



EMBARGOED UNTIL: February 24, 2014

Estimated Federal Impact of H.R. 962/ S. 452 “The Medicare Diabetes Prevention Act”

Summary

The American Diabetes Association and the National Council of Young Men’s Christian Association (YMCA of the USA) asked Avalere Health to estimate the cost or savings on the Federal budget of H.R. 962 / S. 452, titled “The Medicare Diabetes Prevention Act”. This legislative proposal would create a new Medicare benefit covering eligible diabetes prevention programs for Medicare beneficiaries diagnosed with prediabetes. These diabetes prevention programs would meet the standards under the National Diabetes Prevention Program established by the Centers for Disease Control and Prevention (CDC), and would offer group-based lifestyle intervention sessions for eligible Medicare beneficiaries.

We estimate this proposal would reduce federal spending by \$1.3 billion over the 2015-2024 federal budget window. This amount reflects a combination of an estimated \$7.7 billion in new spending on the diabetes prevention program offset by an estimated \$9.1 billion in savings from fewer Medicare beneficiaries diagnosed with diabetes over the next 10 years. In addition, the savings from preventing diabetes would likely continue to increase in years beyond 2024, suggesting even greater impact on longer-term federal spending.

Estimated Change in Federal Spending due to the Medicare Diabetes Prevention Act

	<i>\$ in billions, by fiscal year</i>										
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2015-2024
Total change in Federal spending											
Costs due to prevention program	0.2	0.3	0.4	0.5	0.7	0.9	1.0	1.1	1.3	1.4	7.7
Savings due to fewer Medicare beneficiaries with diabetes	0.0	-0.1	-0.2	-0.4	-0.6	-0.8	-1.1	-1.5	-1.9	-2.4	-9.1
<i>Net change due to proposed legislation</i>	0.2	0.2	0.2	0.2	0.1	*	-0.2	-0.4	-0.7	-1.0	-1.3

* represents less than \$50 million

Background

The Centers for Disease Control and Prevention (CDC) estimates nearly 11 million, or 27 percent, of Americans age 65 or older have diabetes, and an additional 400,000 individuals in this age group are diagnosed with diabetes each year.¹ A recent study published by the American Diabetes Association estimated the per person healthcare costs of individuals age 65 and above with diabetes were \$11,825 in 2012, with much of this cost paid by the Medicare program.²

The CDC also estimates that 50 percent of individuals age 65 or older have prediabetes, which is defined as a person with blood glucose or A1c levels that are higher than normal but not high enough to be classified as diabetes.³ The incidence rate of diabetes for individuals in this age category is high, with an estimated 30 percent transitioning to diabetes within four years.⁴ Studies have demonstrated that intervention programs for this population can reduce the incidence of diabetes by nearly 60 percent over 10 years.⁵

Between 1996 and 1999, the Diabetes Prevention Program Research Group conducted a clinical trial to test the effectiveness of lifestyle intervention or treatment with metformin at reducing the risk of type 2 diabetes. The results of this trial demonstrated that an intensive lifestyle intervention reduced the incidence by 58 percent over an average of three years.⁶ A follow-up study of the same participants over 10 years demonstrated ongoing lower incidence of diabetes for individuals who received lifestyle intervention therapy.⁷

To address the potential for reducing the incidence of diabetes, the CDC created the National Diabetes Prevention Program (National DPP). The National DPP uses the Diabetes Prevention Recognition Program Standards and Operating Procedures to set the requirements for a lifestyle program to prevent type 2 diabetes. These standards include participant eligibility, location and staffing requirements, curriculum content and topics, and other requirements for full recognition. Of particular note, any sanctioned program should contain 16 core sessions provided to eligible individuals with prediabetes, as well as eight follow-up sessions to address ongoing maintenance.⁸

Currently, six groups have received grants from the CDC to operate qualified diabetes prevention programs. These grantees include: the American Association for Diabetes Educators; the America's Health Insurance Plans (working with member companies Aetna, EmblemHealth, Florida Blue, and Molina Healthcare); Black Women's Health Imperative; the National Association of Chronic Disease Directors; OptumHealth Care Solutions; and the YMCA

¹ Centers for Disease Control and Prevention. "National Diabetes Fact Sheet, 2011" Available at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf.

² American Diabetes Association. "Economic Costs of Diabetes in U.S. in 2012." *Diabetes Care*, March 6, 2013. Available at <http://care.diabetesjournals.org/content/early/2013/03/05/dc12-2625.full.pdf+html>.

³ Centers for Disease Control and Prevention. "National Diabetes Fact Sheet, 2011"

⁴ Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin." *New England Journal of Medicine*. February 7, 2002.

⁵ Diabetes Prevention Program Research Group. "10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study." *Lancet*. October 29, 2009.

⁶ Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin." *New England Journal of Medicine*. February 7, 2002.

⁷ Diabetes Prevention Program Research Group. "10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study." *Lancet*. October 29, 2009.

⁸ Centers for Disease Control and Prevention. "Diabetes Prevention Recognition Program: Standards and Operating Procedures". September 2, 2011. Available at http://www.cdc.gov/diabetes/prevention/pdf/dppr_standards_09-02-2011.pdf.

of the USA. The most established of these grantee programs is run by the YMCA, which over the last two years has offered a certified diabetes prevention program to over 6,000 participants in 30 states.⁹ The YMCA is currently conducting a pilot initiative on Medicare beneficiaries with support from an Innovation Challenge award from the Center for Medicare and Medicaid Innovation (CMMI).

The Medicare Diabetes Prevention Act, as currently proposed, would create a new benefit for Medicare beneficiaries with prediabetes. The proposal would require the Secretary of Health and Human Services (HHS) to develop criteria for a diabetes prevention program that are in accordance with the standards already developed by the National DPP. Payment for the sessions offered by certified diabetes prevention programs would be made from the Supplemental Medical Trust Fund (i.e., Part B), and the rate would equal to the lesser of the actual charge for items and services provided or the amount determined under the fee schedule that applies to such items. Beneficiaries would not be required to pay a copay for the sessions, and the spending would not be subject to the annual Part B deductible. The program provider would be required to furnish the necessary items and services in a community setting, and would be allowed to use a delivery partner.

Data Sources

We used the following data sources to develop our estimate:

- Centers for Disease Control 2011 National Diabetes Fact Sheet.
- Busetto, L, et. al. "Predictors of drop-out in overweight and obese outpatients". *International Journal of Obesity*. 2005; (29.1): 122-128.
- Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin". *New England Journal of Medicine*. 2002; 346(6): 393-403.
- Diabetes Prevention Program Research Group "10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study". *The Lancet*. 2009; 374: 1677-1686.
- Ash, S. et. al. "A randomised control trial comparing lifestyle groups, individual counseling and written information in the management of weight and health outcomes over 12 months". *International Journal of Obesity*. 2006; 30: 1557-1564.
- Albright, Ann. "Rolling Out the National Diabetes Prevention Program". Centers for Disease Control and Prevention. Presentation available online at <http://www.businessgrouphealth.org/pub/f312a61d-2354-d714-516a-82962901a993>.
- Centers for Medicare & Medicaid Services. "Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter". April 1, 2013. Available at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf>.
- Nelson, L. "Lessons from Medicare's Demonstration Projects on Disease Management and Care Coordination". Working Paper 2012-01, Congressional Budget Office. Available at <http://www.cbo.gov/publication/42924>.

⁹ Based on information from the Centers for Disease Control and Prevention National Diabetes Prevention Program website, accessed February 2, 2014. Available at <http://www.cdc.gov/diabetes/prevention/about.htm#Funded>.

- Congressional Budget Office. "May 2013 Medicare Baseline". Available at <http://www.cbo.gov/publication/44205>.
- Vojta, D. et. al. "Effective Interventions For Stemming The Growing Crisis Of Diabetes And Prediabetes: A National Payer's Perspective." *Health Affairs*. 2012; 31(1): 20-26.
- Perreault, L. et. al. "Regression from Pre-diabetes to Normal Glucose Regulation is Associated with Long-term Reduction in Diabetes Risk: Results from the Diabetes Prevention Program Outcomes Study". *The Lancet*. 2012; 379(9833): 2243-2251.

Assumptions and Methodology

Enrollment and Participation in Diabetes Prevention Programs

We first estimated that approximately 20 million Medicare beneficiaries in the fee-for-service (FFS) program would be potentially eligible for a diabetes prevention program, based on the CDC's estimate that 50 percent of individuals over the age of 65 have prediabetes. However, two factors will significantly reduce the number of Medicare beneficiaries who actually enroll in a program. One, the rate of undiagnosed prediabetes is estimated to be as high as 90 percent, although appears to have declined in recent years¹⁰. This suggests that many Medicare enrollees will be unaware that they are eligible to enroll in a diabetes prevention program. The second limiting factor will be the availability of a certified diabetes prevention program, due to the likely requirements for program approval. Based on these two factors, we estimate that three percent of the eligible Medicare population with prediabetes will enroll in a diabetes prevention program in 2015, increasing to five percent by 2017 as more programs become available and awareness of the benefits of the program grows. However, we do not believe more than five percent of the Medicare population with prediabetes will enroll in future years due to the low diagnosis rate of prediabetes and general willingness of Medicare beneficiaries to participate in lifestyle intervention programs.

In addition, we estimate that 25 percent of the enrollment group in each year will drop out before completing the program. We based this rate on information provided to Avalere from the YMCA regarding its experience with both its overall diabetes prevention programs, which has seen an approximate 30 percent dropout rate, and its CMMI demonstration, which has seen an approximate 10 percent dropout rate. We believe the total Medicare experience will be closer to the overall program rates, which are also roughly in-line with dropout rates seen in other obesity-focused lifestyle intervention programs. We estimate that individuals who drop out of the program will receive an average of 6 sessions, or slightly less than half of the full core sessions offered by a certified diabetes prevention program.

Of the group that does not dropout of the program, we estimate that the average enrollee will receive 16 sessions during the year out of the 24 maximum sessions (16 core, 8 maintenance). Again, this is roughly in-line with the results witnessed by the YMCA in its overall diabetes prevention program.

Finally, we estimate that approximately one-third of the participants in each year will return for additional sessions in subsequent years. While the National DPP is designed as a single year program, the proposed legislation does not restrict participation by Medicare beneficiaries in multiple years, if the individual continues to meet the definition of prediabetes. Therefore, we

¹⁰ Centers for Disease Control and Prevention. "Awareness of Prediabetes – United States, 2005-2010". *Morbidity and Mortality Weekly Report*. March 22, 2013; 62(11); 209-212.

estimate a portion of the enrollees will continue to participate in the program due to the perceived value they are receiving from the sessions.

We adjust our ongoing enrollment estimates by two factors: mortality and incidence of diabetes. The mortality rates are based on the estimated survival curve for individuals between the age of 65 and 80, while the incidence rates are based on the modeling assumptions described in the next section.

Table 1: Estimated Enrollment in New Diabetes Prevention Programs

in thousands

Enrollment Group	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
First-time program enrollees	585	800	820	1,050	1,075	1,125	1,150	1,175	1,200	1,224
First-year drop-outs (average 5 sessions)	155	211	217	277	284	297	304	310	317	323
First-year completers (average 16 sessions)	430	589	603	773	791	828	846	865	883	901
Subsequent year participants (average 16 sessions)	0	131	303	471	685	895	1,110	1,322	1,532	1,740

Medicare Reimbursement for Diabetes Prevention Program Sessions

The proposed legislation requires Medicare to reimburse for the cost of a session. Studies suggest the total cost of a certified 16-session diabetes prevention program ranges from \$275 to \$550 depending on a variety of factors. Specific to the programs run by the YMCA, many insurers currently use a pay-for-performance model. Reimbursement therefore varies based on results, but on average insurers are paying a per-person per-year cost of approximately \$440.¹¹

We estimate that Medicare will reimburse providers for a single diabetes prevention program session at a rate comparable to the amount paid for similar intervention programs such as self-care management training or kidney disease education. In particular, Medicare currently pays approximately \$25 for group kidney disease education. We have assumed Medicare will pay the same \$25 per person in a group-based diabetes prevention program, and will only pay for the actual number of sessions that an individual attends. Based on the participation assumptions described above, this would result in an average payment of \$400 in 2015 for a participant who does not drop out of the program versus \$125 for a person who does drop out.

We also assume that the reimbursement for diabetes prevention program sessions will be based on the Medicare physician fee schedule, and therefore subject to annual updates based on the Sustainable Growth Rate (SGR). Current estimates of the SGR call for a reduction in the Medicare payment rate in mid-2014, followed by increases in the range of 1-2.5 percent over the next 10 years. Of note, should Congress pass a permanent modification to the SGR that provides annual updates below 1-2.5 percent, the cost of diabetes prevention program sessions would be lower than our current estimates.

¹¹ Based on email correspondence with officials at the YMCA.

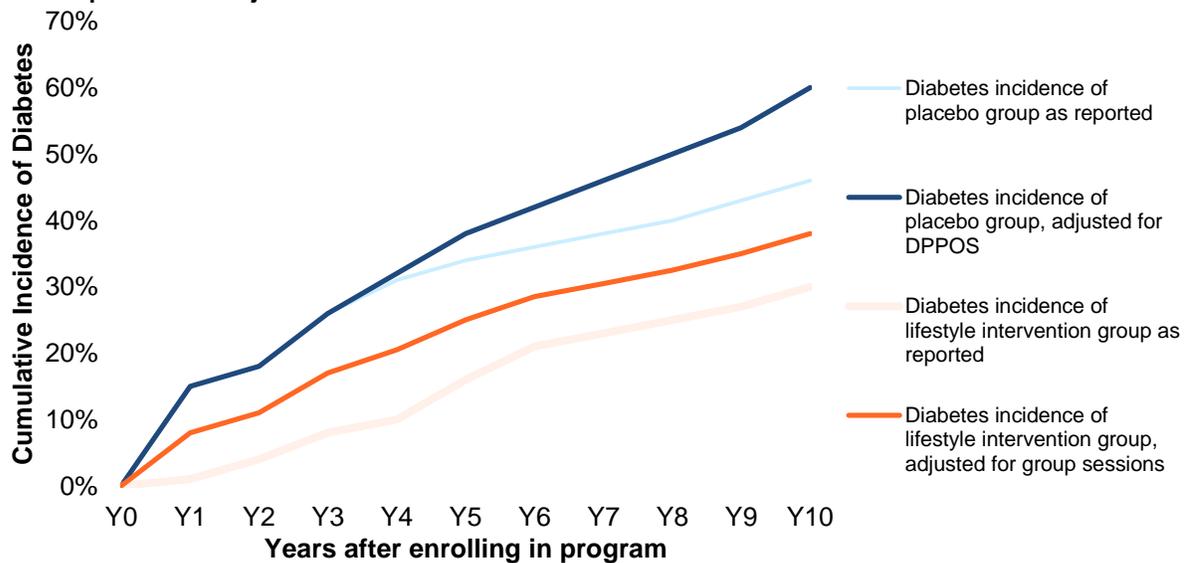
Effect of Diabetes Prevention Program on Diabetes Incidence

To determine the effect of the new diabetes prevention programs on diabetes incidence in the Medicare population, we first started with the evidence from the Diabetes Prevention Program Outcomes Study (DPPOS). This study showed a cumulative reduction of nearly 60 percent for individuals over the age of 60. However, due to the design of the DPPOS, we needed to make two modifications to the reported incidence rates.

- **Control group adjustment:** Under the DPPOS, individuals who were enrolled in the placebo arm of the study received lifestyle interventions starting in year three. This intervention was necessary due to the original study design, but likely had the effect of reducing the incidence of diabetes relative to an entirely unmanaged population of people with prediabetes. Therefore, we increased the reported incidence and prevalence for the placebo group to reflect the expected rate of diabetes among the eligible population absent participation in a new diabetes prevention program.
- **Intervention group adjustment:** The lifestyle intervention offered in the original DPPOS was an intensive one-on-one session with significant amounts of follow-up advice. However, the intervention in the proposed legislation would be a group session. Since the intervention will likely not be as intensive, and since study participants often demonstrate a higher level of involvement than in 'real-world' programs, we assumed the effect of the diabetes prevention programs launched due to the proposed legislation would only be 50 percent as effective as the results from the DPPOS.

After these two adjustments, we estimate the proposed legislation will reduce the cumulative incidence rate of diabetes by 37 percent over 10 years.

Figure 1: Reported and Adjusted Cumulative Incidence of Diabetes



Source: DPPOS and Avalere estimates

Table 2: Estimated Incidence of Diabetes With and Without New Diabetes Prevention Programs

in thousands; reflects estimated incidence of individuals who are expected to enroll in program

2015 2016 2017 2018 2019 2020 2021 2022 2023 2024

Incidence of diabetes without program	0	63	161	296	488	716	981	1,273	1,592	1,933
Incidence of diabetes with program	0	34	93	180	302	449	626	819	1,028	1,251
Change in incidence due to program participation	0	-30	-68	-116	-186	-266	-354	-453	-564	-682

Medicare Savings from Reduced Incidence of Diabetes and Prediabetes

To estimate the marginal cost of diabetes on the Medicare program, we relied on the risk scores developed as part of the payment mechanism for Medicare Advantage plans. Specifically, we used the 2014 rate for diabetes without complications and the rate for diabetes with complications that the Centers for Medicare & Medicaid Services (CMS) calculated using the Hierarchical Conditions Category (HCC) model. The HCC model risk scores reflect the estimated Medicare spending associated with a specific condition.

Of the enrollees who would have developed diabetes without the intervention of the diabetes prevention program, we assumed 90 percent would have developed diabetes without complications, while only 10 percent would have developed diabetes with complications. This mix of diabetes without complications is slightly higher than the overall Medicare population mix, as we estimate that individuals who choose to participate in a new diabetes prevention program will be more engaged in their own health, which suggests that they would have been more focused on controlling the effects of diabetes once diagnosed.

We applied the relevant risk scores to the estimated per-person Medicare spending from the most recent Congressional Budget Office (CBO) baseline to determine the amount per person that the program will save due to avoided incidence of diabetes. Since the HCC score reflects the estimated marginal cost of a specific condition, we assumed that the 2015 per-person Medicare A&B cost of diabetes without complications will be \$1,285, while the per-person Medicare A&B cost of diabetes with complications will be \$4,008. Meanwhile, the average 2015 Part D cost for diabetes without complications will be \$495, while the average Part D cost for diabetes with complications will be \$742. We adjusted the Part D estimate to account for the 65 percent of Medicare FFS enrollees that also have Part D coverage.

This process resulted in an overall estimated Medicare spending for diabetes care of \$1,877 per person in 2015 for the type of person that we project will enroll in a new diabetes prevention program. We increased this spending estimate annually using the growth estimates from the CBO. We estimate that Medicare will save this amount for individuals who avoid developing diabetes due to participation in a new diabetes prevention program.

Table 3: Calculating the Estimated Savings from Reduced Incidence of Diabetes

	Value	Dollars
2015 Average A/B Spending per Person (CBO)		\$10,891
2015 Average D Spending per Person (CBO)		\$2,689
Risk Scores		
HCC19--Diabetes with complications	0.368	\$4,008
HCC20--Diabetes without complications	0.118	\$1,285
RxHCC14--Diabetes with complications	0.276	\$742
RxHCC14--Diabetes without complications	0.184	\$495
Expected enrollment		
Diabetes with complications	10%	
Diabetes without complications	90%	

2015 Estimated A/B Spending on Diabetes per Person	\$1,557
2015 Estimated D Spending on Diabetes per Person	\$520
2015 Total Estimated Spending on Diabetes per Person	\$1,877

Source: CMS, CBO and Avalere estimates

To determine the potential savings from reducing the number of people with prediabetes, we used information from an analysis of all-payer spending on diabetes and prediabetes. This analysis suggested that the annual spending due to prediabetes for individuals with Medicare coverage is approximately \$740 per person per year. However, it is unclear if this entire amount is avoidable, so we assumed only 50 percent of the spending would actually be reduced if individuals cease to have prediabetes due to participation in a new diabetes prevention program. In addition, evidence suggests a modest number of individuals will cease to have prediabetes due to participation in a diabetes prevention program, so we assumed that only 15 percent of participants would see any reduction in Medicare spending.

Federal Program Financing Adjustments

Once we determined the total spending and savings due to the proposed legislation, we adjusted for the interaction effects with the Medicaid program as well as Medicare Advantage.

Interaction with Current CMMI Demonstration

As noted earlier, the YMCA is currently conducting a CMMI demonstration of a diabetes prevention program using a grant from the CMMI Innovation Challenge Award. Under the authority of CMMI, the Secretary of HHS may expand the scope or duration of any CMMI demonstration if it is shown to be successful at reducing Medicare spending and/or improving quality. As such, in theory if the current program that is being tested by CMMI shows positive results, the Secretary could expand the offering to the entire Medicare program absent legislation.

However, we believe it is premature to suggest that the Secretary could expand the program at the same pace as what could be accomplished via the proposed legislation. It is probable that CMMI will require several years of evidence before it suggests to the Secretary a broad expansion of the program is warranted. Given that the savings will not be seen for several years due to the incidence rate of diabetes, we believe CMMI will wait until the evidence is clear that savings are emerging before expansion. Conversely, the proposed legislation would make a diabetes prevention program available to all Medicare beneficiaries with prediabetes in 2015, and it would take 7 years before there would be an overall reduction in federal spending.

Even if CMMI did propose to expand the program within the next several years, it is likely that it would be a modest expansion rather than a nationwide expansion. Therefore, any savings that may already exist from a technical perspective due to the option held by CMMI to expand the current diabetes prevention program demo would be much lower than the estimated savings from a nationwide expansion.