December 19, 2005

Ross Brechner, MD, MS(Stat.), MPH
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore MD 21244-1850

Dear Dr. Brechner:

On behalf of the Obesity Action Coalition (OAC), I would like to take this opportunity to thank the Centers for Medicare and Medicaid Services (CMS) for their efforts in reviewing the scientific-evidence validating bariatric surgery as an effective treatment of morbid obesity and proposing rules that would expand access to bariatric surgery. The OAC strongly supports the coverage of weight-loss surgery as studies show the surgical treatment of morbid obesity decreases mortality, improves or resolves obesity-related illnesses and improves quality of life.

As background, the OAC is a non-profit organization dedicated to bringing a patient voice to the obesity crisis in the United States. The OAC encourages patients to educate themselves about obesity, its complications and treatments. We believe that educated patients are best able to make decisions about their healthcare, and therefore are able to be healthier and happier. The OAC encourages patients and their families to support one another, as there is no one better to share the social, emotional, physical and medical impact of obesity than people who have been personally affected. The OAC empowers patients to become proactive advocates for change by helping to eliminate the negative stigma associated with obesity and working to ensure that obesity is treated as a national disease.

The OAC would like to raise the following concerns regarding National Coverage Decision (NCD):

**Medicare Recipients 65 and Older**

In the NCD, CMS specifically cites data from a recent study by David Flum, MD, which illustrates an elevated risk for older patients as their reason for non-coverage of those 65 an older. However, Dr. Flum points out in his study, and in his own comments to CMS, that the risks of weight-loss surgery among those 65 and older were similar to younger patients when performed by experienced surgeons. As such, the OAC is requesting that Medicare cover surgery for those more than 65 years of age under Medicare’s Coverage with Evidence Determination (CED) program, with the conditions that surgeons be appropriately experienced (granted status as an American Society of Bariatric Surgeons’ Centers of Excellence Program or similarly developed future programs) and that mortality and complication data be collected to evaluate the potential of a future expansion of coverage.
Previous Unsuccessful Medical Treatment

The NCD mentions a requirement of previous unsuccessful medical treatment of obesity but does not apply specific definitions or requirements. As there is no clinical evidence that such programs improve the outcomes of weight-loss surgery and as requirements can vary widely between Medicare intermediaries, the OAC requests that Medicare adopt a policy of three to six months of medically supervised (physician, allied health professional or commercial agency) weight-loss during the past five years but not necessarily within one year of surgery.

Biliopancreatic Diversion with Duodenal Switch (BPD/DS)

Although not as common as gastric bypass and laparoscopic adjustable banding procedures, BPD/DS may be the preferred surgery type for some patients. The OAC believes that a patient and their surgeon are best able to make the appropriate decision regarding their surgery options. As such, the OAC is also requesting that Medicare’s CED program be utilized to allow for coverage of BPD/DS under similar circumstances to the 65 and older population – a requirement for appropriately experienced surgeons and data collection for comparative studies to other types of weight-loss surgery.

Payment of Follow-up Visits

As part of the OAC’s belief that comprehensive long-term follow-up care is required to be a successful weight-loss surgery patient, the OAC is concerned that follow-up physician and healthcare professional visits are not discussed in the NCD. Such visits could include follow-up consultations with a surgeon and/or dietitian and in the case of laparoscopic adjustable banding patients, required fills to assure their band is working effectively. The OAC requests Medicare adopt policies to allow for coverage of medically necessary follow-up care.

Obesity is a disease. It is not simply a condition caused by overeating. As such, patients, with guidance from healthcare professionals, should have access to appropriate medical care to treat the disease. Bariatric surgery is the most successful option for treating morbid obesity currently available and too often, appropriate candidates are denied access to this life-changing and life-saving treatment. The OAC believes that the proposed new rules for bariatric surgery, with the adjustments suggested above, will guarantee appropriate candidates have access to high-quality, safe and effective treatment of their obesity.

Thank you for the opportunity to comment. If you have any questions, please do not hesitate to contact the OAC at (800) 717-3117.

Sincerely,

Joseph Nadglowski Jr.
President & CEO