News from the American College of Surgeons
and the American Society for Metabolic and Bariatric Surgery

FOR IMMEDIATE RELEASE

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MAJOR MEDICAL SOCIETIES URGE MEDICARE TO RECONSIDER PROPOSED DECISION TO DROP BARIATRIC SURGERY FACILITY CERTIFICATION REQUIREMENT

Decision May Significantly Raise Risk of Mortality for Medicare Bariatric Surgical Patients

GAINESVILLE, FL -- July 31, 2013 -- The Centers for Medicare & Medicaid Services (CMS) is considering a reversal of its 2006 decision requiring certification of facilities that perform bariatric surgery, a move the American Society for Metabolic and Bariatric Surgery (ASMBS), the American College of Surgeons (ACS), and other medical societies say could endanger Medicare patients who undergo bariatric surgery.

In a joint letter to CMS, the societies say they "believe the proposal to remove the Bariatric Surgery Facility Certification will place the highly vulnerable Medicare population at risk" and "is based upon an incomplete review and analysis of the evidence." The ASMBS and ACS, joined by The Obesity Society, American Society of Bariatric Physicians and The Society of American Gastrointestinal Endoscopic Surgeons, collectively wrote that they "strongly oppose CMS' decision to overturn current, established policy."

"Substantial gains have been made in the quality of bariatric surgery because of certified and accredited programs," said David B. Hoyt, MD, FACS, ACS Executive Director. "This proposed decision by CMS could be a setback, particularly for the Medicare beneficiaries, who have a higher risk of morbidity and mortality than the general bariatric surgery population."

"The evidence shows facility certification, and all that it entails, improves patient outcomes and reduces risk," said Jaime Ponce, MD, ASMBS President. "There is very little rationale to reverse a policy that has clearly worked. We urge CMS to continue the facility certification requirement."

In its proposed decision memo, CMS said "there is little evidence that the requirement for facility certification/COE (center of excellence) designation for coverage of approved bariatric surgery procedures impacts outcomes for Medicare beneficiaries."

However, the societies counter that numerous studies point to the positive impact of facility certification, including a new study, not yet considered by CMS that found non-accredited bariatric centers had an alarming in-hospital mortality rate more than three times higher than accredited centers (0.22% vs. 0.06%). University of California Irvine researchers analyzed 277,760 bariatric procedures performed between 2006 and 2010. The study is in press for publication in the journal *Surgical Endoscopy*.

During its public comment period, which closed on July 26, 2013, CMS received nearly 500 comments, the vast majority opposing CMS' proposed change in policy and supporting facility certification as a condition of coverage. CMS is expected to make its final ruling by the end of September 2013.

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About The American College of Surgeons
The American College of Surgeons is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and to improve the quality of care for surgical patients. The College is dedicated to the ethical and competent practice of surgery. Its achievements have significantly influenced the course of scientific surgery in America and have established it as an important advocate for all surgical patients. The College has more than 79,000 members and is the largest organization of surgeons in the world. For more information, visit www.facs.org.

About the ASMBS
The ASMBS is the largest organization for bariatric and metabolic surgeons and integrated health professionals in the world. It is a non-profit organization that works to advance the art and science of bariatric surgery and is committed to educating medical professionals and the lay public about bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in bariatric surgery, while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for morbidly obese patients. For more information, visit www.asmbs.org

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Source: American Society for Metabolic and Bariatric Surgery and American College of Surgeons

Friday, July 26, 2013

Louis Jacques, MD
Director, Coverage and Analysis Group
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Dear Dr. Jacques,

The American Society for Metabolic and Bariatric Surgery and American College of Surgeons along with all the undersigned professional societies have reviewed the Centers for Medicare and Medicaid Services (CMS) early-released June 27, 2013 Proposed Decision Memo on Facility Certification for Bariatric Surgery for the Treatment of Morbid Obesity (Facility Certification Requirement CAG-00250R3). **As organizations committed to quality improvement and safety protections for our patients, we fully support the continuation of the Facility Certification Requirement established in 2006; and therefore, strongly oppose CMS' decision to overturn current, established policy.**

We are concerned that the Proposed Decision Memo to remove the Bariatric Surgery Facility Certification requirement is a radical departure from previous Bariatric Surgery quality initiatives, is contrary to general CMS Facility Certification efforts, and is based upon an incomplete review and analysis of the evidence. In addition, we believe the proposal to remove the Bariatric Surgery Facility Certification will place the highly vulnerable Medicare population at risk. We believe that the Proposed Decision Memo to remove Facility Certification is not compatible with CMS published standards of scientific integrity and relevance. While concern regarding access has been raised, little evidence supports diminished access to care with substantial increases in Medicare bariatric surgery since the 2006 NCD. Furthermore, within the unified Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MSAQIP), there are 725 Accredited Centers nation-wide and, with a new lowered volume standard of 50 stapled bariatric cases annually, we anticipate even more accredited centers with the same demonstrated level of quality that beneficiaries and the Medicare program have come to rely upon. Finally, removal of the Bariatric Surgery Facility Certification puts CMS in the unique situation of being the only major insurer not providing Facility Certification for Bariatric Surgery.

We appreciate the opportunity to provide comments on this Proposed Decision memo. However, given the quality and safety implications for Medicare patients, we are concerned with the lack of communication between CMS and our organizations as the administrators of the accreditation programs most active in bariatric surgery. In this capacity, both ASMBS and ACS have a tremendous amount of data and experience that could help CMS better understand the value of

accreditation for patients; yet, CMS has sought little counsel from our organizations, while using language in the Proposed Decision memo that seems to rely almost solely on information from a single source. Of note, we have polled out membership regarding bariatric surgery facility certification and have found that over 80% support continued facility certification. We ask you to carefully review the contents of this letter and come to the appropriate conclusion that Bariatric Surgery Facility Accreditation continue with a lowered volume standard.

Previous Evidence for Facility Accreditation

We have previously reviewed the evidence supporting Facility Accreditation in our letter dated February 22, 2013 (http://asmbs.org/2013/02/cms-responses-facility-accreditation/#CMS Response to Facility Accreditation). At the time of the February 2013 letter, there were **seven** studies in support of facility accreditation and **two** studies against facility accreditation. The first study offered against facility accreditation was the 2009 *Archives of Surgery* Livingston publication. It should be noted that the Livingston study utilized 2005 Nationwide Inpatient Sample data, which **predates** the 2006 NCD. The second article cited against facility certification was from Birkmeyer in a *JAMA* 2010 article. At the time of study, it should be noted that of the **25 hospitals participating in the Michigan Bariatric Surgery Collaborative (MBSC) 19 were Centers of Excellence**. Participation in MBSC has virtually the same elements as the current accreditation process. In addition, in closer examination of the study, there is a question of how applicable these results are for Medicare patients. In the MBSC, the average BMI and Age was a modest 46 with a peak of 56 for both demographic measures. This MBSC population may not be generalizable to the Medicare population, which tends to be older and heavier (Yuan *SOARD* 2009).

New Evidence Regarding Facility Accreditation

Since our February 22, 2013 letter, there have been two new relevant publications that merit review. In the proposed June 27, 2013 decision memo, the 2013 *JAMA* Dimick article is given ample weight as demonstrating lack of support for facility accreditation. This article like the other articles utilize administrative, claims data. It is important to reference the 2011 Flum study which clearly demonstrates the value of accreditation **specifically for Medicare beneficiaries** whereby 90-day mortality fell 50% (1.5% to 0.7%), readmissions decreased 25% (19.9% to 15.4%), reoperations declined 33% (3.2% to 2.1%) and costs fell 20% ($24,363 to $19,746) post-NCD.

***JAMA* Dimick 2013**

As outlined in the Morton/Nguyen commentary (*SOARD* 2013), the Dimick study found the same improvement for the Medicare population with reductions in any complication (12.3% to 7.9%) and serious complications (7.5% to 3.4%) after the NCD, as did the Flum study. Not surprisingly, the comparison population (Non-Medicare) had the same improvement. Surprisingly, the authors do not utilize mortality as an outcome. What is stunning is that the improvements in outcomes between Medicare and Non-Medicare populations were not significantly different is noteworthy given the high comorbid condition of the Medicare population. The authors utilize a difference-in-differences analysis and make a flawed

assumption that the control group wasn't exposed to the policy change. By 2006, non-Medicare patients were already exposed to the accreditation process given the requirement by private payors for hospital accreditation and that accreditation by ACS and ASMBS **preceded** the CMS NCD. Health policy impact analysis is commonly performed by Joinpoint regression analysis not by the econometric difference-in differences techniques. Furthermore, the authors don't account for migration to and from accredited status.

Another major limitation to the study is administrative data, which lack specificity and sensitivity for complication reporting, as well as the data source, which is only for 25% of the nation. The study notes robust improvements for bariatric surgery may be due to greater utilization of laparoscopy, increasing surgeon experience, and fellowship training. All of these drivers for improvement were *accelerated* by facility accreditation, which provides a vehicle for hospital resource prioritization. The authors' main objection against accreditation is the issue of limiting access. This is unfounded. In their own study, access for bariatric surgery in Medicare beneficiaries actually *did* improve after the NCD. Operations in Medicare beneficiaries increased from 6,273 procedures pre-NCD to 15,854 post-NCD. The article also inaccurately asserts a minimal volume effect in bariatric surgery despite multiple studies confirming that volume improves outcomes including a study by the article's senior author.

Surgical Endoscopy Nguyen 2013

Many of the studies, either for or against facility certification, cite the difficulty in determining if the benefit of Bariatric Surgery Facility Certification is due to Accreditation or to a Volume Standard, which is a component of Facility Certification. In the recent *Surgical Endoscopy* study, Nguyen addresses both the utility of facility accreditation and the volume threshold. In Nguyen's study "Volume and Outcome relationship in Bariatric Surgery in the Laparoscopic Era," he utilized 2006-2010 laparoscopic, stapled bariatric surgery data from the Nation-Wide Inpatient Sample (NIS). Of note, the Dimick study utilized State-Inpatient Databases, which are a component of the NIS. In the Nguyen study, he found 277,760 cases performed between 2006-2010 with 85% performed at high volume centers (HVC, annual volume >50). The mean number of annual laparoscopic stapled cases at HVC was 144 ± 117 and at LVC 17 ± 14. In-patient hospital mortality was 0.17% at LVC and 0.07% at HVC.

Within the HVC population alone, the in-hospital mortality at HVC non-accredited centers was 0.22% and at HVC accredited centers it was 0.06%. Once correcting for confounders with multivariate analysis, non-accredited centers had significantly higher mortality (odds ratio 3.6, 95% CI, 1.5, 8.3, $p<0.01$) and lower serious morbidity (odds ratio 0.8, 95% CI, 0.7, 0.9, $p<0.01$). Accredited high volume centers have significantly lowered in-patient mortality while non-accredited high volume centers have worse mortality outcomes indicating that accreditation provides a benefit beyond volume. While non-accredited, high volume centers have less serious morbidity; this is coupled with significantly higher mortality indicating a *failure to rescue* patients who have complications. Hallmarks of accreditation include culture of commitment, proven experience, ancillary staff and bariatric specific resources, which are critical for the rescue of these patients if they encounter complications.

In addition to safeguarding compromised patients, the accreditation process has also contributed to enhancing bariatric surgery effectiveness. A key component of facility accreditation includes

appropriate patient selection whereby key personnel provide essential service to the accredited bariatric center. The preoperative evaluation of the patient seeking bariatric surgery involves multiple professional disciplines, including surgery, internal medicine, registered dieticians, cardiology and mental health professionals (Mechanic *SOARD* 2008). Without the facility certification requirement, nutritional/psychological evaluation services may not be provided or supported (Wadden & Sarwer, *SOARD* 2006).

CMS and Facility Certification

In addition to the new evidence to be reviewed, we believe that this proposed decision to remove Bariatric Surgery Facility Accreditation is a radical departure from previous CMS policy. The following interventional National Care Determinations all have facility criteria requirement and/or certification: Adult Liver Transplantation (260.1), Artificial Hearts and Related Devices (20.9), Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24), Pancreas Transplants (260.3), Lung Volume Reduction Surgery (Reduction Pneumoplasty) (240.1), Pediatric Liver Transplantation (260.2), Transcatheter Aortic Valve Replacement (TAVR) (20.32), and Transmyocardial Revascularization (TMR) (20.6). Of note, some these NCD facility criteria requirement and/or certification have existed for over 20 years. While substantial gains have been made in bariatric surgery, quality and patient safety are enduring goals that best take place in the setting of Facility Certification. Facility Certification allows for the marshaling of needed resources from a hospital perspective such as data collection, which may not occur with Facility Certification.

As noted previously and below, the four main private payors have embraced and continue to support bariatric surgery facility accreditation as confirmed by ASMBS leadership (all accessed July 2013). Removal of bariatric surgery facility certification would place CMS in the unique situation of being the only major payor not to have Facility Certification for Bariatric Surgery for a highly vulnerable population.

Aetna
"Institutes of Quality Bariatric Surgery Facilities"
http://www.aetna.com/healthcare-professionals/quality-measurement/institutes.html
http://www.aetna.com/healthcare-professionals/documents-forms/Bariatric_IOQ_Program_Requirements.pdf

Anthem Blue Cross and Blue Shield / Wellpoint
"Blue Distinction Centers for Bariatric Surgery"
http://www.anthem.com/wps/portal/ahpfooter?content_path=shared/noapplication/f0/s0/t0/pw_ad093285.htm&label=Centers%20for%20Excellence
http://www.anthem.com/shared/noapplication/f0/s0/t0/pw_ad093282.pdf?refer=ahpfooter

Cigna
"3 Star Quality Bariatric Centers"
http://www.cigna.com/healthcareprofessionals/resources-for-health-care-professionals/health-and-wellness-programs/certification-for-bariatric-surgery.html
http://www.cigna.com/assets/docs/health-care-professionals/3star_designation.pdf

United Healthcare / Optum Health
https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/UnitedHealthcare%20Medicare%20Coverage/Obesity_SH_Ovations.pdf
https://www.myoptumhealthcomplexmedical.com/gateway/public/bariatric/bariatric.jsp
https://www.myoptumhealthcomplexmedical.com/gateway/cmsrepository/DOCUMENT/1354747298296_121205_BRS_Internal_COE_MAP_md_w_UHC_brand_md.pdf

The Medicare population is at high risk

The Medicare population is specifically an at-risk population for obesity and its consequences. Eligibility for Medicare benefits include age >65 and disability including end-stage renal disease (ESRD). Numerous studies have detailed the impact of obesity leading to disability. In a 2008 *Obesity Review* article, Neovius and colleagues found that patients with a BMI>35 had a Three-Fold risk of being disabled. The same article highlighted the strong impact of bariatric surgery upon potential reversal of disability with a doubling of return to work for obese disabled patients who had surgical treatment for their obesity. Flegal in a 2010 *JAMA* article found a 12.1 % incidence of BMI>35 in the population age>60. Obesity has also been found to lead to increased waiting times for ESRD patients awaiting transplant leading to weight-related disparities in care for these Medicare patients in need (Segev, *J Am Soc Nephrol*, 2008*).*

The specific impact of Medicare status upon bariatric surgery outcomes is undeniable: *Medicare patients have higher risk of morbidity and mortality than the general bariatric surgery population*. In *American Surgeon*, Carbonell et al reported in 2005 that age greater than 60 years, Medicare or Medicaid-insured status, and surgery performed in nonteaching, large, urban-located hospitals with low case volumes is associated with longer LOS and higher charges. In another 2005 *American Surgeon* article, Poulose found that Medicare coverage compared to private insurance increased the risk of post-operative respiratory failure significantly (OR 2.2 [1.2-3.8], $P < 0.05$).

In a 2006 *Archives of Surgery* publication by Livingston, he found Medicare status unadjusted for age, gender, and comorbidities had an increased odds ratio for mortality of 4.31 and once adjusted 1.44. In a 2006 *American Surgeon* article by Nguyen, Nationwide Inpatient Sample patients similar to Medicare population (age>60) had more than twice the mortality rate as younger patients (0.7 vs. 0.3%). In a *SOARD* 2009 article, Yuan described an academic center's operative experience pre-2006 NCD (1981-2006) for 3300 patients. As seen below, Medicare status increased mortality for 30, 90 and 1-year mortality rates in comparison to Non-Medicare patients.

Mortality rates at 30 days, 90 days, and 1 year (Yuan, SOARD 2009)

Interval	Medicare, %	Non-Medicare, %	P value
30-Day	2.48	0.76	0.0090
90-Day	3.19	1.04	0.0041
1 -Year	3.90	1.45	0.0044

In a 2011 *Archives of Surgery* publication, Nguyen et al found that Medicare status increased the risk of potentially fatal anastomotic leaks by 54%, a stronger risk factor than chronic lung disease or male gender. In a 2012 *SOARD* paper by Gould et al, Medicare status significantly increased readmissions and ED visits.

In a 2008 *Annals of Surgery* article by Perry et al, morbidly obese Medicare patients who underwent bariatric surgery had increased survival rates over the 2 years of this study when compared with a similar morbidly obese nonsurgical group ($P<0.001$). For patients under the age of 65, this survival advantage started at 6 months postoperatively and for patients over age 65, at 11 months. These clear survival benefits for the Medicare population would be extinguished if surgeries are performed at non-accredited centers which have higher mortality rates even if they are high volume centers as noted in the 2013 Nguyen *Surgical Endoscopy* paper.

There are approximately 15,000 Medicare bariatric surgery performed annually. If we extrapolate the impact of loss of Medicare Facility Certification upon operative mortality, there will be an additional 240 deaths annually based on the mortality at Accredited High Volume Centers (0.06%) and Non-Accredited High Volume Centers (0.22%) as stated in the 2013 Nguyen *Surgical Endoscopy* paper.

Access

In the proposed Decision Memo, the issue of access to care for Medicare bariatric surgery patients has been raised. Every study since implementation of Facility Certification has demonstrated an increase in access. In the 2013 Dimick *JAMA* article, operations in Medicare beneficiaries increased from 6,273 procedures pre-NCD to 15,854 post-NCD. In the 2011 Flum *Annals of Surgery* article, Medicare bariatric surgery operation in the two years prior to the NCD increased from 17,127 to 29, 903 for the two years after the NCD. Of note, since implementation of the unified MBSAQIP program, there are now 725 centers available nation-wide for Medicare beneficiaries. An additional benefit to the unified MBSAQIP program is the ability to coordinate care on a national level. If the CMS Coverage Group has specific documented examples of lack of access, ASMBS and MBSAQIP is fully equipped and willing to address any access issue. As Adams noted in *JAMA* 2000, selective referral to appropriate centers can save lives and does not add undue burden upon the patient, particularly when there are more than 700 accredited bariatric surgery centers nationwide. We are all of the belief that all bariatric patients should all have access to *quality* care.

MBSAQIP Quality Standards are now available for public review. Of note, a key component to the new Quality Standards is the Facility Volume Requirement, which has been lowered from an annual 125 total to 50-stapled bariatric cases. Hospital volume does have an effect in bariatric surgery with the beneficial effect at 50 annual hospital stapled cases as confirmed by the Nguyen 2013 *Surgical Endoscopy* study. All of the eight studies supporting accreditation support provide evidence for hospital volume as part of the accreditation process. In addition, there are multiple studies confirming that volume should be a cornerstone of the certification process including the systematic review by Zevin in *Annals of Surgery* 2012. Additional studies supporting volume in bariatric surgery include the 2010 *JAMA* Birkmeyer study as well as the following: Courcoulas, *Surgery* 2003; Liu, *American Surgeon* 2003; Flum, *JACS* 2004; Nguyen, *Annals of Surgery* 2004; Smith, *SOARD* 2010; Flum, *JAMA* 2005; Weller, *JACS* 2007; Murr, *Annals of Surgery* 2007; Parker, *Surgical Endoscopy* 2007; Kelles, *Obesity Surgery* 2009; Birkmeyer, *JAMA* 2010.

Conclusion

Bariatric patient safety, cost and effectiveness have been vastly improved without decrease in access as a direct result of the 2006 Medicare National Coverage Determination for Bariatric Surgery. Overwhelmingly, bariatric surgeons support continued facility certification as noted in in an internal survey of the American Society of Metabolic and Bariatric Surgeons membership and the previous CMS public comments even after removing any perceived form letters.

It also should be noted that facility accreditation programs of the ASMBS and ACS were not established for nor intended to be research projects to determine the efficacy of certification. To abandon an existing, successful policy for which there is limited new evidence against facility certification is premature and places vulnerable Medicare patients at risk. Careful review of the evidence particularly the new 2013 literature support facility accreditation. Given the current state of the evidence, we strongly suggest that facility certification continue.

We believe that it is critical that bariatric programs look at meaningful measures with high-quality, standardized, valid data on clinically, impactful outcomes. Quality improvement is an iterative process that must continue to develop and move forward to enable innovation, evaluation of efforts around the country, and rapid-cycle learning and disseminating evidence about what works (Arch Surg 2009; http://www.ahrq.gov/workingforquality/nqs/principles.htm. Accessed July 2013). These concepts are supported by all undersigned and also align with the National Quality Strategy. Without accreditation, there is simply no validation for the success of such programs. CMS has also recognized the value and importance of accreditation, as seen in the support of the Joint Commission Hospital Accreditation program. Removing the accreditation requirement could result in a fragmented system with disconnected information and standards, which will reduce the sharing of best practices and consistent high-quality care for the obese population.

In keeping with the CMS Coverage with Evidence requirements, MBSAQIP has developed the bariatric surgery data registry and is committed to its maintenance and active use in quality improvement. Our first national collaborative will be an initiative to reduce 30-day readmissions, a quality initiative that CMS has embraced. In developing its program, MBSAQIP has worked

with multiple stakeholders including manufacturers, health care providers and facilities, professional societies, foundations, and health plans.

Since the CMS NCD supporting accreditation, lives have been saved, complications have been prevented, readmissions have been averted, cost has been lowered and access has been broadened. Without accreditation, long-term data collection will be impaired and quality improvement efforts will be severely impeded. In any analysis, it is apparent that accreditation has caused no harm and the preponderance of the evidence indicates that facility certification has lead to improved outcomes. Removing the facility certification process will not benefit patients and a real question arises as to who would actually benefit if the facility accreditation process were removed. We can safely say that the Medicare patient will not benefit from loss of accreditation and may be harmed. Accreditation has worked to date and we question why we should gamble with patient lives now. Quality improvement and patient safety are enduring efforts, which can best be accomplished by the bariatric surgery facility accreditation. We appreciate the opportunity to review the many benefits of Bariatric Surgery Facility Certification and strongly urge you to continue this valuable initiative for your beneficiaries.

Sincerely,

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July 26, 2013

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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
OAC President and CEO

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OAC Chairman of the Board

Ted Kyle, RPh, MBA
OAC Vice-Chairman

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Louis Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services

RE: Proposed Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement (CAG-00250R3)

Dear Dr. Jaques:

The American Association of Clinical Endocrinologists (AACE) appreciates the opportunity to provide comment regarding the proposal by CMS to eliminate the designation for bariatric surgery "Centers of Excellence" (COE) [Proposed Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement (CAG-00250R3)]. CMS proposes to remove the COE certification requirement based evidence indicating that continuing the requirement for certification of bariatric surgery facilities would not improve health outcomes for Medicare beneficiaries.

The American Association of Clinical Endocrinologists (AACE) represents over 6,000 endocrinologists in the United States and abroad. AACE is the largest association of clinical endocrinologists in the world. The majority of AACE members are certified in Endocrinology and Metabolism and concentrate on the treatment of patients with endocrine and metabolic disorders including diabetes, thyroid disorders, osteoporosis, growth hormone deficiency, cholesterol disorders, hypertension and obesity. AACE members are committed to providing the highest quality of care to the patients they serve.

AACE physicians require effective and safe interventions for treating patients with obesity. In fact, AACE has recently published a complications-centric approach for management of this disease as component of its overall Comprehensive Diabetes Treatment Algorithm. Bariatric surgery is an essential treatment option, particularly for patients who have not achieved therapeutic targets with lifestyle modification and/or weight loss medications. It is in the interest of our patients to have access to bariatric surgery when indicated under conditions that maximize patient outcomes and safety. It is in this context that we provide comment regarding the COE requirement.

AACE does not support the proposal, and contends that continuation of the COE requirement is in the best interest of patients with obesity. The 2006 CMS National Coverage Determination indicates that bariatric surgery should be performed in facilities conducting 125 bariatric surgery cases per year (and 50 cases per year for each surgeon); by experienced and credentialed providers; in programs with comprehensive pre- and post-operative care; as part of an integrated program that includes nutrition counseling, support groups, exercise training, and psychological assistance as needed. AACE sees high value in these requirements, and is concerned about potential harm if bariatric surgery programs are not required to maintain a critical patient volume and comprehensive care programs. A high level of compelling evidence is required if incentives

for maintaining high-quality comprehensive programs are to be dismantled; otherwise, patient safety and clinical outcomes may be compromised.

The CMS proposal is in response to supporting data submitted by the requestor, and it in on the basis of scientific data that we oppose the proposal. First, it has been widely established that mortality and operative morbidity are minimized when procedures are conducted by experienced surgeons who maintain a high caseload on an ongoing basis. This is true of bariatric and non-bariatric procedures and represents, in part, the rationale for the COE designation in the first place. Another point to consider is that the CMS COE requirement has improved bariatric surgery outcomes in the US, both at COE and non-COE centers, as non-COE strive to satisfy COE requirements and model their care programs accordingly. It is a concern that the elimination of COE requirements may lead to a diminution in the quality of care particularly at the non-COE. Furthermore, the evidence marshaled to support the elimination of the COE requirement has multiple shortcomings as follows:

1. All studies are retrospective including the 3 articles submitted by the requestor (Livingston 2009, Birkmeyer 2010, Dimick 2013) and the articles identified through the CMS literature search (Kwon 2012, Kohn 2010, Nguyen 2010, Flum 2011, Nguyen 2012). The retrospective surveys involve various patient medical record databases and non-scientifically selected sample populations with uncertain relevance to the general patient population. This retrospective design is inferior to prospective randomized trials.

2. The studies are confined to in-hospital mortality and complications. Longer-term complications were not considered, and this is a major shortcoming. The COE designation is designed to assure comprehensive post-operative care to minimize longer-term complications, which are not addressed in these studies.

3. Information about the BMI and specific types of bariatric procedures being performed is lacking in most studies. The fact that outcomes and complications were not stratified by BMI and type of procedure markedly weakens the data regarding conclusions on the value of the COE designation.

4. The use of hospital databases (e.g., UHC) will not capture complications or deaths occurring during subsequent admissions to other hospitals or health care systems.

5. Many of the authors recognize another limitation that coding of complications may be inaccurate because post-operative adverse events can be subjectively defined.

6. The procedures being performed may not reflect current preferences for bariatric surgery options. For example, in Flum 2011, 61% of surgeries were ‘open’ and not performed by laparoscopy. In Birkmeyer 2010, a very high proportion of patients underwent lap band procedures, which are being performed with decreasing frequency, and patients needing revisional surgery and duodenal switch were excluded.

7. Finally, the data in several papers support the COE requirement for a critical number of cases per year. In Livingston 2009, logistic regression modeling of the combined data from COE and non-COE hospitals confirmed that procedure volume was inversely related to complication rates, and “bariatric procedures conducted at hospitals performing fewer than 125 cases per year would

appear to have an 18% greater likelihood of being associated with complications"! Nguyen 2012 reported "Non-accredited centers are associated with a 3.5-fold increase in observed in-hospital mortality risk (95% CI 1.5 to 8.0) compared with accredited centers (p = 0.003)"; the "calculated risk-adjusted in-hospital mortality was 0.045% at accredited centers and 0.175% at non-accredited centers."

On balance, AACE does not feel that there is sufficient quality of data to warrant the conclusion that the COE requirement for bariatric surgery centers should be eliminated. We believe it is prudent to maintain the status quo unless there are compelling data to dispense with a COE program that has helped evolve comprehensive programs for bariatric surgical care and contribute to decreasing rates of mortality and morbidity. This is a complex yet critically important issue that directly involves the well-being of our patients who are referred for bariatric surgery, and it is entirely in the interest of patient safety that we answer this request for commentary. Again, we believe that such an important decision should be based on a firm and conclusive body of evidence that is currently lacking.

Sincerely,

Jeffrey Mechanick,
MD, FACN, FACP, FACE, ECNU
AACE President

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Chair, AACE Obesity Scientific Committee

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July 26, 2013

Louis Jacques, MD
Director, Coverage and Analysis Group
CMS/OCSQ/Coverage and Analysis Group
7500 Security Blvd. Mailstop C1 -09-06
Baltimore, MD 21244

Re: CAG-00250R3 (National Coverage Analysis (NCA) for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement)

Dear Dr. Jacques:

The Academy of Nutrition and Dietetics (the "Academy") is pleased to comment on the proposed decision memorandum regarding the NCA for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement issued June 27, 2013. The Academy is the world's largest organization of food and nutrition professionals, with more than 75,000 members comprised of registered dietitian nutritionists (RDNs), registered dietitians (RDs), dietetic technicians, registered (DTRs), and advanced-degree nutritionists. Every day we work with Americans in all walks of life—from prenatal care through old age—providing nutrition care and conducting nutrition research. We are committed to improving the nation's health and work treat individuals with obesity, including significant counseling before and after they undergo bariatric surgery.

The Academy associates itself with the comments submitted by (1) the American Society for Metabolic and Bariatric Surgery and American College of Surgeons ("ASMBS/ACS comments") and (2) the American Association of Clinical Endocrinologists ("AACE comments"). **On the bases detailed therein, we do not support the proposal to discontinue the certification requirement for bariatric facilities,** referred to as the center of excellence (COE) program.

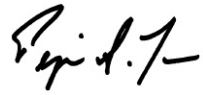
The Academy believes that there is insufficient quality data to conclude that the COE requirement for bariatric surgery centers should be eliminated. Given this lack of compelling data and the absence of any consensus in the literature, we believe it is prudent to maintain the status quo for the COE program, which has helped evolve comprehensive programs for bariatric surgical care and has contributed to decreasing rates of mortality and morbidity. Facility certification directly involves the well-being of our patients referred for bariatric surgery; patient safety is the primary concern underlying the Academy's opposition to the proposed decision memorandum. **The Academy urges CMS**

to consider the specific concerns detailed in the ASMBS/ACE comments and the ACE comments. A decision of such import and consequence should be based on a firm and conclusive body of evidence that does not yet exist.

The Academy appreciates the opportunity to comment on the proposed decision memorandum and we hope you will look towards the Academy and our members' expertise as you promulgate additional regulations related to patient safety and bariatric surgery. Please contact either Jeanne Blankenship at 202-775-8277 ext. 1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 ext. 6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

Jeanne Blankenship, MS RDN
Vice President, Policy Initiatives and Advocacy
Academy of Nutrition and Dietetics



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