Scoring Medicare Coverage of Diabetes Self-Management Training Using Microsimulation

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Executive Summary

- Expanding Access to Diabetes Self-Management Training (DSMT) Act of 2018 ('the Act') proposes to allow more providers to furnish more hours of DSMT to eligible Medicare beneficiaries and improve access by eliminating cost sharing
- This study projected 10-year budget impact to gross Medicare outlay by care setting (inpatient stays, outpatient visits, emergency care, prescription drugs, and other) using a published and validated microsimulation model under different utilization and legislation scenarios
- Under the current epidemiology trajectory of diabetes, the microsimulation model projected the annual Medicare spending on diabetes patients to be approximately $265 billion in the next 10 years. Over the same period, Medicare could save $4.9 and $9.4 billion under modest and aggressive DSMT utilization, respectively
- If the full Act was passed, including the provision on eliminating cost sharing, each Medicare beneficiary participating in DSMT is expected to incur $670 - $1,300 more in spending. This increase in Medicare expenditure will be more than offset by lower medical cost associated with long-term improvement in the participant's overall health condition, resulting in net savings of $9,470 - $12,760 per participant over 10 years. It is projected 80-90% of the savings will be from lower utilization of inpatient careIf the Act were passed without the cost sharing provision, our results suggest program attendance can decrease by 10%. As a result, each program participant will have a net savings of $8,790 and $11,770 over 10 years after offsetting the program costs ($540 and $1040, respectively), which are approximately 8% less than estimations from passage of the full Act.

Background

Diabetes is a critical public health issue that is causing a significant health, social and economic burden to society. Approximately 30.3 million people, or 9.4% of the U.S. population, had diabetes in 2015.[1] The American Diabetes Association estimates that the total cost of diagnosed diabetes in 2017 was $327 billion, a 26% increase from the 2012 estimate of $245 billion. Most (approximately 66%) of the cost of diabetes care in the United States, is paid for by government insurance such as

[1] Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion website. Reports to Congress: Diabetes Report Card 2017. https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf

Medicare, Medicaid and Tricare.[2] Diabetes-related complications like heart disease, end-stage renal failure, and blindness are costly and can be life-threatening. Investments into preventive interventions are crucial to help patients manage their symptoms and learn effective coping strategies, while minimizing healthcare-related costs, improving quality of life and increasing productivity.

Diabetes self-management training (DSMT) is an evidence-based health education training course that teaches patients with diabetes to effectively self-manage their symptoms and learn lifestyle and behavioral change methods that help prevent hospitalizations and diabetes-related complications. DSMT empowers patients with the knowledge and skills to perform diabetes self-care tasks and encourages informed decision making, problem solving and effective collaboration with their healthcare team.[3] DSMT sessions are offered in a variety of healthcare settings, can be administered individually or in a small group, and focus on a range of topics such as blood sugar control, weight loss methods, managing stress level, diet and exercise, cultural norms, and goal setting.[4]

There is wide-ranging evidence that indicates DSMT improves hemoglobin A1C levels[5,6], improves quality of life[7], reduces the advancement and/or onset of diabetes complications[8], enhances self-efficacy and empowerment[9], increases healthy coping[10], and decreases the presence of diabetes-related distress[11] and depression.[12] Despite all these benefits, only 5% of newly diagnosed Medicare

[2] American Diabetes Association: Diabetes Care. The Economic Cost of Diabetes in the U.S. in 2017. *Diabetes Care 2018 May; 41(5): 917-928.* http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007.full-text.pdf https://doi.org/10.2337/dci18-0007

[3] Step-by-Step Guide to Medicare Diabetes Self-Management Training Reimbursement. Indian Health Service, Division of Diabetes Treatment and Prevention. October 2011. https://www.ihs.gov/MedicalPrograms/Diabetes/HomeDocs/Resources/InstantDownloads/DSMT_Guidebook_508c.pdf

[4] Norris, Susan et al. Effectiveness of Self-Management Training in Type 2 Diabetes: A systematic review of randomized controlled trials. http://care.diabetesjournals.org/content/24/3/561.short

[5] Steinsbekk A, Rygg LO, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. BMC Health Serv Res. 2012;12:213.

[6] Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta analysis of the effect on glycemic control. Diabetes Care. 2002;25:1159-1171.

[7] Cooke D, et al.UK NIHR DAFNE Study group. Structured Type 1 Diabetes Education delivered within routine care: Impact on Glycemic Control and diabetes specific QOL. Diabetes Care. 2013;36:270-272.

[8] The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329:977-986.

[9] Tang TS et al. lasting effects of a 2-year diabetes self-management support intervention: outcomes at 1-year follow up. Prev Chronic Dis. 2012;9:E109.

[10] Thorpe CT et al. Facilitating healthy coping in patients with diabetes: a systematic review. Diabetes Educ. 2013:39:33-52.

[11] Fisher L et al. REDEEM: A pragmatic trial to reduce diabetes distress. Diabetes Care. 2013:36:2551-2558.

[12] De Groot M et al. Can lifestyle interventions do more than reduce diabetes risk? Treating depression in adults with type 2 diabetes with exercise and cognitive behavioural therapy. Curr Diab Rep. 2012;12:157-166.

beneficiaries reported using DSMT services.[13] Access barriers to DSMT related to patients include high out-of-pocket cost, patient uncertainty about the effectiveness of DSMT, lack of understanding and education about the benefits of preventive healthcare methods, and limited number of service providers in rural areas. Access barriers related to the healthcare system include low reimbursement rate by Medicare and time constraints on service utilization.,

In May 2018, Representative Tom Reed [R-NY-23], co-chair of the Diabetes Caucus and father of a Type-1 diabetes patient, introduced new legislation titled "Expanding Access to DSMT Act of 2018" (H.R. 5768) that would improve access to DSMT for Medicare beneficiaries. The bill would allow these additional benefits, among others:

1. Permitting physicians and qualified non-physician practitioners, who are not managing a patient's diabetes, to order DSMT services
2. Extending the initial 10 hours of DSMT covered by Medicare beyond the first year until fully utilized
3. Allowing 6 additional hours of DSMT per year, after the year in which the initial 10 hours are used
4. Removing Part B cost-sharing for DSMT services.[14]

Methodology

With a goal to project the economic costs and cost savings of the proposed Expanding Access to DSMT Act for various levels of DSMT utilization under Medicare, this analysis was conducted using a peer-reviewed and validated Markov-based microsimulation model to estimate the budget impact of expanding utilization of DSMT covered by the Medicare program.[15] The model's sample population was diagnosed diabetes patients age 65 and above. Data was extracted from the 2007 to 2014 National Health and Nutrition Examination Survey (NHANES), a nationally representative dataset on demographic, socioeconomic, and health information for the US population. Individual profiles contained demographics (age, sex, race, and Hispanic ethnicity), biometrics, current smoking status, and presence of recognized risk factors and complications of diabetes —hypertension, ischemic heart

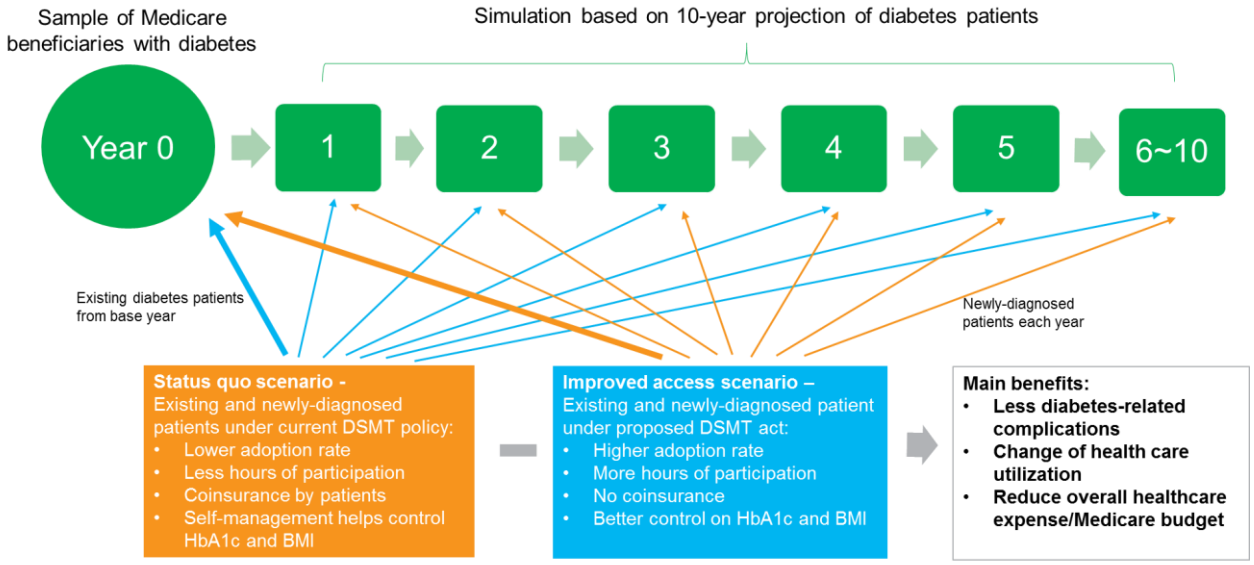
[13] Strawbridge LM et all. Use of Medicare's Diabetes Self-Management Training Benefit. Health Educ Behav. 2015 Aug;42(4):530-8.
[14] Summary of "Expanding Access to Diabetes Self-Management Training Act" – HR 5768. Representative Tom Reed (R-NY) and Diana DeGette (D-CO). https://www.ncoa.org/wp-content/uploads/Fact-Sheet-HR-5768-Expanding-Access-to-DSMT-Act.pdf
[15] Dall, Timothy M., et al. Value of lifestyle intervention to prevent diabetes and sequelae. American Journal of Preventive Medicine. 48.3 (2015):271-280.

disease, congestive heart failure, stroke, heart attack, renal failure, amputation, and blindness. Each person's current characteristics were used to predict next year's health outcomes, with this process repeated through 10 years or death. The annual medical expenditures were estimated based on their characteristics and modelled disease conditions.

As depicted in Figure 1, the model simulates the clinical and economic consequences of Medicare beneficiaries with diagnosed diabetes who are qualified for the DSMT program under the current *status quo* scenario and improved access scenarios. The *status quo* scenario assumed the progression of disease condition under current utilization status of DSMT by newly diagnosed and existing diabetes patients, i.e., lower program participation rate, less hours of utilization, requires co-insurance by patients. Alternatively, the hypothetical improvement scenarios assume better control on blood glucose level and body weight as a result of improved utilization of the disease management program, i.e., higher participation rate, more hours of training and elimination of co-insurance (for regulation with cost share provision). The budgetary impact of proposed regulation was calculated based on increased DSMT program cost and reduced healthcare expenditure due to less medical resource use. The program cost was calculated based on Medicare reimbursement rate of each 30-minute training session ($52 in individual and $14 in group setting[16]) and number of training hours. The total healthcare expenditure was further allocated by five service categories, i.e. ambulatory, inpatient, emergency, pharmacy, and other medical expenditures (e.g., dental, medical device etc.), to help illustrate expenses related to Medicare Part A, Part B and Part D.[17]

[16] Garfield K, Downer S, Rosenberg A. Reconsidering cost-sharing for diabetes self-management education: recommendations for policy reform. Center for Health Law and Policy Innovation website. http://www.chlpi.org/new-publication-reconsidering-cost-sharing-for-diabetes-self-management-education-recommendations-for-policy-reform/. Published July 9, 2015.
[17] Chen F et al. Clinical and Economic Impact of a Digital, Remotely-Delivered Intensive Behavioral Counseling Program on Medicare Beneficiaries at Risk for Diabetes and Cardiovascular Disease. PLoS ONE. 2016 11(10): e0163627.

Figure 1. Diagram of model schematic



Based on the proposed Expanding Access to DSMT Act, we modelled five scenarios for our analysis. Key specifications of model scenarios are described in detail as follows and summarized in Table 1:

- ***Status quo scenario*** – A previous study by Strawbridge et al. found only 5% of newly diagnosed diabetes patients participated in DSMT, and the participants used on average 1.5 hours over the first year.[18] Our analysis of the report from Dobson DaVanzo et al. showed about 2% of other non-newly diagnosed beneficiaries with diabetes participated in DSMT, and they used on average 0.4 hours in each subsequent year.[19] Medicare provides reimbursement for the DSMT service in 30-minute increments, with the patient paying 20% after deductible.
- ***Moderate improvement scenario (full act)*** – Under the moderate access improvement assumption, we assume the participation of DSMT will increase by 10% annually among both newly and non-newly diagnosed diabetes patients, while the number of training hours is also doubled among all participants. Medicare would reimburse 100% of the program cost per the proposed cost provision portion of the act which would remove patient cost-sharing.

[18] Strawbridge LM et all. Use of Medicare's Diabetes Self-Management Training Benefit. Health Educ Behav. 2015 Aug;42(4):530-8.
[19] IHSM analysis based on Dobson DaVanzo & Associates, Cost Estimation of H.R. 2787 using Congressional Budget Office Scoring Methodology: Medicare Diabetes Self-Management Training Act. 2012 (https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/advocacy/cbo_2012_final.pdf?sfvrsn=2)

- ***Aggressive improvement scenario (full act)*** – Under the aggressive access improvement assumption, DSMT program participation is expected to increase by 20% annually among all Medicare patients, while the number of training hours becomes tripled among all participants. Medicare would reimburse 100% of the program cost.
- ***Moderate improvement scenario (without cost share provision)*** - Previous studies on smoke cessation therapies have shown that eliminating cost-sharing from patients increased service use by about 10%.[20] [21] Therefore, taking out the cost share clause from the proposed act (i.e. Medicare still reimburse 80% of the program cost) is assumed to reduce attendance (participate rate, hours on the program) by approximately 10% when compared to the full act moderate improvement scenario.
- ***Aggressive improvement scenario (without cost share provision)*** – Medicare still reimburses 80% of the program cost. DSMT attendance is 10% lower than the full act aggressive improvement scenario.

Table 1. Key specifications of model scenarios

	Status quo	Moderate improvement scenario (full bill)	Moderate improvement scenario (without cost share provision)	Aggressive improvement scenario (full bill)	Aggressive improvement scenario (without cost share provision)
Hours: 1st Year of DSMT	1.5 hours	3 hours (100% improvement)	2.7 hours	4.5 hours (200% improvement)	4.1 hours
Hours: subsequent years	0.4 hours	0.8 hours (100% improvement)	0.7 hours	1.2 hours (200% improvement)	1.1 hours
DSMT participation among newly diagnosed diabetes patients	5.0%	10% annual increase (13.0% by 2028)	10% lower adoption than full bill (11.7% by 2028)	20% annual increase (31.0% by 2028)	10% lower adoption than full bill (27.9% by 2028)
DSMT participation among non-newly diagnosed diabetes patients	2.0%	10% annual increase (5.2% by 2028)	10% lower adoption than full bill (4.7% by 2028)	20% annual increase (12.4% by 2028)	10% lower adoption than full bill (11.1% by 2028)
Medicare reimbursement of DSMT (after deductible)	80% of allowed charge*	100% of allowed charge	80% of allowed charge	100% of allowed charge	80% of allowed charge

* Allowed charges is the amount recognized for payment by the insurer, including both the insurer payment and patient cost-sharing.

Our systematic literature review suggests that the two most significant clinical benefits of DSMT are better control on blood glucose level and excess body weight. Based on results from 31 clinical trials

[20] Trivedi AN et al. Elimination of Cost Sharing for Screening Mammography in Medicare Advantage Plans. N Engl J Med. 2018 Jan 18; 378(3): 262–269

[21] Young-Wolff KC et al. Evaluating the Impact of Eliminating Co-payments for Tobacco Cessation Pharmacotherapy (TCP). Med Care. 2018 Nov;56(11):912-918

with mean participants' age 55 and above, we derived a dose-response relationship between the number of training hours and HbA1c reduction among DSMT participants using linear regression weighted by the study sample size (Appendix Figure 1).[22] Using this approach, instead of treating each data point treated equally studies with larger sample size were given more influence. The effect of DSMT on body weight was summarized from 6 studies published between 1999 and 2011, which shows elderly participants on average lose 3.3% in body weight over 12 months (Appendix Table 1). For modelling purposes, we assume each program participant would have average weight loss during the first year and then maintain the effect of DSMT over subsequent years.

Study findings

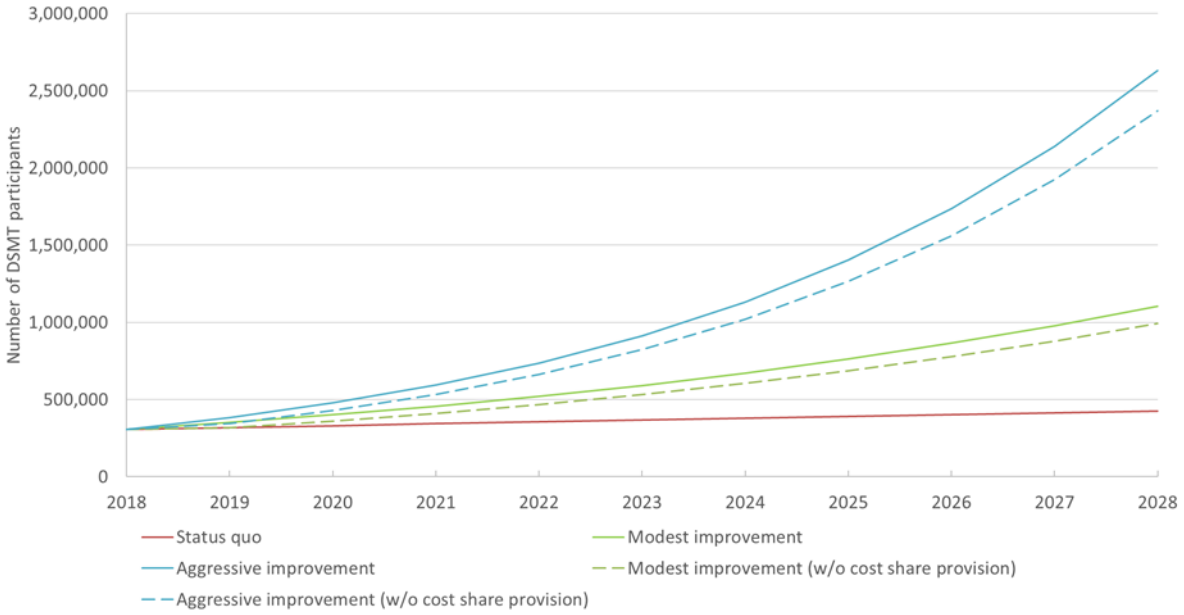
DSMT participation rate among eligible Medicare beneficiaries

Based on the population projection of elderly people in the US,[23] the number of Medicare beneficiaries with diagnosed diabetes is expected to rise over the next 10 years, increasing from 11.4 million in 2018 to 15.7 million by 2028. Assuming the overall DSMT participation remains at current level of 2.7% (5.0% among newly diagnosed and 2.0% among non-newly diagnosed), the number of participants will increase from 308 million to 425 million over next the 10 years. Under the modest and aggressive improvement scenarios, we estimated about 1.1 billion (7.0%) and 2.6 billion (16.7%) of diabetes patients would attend DSMT sessions by 2028 (Figure 2). Without the cost share provision in the proposed act, the total participation of DSMT would reach 1.0 billion (6.3%) and 2.4 billion (15.0%) by 2028 under each of the access improvement scenarios.

[22] Carole et al. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Source: Patient Educ Couns. 2016 Jun;99(6):926-43

[23] The U.S. Census Bureau. Older People Projected to Outnumber Children for First Time in U.S. History. MARCH 13, 2018. https://www.census.gov/newsroom/press-releases/2018/cb18-41-population-projections.html

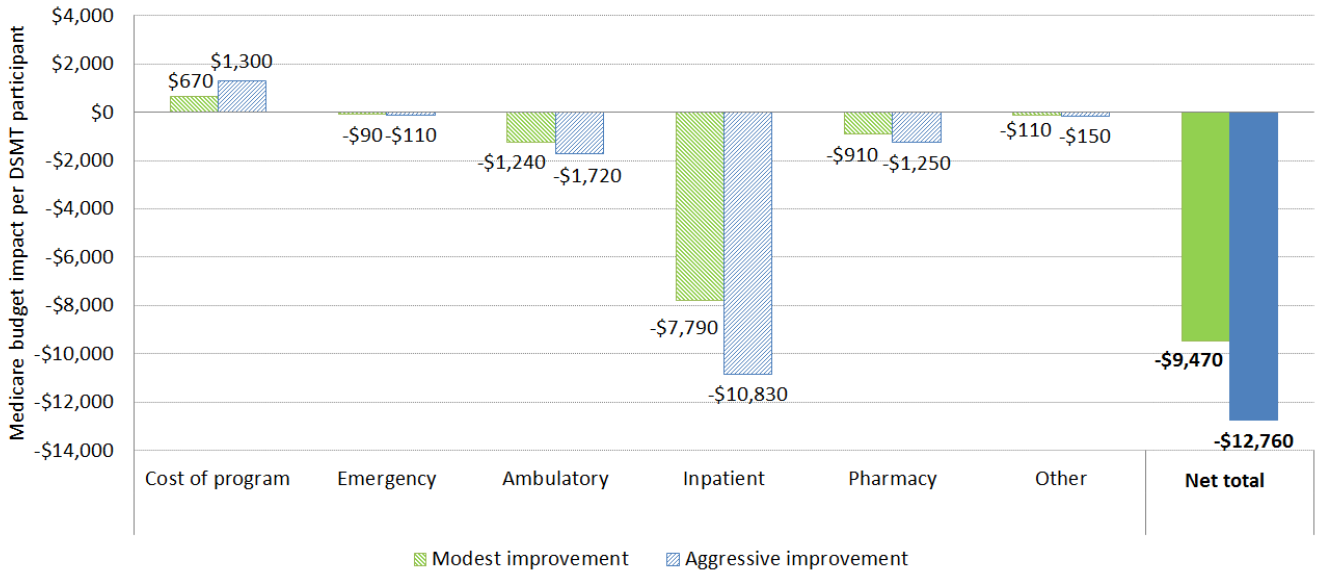
Figure 2. Projection of DSMT participation among Medicare beneficiaries with diabetes



Estimated 10-year budget impact per DSMT participant (full bill)

Under the status quo scenario, the annual Medicare cost incurred by each diabetes patient is expected to increase from $17,680 in 2018 to $23,760 in 2028. Through modestly improved utilization of DSMT, on average each participant is expected to spend $670 more on the diabetes management program but save $10,140 in healthcare expenditure over 10 years, resulting in a net savings of $9,470 (Figure 3). We estimate that a majority of the savings ($7,790) would come from reduced utilization of inpatient care, then ambulatory care ($1,240), prescription drug costs ($910), other costs ($110) and emergency department care ($90). Alternatively, under the aggressive improvement scenario, each DSMT participants could incur a net saving of $12,760 over 10 years after deduction of $1,300 of program cost. About 85% ($10,830) of the saving is due to less utilization of inpatient care.

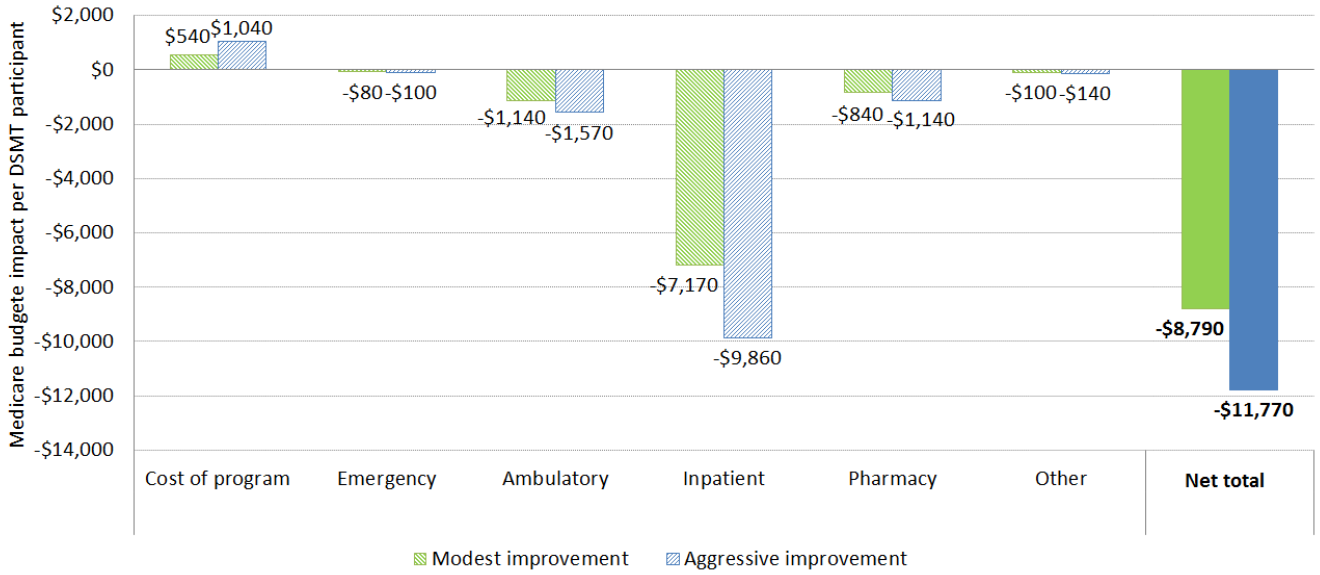
Figure 3. 10-year budget impact on Medicare per DSMT participant (full bill)



Estimated 10-year budget impact per DSMT participant (with cost sharing provision removed)

As a result of keeping treatment copay as out-of-pocket cost from patients, Medicare is expected to have less budgetary savings due to reduced utilization of DSMT program than the full bill. . Under the modest and aggressive improvement scenarios, our model suggests each program participant will have a net savings of $8,790 and $11,770 over 10 years after offsetting the program costs ($540 and $1040, respectively), which are approximately 8% less than estimations from previous scenarios with cost share provision (Figure 4).

Figure 4. 10-year budget impact on Medicare per DSMT participant (without cost sharing provision)



Estimated 10-year total net saving in gross Medicare outlay

Our simulation suggests that under the current trend of diabetes prevalence annual Medicare outlay on diabetes patients is approximately $265 billion over the next 10 years. Improving access to DSMT is expected to save Medicare $4.9 to $9.4 billion ($70 to $130 per Medicare beneficiary) of the 10-year total budget for modest and aggressive utilization increase, respectively. Without the cost share provision of the proposed act, the total budgetary savings can decrease to $4.5 and $9.3 billion due to less coverage utilization compared to the full act.

Put Results in Context

This study projected total Medicare outlay over the next 10 years under different DSMT utilization and legislative scenarios using a validated microsimulation model. Significant return on investment is observed in all scenarios. If the full bill is passed, the model projected a $670 upfront investment is required to bring modest improvement in DSMT utilization. This investment will lead to $9,470 in net Medicare budget savings (1,400% return on investment) over 10 years. The net savings will be larger at $12,760 under the more optimistic assumptions of higher participation rates and more hours on DSMT. If the cost sharing provision is no longer in the bill (i.e. participants still pay 20% of the program cost after the bill is passed), Medicare's net savings is expected to drop by $680 - $990 compared with the "full bill" scenario as a result of lower program attendance.

Better diabetes management with DSMT is expected to bring down Medicare spending across all care settings in emergency care, inpatient stays, outpatient visits, prescription drugs, and others. It is projected that 80-90% of the savings in Medicare outlay can be attributed to lower utilization of inpatient care. This is partially explained by the high per-diem cost of inpatient stays (national average expense per inpatient day is $2,338 in 2016). Another contributing factor is many comorbidities of diabetes, such as amputation and stroke, may require surgery and/or a long recovery period in an inpatient environment. Noticeable cost savings are also projected in ambulatory service and prescription drugs, which is associated with improved overall health caused by better drug adherence

A number of studies have analyzed the economic benefit and cost of diabetes management education. For example, a 2009 systematic review found 18 of 26 publications reported cost decrease/saving or positive return-on-investment.[24] A claims data analysis by Sidorov et al. showed patients who enrolled in a diabetes management program had 25-43% lower inpatient use, 13% less emergency visits and 7% more primary care visits over 2 years than those not in the program.[25] As a result, on average Medicare payed $912 less per patient per year on healthcare for the enrolled patients. A report by Duncan et al. conducted 3- and 4- year longitudinal studies to assess the cost-effectiveness of accredited DSMT programs covered by Medicare Advantage insurance plans, and they observed per capita saving of $422 to $976 among program participants compare to those did not receive the education.[26] A breakdown of the medical expenditure by service type indicated the savings were exclusively due to reduced inpatient cost, with increased spending in outpatient, office visits and pharmacy. Both studies have shown DSMT can effectively reduce healthcare spending, especially in the hospital care setting, which are in line with our results. Our estimation also suggested positive returns across care settings can be realized over a longer period than what was reported in the aforementioned studies.

DSMT may have other benefits beyond what's modeled in our study. The day-to-day challenges of living with diabetes can cause a range of emotional symptoms such as diabetes-related distress (DRD). The American Diabetes Association defines DRD as "experiencing unique emotional issues directly related to the burdens and worries of living with chronic disease." Dr. Lawrence Fisher and his team at the Diabetes Center of UCSF created a test that aims to identify DRD in patients with

[24] Boren, S., Fitzner, KA, Panhalkar, PS, Specker, JE, Costs and Benefits Associated with Diabetes Education, The Diabetes Educator, Vol 35, No. 1, 2009
[25] Sidorov, et al., Does diabetes disease management save money and improve outcomes? A report of simultaneous short-term savings and quality improvement associated with a health maintenance organization-sponsored disease management program among patients fulfilling health employer data and information set criteria. *Diabetes Care.* 2002 Apr;25(4):684-9.
[26] Duncan I, Ahmed T, Li Q, et al. Assessing the value of the diabetes educator. Diabetes Educ. 2011;37(5):638-657

diabetes and assesses four general areas: (1) regimen distress, (2) concerns about the future and possible complications, (3) quality and cost of care, and (4) social burden and stigma. [27] During the REDEEM study, a trial to reduce diabetes-related distress, Dr. Fisher and team showed interventions that enhance self-management also reduce DRD significantly.[28] Similarly, during the TREAT (Telemedicine for Reach, Education, Access and Treatment) study, behavioral and psychosocial outcomes in a rural patient population were examined at baseline and follow-up after telemedicine diabetes management sessions. Patients reported improvement in empowerment, self-care (adherence to diet and monitoring) and reduction in DRD after telemedicine sessions administered by an endocrinologist.[29] Particularly in rural areas where diabetes educators are scarce, the TREAT model that delivers improvements in diabetes-related behavioral health outcomes through telemedicine may be a viable alternative to in-person DSMT services.

Despite the evidence of DSMT's effectiveness in the management of A1c and weight, lifestyle, and mental health, low utilization among eligible beneficiaries remains a concern to industry stakeholders and policy makers. Access barriers can come from all corners of the industry such as the health system, health care professional, community resources, and diabetes patients. In a joint statement[30] by ADA (American Diabetes Association), AADE (American Association of Diabetes Educators), and AND (Academy of Nutrition and Dietetics), further barriers were identified such as misunderstanding of the necessity and effectiveness of DSMT and confusion about referral rules. Furthermore, in the 2017 Physician Fee Schedule proposed rule (81 FR 45215), CMS solicited feedback and identified access barriers that may have potentially contributed to the low utilization. [31] Low payment rates were cited as one of the factors limiting access. CMS also received several recommendations which addressed regulatory and statutory DSMT requirements to improve utilization. Most of these recommendations, such as eliminating copay and deductibles and expanding the provider base to include certified diabetes educators, have already been incorporated into Expanding Access to DSMT Act of 2018. Last but not the least, another CMS study reported that adverse health conditions among the elderly population like COPD, heart disease, Alzheimer's/dementia, functional or cognitive

[27] Gebel, Erika. American Diabetes Association. *Diabetes Distress.* June 2013. http://www.diabetes.org/living-with-diabetes/complications/mental-health/diabetes-distress.html
[28] Fisher L, Hessler D, et al. REDEEM: a pragmatic trial to reduce diabetes distress*. Diabetes Care*, 2013. https://www.ncbi.nlm.nih.gov/pubmed/23735726
[29] Siminerio L. TREAT: Telemedicine for Reach, Education, Access and Treatment. Linking telemedicine with diabetes self-management education to improve care in rural communities. AADE News: The Diabetes educator. 2014. https://ncbi.nlm.nih.gov/pubmed/25253624
[30] Powers, MA, Bardsley, J, Cypress, M, Duker, P, Funnell, MM, et al., Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics, *Clin Diabetes*, 2016; 34(2): 70–80
[31] Center for Medicare and Medicaid Services, Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, https://www.gpo.gov/fdsys/pkg/FR-2016-11-15/pdf/2016-26668.pdf, accessed November 27, 2018

limitations may also be barriers to service use.[18] Introducing virtual DSMT programs has the potential to alleviate barriers caused by functional limitations. Even though the Act proposes to launch a 2-year demonstration program of such virtual programs, due to the limited scope and experimental nature of this proposal virtual DSMT programs were not included in this study.

Disclosure: This research was sponsored by Novo Nordisk Inc.

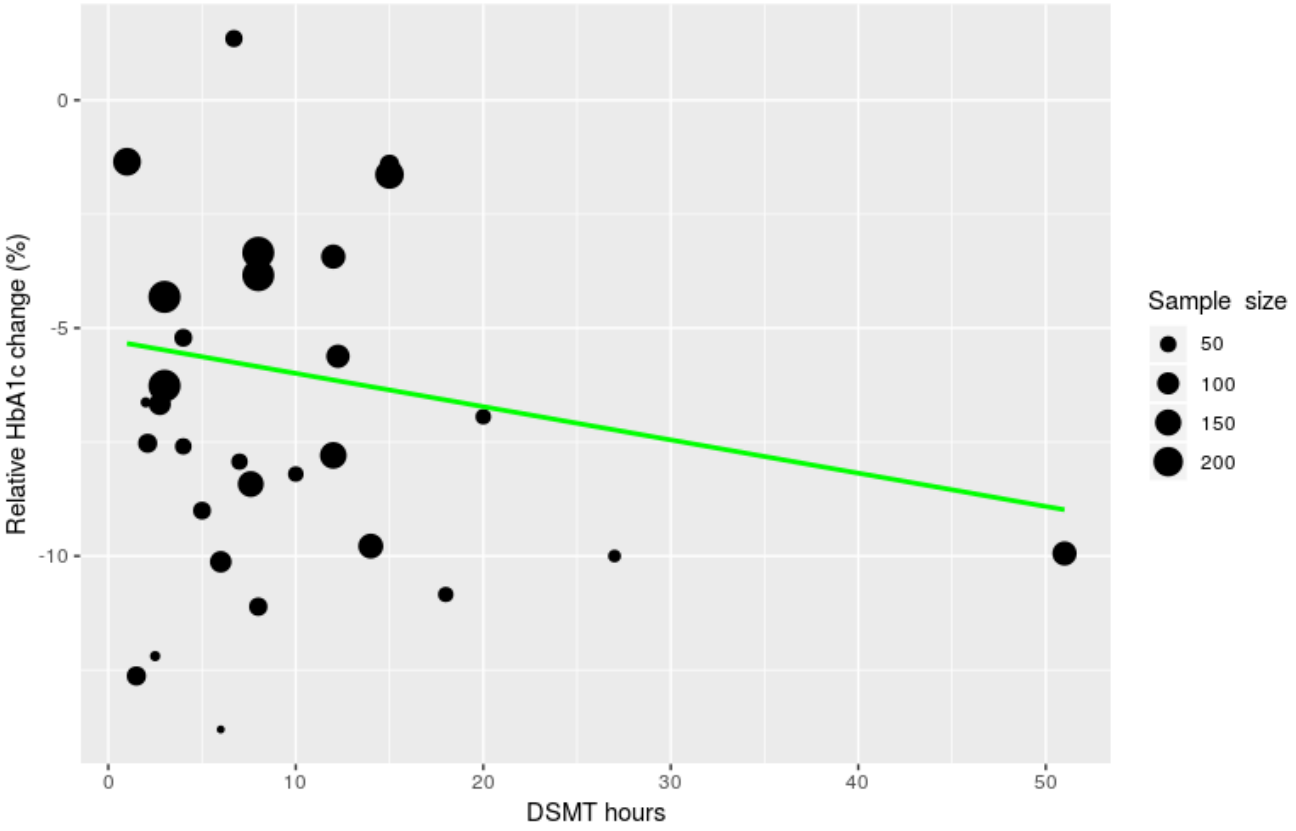
Appendix

Key Model Assumptions

1. Prevalence of Diabetes
    - The model was populated using data of senior adults (aged 65+) from the 2007 to 2014 National Health and Nutrition Examination Survey (NHANES). It is assumed that this data is representative of older adults in the United States on demographic, socioeconomic, and health information.
    - The 10-year projection on number of diabetes patients covered by Medicare was estimated based on current prevalence of diabetes and population projections published by the United States Census Bureau.
2. Biometrics and Disease Incidence
    - The annual changes in BMI and HbA1c in diabetic patients were derived based on our analysis of NHANES patients with similar demographic profiles. The incidence of diabetes-related complications was predicted using regression equations published by peer-reviewed research studies.
3. Year since Diagnosis of Diabetes
    - This information was recorded in the NHANES dataset. In cases of missing data, values are imputed by a prediction equation based on the person's demographic and biometric parameters.
4. Direct Health Care Expenditures
    - The equations simulating medical expenditures for each participant were estimated using the 2009–2014 Medical Expenditure Panel Survey (MEPS)—a nationally representative of the non-institutionalized population in the U.S. Explanatory variables include body weight, demographics, presence of diabetes as well as other disease conditions, e.g. cardiovascular diseases, various cancers, kidney diseases and mental disorders etc.

- A similar set of regression equations were derived to estimate the allocation of total medical expenditures across the following cost categories: ambulatory care, inpatient care, emergency care, prescription drug costs, and "all other" medical expenditures.

Figure 1. Dose-response relationship between number of training hours and relative reduction in HbA1c level among DSMT participants



Based on 31 clinical trials review by Carole et al. with participants' mean age 55 and above,[32] a dose-response relationship between number of training hours and percentage reduction in HbA1c among DSMT participants was derived using linear regression weighted on study sample size (formula: % reduction in HbA1c = -0.073 x DSMT hours - 5.26, R-square = 0.05).

[32] Carole et al. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Source: Patient Educ Couns. 2016 Jun;99(6):926-43

Table 1. Summary of efficacy on reducing body weight among DSMT participants

Year of study	Mean age	Sample size	Baseline Weight (pounds	% weight drop @ 3 month	% weight drop @ 6 month	% weight drop @ 12 month	Reference
1999	64	56	193.8		-1.9%	**-4.0%**	Link
1997	62	64	205.7	-2.7%	-2.8%	**-2.8%**	Link
2012	66	146	191.4		-0.1%	**-1.6%**	Link
2009	60	43	229.5		-2.2%	**-3.2%**	Link
2010	57	53	209.4	-3.7%		**-3.7%**	Link
2011	61	702	200.4			**-4.2%**	Link

We collected 6 studies with participants mean age 55 and above, the change in weight range from -0.1% to -4.2% from 3 to 12 months. Assuming Last-Observation-Carried-Forward, the mean weight loss is -3.3% over 12 months. Full reference for the studies is listed below: