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August 24, 2010

Donald M. Berwick, M.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1503-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Re: Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011

Dear Administrator Berwick:

On behalf of the Obesity Action Coalition (OAC), a national non-profit organization dedicated to helping those affected by obesity, we appreciate the opportunity to submit comments to the proposed rule: Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for calendar year (CY) 2011 that was published in the Federal Register on July 13, 2010. In particular, the OAC will be focusing its comments on preventive screening and referral for treatment services for Medicare patients affected by obesity.

#### SECTION 4103: MEDICARE COVERAGE OF ANNUAL WELLNESS VISIT PROVIDING A PERSONALIZED PREVENTION PLAN

##### Elements of a Personalized Prevention Plan

The OAC is pleased that the Affordable Care Act (ACA) included Medicare coverage for a number of preventive services, including BMI screening and referral for treatment services as recommended by the United States Preventive Services Task Force (USPSTF). Access to, and coverage for these preventive services is critically important for the Medicare population.

Multiple large epidemiologic studies have demonstrated that increasing body mass index (BMI), particularly above 30 (defined as obesity), is associated with an increased risk of death or premature mortality. For this reason, the OAC is supportive of the Centers for Medicare & Medicaid Services' (CMS) proposed approach for implementing the personalized prevention plan as required by the ACA, including the need for a written checklist of an individual's screening schedule. We agree with CMS that it is important that this written schedule contain a comparative list of an individual's health status, risk factors, personal and family history along with the screening and preventive services he or she should be receiving for the next 5-10 years using a method such as a "checkbox" to ensure that screening and preventive services were obtained in a timely manner instead of waiting for an entire 12 months to verify that they were received.

OAC also believes it is important that this checklist contain not only those services that Medicare covers but also services that may be appropriate for individual patients, regardless of coverage status. Insurance coverage alone should not be the deciding factor regarding whether a screening or preventive service should be discussed with a patient. Treatment approaches should include: community-based programs; lifestyle interventions; educational programs; drug, diet and physician-supervised programs; and surgery.

This point is extremely critical in the case of those affected by obesity because patients and their healthcare providers need an arsenal of treatments -- as any one treatment may not work for every individual. Furthermore, patients must have access to this comprehensive treatment approach through reasonable means and this access to care should not be hindered by undue tests or prerequisites on the part of the patient.

The OAC will be very interested to see how CMS will “treat” the Medicare patient who is categorized as obese during their Initial Preventive Physical Examination (IPPE). The proposed rule defines “personalized health advice and referral, as appropriate, to health education or preventive counseling services or programs” as those, which are “*aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition; and any other element determined appropriate by the Secretary through the National Coverage Determination process.*”

The USPSTF recommends “clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.” In further defining what the Task Force means by “intensive counseling and behavioral interventions,” we believe that CMS should consult the attached *Managing Obesity: A Clinician’s Aid* – a publication developed by the Agency for Healthcare Research and Quality (AHRQ), which is the parent agency for the USPSTF.

Within the AHRQ document, the agency includes a section entitled “Counsel Intensively, or Refer” that suggests the following interventions:

**The most effective interventions to help patients change their eating patterns and become physically active combine:**

- **Nutrition education.**
- **Diet and exercise counseling.**
- **Behavioral strategies.**
- **High-frequency interventions—i.e., more than 1 person-to-person (individual or group) session per month for at least 3 months—can lead to a 3-6 kg weight loss maintained for more than 2 years.**
- **Maintenance interventions help people sustain weight loss over time.**

It is also interesting to note that the description of purpose on the document states: “This clinician’s aid highlights research from AHRQ’s evidence-based practice program. This research informs many science-based recommendations in the public and private sectors, including the U.S. Preventive Services Task Force (USPSTF).”

List of Risk Factors and Conditions

The OAC applauds CMS for calling for establishment of “*a list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under § 410.16), and a list of treatment options and their associated risks and benefits.*”

We believe that obesity must be included in such a list given the proven benefits of treatments of obesity as well as the profound risks associated with failure to treat obesity. Furthermore, subsequent Annual Wellness Visits should also promote behavioral and medical support for patients -- both prior to, and after a secondary or tertiary intervention.

#### Subsequent Annual Wellness Visits

Finally, OAC disagrees with the agency's proposal that BMI need not be calculated during subsequent annual wellness visits because "given the general stability of adult height, we would not expect the BMI to meaningfully change in the absence of significant weight change. We have not in the definition of the subsequent annual visit required measurement of the individual's height."

We believe that measurement of BMI must be viewed as a vital sign that should be included in any annual wellness visit. Annual monitoring of weight is widely endorsed. It is very important to monitor trajectory of weight change, since identifying small weight gain from year to year can lead to preventive actions on the physician's part. Annual calculation of BMI is also important. It is not widely recognized that the amount of weight gain to increase BMI by one unit is only about 5-6 pounds on average. The natural history of obesity is that one frequently observes only a small annual weight gain (1-2 kg) that, over time, results in significant risk of overweight or obesity. Thus, an annual calculation of BMI would be important for assessing health risk.

Again, we appreciate the opportunity to comment on the proposed rule for the 2011 Medicare Physician Fee Schedule. Should you have any questions, please feel free to contact me or OAC Washington Policy Consultant Christopher Gallagher at 571-235-6475.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Nadglowski, Jr.", written in a cursive style.

Joseph Nadglowski, Jr.  
President/CEO