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Dear Dr. Schafer,

We are writing to make a formal request that CMS reconsider its National Coverage Decision (NCD) related to professional and hospital services for bariatric surgery. That NCD, which took effect February, 2006, established which procedures would and would not be covered, under what clinical indications, and at what facilities. With regard to the last, the NCD restricted coverage of bariatric surgery to hospitals designated as Level 1 by the American College of Surgeons (ACS) or as Centers of Excellence (COEs) by the American Society of Metabolic and Bariatric Surgery (ASMBS). (In this letter, we refer to both groups as "COEs.")

This request for NCD reconsideration focuses on the component specific to COE designation. Although we believe that the original NCD was reasonable based on information available in 2006, more recent scientific evidence calls into question whether the policy continues to serve the interests of Medicare patients.

While this letter is not intended to represent a comprehensive review of all published research, we believe that the best evidence currently available indicates that:

1. Hospitals designated as COEs by either ACS and/or ASMBS are not safer than non-COEs, defeating the primary purpose of this component of the NCD.
2. Independent of the 2006 NCD, mortality and serious complication rates with bariatric surgery have declined considerably across the US and are now considerably lower than those of most common inpatient surgical procedures covered without restriction by CMS.

Comparative quality of COEs and non-COEs

At the time of the original NCD in 2006, there were no evidence-based criteria for defining COEs in bariatric surgery. Instead, separate committees of the ACS and the ASMBS (with its vendor partner Surgical Review Corporation) developed criteria based largely on clinical consensus. In short, hospitals had to 1) meet a long list of structural requirements (mainly resources required for severely obese patients receiving any type of hospital care), 2) meet minimum hospital volume standards (125 bariatric cases per year), and 3) submit data to national registries administered by the two societies.

Two published studies—each based on different patient populations—provide evidence that these COE criteria have failed to identify safer hospitals for bariatric surgery. In both cases, patients at COEs had equivalent rates of death or complications as patients treated at non-COEs.

Table 1. Outcomes of bariatric surgery at COE vs. non-COE hospitals

Author (source)	Data source / study population	Main finding
Livingston et al. (*Arch Surg*, 2009) (1)	National Inpatient Sample (n=24,383)	In-hospital mortality: COE, 0.17% vs. non-COE, 0.09%; p=0.13 Complications: COE, 6.3% vs. non-COE, 6.4%; p=0.93
Birkmeyer NJ et al. (*JAMA*, 2010) (2)	Externally audited, population-based clinical outcomes registry in Michigan (n=15,275)	Serious complications: COE, 2.7% vs. non-COE, 2.0%; p=0.41

These findings indicate that the criteria used for COE designation are collectively not associated with patient safety outcomes. Second, it suggests that the 125 case per year volume threshold, which was set somewhat arbitrarily, does not reliably discriminate hospital performance. While numerous studies have demonstrated hospital volume-outcome relationships with bariatric surgery, this effect is relatively small (compared to cancer surgery, for example) and has declined over time as the field has matured. Finally, while both societies required that hospitals submit outcomes data to these registries, these data have never been used to assess hospital quality, provide feedback to providers, or as a component of COE determinations.

Declining morbidity and mortality

In restricting coverage to certain hospitals, CMS was concerned about the general safety of bariatric surgery and about variation in outcomes across hospitals. In light of a national study by Flum et al. documenting high morbidity and mortality in Medicare patients, that concern was justified at the time of the original NCD. (3)

Since 2006, however, morbidity and mortality with bariatric surgery has declined substantially. According to large, population-based studies, overall perioperative mortality is now less than 2 per thousand (0.2%). Estimates of complication rates vary according to how adverse events are defined and across procedures. In a large Michigan study based on externally-audited, clinical data, serious complications occurred in less than 3% of patients undergoing bariatric surgery between 2006 and 2009.

As a result of increased age and higher comorbidity burdens, Medicare patients have higher morbidity and mortality rates than other patients. With falling complication rates, however,

disparities in outcomes between Medicare and non-Medicare patients, originally quite marked, have converged considerably over time.

Declining morbidity and mortality with bariatric surgery no doubt reflect numerous factors. As the field has matured and bariatric surgery has become commonplace, hospitals and surgeons have accrued more experience and proficiency. New surgeons have more training in bariatric surgery during their residencies and fellowships and hospitals have tightened up credentialing requirements. In addition, technology has improved and bariatric surgery has evolved from a predominantly open to a laparoscopic discipline.

Regardless of the underlying reasons, bariatric surgery now has a safety profile comparable to procedures as ubiquitous as total hip or knee replacement, hysterectomy, or robotic prostatectomy. It is markedly safer than coronary artery bypass, colectomy and virtually every other major cardiovascular or cancer procedures covered without restriction by CMS.

Recommendations for a revised NCD

We believe that CMS should abandon the COE component of the NCD altogether, as many large private payers have already done. The data presented above suggests that hospital-specific coverage restrictions can no longer be justified on safety grounds. More broadly, the field of bariatric surgery has matured and can no longer be considered investigational or a "special case," like lung reduction surgery, carotid arterial stenting or other procedures with which it is commonly lumped. At 200,000 procedures annually, bariatric surgery is the third most common abdominal procedure performed in the US (behind gallbladder surgery and appendectomy). Its effectiveness has also become better studied and understood than the large majority of common inpatient procedures covered without restriction by CMS. Despite recent debates about specific procedures (e.g., sleeve gastrectomy), a growing list of randomized trials and other high impact studies, many published in the *New England Journal of Medicine*, suggest that bariatric surgery extends longevity in morbidly obese patients and is highly effective in achieving substantial weight loss and in improving diabetes and other weight-related comorbidities. (4-7)

In addition to reducing the access of Medicare beneficiaries to services with proven benefit, the NCD is unfair to smaller hospitals and others not designated as COEs by the professional societies. Hospitals that are designated as COEs are subjected to ongoing society fees and other substantial costs associated with maintaining that status.

Despite our concerns about the COE component of the NCD, we believe that CMS should continue to encourage surgeons of all specialties to participate in clinical outcomes registries and quality improvement programs. In the case of bariatric surgery, surgeons could choose to participate in registry programs administered by professional societies, payer-supported collaborative improvement programs (like those in Michigan or Washington State), or other qualified organizations. Although participation would not be mandated, CMS could encourage such activities through PQRS and other incentive-based mechanisms.

Thank you in advance for your consideration. Please let us know if additional information would be useful.

Yours truly,

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