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February 21, 2013

Jyme H. Schafer, MD, MPH  
Director, Division of Medical and Surgical Services  
CMS/OCSQ/Coverage and Analysis Group  
7500 Security Blvd. Mailstop C1 -09-06  
Baltimore, MD 21244

Dear Dr. Schafer,

The Obesity Action Coalition (OAC) appreciates the opportunity to provide the following public comment regarding the Centers for Medicare & Medicaid Services (CMS) January 24, 2013 national coverage analysis (NCA) surrounding the facility certification requirement for "Surgery for the Treatment of Morbid Obesity (CAG-00250R3)." Our comments represent the views of our 42,000 members, the vast majority of whom have personally struggled with obesity and sought obesity treatment.

While we defer to clinical and scientific organizations such as the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS) to comment on the quality of the outcomes data, the OAC urges CMS to adopt a measured approach surrounding facility certification and surgical volume requirements. Recognizing the complexity of the issue, OAC urges CMS to retain the facility certification requirement but allow the certifying bodies flexibility in setting surgical volume requirements.

#### **Bariatric Surgery Accreditation Is About More than Just Safety**

While there is little doubt that patient safety improved since CMS issued its national coverage decision for bariatric surgery in 2006, we believe it would be short-sighted if CMS focused solely on 30-day surgical mortality/morbidity as the agency examines its coverage criteria.

Bariatric surgery is about long-term health improvement and that while a safe surgical procedure is the first step in the process; it does not guarantee successful long-term outcomes. In our opinion, the keys to successful long-term patient outcomes revolve around comprehensive care including patient commitment, a multidisciplinary treatment team approach and long-term follow-up. We would suggest that bariatric surgery is similar to transplant care in this aspect and that CMS should consider transplant data in its review of this analysis.

While we acknowledge that patient safety has greatly improved in the current environment, it is not always assured in every program. Past media headlines featuring California's "800-GET-THIN" program are clear evidence that bariatric surgery carries risks and all programs should not be providing Medicare bariatric surgical services.

#### **Accreditation Assures Program Commitment**

Our fear is that without facility certification, we will see care focused solely on the surgical event and not the long-term health outcomes of a patient. Accreditation helps assure a comprehensive approach through the commitment of bariatric surgery programs (through their many requirements dictating resources and program details) offering the services necessary to give a patient the best opportunity for long-term health. One fear is that unaccredited programs would neglect the wide variety of services (such as nutrition, exercise and support groups) that contribute to patient success.



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#### **Current Accreditation Volume Requirements May Need to be Reconsidered**

We acknowledge that volume appears to be a less significant factor in short-term bariatric surgical outcomes based upon the data from the NCA requestor and others. Currently, the NCD for bariatric surgery requires a minimum volume of 125 cases per-institution. We recognize in some cases that the 125 case surgery volume requirement has effectively limited the number of institutions where Medicare beneficiaries can obtain bariatric surgical care and likely denies some quality programs access to the Medicare population. As a result, patients sometimes need to travel significant distances for surgical intervention – making follow-up and complication-care extremely problematic. With that being said, the current volume requirements enable bariatric programs to have the financial resources required to support long-term patient support programs.

OAC is open to the volume requirement being lowered, ideally by the ASMBS and ACS in conjunction with CMS, to improve access, however, it is **essential** it is done so in combination with efforts that guarantee program commitment and long-term services for Medicare recipients who receive bariatric surgery. We believe facility certification helps guarantee such commitment.

Therefore, we recommend that CMS maintain the facility certification requirement but allow the certifying bodies the flexibility to modify volume requirements. Maintaining the other facility and program requirements will ensure the appropriate patient resources and multidisciplinary treatment team are in place – allowing patients to receive the best standards of care, both in terms of the care coordination, and the clinical environment in which they are delivered.

Thank you,

A handwritten signature in black ink, appearing to read "Joe Nadglowski".

Joe Nadglowski, OAC President and CEO