdrawal (DPRP Standards, page 10)
NACDD has strong concerns that organizations must wait 12 months to reapply if they voluntarily withdraw at any point. This is an enormous disincentive for organizations to ever reapply in the future. It requires a lot of time and effort to develop the organizational structure and staff capacity to implement the National Diabetes Prevention Program (NDPP) lifestyle change program successfully. Organizations may withdraw and reapply to the DPRP for a variety of reasons, including staff turnover or other events that may be outside of their control. Requiring organizations to wait a year to reapply may reduce organizational momentum and could ultimately cause the program to not reapply to deliver the

program. For this reason, NACDD urges CDC to shorten the amount of time an organization can reapply. We recommend a one-month waiting period or at the very most a six-month waiting period. If CDC is concerned with abuse of this feature, we recommend putting a cap on the number of times an organization can withdraw and reapply.

Type 2 diabetes diagnosis after enrollment
NACDD is pleased to see that participants diagnosed with type 2 diabetes after enrollment will be able to continue with the diabetes prevention program services. This is consistent with Medicare DPP coverage. However, since the person's data will not be part of the DPRP data submission, NACDD strongly recommends that DPRP develop a code to identify people who have developed type 2 diabetes. The code can be used for data anlaysis (that is, participant data with this code will not be included in data analysis.) Without this, the person may be on one data submission but in the next submission 6 months later their data would not be included due to the diagnosis of type 2 diabetes. We recommend that CDC ask organizations to continue to submit data for people who develop type 2 diabetes, but have a code for this on the data submission form; this change will also assist with the Medicare DPP and DPRP data crosswalk that suppliers must submit to CMS.

Preliminary Recognition
NACDD supports the new recognition category of Preliminary Recognition and supports the criteria outlined for achieving preliminary recognition.

Data evaluation methods (Attachment 6, number 1)
NACDD requests further clarification regarding the statement that the standards will "liberalize data evaluation methods to ensure that organizations serving low SES and racial/ethnic minority populations can succeed (e.g., allowance for 60% of cohort to meet the 12-month weight loss requirement vs. 80%)." NACDD recommends clarification about what the 60% refers to as the evaluation method for low SES and racial/ethnic cohorts are not in the revised standards. NACDD supports liberalized data evaluation methods for organizations that serve low SES and racial/ethnic minority populations.

Biannual data submissions
NACDD is pleased to see that the data submission requirement has been changed to data submission every 6 months. NACDD notes that this change will provide NDPP delivery organizations with data/feedback more often, which will help them make changes and take corrective actions in a timely manner to move toward meeting recognition criteria.

Additional data elements collected for CDC submission
NACDD would like to provide the following comments about data elements.

- In the data dictionary under Enrollment source, NACDD would like to request that the term "health care provider" be defined as the "health care team" to broaden how it can be used. In addition to the examples listed in the revised guidelines for health care provider and we recommend adding dietitian, pharmacist and community health worker. We recommend make this change throughout the entire document (e.g. page 17 under #11, #13, #16).
- The comments column (page 22) for the data element, "Enrollment Source" states, "If a participant's referral source is not provided, this variable will be coded as "9". Should this state "enrollment source" instead of referral source for consistency?
- NACDD supports the collection of education information on program participants as a proxy for SES, but we would like further clarification about how this information will be used. Will this

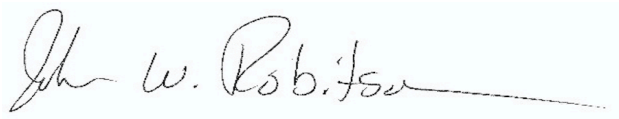
data element be used to determine which sites qualify for the more "liberal data evaluation" criteria as mentioned in the overview of changes document?

Additional data elements for CDC application (DPRP Standards, page 18, number 19)
NACDD recommends providing further instructions for the data element "CDC grantee." We recommend CDC provide a clear definition for sites for how to determine if they have CDC grant support. We recommend stating examples of funding source (e.g., list specific grants) and from which divisions. Some organizations may not know if they are a CDC grantee or if they receive diabetes-related or other CDC funds and this may cause confusion or information that is not useful.

Discussion about Lifestyle Coach training requirements (DPRP Standards, Training, page5)
NACDD fully supports the requirement that Lifestyle Coaches must be trained on the specific curriculum being used by the recognized organization. We urge CDC to allow Lifestyle Coaches who have been previously trained for at least 12 hours or two days and who have been delivering the program within the last year to have a truncated (4 hours) training on a *new* curriculum to match their organization's chosen and approved curriculum.

Thank you for the opportunity to provide comments on the 2018 Diabetes Prevention Recognition Program Standards and Operating Procedures and for considering our comments.

Sincerely,



John W. Robitscher,
MPH
Chief Executive Officer
National Association of Chronic Disease Directors

THE COUNCIL FOR
Diabetes Prevention

4501 N. Fairfax Dr., Ste. 900
Arlington, VA 22203
202.285.3092
info@nationaldpp.org
www.nationaldpp.org

September 1, 2017

Ann Albright, PhD, RD
Director
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Division of Diabetes Translation

Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road N.E.
MS– D74
Atlanta, Georgia 30329

Submitted electronically via: http:www.regulations.gov

Re: [60 Day–17–0909; Docket No. CDC–2017– 0053] Proposed Data Collection Submitted for Public Comment and Recommendations, CDC Diabetes Prevention Recognition Program (DPRP) - Revision

Dear Director Albright:

The Council for Diabetes Prevention (Council) submits comments on the Centers for Disease Control and Prevention (CDC) Proposed Data Collection on the CDC Diabetes Prevention Recognition Program (DPRP) issued on July 14, 2017, (82 Fed Reg 32549 - 51) and looks forward to other opportunities to offer suggestions on the National Diabetes Prevention Program (DPP). The Council wants to continue working with federal and state partners to scale and deliver this evidence-based intervention and to avert the onset of diabetes in America's seniors.

The Council for Diabetes Prevention is a non-profit, membership-based[1] organization that brings together National Diabetes Prevention Program industry stakeholders to increase

[1] Most notably and distinctive from other diabetes alliances, membership in the Council is open to any organization that shares its vision. The Council has not excluded any entity seeking to participate in this organization. The Council for Diabetes Prevention is committed to being an inclusive organization and allowing stakeholder participation in developing its positions. A modest membership fee is requested but scholarships are available if needed in order to promote broad engagement.

access to the program, promote high quality standards, and support the long-term scalability and sustainability of the unique patient-centered program, which is delivered using both community-based and virtual methods. Our membership includes more than 75 stakeholder organizations – community-based DPP providers, virtual DPP providers, health systems, departments of health, foundations and aging agencies. We are an inclusive organization that is exclusively focused on scaling the DPP. The Council membership has delivered the DPP to diverse communities and in innovative ways. For example, the DPP is being integrated into pharmacies, is culturally competent and linguistically diverse, and incorporates hybrid models of in-person and virtual delivery. A list of members of the Council for Diabetes is found as an Appendix to these comments.

We address common themes that should be incorporated below, and then turn our comments to a few specific data elements of the Capacity Assessment and the Participant Eligibility. The Council recognizes the commitment of the CDC, and specifically, the Division of Diabetes Translation to advance the National DPP and to lend its structure and support to the newest preventive service under the Centers for Medicare and Medicaid Services (CMS), the Medicare DPP. The Council submitted comments on the MDPP to CMS, and is equally as interested in developments related to the National DPP.

The Council supports the revision of the participant eligibility to a body mass index (BMI) of 25 or greater, and 23 or greater for Asian-Americans. We acknowledge both that this is based on evidence, and it is analogous to the standard in the Medicare DPP proposed rule. Support is also given for the creation of the DPRP Preliminary Recognition status. The Council is in favor of the Preliminary status using an attendance-based requirement for determining this recognition. New organizations may have trouble reaching the weight loss requirement in the timeframe, but they can be measured on their engagement by assessing participant attendance. The Council notes that virtual DPP providers have experienced challenges when submitting their data to DPRP because the recognition process seems tailored to an in-person model. Council members seek consistency and clarity on how the CDC will apply the standards to providers, regardless of delivery mode. We acknowledge that the primary method of delivery is in-person; the CDP seeks preliminary status criteria that consider the delivery mode and that providers are able to feasibly meet.

The Council takes issue with the **broad collection of any and all data where the purpose is not directly linked to recognition and where the purpose is unstated or unclear**. It is not the practice of DPP providers and stakeholders to delve into personal aspects of participant lives that do not or should have bearing on the delivery and efficacy of the program.

The Council also **opposes the expansion of data elements that may form a barrier to participant access that are drawn out and unduly burdensome**. It takes a great deal of readiness and willpower to initiate the DPP. Providers can attest to the fragile nature of participant enrollment, especially where participants fail to complete the intake process or decline to follow through on their initial commitment. Therefore, extending the list of questions asked as a condition of participation or lengthening the required data collection where there is no plausible relation to program efficacy is not supported by the Council.

While the CDC lists the 12 data elements it proposes to include in the 2018, it appears the CDC has not made efforts to eliminate current data elements from the 2015 Standards. The Council asks the CDC to **review the current data elements and suggest what can be removed**

from the Capacity Assessment and the DPRP Recognition Criteria. Members of the Council believe the National DPP DPRP is being clogged with numerous information requirements that do not enhance the program delivery or lead to better results.

The Council realizes that the CDC will likely collect the information it has proposed in the data elements. If that is indeed the case, **the Council asks for the data elements to be made available to the public and searchable on the CDC's National DPP website**. To the extent that participants are interested in the data elements to evaluate and select a program, the CDC should be transparent and consumer friendly by listing the data element values. For instance, a DPP may not have a name that connotes a religious affiliation, but a participant may be interested or averse to a particular program because of their own personal beliefs. The CDC is asked to empower the general public by providing maximum access in a usable format on the information being collected.

The Council is **against the collection of any information that may lead to an inherent bias to the way the National DPP or the Medicare DPP is delivered**. For instance, one of the new data elements is whether the organization is a CDC grantee. Concern is raised that the CDC may be more generous in granting pending and full recognition to its own grantees. The CDC receives required submissions from its grantees and their affiliates, therefore this data element should not have bearing or need to be collected on the application form. The inclusion of this data element may give the appearance of favoring grantees more than non-grantees.

The return to the **reporting requirement of every 6 months is burdensome on providers**. Many providers must evaluate participant data for meeting weight loss milestones and also prepare files for the CDC DPRP. The timeframe of reporting is more aggressive than what Council members would prefer; the CDC is asked to lengthen the timeframe for receiving DPP provider data. Additionally, the estimated annualized burden hours, 2 hours per response, is greatly under estimated for the collection and submission of DPRP recognition data. The CDC is asked to evaluate the burden hours of a larger group of providers, and encourage more earnest reporting.

Specific Concerns on Data Elements

1. The **terminology used by the CDC is not consistent** with that used by CMS. For example, the "delivery modes" are in-person and virtual for the CMS MDPP proposed rule. CMS defers to the CDC for a definition of virtual providers. However, the CDC proposes in-person, online, business learning, and combination at the delivery modes. The CDC and CMS should harmonize the terminology used to describe the programs. During a CDC listening session on the proposed new application data elements, CMS staff defined the distance learning mode as including remote, telehealth, and video conferencing that is 100% delivered by a trained lifestyle coach. The Council asks for CMS and the CDC to align the terms used in both of their proposals.

2. The CDC continues to require the collection of **physical activity minutes** as a part of the criteria for Full recognition. Clinical evidence proves physical activity is more important to maintenance rather than weight loss. Furthermore, there is no performance payment tied to the collection or achievement of goals related to physical activity. Council organizations acknowledge the difficulty in assessing whether moderate or physical

activity has taken place through participant reporting. The physical activity minutes and the intensity are doubtful at best. The CDC should eliminate the reporting requirement of physical activity minutes.

3. The CDC proposes to collect the **education level of the participant**. Council members take great exception to the collection of this element, as it is not stated or obvious how this relates to the delivery or success of the DPP. Educational attainment as a socio-economic status factor correlates as a great benefit to health; those with more education have an increased knowledge of health risks and protective factors, and the economic resources to seek healthy behaviors.[2] DPP providers do not want to cause any potential participant to feel marginalized, and the collection of this data element may lead individuals to think the class may depend on a particular level of educational attainment. Coupled with the required collection of race, this information exceeds what the CDC should require. Further, it is not possible for the DPP providers to validate the responses provided; the value of this data is slight and the level of intrusion is high.

In sum, the Council for Diabetes Prevention looks forward to the CDC producing the 2018 DPRP Standards that reflects the feedback provided herein. We acknowledge the rapidly developing National DPP, but want to make sure the information collected is relevant and does not unduly burden a potential participant or DPP suppliers. We ask for the streamlining of data elements, and for website features to enable a participant to search DPPs on the entries. Nothing collected should lead to an inherent bias (such as educational attainment level) or favor organizations with CDC funding (grantee status).

We remain very engaged in the National Diabetes Prevention Program, and recommit to working with all stakeholders, state and federal partners to prevent diabetes. Thank you for considering our official positions.

Respectfully Submitted,

The Council for Diabetes Prevention

[2] Education and Health, National Poverty Center Policy Brief #9, University of Michigan, 2007. Accessed August 24, 2017.

THE COUNCIL FOR
Diabetes Prevention

4501 N. Fairfax Dr., Ste. 900
Arlington, VA 22203
202.285.3092
info@nationaldpp.org
www.nationaldpp.org

Attachment A
Membership Roster *
Council for Diabetes Prevention

A Vision of Health
ACAP Health
Active Wellness
American College of Preventive Medicine (ACPM)
Annex Nutrition Services, Inc.
Baptist Medical Group, Inc.
Bettr Life, Corp.
Black Women for Wellness
Black Women's Health Imperative
Blood Centers of America, Inc.
Blue Mesa Health, Inc.
Boulder County Area Agency on Aging
Canary Health
Caroline County Health Department
Carter County Health Department
Cayuga Community Health Network
Cedar County Public Health
Chattanooga-Hamilton County Health Department
Collins Wellness Center
Corporate Health Partners
Crook County Health Department
Davis County Health Department
Elkhorn Logan Valley Public Health Department
Empower Outcomes
Endocrine Technology, LLC
Face of Hope International
Fit for Service Wellness
Florida Department of Health – Hillsborough
Friends of Newport Senior Activity Center
Fruit Street Health, Public Benefit Corporation
Functional Medicine Coaching Academy
Fundamental Health Solutions
Gain Life
Harney District Hospital
HealthDove, Inc.
HealthSlate
HMR Weight Management Services, Corp.
Hope 80/20, LLC
IControlMyHealth, Inc.
Innovative Wellness Solutions, LLC
Integrative CAP Health Practices, LLC
Jenny Craig
John Stampfli
Joslin Latino Diabetes Initiative
Keatley Medical Nutrition Therapy
Kent County Health Department
Lark Technologies
Lindora Clinic
Los Angeles Department of Public Health, Division of Chronic Disease and Injury Prevention
Magnolia Medical Foundation
Martin Luther King Health Center and Pharmacy
MedPro Wellness
Michigan Health Improvement Alliance, Inc. (MiHIA)
Network Builders Team, Inc.
Noom, Inc.
Nutrition Pair, LLC
Pack Health
Perfect Lifestyle
Population Health Alliance
Public Health Advocates
Retrofit, Inc.
Richland Public Health
Roche Diabetes Care, Inc.
Rocky Mountain Human Performance, Inc.
Roxmater, LLC
Skinny Gene Project
Solera Health
Soul So Good Healthy
Southeast District Health Department
State of Wellness, Inc.
Sun Health
The HIT Center of Jacksonville
Turnaround Health
Urban Health Resource
Valley Jewish Community Center
Web Health Club, LLC
WebMD Health Services Group
Wellness Beyond Fifty, LLC
Yes Health, Inc

* As of DATE

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Submitter Info

Comment: As an organization in Pending Recognition Status with years of experience in implementing the NDPP at 2 locations, we appreciate the opportunity to provide feedback. The majority of the proposed revised standards are acceptable and should be straightforward to implement if approved so we will focus these comments on a few areas of concern: 1) By only measuring weight loss at the 12 month mark vs. the current 6 and 12-month mark, we have greater concerns about our participants achieving the already difficult minimum 5% weight loss. Our data shows that participants may achieve the 5%, or greater, weight loss at the conclusion of the 16-sessions but then start to plateau or gain weight as attendance/engagement drops off in the second 6 months. We remain committed and work very hard to increase engagement, attendance and therefore weight loss results for our participants throughout the entire 12-month program. Therefore, we recommend maintaining the weight loss % documentation at both the conclusion of the Core and the conclusion of the Core Maintenance. 2) Although body weight was the measurement of success in the NIH DPP study and is a DPRP standard (due to it being a non-invasive and cost-effective measurement of reduction in risk), there is also an evidenced-based correlation between a drop in A1C and reduction in risk for developing diabetes. These two measurements - weight and A1C - should be independent of one another. We recommend adding a reduction in risk based on blood-based values as an outcome-measure beyond just body weight loss. 3) Documentation of PA minutes - if we offer more than 30 sessions a year to help keep engagement higher during the Core Maintenance, we are not clear on how we should be documenting PA minutes in the second 6 months and if we are penalized for offering more than the required sessions when participants are less likely to self-report PA minutes in the second 6 months? Thank you for your consideration of our input and experience in implementing the NDPP locally. *

First Name: Rebecca

Last Name: Rice

ZIP/Postal Code: 81211

Email Address: rrice@chaffeecounty.org

Organization Name:

Cover Page: HTML

DAVID Y. IGE
GOVERNOR OF HAWAII

VIRGINIA PRESSLER, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

Comments in SUPPORT of Diabetes Prevention Recognition Program (DPRP) Standards, Docket No. CDC-2017-0053

Centers for Disease Control and Prevention
September 12, 2017

The Hawaii State Department of Health (DOH) strongly supports updates to the Diabetes Prevention Recognition Program (DPRP) standards to align with the Medicare Diabetes Prevention Program Model (MDPP).

Diabetes and pre-diabetes rates in Hawaii have been steadily increasing; nearly one quarter of all adults in Hawaii (24.1%) report having diabetes or pre-diabetes.[1] Alarmingly, these rates do no fully capture the burden of these conditions. Based on a study by Dall, et al, (2014) and a methodology developed by the American Diabetes Association, half of all adults in Hawaii (52.7%) currently have diabetes (11.2%) or pre-diabetes (41.5%).[2,3]

The Hawaii DOH offers the following comments on the proposed rules.

Impact on community-based organizations

We feel that the 2018 Standards includes detailed and nuanced information, especially around data collection and evaluation, which may deter many community-based organizations from offering the program due to data collection complexities. We are concerned this may shift the program delivery to major health systems and larger entities and unintentionally undermine access in community settings. We urge CDC to provide targeted technical assistance to organizations serving at risk populations.

[1] Hawaii Health Data Warehouse. Diabete Prevalence – Categorical. Honolulu, Hawaii: Hawaii State Department of Health; 2016.
[2] Dall TM, Yang W, Halder P, et al. The economic burden of elevated blood glucose levels in 2012: Diagnosed and undiagnosed diabetes, gestational diabetes, mellitus, and prediabetes. Diabetes Care. 2014; 37:3172-3179.
[3] American Diabetes Association. The burden of diabetes in Hawaii. In: Association AD, ed. Alexandria, VA: n.d.

Voluntary Withdrawal (DPRP Standards, page 10)

We have strong concerns that organizations must wait 12 months to reapply if they voluntarily withdraw at any point. This is an enormous disincentive for organizations to ever reapply in the future. It requires a lot of time and effort to develop the organizational structure and staff capacity to implement the National DPP lifestyle change program successfully. Organizations may withdraw and reapply to the DPRP for a variety of reasons, including staff turnover or other events that may be outside of their control. Requiring organizations to wait a year to reapply may reduce organizational momentum and could ultimately cause the program to not reapply to deliver the program. For this reason, we urge CDC to shorten the amount of time an organization can reapply. We recommend a one-month waiting period or at the very most a six-month waiting period. If CDC is concerned with abuse of this feature, we recommend putting a cap on the number of times an organization can withdraw and reapply.

Type 2 diagnosis after enrollment

We are pleased to see that participants diagnosed with type 2 diabetes after enrollment will be able to continue with the diabetes prevention program services. This is consistent with Medicare DPP coverage. However, since the person's data will not be part of the DPRP data submission, we strongly recommends that DPRP develop a code to identify people who have developed type 2 diabetes so that CDC does not calculate them in the DPRP analysis (the person may be on one data submission but in the next submission 6 months later their data would not be included due to the diagnosis of type 2 diabetes). We recommend that CDC ask organizations to continue to submit data for people who develop type 2 diabetes, but have a code for this on the data submission form; this change will also assist with the Medicare DPP (MDPP) and DPRP data crosswalk that suppliers must submit to CMS.

Biannual data submissions

We are pleased to see that the data submission requirement has been changed to data submission every 6 months. This change will provide DPP delivery organizations with data/feedback more often, which will help them make changes and corrective actions in a timely manner to move toward meeting recognition criteria.

Additional Comments

- We support the new recognition category of Preliminary Recognition and the criteria outlined for achieving preliminary recognition.
- We would appreciate further clarification on how data on the educational level of program participants will be used.
- We would also appreciate clarification on how the standards will “liberalize data evaluation methods to ensure that organizations serving low SES and racial/ethnic minority populations can succeed (e.g., allowance for 70% of cohort to meet he 12-month weight loss requirements vs. 80%).”

Thank you for the opportunity to provide comments.

SOCIETY FOR PUBLIC HEALTH EDUCATION

Global Leadership for Health Education & Health Promotion

September 11, 2017

Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-D74
Atlanta, GA 30329
Attn: CDC-2017-0053

RE: Society for Public Health Education's (SOPHE) comments on the proposed data collection submitted for public comment and recommendations pertaining to the CDC Diabetes Prevention Recognition Program (DPRP) (CDC-2017-0053)

Dear Chief Richardson:

The Society for Public Health Education welcomes the opportunity to comment on the CDC proposed rule regarding the CDC Diabetes Prevention Recognition Program (DPRP) (CDC-2017-0053). According to the 2017 National Diabetes Statistics Report, an estimated 84.1 million adults have prediabetes and are at risk for developing Type 2 diabetes.[1] The provision of an evidenced-based nationally recognized lifestyle change program that allows at-risk beneficiaries access to trained professionals is vital to stopping the progression of Type 2 diabetes and reducing the costs and suffering associated with diabetes.[1]

SOPHE is a non-profit professional organization founded in 1950 to provide global leadership to the profession of health education and health promotion. SOPHE contributes to the health of all people and the elimination of health disparities through advances in health education theory and research; excellence in professional preparation and practice; and advocacy for public policies conducive to health. SOPHE is the only independent professional organization devoted exclusively to health education and health promotion. Members include behavioral scientists, faculty, practitioners, and students engaged in disease prevention and health promotion in both the public and private sectors. Collectively, SOPHE's 4,000 national and chapter members work in universities, medical/health care settings, businesses, voluntary health agencies, international organizations, and all branches of federal/state/local government.

Comments on Proposed Rule

We applaud the CDC for expanding the National Diabetes Prevention Prevention Program (DPP) and authorizing CDC-recognized organizations to become MDPP suppliers beginning in 2018. CDC proposes a new effective date of April 1st, 2018, adjusted from January 1st, 2018, to allow for sufficient time to apply as an organization and begin furnishing services. We understand the rationale for the extension and believe this is sufficient time for organizations to meet the requirements to become preliminarily recognized to begin offering DPP services and begin billing. Additionally, we support CDC's proposal to establish an MDPP "interim preliminary recognition" standard to permit DPP organizations to enroll in Medicare even if they do not have full CDC recognition. This would increase potential providers and ensure that beneficiaries begin receiving these much needed services in a more timely manner.

CDC also proposes to discontinue eligibility for beneficiaries who progress to a diagnosis of Type 2 diabetes during the duration of the MDPP services period. We understand that DPP services are meant to be preventive of the onset of Type 2 diabetes and that there are other covered services that may be more appropriate for the treatment and management of Type 2 diabetes such as the Diabetes Self-Management Training (DSMT) program furnished by Certified Diabetes Educators (CDE) once a beneficiary progresses to diabetic status. **While we understand the rationale for this proposed rule, we are wary of releasing a beneficiary from MDPP services without mandatory referral to an appropriate Type 2 diabetes program.** We also caution CDC that even with an appropriate referral to a diabetes control and management curriculum there may be significant drop off between MDPP and the referral program. Beneficiaries may feel discouraged after a Type 2 diabetes diagnosis or may not be able to attend the diabetes management program due to socioeconomic and environmental factors. It is necessary to consider common barriers for beneficiary access to care and program services.

Additionally, CDC proposes to revise the definition of an "ongoing maintenance session" and add a definition for "MDPP session," which means a core session, a core maintenance session, or an ongoing maintenance session. The curriculum of the diabetes prevention lifestyle change program is intended to prevent or delay Type 2 diabetes and improve the participants health and well-being. **We support the proposed rule to require beneficiaries to attend all three sessions in an interval in order to continue to have coverage in the subsequent interval.** As suggested, in-person measurements for weight loss is aligned with program participation as well as provision of the necessary skills to sustain the achieved weight loss and to continue to implement the behaviors and habits from the program. We believe it would be in the best interest of beneficiaries to attend all of the required sessions in an interval before they are able to move on to the next interval. This will ensure that they achieved their weight loss goals as well as acquire the skills imparted in that interval.

We are encouraged that the curriculum proposed also includes social risk factors in the context of the set of MDPP services that would inform any future considerations of additional payment policies for the MDPP expanded model. Some of the social risk factors that impact health outcomes of Medicare beneficiaries include: socioeconomic position; race, ethnicity, gender; social relationships; and residential and community context. These social risk factors can be influenced by the trained Lifestyle coach such as the individuals competency.

CDC proposes that MDPP enrollment be limited to a once per lifetime benefit for beneficiaries. SOPHE urges CDC to reconsider this proposed rule as there is a myriad of evidence that it may take multiple attempts for an individual to achieve the kind of significant weight loss associated with the goals of the DPP program.[2] Additionally, emerging research shows that metabolic changes in the body make sustained weight loss more difficult and that multiple attempts may be necessary to achieve lasting weight loss.[3,4]

The Role of Health Education Specialists in Providing the Diabetes Prevention Program to Reduce onset on Type 2 Diabetes

Health Education Specialists work to encourage healthy lifestyles and wellness through educating individuals and communities about behaviors that can prevent diseases, injuries, and other health problems. Although many professionals may possess the requisite skills to conduct

education campaigns, Health Education Specialists are equipped to provide the necessary education to more vulnerable populations, those that are more susceptible to social determinants that lead to increased incidence of chronic conditions such as Type 2 diabetes. A core competency of Health Education Specialists is communicating with and understanding the needs of the underserved, vulnerable and/or limited English-speaking populations, including those who are disabled and suffer from one or more chronic diseases. Health education specialists also supervise community health workers, trusted members of the community served, who can facilitate access to priority populations, and improve the cultural competence of the education or service delivery. Given the wide range of populations with which they work and the diverse settings in which they are employed, health education specialists have significant capacity to conduct the Diabetes Prevention Program. Health Education Specialists' skills in health communications, cultural competency, community engagement, community needs assessment, health coaching, and inter-disciplinary collaboration make them natural leaders to work with public health partners including CMS and CDC toward an integrated preventive health care system that better serves beneficiaries as they access prevention programs.

Thank you for consideration of our comments. In the U.S. one in two adults has a chronic disease, whereas one in four adults has two or more chronic diseases.[5] The time is now to reverse this trend of poor behavioral health choices and reduce risk across all communities. SOPHE looks forward to working with CMS and CDC to improve the reach and effectiveness of prevention programs for conditions that can be avoided, such as diabetes and heart disease. Please contact Dr. Cicily Hampton at (champton@sophe.org) or 202-408-9804 with any additional questions.

Sincerely,

Elaine Auld, MPH, MCHES
Chief Executive Officer

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[1] Centers for Disease Control and Prevention. (2017). National Diabetes Statistics Report, 2017. Retrieved from https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

[2] Delahanty, Linda M., Mark Peyrot, Peter J. Shrader, Donald A. Williamson, James B. Meigs, and David M. Nathan. 2013. "Pretreatment, psychological, and behavioral predictors of weight outcomes among lifestyle intervention participants in the Diabetes Prevention Program (DPP)." Diabetes Care 36 (1): 34-40. http://dx.doi.org/10.2337/dc12- 0733.

[3] Anthanont, P, and Jensen, MD. "Does basal metabolic rate predicat weight gain?"Am J Clin Nutr. 2016 Oct;104(4):959-963. Epub 2016 Aug 31.

[4] Harvard Health Publications. (2015, July). Does metabolism matter in weight loss? Retrieved from https://www.health.harvard.edu/diet-and-weight-loss/does-metabolism-matter-in-weight-loss

[5] Centers for Disease Control and Prevention. (2017). Chronic Disease Prevention and Health Promotion. Retrieved from https://www.cdc.gov/chronicdisease/index.htm

Comments re: Docket No. CDC–2017–0053 Proposed Data Collection

Comment #	Topic	Comment
1	(a) necessity of proposed information to be collected	Additional data elements proposed are reasonable and will add important dimensions to evaluation; will also align with proposed MDPP requirements
2	(b) accuracy of estimated burden	a) Application response time of 1 hour is reasonable. b) Semi-annual data submission time of 2 hours is questionable once an organization has passed the first year of submissions. As organizations implement more programs, the amount of data increases substantially. All data must be reviewed for accuracy prior to compilation and submission. Even with an electronic system for data entry, the accuracy check must occur, and can be very time-consuming with a large data set.
3	(d) ways to minimize the burden	CDC makes available Epi Info7 in the public domain. CDC could develop an input form for DPRP data collection and make it available to DPRP recognized organizations to use. It would need to allow multiple entries with the same self-selected ID number. This would be a great benefit for data entry and extraction to those organizations without IT support.
4	(e) estimate of costs	Organizations new to the National DPP or enrolling as Medicare suppliers for the first time may need to hire an IT consultant and may also need additional hardware and/or software in order to manage their data for DPRP and Medicare.
5	Other	It would be most helpful if we were offered the complete proposed new standards for DPRP and the chance to comment each time they are revised. If that is not a requirement for CDC, perhaps it should be. Or at least a draft version available to use with the informational webinar like we had in August.

MDH Comments to CDC DPRP Proposed 2018 Standards

CDC Proposed Standards:

Page 4 and 16: Organizations may offer the program through any or all of the following delivery modes but are **required to submit a single application for each delivery mode being used**. This will result in a separate orgcode for each delivery mode being used. Data for each delivery mode will be submitted under the corresponding orgcode during the anniversary month of the effective date for that orgcode.

MDH Comment:

Requiring each organization to submit a new application for each mode of DPP delivery that they provide seems redundant and overly burdensome for administration purposes. It may create confusion and lead to more organizational error, with multiple applications and orgcodes for the same organization. It is not clear why CDC would require separate applications and separate orgcodes per delivery mode when one of the data elements included in a standard data submission is delivery method for all classes attended. CDC could assess the delivery mode for the entire course based on this data field by looking at the categories coded for standard and not make-up sessions.

MDH Recommendation/Suggestion:

For organizations, it would be administratively simpler and less confusing to have each organization **complete one application and have one orgcode**. The application could then break out into separate sections to address each mode of delivery with related required information. If needed (for data reporting) there could be sub-orgcodes for each mode of delivery, but overall there would be one orgcode per organization. So that coaches don't need to look them up, possible more intuitive sub-orgcodes might look like:

- XXXX-IP (in-person)
- XXXX-WEB (online)
- XXXX-DL (distance learning)
- XXXX-MIX (mix modality)

CDC Proposed Standards:

Page 6: Additional new or **refresher training for experienced coaches is highly recommend**, since program evaluation have demonstrated that well trained and highly motivated Lifestyle Coaches have significant impact on participant outcomes.

MDH Comment:

We are pleased to see that the CDC highly recommends additional new or refresher training for experienced coaches. Our partners have requested such trainings. Unfortunately, after reviewing Common Ground and talking with Master Trainers, we are not aware of any developed refresher trainings for our Master Trainers to utilize with Lifestyle Coaches. With our limited funding, we would appreciate it if CDC, in conjunction with DTTAC, would develop a standardized refresher training we can offer to our Lifestyle Coaches. This will also provide confidence that the refresher training is appropriate and approved by CDC given the quality of existing DPP Lifestyle Coach trainings.

MDH Recommendation/Suggestion:

We recommend that together CDC and DTTAC **develop a standard refresher training for Master Trainers** to offer Lifestyle Coaches.

MDH Comments to CDC DPRP Proposed 2018 Standards

CDC Proposed Standards:

Page 8: Organizations that are Medicare DPP suppliers **may repeat any curriculum topic** from months 1-6 or months 7-10, with the exception of the introductory session, for use in ongoing maintenance sessions.

MDH Comment:

Can Medicare DPP suppliers use one curriculum for the core and core maintenance sessions (months 1-12), then change to a new approved curriculum for ongoing maintenance sessions (months 13-36)? For example, if they used the T2 curriculum during the core months 1-12, can they then use topics from the 2012 National DPP curriculum for ongoing maintenance sessions in months 13-36, or vice versa?

MDH Recommendation/Suggestion:

We recommend **allowing Medicare DPP suppliers to use and switch between both T2 and 2012 National DPP curriculum sessions during the ongoing maintenance phase**, regardless of which curriculum was used during the core phase. This provides more options to coaches and participants, which will help meet the needs of individual class cohorts.

CDC Proposed Standards:

Page 9: An organization may remain in pending status for up to 36 months if it continues to submit data every 6 months.

And

Organizations may remain in preliminary recognition status for four consecutive 6-month data submission periods (i.e., two years).

MDH Comment:

According to the proposed standards, an organization could remain in pending and preliminary status for a total of five years (three and two years respectively). The additional two years in preliminary status, where an organization has not met weight-loss-average requirements, adds a substantial amount of time for a DPP organization to be part of the DPRP without reaching full recognition. We argue that intervening early and often when an organization stalls in one of these two statuses is warranted and important as participants could be utilizing a DPP organization that is not performing well. Early and frequent one-on-one technical assistance is important because an organization may be trying very hard to succeed but serving a challenging population in terms of weight-loss trajectory differences or other social determinants of health. Such organizations may not survive without technical assistance, though they may be the best organization to service particular populations and address health disparities.

MDH Recommendation/Suggestion:

We recommend that CDC **improves upon, and provides more, technical assistance to DPP organizations that stall in pending or preliminary status**. In addition, we recommend that CDC fund local entities such as state health departments to provide local state-specific technical assistance to organizations in need. In order to do this, health departments would also need to collaborate with CDC, to share which organizations are struggling to meet full recognition in our state.

CDC Proposed Standards:

Page 9: Preliminary criteria

MDH Comments to CDC DPRP Proposed 2018 Standards

1. The 12 month data submission includes at least 5 participants who attended **at least 3 sessions** in the first six months and whose time from first session attended to last session of the lifestyle change program was at least 9 months (a statistical package used by the DPRP calculates months lapsed; this is an automated process).
2. Of the participants eligible for evaluation in #1, at least 60% attended at least 9 sessions in months 1-6, and at least 60% attended **at least 3 sessions** in months 7-12 (Requirement 5 in Table 3).

MDH Comment:

Regarding the standards for establishing interim preliminary recognition, the plan seems reasonable. The only change that we would request is that the individuals included in the data set should attend four sessions and not three in months 1-6. This would align with both the previous and current DPRP standards.

Rationale:

1) Programs have to build reports and tracking around the current criteria for inclusion as an "engaged" participant. There are costs associated with changing current reporting and tracking and this is an added burden on programs already on a tight budget.
2) There is a body of knowledge within organizations and in the scientific literature around CDC's threshold of four or more sessions attended. It does not make sense to change this threshold, especially when there is lack of data (none was provided by CMS or CDC's DPRP in their proposed 2018 standards) to support the change.
3) Even high-quality programs can have a tough time meeting the 5 percent weight-loss standard when participants attending four or more sessions are used to assess achievement. This problem will worsen by setting the threshold for inclusion even lower. This runs counter to CMS' and CDC's interest in offering classes to all adults, to achieving health equity.

MDH Recommendation/Suggestion:

Interim Preliminary Recognition and all other kinds of recognition **should be based on individuals attending four or more sessions** and not the changes proposed by CDC and CMS.
We will share the same comment with CMS regarding their proposed 2018 MDPP rules.

CDC Proposed Standards:

Page 14: Table 3. The **average weight loss** across all participants in the yearlong cohort must be a **minimum of 5%** of starting body weight. The **first and last weights recorded** for each participant during months 1-12 will be used to calculate this measure.

MDH Comment:

We understand CDC's need to set minimum criteria to obtain full recognition. However, we are concerned that the proposed minimum criteria set at 5 percent average weight-loss at 12 months severely limits the potential health benefits obtained by offering the DPP to certain populations. Allowing a lower percent weight loss (e.g. 4 percent or 3 percent, especially for certain races) and/or allowing 5 percent weight-loss at any time during the 12 months would be a better alternative.

First, researchers have documented variations in individual weight-loss trajectories, suggesting that a non-trivial proportion of participants may continue to experience weight-loss beyond an initial four to

six month period and achieve goals at a later time. Furthermore, these patterns can differ by gender and race/ethnicity[i,ii,iii]. In addition, analyses of data from the original Diabetes Prevention Program Trial support that health benefits accrue with successive weight loss, with roughly a 10 percent reduction in diabetes-risk associated with each percentage of body weight lost after completion of the core phase (equivalent to the 16-week phase)[iv]. Diabetes Prevention Program Trial participants who met their physical activity goals over the yearlong program, but did not attain the weight-loss goal, still had lowered diabetes incidences – an estimated 46 percent reduction (95% CI: 16-66%) over three years[v]. In addition, a recent analysis of data from the *VA MOVE! Program*, which also focuses on making lifestyle changes, demonstrated that participants who were less successful in achieving the desired lifestyle changes still reduced their risk of developing type 2 diabetes[vi]. Lastly, a systematic review found that of the studies that reported the proportion of successful participants who achieved the primary outcome of 5 percent weight loss, successful participants ranged between 20-64 percent[vii].

Second, a policy that is too stringent will only perpetuate existing disparities related to type 2 diabetes. Non-white adults, Hispanic adults and adults with lower incomes tend to have higher rates of type 2 diabetes. Evidence in scientific literature shows that African American participants in lifestyle interventions or weight-loss studies who were tested in randomized clinical trials saw lower levels of weight loss[i,viii] not necessarily because of poor compliance[ix]. Data from the Special Project for American Indians, which has offered a culturally-tailored DPP class for American Indians and Alaska Natives, shows lower percentages of weight loss and fewer reductions in consumption of unhealthy foods among individuals in the lowest income group[x]. Data from the original DPP trial showed non-Hispanic whites were more likely to achieve the 7 percent individual weight-loss goal than participants of other races or ethnicities[xi].

MDH Recommendation/Suggestion:

1) We recommend reviewing all the literature and **setting a new weight-loss standard** for full recognition at a lower rate than 5 percent to limit disparities.
2) We suggest **using baseline and the lowest weight obtained at any time within 12 months** instead of baseline and last weight obtained to determine percentage weight-loss.

CDC Proposed Standards:

Page 15: The DPRP Standards also contains a capacity assessment. This is a list of questions designed to help an organization determine its readiness to deliver a CDC-recognized lifestyle change program (see section titled Organizational Capacity Assessment). **All organizations are strongly encouraged to complete this assessment.**

MDH Comment:

Our experience in Minnesota with training DPP coaches and provider organizations is that it is important for organizations to have a clear sense of their capacity to provide the DPP. It is also important for organizations to have a clear plan for how they intend to become a successful DPP provider. It is a waste of time and resources to train DPP coaches at an organization that has no clear organizational plan, and one with limited capacity for DPP program development and implementation. Therefore, we would suggest requiring the Organizational Capacity Assessment.

MDH Comments to CDC DPRP Proposed 2018 Standards

MDH Recommendation/Suggestion:

We recommend that CDC **require organizations to complete the Organizational Capacity Assessment** to determine their readiness to deliver a CDC-recognized lifestyle change program before they jump into becoming a DPP provider organization and go down the path of seeking recognition.

CDC Proposed Standards:

Page 16: Organizations offering classes to the public **should provide the physical addresses of the classes** or online link to class offerings to DPRPApply@cdc.gov.

MDH Comment:

Classes listed in an organization's original application will change over time, so this listing is just a snapshot in time of classes offered. The system that DPRP currently uses (receiving information via email to list DPP class locations after someone goes through the application process on their website) is cumbersome and ineffective in providing up-to-date and accurate information on class locations. Minnesota has heard complaints from DPP providers, saying that the "manual" back and forth email process for notification of new classes and removal of old classes is burdensome. Providers get frustrated when they have numerous classes going on and they may stop notifying CDC about new class locations or asking them to remove old ones. This reduces accuracy of available DPP classes. In addition, class locations change on a regular basis and providers may not know address locations until a month beforehand.

MDH Recommendation/Suggestion:

We recommend CDC set up a national class management system, such as the QTAC Compass software out of University of New York at Albany. All provider organizations across the U.S. would be able to enter **their real-time class dates and locations** into a system like this. We strongly believe a real-time class management system is important to the success of the DPP and will eliminate barriers to locating a class

Minnesota is having this same issue and is convening a work group to strategize setting up a state-level class management system. We would appreciate a national solution versus a state solution to limit burden on nationwide DPP providers having to enter information into multiple class management systems.

CDC Proposed Standards:

Page 20: Participant's **race should be recorded** at enrollment and included on all sessions attendance records generated for an individual participant.

MDH Comment:

We are pleased that participants' races are collected as part of DPRP's evaluation elements, as health care quality can vary by race. An Institute of Medicine Report Brief emphasizes the need to collect race data in order to identify disparities in access to (and quality of) health care, with the hopes of improving care and closing disparity gaps[xii]. Race may be an uncomfortable question for Lifestyle Coaches to ask, and participants may be uneasy about sharing their race for a number of reasons. Hasnain-Wynia and Baker[xiii] suggest a number of ways to overcome the obstacles to collecting race data, including increasing patients' comfort level by explaining the reasons for collecting this information, how the information will be used and addressing staff discomfort (providing scripts, case examples and staff training). We believe providing training and guidance to Lifestyle Coaches would improve the response rate for this data

element. CDC could utilize resources such as the Health Research and Educational Trust in partnership with American Hospital Association's Toolkit for Collecting Race, Ethnicity and Primary Language Information from Patients[xiv].

In addition to supporting Lifestyle Coaches to collect race data, we would encourage CDC to analyze and interpret the data with consideration to those who choose not to provide race information. What is the data showing us for this group of individuals that choose not to disclose their race? Are there disparities in this sub-population?

MDH Recommendation/Suggestion:

1) We recommend providing **training and guidance** to Lifestyle Coaches on how to ask and respond to participant questions about why a DPP organization is collecting race information.
2) We recommend **analysis and transparency of data and disparities** as they relate to race and to those who do not self-identify or refuse to disclose their race.

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[i] Wingo, B et al. (2014). Differences in weight loss and health outcomes among African Americans and whites in multicentre trials. Obesity Reviews 15(Suppl. 4), 46-61.

[ii] Kumanyika, SK et al. (2002). Ethnic comparison of weight loss in the Trial of Nonpharmacologic Interventions in the Elderly. Obes Res 10(2), 96-106.

[iii] Espeland, MA et al. (2009). Describing patterns of weight changes using principal components analysis: results from the Action for Health in Diabetes (Look AHEAD) research group. Ann Epidemiol 19(10), 701-710.

[iv] Marurthur, N et al. (2013). Early Response to Preventive Strategies in the Diabetes Prevention Program. J Gen Intern Med 28(12), 1629-1636.

[v] Hamman, RF et al. (2006). Effect of weight loss with lifestyle intervention on risk of diabetes. Diab Care 29(9), 2102-2107.

[vi] Jackson, S et al. (2015). Weight Loss and Diabetes Incidence with the VA Lifestyle Change Program. Lancet Diabetes Endocrinol 3(3), 173-180.

[vii] Aziz et al. (2015) A systematic review of real-world diabetes prevention programs: learnings from the last 15 years. Implementation Science, 10:172

[viii] Samuel-Hodge, CD et al. (2014) Effectiveness of Diabetes Prevention Program translations among African Americans. Obes Rev 15(S4), 107-124.

[ix] DeLany, JP et al. (2014). African American women exhibit similar adherence to intervention but lose less weight due to lower energy requirements. Int J Obes 38(9), 1147-1152.

[x] Jiang, L et al. (2015). Socioeconomic Disparities in Weight and Behavioral Outcomes Among American Indian and Alaska Native Participants of a Translational Lifestyle Intervention Project. Diabetes Care 38, 2090-2099.

[xi] Wing, RR et al. (2004). Achieving weight and activity goals among diabetes prevention program lifestyle participants. Obes Res 12(9), 1426-1434.

[xii] The Institute of Medicine (2009). Race Ethnicity and Lanagute Data: Standarization for Heltah Care Quality Improvement. http://www.nationalacademies.org/hmd/Reports/2009/RaceEthnicityData.aspx accessed on August 29, 2017.

[xiii] Hasani-Wynia R and Baker DW (2006). Obtaining Data on Patient Race, Ethnicity, and Primary Language in Health Care Organizations: Current Challenges and Proposed Solutions. Health Services Research 41, 1501-1518.

[xiv] Hasnain-Wynia, R et al. (2007) Health Research and Educational Trust Disparities Toolkit. hretdisparities.org accessed on August 29, 2017.

weightwatchers

September 11, 2017

Mr. LeRoy Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity, Office of the Associate Director for Science
Centers for Disease Control
1600 Clifton Road, MS D-74
Atlanta, GA 3033

Re: Comments Submitted on "Proposed Data Collection Submitted for Public Comment and Recommendations"
Docket No. CDC–2017–0053

Delivered by electronically via Regulations.gov

Dear Mr. Richardson,

On behalf of Weight Watchers International ("Weight Watchers"), I am writing to comment on the "*Proposed Data Collection Submitted for Public Comment and Recommendations*" for the CDC Diabetes Prevention Recognition Program (DPRP), published in the Federal Register on July 14, 2017. Weight Watchers' strongly supports and operates programs to promote healthy lifestyles clinically proven to prevent and delay the onset of type 2 diabetes (T2D). The nutrition and diabetes clinical community have the tools and knowledge to help people delay and manage T2D, and our challenge now is to identify Americans at risk for T2D and provide broad and easy access to these tools and knowledge.

Weight Watchers offers recommendations to the DPRP proposed standards and operating procedures with the goal of making vital diabetes prevention accessible and consumer friendly for those with pre-diabetes and at high risk of developing T2D. Our recommendations are based on 50 decades of experience providing multi-component intensive behavioral counseling for healthy lifestyle to consumers throughout the United States. We offer comment from the consumer service point of view, specifically applying the following questions in our review: is NDPR set up to ensure DPPs are consumer accessible, consumer useable, and consumer friendly.

In our review, and through the accompanying CDC appendices we noted four groups of policy – 1) modifications to data evaluation formulas; 2) changes to align the DPRP with expected Medicare Diabetes Prevention Program (MDPP) standards; 3) new data element collection

(not related to MDPP); and 4) data element collection not aligned with evidence base for efficacious performance. We provide comments on each of these areas as well as a list of questions that we hope future guidance and documentation can answer.

Modifications to Data Evaluation Formulas:

- We generally support and applaud the revised data evaluation standards for full recognition. The proposed change will focus program performance on those DPP enrollees who commit and use the program by focusing evaluation on those who attend 3 sessions in the first 6 months and at least one session in the last six months of the program. This modification will give consumers confidence that CDC recognition evaluates efficacy of the full program, not just the first few weeks of the program.
- We are concerned that the proposed minimum data submission of 5 participants is too few for a reasonable program evaluation. Such a small number does not provide assurance that consumers expect from CDC recognition. We urge CDC to increase the minimum data submission to 30 participants for each of these data elements.
- We applaud CDC's understanding that the need for and challenges to DPP is greater in some subgroups. Currently, CDC implies it is adjusting evaluation those serving low SES, but has no proposed standard or formula for review. If CDC will use a modified formula for some DPPs or for some DPP enrollees, that formula must be transparent and publicly disclosed.
  - ✓ In "Attachment 6: Overview of Changes to 2015 DPRP Standards", the CDC states "liberalize data evaluation methods to ensure that organizations servient low SES and racial/ethnic minority populations can succeed (e.g. allowance for 60% of cohort to meet the 12-month weight loss requirement vs. 80%)"
  - ✓ In tables for proposed data evaluation and standards, there is no formula that reflects adjustment for low SES, there is no clear definition of what comprises low SES, and there is no modified 'weight loss' standard.

Changes to align the DPRP with expected Medicare Diabetes Prevention Program (MDPP) standards:

While it is our hope that CMS will modify its proposed MDPP so that it can and will operate as a successful, evidence based consumer service program and DPPs will enroll to be MDPP suppliers, many DPPs will not become MDPP suppliers. We are perplexed as to why CDC would propose to collect information pertinent only to Medicare reimbursed enrollees, data and information that will be reported to Medicare as part of its complex supplier enrollment and reimbursement systems. To that end we recommend that CDC:

- Eliminate MDPP data elements from the required DPP data reports.
- And, if CDC is being asked to conduct evaluation of MDPPs operations by CMS, it can obtain Medicare specific data from CMS.

Our review identified the following 'MDPP' data elements, these are elements that would be collected via Medicare reimbursement systems and would not apply to those DPPs that do not become an MDPP supplier:

Session ID (can be inferred by enrollment and attendance dates, not needed),
Session Type (can be inferred by enrollment and attendance dates, not needed),
Delivery Mode (each DPP is only delivering via one mode, this can be obtained from enrollment data),
Lifestyle Coach Medicare assigned NPI (this is un-necessary for CDC program evaluation).

New Data Element Collection Proposed:

The NDRP data element collection proposes to add education information on program participants. Yet, this data element is not used for performance evaluation, and, is not routinely or willingly provided by consumers when they seek services. We do not understand why or how this data element would be used and would not have a clear, justifiable explanation to provide to a consumer should they ask why we need information that is unrelated to service delivery. The Standards and Operations manual does not provide this information.

We urge CDC to eliminate all data elements that are not directly related to service delivery as they erect barriers to program enrollment and suppress enrollment in a program that is vital to improving health of our nation. We note:

- Each data element added to consumer eligibility, enrollment processes, and/or program operation creates one more barrier to entry, one more point at which consumers choose to stop enrollment or to dis-enroll.
- Our experience is that these requests for personal data, particularly if the data is to be shared with government entities or others outside the collecting organization, are not well received by consumers and present a significant barrier to program participation.
- When asked what or why this data is needed, DPPs must be able to clearly tell consumers **how** the information is to be used and which entities will receive it.
- If we collect this information, share it with CDC, and then it is used for research, we would generally be required to obtain informed consent.

- Again, we ask CDC to eliminate data elements that are not part of the evaluation of the program. Consumers react quite negatively to sharing of collected information with government entities and other outside organizations.

Data Elements NOT Aligned with Evidence Base:

The individual session level data collection and reporting includes several data fields that are not scientifically linked to program performance and diabetes prevention. As noted above, the collection of data that is not directly tied to delivery of DPP establishes barriers to enrollment through lengthy questionnaires, each added question or data collection is another opportunity to a consumer to say 'no' and to discontinue the program. Hence, it is vital that the data elements collected be clearly related to DPP service delivery, this is what consumers who seek a service expect and deserve.

The data required for the program evaluation include two items that are NOT routinely collected and what is requested, i.e. the specific data element, is not aligned with the evidence base.

We urge CDC to provide flexibility and/or modify collection of these data elements. We note each data field that is not scientifically associated with diabetes prevention.

> **Recording physical activity minutes**: We urge CDC to modify this data element. We recommend that the data element on physical activity record whether curriculum for the week included information on importance of physical activity, encouraged physical activity, or discussed role of physical activity in healthy lifestyle? It would be a 'yes or no' answer for each session attended.
>
> While routine physical activity is linked to maintenance of weight loss, recording the actual MINUTES of activity is not linked the diabetes prevention (nor to maintenance of weight loss). Recording of minutes of physical activity is laborious, time consuming and may be quite inaccurate. The study cited in the DPRP standards and policy operation manual supporting the collection of this data element does not evaluate the role of recording of physical activity minutes in preventing diabetes. Instead it documents that recording of physical activity is sporadic in DPPs. We note that research on the use and role of activity trackers (pedometers, smart phone apps, etc.) in conjunction with healthy lifestyle counseling shows that use of activity tracking did not improve weight

loss, the primary outcome leading to diabetes prevention.[1],[2] Additionally, recent studies show the use of an activity tracker did not improve health outcomes.[3]

The citation listed in the "Supporting Statement: Part A" for collection of physical activity minutes concludes that there is a need for more research. Collecting data from a consumer service program that has a primary objective of encouraging enrollment and participation is not an appropriate means to collect research data. And, if this collected data is to be used for research, even if it is later de-identified, may require informed consent. Rather, the appropriate approach for studying the role of documenting physical activity minutes (or better alternatives to documenting physical activity and its link to diabetes prevention) would be a survey of those who completed DPP or a randomized clinical trial with multiple arms examining approaches to documenting physical activity (which may have already been done, see citation 1.) Given the onerous and anti-consumer nature of this data element, analysis of the accuracy of physical activity documentation that programs collect would be appropriate as well.

Questions and Requests for Guidance and Standards Development

- ➔ New data evaluation formula –
  - ✓ Does this mean that participants will not be evaluated until they reach 9 months?
  - ✓ Will data evaluated every 6 months regardless of when a participant enters OR only for those that completed the 12 month program based on participant attendance date?
  - ✓ Are the minimum of 5 participants required to meet all criteria (i.e. weight loss, PA, Blood test etc) in order to be evaluated or is this purely single criteria based?

- ➔ Will organization have the ability to obtain the information on PA post activity?
- ➔ Will organizations still have the ability to obtain blood test result information post sign up (for non-Medicare paid enrollees)?
- ➔ How will CDC differentiate a Medicare participant and a non-Medicare participant, via the PAYER variable or via separate data submission?

[1] Jakicic JM, Davis KK, Rogers RJ, King WC, Marcus MD, Helsel D, Rickman AD, Wahed AS, Belle SH. Effect of Wearable Technology Combined With a Lifestyle Intervention on Long-term Weight LossThe IDEA Randomized Clinical Trial. JAMA. 2016;316(11):1161–1171. doi:10.1001/jama.2016.12858

[2] Thomas JG, Raynor HA, Bond DS, Luke AK, Cardoso CC, Foster GF, Wing RR. Weight loss in Weight Watchers Online with and without an activity tracking device compared to control: a randomized trial. Obesity 2017; 25(6):1014-1021.

[3] Finkelstein EA, Haaland BA, Bilger M, Sahasranaman A, Sloan RA, Khaing Nag EE, Evenson KR. Effectiveness of activity trackers with and without incentives to increase physical activity (TRIPPA): a randomized controlled trial. Lancet Diabetes Endocrinol 2016;4(12):983-995.

weightwatchers

- ➔ Re-enrollment – the session ID could change, what does CDC expect or advise? For example, if someone re-enrolls, should the session ID restart?
- ➔ How will the switch from 2015 data evaluation standards to 2018 standards be handled? For Weight Watchers will next data submission be 6 months from the last 2017 data submission? Will carry over data from previous year be included in the evaluation?
- ➔ How will a DPP qualify for the new status of "Preliminary"? How long will the determination take, can it only occur upon the first 2018 data submission?

Conclusion:

Weight Watchers International applauds the CDC for developing and implementing the National Diabetes Recognition Program. The CDCs work has been critical to the prevention of diabetes through evidence supported community based programs, creating a model for taking NIH clinical research to translational research to a program that can be implemented throughout the nation. We do have substantial concerns regarding the CDCs program evaluation data collection, specifically, the collection of data that is not directly relevant to program evaluation. Collection of data from consumers that is not clearly and directly linked to the service being provided establishes real concern among the consumers DPPs serve. We strongly believe that minor modifications of the program evaluation data collection, specifically, modification of the physical activity minutes reporting to focus on physical activity in the curriculum; dropping or making the reporting of education level and race/ethnicity voluntary; and eliminating the collection of MDPP specific data elements, which will be collected by Medicare through its supplier enrollment and reimbursement systems.

If you have any questions or need any additional information, please do not hesitate to contact me.

Sincerely,

Gary Foster
Chief Scientific Officer

Secretary Tom Price
U.S. Department of Health and Human Services
200 Independent Avenue, S.W.
Washington, D.C 20201

Brenda Fitzgerald, MD
Director
Centers for Disease Prevention and Control
1600 Clifton Road Atlanta, GA 30329-4027

RE: Docket No. CDC-2017-0053
Agency: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

Dear Secretary Price, CDC Director Brenda Fitzgerald, MD

We are writing on behalf of the WA State Diabetes Network Leadership Team (DNLT). This group is a compendium of over 40 different public, private and tribal organizations dedicated to the mitigation of diabetes and hypertension rates, as well as increasing our capacity to prevent new cases of diabetes in WA State. WA State is a leader of health care innovation in our country. We are writing today to provide comments on the revision of the Diabetes Prevention Recognition Program Standards and Operating Procedures. We appreciate this opportunity.

The DNLT would greatly appreciate your consideration of the following revisions of the Diabetes Prevention Recognition Program Standards and Operating Procedures.

Withdrawal and Reapplication for Recognition

The DNLT has concerns where organizations must wait 12 months before reapplying for recognition. There are many reasons why organizations may choose to withdraw, some of which are beyond the organization's control. It takes a lot of time and organizational support to meet the requirements of recognition. Having to wait a year could reduce an organization's support and momentum to move forward as other competing projects are worked on. In an effort to make this as easy as possible and expand the reach, the DNLT strongly urges CDC to reconsider a reapplication timeframe of one month to no more than three months.

Continued Enrollment Following Conversion to Type 2

The DNLT agrees with the proposed change of allowing participants who convert to type 2 diabetes after enrollment to continue with the DPP. This change is consistent with Medicare Diabetes Prevention Program (MDPP) coverage criteria. In addition, we ask that a process be put in place to identify participants who convert to Type 2 diabetes. National Association of Chronic Disease Directors (NACDD) offers a good recommendation of developing a code to identify converters so that CDC does not calculate them in the Diabetes Prevention Recognition Program (DPRP) analysis. Furthermore, NACDD recommends that CDC ask organizations to continue to submit data for converters, but use a specific converter code on the data submission form.

Lifestyle Coach Training

The DNLT fully supports the decision to have lifestyle coaches trained on the specific curriculum being used by the recognized organization. We agree with NACDD recommendation of having truncated (4hour) training on a new curriculum to match their organization's approved curriculum.

Preliminary Recognition

While we are happy to see the preliminary recognition requirements, we are concerned about the 12 months of data submission for 1 cohort. The DNLT asks that CDC reconsider the 12 month data submission to 9 months and at least 5 participants who attend at least 3 sessions in the first six months and whose time from the first session attended to last session of the lifestyle change program was at least 9 months.

Data Evaluation Methods

The DNLT supports NACDD request for clarification regarding "liberalize data evaluation methods to ensure that organization serving low socioeconomic status (SES) and racial/ethnic minority populations can succeed (eg., allowance for 60% of cohort to meet the 12-month weight loss requirement vs. 80%)" The DNLT encourages data evaluation methods that enhance success of organizations which service low SES, racial/ethnic minority, Tribal, and hard-to-reach (i.e. rural) populations.

Additional Comments

Given the tremendous burden on organizations who provide DPP the DNLT asks that CDC invest in data solutions that streamline and aggregate data submission. Ideally the product developed would be offered at no cost to the organization while meeting CDC data collection needs and requirements.

In order to provide feedback in the future and to improve access to DPP in WA State we welcome greater transparency about the success and challenges of DPP implementation. Publishing or sharing the information at in person meetings is helpful to us in increasing access to DPP in WA State.

MARYLAND
Department of Health
Larry Hogan, Governor · Boyd Rutherford, Lt. Governor · Dennis Schrader, Secretary

September 12, 2017

Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE., MS-D74
Atlanta, Georgia 30329

Re: Docket No. CDC-2017-0053

Thank you for the opportunity to provide comments on the Centers for Disease Control and Prevention proposed Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures (January 2018). Please see the Maryland Department of Health's comments below:

Lifestyle Coach Credentialing and Training

- Establish a national standard for credentialing and re-credentialing of lifestyle coaches.

While there appears to be a focus on initial training for Lifestyle Coaches for approved curriculum, continued education and training for lifestyle coaches is generalized and not specific. This lack of specificity on continued education and measurement of coach quality highlights the need for a credentialing system which would standardize and benchmark the skills and requirements of qualified Lifestyle Coach. Additionally, the proposed Medicare rule addresses credentialing by placing the responsibility on recognized organizations (or Medicare Diabetes Prevention Program (DPP) suppliers) to oversee and guarantee the quality and sufficiency of individual Lifestyle Coaches. Proper oversight of Lifestyle Coaches through a credentialing process is essential to ensuring high quality, consistent delivery, and fidelity of the DPP to meet DPRP integrity standards and requirements. A national standard would indicate all essential requirements are met by the lifestyle coaches in DPP supplier organizations; potential requirements could include: 1) training is received using an approved curriculum from an approved master trainer; 2) Lifestyle Coaches complete a required number of training classes and hours; 3) training occurs within designated timeframe before re-credentialing to remain in good standing; and 4) for re-credentialing, continuing education credits are standardized and approved by CDC. In Maryland, a centralized credentialing and re-credentialing process is essential for sustainability of DPP, protects Medicare and beneficiaries from fraud, provides subsequent updates to CDC's DPRP standards are adequately addressed through training, and ensures all lifestyle coaches meet the same minimum standard. CDC may wish to consider establishing a credentialing system, or utilizing a designee, such as the National Committee for Quality Assurance

or the National Commission for Health Education Credentialing, to conduct and managed the Lifestyle Coach credentialing process.

Requirements for Pending, Preliminary, and Full Recognition

- Allow providers who lose recognition be able to reapply within a significantly shorter time period

The proposed DPRP standards eliminate the option for an organization to withdraw the DPRP application without the 12 month wait to reapply, an option previously recommended by the CDC to organizations. This provision appears to penalize program providers who determine a need for additional time to meet the outcomes requirements and also runs the risk of drop out due to the lapse in program delivery. We recommend that providers who lose recognition or withdraw be able to reapply within a significantly shorter time period, for example, three months.

- Provide guidance and technical assistance to organizations on recognition requirements

The requirements for pending, preliminary and full recognition are complicated. We anticipate a need for CDC to provide significant guidance and technical assistance to assure those organizations are prepared to apply and reapply, and ultimately be a successful fully recognized organization.

Application, Class Type and Lifestyle Coach Training Entity

- Clarify whether organizations will be required to notify the CDC if there are class location changes.

The proposed DPRP standards require DPP applicant organizations to report anticipated class locations, as well as the training entity on their applications. We anticipate that DPPs will have changes in class locations as their programs grow and expand to include new locations. There could be many reasons training entities would change locations (such as contract requirements, etc.), therefore flexibility in this is essential. Guidance from CDC to the organization for planning these requirements will be helpful in developing start-up processes within the organization. These requirements could prove burdensome administratively, depending on CDC's update needs.

Make-up Sessions and Submitting Evaluation Data to the DPRP

- Clarify how data should be reported when a participant has a regular class session and a make-up session on the same date

The proposed standards state "make-up sessions can be provided in any delivery mode, but only one make-up session can be held on the same date as a regularly scheduled session," and "a participant should not have more than one record (line of data) for any specific session date.".

National Registries of Organizations and Lifestyle Coaches

- Create and maintain a registry of Lifestyle Coaches

One of the 3 objectives of DPRP standards is to develop and maintain a registry of organizations recognized to deliver effective type 2 diabetes prevention lifestyle change programs to people at high risk. It would be beneficial for CDC to maintain a similar registry of Lifestyle Coaches to allow for search ability by certification or identification of the Lifestyle Coach. This registry would be beneficial for payers to assure credentialing and training for Lifestyle Coaches and protect against fraud.

Data Dictionary: Evaluation Data Elements, Participant's Prediabetes Determination

- Clarify how the CPT code would fit into data reporting.

In Table 4, the claims-based Current Procedural Terminology (CPT) code specifying the screening of or diagnosis for prediabetes is allowed in the same category as the Risk Test. This section does not include any reference to the CPT code.

- Continue to allow "0" minutes of physical activity to be reported

During the listening session on August 23, 2017, it was noted that organizations will no longer be allowed to report zero minutes of physical activity (beginning 6 months after the new standards are effective). The proposed DPRP standards do not specify this change; it appears to allow "0" minutes to continue to be reported. We are concerned about inaccurate reporting if "0" is not allowed, and anticipate organizations may simple report "1" to comply with such a data entry change. We recommend continuing to allow "0" minutes to be reported to reflect the times when participants report their physical activity as "0" minutes.

Overall, the DPRP standards and data elements are supportive toward scaling and sustaining the National DPP, and align with the proposed Medicare rule for reimbursing the DPP. We request clarification on the topics stated above, as well as continued high quality technical assistance from the CDC to Maryland DPRP organizations in maintaining fidelity to the National DPP.

Thank you for the opportunity to respond to the proposed standards, and for considering our comments.

Sincerely,

Kristi Pier, MHS, MCHES
Director, Center for Chronic Disease Prevention and Control

Cc: Sue Vaeth

C I T Y O F P H I L A D E L P H I A

DEPARTMENT OF PUBLIC HEALTH
1401 JFK Boulevard, Suite 600
Philadelphia, PA 19102
Tel: (215) 686-9009
Fax: (215) 686-5212

Thomas A. Farley, MD, MPH
Health Commissioner

Docket No. CDC-2017-0053

Dear CDC,
This comment relates to the revised version of the Centers for Disease Control and Prevention DPRP Standards and is submitted on behalf of the Philadelphia Department of Public Health.

1) We applaud the CDC for creating an "interim preliminary recognition" status for DPP programs to parallel the CMS interim preliminary recognition category of MDDP supplier, for programs that may not have achieved full CDC recognition but that are nonetheless capable of delivering the DPP/MDPP.

2) We agree with the change in the CDC's Standards regarding frequency of data submission for DPP suppliers, but we also wish to advocate for a more flexible weight loss goal.

It is crucial that DPRP providers be able to gauge their status under the CDC Standards, particularly when the DPRP provider is in the early years of program development. More frequent data submissions will allow programs to better benchmark their progress toward full recognition. Many DPP suppliers, particularly those established through the CDC's 1305 and 1422 grants (CDC 1305—awards to 50 states, and CDC 1422—awards to 17 states and 4 large cities), are still on a steep learning curve with regard to recruitment, retention and successful achievement of the weight loss goal for DPP participants. The more frequently they receive feedback from the CDC, the better informed they are as to program status.

The CDC 1305 and 1422 grants have resulted in tremendous expansion of the DPP nationwide. The DPRP State Evaluation Report published by the CDC indicates that between January and July 2017, the number of DPP programs in the nation grew by 16.6%, from 1,237 in January to 1,442 in July. Participants (enrollees attending at least one session) grew as well by 11.6%, from 92,761 to 103,499. Completers (those having a blood-test or GDM who completed the 12 month program and attended at least 4 sessions) rose by 3.6%. All of the programs covered by the CDC State Report are striving to achieve CDC full recognition by fulfilling the CDC's established DPP standards concerning attendance, activity minutes, and average weight loss of 5% from baseline.

It is important to note, however, that the State Evaluation Report also shows mixed success in terms of the CDC's 5% average weight loss goal. In both the January and July 2017 DPRP State Evaluation Reports, only 25 out of 48 states and the District of Columbia achieved or maintained 5% average weight loss among DPP completers. While there were 21 states whose percent average overall weight loss improved, 15 states experienced declines in percent average overall weight loss. Thirteen states that had achieved 5% or greater average weight loss in January improved their average weight loss by July, but

nine states that had achieved 5% or greater average weight loss in January experienced declines in average weight loss. Among the 10 most populous states, only 2 achieved a statewide level of 5% average weight loss in January and in both of those states, there was a slight decline between January and July. The CDC investment in DPP expansion has been extensive, but if programs cannot achieve or maintain 5% average weight loss and therefore lose recognition and with it any proposed Medicare or other insurance payment, the initial support provided by CDC will have been wasted, and programs will die in a relatively short period of time.

The insistence on 5% average weight loss to qualify for CDC recognition may also encourage cherry-picking. At least one recent publication (Ritchie, et al) asserts that some fully-recognized DPP programs submit information to the CDC only on those enrollees who have signed compliance agreements demonstrating their full commitment to the program. Persons who doubt their ability to succeed or who face other challenges may not sign such agreements and therefore may simply be omitted from reports, but they may also be discouraged from even taking the classes. Furthermore, if the CDC does not require uniform reporting of ALL participants, not just those signing compliance agreements, this amounts to an unequal enforcement of the Standards, and only those programs practicing selective reporting will ultimately achieve full recognition.

While there are evidence-based articles documenting the benefits of 5% weight loss, there is also evidence that lower weight loss (for example, 3% or 4%) will still significantly reduce the risk of diabetes (Hamman, et al). We urge the CDC to replace the average 5% weight loss goal with a range of 3%-5% average weight loss. CDC could use something like the STAR ratings system: if programs achieve a 5% average weight loss, they are designated as 5 STAR Programs; if 4% average weight loss, the program is ranked as 4 STAR, etc. Programs then could fluctuate as to average percent weight loss, but as long as they stayed at 3% average weight loss or better, they would maintain CDC recognition. If programs exceeded the 5% average weight loss goal, they could be given special recognition. Using this more flexible standard, DPP suppliers would not be deterred from focusing on more vulnerable, higher risk populations, and more programs would survive the developmental learning curve, thereby ensuring greater and more consistent access to the DPP.

Thank you for the opportunity to comment.

Sincerely,

Claudia Siegel, MA, MPA
Director, Office of Health Information and Improvement
Philadelphia Department of Public Health
1401 JFK Blvd., Room 600
Philadelphia, PA 19102

Articles cited in this comment:

Hamman RF, Wing RR, Edelstein SL, et al. Effect of weight loss with lifestyle intervention on risk of diabetes. Diabetes Care. 2006; 29(9):2102-2107. https://doi.org/10.2337/dc06-0560.

Ritchie ND, Havranek EP, Moore, SL, Pereira RI. Proposed Medicare coverage for diabetes prevention: strengths, limitations, and recommendations for improvement. Am J Prev Med. 2017;53(2):260-263. https://doi.org/10.1016/j.amepre.2017.02.005

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Submitter Info

Comment:	Here is a summary of AADE's comments that I support: AADE commends the CDC for encouraging DPRP programs to refer participants who develop type 2 diabetes to a diabetes self-management education and support (DSMES) program. CDC also suggests that participants can continue in the CDC-recognized lifestyle change program while receiving DSMES. AADE encourages CDC to allow Diabetes Prevention Program suppliers to submit under one DPRP code regardless of the delivery mode (in-person, online, distance learning and a combination), as opposed to the proposal to provide separate reports on each. AADE suggests the CDC require lifestyle coaches to receive formal and continued education to ensure effective delivery of the lifestyle change program. AADE commends the CDC for adding preliminary recognition which is a new recognition status. Preliminary recognition is an attendance-based requirement that we feel will acknowledges organizations that are in a good position to achieve full recognition. AADE agrees with the CDC's decision to require organizations with pending, preliminary or full recognition to submit evaluation data to the DPRP every 6 months versus every 12 months. AADE has provided comments on the newly proposed data reporting variables: Lifestyle Coach Medicare NPI Number, Enrollment Source, Payer Type, Education, Delivery Mode, Session ID, and Session Type. AADE is in support of the proposed transitional phase for existing DPRP organizations submitting data elements previously approved by OMB (2015) once between 01/01/18 and 06/30/18. *
First Name:	Sareena
Last Name:	Oncea
ZIP/Postal Code:	97222
Email Address:	sareena.oncea@providence.org
Organization Name:	
Cover Page:	

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

September 12, 2017

Brenda Fitzgerald, MD
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
1600 Clifton Road
Atlanta, GA 30329-4027

Re: AMA Comments on Updated Standards for the Centers for Disease Control and Prevention's Diabetes Prevention Recognition Program, (Docket No. CDC-2017-0053)

Dear Dr. Fitzgerald:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am pleased to offer our comments to the Centers for Disease Control and Prevention (CDC) Prevention's Diabetes Prevention Recognition Program (DPRP), regarding Docket No. CDC-2017-0053.

Section II, Standards and Requirements for Recognition, subsection on Participant Eligibility, item #3: "a recent (within the past year) blood test (may be self-reported; however, for Medicare DPP (MDPP) suppliers, a self-reported blood test is not permitted for billing)" and "Fasting glucose of 100 to 125 mg/dL (CMS eligibility requirement for Medicare DPP suppliers is 110 mg/dl)."

In its MDPP proposal, the Centers for Medicare & Medicaid Services (CMS) stressed that its MDPP eligibility aligns with the CDC DPRP standards, but there is a discrepancy for fasting glucose results. The differences between the eligibility criteria to participate in a DPP using CDC recognition program guidelines compared to the proposed criteria for Medicare DPP eligibility may limit access. The MDPP proposed fasting plasma glucose testing threshold of 110-125 mg/dL is higher than the threshold of 100-125 mg/dL recommended by the US Preventive Services Task Force (USPSTF) screening guidelines and virtually all other clinical guidelines for managing prediabetes (note: CDC incorrectly describes the MDPP standard as 110 but it is actually a range of 110-125). This is inconsistent with accepted standards of care in the U.S. and is likely to cause confusion among physicians about when to diagnose a Medicare patient with prediabetes and when to refer them to the MDPP. The AMA urges the CDC and CMS to support

access to population-based health care by aligning the DPRP and MDPP eligibility criteria with one another and with accepted standards of care and clinical practice guidelines.

The AMA supported CMS' proposal to permit patients who meet the proposed blood value criteria to obtain MDPP services by self-referral, community-referral, or health care practitioner-referral. We asked CMS for further clarification, however, as to how the MDPP provider will obtain and document the required blood value in order to verify the participant meets MDPP eligibility for the benefit. As with the other eligibility requirements, the AMA urges CDC and CMS to work together to clarify and align their policies on this issue.

Section II references the CDC Prediabetes Screening Test and includes a link http://www.cdc.gov/widgets/Prediabetes /Prediabetes.swf – and references that a hard copy is included in the Guidance section – Appendix B. There is also a link in Appendix B, but it is different from the link in Section II. The AMA recommends that Section II include the link that is in the Appendix section – https://doihaveprediabetes.org/prediabetes-risk-test.html as it is the proper link for the hard copy.

Section II outlines the accepted screeners/tests to determine participant eligibility. One of accepted tests is a "claims-based Current Procedural Terminology (CPT) code specifying the screening of or diagnosis for prediabetes." CPT codes are not diagnostic codes. They are only used to indicate that a patient was screened. The AMA recommends that this language be amended.

Table 4. Data Dictionary: Evaluation Data Elements

The AMA supports CDC's adding a referral source to data that DPP providers are required to collect from DPP participants as part of the Data Dictionary. The referral source list proposed by CDC includes "health care provider" which is defined as a physician or any member of the care team. Studies have shown that physician engagement contributes to participant enrollment. Collecting process data on physician referral will provide DPP providers, health systems and medical organizations with information needed to demonstrate an increase in clinical practice change.

Sincerely,

James L. Madara, MD

Academy of Nutrition and Dietetics
www.eatright.org

120 South Riverside Plaza
Suite 2000
Chicago, Illinois 60606-6995
800.877.1600

1120 Connecticut Avenue NW
Suite 460
Washington, D.C. 20036

September 12, 2017

Mr. Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE
MS-D74
Atlanta, Georgia 30329

Re: Docket Number- CDC-2017-0053; Revision to CDC Diabetes Prevention Recognition Program (DPRP) Standards and Operating Procedures 2018

Dear Mr. Richardson:

The Academy of Nutrition and Dietetics (the "Academy") is pleased to provide comments on CDC-2017-0053, Revision to CDC Diabetes Prevention Recognition Program (DPRP), Standards and Operating Procedures 2018, published in the Federal Register on July 14, 2017. Representing more than 100,000 registered dietitian nutritionists (RDNs)[1], nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation's health through food and nutrition across the lifecycle. Academy members provide professional services such as medical nutrition therapy (MNT) and have been involved in the National Diabetes Prevention Program (NDPP) from the start, participating in the development, implementation and provision of services. We look forward to continuing to work with CDC to ensure that the NDPP is scalable, sustainable and effective at providing evidence-based services to prevent diabetes throughout the country.

The Academy supports the proposed revisions to the DPRP and we offer the following substantive comments to ensure the integrity of the NDPP is maintained. We continue to strongly support the NDPP as an evidence-based lifestyle change program aimed at preventing type 2 diabetes[2], and urge that the revised DPRP adhere to the strong standards set in programs across the country.

A. Alignment with Medicare Diabetes Prevention Program

The Academy is pleased that in the proposed data collection, CDC has repeatedly underlined its intent to align the revised Diabetes Prevention Recognition Program (DPRP) guidelines with the Medicare Diabetes Prevention Program (MDPP) expansion model standards. We have urged CMS to maintain close alignment with the DPRP so MDPP suppliers

[1] The Academy has approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

[2] Centers for Disease Control and Prevention; National Diabetes Prevention Prevention Program; About the Program. Available at http://www.cdc.gov/diabetes/prevention/about.htm. Accessed September 7, 2017.

are not hampered by conforming to two different regimes, and encourage CDC to continue to provide evidence-based standards that serve as the basis for the MDPP expansion model.

Specifically, we recommend that CDC finalize the interim preliminary recognition standard, which will align with reimbursement for the MDPP standards. We urge CDC to finalize these guidelines in a timely manner so as to expand the pool of potential MDPP suppliers available to service this population, and to not create unnecessary confusion in the supplier community and impose undue administrative burden on the Medicare program.

The Academy also continues to encourage the CDC to evaluate models of virtual delivery programs for the DPP, including platforms that allow remote access and can meet the patient or client at a location that is accessible, particularly for rural communities.

B. Information on Type, Training and Location of Providers

The Academy recommends collecting information on the qualifications of the NDPP lifestyle coaches as part of the new "lifestyle coach" item on the questionnaire. Collecting and evaluating this data would meet two of the future research needs identified by the Institute for Clinical and Economic Review (ICER) in its 2016 *Final Evidence Report – Diabetes Prevention Programs*: (1) identify specific elements of DPPs that are associated with participant success, and (2) examine the long-term impact of DPPs on population health, and diabetes prevention, and on health care utilization and costs.[3]

The Academy continues to urge CDC to include a requirement in the DPRP curriculum that the program be delivered by or under the supervision of qualified health care providers, such as an RDN, NDTR, or CDE. We feel such a requirement provides better program integrity by ensuring quality oversight of coaches. The current CDC program recognition standards do not include any specific requirements to ensure these individuals are identified and appropriately referred to necessary health care services and providers. In addition, experience of RDNs/NDTRs who are Academy members delivering DPP's or providing MNT services to participants of such programs reveals the unfortunate frequent occurrence of participants being provided with incorrect nutrition information and advice that is detrimental to their health. Data to date on CDC recognized programs indicates some of the most successful programs use both lay coaches and health professional coaches, such as RDNs. Finally, one of the barriers to expansion of the DPP noted in the ICER report is "the extensive efforts required to screen, identify, train, and retain skilled lifestyle program coaches who can connect to the community targeted by the DPP."[4] RDNs and NDTRs already possess these skills and so provide a readily available workforce for the MDPP program.

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[3] Diabetes Prevention Programs: Effectiveness and Value. California Technology Assessment Forum. https://icer-review.org/wp-content/uploads/2016/07/CTAF_DPP_Final_Evidence_Report_072516.pdf. Accessed September 7, 2017.

[4] Diabetes Prevention Programs: Effectiveness and Value. California Technology Assessment Forum. https://icer-review.org/wp-content/uploads/2016/07/CTAF_DPP_Final_Evidence_Report_072516.pdf. Accessed September 7, 2017.

C. Value of RDNs as NDPP Providers

RDNs remain the most qualified healthcare professional group to provide nutrition-based lifestyle interventions, including MNT and evidence-based nutrition counseling and weight loss management services. RDNs have demonstrated competencies and outcomes that other, less qualified providers of non-medical nutrition services have not been able to demonstrate. The Institute of Medicine found that "the registered dietitian is currently the single identifiable group of healthcare professional with standardized education, clinical training, continuing education and national credentialing requirements necessary to be directly reimbursed as a provider of nutrition therapy."[5]

A recent study provides more evidence that registered dietitian nutritionists are an effective solution to the expensive health care cost of preventing diabetes. A review of dozens of research studies shows diabetes prevention programs that include nutrition education provided by registered dietitian nutritionists help people reduce their risk of diabetes and are more effective than programs delivered by non-dietitians.[6]

The review analyzed 69 studies that focused on diabetes prevention for high-risk adults through lifestyle interventions. "This systematic review and meta-analysis indicated that diabetes prevention programs including nutrition education were associated with a reduced risk of diabetes," assessed by standard measures such as weight, body mass index and glucose measurements including FBG, 2-h BG and HbA1c. It found that dietitian-delivered intervention programs demonstrated greater effectiveness than those delivered by non-dietitian delivery agents, which supports the role of dietitians in diabetes prevention programs. Furthermore, RDNs' training could allow them "to more effectively communicate nutrition information, facilitate skill development, and develop strategies for implementation with their patients."

As CDC revises the DPRP standards, it is critical to ensure that the practitioners who delivered results in the NIH's foundational studies demonstrating effective clinical practice are the same practitioners providing or supervising the interventions.

D. Value of Individualized MNT for NDPP Participants Upon Referral

The Academy continues to recommend that CDC include information about referral services for patients who develop diabetes in conjunction with the NDPP, particularly as the MDPP proposes to allow beneficiaries to continue to receive coverage of the program after developing diabetes, if

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[5] Committee on Nutrition Services for Medicare Beneficiaries. "The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population." Washington, DC: Food and Nutrition Board, Institute of Medicine; January 1, 2000 (published).

[6] Sen, Y., Almeida, F., Estabrooks, P. Davy, B. Effectiveness and Cost of Lifestyle Interventions Including Nutrition Education for Diabetes Prevention: A Systematic Review and Meta-Analysis. J Acad Nutr Diet. 2017: Vol. 117, Issue 3, p404–421.e36.

applicable. In a study of a NDPP in Ohio, it was found that a client who had not reached the target weight loss after five weeks would be less likely to benefit from completing the NDPP course.[7] These clients would have a greater benefit from receiving a more individualized, targeted intervention at that point, including MNT. In order to ensure the best outcomes for all NDPP participants, is is important to include a referral mechanism for those who would benefit from a more targeted and personalized intervention.

In order to prevent the onset of diabetes and reduce the costs associated with diabetes, the Academy urges CDC to ensure access to MNT for individuals diagnosed in the NDPP who are not responding to standardized care. This would allow the best care for all program participants, and provides flexibility for participants to choose the best program for their individual needs and lifestyle.

E. Conclusion

Diabetes is a costly and complex disease, and we applaud the progress that CDC has made to scale up the NDPP, in particular by demonstrating cost-savings for the Medicare population. The DPRP is vital to reducing the burden of diabetes in the United States. The Academy understands the challenges in revising the DPRP to ensure the integrity of the MDPP, and we offer our assistance and evidence-analysis resources regarding these important services. Please contact either Jeanne Blankenship at 312-899-1730 or by email at jblankenship@eatright.org or Stefanie Winston Rinehart at 202-775-8277, ext. 6006 or by email at swinston@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS RDN
Vice President
Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics

Stefanie Winston Rinehart
Director
HHS, Legislation and Policy
Academy of Nutrition and Dietetics

[7] Miller CK, Nagaraja HN, Weinhold KR. Early Weight-Loss Success Identifies Nonresponders after a Lifestyle Intervention in a Worksite Diabetes Prevention Trial. J Acad Nutr Diet. 2015;115(9):1464-71.

I am writing to respond to the proposed 2018 Diabetes Recognition Program (DPRP) Standards. I act to coordinate DPRP data for the University of Minnesota Extension – SNAP-Ed program. The DPRP participants that we serve are limited income. Individuals with limited income face many barriers to participating in DPRP classes including transportation, access to health care to obtain a blood glucose value, and access to healthy foods. A recently published study underscores that SNAP benefits are not adequate to provide enough food to meet federal dietary guidelines. Additionally, some participants take medications that make weight loss very difficult. Other participants struggle with cultural change to participate using DPRP approved curriculum.

In reviewing the 2018 Diabetes Prevention Recognition Standards, I am suggesting that there be more flexibility in requirements for full recognition or remaining in preliminary status. I suggest that the % weight loss be measured at any point in time during the 12 months. Sometimes participants do well during the 16 weeks and then fall back during the monthly course attendance. A 5% weight loss is challenging for many of our participants. With each pound loss there is still good benefit. I am not sure what that rate should be but a realistic weight loss is within the 3% range. Requiring programs to withdraw for one year prior to reapplying could also be reconsidered to better serve limited resource audiences. We currently collaborate with hospitals to conduct NDPP courses. As we become more community based with hospitals doing their own NDPP, it becomes more of a challenge to get blood glucose values and reach 50% with a documented value.

Other recommendations would be to allow a new coach in an existing org to have 1 class to learn from and not have that class affect the date for the whole org. We also need flexibility when starting to work with a new ethnic group. We need a learning period.

Thank you for considering these comments for the DPRP proposed standards.

September 12, 2017

Submitted via www.regulations.gov

The Honorable Ann Albright, PhD, RD
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329

Leroy A. Richardson
Chief, Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-D74
Atlanta, GA 30329

RE: ***CDC-2017-0053; CDC Diabetes Prevention Recognition Program (DPRP);*** *Revisions to DPRP Standards and Operating Procedures*

Dear Dr. Albright and Mr. Richardson:

Thank you for the opportunity to comment on the proposed revisions to the Centers for Disease Control and Prevention ("CDC") Diabetes Prevention Recognition Program ("DPRP") standards.

For the last seven years, the CDC's Division of Diabetes Translation ("The Division") has raised awareness of prediabetes widely; encouraged wide-scale screening and referral of at-risk individuals by physicians and provider groups; developed an adaptable Diabetes Prevention Program ("DPP") curriculum used by thousands of organizations across the country; and created a recognition structure for DPP providers that sets standards for a critical, and growing, industry of diabetes prevention. In the process, the Division has amassed an impressive data set on the demographics, engagement, and outcomes of a diverse group of individuals at elevated risk for chronic disease, creating the most comprehensive picture of prediabetes in the United States currently available.

As the market for diabetes prevention has evolved, so too has the Division for Diabetes Translation, as well as the recognition standards the Division sets for DPP providers. The standards proposed to take effect in 2018 are a critical step in this evolution – especially as the market for diabetes prevention services has grown exponentially over the last three years, and as Medicare plans to begin reimbursing for the service.

Omada Health would like to first applaud the Division, both for the unit's work over the last seven years, and for the obvious amount of careful consideration which went into revising the standards for 2018. As the number and variety of organizations which deliver the DPP have exploded in recent years, the employees within the Division have been asked to oversee an industry that encompasses non- and for-profit entities; community-based programs which serve a few dozen participants, and national organizations which serve tens of thousands; and in-person and digital practitioners. The staff within the Division has risen to this challenge,

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crafting a set of proposed standards which both recognize the diversity of participants served by organizations, while setting rigorous standards for DPP curriculum delivery, engagement, and outcomes in order for organizations to graduate to preliminary or full recognition. With one major exception detailed below, as well as several clarifying questions, Omada is extremely supportive of the 2018 standards proposed by the CDC.

It is clear from the proposed rule that CDC is making a subtle but important shift in how the Division of Diabetes Translation evaluates DPP providers for recognition. By focusing on the outcome measures for the most engaged populations with DPP programs, CDC is removing a systematic disincentive for DPP providers to serve only those individuals who they think will perform best in the program. By maintaining strict but adaptable curriculum standards, the Division maintains program fidelity while allowing for innovation and personalization for subpopulations and individual participant needs. By aligning standards more closely with those proposed by the Centers for Medicare and Medicare Services for Medicare DPP, the Division is clearly working towards a frictionless implementation of the new benefit. On all of these fronts, CDC has balanced the public health needs and system incentives quite well.

In evaluating DPP providers for full recognition, the CDC proposes six standards a provider must meet. Five of these standards focus on how well DPP programs are in getting participants to adhere to the program and generate positive clinical outcomes: percentage of participants attending nine sessions in Months 1-6; percentage of participants attending three sessions in Months 7-12; average percentage of sessions with weight recorded; average percentage of sessions with physical activity recorded; and average percentage weight loss at 12 months. Omada Health is fully supportive of both these standards, and the population on which DPP providers will be evaluated.

However, there is one standard for full recognition that fails to comport with the thoughtful approach undertaken elsewhere by the Division: the requirement that more than 50% of participants enrolled in a DPP program have confirmed biometric eligibility, as defined in the eligibility standards and confirmed by a blood test or participant attestation. It is with this standard that Omada Health would like to register its objection, and suggest a different approach.

Unlike the five other requirements for full recognition, biometric screenings are not a core function of the service provided by a DPP organization. Organizations are focused on delivering the DPP curriculum, and achieving the best outcome results possible. Many DPP providers, Omada included, identify and intake eligible participants via contracts with third parties – employers, health plans, and others. In those cases, the DPP provider does not have control over whether an employee or beneficiary has recently had a qualifying blood test or recently seen a physician. In fact, many employers and health plans specifically request that biometric

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screening *not* be a requirement for entry into a DPP program, given that very few individuals with prediabetes know they have the condition.

Furthermore, DPP providers do not have the capacity, nor the desire, to incorporate biometric screening into the organization's offerings; such an offering would be wholly separate from the core service provided (the DPP). As client organizations (employers and health plans) begin to see positive clinical and financial effect from the DPP intervention, those organizations are often incentivized to err on the side of allowing "borderline cases," or those individuals who qualify through the CDC risk screener, to participate in DPP program.

As CDC works to finalize the 2018 Recognition Standards, Omada strongly requests CDC eliminate the biometric screening requirement to advance to full recognition. While DPP providers should be required to report the percentage of individuals who enter the program via biometric screening vs. the risk screener (in order to monitor levels of screening and referral by health systems and physicians), a DPP organization's recognition status should not hinge on delivering a service which is a precursor to the DPP itself, and tangential to the DPP provider's core function.

Ultimately, decisions on the need for biometric screening should be left to the discretion of the payer. For instance, it is clear that Medicare plans to require a qualifying blood test to confirm eligibility for all MDPP participants. Private payers, including employers and health plans, should have the flexibility to route individuals to qualified DPP programs through the risk screener, if they so choose. While Omada is aware of studies demonstrating that biometric screening of participants correlate to stronger engagement and outcomes, DPP providers are already being directly measured on those standards. Omada looks forward to continuing to work with the CDC, as well as advocacy organizations like the American Medical Association, the American Diabetes Association, and the American Academy of Family Physicians to expand opportunities for screenings and referral to the DPP; however we strongly believe that an organization's recognition status should not hinge on a standard so far outside of its control or core function.

In the event CDC is not comfortable eliminating the biometric screening standard for full recognition, Omada strongly encourages the Division to lower the threshold to 25% for full recognition. This standard would still require DPP providers to encourage screening, but is more feasible given current market standards for organizations delivering the DPP at scale. As the market continues to evolve, Omada would be open to this percentage rising in future standards revisions. In either case, we look forward to continued discussions with the Division regarding how to best align biometric screening requirements with market standards.

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Omada's reactions to other standards revisions are summarized below:

Clinical Eligibility

- BMI Standards revised to 25 (23 if Asian) – Omada has no objections, and applauds CDC for aligning with CMS standards;
- Development of Pregnancy During Participation – Omada has no objections to allowing DPP discretion upon detection; and
- Development of Type 2 Diabetes During Participation – Omada has no objections, however encourages CDC to work with CMS to confirm how this will affect CDC-CMS crosswalk reporting. Under current rules, CMS will allow services up to the point a diagnosis is discovered, but the proposed CDC standards state participants who develop type 2 diabetes while enrolled in the program should not be reported to the DPRP dataset. We request clarification from CDC on this point.

Program Content

- Location – Omada applauds CDC for explicitly stating that online organizations can obtain weights via digital technology. However, we encourage CDC to explicitly state the phrase "Bluetooth-enabled" also refers to scales which transmit weights securely via wireless or cellular transmission;
- Delivery Mode – Omada has no objection to organizations being limited to one program per mode, however we encourage CDC to allow organizations to have tailored versions of approved curriculum with different but acceptable curricula emphases for specific participant subgroups (low-literacy, low-income, senior, etc.);
- Coaches – Omada encourages CDC to retain the requirement that DPP coaches use CDC-approved master trainers or a CDC-approved lifestyle coach training organization. This requirement in the current standards is critical to maintaining program integrity and curriculum fidelity; and
- Auditing – Omada suggests that CDC add stronger organizational attestation language to data submission by DPP providers, and the DPRP registry contain a public field showing how many participants each recognized DPP provider has contributed to the DPRP database. These measures will increase both transparency and accountability of DPP providers in a growing field.

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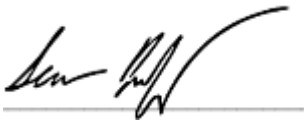
OMADA HEALTH INC.
500 SANSOME STREET, SUITE 200 SAN FRANCISCO, CA 94111 | OMADAHEALTH.COM | 888.987.8337

Thank you for the opportunity to provide comment on the proposed rule. Please do not hesitate to contact Omada's Director of Public Policy Adam Brickman at Adam.Brickman@omadahealth.com or 914-548-3748 if we can be of further assistance.

Sincerely,



Sean Duffy

CEO, Omada Health

OMADA HEALTH INC.
500 SANSOME STREET, SUITE 200 SAN FRANCISCO, CA 94111 | OMADAHEALTH.COM | 888.987.8337

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Submitter Info

Comment: The proposed changes to the DPRP will have a significant impact on the ability for frontier and rural states to expand their DPP offering. The specific change that will have the greatest impact on these frontier states is the proposed change that would require DPPs to start a new class every six months. In Wyoming, we have a small population - less than 600,000 statewide. 17 out of our 23 counties are frontier, 4 are rural, and only 2 are considered urban. In these frontier and rural counties, the population is sparse and widely disbursed. This low population size makes it difficult to fill a class with enough participants to meet the existing requirements for a recognized DPP. To make things even more difficult, Wyoming has extreme winters. Oftentimes the roads are impassable and highways and interstates are shut down to travel. Small populations and difficult travel conditions will make it extremely challenging for Wyoming DPPs to start two classes per year and keep the attendance at a level that meets requirements for gaining or maintaining recognition. Other rural and frontier states will have similar problems. I highly encourage the inclusion of special exemptions for DPPs in rural/frontier areas, or the removal of this rule from the proposed changes. I don't want rural/frontier areas to be discouraged from starting a DPP and applying for recognition. *

First Name: Hannah

Last Name: Herold

ZIP/Postal Code:

Email Address:

Organization Name:

Cover Page: 

SOLERA
AN INTEGRATED HEALTH NETWORK

September 13, 2017

Ann Albright, PhD, RD
Director
Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Division of Diabetes Translation

Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road N.E.
MS– D74
Atlanta, Georgia 30329

Submitted electronically via: http:www.regulations.gov

Re: [60 Day–17–0909; Docket No. CDC–2017– 0053] Proposed Data Collection Submitted for Public Comment and Recommendations, CDC Diabetes Prevention Recognition Program (DPRP)

Dear Director Albright:

Solera Health submits comments on the Centers for Disease Control and Prevention (CDC) Proposed Data Collection on the CDC Diabetes Prevention Recognition Program (DPRP) issued on July 14, 2017, (82 Fed Reg 32549 - 51) and looks forward to other opportunities to offer suggestions on the National Diabetes Prevention Program (DPP). Solera wants to continue working with federal and state partners to scale and deliver this evidence-based intervention and to avert the onset of diabetes in America.

Solera is an integrated network of Diabetes Prevention Program (DPP) providers that functions as the administrative contractor to manage the DPP for health plans. Currently, Solera is contracted with over 30 health plans which cover 70 million individuals. We partner with health plans and Solera administers the DPP through our national network of in-person, community DPP providers and virtual DPP partners. Solera is uniquely positioned to solve for both scale and personalization when implementing the Medicare DPP benefit as a new model for chronic disease prevention. As a DPP integrator, Solera has created a unique marketplace that connects the critical sectors in the DPP ecosystem – payers, physicians, consumers and DPP providers. Solera contracts with DPP providers as our sub-delegates and ensures access, quality, service, and compliance for those entities accepted into the Solera network. Solera is currently contracted

or in-contract negotiations with over 100 DPP providers representing thousands of community locations. We have a robust in-person delivery network in all 50 states. Solera provides the technology platform to support administrative processes for the DPP providers including eligibility verification, qualification, enrollment, claims submissions, reimbursement, reporting, data validation and program integrity. Solera's patent pending matching science matches consumers with the "best fit" DPP provider and location based on their unique needs and preferences, offering consumer choice, and driving engagement and outcomes.

Solera categorically opposes the broad collection of data where the purpose is vague, and not directly linked to recognition. As an Integrator, Solera is responsible for the collection and validation of data fields, and must protect the data we collect. We have a requirement from our health plan clients to collect the minimum amount of personal information required to deliver the program. Where proposed data fields solicit participant information that does not have bearing on the qualification, delivery and efficacy of the program, Solera does not support the requirement to collect this data.

Solera is also against the expansion of data fields that are unduly burdensome and limit participant engagement. Solera has keen insight into the fragile nature of participant enrollment, especially where participants decline to fully execute on their initial commitment to participate in the DPP. We also know how much effort is required to reach a person who may have reservations about participating. Expanding the list of questions posed or lengthening the required data collection where there is no plausible relation to program efficacy is not supported by Solera Health. We ask the CDC to review the current data elements and suggest what can be removed from the Capacity Assessment and the DPRP Recognition Criteria. CDC proposes to add 12 new data elements in addition to all data elements that are currently required.

The 6 month DPRP reporting requirement is burdensome on DPP providers. Solera asks the CDC to extend the reporting interval timeframe to 12 months. The CDC's calculation of the estimated annualized burden hours, 2 hours per response, significantly underestimates the time needed for collecting and submitting DPRP recognition data.

CDC proposes that organizations apply for a separate DPRP number for each type of DPP delivery modality, such as in-person, telephonic, telehealth, voice-response (i.e. Alexa), video, paper, digital, telehealth, etc. While we appreciate CDC's desire to document the effectiveness of these various DPP delivery modalities, the DPP is increasingly delivered in a hybrid modality that includes in-person AND digital delivery at the participant level rather than the organization level. It would be very difficult for an organization delivering the DPP in-person or telephonically while also providing digital tools to participants who wish to use them to determine at the organization level which DPRP category to select, as many DPP cohorts would include participants who may or may not be utilizing a hybrid model in the same class. Solera suggests that organizations have a single DPRP number, and the delivery modality is indicated in DPRP reporting at the individual rather than the organization level for the various modalities. This would allow CDC to determine the comparative effectiveness of these modalities based on age, gender, ethnicity, BMI, etc.

Specific Concerns on Proposed Data Elements

1. Lack of consistency in the terminology used by the CDC and CMS.

In describing the different ways to deliver the Medicare DPP, CMS uses the term, "delivery modes" for either in-person or virtual program delivery. CMS defers to the CDC definition for "virtual providers." The CDC categories delivery modes for the National DPP as in-person, online, business learning, and combination. The CDC and CMS should standardize the terminology used to describe the DPP delivery modalities.

For another example, there was confusion about the delivery modalities stemming from a CDC listening session on August 23, 2017. CMS staff defined the distance learning mode as including remote, telehealth, and video conferencing that is 100% delivered by a trained lifestyle coach. The fact that a class is delivered 100% by a trained lifestyle coach could lead one to believe it is an in-person class. Solera asks CMS and the CDC to provide greater clarity and alignment on the terms and definitions used in their proposals, requirements and rule making.

2. Opposition to the required collection of physical activity minutes.

The CDC continues to require the collection of physical activity minutes as a condition for DPRP recognition. Physical activity in the DPP has been difficult for Coaches to accurately obtain from participants, and proves challenging for some participants to accurately report. It is sometimes the case that reporting of physical activity minutes has included routine activity instead of the moderate or rigorous activity should be recorded. The accuracy and utility of self-reported physical activity minutes and intensity are doubtful at best. Clinical evidence has demonstrated that physical activity is more important to maintenance as opposed to weight loss. Additionally, in the Medicare DPP there is no performance payment tied to the collection or achievement of goals related to physical activity. Solera asks the CDC to eliminate the reporting requirement of physical activity minutes.

3. Opposition to collection of the education level of the participant.

Solera has extensive experience engaging potential DPP participants in the DPP with multiple engagement strategies and referral channels. Solera knows firsthand that the enrollment must be simple and straightforward, and the addition of any additional steps or collection of unrelated information will adversely impact program enrollment. Solera is opposed to the collection of the data element on education level of the participant because it does not relate to the DPP delivery or success factors.

Educational level is often used as a proxy for socio-economic status; those with advanced levels of education typically have increased knowledge of health risks and protective factors, and the economic resources to seek healthy behaviors.[1] Solera does not want educational level to marginalize potential DPP participants by making individuals think the classes may

[1] Education and Health, National Poverty Center Policy Brief #9, University of Michigan, 2007. Accessed August 24, 2017.

depend on a particular level of educational attainment. Together with the required collection of race, the collection of educational attainment exceeds what should be allowed by the CDC.

Finally, since it is not possible for the DPP providers to validate the responses provided, the value of the educational level of the participant is questionable, and the level of intrusion into the lives of the beneficiaries is high. Solera believes that the required collection of this information at enrollment will be a deterrent and opposes it as a new data field.

Solera continues to looks for ways to continue working with the CDC on the National DPP. We want to ensure the required information collected by DPP providers is relevant and does not intrude on participant privacy or create an undue burden. Solera asks that the data elements be streamlined and reduced to that which is essential for DPRP recognition.

Thank you for considering our feedback. If there are questions or if additional information is needed, please do not hesitate to contact Danielle Turnipseed at 202-930-5961 or Danielle.Turnipseed@SoleraNetwork.com.

Sincerely,

Brenda Schmidt
Founder and CEO
Solera Health, Inc.

KAISER PERMANENTE®

September 13, 2017

Leroy A. Richardson
Chief, Information Collection Review Office
Centers for Disease Control and Prevention
Department of Health and Human Services
1600 Clifton Road, NE
Atlanta, GA 30329

Submitted electronically to: www.regulations.gov

RE: *CDC Diabetes Prevention Recognition Program (DPRP) Information Collection; Docket No. CDC-2017-0053*

Dear Mr. Richardson:

Kaiser Permanente offers the following comments in response to the proposed information collection on the Centers for Disease Control and Prevention's (CDC) Diabetes Prevention Recognition Program (DPRP).

The Kaiser Permanente Medical Care Program[1] is the largest private integrated health care delivery system in the U.S., with more than 11.8 million members in eight states and the District of Columbia. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. As such, we strongly support health behavior change programs and interventions that focus on chronic disease prevention. Three of our Kaiser Permanente regions have Pending Recognition under the DPRP.

Kaiser Foundation Health Plan, Inc. and our health plan subsidiaries collectively serve more than 1.5 million Medicare beneficiaries. Our Medicare members who meet the clinical eligibility criteria will become eligible for the Medicare Diabetes Prevention Program (MDPP) benefit upon the effective date finalized by the Centers for Medicare & Medicaid Services (CMS).

As a leader in diabetes and pre-diabetes care delivery improvements and health outcomes, we support the CDC's efforts to implement quality assurance standards to ensure access to evidence-based programs. After reviewing the proposed final version of the DPRP Standards and Operating Procedures, we have concerns regarding the requirements for preliminary recognition and the burden of semi-annual data collection on DPP providers.

Standards for Preliminary Recognition

Kaiser Permanente is concerned about the limited supply of recognized DPP providers and believe the supply will not meet anticipated demand for the MDPP benefit. We support the availability of

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

One Kaiser Plaza
Oakland, CA 94612

a "preliminary" recognition status but believe the participation criteria may limit the number of qualified providers available to participate in the MDPP, thereby limiting access and choice for eligible Medicare beneficiaries.

Prospective DPP providers who fall short of the participation criteria will not be afforded the opportunity to learn from and pursue quality improvement initiatives to strengthen performance since they would be ineligible to provide DPP services to Medicare beneficiaries. This is particularly true of attendance during the maintenance period, which historically has been the period of greatest drop-off and is reflected in the weight management literature.

The 60-percent participation requirement may be particularly challenging for providers who serve higher risk or vulnerable communities, as we know that transportation barriers or other socio-economic factors can make attending classes in person challenging. Therefore, Kaiser Permanente recommends eliminating the attendance requirement for preliminary recognition and providing technical assistance for those providers not meeting the 60-percent benchmark.

Data Collection Burden

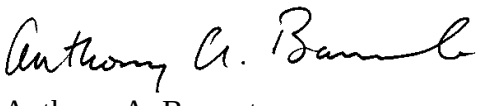
While Kaiser Permanente recognizes the value in reviewing DPP program data on a more frequent basis (every six months rather than annually), we believe this can be done by individual DPP providers and therefore recommend maintaining the annual data collection requirement. Increased data collection imposes a significant burden on the DPP provider to collect, scrub and submit the necessary data and would require significantly more staff time.

In particular, the proposal to add participant level of education as a new data collection item would require developing a new process to gather that information since that is not something routinely collected in the electronic medical record. Kaiser Permanente DPP providers have also expressed concern about the sensitivity of asking participants this question. For these reasons, we recommend including patient level of education as an optional data item.

* * *

Kaiser Permanente appreciates the CDC's consideration of these comments. We would be pleased to provide additional information or answer any questions. Please contact Keavney Klein at (510) 271-6482 or keavney.f.klein@kp.org, or me at (510) 271-6835 or anthony.barrueta@kp.org.

Sincerely,



Anthony A. Barrueta
Senior Vice President, Government Relations

NORTHWEST PORTLAND AREA INDIAN HEALTH BOARD

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2121 S.W. Broadway
Suite 300
Portland, OR 97201
Phone: (503) 228-4185
Fax: (503) 228-8182
www.npaihb.org

SUBMITTED VIA: *www.regulations.gov*

September 13, 2017

Leroy A. Richardson
Chief
Information Collection Review Office
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
1600 Clifton Road NE., MS-D74
Atlanta, GA. 30329

RE: CDC Diabetes Prevention Recognition Program (DPRP) Notice (Docket No. CDC-2017-0053) Comment

Dear Mr. Richardson:

On behalf of the Northwest Portland Area Indian Health Board (NPAIHB), we submit comments on the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) notice – Docket No. CDC-2017-0053), issued in the Federal Register on Friday, July 14, 2017. The NPAIHB is a Public Law 93-638 Tribal organization that advocates on health care issues for the forty-three federally-recognized

Tribes as sovereign nations have the inherent authority to address and meet the health and welfare needs of their citizens; and many tribes assume responsibility for education, health and social service programs for their citizens under the Indian Self-Determination and Education Assistance Act (ISDEAA). Diabetes is a chronic disease that tribes have made a priority. During the 17 years of the SDPI, the IHS, tribal, and urban (I/T/U) health programs have implemented evidence-based and community-driven strategies to prevent and treat diabetes. SDPI is changing these disproportionate AI/AN community statistics with improvements in average blood sugar levels, reductions in the incidence of cardiovascular disease, prevention and weight management programs, and a significant increase in the promotion of healthy lifestyle behaviors.

Congress established SDPI in 1997 as part of the Balanced Budget Act to address the growing epidemic of diabetes in AI/AN communities. The SDPI provides grants for diabetes treatment and prevention services to 301 I/T/U Indian health programs in 35 states.[1] The SDPI funding has enabled AI/AN communities to develop, sustain, and significantly increase access to successful quality diabetes programs where few resources

On April 14, 2015, the U.S. Senate passed a two-year renewal of the Special Diabetes Program for Indians (SDPI). The extension of the Special Diabetes Program for Type I Diabetes and for Indians through FY 2017 is included in Section 213 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which became Public Law No: 114-10 on April 16, 2016.

NPAIHB applauds the effort of CDC to recognize organizations that deliver preventative services to individuals diagnosed with pre-diabetes through the CDC DPRP. However, the structure of the CDC National Diabetes Prevention Program (DPP) is problematic

[1] Indian Health Service Special Diabetes Program for Indians – Changing the Course of Diabetes Fact Sheet.

with respect to I/T/Us participation. The Indian health care system as a whole is chronically underfunded, at about 59% of need,[2] and overburdened. Our health programs often lack the resources and/or staffing to make needed reforms and upgrades, or to meet reporting and technology requirements. Further, our health programs are frequently forced to prioritize limited funding, resulting in a lack of resources for preventive care and other measures that would be expected to improve outcomes and maximize efficiency, but that require an up-front investment.

Program Recognition

There are three types of recognition for community-based organizations to participate in the National Diabetes Prevention Program (DPP) including pending, preliminary, and full recognition. Organizations can remain in the pending recognition status for up to 36-months and must submit data every 6-months. The preliminary status is a new recognition status where organizations must be in a pending status for at least 12-months and submit 12-months of data on at least one completed cohort. Organizations must remain in the preliminary recognition status for up to 24-months. During the preliminary recognition status, at least 60 percent of participants must attend the core and maintenance sessions. Organizations must remain in the full recognition status for up to 24-months. The full recognition status requires a year-long cohort of participants with weight documentation during at least 80 percent of the sessions and physical activity documentation during at least 60 percent of the sessions. The full recognition status requires the average weight loss to be 5 percent of the participant's starting body weight

CDC must recognize that tribes do not have the infrastructure and capability to implement and monitor the CDC DPP without additional funding to support the operational and logistical components needed to participate. This program is labor intensive and requires a number of individuals to be key leaders as well as educators and alternates that are needed to increase support and beneficiary participation. NPAIHB and our member tribes recommend that CDC create another recognition path to grandfather SDPI programs using the SDPI measurement and reporting criteria through a CDC pilot project. Tribal health care providers are the experts of the needs of their tribal members and should be recognized for their expertise and use of evidence-based methods in a culturally-relevant environment, which have been developed in tribal communities to decrease the incidence of Type II diabetes diagnosis. A majority of tribal health programs are unaware of the process, the criteria, and the period of time it takes programs to become CDC-recognized.

NPAIHB and our member tribes believe that the CDC Diabetes Prevention Program (DPP) participation requirements are significant barriers for tribal health programs to pursue recognition, especially small community health centers in Indian Country. The program, in its current form, deters tribal health program participation and will not benefit tribal health programs. NPAIHB recommends that CDC work with IHS and tribes through meaningful tribal consultation to incorporate SDPI and tribal participation in the DPP. Additionally, NPAIHB would like to recommend for CDC to conduct an outreach and education initiative for SDPI and tribal health care programs to become CDC-recognized DPP organizations.

NPAIHB is concerned about the 12-month data submission to CDC because it is not applicable in our communities to collect the data when there is no support or funding within an already under-served health care community. The CDC recognition process can take up to two years to accomplish full CDC-recognition status. A majority of tribal health care programs are unaware of the process,

[2] NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP'S RECOMMENDATION ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2017 BUDGET, 8 (2015).

the criteria, and the period of time it takes programs to become CDC-recognized. For over ten years, AI/AN communities have been implementing the SDPI DP program and continue to achieve similar results as the National Institutes of Health DPP lifestyle intervention group.[3] The SDPI DP Toolkit was developed over 5 years ago to ensure that tribes are able to implement a cost effective, highly successful, diabetes risk reduction and prevention program that works.

IHS administers the SDPI grant as well as provides technical assistance to IHS, tribal, and urban Indian (I/T/Us) and coordinates program evaluation. NPAIHB requests that I/T/U health programs not be required to coordinate with an additional federal agency to IHS regarding recognition. It is a burden for tribal health programs to report and participate in three different diabetes prevention recognition programs administered by three federal agencies under the U.S. Department of Health and Human Services (HHS). This will prove to be a cumbersome and inefficient process. We request that CDC work with the SDPI programs and recipients to ensure there is alignment, consistency, and coordination of these programs to receive recognition and reimbursement for diabetes prevention services.

NPAIHB recommends recognition of other health outcome measures for performance payment because weight loss does not provide an incentive, the goal should be to become a healthier Medicare beneficiary to prevent Type II diabetes. There are various successful evidence-based methods that can be utilized in addition to attendance as performance measures such as reductions in blood sugar levels, lower BMI levels, and increased intake of healthy foods and physical activity. The CDC DPP must include various methods to achieve a healthier preventative lifestyle because one method will not be successful for the majority of eligible patients.

The goal of diabetes prevention programs is to reduce the incidence of Type II diabetes, and reaching that goal is more complicated than merely implementing a weight loss program. Lifestyle change is not a linear process and should not be reduced to one measurement. The social and environmental conditions in which behavior change occurs can greatly affect one's lifestyle change progress and often communities with the highest risk of chronic disease also have the most challenging social and environmental conditions. AI/ANs have the highest risk of Type II diabetes and many are also challenged by lack of quality medical care, lack of access to healthy food and lack of access to safe or adequate places for physical activity. Tribal health programs, especially SDPI, should be granted the flexibility to determine their own diabetes prevention measures of success. NPAIHB recommends the utilization of measures that have been successful variables in the SDPI such as reductions in blood sugar levels, reduced hypertension risk, lower BMI levels, increased intake of healthy foods, increased rate of physical activity, or risk reduction factors should be used instead of weight loss. We also recommend that CDC include a mental health measurement as part of integrated care because behavioral health plays a significant role in changing lifestyle behaviors as well as achieving weight loss, especially in Indian Country where patients may struggle with historical trauma.

CDC must take into account the unique position of Tribal and urban Indian health care programs in the national health care system. To that end, it is critical that CDC engage in a face-to-face consultation with Indian tribes and urban Indian health organizations in each IHS area, so that we can determine how tribes who administer successful SDPI can become recognized by CDC.

[3] IHS SDPI Report to Congress 2011; IHS SDPI Report to Congress 2014.

Tribal Consultation

NPAIHB appreciates the opportunity to submit comments on the CDC DPRP. We note, however, that the public notice and comment period is not a substitute for Tribal consultation pursuant to the CDC Tribal Consultation Policy and Executive Order 13175. The Federal government's trust responsibility provides the legal justification and moral foundation for Indian specific health policymaking—with the objectives of enhancing their access to health care and overcoming the chronic health status disparities of this segment of the American population.

Indian health care programs are unique. Tribal health programs implement the United States' trust responsibility to provide health care services to AI/ANs.[4] The IHS is the primary federal agency tasked with carrying out this responsibility; however, the federal trust responsibility extends to every branch of the federal government and to every Executive Department and agency, including CDC. CDC must not abdicate its trust responsibility by failing to account for the unique needs of the Indian Health system as it finalizes and implements this rule. The trust responsibility requires that the federal government assist I/T/Us in meeting the highest standards for efficiency and quality of patient care.

The federal government's trust responsibility requires it to take affirmative steps to improve the health status of AI/ANs. AI/AN communities are significantly different and AI/AN Medicare beneficiaries experience additional hardships that CDC must take into consideration in order to ensure that AI/AN communities can participate in the National DPP. NPAIHB urges CDC to engage in formal consultation with tribes and the Indian Health Care system, including I/T/Us.

Conclusion

NPAIHB hopes that CDC, in the spirit of its partnership and shared interest in improving AI/AN health care will work with the IHS and Tribal clinics in our Area to . We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CDC on the inclusion of IHS and Tribal clinics participating as recognized organizations that deliver diabetes prevention programs through the CDC DPRP.

If you have any questions about the information discussed above, please contact Laura Platero, Government Affairs/Policy Director at (503) 407-4082 or by email to lplatero@npaihb.org.

Sincerely,

Joe Finkbonner, PPh, MHA
Executive Director
Northwest Portland Area Indian Health Board (NPAIHB)

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[4] *See, e.g.*, 25 U.S.C. § 1601 ("Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government's historical and unique legal relationship with, and resulting responsibility to, the American Indian people."); The White House, *Memorandum for Heads of Executive Departments and Agencies re: Tribal Consultation* (Nov. 5, 2009), https://www.whitehouse.gov/the-press-office/memorandum-Tribal-consultation-signed-president.

Attached below are comments from the Harold Schnitzer Diabetes Health Center at Oregon Health and Science University on the proposed changes to the CDC's National DPP Diabetes Prevention Recognition Program for 2018.

The comments below are based on our review of the document entitled "CDC National DPP DPRP, Supporting Statement: Part A, May 16, 2017."

Comment on the 5% Weight Loss Target

It is well known that the participants in the original DPP clinical trial, published in 2002 (NEJM 2002, 346 (6): 393-403), achieved a mean weight loss of 7.2%. Based on this weight loss achievement, in 2011, the CDC Diabetes Prevention Recognition Program (DPRP) established a minimum weight loss standard of 5% for participants in the CDC National DPP.

The following sentence is found on page 6 of May 16, 2017 document we reviewed:

"Effectiveness research demonstrated that the DPP curriculum, when modified slightly for delivery in a group setting by community-based organizations, helped program participants achieve the 5–7% weight loss needed to prevent or delay type 2 diabetes in individuals with prediabetes, and that such a program can be cost effective and cost saving.[6-10,23]

Although there are a handful studies that may demonstrate a 5-7% weight loss when the DPP is applied to smaller groups of individuals, the reality is pooled, aggregate data, including 4 years of data from the DPRP, does not support the target of a 5% percent weight loss.

Since the publication of the original DPP research study a number of translational research studies applying the DPP model have attempted to replicate the 7% weight loss achieved in the original DPP research study. At this point we now have outcome data from a number of sources including: 4 years of data from the CDC National DPP, the two-year YUSA test of the DPP with Medicare beneficiaries, as well as detailed reviews of a number of translational research studies on the application of the DPP model in the real world.

The Community Preventive Services Task force reviewed 53 studies of diet and physical activity programs aimed at the prevention of type 2 diabetes. These studies demonstrated a mean weight loss of loss of 3% (Ann Intern med 2015, 163: 437-451).

A Meta-analysis of 28 US based studies applying the findings of the DPP clinical trial showed an average weight loss of 4% (Health Affairs 2012, 31: 67-75). A 4-year evaluation of data from 14,747 participants in the CDC National DPP demonstrated a mean weight loss of 4.2% (Diabetes Care 2017, DOI: https://doi.org/10.2337/dc16-2099).

Finally, 5,696 Medicare beneficiaries who attended at least 4 sessions of the YUSA DPP from 2013-2015 experienced a mean weight loss of 4.73% (CMS Certification of the MDPP, 2016, https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf).

The data above concretely demonstrate that it is difficult to achieve a 5% weight loss target in a non-clinical trial setting of DPP delivery. However, this does not mean that the National DPP is ineffective. To the contrary, the data referenced above demonstrate an effective, moderate amount of weight loss between 3.00-4.73% when the DPP is delivered in a real world setting. Based on the original DPP clinical trial we know that every kilogram of weight lost in the context of the DPP equates to a 16% reduction of risk (Diabetes Care 2006, 29 (9): 2102-2107). To that end, the delivery of the DPP in community settings has been a huge success.

Based on data referenced above we suggest that the minimum average weight loss target be lowered from 5% to 4%.

Andrew Ahmann, MD, Medical Director

Kristin Benn, Administrative Director

Don Kain, MA, RD, CDE, Diabetes Program Education & Outreach Manager

University of Pittsburgh
Diabetes Prevention Support Center
Pittsburgh, PA 15213
Tel 412 - 647- 5200
Fax 412- 647- 2429
http://www.diabetesprevention.pitt.edu/

We are writing in regard to the proposed Centers for Disease Control and Prevention Diabetes Prevention Recognition Program Standards and Operating Procedures for 2018. By way of introduction, we invite you to take a look at the ongoing DPP translation work we have been conducting through the University of Pittsburgh DPSC (**www.diabetesprevention.pitt.edu**). The mission of the DPSC is to prevent or delay type 2 diabetes and improve cardiovascular health by providing education, training, and program support services to teams of health professionals as they implement lifestyle prevention services within diverse communities. At the core of the Center's efforts is providing behavioral lifestyle training in the implementation of a continually updated (based on latest empirical findings), group-based version of the original DPP manual and materials called the Group Lifestyle Balance™ (GLB). Since 2004, our center has been providing two-day training workshops for health care professionals that derive directly from our experience with the foundation and training of the DPP Lifestyle Balance program **http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1282458/.** The DPSC faculty (consisting of academic experts in psychology, behavioral medicine, nutrition, exercise science and epidemiology) developed the training workshop to provide a comprehensive, standardized overview of the DPP-GLB program and its implementation. More than 60 training workshops have been held to date, with approximately 2,500 health professionals having completed training. In addition, we have developed a comprehensive and robust training for DPP-GLB Master Trainers, who are providing training to lifestyle coaches in their local communities, health networks, and organizations. At the present time, we are aware of more than 150 DPP-GLB programs being implemented across the US and internationally.

We would like to take this opportunity to offer our thoughts on the proposed Standards and Operating Procedures during this open comment period:

Participant Eligibility:

"Should a participant develop type 2 diabetes while in the program, it is preferred that the participant be referred to a diabetes self-management education (DSME) program, or the participant may continue in the CDC-recognized lifestyle change program; but, his/her data should not be collected or submitted to CDC."

If the participant who developed type 2 diabetes during the program continues in the CDC-recognized lifestyle change program, we would suggest that the data continues to be collected. This could be an important subgroup to continue to follow over time and may yield important insights.

Safety of Participants and Data Privacy:

"Lifestyle change programs for type 2 diabetes prevention typically do not involve physical activity during class time. If physical activity is offered, it is the organization's responsibility to have procedures in place to assure safety. This may include obtaining a liability waiver from the participant."

Rather than a liability waiver, a procedure that would be much more likely to "assure safety" for the participant is to obtain clearance for physical activity participation from the participant's Primary Care Provider (PCP). There are simple templates for these PCP program clearance requests that can be transmitted by email/FAX with the participant's permission. Beyond obtaining clearance, this approach also promotes valuable linkage with the medical providers, informing them of their patient's involvement in the DPP program and soliciting their support (or lack of) for their patient's participation. We recognize that there are cases where there is no PCP on record, however PCP communications should be encouraged when possible.

Delivery Mode:

Virtual DPP services (alone and in combination with various in-person delivery modalities) can and should keep pace with the highest levels of evidence-based, technology-assisted diabetes prevention care available. Thus, we support the inclusion of virtual options for program delivery as part of an offering of a variety of DPP delivery modes. At this point in time, however, there appears to be a multitude of virtual DPP options listed on the CDC DPRP website and it is not apparent how these programs are being assessed and monitored. There is a listing of "National Providers" and "Other Providers"; are all of these considered DPRP recognized programs? For example, some programs listed provide only a platform for data collection or tracking for a DPP intervention, and do not appear to offer a standardized DPP curriculum at all (example: http://www.healthslate.com, https://agilehealth.com/outcomes/, https://glucoguide.com/). Others do not appear to include anything about DPP http://www.activehealth.com/ and/or have their own programs that are inconsistent with the DPP evidence base: *Reverse Diabetes without Counting Carbs or Calories:* http://www.asugarfreelife.com/about.html; Naturally Slim: https://www.naturallyslim.com/home;https://drive.google.com/file/d/0ByBIFu8NNkklbmVheGM3QXRUXzQ/view ; Wellness Coaching with Jessica: http://www.mozenwellness.com/. Others are listed as online providers but no link is offered (Coach Shellie's Healthy Lifestyle Program, 1bios, Inc., Boston Heart Diagnostics). Many of the links are not active or provide no information: http://www.bewellnetwork.com/Health_Events_Activites.aspx?ID=2&stateID, Better Body, Healthy You!

Thus, although there is emerging evidence to support the effectiveness of virtual DPP deliveries, we would suggest a thorough vetting of these programs as well as additional study regarding best practices for implementation. We suggest that independent guidelines may be required to standardize the use of virtual programs.

Training

We appreciate that the CDC has addressed Lifestyle Coach training in the Standards, with a direction that at least 12 hours (generally two days) of training on the specific curriculum being utilized is required, as well as explicit review of the Standards and Operating Procedures themselves; However, we suggest that additional more specific standards be established to ensure that coaches are receiving high-quality training for the important work they will be doing in service of diabetes prevention. In addition, clear guidelines should also be developed for Master Trainer programs. such as qualifications for acceptance into a Master Training program, curriculum content, training duration, etc. At the present time, there are nine coach training centers listed on the CDC website who have initiated a MOU with the CDC to deliver a minimum 12-hour Lifestyle Coach training following the specific DPP curriculum being utilized. Several clearly describe the training, including content covered, instructor qualifications, timeframe, etc.; others provide little to no information. Uniform standards will be important to

understand and compare what is being offered by these groups. In addition, the Standards indicate that along with the training entities listed on the CDC website, training may be provided by 1) a private organization with a national network of program sites, 2) a CDC recognized virtual organization with national reach, or 3) a Master Trainer (a current or former National DPP Lifestyle Coach who has delivered at least one yearlong lifestyle change program). Greater transparency is needed to evaluate what is being provided in the way of basic Lifestyle Coach and Master Training. We would suggest that 1) the CDC work with the training centers to establish uniform standards for training including minimum required content and instructor qualifications for Master Trainers, and 2) the CDC create a network for trainers to assist with ensuring they are up to date with changes to the Standards and Operating Procedures and other information pertaining to achievement of DPRP recognition.

Finally, if not currently in place, the creation on an expert committee of scientists and public health professionals who could guide CDC in the selection of intervention material content and decisions regarding recognition is suggested given the magnitude of this effort..

Required Curriculum Content

"Medicare DPP suppliers and ongoing maintenance sessions. Organizations that are Medicare DPP suppliers may repeat any curriculum topic from months 1-6 or months 7-12, with the exception of the introductory session, for use in ongoing maintenance sessions."

With regard to the Medicare DPP ongoing maintenance sessions, the currently proposed rule mandates that maintenance sessions be offered for up to two years following the CDC one-year DPP. As these materials currently do not exist, consideration should be given to development of these materials for programs to utilize.

We appreciate all of the work that has gone into updating these Standards and Operation Procedures. We would be more than happy to make ourselves available by phone, on-line, or in-person should you have any questions or desire additional input as you move forward with this exciting endeavor.

Sincerely,

Elizabeth Venditti, PhD
DPSC Director
Assistant Professor of Psychiatry
University of Pittsburgh

M. Kaye Kramer, DrPH, RN
Chief Science Officer
Innovative Wellness Solutions
Adjunct Associate Professor
University of Pittsburgh

Andrea M. Kriska, PhD
Professor of Epidemiology
University of Pittsburgh

Linda N. Semler, MS, RD, LDN
Senior Research Manager
University of Pittsburgh School of Education

Linda M. Siminerio, PhD, RN
Professor of Medicine
Executive Director
University of Pittsburgh Diabetes Institute

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside of the Agency

A 60-day Federal Register Notice was published in the *Federal Register* on September 12, 2017, Docket No. CDC-2017-0053, Document Citation 82 FR 32549, pages 32549-32551 (3 pages). CDC received and responded to 28 sets of unique public comments that were related to this notice from both individuals and organizations that are outside of CDC. Within those 28 unique sets of comments, there were 119 unique questions/comments that CDC answered. The table below summarizes the public comments and how CDC plans to address them:

Standards Area / Topic	Description	Comments	Response
Participant Eligibility	CDC proposed to continue the present policy of allowing a history of gestational diabetes mellitus (GDM) as one of the participant eligibility criteria. However, CDC also noted that CMS would not allow a previous history of GDM as one of the eligibility criteria for Medicare beneficiaries.	a) A commenter noted that the proposed CMS rule on the Medicare Diabetes Prevention Program (MDPP) expanded model, published on July 13, 2017, specified that Medicare beneficiaries with a history of GDM are eligible for participation.	a) CDC will correct this error.
Participant Eligibility- Blood-based tests	CDC proposed a fasting blood glucose range of 100 to 125 mg/dl as one of the eligibility requirements for participants. CDC also noted that CMS had proposed a different eligibility requirement for Medicare participants of 110 mg/dl.	a) One commenter noted that CDC incorrectly described the MDPP expanded model fasting blood glucose requirement as 110, when it is a range of 110-125 mg/dl.	a) CDC will correct this error.
Participant Eligibility- Data Submissions- Women becoming Pregnant	CDC proposed that organizations allow women who become pregnant while participating in the program to continue participating as long as they consult their physician. In these cases, CDC proposed that organizations code pregnant participants' weights as 998 (default) so that they are not included in weight loss calculations.	a) Two commenters asked for further clarification on weight loss calculations for pregnant participants. Specifically, the commenters asked how to handle previously reported pre-pregnancy weights that actually are post-pregnancy weights.	a) To simplify the issue of changing weights for women who become pregnant, CDC will allow organizations to change the eligibility status for these participants to a default value of 2 in lieu of using 998 for weight. This will allow these participants to continue participation while excluding their data (such as weight) from the organizational analysis.

Standards Area / Topic	Description	Comments	Response
Participant Eligibility- Converting to Type 2 Diabetes	CDC proposed that organizations refer participants who develop type 2 diabetes while in the program to a diabetes self-management education (DSME) program.	a) One commenter requested that CDC specify that organizations refer participants to ADA- recognized or AADE-accredited DSME programs. b) Another commenter requested that CDC include information about other referral services for participants who develop type 2 diabetes.	a-b) CDC agrees to amend the current statement to, "Participants who develop type 2 diabetes should be referred to their primary care provider for referrals to ADA-recognized or AADE-accredited diabetes self-management education (DSME) programs and other resources such as Medical Nutrition Therapy (MNT) as appropriate."
Participant Eligibility – Data Submissions- Type 2 Diabetes	CDC proposed that organizations exclude data for participants who develop type 2 diabetes while participating in the program.	a) Several commenters asked for clarification regarding the exclusion of data for participants who develop type 2 diabetes. b) One commenter suggested that CDC develop a new code to identify these participants. c) Another commenter asked that organizations be required to continue to collect this data for reimbursement purposes.	a-c) To simplify the issue of excluding data for participants who develop type 2 diabetes, CDC will allow organizations to change the eligibility status for these participants to a default value of 2. This will allow these participants to continue participation while excluding their data from the organizational analysis.
Participant Eligibility- Medicare and Non-Medicare	CDC proposed participant eligibility criteria that include either 1) a recent blood-based test/history of GDM or 2) a positive screening based on the CDC Prediabetes Screening Test or ADA Type 2 Diabetes Risk Test. CDC noted that CMS had proposed to require a blood-based test for all participants and would not be accepting a positive screening on a paper-based risk test for eligibility for the Medicare expanded model.	a) A commenter suggested that CDC establish "dual enrollment protocols" for non-Medicare and Medicare participants to account for the different eligibility requirements.	a) CDC does not agree to establish "dual enrollment protocols". The proposed Standards delineate the differences between eligibility criteria for non-Medicare and Medicare participants with regard to the MDPP. The Standards do not address operational issues related to enrollment. For purposes of CDC recognition, CDC evaluates eligibility at the organizational level. CDC cannot influence any additional eligibility requirements at the participant level imposed by various payers, including Medicare.

Standards Area / Topic	Description	Comments	Response
Participant Eligibility – Location- use of Bluetooth-enabled scales	CDC proposed to allow organizations to obtain weights via digital technology, such as Bluetooth-enabled scales.	a) One commenter requested that CDC add the phrase, "Bluetooth-enabled also refers to scales which transmit weights securely via wireless or cellular transmission."	a) CDC agrees to clarify the definition of Bluetooth enabled scales as suggested.
Delivery Mode- Data Submission	CDC proposed to allow a single organization to offer the program through any of four delivery modes, but also proposed that organizations submit a separate application and obtain a separate ORGCODE for each delivery mode offered.	a) Several commenters requested that CDC allow organizations to use the new participant/session-level delivery mode data element (DMODE) to indicate a cohort's delivery mode rather than applying for a new ORGCODE for each delivery mode being offered. b) Another commenter asked if the per session delivery mode (DMODE) variable could be removed.	a) CDC does not agree with the suggestion to allow the use of the DMODE participant/session level data element in lieu of obtaining separate ORGCODEs for each delivery mode offered by an organization. First, CDC requires information on delivery mode at both the organizational and participant level in order to align with the CMS MDPP expanded model. An ORGCODE is required because only organizations offering the program in person are eligible to become MDPP suppliers at this time. A participant/session level DMODE data element is required because in-person MDPP suppliers may offer a limited number of virtual make-up sessions. b) Second, CDC does not agree to remove the DMODE variable because it allows CDC to track session level data for organizations offering a combination program. This information will help CDC determine if the Standards require further revision to account for hybrid uses of technology.

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Delivery Mode - Application	CDC proposed to allow a single organization to offer the program through any of four delivery modes, but also proposed that organizations submit a separate application and obtain a separate ORGCODE for each delivery mode offered.	a) Two commenters asked if 2 separate departments within the same hospital could submit separate applications, obtain separate ORGCODEs, and become separate MDPP suppliers.	a) CDC awards recognition at the organization level, so would not accept applications from 2 different departments within the same organization.
Delivery Mode	CDC proposed to allow a single organization to offer the program through any of four delivery modes, but also proposed that organizations submit a separate application and obtain a separate ORGCODE for each delivery mode offered.	a) A commenter suggested that CDC allow a single organization to receive multiple ORGCODEs based on various curricula tailored for specific participant subgroups (low-literacy, low-income, seniors, etc.). b) Another commenter requested that CDC align its terminology regarding delivery modes with that of CMS.	a) While CDC allows organizations to offer alternate curricula tailored for specific populations, we do not agree that a single organization should receive separate ORGCODEs based on each curriculum used. While the majority of organizations are fully committed to serving all participants equally, stratifying program offerings by specific population groups has the potential to adversely impact enrollment and retention of particular population groups that may require additional support to achieve the expected outcomes. b) CDC assures the commenters that we will work with CMS on alignment of terminology regarding delivery modes.
Delivery Mode- Make-up Sessions	CDC proposed changes regarding make-up sessions, including: 1) allowing a single make-up session on the same day as a regularly scheduled session, 2) limiting make-up sessions to one per week, 3) allowing an unlimited number of total make-up sessions, and 4) requiring specification of the delivery mode for make-up sessions. CDC clarified that in-person programs may offer virtual make-up sessions.	Commenters were generally in support of the proposed changes. a) One commenter asked for clarification on the timeframe for conducting make-up sessions. b) One commenter asked if make-up sessions must be the same length as regularly scheduled sessions. c) One commenter asked for clarification regarding the evaluation of make-up session data, and asked for clarification of the language on make-up sessions in the Data Dictionary.	a) CDC agrees to clarify the timeframes for conducting make-up sessions as follows: 1) missed core sessions must be made up within months 1-6, and 2) missed core maintenance session must be made up in months 7-12. CDC will further clarify that make-up sessions must be offered within these timeframes in order for data to be analyzed. b) CDC agrees to clarify that make-up sessions must be comparable to the regularly scheduled session they replace in content and

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			length (approximately one hour). c) CDC agrees to clarify that we will evaluate make-up sessions in the same way that we analyze regularly scheduled sessions. CDC agrees to clarify the language in the Data Dictionary to indicate that an organization can hold a single make-up session on the same date as a regularly scheduled session.
Training	CDC proposed that lifestyle coaches receive a minimum of 12 hours of formal training to a CDC-approved curriculum. CDC also proposed that this training be provided by: 1) an MOU-holding training entity listed on CDC's website, 2) a private organization with a national network of program sites, 3) a CDC-recognized virtual organization with national reach, or 4) a master trainer (a current or former National DPP lifestyle coach who has delivered at least one yearlong lifestyle change program).	a) One commenter asked for additional guidance on the definition of "formal" training for lifestyle coaches. b) One commenter asked for clarification regarding the timeframe within which a lifestyle coach must start offering classes after completing training. c) One commenter suggested that CDC require continuing education for lifestyle coaches every 2 years. d) Another commenter asked if CDC could develop standardized refresher training for lifestyle coaches. e) One commenter asked if the 12-hour training requirement could be reduced to 4 hours for coaches already trained to another CDC approved curriculum. f) One commenter asked for a definition of a master trainer. g) One commenter suggested that CDC include a requirement that the program "be delivered by or under the supervision of qualified health care providers, such as an RDN, NDTR, or CDE."	a) CDC agrees to clarify that 'formal' lifestyle coach training is defined as training conducted by one of the four methods listed in the proposed Standards. b) While CDC agrees that lifestyle coaches should begin offering classes as soon as possible after completing training, CDC does not agree to require a specific timeframe within which this should occur and will leave this up to each organization to determine. However, CDC agrees to clarify that lifestyle coaches should receive additional training each time CDC revises the Standards. CDC agrees to offer free webinar based training each time we issue revised Standards. Organizations can use this training to meet the recommended continuing education requirement. c-d) In the Standards, CDC recommended that organizations provide a minimum of 2 hours of continued training annually for lifestyle coaches and provide additional training when lifestyle coaches are

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		h) One commenter suggested that CDC establish a national standard for credentialing and re-credentialing lifestyle coaches either directly or through a designated agency with experience in credentialing. i) One commenter suggested that CDC create and maintain a registry of lifestyle coaches. j) One commenter suggested that CDC allow exemptions to the data submission requirements for the first class offered by a new coach, and for classes offered for the first time to a new ethnic group in order to provide organizations a learning period without being penalized.	transitioning to a new curriculum. CDC will explore options to provide live and pre-recorded webinars that organizations may use to meet the recommendations regarding continuing education for lifestyle coaches. CDC does not agree to change the timeframe for the recommended continuing education from every year to every 2 years. e) CDC agrees to clarify that the requirement for 12 hours of training applies only to new lifestyle coaches. Lifestyle coaches that have met the 12-hour requirement are not required to complete an additional 12 hours of training when they are training to a new CDC-approved curriculum. f) CDC agrees to add a definition of a master trainer. A master trainer has completed at least 12 hours of formal training as a lifestyle coach, has successfully offered the National DPP lifestyle change program for at least one year, and has completed a Master Trainer program offered by one of the training entities that has an MOU with CDC. g) CDC does not agree to add a requirement for an RDN, NDTR, or CDE to either deliver or supervise the delivery of the program by lay coaches. Emerging evidence demonstrates that lay lifestyle coaches may further contribute to achieving participant outcomes, such as studies on Community Health Workers and Promotoras (e.g., Katula et al., 2013:

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			Collinsworth et al., 2013; Lindberg et al., 2013). Additionally, evaluation of a subset of all DPRP organizations (i.e., 1212 grantees) showed that lay coaches such as community health workers were more likely to increase overall attendance (increased by 1.6 sessions) for participants aged 18–44 years, compared with sites that did not use community member coaches. To meet the potential demand of delivering the National DPP lifestyle change program to the 84 million Americans with prediabetes or at high risk for type 2 diabetes, CDC needs to maximize the capacity of the workforce. h) While CDC does not agree to establish a national credentialing standard for lifestyle coaches at this time, CDC will work with organizations with experience in credentialing to determine whether such a standard should be proposed in the future. i) CDC does not agree to create and maintain a registry of lifestyle coaches as CDC recognizes at the organizational level and not the coach level. Also, CDC does not collect personally identifiable information on lifestyle coaches. j) CDC does not agree to allow exemptions to data submission requirements for new coaches or for new types of participants. Organizations with CDC recognition are required to ensure that coaches are sufficiently trained to offer

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			the program to all eligible participants.
Curricula Topics	CDC proposed that organizations can offer additional sessions beyond the required 16 weekly core sessions in months 1-6 and the 6 monthly core maintenance sessions in months 7-12.	a) One commenter asked whether an organization can use core maintenance session modules in months 1-6 after the 16 weekly sessions have been completed.	a) CDC agrees to clarify that organizations may use core maintenance modules to offer additional sessions in months 1-6 after they have offered the 16 required weekly core sessions. CDC agrees to clarify that organizations must code the use of core maintenance modules in months 1-6 as a core session. Similarly, an organization may use a core module to offer additional sessions in months 7-12 after they have offered the required 6 core maintenance modules. In this case, the organization must code the use of the core module in months 7-12 as a core maintenance session.
Curricula Topic - Ongoing Maintenance Sessions	CDC proposed that organizations that are MDPP suppliers may repeat any core or core maintenance module with the exception of the introductory session for ongoing maintenance sessions (months 13-36). CDC proposed data coding and	a) Two commenters asked for further clarification regarding ongoing maintenance sessions, including whether organizations were required to collect participant weights at these sessions.	a) CDC agrees to clarify that MDPP suppliers must collect and report data for ongoing maintenance sessions in the same way as they do for core and core maintenance sessions, including recording participant weights. CDC

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	submission variables for MDPP suppliers for ongoing maintenance sessions.		has agreed to collect data for ongoing maintenance sessions for CMS to assist with their continued implementation and assessment of the MDPP expanded model.
Requirements for Recognition - New	CDC did not propose to add any new requirements to the nine already specified in the 2015 Standards.	a) One commenter requested that IHS, tribal, and urban Indian lifestyle change programs that were part of the Special Diabetes Programs for Indians (SDPI) not be required to coordinate with other federal agencies regarding recognition. Specifically, they requested that CDC work with SDPI programs to ensure that there is alignment, consistency, and coordination of these programs to receive recognition and reimbursement. b) The commenter further suggested that tribal health programs be allowed to determine their own measures of success in lieu of weight loss. c) This commenter also suggested that CDC include a requirement for recognition related to mental health measurement as part of integrated care. d) Another commenter suggested that we add A1C as an outcome measure.	a) CDC acknowledges the major contributions of the SDPI Diabetes Prevention Program Demonstration Projects and the many resources (e.g., the SDPI Diabetes Prevention Toolkit), insights, and lessons learned these projects have contributed on both a local and national level. However, CDC does not believe a separate path to recognition can be created for SDPI programs without compromising the intent of the Diabetes Prevention Recognition Program (DPRP). Through the DPRP, CDC is responsible for carrying out a quality assurance function at the national level. This helps all National DPP stakeholders, including participants and payers, feel confident that CDC-recognized organizations are delivering the evidence-based lifestyle change program and demonstrating high quality data with fidelity to the original diabetes prevention evidence and any new, emerging evidence. They are achieving the outcomes proven to prevent or delay onset of type 2 diabetes. b) The 9 requirements in the DPRP Standards apply equally to all organizations that apply for CDC recognition, regardless of size, experience, capacity, or populations served. DPRP data collected to date indicate that all types of organizations serving a

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			wide array of populations are successful in achieving full recognition. CDC could not meet its obligation to ensure quality if each organization was allowed to use a different set of measures. CDC suggests organizations conduct quality research and publish the results in a peer-reviewed journal on other measures which they believe should be considered. However, under the proposed 2018 Standards, CDC will increase the time that organizations have to achieve full recognition from 36 months to 60 months. CDC has also proposed changes to include only the most actively engaged participants in the data analysis. Additionally, CDC has proposed a new category of recognition (preliminary recognition) that does not include a weight loss requirement and provides an intermediate step on the path to full recognition. These changes should make it easier for all organizations to achieve and maintain recognition requirements without compromising quality. c-d) CDC does not agree to add new requirements related to mental health and A1C levels, as this would significantly increase the data collection burden for program delivery organizations. Individual organizations are free to collect additional participant data, but should not submit any additional data to CDC.

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Requirements for Pending, Preliminary, and Full Recognition- Pending recognition	CDC proposed a process for organizations to move through the three levels of recognition: pending to preliminary to full. As part of this process, CDC proposed various scenarios where an organization could move back to a lower level of recognition for a limited time period rather than receive a revocation of recognition. CDC also proposed that organizations wait 12 months before reapplying after losing CDC recognition.	a) One commenter noted that the proposed process was difficult to understand and suggested that CDC create a more streamlined approach. b) Several commenters suggested that CDC reduce the 12-month waiting period for reapplication for organizations that lose recognition. c) One commenter requested clarification on their specific situation and asked how their CDC recognition would impact their ability to become an MDPP supplier.	a) CDC agrees to streamline the proposed process for moving through the three levels of recognition by removing options for organizations to move back to lower levels of recognition in lieu of losing recognition. Since CDC has increased the overall time for organizations to achieve full recognition from 36 months to 60 months, this should provide organizations sufficient time to demonstrate compliance with requirements for full recognition. The streamlined process is as follows: 1) Organizations may remain in pending recognition for 36 months. If they have not met preliminary recognition by 36 months, they will lose recognition; 2) organizations may remain in preliminary recognition for 24 months. If they have not met full recognition by 24 months, they will lose recognition; 3) organizations may remain in full recognition for 24 months. If they do not continue to meet full recognition at 24 months, but do meet the requirements for preliminary recognition, they can stay in full recognition on a Corrective Action Plan for an additional 12 months. If they have not re-achieved full recognition at that time, they will lose recognition. The justification for the one-year extension at the full recognition level is to minimize disruption to enrolled participants. b) CDC agrees to reduce the waiting period for reapplication for organizations that lose recognition from 12 months to 6 months.

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			c) For the MDPP Expanded Model, since CMS has proposed that organizations must have preliminary or full recognition in order to become an MDPP supplier, organizations that lose CDC recognition would also lose their eligibility to be an MDPP supplier.
Requirements for Pending, Preliminary, and Full Recognition- Pending recognition	CDC proposed that any organization that has 2017 CMS interim preliminary recognition (subsequently changed to MDPP preliminary recognition) will automatically move to CDC preliminary recognition on January 1, 2018 (or whenever the 2018 Standards are finalized.)	a) A commenter asked how an organization can determine whether they meet the requirements for MDPP preliminary recognition or CDC preliminary recognition.	a) CDC agrees to specify that we will analyze data for MDPP preliminary recognition for all organizations that are eligible when CMS finalizes 2018 Physician Fee Schedule rule that includes the MDPP expanded model. CDC further agrees to clarify that we will analyze data for CDC preliminary recognition for all organizations that are eligible when the 2018 DPRP Standards are finalized. Organizations that received MDPP preliminary recognition will be changed to CDC preliminary recognition when the 2018 Standards are finalized.
Requirements for Pending, Preliminary, and Full Recognition- Preliminary recognition	CDC proposed that organizations must meet two criteria to be awarded preliminary recognition. One of the criteria is that the 12 month data submission include at least 5 participants who attended at least 3 sessions in months 1-6 and whose time from first session attended to last session was at least 9 months. The second criteria is that, of the participants eligible for evaluation in the first criteria, at least 60% must have attended at least 9 sessions in months 1-6 and at least 60% must have attended at least 3 sessions in months 7-12.	a) One commenter stated their concern that requiring a minimum of 5 participants for preliminary recognition may limit the number of organizations eligible to become MDPP suppliers. b) One commenter asked for clarification on whether the attendance benchmark for the second 6 months is assessed only once a full 12 months has passed from the date of the first session.	a) CDC does not agree to change the minimum number of participants required for the 12 month data submission. While preliminary recognition is an interim category, the assumption is that the majority of organizations that achieve preliminary recognition will go on to achieve full recognition. Both categories of recognition require a minimum of 5 participants for evaluation. DPRP data, using this denominator, shows that more than 85% of organizations that meet the criteria for preliminary recognition at 12 months will proceed to achieve full recognition. b) CDC agrees to clarify that the attendance

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			benchmark for the second 6 months is assessed only once a full 12 months has passed from the date of the first session.
Requirements for Pending, Preliminary, and Full Recognition – Full Recognition- Blood Test	CDC proposed to continue to require that at least 50% of eligible participants be enrolled using a qualifying blood-based test or history of GDM. Further, CDC proposed to continue the current policy to allow organizations to collect and submit blood test documentation post-enrollment.	a) One commenter suggested that CDC either remove or lower the 50% eligibility requirement for blood-based screening or history of GDM to 25%. The commenter noted that many organizations identify and enroll eligible participants through contracts with third parties such as employers and health plans. In these cases, organizations do not have control over whether an employee or beneficiary has recently seen a physician or had a qualifying blood test. Further, the commenter noted that many employers and health plans specifically request that biometric screening not be a requirement for entry into the program. b) Another commenter asked if organizations could obtain blood test documentation information post-enrollment for non-Medicare participants.	a) CDC does not agree to eliminate the organizational enrollment eligibility threshold based on a qualifying blood-based test or history of GDM, but does agree to lower it to 35%. CDC acknowledges that the marketplace is evolving, and that an increasing number of organizations are working through employers or health plans who may impose either higher or lower individual level eligibility thresholds based on blood-based testing for participation and reimbursement. We believe that lowering the threshold to 35% will provide organizations with the maximum flexibility to respond to the demands of the marketplace while still ensuring that organizations maintain their focus on enrolling those with prediabetes or at highest risk for type 2 diabetes. CDC will continue to work with organizations and partners to encourage screening, blood-based testing, and referral for all people at high risk for type

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			2 diabetes, including encouraging participants who enrolled on a risk test to obtain a post-enrollment blood test from their health care provider. b) CDC agrees to further clarify that organizations may make a one-time change to a participant's eligibility status based on a post-enrollment blood-based test.
Requirements for Pending, Preliminary, and Full Recognition Status-Program Eligibility Requirement	CDC proposed allowing a maximum of 50% of participants to enroll in programs based on a qualifying risk test or a claims-based Current Procedural Terminology (CPT) code specifying prediabetes screening.	a) One commenter recommended that CDC amend the language on CPT codes, since CPT codes are billing codes and not diagnostic codes. The CPT billing codes indicate only that an individual was screened, but do not indicate whether the individual was diagnosed with prediabetes. b) One commenter asked CDC to clarify how the CPT code would fit into data reporting, since there is no reference to this in the Data Dictionary.	a-b) CDC agrees to remove the claims-based CPT code as a basis for participant eligibility.
Requirements for Pending, Preliminary, and Full Recognition-Previous 6-month weight loss requirement	CDC proposed to remove the 6-month 5% weight loss requirement.	a) Commenters were generally supportive of the elimination of the 6-month 5% weight loss requirement. b) One commenter recommended adding information on MDPP supplier requirements regarding weight loss at 6 months and/or analyzing this information for organizations at six months for technical assistance purposes only.	a) CDC agrees to include clarification that while CDC is eliminating the organizational level requirement for an average weight loss of 5% at 6 months, individual payers, such as CMS, may still impose individual weight loss requirements at 6 months for reimbursement purposes. b) CDC does not agree to analyze organizational information on weight loss at 6 months for technical assistance purposes, since analyzing data on an incomplete cohort may produce misleading

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			projections regarding weight loss at 12 months.
Requirements for Pending, Preliminary, and Full Recognition- Current 12-month weight loss requirement	CDC proposed using the baseline weight and the last recorded weight for participants in analyzing data for the 5% weight loss requirement at 12 months.	a) One commenter suggested using baseline and the lowest weight recorded at any time within the 12-month program for this analysis.	a) CDC does not agree to use the lowest weight recorded at any point during the 12-month program in lieu of using the last weight recorded during the 12-month program. The current data analysis method is based on the data analysis method for the 2002 DPP and for the 10-year, follow-up Diabetes Prevention Program Outcomes Study. Using the last recorded weight is a better indicator of sustainable results.
Requirements for Pending, Preliminary, and Full Recognition- Documentation for physical activity minutes	CDC proposed to continue the current requirement that organizations document physical activity minutes for participants once the organization introduces the topic as part of the curriculum. Until that time, CDC proposed that organizations code the PA data element as either 999 (default) or as 0 to 997 (in minutes.) CDC further specified that sessions coded with 999 are not included in the analysis for compliance with the physical activity (PA) documentation requirement. In the Listening Session on the proposed Standards, CDC further clarified that sessions coded as 0 minutes would not be included in the analysis for compliance with the PA requirement.	Most commenters supported the requirement to document physical activity minutes. a) Several commenters asked for additional information on the rationale for requiring documentation of physical activity minutes. b) One commenter requested clarification on the proposed policy to exclude sessions coded as 0 minutes from the analysis, stating that 0 minutes is a legitimate response if participants report no activity. c) Several commenters requested that CDC remove this requirement, since there is no performance payment tied to it. d) One commenter asked if an organization could collect	a) Physical activity is a key element of the evidence-based curriculum, regardless of whether payers reimburse for this specific activity. There is clear evidence that participants who achieve 150 minutes of physical activity weekly achieve better weight loss outcomes (Ackermann et al. 2008; Amundson et al. 2009; Vincent et al. 2013; Gopalan et al. 2015). b) The main reasons for excluding sessions coded as 0 minutes are: 1) DPRP data indicate that many organizations appear to be using 0 minutes as a default, and 2) it is unlikely that participants are not

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		physical activity minutes post-activity. e) One commenter suggested that organizations may be penalized in months 7-12 for offering more than the required minimum number of sessions, based on their experience that participants are less likely to report PA minutes during months 7-12.	completing any PA minutes, as the curriculum indicates that even simple activities such as walking to the mailbox can count as PA minutes. CDC agrees to clarify this policy further in the Standards. c) CDC does not agree to remove the requirement for documentation of physical activity minutes for recognition purposes. d) With respect to the timing of collecting PA minutes, organizations should encourage participants to log PA minutes continuously once they introduce the topic in the curriculum. The Standards require organizations to report PA minutes completed for the preceding week. For make-up sessions, organizations may collect and report PA minutes logged by participants for the week preceding the missed session. e) CDC does not agree that offering additional sessions in months 7-12 will penalize organizations with respect to the PA documentation requirements as long as organizations are continuing to encourage and support participants in logging PA minutes.
Requirements for Recognition-Session attendance during months 1-6 and 7-12	CDC proposed a change to the denominator for analyzing data for compliance with recognition requirements. Previously, data were included for all participants who attended at least 4 sessions. The current proposal is to include all participants (minimum5) who attended at least 3 sessions in months 1-6 and whose time from first	a) While the majority of the commenters were in support of the new denominator for attendance requirements, several commenters asked that CDC continue to use 4 sessions instead of 3. b) Some commenters noted that this would align with the denominator used in evaluating compliance with the 2015	a) CDC does not agree to revert back to the original denominator of those who attended at least 4 sessions for analyzing data for compliance with the requirements. b) The proposal to use 3 sessions is in alignment with the CMS proposal for MDPP preliminary

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	session attended to last session was at least 9 months.	Standards, and other commenters noted that this would better align with the payment model proposed for the MDPP expanded model.	recognition. Using 3 sessions allows additional organizations to meet the minimum requirements for evaluation for either MDPP preliminary recognition or CDC preliminary recognition. The use of 3 sessions is only for identifying participants for inclusion in the data analysis required for recognition and should not be confused with the 4 sessions proposed by CMS as a payment milestone for the MDPP expanded model.
Application data elements- Organization Type	CDC proposed a new variable for organization type.	a) Two commenters requested clarification on whether organization type refers to the main location or to various class settings.	a) CDC agrees to clarify that organization type refers to the main headquarters location or main office.
Application data elements- Contact Information	CDC proposed that organizations list contact information for key staff in their application.	a) One commenter asked if an organization could list the same person as both the program coordinator and as the data preparer.	a) The Standards address this issue. Guidance on application data element 16 states that the organization's data preparer may be either the program coordinator or the lifestyle coach if the organization has not designated a third person at the time of application.
Applying for Recognition- Class type	CDC proposed a menu of responses for the class type data variable.	a) One commenter asked for clarification on whether an organization could choose multiple responses for the Class Type data variable.	a) CDC agrees to clarify that organizations can choose multiple responses for the Class Type data variable.
Applying for Recognition- Public Class Locations	CDC proposed that organizations offering classes to the public provide either the physical addresses of the classes, or an online link to class offerings. Organizations are required to send this information to DPRPApply@cdc.gov for publication on the CDC website.	a) One commenter suggested that organizations be required to notify the CDC if there are any changes to public class locations.	a) CDC agrees to require organizations to email updated public class location addresses at least every six months to CDC at DPRPAsk@cdc.gov.
Application data elements- CDC Grantee	CDC proposed an application variable to identify organizations receiving CDC grant funds.	a) Several commenters suggested removing the CDC Grantee application data element to eliminate confusion regarding the timing of grant funds (ever or currently?) and to prevent any perception of bias	a) CDC agrees to remove the CDC Grantee application data element. CDC has determined there are other sources for collecting this information.

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		toward organizations receiving CDC grant funds.	
Submitting Evaluation Data to the DPRP- Gap in Data Submission and Requirements- Impact on Rural Communities	CDC proposed that organizations submit data to the DPRP every six months instead of the current requirement of every 12 months.	a) Multiple commenters suggested keeping the current data submission requirement of every 12 months to reduce the data submission burden on organizations. b) One commenter suggested that CDC consider an exemption to the 6-month data submission requirement for rural states and communities where recruiting for more than 1 class a year is challenging.	a) CDC does not agree to change the 6-month data submission requirement. Six-month data submissions allow organizations to achieve recognition sooner. This is critical for organizations seeking recognition in order to qualify for MDPP reimbursement. b) CDC does not agree to consider data submission exemptions for rural areas. For sustainability purposes, an organization must be able to offer at least 1 class per year. Organizations that offer 1 class per year will meet the 6-month data submission requirement. Organizations offering less than 1 class per year will not meet this requirement. CDC acknowledges that some small rural organizations may not have the capacity to be sustainable over the long term and encourages all organizations to complete the Capacity Assessment provided in Appendix A. Rural areas may want to consider recruiting an umbrella organization such as a rural hospital to serve as a recognized organization that can collect data and bill on behalf of small community based organizations. CDC is currently funding 10 national organizations to build sustainable capacity in underserved areas, including rural areas. Previous work in this area has demonstrated that small community-based organizations benefit from the support of a large

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			national, state, or regional organization.
Submitting Evaluation Data to the DPRP	CDC proposed that organizations may remain in preliminary or full recognition for 4 consecutive 6-month periods but did not address data submission and analysis requirements for each of the 6-month periods.	a) A commenter requested clarification on whether an organization's status would be assessed at each 6-month submission. Specifically, they asked if CDC would be conducting a full evaluation every 6 months or only at the end of the 4 consecutive 6-month periods. b) They also asked if organizations must meet the requirements for preliminary or full at each of the 6-month evaluations or only at the last one in the 2-year period.	a) CDC agrees to clarify that organizations must continue to submit data every 6-months after achieving either preliminary or full recognition, and that CDC will conduct an evaluation at each of those points where feasible. (Note: Organizations that offer only 1 class per year must submit data every 6 months but will only be eligible for an evaluation at 12 months when the class has been completed.) b) Organizations must continue to meet the requirements for preliminary recognition every 12 months until they are required to achieve full recognition at the 24-month mark. Organizations may remain in full recognition status for 24 months, even if they are unable to continue to meet the requirements for full recognition at a given 6-month data submission. At 24 months, organizations must meet the requirements for full recognition.
Table 4. Data Dictionary: Evaluation Data Elements: Payer Type	CDC proposed a participant level data element to collect information on payer type. CDC provided six response options, including other and not reported.	a) One commenter asked for clarification on reporting multiple payer types for a single participant, including Dual Eligible (Medicare and Medicaid). b) One commenter asked how to report grant funding as a payer type.	a) CDC agrees to clarify that an organization can only report one main payer source per participant. a-b) CDC agrees to add "Dual Eligible" and "grant funding" as response options.
Table 4. Data Dictionary: Evaluation Data Elements: Education Variable	CDC proposed a participant level data element to collect information on participant education level.	Several commenters were strongly in favor of collecting this data element to serve as a proxy for socioeconomic status (SES). These commenters believe that CDC must have a way to analyze data to determine if there are statistically significant differences in outcomes for low	a-c) CDC does not agree to eliminate the education data element, but will allow a default code for nonresponse. CDC has received numerous anecdotal comments from organizations over the past few years that low SES

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		SES populations that may warrant adjustments to the Standards in the future. Several other commenters were opposed to the new data element for various reasons. a) One commenter stated that it was intrusive and would serve as a barrier to participant enrollment. b) One felt that it would be difficult for lifestyle coaches to collect. c) One felt that it was an additional burden that was not related to compliance with the requirements.	populations are less likely to achieve 5% weight loss. The Education Level data element, as opposed to one that is more difficult to collect (e.g., income), will allow CDC to determine if there are disparities that could require future changes to the Standards.
Table 4. Data Dictionary: Evaluation Data Elements: COACH Variable	CDC proposed a new data element to collect information on the lifestyle coach Medicare NPI number for each session.	a) Several commenters were opposed to collecting this information for various reasons. Most commenters stated that it would create a significant data collection burden. b) Some commenters noted that CMS would already have this information on MDPP claims. c) Other commenters stated that this element would be confusing for organizations that were not also MDPP suppliers.	a-c) CDC has decided not to track lifestyle coach NPIs in its performance data. We believe this data is most pertinent to the MDPP program, and thus CMS is best suited to track lifestyle coach NPIs. CMS has proposed to do so in the CY 2018 Physician Fee Schedule and any additional collection by CDC may duplicate those efforts.
Table 4. Data Dictionary: Evaluation Data Elements: SESSTYPE Variable	CDC proposed a new data element to collect information on session type. One of the proposed response options is ongoing maintenance session, which applies only to organizations that are also MDPP suppliers.	a) A commenter requested that CDC remove this element for ongoing maintenance sessions, since CDC will not be evaluating data for these sessions.	a) CDC does not agree to remove this data element, since it is required to align with the CMS MDPP expanded model. CDC must be able to distinguish between sessions offered in months 1-12 and the ongoing maintenance sessions in months 13-24, since only data for sessions offered in months 1-12 are included in evaluations for CDC recognition. CDC has agreed to collect data for ongoing maintenance sessions for CMS to assist with their continued implementation and assessment of the MDPP expanded model.

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Table 4. Data Dictionary: Evaluation Data Elements: Session Date Variable	CDC proposed guidance for the Session Date data element that noted that participants should not have more than one record (line of data) for any specific session date.	a) One commenter suggested removing this guidance, since it conflicts with other guidance allowing make-up sessions to occur on the same day as a regularly scheduled session.	a) CDC agrees to remove this language and to clarify that the guidance provided in the data dictionary refers only to regularly scheduled sessions.
Table 4. Data Dictionary: Evaluation Data Elements: SESSID Variable	CDC proposed a new data element to collect information to identify weekly core sessions and monthly maintenance sessions.	a) One commenter requested additional information on the need for this data element, and asked how CDC will use it. b) This commenter also asked how CDC will identify participants who switch between classes and repeat a specific session. c) One commenter asked how to code session type if a participant re-enrolls after dropping out.	CDC will use this information to verify that an organization is complying with the intensity and duration requirements of the program. Specifically, CDC will be able to determine if organizations are offering core weekly sessions in months 1-6 and core maintenance sessions in months 7-12, Further, CDC will be able to determine if an organization is allowing a participant to attend a session more than once. CDC will evaluate only 1 record per session for each participant. b) CDC does not track participants who switch classes. c) CDC has provided the following guidance regarding re-enrolling participants who have dropped out and want to re-enroll in a new class: "Organizations should issue those participants a new ID and start them in the new class at session one."
Table 4. Data Dictionary: Evaluation Data Elements: Race	CDC proposed to continue collecting data on the race/ethnicity of participants.	a) One commenter suggested that CDC provide training and guidance to assist lifestyle coaches on asking for this information and responding to participant questions about why the organization is collecting this information. b) This commenter also suggested that CDC analyze data for participants who choose not to respond to this question to determine if there are disparities in this population.	a) CDC agrees to consider offering guidance or training to organizations and their lifestyle coaches on this issue through its forthcoming Customer Service Center. b) CDC also agrees to consider analyzing data for participants who do not choose to respond to this question to determine if there are disparities for this population.

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Table 4. Data Dictionary: Evaluation Data Elements: Enrollment Source	CDC proposed a new data element to collect information about enrollment source. Response options will identify the source (person, place, or thing) which led a participant to enroll in the program.	a) One commenter suggested that CDC add another response option to include a health care team member such as a pharmacist, dietitian, or community health worker.	a) CDC agrees to amend the response options for this data element as follows: 1. Primary care provider/office or specialist (e.g., MD, DO, PA, NP, or other staff at the provider's office), 2. Non-primary care health professional (e.g., pharmacist, dietitian), and 3. Community-based organization or community health worker. The other response options will remain unchanged.
Technical Assistance: Capacity Assessment	CDC proposed an updated Capacity Assessment to help organizations determine their readiness to offer the National DPP lifestyle change program.	Several commenters supported the updated Capacity Assessment. a) Some commenters suggested making completion of the Capacity Assessment a requirement. b) Some commenters suggested that CDC provide additional technical assistance and support for organizations that are having difficulty meeting the requirements for recognition.	a) CDC does not agree to make completion of the Capacity Assessment a requirement. b) CDC is developing tools and resources to address additional needs for technical assistance. These tools and resources, as well as consultation with subject matter experts, will be available as part of the National DPP Customer Service Center.
Appendix B. CDC Prediabetes Screening Test	CDC proposed a link that organizations could use to find a qualifying risk test for participants.	a) One commenter found a discrepancy between the CDC Prediabetes Screening Test link in Section II. of the DPRP Standards and the one included in Appendix B. They requested that CDC include the updated, working link that is in Appendix B. in Section II.	a) CDC agrees to include the Appendix B. Prediabetes Screening Test link in Section II.
Appendix D- Data submission and evaluation for organizations applying on or after January 1, 2018	CDC proposed allowing organizations one 6-month submission period when no data are available for submission.	a) A commenter suggested that CDC should simply state that every organization is required to offer one 12-month cohort per year.	a) CDC agrees to state that organizations must offer at least one class per year.
Miscellaneous (CDC enforcement of the Centers for Medicare and Medicaid Services' (CMS') Medicare Diabetes Prevention Program (MDPP) expanded model)	CDC proposed several new data elements related to the MDPP expanded model.	CDC received several comments regarding the MDPP expanded model. a) One commenter asked if CDC would be requesting additional documentation to enforce the MDPP expanded model eligibility requirement that all Medicare	a-b) CDC will not be collecting any additional documentation associated with the MDPP expanded model other than what we have specified in the Standards. CMS will provide guidance to MDPP suppliers on any additional documentation needed by

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		participants have a blood glucose test. b) Another commenter asked if CMS is requiring documented physician referrals for program participation. c) One commenter incorrectly stated that CDC proposed a once per lifetime MDPP benefit for beneficiaries and urged CDC to reconsider and allow a person to re-enroll multiple times, as needed.	CMS. CDC is responsible only for recognition. CMS is responsible for benefits under the MDPP expanded model. c) For recognition purposes, CDC does not specify a limit to the number of times a person can enroll in the program.
Miscellaneous (Minority or low Socioeconomic Status (SES) participants cannot meet the 12-month 5% weight loss goal)	CDC proposed a 5% weight loss goal.	a) One commenter asked CDC to lower the annual 5% weight loss goal for minority populations to ensure that they meet it. b) Three other commenters suggested a weight loss goal between 3% and less than 5%.	a-b) CDC does not agree to lower the 5% weight loss goal as we have already liberalized the denominator used for data analysis to include only the most engaged participants, and we have extended the time to achieve full recognition. We have based preliminary recognition on attendance only, and have lowered the blood-based eligibility requirement to 35%. Current DPRP data does not show disparities in achievement of weight loss by race/ethnicity. We are not currently able to assess possible disparities related to SES status, but have proposed an Education Level data element to serve as a proxy for future analyses of potential disparities that might require changes to the Standards.
Miscellaneous – Removing Data Elements from the 2015 Standards	CDC proposed some additional data elements for the 2018 Standards that were not included in the 2015 Standards, but did not propose the deletion of any data elements from the 2015 Standards.	a) One commenter asked if CDC could remove data elements included in the 2015 Standards that are not directly linked to recognition and that might be a barrier to participant access.	a) CDC reviewed the 2015 Standards and determined that all of the current data elements are still required as part of the recognition process.

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Miscellaneous – Reporting New or Current Data Elements as part of the DPRP Registry	CDC proposed to include only the following organization-specific information as part of the public facing DPRP Registry: name, address, contact information, and location of publicly available classes.	a) Two commenters asked that CDC make additional data collected by the DPRP publicly available. b) One commenter specifically requested that CDC post the number of participants served by each organization on the DPRP Registry. c) Another commenter suggested that potential participants might want information about organization type, such as whether the organization is faith-based.	a-c) CDC does not agree to add information to the DPRP Registry at this time. However, CDC agrees to develop a publicly available annual report to provide aggregate results of data collected for CDC recognition purposes.
Miscellaneous (Addition of attestation statement to the 6-month data submission requirement)	CDC proposed a one-time attestation statement as part of the application process, but did not propose an attestation requirement for the 6-month data submission.	a) One commenter suggested that CDC add stronger organizational attestation language to the 6-month data submission to increase the accountability of providers.	a) CDC agrees to add an attestation statement to the data submission upload webpage.
Attachment 6	CDC included a parenthetical statement in error regarding the liberalization of data evaluation methods in Attachment 6: Overview of Changes to 2015 DPRP Standards (OMB No. 0920-0909, exp. 12/31/2017) for 2018 DPRP Standards (revision).	a) Several commenters requested an explanation of the parenthetical statement in this sentence: "Liberalize data evaluation methods to ensure that organizations serving low SES and racial/ethnic minority populations can succeed (e.g., allowance for 60% of cohort to meet 12-month weight loss requirement vs. 80%)."	a) CDC is liberalizing the data evaluation method; however the method involves adjusting the denominator of participants for analysis rather than adjusting the metrics. Using the proposed denominator and current data, about 85% of current organizations will achieve preliminary recognition and should go on to achieve full recognition. The parenthetical phrase will be replaced with: "(e.g., basing evaluation for the requirements on participants who attended at least 3 sessions in months 1-6 and whose time from first session to last session was at least 9 months)."

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Transition to 2018 Standards- Guidance	CDC proposed a transition plan for organizations that achieved CDC-recognition based on the 2015 Standards.	a) One commenter requested that CDC provide further guidance to existing recognized organizations on the transition to the 2018 Standards. b) Specifically, they asked if existing organizations would need to complete new applications, and whether organizations that submitted data between January and June 2017 could wait 12 months before transitioning to the new 6-month data submission requirement. c) They also asked if CDC would analyze data submitted between January and June of 2018 against the 2015 or 2018 Standards, particularly for organizations submitting the 2015 data elements.	a) Existing organizations will need to complete the new application form and submit the new data elements, but CDC will allow a 6 month grace period for this purpose. Existing organizations with effective dates in January through June will make their first 2018 data submission in the anniversary month of their effective date. For these organizations only, the submission will include 12 months of records. b-c) Existing organizations with effective dates in July through December will immediately start on a 6-month submission schedule in 2018. CDC will analyze all 2018 data submissions against the requirements in the 2018 Standards. During the 6-month grace period, if an organization submits the 2015 data elements, CDC will map them to the 2018 data elements. Alternatively, during the grace period, an organization may submit the 2018 data elements and use default values for all but two of the new 2018 data elements. There are no default codes for SESSID and SESSTYPE. CDC will use an algorithm to assign these values based on session dates. CDC will provide additional guidance on the transition to the 2018 Standards for existing organizations after the Standards are finalized.
Transition to 2018 Standards – recognition timelines in 2018	CDC proposed adding a new level of recognition as well as changing some of the recognition status timelines.	a) One commenter requested clarification on how the new timelines for the various recognition levels would be applied to existing organizations. Specifically, they asked if an existing organization could remain in preliminary recognition status for two years regardless of how many years they had been in pending status.	a) Organizations may remain in preliminary recognition for 24 months, regardless of how many months they had been in pending status. However, organizations are limited to a period of 36 months in pending recognition, regardless of whether they entered the recognition

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		b) They also asked if organizations would be held to the 36-month maximum time to achieve full recognition under the 2015 Standards or if there would be a reset under the 2018 Standards.	program under the 2015 or 2018 Standards. b) After 36 months in pending recognition, organizations must meet the requirements for preliminary or full recognition or lose recognition and wait 6 months before reapplying.
Supporting Statement B. – Estimated Burden Hours	CDC doubled the estimated burden hours for data collection and submission, per submission, from 1 hour in 2015 to 2 hours in 2018, for a total of 4 hours annually.	a) Several commenters stated that CDC had underestimated the burden hours.	a) CDC quadrupled the estimated burden hours from 1 hour in the 2015 DPRP Standards to 4 hours in the proposed 2018 DPRP Standards due to the proposal of biannual data submissions and the addition of new data elements. We believe this is an accurate estimate for organizations using a data preparer with the necessary data collection and reporting experience. CDC provides an easy-to-use CSV file with pre-populated data elements. CDC also provides monthly webinars on how to complete and submit data. In addition, there are a growing number of publicly available applications to facilitate data collection and submission.
B. Safety of Participants and Data Privacy	CDC recommends that organizations that offer physical activity opportunities as part of the program include safety procedures, including obtaining liability waivers from participants.	a) One commenter suggested that CDC recommend that organizations offering physical activity opportunities also require participants to obtain clearance from their primary care provider.	a) CDC agrees to add this to the recommendation.