Summary of Public Comments and CDC Response

Type of Comment	Comment	What appeared in draft ICR (prepared for Public Comment)	What appears in revised ICR (presented to OMB for review and approval)
Editorial comment	Typographical errors, inconsistent in terminology or unclear text		Reviewed by a writer/editor
Request for Clarification	Data element missing or not well defined	Data elements not clearly defined and no element for height	Includes a data dictionary (with coding instructions), which now includes data elements for height and physical activity
	Control over/consistency of data transmitted to CDC	CDC would accept information in any user-defined format generated by any software system	Information must be submitted in a standardized comma separated value (CSV) format
	Privacy/confidentiality of data at organizational level	Privacy/confidentiality at CDC discussed but not at organizational level	Organizations are responsible for complying with all applicable federal, state, local laws
	Forms (consent form, referral form, etc.)	Sample forms included in standards	Forms removed. Examples of these types of forms will be made available on the DPRP website
Comments on standards	Minimum number of sessions that each client must attend	Participants attending a minimum of 2 core sessions included in data transmitted to CDC	Participants attending a minimum of 3 core sessions would be included in data transmitted to CDC
	Role of the community advisory board	Community advisory board required	Community advisory board no longer required
	Method of calculating weight loss	Weight loss calculated as [(sum of baseline weights)-(sum of final weights)]/(sum of baseline weights)	Weight loss calculated as the average per-person percentage weight loss.
Comments on burden estimate	Burden underestimated	Burden for completing one-time online application estimated as 3 minutes per response	Increased to 60 minutes per response
	Cost to respondents is underestimated	Average hourly wage rate was estimated to be $7.25 per hour	Average hourly wage rate increased to $14.50 per hour

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

July 25, 2011

Neil Nicoll
President and Chief Executive Officer
YMCA of the USA
101 N. Wacker Drive
Chicago, IL 60606

Dear Mr. Nicoll:

Thank you for taking the time to review and comment on the CDC Diabetes Prevention Recognition (DPRP) standards. I appreciate your commitment to improving the clarity of the DPRP standards. All of your comments were carefully considered. Included with this letter you will find specific responses to the suggestions and remarks outlined in your letter dated February 18, 2011.

With the growing number of new cases of type 2 diabetes, it is vital that we implement proven interventions for preventing or postponing this serious disease. The DPRP is an important part of assuring that we meet the goal of reducing new cases of type 2 diabetes.

Again, thank you for your interest in the DPRP.

Sincerely,

Ann Albright

Ann Albright, Ph.D., R.D.
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention

February 18, 2011

Carol Walker
Acting Reports Clearance Officer
Centers for Disease Prevention and Control
1600 Clifton Road, MS D-74
Atlanta, GA 30333

Dear Ms. Walker,

We are writing in response to a Notice, pertaining to the proposed Diabetes Prevention Recognition Program, which was posted in the Federal Register on December 21st, 2010 (Volume 75, Number 244). The Notice (DOCID: fr21de10-48) announced a 60-day opportunity for public comment on proposed data collection projects to be periodically conducted by the Centers for Disease Control and Prevention (CDC). Specifically, the Notice invited 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 2,686 YMCAs (Ys) operating across the country. Our response to the Notice is being made on behalf of those Ys, which are working in more than 10,000 communities to improve the health of more than 21 million members. We are writing on behalf of all the Ys that may eventually be eligible for CDC recognition, but our comments on the Notice specifically represent the concerns of the Ys currently contracted to implement the evidenced-based YMCA's Diabetes Prevention Program (YDPP). The CEO's of those Ys (listed below our signatures) have read and affirmed support the contents of this response.

Some Ys in our movement are working on diabetes prevention in parallel with the YDPP through partnership with their State's Department of Health. Those Ys may have additional comments, but we feel we have represented much of their potential feedback.

Over the past few years, Y-USA has been privileged to work with the leaders of the CDCNCCDPHP's Division of Diabetes Translation (DDT). We are thankful to have had the opportunity to work with such great partners, and appreciate having had the opportunity to discuss many of the proposed recognition program elements with that team. Y-USA is a proud partner of the DDT in shared efforts to prevent the continued spread of the diabetes epidemic. With support from CDC and others, we are actively working to develop and disseminate the YDPP. In just the past two years, we have helped disseminate a proven intervention from one Y (Indianapolis) to Ys in 22 cities. In the next year, 57 YMCAs will be operating the YDPP and we expect the program to be running in nearly 200 branches in 2011.

From the outset of efforts to disseminate this program, the potential of formal CDC recognition has been one of the strongest motivators for Ys. Thus, we are enthusiastically supportive of the creation of a

Diabetes Prevention Recognition Program (DPRP). We believe many Ys may eventually be eligible for CDC recognition under the DPRP. It is our hope that we will be able to leverage the Y's interests in recognition for the greatest possible benefit in efforts to disseminate a proven community-based intervention, and to prevent the increasing incidence of diabetes.

However, we have some concerns about both the *practical utility* of the information to be collected through the DPRP, and the *accuracy of the agency's estimate* of the burden of the proposed collection of information. Our concerns are based on a thorough review of the DPRP data collection plans and instruments, and significant experience in working with local organizations to implement a proven intervention and document its processes and results. The locally-based efforts to disseminate the YDPP through the Y-USA are only about a year old. We appreciate the opportunity to respond to the Federal Register Notice about the DPRP because our understanding of what it will take for community-based organizations to participate has increased very rapidly over the past year. If the comments below differ from any guidance we gave the CDC during the development of the DPRP, it is surely due to that improved understanding of community-level operations of a program like YDPP.

- (C) We believe that prior to the launch of the DPRP, the current plans should be reviewed and amended to:
  a. add clarity and consistency to the documentation in order to give community-based organizations confidence they can successfully meet (and plan for) new and more costly data monitoring and reporting requirements
  (R) The standards have been revised and edited for clarity and consistency. The section dealing with the evaluation data required by CDC has been expanded and a data dictionary has been added.

  b. reflect common community-based organizational structures and processes such that potential recognition recipients can be expected to adhere to DPRP standards without changing their governance or operational standards;
  (R) CDC revised the standards and believes the revisions will address your concerns. For example, recognized organizations are no longer required to have a community advisory board.

  c. document an understanding of challenges community-based organizations will face and how the CDC's DPRP will work with those organizations to translate existing science into sustainable and effective practice; and
  (R) While CDC recognizes that organizations might face challenges in implementing an effective lifestyle program, we do not believe that the standards document is the proper venue for a discussion of possible challenges. Overcoming challenges will likely be addressed by technical assistance and in the frequently asked questions section on the DPRP website.

  d. ensure the overall goal of disseminating proven community-based diabetes prevention programs is not hindered by requirements that may actually discourage participation in the DPRP.
  (R) The DPRP standards were developed by a workgroup which included community-based programs such as the Y. Due to this collaborative effort, CDC does not believe the standards will discourage participation in the DPRP.

Clarity and Consistency

- (C) The DPRP data collection plans and instruments (i.e., the final draft of the *DPRP Standards and Operating Procedures*, and the draft DPRP supporting statement documents) are occasionally inconsistent or imprecise in ways that may unintentionally lead community-based organizations to question whether they can successfully meet (or sufficiently plan for) new and more costly data monitoring and reporting requirements.
  (R) Text has been edited for clarity and consistency.

- (C) Definitions, and the consistent use of terms, would answer many of the questions that arise from a review of the current materials. Some questions that arose in our review of the documentation included:
  - "Complete" This term was used in reference to both individuals and groups, but was never defined for either. Is a person who completes the program someone who attended the last (Core or Post-Core) session? Is a group that completed the 12-month lifestyle program one that had a minimum number of participants attend all the (Core or Post-Core) sessions?
    (R) Text has been edited for clarity and consistency. A data dictionary was developed and is now in the standards document. CDC believes this data dictionary will eliminate any confusion associated with the data elements.

  - "Participant" Is someone who attends only two sessions in one year really a full participant? Are there ever any acceptable reasons why someone might leave the program after two sessions (e.g., death, relocation, etc) that would indicate that they should not be considered a participant at the end of the program (or in the denominator of percentages who complete the program or meet other standards)?
    (R) This section has been modified and changed to 3 sessions. Participants must attend at least 3 core sessions to be considered a full participant.

  - "Organization" This term is often not used specifically enough to let local organizations that have national partners determine if they can allow another organization to submit information to the CDC on their behalf. If, for example, Y-USA wishes to submit its own curriculum for approval; will each local Y have to submit a copy of the curriculum and handouts that they are using, or will the YDPP curriculum only need to be submitted by YUSA?
    (R) The term "organization" refers to the community-based organization that is delivering the lifestyle program. Each organization must submit a copy of the curriculum to the CDC for prior approval.

- (C) There may be other examples worth explaining in the document where a national organization might serve as a resource or conduit to local affiliates or franchises?
  (R) As stated above, in regards to DPRP recognition, the term "organization" refers to the community-based organization that is delivering the lifestyle program. Interactions between national organizations and their local affiliates or franchises are at the discretion of the organizations.

Other concepts that seemed unclear, or to be inconsistently or incompletely addressed in the DPRP documentation were:

- (C) Whether 'individuals' as well as 'organizations' could apply for DPRP recognition (e.g., individuals are mentioned as being able to apply only in the first sentence of the 'Overview of the Data Collection' section on page 6 of the DPRP Supporting Statement);
  (R) Any organization that has the capacity to deliver an approved diabetes prevention lifestyle intervention may apply for recognition. Recognition is granted to the organization, not to individual lifestyle coachers. However, applicant organizations may include small businesses that are individually-owned and operated.

- (C) Whether the interventions should allow only those with pre-diabetes to participate, or whether those 'at risk for pre-diabetes' (Supplemental Statement A.11; pg 14) should also be allowed
  (R) The recognition standards state that no more than 50% of participants can be included based only on screening positive on the diabetes risk test, without a clinical diagnosis of prediabetes.

- (C) What the timeline for curriculum approval or program recognition might be (i.e., how long will it take the CDC to approve curricula, will certain curricula be pre-approved, how long will it take the CDC to recognize an individual or organization after the submission of an application?)
  (R) Organizations using the recommended National Diabetes Prevention Program curriculum will receive a response concerning their application for recognition within 15 business days. Organizations who choose to submit and alternative curriculum will be notified concerning the acceptance/rejection of their curriculum and their application for recognition within 30 business days. At the present time, the only pre-approved curriculum is the National Diabetes Prevention Program curriculum.

- (C) Whether any programs could be recognized as anything other than 'pending' or 'probationary' during the first two years of the DPRP (i.e., while data are being submitted in 6 month intervals)
  (R) Each applicant organization will be required to submit evaluation data to the DPRP every six months from the date of the first lifestyle intervention core group session offered after the application acceptance date. Recognition status will be assessed 24 months after the first session. Until this assessment (24 months after the first session), the status of all organizations will be "pending recognition." After the assessment, an organization's status will either be converted to "full recognition" for a two-year period or will remain as "pending recognition" for an additional 12 months (at which time it's program will be reassessed). There is no longer a "probationary recognition" status.

- (C) Outcome elements that need to be submitted are inconsistent in the documents (e.g., source of referral is not mentioned in the supporting statement, but is a field on the Participant Data, Process and Outcome Elements sheet) should be consistent with the requirements for recognition found on page 12 and 13 in the Standards and Operating Procedures.
  (R) Text has been edited for clarity and consistency.

- (C) Potential complications in monitoring program success between Core and Post-Core periods (e.g., what happens if a participant averages of 5% weight loss during the core sessions go down to 4.5% or

less during the post-core period because people aren't coming as much, are slipping more, and having a hard time sustaining the lifestyle changes; or vice versa)
(R) CDC is interested in weight loss during both the core and post-core sessions. Post-core is a maintenance period and it's important to monitor body weight during the post-core period. Program success depends on average weight loss and participants can lose weight or maintain weight during the post-core period. The DEPLOY Study, on which the recommended lifestyle curriculum is based, demonstrated that after one year a 6% weight loss could be achieved by YMCA lifestyle coaches. The DPRP specifies that program participants, on average, achieve a weight loss of 5% after one year.

- (C) Information on any minimum program size requirements (i.e., how many participants should be enrolled in the program to determine success and warrant recognition?). Reflect community-based organizational structures and processes
  (R) CDC suggests 10–15 participants. However, it is the applicant organization's decision to determine the number of participants per session that would be economically viable and sustainable.

- C) Community-based organizations operate within tight budget constraints, under a number of common governance and operational structures, and within their own Board- or leadership approved processes. If program requirements do not reflect this reality, then CBOs may not be able to meet what seem to be somewhat arbitrary program requirements or to collect and report required information within the estimated costs of seeking DPRP recognition. For these reasons, some specific changes in the DPRP standards should be considered.

  The most significant concern here is that assumptions are made about the staff that will be assigned to collect, monitor and report the DPRP data, and that these assumptions do not reflect the practices of CBOs we work with, and they are likely to result in the underestimation of the burden of these activities. Local Ys, for example, do not commonly collect the amount or variety of data being requested by the DPRP. It is unclear how participant data will be treated if some of the required fields are incomplete and would local Ys have to bear the burden of trying to obtain this information from past participants. Also, local Ys do not in practice assign data-related tasks to volunteers. Both these assumptions are made in the DPRP documentation, and will result in the underestimation of the burden of seeking *and maintaining* DPRP recognition. The estimated burden of participating in the DPRP could be revised to reflect common CBO practices.
  (R) CDC believes that it is requesting the minimum elements necessary to assure quality. CDC agrees that all local Ys may not be collecting all of these data elements. However, those Ys currently delivering structured lifestyle programs for the prevention of diabetes are routinely collecting all of these data elements and more. CDC has recalculated and revised the estimated burden hours and is open to modifying the elements over time based on new data or information. Data quality and completeness is the responsibility of the applicant organization.

- (C) Further, there are some program elements which have recently been excised from proven interventions that, if required, will not always be acceptable or affordable to CBOs. Specifically, if the establishment of calorie goals is to be a requirement of the core curriculum, then CBOs may need to seek out dietitians or nutritionists to administer a significant portion of the program (i.e., for legal reasons related to professional certification/licensure in some states).

  The benefit of obtaining DPRP recognition to CBOs may not ultimately be worth the increased costs of seeking that level of professional support and leadership.
  (R) CDC is unclear as to which program elements you believe may have been "excised from proven interventions" and may not be "acceptable or affordable" to community-based organizations. The only specific goal mentioned above is a "calorie goal." However, there is no calorie goal or requirement in the DPRP standards.

- (C) The requirement that the Community Advisory Board have financial oversight of the diabetes prevention program will not comport with how most CBOs work with advisory groups. Legally, fiduciary responsibility must reside with an appropriate governing Board of a CBO. A CBO may be able and willing to share financial data with the Community Advisory Board, but this should not be a requirement.
  (R) CDC has amended this section and deleted the requirement for a community advisory board. However, applicant organizations are encouraged to foster relationships with health care professionals and/or organizations to increase collaboration and allow for mutual referrals.

- (C) The DPRP documentation is silent on whether non-fasting or random glucose testing would be an accepted diagnostic screening test used to determine program eligibility. Because many CBOs host their own health screenings which reach potential participants that are not always planning to be screened, non-fasting or random glucose testing should be explicitly allowed or disallowed.

  (R) A random glucose, obtained via fingerstick, is not a diagnostic test and cannot be used to meet eligibility requirements. The participant eligibility requirements state:
  "A minimum of 50% of a program's participants must have had a recent (within the past year), documented, blood-based diagnostic test indicating they have prediabetes, or a history of gestational diabetes mellitus (GDM), according to one of the following specifications:

  Fasting plasma glucose of 100 to 125 mg/dl

  Plasma glucose measured 2 hours after a 75 gm glucose load of 140 to 199 mg/dl

  A1c of 5.7 to 6.4 [note that the A1c is a non-fasting test]

  Clinically diagnosed GDM during a previous pregnancy (may be self-reported).

  A maximum of 50% of a program's participants may be considered eligible without a blood-based test or history of GDM only if they screen positive for prediabetes based on the CDC Prediabetes Screening Test."

  Due to the increased complexity related to blood sampling, it may be more convenient for community-based organizations to rely on screening via the paper test.

Document the CDC's DPRP interest in translating science into practice

- (C) As discussed above, we understand and support the need for clear and consistent guidance to potential recognition-seekers. However, we also feel it would be valuable for the DPRP documentation to recognize that work to translate evidence-based programs into community practice is still in its infancy, and consequently, CBOs will encounter many unforeseen challenges. Further, we encourage the CDC to emphasize its willingness to review and revise the DPRP standards at some point in the future to reflect continued knowledge development that will surely come from still-nascent translational efforts.
  (R) CDC is willing to consider revising the program to reflect scientific or program advances. However, changes to the DPRP can only be made after careful consideration and with the prior approval of the Office of Management and Budget.

- (C) More specifically, the DPRP documentation should encourage CBOs to help identify areas of potential future scientific inquiry. These may be from identifiable practices CBOs develop to stay within DPRP standards, but which may affect participant enrollment and completion, data analysis or reporting, etc.
  (R) The purpose of the DPRP is to recognize organizations that have demonstrated an ability to effectively deliver a proven diabetes prevention lifestyle intervention so that decisions about referral, participation, and funding are based on accurate, reliable, and trustworthy information. The standards and reporting requirements reflect that purpose and CDC does not wish to impose any additional burdens on DPRP-recognized organizations. However, as always, the CDC would welcome communication from external partners including those involved in the DPRP.

- (C) One easily anticipated point at which CBOs—and the clinicians that will be referring individuals with prediabetes to them—will likely not adhere to the DPRP guidance is in relation to accepting participants with body mass index (BMI) values that are less than 25. Virtually every CDC resource that has made its way to clinics and CBOs in recent years has declared that a BMI of 24 is a healthy weight. The prediabetes screening tool included in the DPRP documentation assigns points (i.e., risk) to BMI values that are greater than 25. As a result, it may be predicted that no special effort will be made to identify or recruit participants with a BMI of 24.

  The impact of diabetes interventions on participants of relatively low BMI might be worth researching to determine whether future DPRP guidance could come into line with other CDC recommendations for weight.
  (R) CDC recognizes that there might be few participants with a BMI of less than 25 and agrees that the impact of the lifestyle program on these participants might be a topic worthy of further research. However, at this time, CDC chooses to retain the eligibility standard as written: "All of a program's participants must be 18 years of age or older and have a body mass index (BMI) of ≥24 kg/m^2 (≥22 kg/m^2, if Asian)." This BMI is based on that used in the DPP research trial.

- (C) The science behind another aspect of the DPRP that is unclear to us, and will almost certainly become an issue in the nation-wide administration of the Program: we do not understand why participants who may only show up twice in a year (because they die, get a new job, become pregnant, relocate or otherwise permanently leave the program without intention to complete it)

should be counted in the denominator of all program process and outcome measures. We are unclear about what the available evidence tells us about the value of attending two sessions (e.g., vs. four sessions), or any methods which may have allowed participants with low motivation or significant changes in life circumstances to have been screened out of previously researched interventions. We can foresee differences in how these instances are dealt with by DPRP organizations, challenges to quality assurance efforts that CDC will employ to ensure equitable data reporting practices, and variable effects on program integrity. This area of program implementation might warrant future study and refinement.

(R) CDC agrees that there is little or no scientific evidence in this area and that it might warrant future study. Until additional evidence is available, DPRP staff, along with a workgroup including representatives from community-based organizations, determined the minimum number of sessions participants must attend to be considered full participants. However, in an effort to address your concerns, the minimum number of sessions was increased from two to three. Participants must now attend at least three core sessions to be considered a full participant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

July 25, 2011

Rita A. Mays
Diabetes Prevention Planner
Diabetes Program
Center for Health Promotion
Minnesota Department of Health
P.O. Box 64882
St. Paul, MN 55164-0882

Dear Ms. Mays:

Thank you for taking the time to review and comment on the CDC Diabetes Prevention Recognition (DPRP) standards. I appreciate your commitment to improving the clarity of the DPRP standards. All of your comments were carefully considered. Included with this letter you will find specific responses to the suggestions and remarks outlined in your letter dated February 18, 2011.

With the growing number of new cases of type 2 diabetes, it is vital that we implement proven interventions for preventing or postponing this serious disease. The DPRP is an important part of assuring that we meet the goal of reducing new cases of type 2 diabetes.

Again, thank you for your interest in the DPRP.

Sincerely,

Ann Albright

Ann Albright, Ph.D., R.D.
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention

MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

Date: February 18, 2011

To:
Carol Walker
CDC Acting Reports Clearance Officer
1600 Clifton Road, MS D-74
Atlanta, GA 30333
omb@cdc.gov

From:
Rita A.Mays, MS, RD, LN
Diabetes Prevention Planner
Diabetes Program
Center for Health Promotion
Minnesota Department of Health
PO Box 64882
St. Paul, MN 55164-0882

Subject:
Comments Submitted on the CDC Diabetes Prevention Recognition Program (DPRP)
As posted for public comment and recommendations on Tuesday, December 21, 2010, in the Federal Register Vol.75 No. 244

As Minnesota's Diabetes Prevention and Control Program (DPCP), we have been providing training and coordinating the Diabetes Prevention Program (DPP) in a program we market as I CAN Prevent Diabetes. Our initial training for coaches for this program were conducted by Dr. David Marrero from the University of Indiana Diabetes Translation Research Center. Since our first training in 2007 and by continuing to work with Dr. Marrero, we have developed Master Trainers. We have trained and certified over 100 DPP lifestyle coaches, and have helped local sites coordinate and implement over 30 DPP sessions. From this base of experience, we offer these comments on the CDC Diabetes Prevention Recognition Program (DPRP) proposed Standards and Operating Procedures and Supporting Statements.

Congratulations to the CDC for their excellent work in compiling these standards and procedures! They are well thought out and will provide excellent guidance and standardization to DPP programs across the country.

These comments are intended to convey where there are questions and possible suggestions for clarification.

Recognition Program (DPRP) Final Draft Standards and Operating Procedures

Note: (C) indicates a comment; (R) indicates a response from CDC (responses are also in blue font)

- (C) Curriculum page 7: We agree appropriate written materials must be provided to participants. "Appropriate" is assumed to be language appropriate. This will require that materials be available in Spanish. In Minnesota we are also working with fairly large populations of Hmong and Somali, and will need to know that materials are available for those that do not read English. Although other language materials may be needed at some point, these are the top priorities in Minnesota at this time. Certified Coaches can be bilingual, but handing out materials people cannot read won't be helpful.
  (R) DDT will provide the curriculum in English and Spanish, and programs may translate the curriculum into other languages as appropriate for their participants.

- (C) Attendance page 12: Consider basing requirements on those attending 3 or more sessions, rather than 2 sessions. People will try something twice before dropping a program. The first session is an introduction. In the second session people check their weight after one week, and get a sense of what it is like to track their food intake, and what the sessions will be like. They may give it that second session, and then decide if they will keep going or not. Programs could be penalized if they include results of people attending the second session and then dropping.
  (R) The attendance requirement has been changed from two sessions to three sessions throughout the document.

- (C) Appendix A. CDC Pre-diabetes Screening Test. Pages 19–20: We noticed that the At Risk Weight Chart is similar to ones being used by fitness organizations and not the same as the one used by the American Diabetes Association. Your choice seems like a good one for this program, but it is confusing to have similar looking At Risk Weight Charts used on Risk Tests. Can the name be changed or a reference given?
  (R) A reference for the At-Risk Weight Chart has been added to the text.

- (C) Appendix B. Sample Physician Referral Form. Section indicating patient permission to be contacted by DPP organization. Page 21: It's not clear if you are expecting the clinic to send this form to a DPRP recognized program or if the patient is expected to contact the DPRP organization and bring this form with them. Likewise, is it expected that the provider or the participant go to the CDC recognized program web site and determine where the DPP program is offered?
  (R) A health care professional may refer potential participants to the program, but a referral is not required. Since a referral is not a CDC requirement, we have no say in whether a physician or other health care provider might provide a referral to the potential participant or to the DPRP-recognized organization. The form has been deleted from the standards

document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a health care provider referral form might include if a health care provider chooses to use such a form.

(R) DDT, and possibly some of its partners such as the state diabetes prevention and control programs, will be marketing the recognition program and the list of recognized organizations. In addition to the marketing efforts, the list of recognized organizations will be available on the internet. We hope that health care professionals and potential participants will respond to marketing efforts by visiting the website to locate recognized programs.

- (C) Appendix B. Sample Consent Form. Page 24: This is a simple and easy to use consent form. However, different states may have laws requiring that participants receive more information about the program. For example, Minnesota state law requires the Tennyson warning be explained to individuals if data is being collected by government agencies, even if for the purposes of reports. In the future when this DPRP program is in place, clinics in Minnesota that seek recognition but do not submit data to the Minnesota Department of Health, might use the sample consent form as long as they are covered in their own HIPPA requirements for them. A check list of additional considerations might be offered for them. (R) CDC does not require recognized programs to use consent forms. The form has been deleted from the standards document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a consent form might include if a state requires use of or chooses to use such a form. Recognized organizations are responsible for customizing necessary forms to comply with all applicable laws and regulations, including those governing privacy and data security.

- (C) Impact on programs: We asked for input from sites in Minnesota already conducting the DPP for their thoughts about the potential difficulty of submitting these forms. One person responded that the application for recognition status is reasonable if the recognition brings reimbursement. The process is similar to the American Diabetes Association Recognition for Diabetes Education Programs, and appear to be less demanding based on this the coach should have consistent training and expectations to provide the material. The data collection estimated at 5 minutes per response seems underestimated, according to this site. This person's experience with data collection and compellation is that it is time consuming especially if the recorder is requesting data from multiple sources, which is often the case. They also noted that the process would be a very familiar one for any Diabetes Education program but may be new for other organizations. Another person reviewed the appendixes and thought it will be good to have universal job descriptions for all the DPP programs, including they YMCA programs. They also felt the certification for coaches was not defined clearly in the document in the Appendix C and noted that the Master Trainer is referenced by not explained.

(R) The Recognition Standards are designed to give the payer community confidence that appropriate evidence-based lifestyle programs are delivered to at-risk populations in a consistent manner that achieves 5% to 7% weight loss, increases physical activity in participants, and that delays or prevents the onset of type 2 diabetes. It is our intention that recognition of evidence-based lifestyle programs will lead to reimbursement, but there is no guarantee.

(R) There is no requirement for a certification or credentialing process for lifestyle coaches stated in the standards document. CDC does not require lifestyle coaches to be certified or credentialed. The standards document states: "People who have been trained to deliver the required curriculum content and possess the skills, knowledge, and qualities listed below are eligible to be lifestyle coaches." The recognized organizations will determine what types and amount of training meet this requirement. The term "master trainer" has been removed from all documents.

(R) The time burden listed for recognized organizations is not for the data collection but for transmitting the data to CDC in an electronic format. However, we thank you for pointing out that the requested data might come from multiple sources and that compiling and transmitting it will take longer than our estimate. We have revised the time burden per respondent for each data transmission from five minutes to sixty minutes.

(R) Although the DPRP standards document identifies the responsibilities, eligibility criteria, skills, knowledge, and qualities for certain staff (e.g., lifestyle coach), CDC does not require universal job descriptions. Recognized programs can develop their own job descriptions.

Supporting Statement and Justification

- (C) Technical Assistance. Page 5: How will DDT provide Technical Assistance nationally? Will this be through DTTAC at Emory University, with CDC staff, or through Diabetes Prevention and Control Program (DPCP) staff? DPCP's may be in the best position geographically and knowing the local communities to do this. However, if DPCP's will be involved, they may need to build this into their staffing and budgets in their annual plans with CDC.
  (R) Requests for technical assistance will be directed to DDT. When appropriate, CDC will reach out to DPCPs where there is mutual agreement for them to provide technical assistance.

Forms

- (C) Do any forms collect information on the coach and their training and certification? We understand that the organization is being approved as a recognized site, but how does CDC verify that the coaches have attended a training conducted by a Master Trainer and that the requirements of that training?

(R) There is no CDC-required certification process for lifestyle coaches and CDC does not require recognized organizations to compile or transmit any information about lifestyle coaches.

(R) The standards document states: "People who have been trained to deliver the required curriculum content and possess the skills, knowledge, and qualities listed below are eligible to be lifestyle coaches." The recognized organizations will determine what types and amount of training meet this requirement.

(R) The term "master trainer" has been removed from all documents.

Incentive for Recognition (page 7)

- (C) The reason for the Recognition Program described is to seek reimbursement for the recognized programs from insurers, including Medicare and Medicaid. Is it expected that reimbursement will be administered by the insurer directly to the individual Recognized program?
  (R) CDC does not have oversight over how an insurer will choose to reimburse recognized programs.

- (C) Is there an expectation that CDC will receive money based on the data base of Fully Recognized Programs and if so, that it will be re-directed to the individual sites according to the number of participants and their success rates? Or will this be handled by the insurer?
  (R) CDC will not receive payment from any entity for the recognition program or the National Diabetes Prevention Program curriculum. The recognition program is intended to assure quality that could potentially attract reimbursement for recognized programs, but CDC has no control or oversight over reimbursement processes.

- (C) Will CDC make recommendations to insurers on an individual program's full or pending recognition to such insurers? Will CDC share the results of the individual program with outside agencies or simply issue a certificate of recognition.
  (R) CDC will publish a registry of recognized programs, with pending or full recognition noted, on the CDC DPRP website. Additionally, CDC will notify individual organizations, by email, of changes to their recognition status (i.e., pending recognition awarded or full recognition awarded). CDC will not make recommendations to insurers about an individual program or reimbursement for recognized programs.

- (C) We also are aware that some programs work with uninsured populations or non-citizen immigrant workers. Is there an incentive for these organizations to become a recognized program? If not, is there any reason that such programs cannot continue to offer the full DPP program, using the curriculum from CDC Master and Coach trainings, but not seek reimbursement, if they are unable to achieve the attendance and weight loss goals?

(R) Recognition is voluntary and it is each organization's decision whether or not to apply for recognition status. While programs do not have to be recognized to access and use the National Diabetes Prevention Program curriculum, CDC believes there are advantages to being recognized. Recognized programs will be eligible for technical assistance from CDC; CDC will calculate their performance measures; recognized programs will be listed in a directory published by CDC; and CDC anticipates that quality demonstrated via the recognition program will drive referrals and reimbursement to recognized programs.

Privacy Impact Assessments/Assurance of Confidentiality for respondents (pages 9 & 12)

- (C) Is the respondent the recognized organization or participants in their program?
  (R) The applicant organization or recognized organization is considered the respondent.

- (C) Will data be available to MN DPCP for Minnesota organizations? If so, will it be available both by site within Minnesota (our preference) and aggregated across all organizations operating in Minnesota? Would the MN DPCP have access to Minnesota's Y-DPP data as well as data for organizations operating under the DPP I CAN Prevent Diabetes program. We anticipate using the results to further promote the program and possibly seek additional funding or reimbursement form state programs.
  (R) CDC may release or publish aggregated data. One example is the registry of recognized organizations. Another example might be a published report on National Diabetes Prevention Program outcomes, aggregated across recognized organizations. CDC will not share or release any raw data. As far as CDC is concerned, the raw data is the property of each recognized organization. Recognized organizations may or may not choose to share or release raw or aggregated data to parties others than CDC, subject to the provisions of all applicable laws. CDC does not intend to provide reports on individual organizations to state health departments or to any organization other than the organization that provided the data.

Impact on Small Businesses (page 10)

- (C) There seems to be a typo on p. 10, do you or don't you expect small business to apply? What about small or large non-profits? For example, we are particularly concerned about the impact on community organizations serving high risk populations. Yes, based on experience, we agree they may need more technical assistance.
  (R) The typographical error has been corrected. The standards document states that : "Any organization that has the capacity to deliver an approved diabetes prevention lifestyle intervention may apply for recognition."

Thank you for the opportunity for the public to respond to these proposed standards. If you have questions or wish to discuss our comments, please contact me.

Sincerely,

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

July 25, 2011

Shadi Chamany, MD, MPH
Director, Diabetes Prevention and Control Program
NYC Department of Health and Mental Hygiene
2 Lafayette St, 20th Floor, CN-46
NY, NY 10007

Dear Dr. Chamany:

Thank you for taking the time to review and comment on the CDC Diabetes Prevention Recognition (DPRP) standards. I appreciate your commitment to improving the clarity of the DPRP standards. All of your comments were carefully considered. Included with this letter you will find specific responses to the suggestions and remarks outlined in your letter dated February 18, 2011.

With the growing number of new cases of type 2 diabetes, it is vital that we implement proven interventions for preventing or postponing this serious disease. The DPRP is an important part of assuring that we meet the goal of reducing new cases of type 2 diabetes.

Again, thank you for your interest in the DPRP.

Sincerely,

Ann Albright

Ann Albright, Ph.D., R.D.
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention

Drafted by NYC Dept of Health and Mental Hygiene
Last revised Feb 18, 2011

Comments on the Proposed Data Collections for the CDC Diabetes Prevention Recognition Program submitted by Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

Source: Federal Register, December 21, 2010, Vol. 75, No. 244, p. 80057

General comments and questions

- (C) Attention to security of identifiable and/or sensitive information should be addressed more thoroughly.
  (R) CDC will not request or accept identifiable information. Applicant (and recognized) organizations are responsible for complying with all applicable federal, state, and local laws including those dealing with data privacy and security.

- (C) Similarly, there should be more attention to data quality and control. We foresee possible lack of data quality and control for certain organizations with little experience handling such data, and therefore recommend provisions to ensure data quality.
  (R) CDC has more clearly defined the terms used for the data elements by providing a data dictionary with specific response codes and parameters for the data ranges. In addition, rather than allow organizations to submit data to CDC in any software and format, CDC is now requiring organizations to submit data using the comma separated value (CSV) format and has provided specific instructions for the rows and fields. CDC believes that these revisions provide the requested clarification and will result in the submission of data that satisfies DPRP analytic requirements and is of consistently high quality.

- (C) A flowchart which outlines processes for recognition and data flow is recommended to assist with clearly presenting standards, procedures and timelines.
  (R) A flowchart is now included in the standards document.

Detailed comments on "Final Draft Standards and Operating procedures"

Page 3

- (C) Consider adding "Policy" as a fourth key objective of the Diabetes Prevention Recognition Program since a recognition program would support the creation of a standard and reliable process to facilitate reimbursement by insurers and this is the only sustainable approach to this prevention effort.
  (R) CDC's role is to ensure fidelity and quality to the National Diabetes Prevention Program. Although reimbursement is an important policy issue, this is wholly the decision of third party payers, and not under the purview of the CDC.

Page 4

- (C) Suggest adding "Provider-confirmed" to clinical diagnosis of gestational diabetes mellitus in the eligibility section.
  (R) The participant's self-report that she had been told by a physician during a past pregnancy that she had GDM should be adequate. Requiring confirmation by a health care provider would complicate recruitment of participants.

- (C) The following paragraph does not fit in the "Participant Eligibility Established" section, as it does not address participant eligibility. It should be a separate comment, or included in a different section. "Occasionally, family members may wish to attend group sessions with the participant. Although this is permissible, data from family members should not be collected or reported to the DPRP."
  (R) We agree and the phrase has been moved

- (C) Suggest combining referral form and form for physicians to provide information on potential exclusions, limits and recommendations into one form, possibly front/back.
  (R) A health care professional may refer potential participants to the program, but a referral is not required. The form has been deleted from the standards document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a health care provider referral form might include if a health care provider chooses to use such a form.

- (C) In the "Safety of Participants Ensured" section, the sentence "*There will also be an opportunity* for the referring health care professional to do the following:" would be more clear if it were stated as follows: "*The referral form should include space for* the referring health care professional to do the following:"
  (R) The "Safety of Participants Section" has been revised. A health care professional may refer potential participants to the program, but a referral is not required. The form has been deleted from the standards document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a health care provider referral form might include if a health care provider chooses to use such a form.

Page 5

- (C) The role of the consent form included in Appendix B is not described in the text. It should be made clear if this is a CDC recommendation or requirement. We suggest you recommend that all participants have a consent form.

  (R) CDC does not require recognized programs to use consent forms. The form has been deleted from the standards document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a consent form might include. Recognized organizations are responsible for customizing necessary forms to comply with all applicable laws and regulations, including those governing privacy and data security.

Page 6

- (C) Require that participant organizations must also be able to provide a list of community advisory board members and their respective titles.

  (R) CDC has eliminated the requirement for a community advisory board from the standards document.

Page 11

- (C) A flowchart which outlines processes for recognition and data flow is recommended to assist with clearly presenting standards, procedures and timelines.

  (R) A flowchart is now included in the standards document.

Page 12

- (C) We agree with the allowance of use of curricula other than that provided by the National Diabetes Prevention Program, in order to promote innovation and development programs that may be as or more effective. However, we recommend providing details regarding on how acceptability of proposed curriculums will be assessed. This is necessary to maintain the standard nature of the recognition program.

  (R) Organizations that choose to apply for recognition status with CDC and choose to use a different curriculum must ensure that it meets all the key elements of the DPP research trial lifestyle curriculum as outlined in the standards document or it will not be approved. The proposed curriculum will be reviewed by the DPRP Project Officer and, as appropriate, by other DPRP staff. Proposed alternative curricula will be assessed using a curriculum checklist consisting of criteria for content, duration, and intensity drawn directly from the DPRP Standards. CDC is dedicated to monitoring and reviewing published evidence related to diabetes prevention. As the science changes or evolves CDC will amend the standards document accordingly.

Page 13

- (C) The language currently used regarding documentation of body weight "During the core phase, *80% of participants must have body weight recorded* during the sessions attended (including makeup sessions)." Suggest changing to "During the core phase, *on average, participants had body weight recorded at 80% or more* of sessions attended (including makeup sessions)." Similarly, with regards to documentation of body weight during post core, consider changing wording to "During the post core phase, *on average, participants must have body weights recorded at 60% or* more of sessions attended."

  (R) The language in the standards document was changed to:
  - Documentation of body weights will be based on all participants who attended at least three core sessions. Body weight must have been recorded at 80% or more of all core sessions (including makeup sessions) attended by these participants.
  - Documentation of body weights will be based on all participants who attended at least one post-core session. Body weight must have been recorded at 60% or more of all post-core sessions attended by these participants.

- (C) As described in the text, standards for calculation of percent weight change achieved by participants do not specify whether 1) percent change of starting body weight is calculated for each individual and averaged OR 2) it is aggregated across the entire group. However, in the example provided in Appendix D: Example of Data for Performance Assessment, percent weight loss is calculated by dividing the difference between the sum of the weights of all individuals in the group at baseline and the sum of weights at the last core session by the sum of the weights of all individuals at baseline. That being said, we strongly recommend that this approach be replaced with an alternate method of calculating weight loss, specifically the way in which it was done in the DPP study published in 2002. Percentage weight loss was calculated for each individual and then averaged (mean average) across groups. In the previous system, the percentage weight loss indicator is not a standardized indicator as it does not take into account differences in baseline weight and variation in

weight loss for each individual across different classes. As such, it is not a useful metric for certifying programs. We have included a description of two situations to demonstrate this bias.

Case 1: Two classes with large difference in average weight of class.

	Weight at baseline	Weight at end	Change	% change	Using current method described in SOP	Using suggested alternate method
Case 1						
Group 1						
1	350.0	315.0	−35.0	−10.0%	−11.2%	−11.6%
2	280.0	250.0	−30.0	−10.7%		
3	220.0	200.0	−20.0	−9.1%		
4	180.0	150.0	−30.0	−16.7%		
TOTAL	1030.0	915.0	−115.0			
Group 2						
1	220.0	198.0	−22.0	−10.0%	−11.7%	−11.6%
2	145.0	129.5	−15.5	−10.7%		
3	175.0	159.1	−15.9	−9.1%		
4	200.0	166.7	−33.3	−16.7%		
TOTAL	740.0	653.2	−86.8			

In this case, Group 1 will appear to have lost less weight on average than Group 2 when in fact each individual had the same percent weight loss.

Case 2: Large or small weight changes among individuals who weigh more at baseline.

	Wt at baseline	Wt at end	Change	% change	Using current method described in SOP	Using suggested alternate method
Case 2						
Group 1						
1	400	350	−50	−12.5%	−11.2%	−10.6%
2	150	135	−15	−10.0%		
3	150	135	−15	−10.0%		
4	150	135	−15	−10.0%		
TOTAL	850	755	−95			
Group 2						
101	400	392	−8	−2.0%	−6.2%	−8.0%
102	150	135	−15	−10.0%		
103	150	135	−15	−10.0%		
104	150	135	−15	−10.0%		
TOTAL	850	797	−53			

In this case, while outliers will always have the tendency to skew results, the difference between Group 1 and Group 2 is greatly exaggerated using the method proposed in this SOP.

(R) The language in the standards document was changed to:

- The average weight loss (mean percentage weight loss) achieved over the entire intervention period by participants attending at least one post-core session must be at least 5% of "starting" body weight (defined as the body weight measured at the first core session attended). For those who do not complete the post-core phase, the end-of-post-core weight will be the weight recorded at the last post-core session attended.
- Below is a table (appendix C of the standards) in which a hypothetical example of weight loss is calculated.

Participant	Core sessions attended	Core sessions with weight measured	Weight (lbs) at *first* core session attended*	Weight (lbs) at *last* core session attended	Post-Core sessions attended	Post-Core sessions with weight measured	Weight (lbs) at *last* post-core session attended
1	9	7	200	180	3	2	182
2	8	6	175	166	2	2	168
3	12	12	305	275	5	2	288
4	13	11	181	183	6	4	175
Total	42	36	861	804	16	10	813
Standard	9.0	80.0%		–5.0%	3	60.0%	–5.0%
Achieved	10.5[1]	85.7%[2]		–6.0%[3]	4[4]	62.5%[5]	–5.5%[6]

* Starting Body Weight

[1] Average number of core sessions attended:
42 sessions/4 participants = 10.5

[2] Percentage of core sessions in which weight was measured:
(36/42) × 100 = 85.7%

[3] Average per-participant percentage weight loss at end of core phase:
([180/200 – 1] + [166/175 – 1] + [275/305 – 1] + [183/181] – 1) × 100/4 = –6.0%

[4] Average number of post-core sessions attended:
16 sessions/4 participants = 4

[5] Percent of post-core sessions in which weight was measured:
(10/16) × 100 = 62.5%

[6] Average per-participant percentage weight loss at end of post-core phase:
([182/200 – 1] + [168/175 – 1] + [288/305 – 1] + [175/181] – 1) × 100/4 = –5.5%

- (C) Regarding the requirement for providing evidence that there is a system in place for monitoring of participants physical activity, please provide clarification of what would constitute compliance with this standard.

  (R) The standards document has been revised to include an evaluation data element for physical activity. This element reads as follows: **"Documentation of physical activity minutes during the core**

phase. Documentation of physical activity minutes will be based on all participants who attended at least three core sessions. Physical activity minutes must have been recorded at 80% or more of all core sessions (including makeup sessions) attended by these participants."

Page 14

- (C) In the table outlining the standards for recognition, signed agreements are referred to in terms of documentation needed to determine compliance with standards. A template for these signed agreements is needed. Also suggest including in signed agreements language related to commitment to observe appropriate data confidentiality and HIPAA standards, when applicable, between CDC and organizations.

  (R) Language concerning signed agreements has been deleted. The application form now includes language that reads as follows: "By submitting this application, your organization **[applicant enters name, title, organization name, and date in XX/XX/XXXX format]** asserts that it has thoroughly reviewed the *CDC Diabetes Prevention Recognition Program Standards and Operating Procedures* and would like to participate in the CDC's voluntary recognition program. Your organization agrees to comply with all of the recognition criteria specified in the standards, including the transmission of data to CDC every six months from the date of the initial lifestyle class for the purpose of program evaluation, continuing recognition, and technical assistance." Additionally, random audits will also be used to ensure compliance. Concerning the random audits, the standards document reads as follows: "Random audits will be conducted to assure that applicant organizations are accurately collecting and reporting data and addressing all of the DPRP requirements for recognized diabetes prevention programs. As explained in the standards, it is the applicant organizations' responsibility to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to data collection, storage, use, and disclosure."

- (C) With regards to wording for documentation of body weight during core and post core phase, suggest to changing "On average, participants must have their body weight recorded at XX % or more of sessions attended," as suggested for corresponding text on page 13.

  (R) The language in the standards document was changed to:
  - Documentation of body weights will be based on all participants who attended at least three core sessions. Body weight must have been recorded at 80% or more of all core sessions (including makeup sessions) attended by these participants.
  - Documentation of body weights will be based on all participants who attended at least one post-core session. Body weight must have been recorded at 60% or more of all post-core sessions attended by these participants.

Page 15

- (C) Recommend adding requirement that "Evidence of program being conducted by a lifestyle coach trained by a master trainer" to this section.

  (R) The term "master trainer" no longer appears in the standards document. Appendix B of *DPRP Standards* states that "recognized programs must use a lifestyle coach to deliver the program to participants." The standards document requires that a lifestyle coach ID number "be assigned by the applicant organization to uniquely identify each lifestyle coach conducting lifestyle intervention

sessions for the applicant organization." This ID number is among the data elements transmitted to CDC and will serve as evidence that each session is conducted by a lifestyle coach.

- (C) Recommend adding a requirement of proof of confidentiality and HIPAA, if applicable, training.
  (R) The standards state: "It is the applicant organization's responsibility to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to data collection, storage, use, and disclosure."

Page 16

- (C) In the "Data Elements Included in the Online Application" table, the term "Organization Code" is given different labels in different documents in this packet. The same term needs to be used throughout documentation.
  (R) Text has been edited for clarity and consistency.

Page 17

- (C) In the Participant Level Data Elements table, ensure that the term "Organization Code" is used consistently throughout package.
  (R) Text has been edited for clarity and consistency.

- (C) "Session ID Number" should be added as a data element.
  (R) The evaluation data elements have been revised to include an element for "Session ID." "This element will identify the session attended as one of the core sessions (numbered 1 through 16) or as a post-core session (coded as "999")."

- (C) While participant weight is included, participant height is not recorded as a data element. This should be included in order to verify that participants meet BMI standards for participation in program.
  (R) The evaluation data elements have been revised to include an element for:"Participant's Height." This element "should be recorded at enrollment and included on all session attendance records generated for an individual participant. Height may be self-reported (i.e., it is not necessary to measure the participant's height, the participant may simply be asked, "What is your height" or "How tall are you?") Participant's height should be recorded in inches."

- (C) The data element "Lifestyle Coach" is shown to have a unique identifier; however, it is unclear who will create the unique identifier and/or guidelines for the format of this identifier code. There should be standard guidelines for creating the lifestyle coach unique identifier so this is consistent across organizations and for ease of handling different streams of data.
  (R) The evaluation data elements for the lifestyle coach ID has been revised. This identifier "will be assigned by the applicant organization to uniquely identify each lifestyle coach conducting lifestyle intervention sessions for the he applicant organization. The Lifestyle Coach ID should not be based on social security number or other information in identifiable form." The code may be "up to 25 alphanumeric characters."

- (C) The "Participant Race and Participant Ethnicity" classification method used here should be used wherever these variables are collected.
  (R) The evaluation data elements for race and ethnicity have been revised to meet the reporting requirements required by the Office of Management and Budget and are uniform throughout the documents. The evaluation data elements now read: " **Participant's Ethnicity.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one of the following: "Hispanic or Latino" or "Not Hispanic or Latino." **Participant's Race.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one or more of the following: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Multiple responses are allowed. This element requires responses for five fields (refer to Table 2, the data dictionary)."

<u>Page 19</u>

- (C) The instructions given at the bottom of the "Prediabetes: You Could Be at Risk" test are not tailored to outreach for this program. This test is designed to be used as a tool to screen individuals who may not have a blood test, permitting up to 50% of participants to enter the program without having to see a physician, as proposed. Therefore, we suggest including language that encourages individuals to find out more about and/or join program in addition to encouraging them to contact their healthcare provider.
  (R) The CDC Prediabetes Screening Test is based on work by WH Herman and others and is currently used by many programs. CDC intends for the test to be used by applicant organizations with potential program participants. The risk test raises awareness about risk factors and encourages participants who screen positive on the risk test to see their health care provider. If an organization wants to use the test to encourage use of a particular lifestyle program, then CDC suggests the test be used in conjunction with an organization's promotional materials.

<u>Page 21</u>

- (C) The blood-based test ranges listed as criteria for eligibility in the "Eligibility Criteria" section of the sample referral form include the "≥" symbol in error. These symbols should be removed.
  (R) Forms have been corrected.

<u>Page 22</u>

- (C) Change from "Existing *type 2 diabetes* has been excluded" to "Existing *type 1 or type 2 diabetes* has been excluded."
  (R) Form has been modified to "existing diabetes".

<u>Page 23</u>

- (C) Patient name should be included at top of the "Limitations and Recommendations" form.
  (R) The sample form has been removed from the standards document and will be included elsewhere on the CDC DPRP website (www.cdc.gov/diabetes/prevention/recognition). This is a sample form, which applicant organizations are encouraged to modify to meet their program needs.

- (C) We suggest you recommend the use of consent form for all organizations and all participants.
  (R) CDC does not require recognized programs to use consent forms. The form has been deleted from the standards document and will appear elsewhere on the DPRP website (www.cdc.gov/diabetes/prevention/recognition) as an example of what a consent form might include. Recognized organizations are responsible for customizing necessary forms to comply with all applicable laws and regulations, including those governing privacy and data security.

Page 25

- (C) There is no mention in the text of why or when the sample authorization for release of information form will be used so this should be added. In addition, contact information for parties to which information will be granted release should be included. Because some organizations may be reimbursed by insurers for their members, ensure that the language in the release of information form is HIPAA compliant.
  (R) The sample form has been removed from the standards document and will be included elsewhere on the CDC DPRP website (www.cdc.gov/diabetes/prevention/recognition). Recognized organizations are responsible for customizing necessary forms to comply with all applicable laws and regulations, including those governing privacy and data security.

Page 26

- (C) In the "Sample Communication Preferences Form," there is a reference to the Health Insurance Portability and Accountability Act (HIPAA). However, since some organizations will not be billing for the program, these organizations would not fall under HIPAA rules. Therefore, language related to privacy should be made broader in order to encompass organizations that are not billing.
  (R) The sample form has been removed from the standards document and will be included elsewhere on the CDC DPRP website (www.cdc.gov/diabetes/prevention/recognition). Recognized organizations are responsible for customizing necessary forms to comply with all applicable laws and regulations, including those governing privacy and data security.

Page 27

- (C) Compliance with health information privacy and applicable HIPAA standards should be included as a Primary Responsibility.
  (R) The standards state: "It is the applicant organization's responsibility to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to data collection, storage, use, and disclosure."

Page 28

- (C) The list of "Primary Responsibilities of the Diabetes Prevention Coordinator" position is very broad and should either be presented as an option list from which organizations
  (R) This has been changed to "responsibilities may include. . ."

- (C) Compliance with health information privacy and applicable HIPAA standards should be included as a Primary Responsibility.
  (R) The standards state: "It is the applicant organization's responsibility to comply with any federal,

state, and/or local laws governing individual-level identifiable data, including those laws related to data collection, storage, use, and disclosure."

Page 31

- (C) See comments related to page 13.
  (R) CDC has addressed your comments. Please refer to the earlier responses.

Detailed comments on "DPRP Application Instructions"

- (C) The terms "Recognition Number" and "Organization Code" are used interchangeably throughout all documents. Terminology should be consistent.
  (R) Text has been edited for clarity and consistency.

- (C) Guidelines on how to report relationship between national, regional, local and individual entities of the same organization (for example, YMCA USA, Regional YMCAs, YMCA of Greater New York, individual YMCA locations within New York City) are needed to ensure standard reporting practices across all organizations.
  (R) CDC recognizes that organizations may have a variety of structures. However, CDC has determined that the applicant and/or recognized organization will be the entity that delivers the program. Thus, the language in the standards document now reads as follows: "The application should be submitted by the organizational entity that delivers the intervention."

- (C) Regarding the option for organizations to submit a different curriculum for use, more specific guidelines should be provided regarding what components are required to be submitted to the CDC. In addition, to maintain the standard nature of recognition program, how the CDC will assess the appropriateness of the curriculum in a standard fashion should be described.
  (R) Organizations that choose to apply for recognition status with CDC and choose to use a curriculum other than the National Diabetes Prevention Curriculum must ensure that the alternative curriculum is based directly on the DPP research trial lifestyle intervention curriculum and contains all of the required curriculum content as detailed in the DPRP Standards or the alternate curriculum will not be approved. The proposed curriculum will be reviewed by the DPRP Project Officer and, as appropriate, by other DPRP staff. Proposed alternative curricula will be assessed using a curriculum checklist consisting of criteria for content, duration, and intensity drawn directly from the DPRP Standards.

Detailed comments on "DPRP Application"

- (C) Provide a way for the respondent to specify if the application being submitted is an initial application or if it is for changes or renewals.
  (R) The text of the form has been revised to address this comment..

- (C) The terms "Recognition Number" and "Organization Code" are used interchangeably throughout all documents. Terminology should be consistent.
  (R) Text has been edited for clarity and consistency.

- (C) For organization's physical address, suggest "Address of Operations" as the label instead.
  (R) CDC prefers "physical address/mailing address".

- (C) For the organization's DPRP contact, suggest including contact address in case it is different from the organization address.
  (R) CDC believes that the physical address and mailing address are sufficient.

Detailed comments on "Participant Data, Process and Outcome Elements"

Page 1

Data elements

- **Participant Identifier**
  (C) Suggest requiring consistent format for participant identifier across all organizations in order to facilitate ease of CDC data collection and management. For example, the same number of digits, all numerical characters, etc.
  (R) A data dictionary for coding the data has been added and the instructions for the participant ID are as follows. The ID will "be assigned by the applicant organization" and "should not be based on social security number or other IIF"* and may be "up to 25 alphanumeric characters." CDC does not believe that additional instructions or parameters are needed. (*information in identifiable form)

- **Participant's Prediabetes Status**
  (C) Suggest changing this variable to "diabetes risk" since those who enter the program with only a positive screen on the risk factor test are not necessarily diagnosed with prediabetes. In addition, consider need to specify the type of blood test used for the individuals who enter with a blood-based test.
  (R) Changes to the text in this section and the addition of the data dictionary clarify the reporting of prediabetes status.

- **Participant's Race/Ethnicity**
  (C) This variable is inconsistent with the two variables listed in "How to apply for recognition", Section IV of the draft Standards and Operating Procedures (SOP). Suggest using two variables, 1) Participant Race and 2) Participant Ethnicity, as used in the SOP.
  (R) The evaluation data elements for race and ethnicity have been revised to meet the reporting requirements required by the Office of Management and Budget and are uniform throughout the documents. The evaluation data elements now read: "Participant's Ethnicity." Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one of the following: "Hispanic or Latino" or "Not Hispanic or Latino." "Participant's Race." Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one or more of the following: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Multiple responses are allowed. This element requires responses for five fields (refer to Table 2, the data dictionary)."

Page 2

- **Referral Source**
  (C) Suggest changing this from an open-ended question to a multiple-choice question with pre-defined categories (healthcare provider, self referral, community screen, etc.) and leaving options for

"other" with space to fill in, in order to ensure consistent data collection and facilitate evaluation of program marketing and recruitment. In addition, consider creation of two separate variables, 1) Referral Source, and 2) "How did you find out about the program?" in order to capture information about how people learned about the program as well as by whom they were referred.
(R) This evaluation data element has been deleted.

- **Organizational Code**
  (C) For organizations with multiple levels such as the YMCA which has national, regional, municipal and local branches, how will "organization" be defined? Should be clear on definition to ensure standard practice across all respondents. In addition, this variable is labeled "Recognition Number" in application instructions. Consistent labeling should be used across all documents in package.
  (R) Text has been revised for clarity and consistency. CDC has determined that the applicant and/or recognized organization will be the entity that delivers the program.

Page 3

- **Location Code**
  (C) Recommend providing guidelines on how to create location code so that format is standard. Consider including in those guidelines, some way of denoting the geographic location of where the program is actually being delivered (zip code or standard state abbreviation). This will be important for tracking purposes to enable CDC to summarize geographic distribution of the certified programs.
  (R) A data dictionary for coding the data has been added and the instructions for the location code are as follows. The code will "be assigned by the applicant organization to uniquely identify each venue or location used to conduct the applicant's lifestyle intervention program sessions. The location code will indicate the venue used for each session." The code may be "up to 25 alphanumeric characters." CDC does not believe that additional instructions or parameters are needed.

- **Core Group Code**
  (C) Replace the words "participating is" with the words "participating in."
  (R) The data dictionary has been revised.

- **Lifestyle Coach**
  (C) Should change "element number 2" to "element number 10."
  (R) The data dictionary has been revised.

- **Participant Weight**
  (C) Documentation of participant height should also be included in order to calculate BMI, to ensure organizations are meeting program requirements that all participants meet BMI requirements.
  (R) The data dictionary has been revised.

  (C) Should change "element number 2" to "element number 10".
  (R) The data dictionary has been revised.

Detailed comments on "Supporting Statement: Part A and B"

Page 4

- (C) Change "In 2003" to "In 2002" since DPP paper was published in 2002.
  (R) Text has been revised.

- (C) Change "do they follow a science-based curriculum" to "do not always follow a science-based curriculum."
  (R) Text has been revised.

- (C) Consider adding "Policy" as a fourth key objective of the Diabetes Prevention Recognition Program, since a recognition program would support the creation of a standard and reliable process to facilitate reimbursement by insurers and this is the only sustainable approach to this prevention effort.
  (R) CDC's role is to assure the fidelity and quality of the National Diabetes Prevention Program. Although reimbursement is an important policy issue, this is wholly the decision of third-party payers and not under the purview of the CDC.

Page 5

- (C) Change "A program with have" to "A program will have."
  (R) Text has been revised.

Page 6

- (C) Suggest adding language regarding the method by which confidentiality will be maintained in the transmission and storage of potentially re-identifiable data.
  (R) The supporting statement follows specific guidelines set forth by the Office of Management and Budget. Thus the sections of the document where privacy and confidentiality of the data are discussed are dictated by the Office of Management and Budget (OMB).

  Although the DPRP Application Form will include IIF (the name and contact information for the organization's contact person), the contact person will only provide information relating to his or her designated role in the organization. The contact person will not provide personal information to the CDC. The data submitted to the CDC for evaluation purposes will be identifiable by organization. The organization code will be assigned and maintained by the CDC. The participant-level evaluation data submitted to the CDC will not include participant names, but will include participant and lifestyle coach codes. The participant and lifestyle coach codes will be assigned and maintained by the applicant organization.

  Application form information will be submitted to CDC via an email generated by the online application form software. Evaluation data will be submitted to CDC as email attachments. These transmission methods were reviewed and recommended by CDC's Information Systems Security Officer. After they have been transmitted to CDC, all DPRP data will be maintained on password secured computers in secure CDC facilities and accessible only to DPRP staff for approved analyses. CDC will protect the data to the extent allowed by law. CDC will not release, publish or disclose IIF relating to individual program participants. CDC will only publish aggregated data. At the discretion of

the DPRP project officer or the division director, aggregated data may be shared with external partners for the purpose of preparing reports or manuscripts.

- (C) The terms "recognition number" and "organization code" are used interchangeably throughout all documents. Terminology should be consistent.
  (R) Text has been revised.

Page 7

- (C) Add "person's address" as an item of information to be collected for the organizations DPRP contact person in case the address is different.
  (R) CDC believes that the physical address and mailing address are sufficient.

- (C) Suggest requiring consistent format for participant identifier across all organizations in order to facilitate ease of CDC data collection and management. For example, the same number of digits, all numerical characters, etc.
  (R) A data dictionary for coding the data has been added and the instructions for the participant ID are as follows. The ID will "be assigned by the applicant organization" and "should not be based on social security number or other IIF"* and may be "up to 25 alphanumeric characters." CDC does not believe that additional instructions or parameters are needed. (*information in identifiable form)

- (C) The variable, "Participant's Race/Ethnicity" is inconsistent with the two variables listed in "How to apply for recognition," Section IV of the draft Standards and Operating Procedures (SOP). Suggest using two variables, Participant Race and Participant Ethnicity, as used in the SOP.
  (R) The evaluation data elements for race and ethnicity have been revised to meet the reporting requirements required by the Office of Management and Budget and are uniform throughout the documents. The evaluation data elements now read: "Participant's Ethnicity." Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one of the following: "Hispanic or Latino" or "Not Hispanic or Latino." "Participant's Race." Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one or more of the following: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Multiple responses are allowed. This element requires responses for five fields (refer to Table 2, the data dictionary)."

- (C) The terms "recognition number" and "organization code" are used interchangeably throughout all documents. Terminology should be consistent.
  (R) Text has been revised.

Page 8

- (C) The terms "recognition number" and "organization code" are used interchangeably throughout all documents. Terminology should be consistent.
  (R) Text has been revised.

Page 9

- (C) Write out "IIF" since not written out previously in this document.
  (R) Text has been revised.

Page 10

- (C) It is unclear what is meant by "While we do expect any small businesses to apply, it is a possibility.", and it appears to be an error.
  (R) Text has been revised.

Page 13

- (C) The text states "Although DDT will publish a list of recognized programs, DDT will not disseminate performance data as it relates to a specific site or organization". It is unclear whether an organization's recognition status, such as pending, probation, or full, will be publicized. Please clarify.
  (R) Recognition status (pending or full) will be included in the list of recognized programs.

- (C) The text states that "DDT will maintain all data on password-protected computers in secure facilities and will protect the data to the extent allowed by law." Suggest adding language such as "will implement appropriate operating procedures, consistent with organization standards in order to maintain security and confidentiality."
  (R) "To the extent allowed by law" is standard language used by CDC when discussing the privacy/confidentiality of data in our possession. CDC believes this language is sufficient, particularly since CDC will only be in receipt of data from which personal identifiers have been removed.

- (C) Suggest describing the "project officer" role in more detail. For example, is this person at the division level?
  (R) The project officer is similar to a project manager and will, among other things and along with other DPRP team members, oversee the DPRP program. The project officer will be a division staff member.

- (C) With regards to the statement that "other than submission of the application form, no additional consent or agreement to participate is required." However, in SOP, there is a "signed agreement" mentioned. Suggest including language regarding responsibility of each party around data handling both here and in the signed agreement.
  (R) Other than submission of the application form, no additional consent or agreement to participate is required. Any other text has been revised appropriately or removed.

Page 17

- (C) With regards to timelines for organizations to submit data to meet performance goals, it should be emphasized here that organizations will need to report data every six months since that is explained elsewhere but not here. Also, provide clarity on consequences of not reporting data every six months. Otherwise, there may be a lack of incentive to report data regularly, and organizations may not be aware that they are not meeting standards and may miss opportunities for needed technical assistance.

  (R) This information has been added to the appropriate sections of the supporting statements. It is also discussed in the standards document. The standards document will be available online after OMB approval is granted.