



OFFICE OF THE ACTUARY

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Subject: Certification of Medicare Diabetes Prevention Program

Certification

Section 1115A of the Social Security Act established the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS) to test innovative payment techniques and service delivery models. For successful models, the law states that “the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested...to the extent determined appropriate by the Secretary, if—

- (1) The Secretary determines that such expansion is expected to—
 - (A) reduce spending under the applicable title without reducing the quality of care; or
 - (B) improve the quality of patient care without increasing spending;
- (2) The Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending¹ under the applicable titles; and
- (3) The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.”

We were asked to consider an expansion of the YMCA of the USA Diabetes Prevention Program (Y-USA DPP) with some specification changes. The expansion would include a core curriculum consisting of 16 sessions delivered by lifestyle coaches approximately weekly followed by six sessions delivered approximately monthly that promote healthy lifestyle changes and weight loss. In addition, maintenance sessions would be offered after the first year of the program to aid participants in maintaining their healthy lifestyle and weight loss. Medicare beneficiaries would have to meet the following requirements to be eligible for the benefit:

- Body Mass Index (BMI) of 25 or greater.

¹ For this analysis, CMS has made the determination that “...costs associated with expected improvements in longevity are not appropriate for consideration in the evaluation of net program spending.” That determination can be found at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/DPP-Longevity-Memo.pdf>.

- A1C of 5.7 percent to 6.4 percent (39 to 46 mmol/mol), or Impaired Fasting Glucose: Fasting plasma glucose of 110-125 mg/dl (5.6 to 6.9 mmol/L), or Impaired Glucose Tolerance: 2-hour plasma glucose after the 75 gram Oral Glucose Tolerance Test of 140 mg/dl-199 mg/dl (7.8 to 11.0 mmol/L).
- No previous diagnosis of diabetes.
- No life-threatening conditions, mobility issues, etc. that would prohibit them from participating in the program.

For this considered DPP expansion, the proposed payments made for each participant in the program are shown in the table below (note that the 5 percent weight loss target is the minimum specified in the national standards contained in the National Diabetes Prevention Recognition Program; future evidence may possibly alter this minimum target depending on scientific evidence).

Summary of the payments made on behalf of participants in the considered DPP expansion

Service Provided	Payment
Core Sessions	
1 session attended	\$25
4 sessions attended	+ \$50
9 sessions attended	+ \$100
5 percent weight loss from baseline	+ \$160
9 percent weight loss from baseline	+ \$25
Maximum Total for Core sessions in Year 1	<u>\$360</u>
Maintenance Sessions (Maximum of 6 monthly sessions over 6 months in Year 1)	
3 Maintenance sessions attended with maintenance of 5 percent weight loss	\$45
6 Maintenance sessions attended with maintenance of 5 percent weight loss	+ \$45
Maximum Total for Maintenance sessions in Year 1	<u>\$90</u>
Maximum Total for Year 1	<u>\$450</u>
Maintenance Sessions After Year 1 (minimum of 3 sessions attended per quarter with no maximum)	
3 Maintenance sessions plus maintenance of 5 percent weight loss	\$45
6 Maintenance sessions attended plus maintenance of 5 percent weight loss	+ \$45
9 Maintenance sessions plus maintenance of 5 percent weight loss	+ \$45
12 Maintenance sessions attended plus maintenance of 5 percent weight loss	+ \$45
Maximum Annual Total After Year 1	<u>\$180</u>

Based on historical evidence from evaluations of the Y-USA DPP, other DPPs, and independent modeling of savings projections, I certify that an expansion of this considered DPP would not result in an increase in spending. If the actual parameters of the DPP expansion differ from those specified above, or if there is additional evidence available that would cause us to update our methods or assumptions, this certification would not apply and the program would need to be re-evaluated. The remainder of this memorandum summarizes the analysis supporting this certification.

Office of the Actuary Analysis

For our analysis, we reviewed the evaluation results available from the first 2 years of the Y-USA DPP. To supplement this information, we also considered a DPP clinical trial conducted by the Center for Disease Control and Prevention (CDC). In addition, we reviewed programs recognized by CDC's Diabetes Prevention Recognition Program (DPRP), including a CDC-recognized DPP from a large national carrier. Finally, we developed a model to project savings for a DPP, with assumptions based on evaluation information from other DPPs and studies related to diabetes and/or pre-diabetes.

Health Care Innovation Award: Y-USA DPP

The Y-USA was the recipient of a CMS Health Care Innovation Award to test its DPP. Participants began enrolling on February 15, 2013. The benefit is based on the DPP clinical trial in which lifestyle coaches provide a core curriculum consisting of 16 sessions delivered approximately weekly followed by six sessions delivered approximately monthly that promote healthy lifestyle changes and weight loss. The main goal of the program was to improve participants' health through improved nutrition and physical activity, resulting in at least a 5-percent weight loss for each individual. This outcome was expected to lead to a reduction in the incidence of diabetes and total health care expenditures.

The Y-USA received \$11,885,134 from the CMS Health Care Innovation Awards program to fund its DPP. The program has met the standards set forth by the CDC Diabetes Prevention Recognition Program Standards and Operating Procedures and earned recognition. The Y-USA DPP includes two components: (i) hiring and training lifestyle coaches to deliver the program's curricula, and (ii) implementing the DPP among eligible participants. Lifestyle coaches receive about 30 hours of training; however, aside from this instruction, a high school diploma is the only requirement for employment. The DPP curriculum is delivered over 10 to 12 months to groups of 8 to 15 participants. Weekly core sessions are completed over 20 weeks and are followed by 8 monthly maintenance sessions. The program's core curriculum includes 16 sessions that cover topics related to diet, exercise, and healthy lifestyle changes. The core curriculum is expected to lead to weight loss of at least 5 percent, and maintenance sessions help participants maintain their weight loss.

All participants are Medicare beneficiaries. The eligibility requirements are the same as under the considered DPP expansion discussed throughout this document, except that the range of eligible Impaired Fasting Glucose is 100 to 125 mg/dl (as opposed to 110 to 125 mg/dl for the considered expansion).

RTI International evaluated the results of the Y-USA DPP over the first eight quarters of the program and prepared follow-up reports. Some of the key findings in these reports are as follows:

- YMCA began enrolling participants on February 15, 2013. As of March 2015, 6,874 beneficiaries have been recruited (that is, have attended at least one session), and, of those recruited, 5,696 have been enrolled (that is, have attended at least four sessions).
- Over 60 percent of the participants are between the ages of 65 and 75.

- Average weight loss shown in the 12th quarterly report was 4.73 percent for participants attending at least four core sessions and 5.17 percent for participants attending at least nine sessions.
- Of participants attending at least four core sessions, 44 percent reached the 5-percent weight-loss target.
- Over 80 percent of participants who have been recruited attended at least four core sessions, and significant weight loss has been achieved by these participants. Participants attending nine sessions have achieved even more weight loss.

For the impact on total cost of care, RTI used a difference-in-difference regression analysis, which showed statistically significant gross savings in each of the first five quarters of the program, totaling \$2,650. The analysis also showed aggregate savings for quarters six through eight combined, but this amount was not statistically significant. Since the participants entered the program over time, very few were included for all 8 quarters. The lack of statistically significant results could be due to the small sample size in these quarters. The report also showed significant reductions in inpatient hospital admissions.

Although the savings estimates in early quarters look promising, there are limitations to these evaluation results. First, the results are very preliminary, and additional years would greatly reduce their uncertainty. Second, since the model was not conducted as a randomized control trial, RTI used propensity score matching to determine a comparison group. To identify pre-diabetic patients, the carrier used ICD-9 codes related to abnormal glucose levels. This method does not match the criteria for inclusion in the demonstration and could create biased results. In particular, 38 percent of the participants in the treatment group were diagnosed with diabetes at some point, a factor that would have made them ineligible for the intervention. RTI recalculated their results after removing the diabetic participants, and the savings figures were approximately halved, but still statistically significant. Data for cost savings in later program years would provide stronger support for savings achievable by an expansion.

DPP Clinical Trial

The DPP was a randomized clinical trial lasting from 1996 to 2001. The goal was to determine whether lifestyle intervention or drug therapy (metformin) would prevent or delay the onset of type 2 diabetes for participants meeting the definition of pre-diabetes. The lifestyle intervention focused on providing education regarding healthy lifestyle choices and participant weight loss. Participants who received the lifestyle intervention were assigned lifestyle coaches, the majority of whom were registered dietitians. In the first 24 weeks of treatment, a lifestyle coach provided 16 private sessions, which made up the core curriculum. After completion of the core curriculum, lifestyle coaches were required to meet with participants face-to-face once every 2 months, in either a group or an individual setting. The lifestyle intervention also required that each clinical center offer supervised physical activity at least twice per week throughout the treatment, though participants were not required to take part in these activities. To mitigate adherence issues, the program budget allowed individualized strategies to be implemented. For example, a participant might be given portion-controlled foods to help achieve his or her weight-loss goal. Participants were expected to achieve a 7-percent weight loss upon completion of the core curriculum and to maintain that weight loss for the remainder of the 3-year study.

Participants in the DPP clinical trial were aged 25 and above. The eligibility requirements for participation in the program differed slightly from the considered DPP expansion requirements. In particular, to participate in the DPP clinical trial, an individual had to have a BMI of at least 24 (instead of 25), and the range of eligible Impaired Fasting Glucose was 95 to 125 mg/dl (instead of 110 to 125 mg/dl for the considered expansion).

We reviewed literature regarding the DPP clinical trial and follow-up studies performed after its conclusion. Based on this literature, we note the following:

- Of the 1,079 participants in the lifestyle intervention, the starting average age was 50.6 with a standard deviation of 11.3.²
- The direct medical cost per participant of the lifestyle intervention was \$2,780.³
- After the end-of-study follow-up (which was on average 2.8 years after the start of treatment), diabetes incidence was reduced by 58 percent in the lifestyle group when compared to the placebo group.⁴
- After an average 15-year follow-up, diabetes incidence was reduced by 27 percent in the lifestyle intervention group when compared to the placebo group.⁵
- When the DPP ended in 2001, all participants were offered lifestyle training.

Based on CDC's evaluation results, the lifestyle intervention under the DPP significantly reduced the incidence rate of diabetes for pre-diabetics in the short term. The lifestyle intervention seemed to have a long-term effect on diabetes incidence as well—and probably a larger effect than the 27-percent reduction shown above—as the lifestyle training was offered to all of the placebo group after the DPP clinical trial ended.

While the results regarding the health improvement of the participants are overwhelmingly positive, there are a few limitations in using this evidence to assess the impact of the expansion. First, the clinical trial was open to all ages, and the amount of data from the participants over age 65 is limited. In addition, because the DPP clinical trial focused on diabetes prevention and not on reducing the total cost of care for diabetics, actual program savings amounts are unavailable. Finally, the lifestyle intervention under the DPP clinical trial was more costly and provided a seemingly stronger benefit than the benefit included in the considered DPP expansion. As a result, the effectiveness of the considered DPP expansion might not be as strong.

CDC DPRP

The CDC DPRP recognizes DPPs nationwide that effectively deliver lifestyle-change programs that prevent the onset of type 2 diabetes. As of September 2015, there were 696 recognized DPP providers under the DPRP. These programs are offered to pre-diabetics aged 18 and older, and they have the same eligibility requirements as the considered DPP expansion except that the

² N Engl J Med. 2002 February 7; 346(6): 393–403.

³ Diabetes Care 26:36–47, 2003.

⁴ Diabetes Care 25:2165–2171, 2002.

⁵ See [http://dx.doi.org/10.1016/S2213-8587\(15\)00291-0](http://dx.doi.org/10.1016/S2213-8587(15)00291-0).

eligible Impaired Fasting Glucose range is 100 to 125 mg/dl (compared to 110 to 125 mg/dl for the considered expansion). Lifestyle-change programs are 1 year in length and provide a minimum of 16 classes during the first 6 months and 6 follow-up classes during the last 6 months. Classes are led by a trained lifestyle coach and are offered in individual, group, and online settings. Along with promoting healthy lifestyle changes, programs target a 5-percent weight loss from each participant.

Recognized programs deliver participant progress data to CDC every 12 months, and CDC was able to provide us with participant data for 69 of the programs. The following is a sampling of this information:

- Of enrolled participants, 31 percent are aged 65 or older.
- Of the participants aged 65 or older, more than 80 percent are between the ages of 65 and 75.
- For participants aged 65 or older that attended at least four sessions, average weight loss was 5.2 percent, which was greater than the average weight loss percentages for younger age groups.
- Participants aged 65 or older had a higher adherence rate than younger groups (that is, older participants attended more classes on average).

The data from CDC are encouraging in that they show that the older population has a higher adherence rate and a higher weight-loss average than do younger age groups. Thus, a Medicare expansion of these programs would seem to increase the number of participants who would achieve a higher rate of success. However, CDC was unable to provide any data for these participants regarding changes in total cost of care or reductions in type 2 diabetes progression rates.

A large national carrier with a recognized DPP provided us with evaluation results from their program. The following are key points from our review of the data:

- Less than 10 percent of participants are aged 65 or older.
- On average, participants of all ages experienced higher weight loss when they attended more sessions:
 - 1-3 sessions attended = weight loss of 0.2 percent.
 - 4-8 sessions attended = weight loss of 1.4 percent.
 - 9-15 sessions attended = weight loss of 3.8 percent.
 - 16+ sessions attended = weight loss of 6.2 percent.

The evaluation of their program included results from the first 3 years of the intervention. The carrier spent nearly \$200 per person, and the medical spending reductions were nearly that amount over the 3 years evaluated. Therefore, the DPP is expected to break even in program year 4. The spending reductions achieved for the participants aged 55 or older were slightly higher than the average for the entire group. In addition, the carrier noted that the savings were significantly higher for the participants who achieved the 5-percent weight-loss goal.

The data provided by this insurer support positive program savings in early years and larger savings from the older participants. However, data were extremely limited for participants aged 65 and older, and cost data were available for only the 3 program years.

OACT Modeling

Since the spending results from the evaluations outlined above were only for the first 2 – 3 years of the programs, we developed a model that projects lifetime per participant savings of a Medicare beneficiary participating in the considered DPP expansion discussed throughout this document. The savings were reduced by the costs of administering the program to determine the net financial impact. This model was constructed to analyze a range of potential outcomes resulting from the expansion of the DPP and also allows us to conduct a sensitivity test on each of the assumptions.

The program cost assumptions were based on the incentive payments described earlier. On average, we assumed that CMS would make per participating beneficiary payments of \$300 in year 1, \$150 in years 2 and 3, and \$100 in years 4 and after. Continued participation in a DPP after year 3 has been generally untested, so questions remain regarding how long participants would continue to attend maintenance sections.

To estimate the savings from the intervention, the model first calculates the probabilities of progressing from pre-diabetes to diabetes by gender for each year until age 85 for beneficiaries aged 65 to 75 at the time of the intervention. An estimated program effectiveness is applied to these probabilities to determine the progression rate with the intervention. Probabilities of becoming diabetic are multiplied by corresponding estimated lifetime marginal costs, and these amounts are summed to get an expected marginal cost for each starting age from 65 to 75. For each starting age, the estimated program cost is subtracted from the difference in the expected lifetime marginal costs with and without intervention to estimate program net cost/savings. An age/gender distribution is applied to the estimated program net cost/savings for each starting age to estimate the average program net cost/savings per participant life.

The distribution of starting ages was based on participation data from Y-USA and the CDC DPRP for participants aged 65 and older. Including starting ages 65 to 75 in the model seemed reasonable since over 80 percent of the DPRP participants who were ages 65 or older, and over 60 percent of the Y-USA participants, fell in this range. The base assumption for the gender distribution was 60 percent female, also using the participation data from CDC DPRP and Y-USA.

A meta-study including 16 studies supported a range of progression rates from pre-diabetes to diabetes with an average of roughly 5 percent.⁶ The assumptions for program effectiveness, defined as the reduction in diabetes progression, were based on the results of the CDC trial. Since that trial included greater funding, we assumed an effectiveness that was somewhat less than it had achieved. Specifically, we included a base assumption of an effectiveness of

⁶ Zhang *et al.* *Diabetes Care* 33: 1665-1673, 2010

50 percent in year 1, with a 5-percent reduction in effectiveness each year until year 7. We assumed a constant 20-percent effectiveness thereafter.

Expected lifetime marginal costs of diabetes were difficult to determine. Based on a study using linked data from the 2005-2008 National Health Interview Survey and the 2006-2009 Medical Expenditure Panel Survey, additional lifetime medical spending attributed to diabetes at age 65 is \$43,900, which includes the difference in mortality between diabetics and non-diabetics.⁷ CDC attempted to calculate lifetime marginal costs of people with diabetes compared to people without diabetes for ages 70 and 75 using the same methodology from the study; the resulting marginal cost estimates were \$17,960 and \$5,100, respectively.

These marginal cost assumptions included all health care spending for 2012. As a result, we adjusted these estimates for the portion that would be covered by the Medicare program and trended the data forward to 2017. Taking all of these assumptions together, the model estimated a small program cost.

There were a few caveats to note with these estimates. First, the estimates compared the costs for diabetics to non-diabetics, and the appropriate comparison is diabetics versus pre-diabetics. In addition, the sample sizes used to calculate the estimated costs for ages 70 and 75 were much smaller than the age 65 cohort, which leads us to question the creditability of the costs. Further, it appeared that baseline non-diabetic costs were held constant for all ages. Finally, the estimate only considers the impact for individuals in which the onset of diabetes is prevented or slowed. It is possible that this lifestyle intervention could have an impact on the health care costs of participants who would never transition to diabetes, or on the costs for participants who transition to diabetes but are healthier as a result of the program.

We observed that the main driver of the projected program cost was the possibility of mortality improvement associated with the delay or prevention of diabetes, which would result in longer Medicare coverage. Since mortality effects are to be excluded from consideration for the purpose of certification, we did some additional analysis.

Another way to consider the impact would be to examine the annual cost differences. CDC determined that the marginal cost difference for the first year of diabetes was about \$3,000 and assumed that this difference would increase over time. We performed independent data analysis tracking diabetes ICD 9 claim codes in the CMS Integrated Data Repository and determined that \$3,000 was a reasonable first-year cost, but we could not confirm if annualized marginal costs increased over time. We developed lifetime marginal cost estimates by age and gender, using diabetic and pre-diabetic mortality assumptions with a constant diabetes marginal cost per year. These projections were sensitive to assumptions for the mortality rates of pre-diabetics who eventually transition to becoming diabetic, leading to a wide projected range of lifetime marginal costs.

If the assumed mortality rates for pre-diabetics and diabetics had been the same and a marginal diabetes cost of \$3,000 per year had been used along with the other base assumptions, the model would have projected significant program savings. Using our model, a break-even analysis

⁷ Zhuo *et al.* "The Lifetime Cost of Diabetes and Its Implications for Diabetes Prevention," *Diabetes Care* 2014; 37: 2557-2564

showed that assuming the same mortality between diabetics and pre-diabetics provided a significant buffer that allowed other assumptions to change while still achieving a result of budget neutrality. Assuming that all other assumptions were kept constant, the following individual inputs in the model would still project budget neutrality:

- Diabetes progression = 2 percent.
- Program effectiveness in all years = 14 percent.
- Marginal cost of diabetes per year = \$1,321.

Overall, the model estimated a small cost over the lifetime of the participants. However, when the mortality of diabetics was assumed to be the same as for non-diabetics, the model estimated significant program savings. In addition, for each of the three main assumptions, the model's estimated break-even rates are far lower than the best estimate and are therefore likely achievable.

Conclusion

The evaluation results from Y-USA, CDC, and a large national provider DPP indicate that beneficiaries participating in diabetes prevention programs have achieved success with losing weight and reducing the incidence of diabetes. While each of the programs we evaluated has some limitations, we believe that the results indicate that the intervention has resulted in reductions in medical spending in the near term.

The considered DPP expansion discussed throughout this document is somewhat different from these models. The considered expansion program includes only beneficiaries with an Impaired Fasting Glucose of 110 to 125 mg/dl and provides maintenance sessions from the lifestyle coaches indefinitely. Both of these changes could improve the savings achieved by the program. In particular, since the progression rate to diabetes for individuals with an Impaired Fasting Glucose of 100 to 109 mg/dl is very low based on empirical studies, excluding this group would place a greater focus on those who are far more likely to become diabetic.

The longer-term impacts are less clear. Many of the DPPs have not existed long enough to determine the impact beyond the first few years. Based on modeling of the long-term financial results using evidence from the demonstrations coupled with the longer-term qualitative results from CDC's clinical trial, it is unclear whether the program would break even over the participants' lifetimes. These results appear to stem from improvements in mortality experienced by the participants. Mortality improvement would result in additional years of coverage under the Medicare program, which would offset a portion of the near-term savings. Since the cost effects of the potential mortality improvement shall not be considered for the purposes of certification, the modeling supports this certification that the considered DPP expansion is expected to reduce Medicare expenditures.