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FOR HEALTHY LIVING
FOR SOCIAL RESPONSIBILITY

Leroy Richardson
Chief, Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road, MS D-74,
Atlanta, GA 30333

June 10, 2014

Dear Mr. Richardson,

We are writing in response to a Notice (Document Number: 2014-08170) posted in the Federal Register on April 11th, which pertains to proposed changes in the Diabetes Prevention Recognition Program (DPRP). Specifically, the Notice invited public 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; and
- 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.

The YMCA of the USA (Y-USA) is the national resource office for approximately 900 independent YMCAs (Ys) which work through more than 2,700 branches and more than 10,000 program sites to improve the health of their members and communities. Our response to the Notice referenced above is being made by Y-USA on behalf of all these Ys, but especially those that are current and future providers of the YMCA's Diabetes Prevention Program (the YMCA's DPP). The Chief Executive Officers of the 128 YMCAs that are currently licensed to implement the YMCA's DPP, and under contract with Y-USA to eventually seek CDC Recognition through the DPRP, have reviewed this document and unanimously agree with the comments provided herein.

Y-USA is proud to be known as an inaugural partner of the CDC's National Diabetes Prevention Program, which is an important piece of national infrastructure that includes the DPRP and is managed by the Division of Diabetes Translation within the National Center for Chronic Disease Prevention and Health Promotion. We share the

CDC's goals to prevent the continued spread of the diabetes epidemic, and with support from CDC and many other partners, we are actively working with local YMCAs and organizations such as the American Medical Association to disseminate the YMCA's DPP as one licensed version of all Diabetes Prevention Programs (DPPs). In just four years, a network of YMCAs has grown from 2 DPP providers to our current level. In achieving this scale, we have collectively become the largest provider of DPPs in the nation. As of April 30, 2014, we have served over 20,000 individuals with prediabetes, and helped those that completed the YMCA's DPP under the current DPRP standards lose an average of more than 6% of their total body weight. We have approximately 900 program sites, and nearly 2,000 trained Lifestyle Coaches. Based on these internal data, and CDC data from the DPRP, we believe that YMCAs are providing as much as 80% of the total recognizable DPP programming across the country. No other organization has the amount of cumulative experience in the successful implementation of a DPP, or in the reporting of DPRP data.

From the outset of efforts to disseminate the YMCA's DPP, the potential of formal CDC recognition has been one of the strongest motivators for YMCAs and their partners. Thus, we have been enthusiastically supportive of the creation of the DPRP, and have been glad to inform its development. Many Ys have applied for DPRP recognition under the DPRP, and many more will. It is our goal to have more than 300 YMCAs running the YMCA's DPP, and seeking DPRP recognition, by 2017. Our goal has been and continues to be to leverage the DPRP as a means of documenting the quality of the YMCA's DPP. By doing so, we aim to increase the number of insurance plans covering this intervention to reduce barriers to entry, control costs for participants, the long-term sustainability of the program, and the greatest possible benefit to society.

However, we have some significant concerns about the *practical utility* of the information being proposed to be collected through a revised set of standards for the DPRP. We also have concerns about the *accuracy of the agency's estimate* of the burden of the newly proposed requirements for the collection of information. We believe, and have data to demonstrate, that the proposed changes to the DPRP will potentially be counter-productive. This letter outlines all our concerns, which have been established after a thorough review of the DPRP data collection plans and instruments, and the generation of significant real-world experience in documenting the implementation of the YMCA's DPP.

Overview of Y-USA's Comments

We believe that prior to adopting the proposed changes to the DPRP, current providers should be consulted and the proposed changes should be reviewed to:

- A. Ensure the practical utility of the DPRP by holding program providers to clear, evidence-informed, and equitable standards regarding

1. the mode of DPP delivery,
 2. risk assessment practices,
 3. eligibility verification requirements,
 4. reporting processes; and
- B. Assess more accurately the additional time and costs that will be incurred by the majority of current successful DPP providers, who have made significant investments to conform to existing standards, and who will have to make changes to current operations, training practices, and technologies that currently allow for efficient and high-quality DPRP reporting.

Upon completion of the review of our concerns, we would hope that the proposed revisions to the DPRP reporting processes would be further amended to minimize the time and material costs associated with making changes to reporting systems, and to not put current providers at a financial and operational disadvantage when delivering recognition-worthy programs and reporting our successes.

A. Specific Concerns Regarding the Practical Utility of DPRP Data Requirements

There are many changes being proposed to the DPRP which will have limited practical utility—and potentially even unhelpful effects—if greater clarity and consistency are not included in the revised standards. Areas of concern in this regard include:

1. In Section II. Standards and Requirements for Recognition, the subsection on *Participant Eligibility* includes (in item #2) a description of options for verifying eligibility of participants using values from screening tests. For DPP providers that offer in-person interventions, these values have been and will be required to be documented lab test values; but proposed changes would allow virtual providers to provide self-reported data from their participants. It is unclear and impractical that a difference should be allowed in the documentation practices for recording blood tests between in-person delivery and virtual delivery modes. A great deal of work is involved in documenting of blood screening test results, and for good reason. The evidence behind all DPP interventions is based on the effectiveness of these interventions on a group of individuals with a specific range of blood test values. The lack of a consistent standard in eligibility verification sets up a very real risk that the data submitted by providers offering different forms of DPPs will not be comparable, because the quality of self-reported data cannot reasonably be expected to be as valid or reliable as the quality of documented results. It is impractical and unequitable to hold in-person providers to a higher standard than virtual providers. At the very least, standards for documenting the eligibility of participants in recognizable programs should be consistent. Without consistency, the DPRP standards will produce data with less practical utility. Perhaps worse, the providers of the most proven and reliable form of the DPP (i.e, in-person) will essentially be

subject to a “**quality tax**” by having to work harder to enroll participants than providers of less-proven modalities. If any inequalities are to be established by the DPRP, one would think that the efforts to prove the quality of less-proven modalities would have to reach a higher standard.

2. The same section and subsection referred to in the previous point includes new language regarding the utilization of claims-based coding data to identify potentially eligible participants (in bullet point #2) and new language regarding the use of claims-based risk tests (in bullet point #3). However, there are no concrete or detailed standards established for these tests and methods of eligibility verification. Additionally, there is not any language provided on how DPRP will track the use of these codes. This lack of clarity makes it difficult to determine what, if any, operational changes would be required by YMCAs that benefit from the use of a claims-based data mining system to establish eligibility. Further, the developers of any such methodology will have no clear understanding of whether the potentially eligible participants identified in future coding analysis systems would actually meet the eligibility criteria. Thus the data are likely of minimal practical utility and more thought and detail should be added to the proposed DPRP standards to ensure that innovations in data mining produce meaningful and actionable information for DPP providers and the CDC.
3. In the subsection titled *Required Curriculum Content*, the language around *Intervention Intensity* has changed substantially and has raised several concerns. This section under the current standards used to reflect the science behind the vast majority of DPP translations. The lifestyle intervention currently begins with an initial core phase during which a minimum of 16 one-hour, in-person, group-based sessions are offered to all participants over a period lasting at least 16 weeks and not more than 26 weeks. The proposed revisions now say the lifestyle intervention must begin with an initial six-month phase during which a minimum of 16 sessions are offered over a period lasting 16 weeks and not more than 26 weeks. Each session must be of sufficient duration to convey the session content – or approximately one hour in length. It is unclear how increasingly flexible standards will affect the utility of data collected on DPPs, but it is difficult to imagine that the utility of the data will be increased by allowing for more variability in the delivery of curriculum content.
4. In Section II’s subsection on *Additional Requirements for Full Recognition Status*, the changes being proposed in point #5 are very significant. The practical utility of the data to be collected under this new approach must be questioned, because the standards have essentially changed to capture data on participants in ways that do not reflect well-established program delivery methods in previously approved curricula and the result will be that some providers will be reporting only core session data at the six-month point while others will be submitting data on both core and maintenance sessions. This will be problematic for data collection related to attendance, and will make analyses

of potentially incomparable data less practically useful to the CDC, DPP providers, the public, etc.

5. The next item in this same subsection (i.e., #6) includes changes to the DPRP standards that have essentially reduced weight loss data reporting requirements. On one hand, this could be seen as an attempt to make an allowance for efficiencies in program delivery. However, the concern is that changing the standards (i.e., to allow for weight data to be captured in at least 80% attended classes for all people who attend at least four sessions) will in effect remove any requirement to collect weight loss data during the maintenance phase (now called Phase II) of program delivery. This new section should be tied to all weight data collected across the entire year of the intervention, but it's not clearly called out by the revised requirements.
6. Another item in this same subsection (#8) describes how weight loss data will be averaged across all participants attending a minimum of four sessions. In the existing standards, this requirement was specific to just core sessions but because of changes referenced above this will now include data on both core and maintenance sessions. There are purposefully designed differences in approved curricula between core and maintenance sessions. By removing the distinction between weight lost in core and maintenance phases the utility of the data reported to DPRP will likely be reduced as the effectiveness of distinct coaching strategies will not be discernable. Additional lack of clarity on how this standards will actually be applied comes from the relationship of an earlier standard (i.e., in #5, the average number of sessions attended must be a minimum of 9) to this standard. Why would DPRP anchor on that number for attendance but not for weight loss reporting? Consistency in the approach to data collection across attendance and weight loss data would likely increase the utility and efficiency of data reporting.
7. Changes to the very next bullet point (#9) have essentially just removed language around post core session attendance, and shifted to language describing session attendance for months 7-12 as Phase II. The metric for success is still the same (i.e., average number of sessions attended during months 7-12 must be 3 sessions attended). The anticipated result is a decrease in the time available for achieving success in this metric. This is probably an unintended consequence of trying to build more flexibility into the core session phase (i.e., Phase I). With an expected diminished rate of success in this aspect of DPP delivery, the utility of collecting data on this phase of the program under the proposed changes should be evaluated and explained.
8. In Section III, *Applying for Recognition*, point #14 states that organizations can now select various modes of delivery from all that apply. Options are in-person, virtual or "other". It would be useful to define or clarify what is meant by "other". Without greater clarity, this vague standard will reduce the value of collecting any data on the mode of delivery.

9. In Section IV, *Submitting Evaluation Data to DPRP*, the subsection on *Evaluation Data Elements* includes a list of data elements that have been re-ordered from the previous version of DPRP standards. This seems to indicate that the packaging of data to CDC will now be required to be submitted in a revised format. If this is the intent of the CDC, then it would be beneficial to clarify this as an expected change.
10. In this same section and subsection, one of the points (#2) has been changed to "class code". We think the existing "group code" field will map to this new field, but it has previously been allowable for participants to switch between groups if they must (e.g., when participants might start the year-long program in a community where they spend their winters, but end the program in a community where they live in the summer). It is unclear if CDC will allow more than one class code now per participant.
11. CDC has also eliminated data that had to be reported on the "session type" (e.g., core vs. maintenance). We are concerned about this for many practical reasons mentioned above. With the transition to a system of recognition that is built on two 6 month phases, the concepts of 'core' and 'maintenance' which have proven useful and effective will be diminished in relevance to DPP providers and DPRP data will not distinctively discern the effectiveness of these independently valuable concepts.

B. Specific Concerns Regarding Efforts Required for DPRP Data Submission

Y-USA has several concerns about the estimates of time (and other associated costs) related to the preparing and submission of DPRP data. In each of the sections referenced below, changes have been made to the DPRP standards which will result in the need for significant time and treasure to be spent adapting current systems and technology to the new requirements. Past experience has shown that these adjustments may take a year or more to complete, and require significant investment of resources. Disruption in data reporting for programs that are in the midst of program delivery will come with additional costs and challenges.

1. In section II's subsection on *Required Curriculum Content*, changes to the way DPRP is recognizing the structure of any DPP (i.e., to Phase I and Phase II) will create a need for changes in the timing of reporting and our delivery cycle for the program, and there will be time and costs associated with adapting our reporting platform to these new requirements. Because Y-USA does not own this system, it is unclear what the exact costs or timeline for adjustments might be. We simply do not have knowledge of how other CDC partners, such as the Diabetes Prevention and Control Alliance, will adapt to these new requirements. As they are the owner of the reporting system used by all YMCA's we cannot precisely define the change in time and effort required for reporting.

2. Point #4 in this section, discussed previously, includes language around *Intervention Intensity*. Changes in language related to the collection of weight loss data reporting requirements will result in the same types of increases in time and resources to rebuild our current reporting system.
3. In the subsection *Additional Requirements for Full Recognition Status*, point #5 refers to the same changes outlined above, and our concerns about increases in time and resource requirements are the same.
4. In the same subsection, point #9 highlights data reporting requirements specific to both Phase I and Phase II. This is an appropriate part of the document to cite to make the point that many changes to one side of our reporting systems (i.e., core) will automatically trigger changes to the programming related to the other side of our reporting systems (i.e, maintenance). This may help to again establish our concerns about the lack of estimated time and resources required for current and successful providers to come in line with new standards. Again, the result is a perception that these early and experienced providers of DPP are paying an inequitably high cost for the transition to a new system, when compared to others (e.g., future providers of DPPs which may use more or less evidence-based modes of delivery).
5. The next bullet point (#10) provides one more example of how changes in the way weight loss data are to be reported will require an investment of time and resources to adapt to new reporting requirements.
6. Changes to the way claims-based risk tests will be reported (#11) again will require report changes and increased time and costs of reporting for many current DPP providers and their partners.
7. If there are indeed changes to the order in which data are to be reported to CDC, as might be implied by changes to Section IV. *Submitting Evaluation Data to DPRP*, then it is worth pointing out that even these superficial changes will require programming and resources to be accommodated (and the time to produce these changes).
8. In bullet point #4 of this section, a new category of data is required. We understand the use of these data; CDC can't currently give States' Department of Health any of the DPRP data specific to their population at this time. This change would allow them to do so and we are supportive of the change. Y-USA's data system already collects these data. Again, however, time and resources will be involved in making changes to our reporting system aligned with these new requirements.

Comments on the Strategic Value of the Proposed Changes

In addition to concerns about the practical utility of and assumptions about the time required to implement the proposed changes to the DPRP, we also have questions about the strategic value of the proposed changes. Generally, it appears as though the intent behind many of the proposed changes to DPRP standards is to attempt to

speed the dissemination of “DPPs” and to reach more people with prediabetes via new and relatively less tested modes of delivery. These are laudable goals in principle; and the Y shares them... But our data and experience suggest the proposed changes would likely produce undesirable unintended effects.

Due to an approximate one-year lag between the training of any YMCA’s DPP program provider and their first submission of data to the DPRP, Y-USA has internal data which come from a much larger data set than the CDC currently has access to via the DPRP. These data are all collected using methods that are entirely consistent with current DPRP standards. They just simply include many data points that haven’t been submitted to CDC by Ys in their 12-18 months of delivering the YMCA’s DPP. This is because our internal data show that Ys get better at program delivery in these first months. Thus, it has been Y-USA’s policy to discourage the application of local YMCAs to the DPRP until they have delivered the program for a year or more, or until they have had four classes of participants complete the program. Using these data, we have modelled what the effects will be of revising the DPRP standards as is currently being proposed by the CDC. The results of our analyses (Table 1A-C) show the proposed changes will actually reduce the ability for the CDC to report successes from DPPs.

Tables 1A-C: YMCA’s DPP Weight Loss Data Under Current and Proposed DPRP Requirements

Weight loss results under current DPRP standards (goal of 5% WL):

4+ Sessions	End of Year	9+ sessions	Included because we report on those who are considered completers by CDC’s standard indicating a minimum of 9 sessions should be attended for all who attend 4 or more
4.21%	6.06%	4.77%	
(N=9357)	(N=3736)	(N=7730)	

Weight loss results under proposed DPRP standards (goal of 5% WL):

6 mo. %WL*	E.O.Y. %WL
3.64%	4.33%
(N=3528)	(N=9357)

*approximation – we do not have a report currently that shows weight loss at this juncture in the program

Merely by applying the newly proposed standards to existing data on more than 20,000 participants served since 2010, the average weight loss at the end of the program that would be reported by the YMCA's DPP to the DPRP would fall from 6.06% to 4.33%. To be clear: the first 20,000+ participants in the YMCA's DPP would have lost no more or less weight under the new method of DPRP reporting; the new lower weight loss values reported to the DPRP would be only due to a difference in the reporting methodology (i.e., reporting %WL on participants with a minimum of 4 phase I sessions attended vs. the current requirement of reporting %WL on participants with a minimum of 4 core and 1 maintenance session attended). Studies done by the CDC, such as the meta-analysis of 28 community-based translations of DPPs that was published by Ali et. al. in the journal *Health Affairs* in 2012, have demonstrated that the "dose" of the DPP is what drives success. By removing the requirement for at least one maintenance session to be included, dose is reduced. Additionally, the effect on the %WL average is likely increased because the session that is being removed from consideration is a maintenance session that comes later in the most widely recognized program model. People attending maintenance sessions have by definition "kept with the program", and eliminating even one data point has a clear effect on the average %WL of all participants.

Moving to the newly proposed DPRP reporting requirements would also likely create a decrease in reported average maintenance session attendance (i.e., Phase II attendance in the new DPRP reporting system). This is troubling because, again, this would likely just be an effect of changing reporting requirements. Assuming the actual attendance patterns do not change, Ys would likely report decreased attendance at the proposed 6 month time-point vs. the 20 week time-point used in the current system simply due to routine attrition between the 20 week and 6 month time-points. In addition to the reasons outlined above (cost, consistency, clarity) Y-USA would recommend requiring attendance reports to be synchronized with weight loss reports. In that scenario, attendance standards would be modified to consider a 'completer' to be someone who has attended (a) at least 4 core sessions attended and (b) at least 1 maintenance session. If this were the definition, then the average number of maintenance sessions attended by completers across all 880 program sites run by YMCAs to date would be a very successful 3.35.

The concerns we have about sacrificing the perception of quality results for a potential increase in the quantity of participants served are also being created by numerous proposed changes in the DPRP's requirements which clearly distance the DPRP standards from the best available science. Examples of the changes where we've seen a clear change in the commitment to holding DPP providers accountable to high-fidelity implementation of the evidence based DPP methods include:

1. In Section II's subsection on "Location" heading, Organizations may now choose to deliver the lifestyle intervention virtually or via one or more distance-learning

modalities or approaches (e.g. online, remote classroom). We are not aware of published results of any large-scale online or distance-learning modes of DPP delivery and question whether there is sufficient science to allow for these modalities to be seen as equivalent to in-person delivery models.

2. We noted in Section II's subsection on "Requirements for Pending Recognition Status" several changes to *Required Curriculum Content* (#2). Previously existing language requiring the use of curriculum with 'direct' connections to the curriculum that was proven in the DPP Trial has been removed. How many deviations from proven methodology will be allowed before anyone rightly questions the fidelity of less "direct" translations of the original curriculum?
3. In Section II's subsection on "Requirements for Pending Recognition Status" we were concerned by change to *Intervention Intensity* (#4) to delete group based delivery, hour long class sessions, and in-person program delivery requirements. Obviously, we understand the original DPP Trial showed the effectiveness of one-on-one program delivery. Our main concern is with the other deletions and modifications. We are not aware of published results of any large-scale online or distance-learning modes of DPP delivery, or of DPP delivery that occurs in sessions that last less than an hour. These deletions seem to be significant changes to the DPRP, which are not yet supported by sufficient science to be seen as comparable to in-person delivery methods.
4. In Section II's subsection on "Requirements for Pending Recognition Status" we were concerned by the assumption (in #4; intervention intensity) that self-reported weights provided by participants of online or distance-learning versions of the program would be considered valid, or somehow equivalent to data collected and reported by in-person Lifestyle Coaches. The lack of validity of self-reported weights as a measure has been well established in the public health literature. Allowing these data to be seen as equivalent to data obtained by a trained data collector will only make all weight loss data suspect.
5. In Section II's subsection on "Additional Requirements Additional Requirements for Full Recognition Status" we noted a change to how weight loss is to be reported at the end of the year (#10). The proposed standard says that average weight loss achieved over the entire intervention period by participants attending at least 4 sessions must be a minimum of 5% of "starting" body weight. Under the current standards the requirement is that average weight loss achieved over the entire intervention period by participants attending at least 4 core sessions and 1 post-core session must be a minimum of 5%. This new language is at least inconsistent with recent science, and can be expected to result in lower reported weight loss averages. Studies done by the CDC, such as the meta-analysis of 28 community-based translations of DPPs that was published by Ali et. al. in the journal *Health Affairs* in 2012, have demonstrated that the "dose" of the DPP is what drives success.
6. In Section IV's subsection on "Evaluation Data Elements" we noted a change to no longer require the reporting of a session ID. Until now, this measure was

used to demonstrate fidelity to the proven curriculum. We can understand why DPP providers might want to deliver different sessions of a DPP model in a different order, and thus why eliminating the need to report this variable would be desirable, but behavioral science was used to design the original curriculum and we believe the science clearly supports fidelity to the order of the sessions (i.e., nutrition topics are covered well in advance of physical activity topics for a reason).

The allowance for less- proven methods of DPP program delivery (i.e., via “virtual, online or other” delivery modes) also leads us to question the strategic value of adopting the new DPRP standards. We are only aware of two peer-reviewed studies of these types of delivery modes—and one was just published this month! There is thus a seemingly large divide between the evidence base behind “virtual, online or other” forms of DPP delivery and the evidence behind the in-person delivery of DPPs. Including these versions of DPPs as equivalents of the in-person program modes (or even making the reporting requirements under the DPRP more lax for these new modes) may undermine confidence in the overall science behind, and value of, one of the most well-researched prevention strategies ever developed by the National Institutes of Health or the CDC.

We are especially nervous that the early successes we are having in the engagement of payors, health care providers, and employers—who all invariably state the evidence behind the in-person DPP model is what sets it apart from all the other interventions that they do not support—will be potentially diminished by a general loosening of the existing DPRP standards and the perception that the science behind the CDC’s National DPP is being watered-down. Our enrollment data have consistently shown that payor, provider, and employer involvement in recruitment is what drives sustainable levels of enrollment and implementation. Supporters of the current DPP model, such as the American Medical Association, are often having to convince others of the science behind the DPP. In health care circles, the DPP intervention has not completely taken hold because, in part, of the ‘newness’ of the science behind the DPP. Clinicians are looking for longer-term data on program outcomes. Without these partners’ confidence in the intervention, DPP providers will need to spend much more time per capita in recruitment efforts. Thus there is a real risk, in our view, that without credible DPRP standards, DPRP recognition will be meaningless to providers such as the YMCA.

Conclusion

We have offered these comments with the best of intentions. The staff members at the YMCA of the USA, and thousands of our YMCA colleagues across the country, are working hard every day to put a proven model to work. We share CDC’s goals of serving as many people with prediabetes as possible. We simply urge the DPRP team

to take advantage of data we can make available to inform changes to the standards and avoid potential pitfalls that could include sacrificing long-term sustainability and value of the DPP for a short-term goal of loosening the standards.

There is great strategic value in the recognition of community-based efforts to reduce the incidence of diabetes. We are thankful for our ongoing partnership with CDC and for having had the opportunity to formally review and respond to the current version of the DPRP plans.

Sincerely,

A handwritten signature in black ink, appearing to read "Matt Longjohn". The signature is fluid and cursive, with the first name "Matt" being more prominent.

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