American Society for Metabolic & Bariatric Surgery

October 1, 2010

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Dear Dr. Rifkin:

On behalf of the American Society for Metabolic and Bariatric Surgery (ASMBS), we are concerned regarding your recent Milliman's Care Guidelines (14th Edition) governing bariatric surgery. In particular, ASMBS disagrees with your recommendations governing Goal Length of Stay (GLOS) for Gastric Restrictive Procedure with Gastric Bypass by Laparoscopy, ORG code S-513 and Gastric Restrictive Procedure without Gastric Bypass by Laparoscopy, ORG code S-515. **Specifically, our concerns regarding the guidelines center on the lack of evidence, exceeding small number of patients achieving GLOS, and patient safety.**

While we appreciated Milliman sharing both the cited literature and supporting hospital data, which was your basis for the change in the guidelines (one day to ambulatory for ORG code S-513 & ambulatory or one day to ambulatory for ORG code S-515), ASMBS believes that this supporting evidence is lacking and does not support your conclusions. **Furthermore, we are of the firm belief that these GLOS recommendations are not evidence based and if implemented will decrease patient safety.** We have had the opportunity to review considerably more data than what was available to you. We are unanimous in our opposition to these new proposed guidelines. We are asking for a meeting in person as soon as possible to discuss potential remedy to these guidelines by **restoring your previous recommendations**.

ASMBS Review of Milliman Evidence

In evaluating your evidence, we found several concerns. **First, the cited literature is of poor quality and essentially limited to a single case series from a single center.**

- The McCarty paper is of definite interest but its report of 83% one-day LOS for laparoscopic RYGB has not been duplicated by any other report in the five years since its publication.

- The Rutledge paper describes a single surgeon experience, and the surgeon in question does not perform a Roux-en-Y gastric bypass but instead a “mini-gastric bypass,” which is a different operation not sanctioned by our Society as an acceptable or recognized bariatric surgical procedure.

- Finally, the Ballentyne paper does not support GLOS of one day, as it is a description of a single hospital experience whose median RYGB LOS is two days and the paper does not describe or promote a GLOS of one day. There is no mention of same-day discharge.

- As you provided, there are only nine hospitals achieving at least 57 percent of GLOS of one day. There are over 675 hospitals performing CMS-approved Center of Excellence bariatric surgery. ***Among the very best hospitals practicing bariatric surgery, only 1.3 percent of these hospitals were able to achieve your GLOS of one day.*** Your supporting dataset was Med Stat, which is derived administratively; insufficiently risk adjusted (no BMI data); and without long-term data regarding specifically readmissions and complications -- outcomes of high interest in any early discharge.

Current Bariatric Surgery LOS Evidence

In examining other national datasets, it is clear that conduct of this GLOS of one day is exceedingly rare.

- The **Nationwide Inpatient Sample**, an Agency for Healthcare Research and Quality national dataset of seven million admissions annually, found a median LOS of 2.7 days with less than 1 percent of the patients having a LOS of less than one day.

- The Surgical Review Corporation clinically derived **Bariatric Outcomes Longitudinal Database (BOLD)** including over 250,000 patients was also reviewed. In BOLD, mean LOS for all RYGB was 2.4 days with again less than one percent of hospitalizations being shorter than 24 hours.

- In addition, we have examined the **University Health Consortium** database and found that only 8.3% of patients in the leading hospitals in the US had a LOS of one day or less. The 30-day readmission rate was 36% higher in the <one-day group than in the two-day LOS group (2.15 vs. 1.58%). A hallmark of current health care reform involves reduction in readmissions which these guidelines may in fact stimulate.

Given these data, it is clear that only a very small minority of RYGB patients could comply with the GLOS of one day. The Milliman guidelines will establish a precedent for a one-day length of stay for a laparoscopic gastric bypass that the bariatric surgery community will not be able to meet. **This expectation of a GLOS of one day represents a radical and potentially dangerous change in current bariatric surgery practice.**

Additionally, we are very concerned that the ability to extend a LOS beyond your GLOS of one day is limited to a set group of clinical circumstances that are not inclusive or data-driven. There are no data to support these limited reasons for extension of the LOS and are by no means an adequate

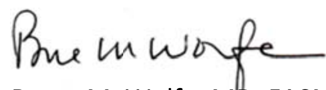
substitute for the clinical judgment of an experienced bariatric surgeon. Any attempt to specify limited circumstances in which a LOS may be extended beyond 23 hours is inappropriate, as any risk adjustment scheme cannot include infrequent but problematic risk factors that do not have statistical power to emerge in a risk adjustment analysis.

Also, the proposed guideline changes include a GLOS of *ambulatory*. **There are absolutely no data or literature to support this very radical change to ambulatory laparoscopic gastric bypass surgery**. Furthermore, as described, these guidelines already have the potential of misguided application. For example, the *sleeve gastrectomy* might be misconstrued to be included in the category of Gastric Restrictive Procedure without Gastric Bypass by Laparoscopy, ORG code S-515 (GLOS change from Ambulatory *or* one day to Ambulatory) generally acknowledged as a *gastric banding* procedure. There is absolutely no evidence supporting a GLOS of ambulatory for this extensive stapling procedure where there is real potential for leaks or bleeding in the early post-operative period. This is a prime example of unintended consequences with a radical shift in current bariatric surgery practice.

We can all recall the public furor and outrage that occurred with ambulatory guidelines for both mastectomy and caesarean section, the “drive-by delivery.” Those populations and procedures were respectively much healthier and less complex than our bariatric patients and procedures. We believe that public and payor alike will recognize that the Milliman GLOS recommendations for bariatric surgery will not pass the tests of scientific evidence, sound judgment or patient safety.

We have been witness to a rapid growth in utilization and quality in bariatric surgery in the past decade. This high level of accomplishment has occurred through the hard work and prudent judgment of thousands of dedicated bariatric practitioners who remain the last and best hope for obese patients desperately in need of care. Again, we are asking Milliman to retract this latest iteration of its guidelines and revert back to Milliman’s previous recommendations regarding length of stay in bariatric surgical patients. We would like to meet with you as soon as possible to determine how to best accomplish this task and are proposing the morning of Monday October 11, 2010 in San Diego, CA or sooner. We look forward to meeting with you.

Sincerely,



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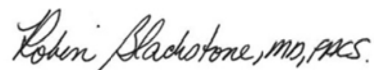

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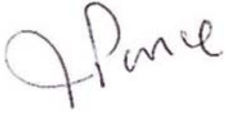

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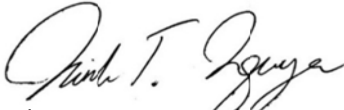

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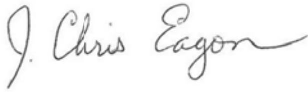

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