

# 1) Metabolic and Bariatric Surgery Accreditation Program

Standards and Verification of High Quality  
Accredited Programs

## 2) Gastric Balloons

Wayne J English, MD, FACS

Vanderbilt University Medical Center

# Disclosures

- Personal Disclosures

- ReShape
  - Investigator - Research Support      Major
- Obalon
  - Investigator - Research Support      Major
- BAROnova
  - Investigator - Research Support      Major
- Vanderbilt University      Medical Center
  - Faculty      Major
- American Society for Metabolic and Bariatric Surgery (ASMBS)
  - Executive Council Member      Minor

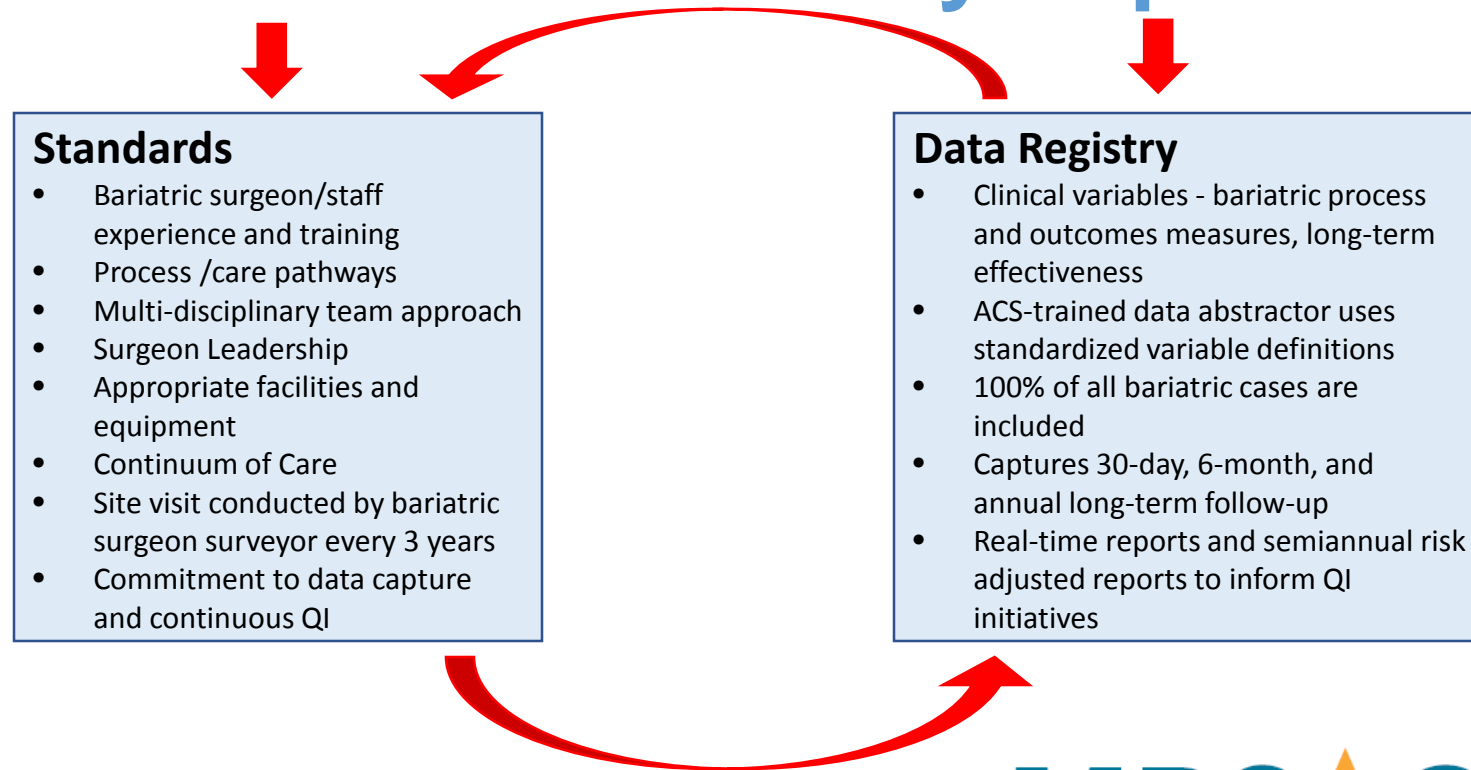
- ASMBS Disclosures

- Ethicon - Educational Grant – Major
- Medtronic – Educational Grant – Major
- Apollo Endosurgery – Educational Grant – Major
- W.L. Gore -Educational Grant – Major
- Olympus – Educational Grant – Major
- NovoNordisk – Educational Grant – Major
- Bariatric Advantage - Meeting Sponsorships – Major
- KVK Tech – Meeting Sponsorships – Major
- Karl Storz – Meeting Sponsorships – Minor
- USGI – Meeting Sponsorships – Minor
- ConMed – Meeting Sponsorships – Minor
- Mederi – Meeting Sponsorships – Minor

# What is MBSAQIP?

Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

## Accreditation + Quality Improvement



# A joint initiative...



100+years

AMERICAN COLLEGE OF SURGEONS

*Inspiring Quality:  
Highest Standards, Better Outcomes*

NEW



Started in 2012; ~800 centers



OLD



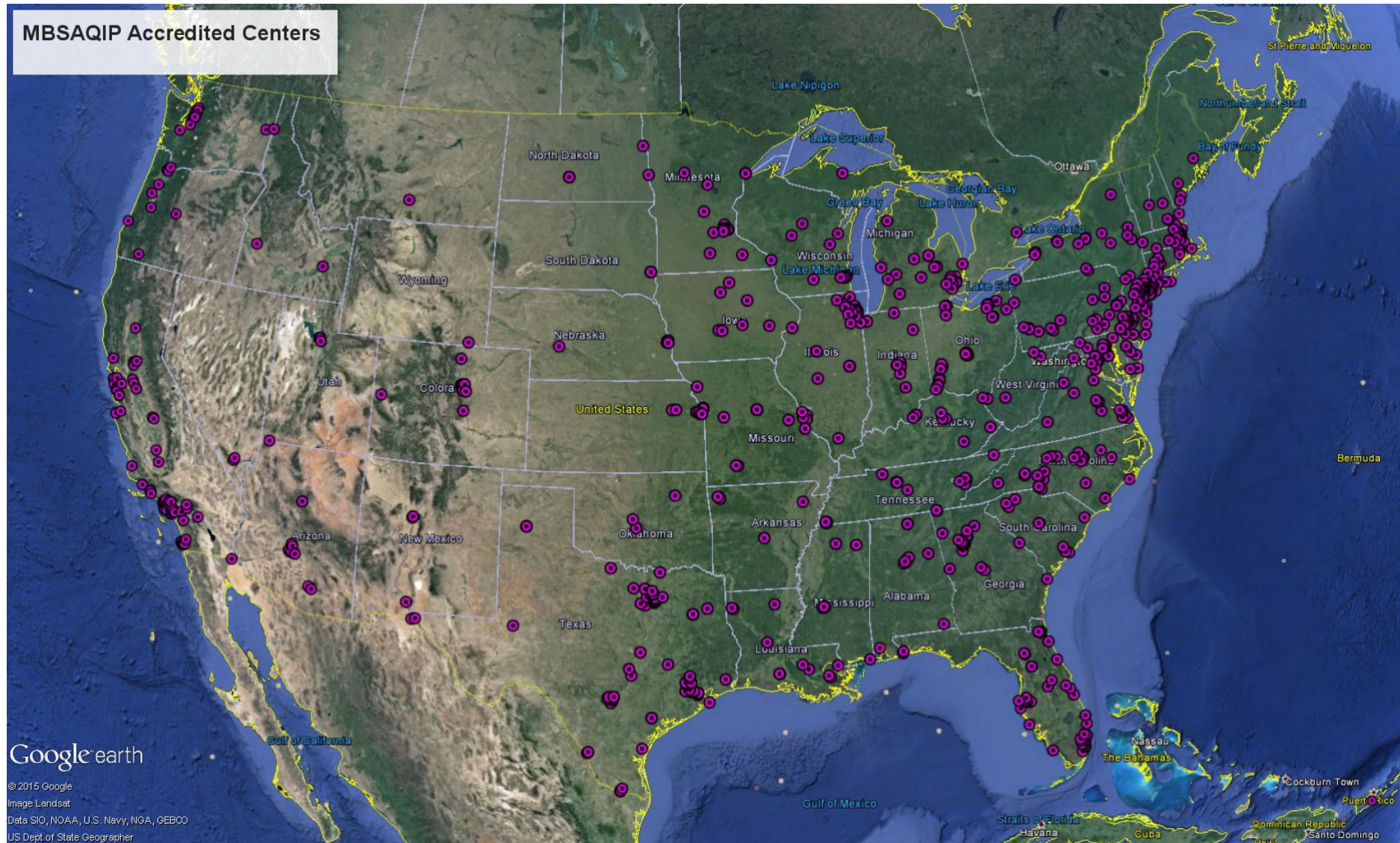
Started in 2006; ~125 centers

OLD



Started in 2005; ~600 centers





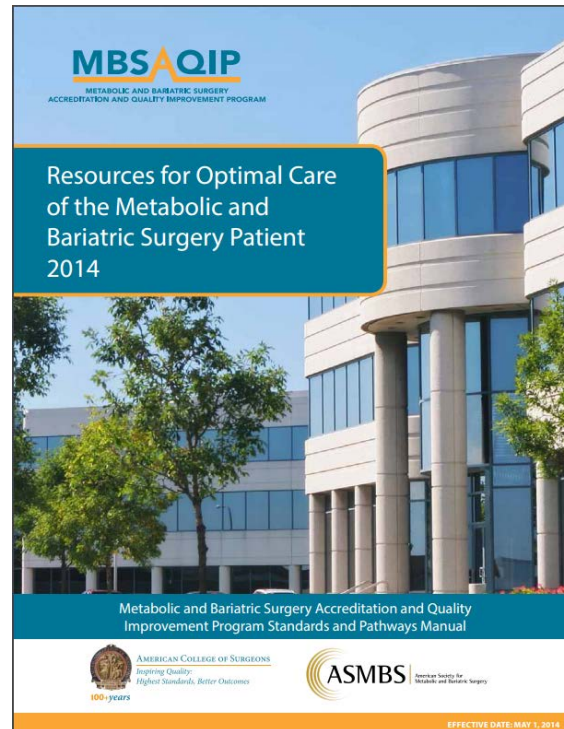
**Over 800 Centers in the United States**

**MBSAQIP**  
METABOLIC AND BARIATRIC SURGERY  
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

# Standards Update

## TWO VERSIONS

**2014 Standards**  
**effective May 2014 -Sept 2016**



**2016 Standards**  
**effective October 2016**



Over 1,100 public comments received  
prior to completing standards

**MBSAQIP**  
METABOLIC AND BARIATRIC SURGERY  
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

# Standards & Verification

## CORE STANDARDS

1. **Case Volume, Patient Selection, & Approved Procedures by Designation Level**
2. **Commitment to Quality Care** (required people) – MBS Director, Coordinator, Clinical Reviewer, Committee (surgeons, dietitians, behavioral specialists, etc.)
3. **Appropriate Equipment and Instruments**
4. **Critical Care Support**
5. **Continuum of Care**
6. **Data Collection**
7. **Continuous Quality Improvement Process**
8. **Ambulatory Surgery Centers**
9. **Adolescent Centers**

## VERIFICATION

- **Surgeon Site Surveyors**
- **Application Reviewers**
- **Adjudication Committee**
  
- **Process involves review of feedback from sites and site surveyors to determine need for changes in the standards when necessary**



# Data & Quality

- National data registry
- Analytical and reporting tools
- Develops initiatives for
  - Performance improvement
  - Collaborative development
  - Sharing of best practices



## QI Initiatives

- *Decreasing Readmissions through Opportunities Provided (DROP)*
  - Over 700 hospitals
  - 150,000 cases/year
  - 7,500 readmissions to 6,000 readmissions (less 1500/year)
  - \$35K/readmission x 1500 cases=\$52.5M
- *Employing New Enhanced Recovery Goals in Bariatric Surgery (ENERGY)*
  - Over 30 MBSAQIP programs
  - Goal of implementing enhanced recovery strategies
  - Reduce Length of Stay and resource utilization



<https://asmbs.org/pathway-for-approval-for-new-devices-and-procedures>



[Patients](#)

[Membership](#)

[Professional  
Development](#)

[Resources](#)

[State  
Chapters](#)

[Newsroom](#)

[Advocacy](#)

### Related Pages

[About](#)

[Patient Learning Center](#)

[Professional Education](#)

[State Chapters](#)

[EHB Advocacy Toolkit](#)

## Pathway for Approval for New Devices and Procedures

### Preamble

Obesity has been recognized as a disease by the American Medical Association in 2013. Bariatric and metabolic surgery is a proven, effective and enduring treatment for obese patients in need. Bariatric and metabolic surgery strives to provide the most innovative therapies for obese patients. As new devices and procedures emerge, it is critical that the American Society for Metabolic and Bariatric Surgery leads the way in creating, evaluating and implementing new devices and procedures for obesity. With the advent of new obesity devices and procedures entering our field, ASMBS is proposing a pathway for official ASMBS approval and sanction of new procedures and devices.

### Problem

Review of prior ASMBS policy for approval of new obesity treatment devices and procedures indicates that there is no standardized pathway. Prior procedures or devices were approved by ASMBS leadership via expert review only. However, our specialty may have procedures that have become obsolete or new procedures that emerge which may be rapidly adopted without ASMBS endorsement.

### Process

1. **Application by an ASMBS Member Sponsor in active practice** for a new procedure or removal of an approved procedure. Multiple ASMBS Member Co-Sponsors are allowed and encouraged.
2. **Primary ECEC Review:** 75% Approval Required to Next Stage. This review will be inclusive and mainly to ensure plausibility of new procedure and device before invoking full review.

Designations	Pathways	Standards								
		1	2	3	4	5	6	7	8	9

## 6.1 Data Entry of All Metabolic and Bariatric Procedures and Interventions

### Requirements

Every metabolic and bariatric operation and intervention must be captured in the MBSAQIP Data Registry, including all:

- Elective primary metabolic and bariatric surgeries
- Reoperations and interventions subsequent to a metabolic and bariatric procedure (regardless of where the primary metabolic and bariatric procedure occurred), including:
  - Nonelective reoperations, revisions, conversions, and interventions performed due to complications related to a primary metabolic and bariatric procedure
  - Elective revisions and conversions performed subsequent to a primary metabolic and bariatric procedure
- Endoluminal therapeutic interventions for the treatment of obesity. Therapeutic interventions include, but are not limited to, the following:
  - Intra-gastric balloons
  - Vascular embolization
  - Endoluminal sleeves
  - Stoma or pouch resizing
  - Endoluminal stapling

All endoluminal therapeutic interventions for the treatment of obesity must be performed with the oversight of the MBS Director and MBS Committee, and all said procedures must be entered into the MBSAQIP Data Registry.

The data from all metabolic and bariatric procedures (open, laparoscopic, hand-assisted, or robotic) on any body mass index must be reported.

Any primary, revision, or conversion procedure, whether surgical or nonsurgical, performed for metabolic or bariatric diagnoses requires entry into the data registry. FDA preapproval trials are the only exception to this rule.

ASMBS publishes an approved list of metabolic and bariatric surgery procedures on the ASMBS website, [asmbs.org](http://asmbs.org). Accredited centers may not perform nonapproved primary or conversional procedures unless approved by an Institutional Review Board (IRB).

The MBS Committee is responsible for overseeing the process in which emerging technologies, new procedures, and variation of existing approved techniques may be safely introduced into the center with adequate patient protection, oversight (including IRB approval when indicated), and outcomes reporting.

### Documentation

- The center provides a copy of an attestation form indicating that both the MBS Director and MBS Clinical Reviewer confirm and attest that data from all metabolic and bariatric operations and interventions are submitted to the MBSAQIP Data Registry Platform.
- The center provides copies of case logs from hospital administrative and/or operational systems and physician records that are provided for site visits, or as requested, in an electronic format.
- The center provides a copy of IRB approval to perform an investigational metabolic and bariatric procedure, if any investigational procedures or procedures not approved by the ASMBS are performed at the center.

### Measure of Compliance

Compliance: The center fulfills the following criteria:

- Provides copy of signed attestation by the MBS Director and the MBS Clinical Reviewer that all cases and interventions for all metabolic and bariatric operations and interventions are submitted to the MBSAQIP Data Registry Platform.
- Provides copy of electronic administrative data file and physician records in electronic format to verify that 100 percent of metabolic and bariatric operations and interventions are submitted and that data do not deviate from the cases entered into the MBSAQIP Data Registry Platform.
- Provides copy of IRB approval to perform an investigational metabolic and bariatric procedure, if any investigational procedures or procedures not approved by the ASMBS are performed at the center.

Comprehensive

Comp w/Adol

Low Acuity

Ambulatory

Adolescent

# Standards Update

## 6.1 Data Entry of All MB Procedures/Interventions

- Endoluminal therapeutic interventions for the treatment of obesity. Therapeutic interventions include, but are not limited to, the following:

All endoluminal therapeutic interventions for the treatment of obesity must be performed with the oversight of the MBS Director and MBS Committee, and all said procedures must be entered into the MBSAQIP Data Registry.

surgical or nonsurgical, performed for metabolic or bariatric diagnoses requires entry into the data registry. FDA preapproval trials are the only exception to this rule.

ASMBS publishes an approved list of metabolic and bariatric surgery procedures on the ASMBS website, [asmbs.org](http://asmbs.org). Accredited centers may not perform nonapproved primary or conversional procedures unless approved by an Institutional Review Board (IRB).

The MBS Committee is responsible for overseeing the process in which emerging technologies, new procedures, and variation of existing approved techniques may be safely introduced into the center with adequate patient protection, oversight (including IRB approval when indicated), and outcomes reporting.

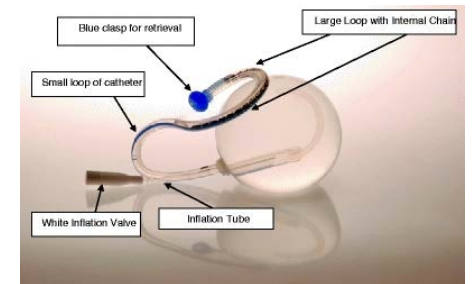
# Intragastric Balloons

- **FDA approved**

- Fluid-filled & requires endoscopy for insertion and retrieval
  - Orbera
  - ReShape DUO
- Air-filled and requires endoscopy for retrieval only
  - Obalon (Swallowable)

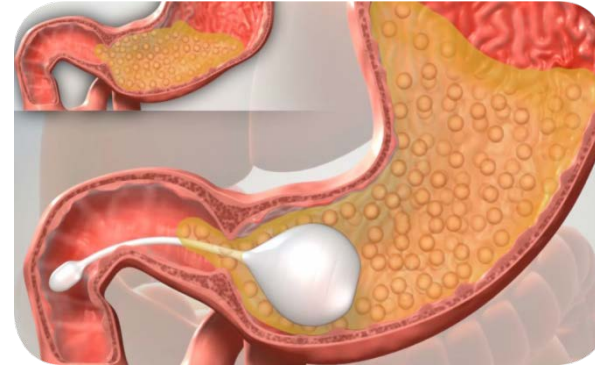
- **Investigational**

- Fluid-filled & requires endoscopy for insertion and retrieval
  - Spatz
- Fluid-filled and does not require endoscopy for insertion or retrieval
  - Allurion Elipse (Swallowable)

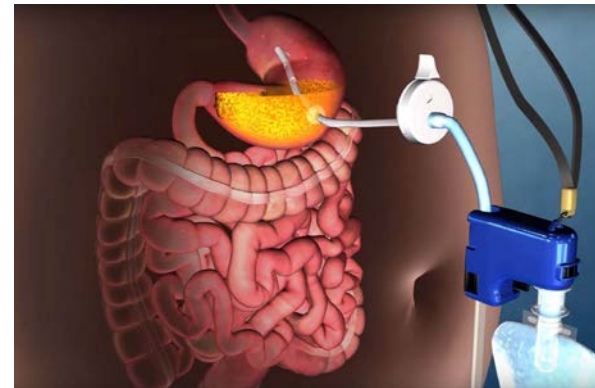


# Other Non-Surgical Weight Loss Devices

- BAROnova: Transpyloric Shuttle
  - Investigational



- Aspire Assist
  - FDA approved



# Intragastric Balloons

- Fills the treatment gap between medication management of obesity and surgery
  - Patients with BMI of 30-40 kg/m<sup>2</sup>
- Combination of lifestyle modification and balloon therapy
  - low risk option with sustained weight loss for patients with obesity
- Bridge to Surgery
  - Making surgical procedures safer
    - Ventral hernias
    - Joint replacement
    - Transplants