

Hope Warshaw Associates

in FOOD • NUTRITION • DIABETES

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May 20, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2004N-0086
Diabetes: Targeting Safe and Effective Prevention and Treatment

I file the following comments as a registered dietitian and certified diabetes educator who has been involved in diabetes management for nearly 25 years. From this perspective I have witnessed huge strides in both the way that practitioners manage diabetes and the technological advances. While the technological advances have been gratifying to witness, I continue to be amazed by the un- and underutilization of two both clinically and cost effective diabetes management tools— Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT). This is the topic of my 3 comments.

1) Need for additional hours for DSMT and MNT:

Over the last decade legislative strides have been made to have DSMT and MNT for diabetes added as Part B Medicare benefit for those individuals with diabetes. At present Medicare beneficiaries with Part B who have diabetes are allowed, with referral from their treating provider, an initial and one time DSMT benefit of 10 hours and an annual 2 hours of follow up DSMT. The MNT benefit for the same population is approximately 3 hours initially and 2 hours of annual follow up. While these hours of DSMT and/or MNT are certainly a move in the right direction, they hardly represent the amount of time on a continual and consistent basis that people with diabetes need over time to implement the self-care behaviors necessary to produce positive clinical and economic cost savings.

2) Need to broaden the criteria for DSMT and MNT to people with Pre-diabetes:

As stated above, the criteria for DSMT and MNT is that the Medicare beneficiary must be diagnosed with type 1, type 2 or gestational diabetes. Today the very people who, we know from studies such as the NIH Diabetes Prevention Program (DPP) and other like studies, could potentially benefit the most from DSMT and MNT cannot be referred for these services because they don't yet have diabetes and thus aren't eligible. HHS's translation of the DPP results to date has been to develop and promote the *Small Steps, Big Rewards: Prevent Type 2 Diabetes* program. While this program consists of excellent materials, it is hardly a translation of the results of the DPP. The DPP clearly showed that intensive lifestyle intervention with skilled

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interventionists over the course of 3 years helped the people in this study group lose weight and become more active. These individuals reduced their development of type 2 diabetes by 58%. This arm of the study exceeded the use of the medication metformin and minimal nutrition and physical activity counseling. Therefore shouldn't the sensible translation of this study be to open the eligibility gate for DSMT and MNT to those people diagnosed with Pre-diabetes. The diagnostic criteria for Pre-diabetes exists from an International Expert Panel and in fact has recently been revised to an even lower number for the diagnosis. It is estimated that there are approximately 14 million Americans with Pre-diabetes.

People with Pre-diabetes who attempt to make the difficult yet critical lifestyle and behavior changes to improve eating habits and increase their activity level need the expertise and support of the very clinicians who deliver DSMT and MNT for people with diabetes throughout this country. Research on the effectiveness on MNT and DSMT demonstrates that these services are most effective in the early years of diabetes. With an understanding of the disease process of Pre-diabetes and the results of clinical trials, it is reasonable to suggest that DSMT and MNT at this Pre-diabetes stage could be most clinically and cost effective. To promote the *Small Steps, Big Rewards* program without expanding the coverage of DSMT and MNT—the very Medicare services beneficiaries with Pre-diabetes need—is a set up for failure. People simply do not and will not make the necessary lifestyle changes on their own. That has been proven time and time again.

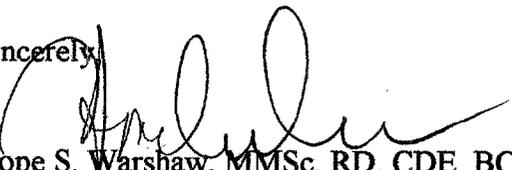
3) Implement Strategies to Communicate the availability of DSMT and MNT services to Primary Care Providers:

Another challenging aspect of the DSMT and MNT benefits is how to encourage physicians and other front line providers of diabetes care to refer people with diabetes for these clinically and cost effective management tools—DSMT and MNT. People with diabetes (and hopefully in the future Pre-diabetes) simply aren't referred to these services. Healthy People 2010 reports that 40% of people with diabetes received any formal diabetes education (age-adjusted to the year 2000 standard population). Yet the Healthy People 2010 objective is to increase this percent of people with diabetes who receive diabetes education to 60%. The goal, according to the report, is to reduce both the economic burden of diabetes and improve the quality of life for persons who have or are at risk for diabetes.

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In closing, I would hope that consideration be given to determine how the health care system can make better use of DSMT and MNT in providing both clinically and cost effective pre- and diabetes care. I would be pleased to talk further about these comments and to provide the research data that supports the above comments. Thank you for your time and consideration.

Sincerely,



Hope S. Warshaw, MMSc, RD, CDE, BC-ADM

c: Honorable Tommy G. Thompson, Secretary HHS
Mark McClellan, MD, PhD, Administrator, CMS