



June 9, 2014

Michael L. LeFevre, M.D., M.S.P.H.  
Chair, United States Preventive Services Task Force  
540 Gaither Road  
Rockville, MD 20850

***Re: Draft Recommendation Statement: Behavioral Counseling to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Known Risk Factors***

Dear Dr. LeFevre:

The Obesity Care Continuum (OCC) appreciates the opportunity to submit comments to the United States Preventive Services Task Force (USPSTF) regarding its May 13, 2011 Draft Recommendation Statement for Behavioral Counseling to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Known Risk Factors (“Draft Recommendation”).

The purpose of the OCC is to pool the resources of its member groups and better coordinate Federal and state advocacy efforts to secure access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity. With a combined membership of more than 125,000 patient and healthcare professional advocates, the OCC covers the full scope from nutrition, exercise and weight management through pharmacotherapy to device and surgery. The coalition is a major force in the continuing debate regarding the critical need to both prevent and treat the disease of obesity.

The OCC generally supports the Draft Recommendation, particularly its recognition of the importance of “referring overweight or obese adults who have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthy diet and physical activity for CVD prevention.” We agree with the USPSTF’s conclusion “that for overweight or obese adults at increased risk of CVD, intensive behavioral counseling had a moderate benefit on risk for CVD, including improvements in body mass index (BMI), blood pressure, lipids, fasting glucose, and levels of physical activity and that the reduction in glucose levels was sufficient to lead to a lower incidence of the diagnosis of diabetes.” The USPSTF’s 2014 Evidence Review clarifies that both medium- and high-intensity interventions improve intermediate CVD health outcomes, but that only high-intensity interventions “reduced diabetes incidence in the longer-term.”

The OCC will be focusing its comments on the key factors that promote effective interventions such as: the intensity of the intervention; the provider type or expertise; and the venue or location. In addition, we will be highlighting the importance of the recently released Guideline for the Management of Overweight and Obesity in Adults developed by the American College of Cardiology (ACC), American Heart Association (AHA), and The Obesity Society (TOS).

## Factors in Effective Interventions

### Intensity of Intervention

Since 1996, the USPSTF and affiliated researchers have undertaken a series of evidence reviews and systematic evidence updates analyzing available studies related to dietary interventions and counseling to promote a healthy diet. These reviews identify intensity of intervention (minutes in a session) as the most significant factor; the largest changes in diet come after medium to high intensity interventions conducted by a registered dietitian nutritionist or other specially trained practitioner conducted outside of the primary care setting.

### Provider Type/Expertise

After intensity, the specialized skills or type of practitioner conducting interventions is the second most significant factor in producing statistically significant improvements in dietary change or physiological results in most trials. The USPSTF concluded that successful “[i]nterventions were delivered by specially trained individuals including dietitians [sic] or nutritionists, physiotherapists or exercise professionals, health educators, psychologists, and other trained professionals.” In the two well-researched interventions discussed in depth in the Draft Recommendation, providers (even when classified as “lifestyle coaches”) were specialized experts—either registered dietitian nutritionists or masters-level trained interventionists. In addition, the 2014 Evidence Review concluded that “dietary counseling practices of primary care clinicians fall short of recommendations, even for patients at high risk of CVD.”

The OCC believes primary care providers play a critical role in the screening and referral of patients with risk factors for cardiovascular disease, and expanded coverage for one biennial CVD visit is an important first step in preventing or minimizing the progression of chronic disease. However, primary care providers are limited in their time, training, and skills to conduct the medium or high-intensity interventions that are scientifically proved to be the most effective in producing the largest, most lasting results.

It is both cost-effective and efficient to have primary care provider-driven referrals of patients with risk factors for CVD to practitioners skilled in conducting dietary interventions who practice both inside and outside of primary care settings.

**Therefore, the OCC asks that the USPSTF explicitly recommend appropriate referrals from primary care providers to a registered dietitian nutritionist or other specialist, such as an obesity medicine specialist, for effective dietary interventions.**

### Venue/Location

USPSTF’s behavioral counseling recommendations are either “feasible for primary care delivery or are available for referral from primary care and delivered in other settings,” which the Draft Recommendation refers to as “primary care-relevant.” The 2014 Evidence Review concluded that “[g]iven the intensity and expertise needed for these interventions, the counseling interventions evaluated are primarily referable from primary care, as opposed to delivered in primary care.”

The Draft Recommendation confirms that both of the “[t]wo well-researched interventions” (The DPP and PREMIER studies) discussed in detail in the Draft Recommendation are typically provided by registered dietitian nutritionists or other appropriately trained professionals. And although the Draft Recommendation notes that these two interventions “could be delivered feasibly in the primary care setting or by local community providers[,]” the OCC notes that the 2014 Evidence Review specifically “excluded interventions delivered through non-referable community settings (e.g., work sites, churches).”

**Thus, given that the 2014 Evidence Review excluded studies of their effectiveness, we seek clarification that the USPSTF’s recommendation does not include interventions at non-referable community settings.**

## **AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults**

The American Heart Association, American College of Cardiology, and The Obesity Society recently published two guidelines directly relevant to the Draft Recommendation in November 2013 “based on the highest quality evidence available” from 1998-2009, although the timing of those guidelines likely precluded the USPSTF from considering them when preparing its Draft Recommendation. Both sets of guidelines are highly relevant to the USPSTF as it finalizes its recommendation. Although the “AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults” evaluates interventions for weight loss, the studies reviewed meet the parameters specified in the 2014 Evidence Review and should thus be considered given the Draft Recommendation’s focus on individuals with overweight and obesity. The 2014 Evidence Review notably excluded studies where obesity was the *only* CVD risk factor, but the AHA/ACC/TOS Guidelines specify that “critical issues identified included . . . the impact of weight loss on risk factors for CVD and type 2 diabetes as well as CVD morbidity and mortality.”

The AHA/ACC/TOS Guidelines make the following specific relevant recommendations:

- Recommendation 3b with a Grade of A (Strong): “Prescribe a calorie-restricted diet, for obese and overweight individuals who would benefit from weight loss, based on the patient’s preferences and health status and preferably refer to a nutrition professional\* for counseling.”
- Recommendation 4a with a Grade of A (Strong): “Advise overweight and obese individuals who would benefit from weight loss to participate for  $\geq 6$  months in a comprehensive lifestyle program that assists participants in adhering to a lower calorie diet and in increasing physical activity through the use of behavioral strategies.”
- Recommendation 4b with a Grade of A (Strong): “Prescribe on site, high-intensity (i.e.,  $\geq 14$  sessions in 6 months) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.”
- “All patients for whom weight loss is recommended should be offered or referred for comprehensive lifestyle intervention (Box 11a and 11b). Comprehensive lifestyle intervention, preferably with a trained interventionist or nutrition professional is foundational to weight loss (Box 11a), regardless of augmentation by medications or bariatric surgery.”
- “The most effective behavioral weight loss treatment is in-person, high-intensity (i.e.,  $\geq 14$  sessions in 6 months) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist (CQ4).
- “In primary care offices where frequent, in-person individual or group [lifestyle intervention] sessions led by a trained interventionist or a nutrition professional are not possible or available by referral, the physician may consider alternative modes of delivery. . . . An additional option if a high-intensity comprehensive lifestyle intervention program is not available or feasible is referral to a nutrition professional for dietary counseling.”
- “By expert opinion, if patients are unable to lose enough weight to meet weight or targeted health outcome goals with their current treatment, consider offering or referring for more intensive behavioral treatment than currently being attempted, an alternate diet including options for meal replacement, referral to a nutrition professional, the addition of obesity pharmacotherapy, or referral for evaluation for bariatric surgery if otherwise appropriate.”
- “In studies to date, low to moderate-intensity lifestyle interventions for weight loss provided to overweight or obese adults by primary care practices alone, have not been shown to be effective. • Strength of Evidence: High”

**We ask that the USPSTF reference the AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults and consider inclusion of the bullet points above in a summary paragraph.**

## **Revising the USPSTF's Draft Recommendation in Light of its Statutory Role**

The OCC is encouraged by the USPSTF's ongoing efforts to develop clinical recommendations for effective preventive care. With the passage of the Patient Protection and Affordable Care Act, the USPSTF's recommendations become more significant: recommendations with Grades A and B are statutorily mandated in Medicare, Medicaid, and insurance sold on the state and federal marketplaces. In addition, the Centers for Medicare and Medicaid Services now has the ability not just to provide coverage for additional preventive services recommended by the USPSTF (as it has since 2008), but also to modify coverage of existing preventive services (such as Medical Nutrition Therapy).

**The OCC urges the USPSTF to draft its recommendations with due consideration to its new statutory role and the manner in which the language of its recommendations has been and may be interpreted by regulatory authorities.**

For example, this Draft Recommendation proposes to update the USPSTF's 2003 Grade B recommendation for "Behavioral Counseling in Primary Care to Promote a Healthy Diet in Adults at Increased Risk for Cardiovascular Disease." The USPSTF recommended "intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians *or by referral to other specialists, such as nutritionists or dietitians.*" However, when CMS decided to provide coverage for the new preventive service of Intensive Behavioral Therapy for Cardiovascular Disease in 2011, the substance of the covered benefit was fundamentally different from the USPSTF recommendations. Not only did this new coverage fail to cover *explicitly recommended* referrals to the most qualified, effective, and cost-effective providers of this therapy—registered dietitian nutritionists—but the limit of just one covered "face-to-face CVD risk reduction visit every two years" is wholly irreconcilable with the USPSTF's recommendation for *intensive* behavioral dietary counseling.

**Given the statutory importance of and interpretive weight given to the USPSTF's recommendation itself, the USPSTF should include explicit language for appropriate providers similar to the 2003 Recommendation for "referral to other specialists, such as nutritionists or dietitians."**

Explicitly denoting the providers demonstrated effective in the relied-upon studies will best facilitate the substance of the USPSTF's Draft Recommendation. The OCC appreciates the USPSTF's recognition of its statutory ability to drive consequential, effective preventive care in this country, and we urge the USPSTF as it finalizes its recommendations to ensure to the extent possible that its recommended preventive services would be covered in substance and not in name only.

### **People First Language**

People with conditions such as obesity, autism, diabetes, or asthma prefer to be considered as people first, and not defined by their condition. And research shows that people-first language affects attitudes and behavioral intentions toward persons with disabilities. Because of this, people-first language has become the standard for most chronic diseases and disabilities.

The rules of APA Style (for professionals in psychology) calls for language in all publications to "put people first, not their disability" and to "not label people by their disability." Likewise, the American Medical Association (in their Manual of Style) requires authors to: "Avoid labeling (and thus equating) people with their disabilities or diseases (eg, the blind, schizophrenics, epileptic). Instead put the person first. Avoid describing person as *victims* or with other emotional terms that suggest helplessness (*afflicted with, suffering from, stricken with, maimed*). Avoid euphemistic descriptions such as *physically challenged* or *special*."

**We strongly encourage the USPSTF to revise the terminology used in its recommendation to recognize the medical conditions/diseases of overweight and obesity by referring instead to “adults with overweight or obesity.”**

Therefore, with consideration of the totality of the above comments, the OCC encourages the USPSTF to revise the language of the Draft Recommendation when finalized to:

**The U.S. Preventive Services Task Force (USPSTF) recommends offering or referring adults with obesity, or those with overweight who have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions or Medical Nutrition Therapy delivered by specialists such as a registered dietitian nutritionist, obesity medicine specialist, or other nutrition professional to promote a healthy diet and physical activity for CVD prevention.**

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher Gallagher".

Christopher Gallagher  
Washington Coordinator  
Obesity Care Continuum

### **About the Obesity Care Continuum**

The Obesity Care Continuum was established in 2011 and currently includes the Obesity Action Coalition, The Obesity Society, Academy of Nutrition and Dietetics, the American Society for Metabolic and Bariatric Surgery, and the American Society of Bariatric Physicians. With a combined membership of over 125,000 healthcare professionals and patient advocates, the OCC is dedicated to promoting access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity. The OCC also challenges weight bias and stigma oriented policies – whenever and wherever they occur.