Obesity Action Coalition

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Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

On behalf of the nearly 50,000 members of the Obesity Action Coalition (OAC), I would like to express our deep concern regarding the Centers for Medicare & Medicaid Services (CMS) June 27, 2013 Proposed Decision Memo on Facility Certification for Bariatric Surgery for the Treatment of Morbid Obesity (Facility Certification Requirement CAG-00250R3). The Memo states that CMS believes "the evidence is sufficient to conclude that continuing the requirement for certification for bariatric surgery facilities would not improve health outcomes for Medicare beneficiaries." We strongly disagree with such a statement and urge significant caution around basing such an important decision on very limited and mixed evidence.

The 2006 bariatric surgery center facility requirements that the agency now proposes to eliminate broadly include procedure volume requirements for surgeon and facility, as well as establishment and maintenance of an integrated program for the care of Medicare patients affected by severe obesity.

The OAC acknowledges that procedure volume requirements likely should be lowered to allow more facilities to participate as a qualified certified facility. Such an approach is already encompassed in the new MBSAQIP being jointly developed by the American Society for Metabolic and Bariatric Surgery and the American College of Surgeons – the two scientific organizations that were deemed acceptable for Medicare COE certification under the February 2006 NCD. However, we worry that the agency, in focusing on the volume requirements, is overlooking the critical benefits of certification associated with maintaining a solid integrated program – one that is specifically tailored to the long term needs of those affected by the disease of severe obesity.

For example, the 2006 NCD states that bariatric surgery Centers of Excellence (COE) "must have ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance, as needed; and a multidisciplinary bariatric surgery team with written descriptions of the responsibilities of each member of the team." Furthermore, this team "must be comprised of individuals with the appropriate qualifications, training and experience in the relevant areas of bariatric surgery, rehabilitation, critical care anesthesia, and nutrition counseling for those affected by morbid obesity and post-bariatric surgery patients." Finally, Medicare COEs "must have sufficient operating room tables, equipment, instruments and supplies specifically designed or appropriate for bariatric surgery; a recovery room capable of providing critical care to patients affected by obesity; and an intensive care unit with similar capabilities."

We strongly believe that Medicare patients continue to need access to the appropriate treatment tools and clinical environment necessary, as detailed above, to receive both safe and effective treatment for the disease of obesity and severe obesity and that an elimination of certification will likely allow facilities providing bariatric surgery to either open without such services and/or we could see facilities eliminate such services.

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Validating the above, we would direct CMS to the latest scientific studies that demonstrate the clear benefits for patient care surrounding accreditation. For example, a new study co-authored by Ninh T. Nguyen, MD, FACS, vice-chair of the department of surgery at UC Irvine School of Medicine, found non-accredited bariatric surgery centers had an in-hospital mortality rate that was more than three times higher than accredited centers (0.22% vs. 0.06%, respectively) with similar volume. These findings suggest that the standards required for accreditation provide important pre-operative and post-operative life-saving safeguards for patients – particularly for those at high risk for surgical and obesity-related complications.

Improved access to bariatric surgery is one of the main reasons cited driving this policy change. However, we were surprised to see no analysis included in the coverage decision on whether or not access to bariatric surgery, because of facility certification, is a problem. While we acknowledge that the OAC initially received complaints from Medicare recipients unable to identify a certified facility in their area; we are happy to report that we have not received any such complaints in years following the maturity of the ASMBS and ACS COE certification programs. However, we do receive complaints from Medicare recipients surrounding Medicare Contractor decisions related to the vague medical weight management requirements included in the NCD, gastric sleeve coverage or difficulty in securing a revision procedure. In fact, we would argue that the lack of clarity around both the medical weight management issue and lack of guidelines on revision procedures are the primary barriers to bariatric surgery among Medicare recipients affected by severe obesity, not facility certification.

The OAC believes that CMS must reject its proposal to eliminate the bariatric surgery facility certification requirement. We stand by our original comment on this issue urging CMS to maintain certification, but work with both ASMBS and ACS to develop a dynamic certification program – adapting to the latest scientific advancements in bariatric surgery and care coordination. This would allow an increase in the number of legitimate hospital-based bariatric surgery programs. Elimination of bariatric surgery facility certification is clearly at odds with previous CMS policy supporting patient safety and measures that promote improved outcomes. Please do not jeopardize the substantial progress that has been made in bariatric surgical outcomes by eliminating Medicare's requirements for facility and personnel resources. Such a decision could have deadly consequences for thousands of future Medicare patients.

Sincerely,

Joseph Nadglowski
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