

**MBSAQIP**<sup>®</sup>

METABOLIC AND BARIATRIC SURGERY  
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM

A **QUALITY PROGRAM**  
of the AMERICAN COLLEGE  
OF SURGEONS

# Optimal Resources for Metabolic and Bariatric Surgery

**2019 Standards — Revised**

[facs.org/mbsaqip](https://facs.org/mbsaqip)



**ASMBS**

American Society for  
Metabolic and Bariatric Surgery



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# Optimal Resources for Metabolic and Bariatric Surgery

2019 Standards — Revised

# Table of Contents

<b>Foreword</b>	<b>ii</b>
<b>MBSAQIP Designations and Accreditation Pathways</b>	<b>vi</b>
Designations	<b>vii</b>
Designation Requirements Overview	<b>viii</b>
Accreditation Pathways	<b>x</b>
<b>Standard 1</b>	
<b>Institutional Administrative Commitment</b>	<b>1</b>
1.1 Administrative Commitment	<b>3</b>
<b>Standard 2</b>	
<b>Program Scope and Governance</b>	<b>5</b>
2.1 Volume Criteria	<b>7</b>
2.2 Low Acuity Center Patient and Procedure Selection	<b>9</b>
2.3 Ambulatory Surgery Center Patient and Procedure Selection	<b>10</b>
2.4 Metabolic and Bariatric Surgery (MBS) Committee	<b>11</b>
2.5 Metabolic and Bariatric Surgery (MBS) Director	<b>13</b>
2.6 Metabolic and Bariatric Surgery (MBS) Coordinator	<b>15</b>
2.7 Metabolic and Bariatric Surgery (MBS) Clinical Reviewer	<b>16</b>
2.8 Obesity Medicine Director (OMD)	<b>18</b>
<b>Standard 3</b>	
<b>Facilities and Equipment Resources</b>	<b>21</b>
3.1 Health Care Facility Accreditation	<b>23</b>
3.2 Facilities, Equipment, and Furniture	<b>24</b>
3.3 Designated Bariatric Unit	<b>26</b>

**Standard 4**

<b>Personnel and Services Resources</b>	<b>29</b>
4.1 Credentialing Guidelines for Metabolic and Bariatric Surgeons	31
4.2 MBSAQIP Surgeon Verification	33
4.3 Metabolic and Bariatric Surgery Call Coverage	35
4.4 Staff Training	36
4.5 Multidisciplinary Team	37
4.6 Advanced Cardiovascular Life Support (ACLS)	38
4.7 Patient Stabilization	39
4.8 Critical Care Unit (CCU) / Intensive Care Unit (ICU) Services	40
4.9 Anesthesia Services	41
4.10 Endoscopy Services	42
4.11 Diagnostic and Interventional Radiology Services	43
4.12 Specialty Services	44
4.13 Pediatric Medical Advisor (PMA)	45
4.14 Pediatric Behavioral Specialist	46
4.15 Children's Hospital Service Requirements	47

**Standard 5**

<b>Patient Care: Expectations and Protocols</b>	<b>49</b>
5.1 Patient Education Pathways	51
5.2 Patient Care Pathways	52
5.3 Written Transfer Agreement	53
5.4 Inpatient Admitting Privileges	54
5.5 Risk Assessment Protocol	55
5.6 Obesity Medicine Services	56

**Standard 6**

<b>Data Surveillance and Systems</b>	<b>59</b>
6.1 Data Entry	61
6.2 30-Day and Long-Term Follow-Up	62
6.3 Data Review	63
6.4 Obesity Medicine Data Collection	64

**Standard 7**

<b>Quality Improvement</b>	<b>67</b>
7.1 Adverse Event Monitoring	69
7.2 Quality Improvement Initiatives	70
7.3 Annual Compliance Reports (ACRs)	72

**Standard 8**

<b>Education: Professional and Community Outreach</b>	<b>75</b>
8.1 Support Groups	77

<b>Accreditation Definitions</b>	<b>78</b>
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<b>Accreditation Process Overview</b>	<b>79</b>
MBSAQIP Accreditation Process for Initial Applicants	79
MBSAQIP Reaccreditation Process for Renewal Applicants	79

MBSAQIP-Accredited centers demonstrate an uncompromising pursuit of quality that has earned the confidence, respect and trust of patients making a commitment to healthier living.

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for your patients.  
for your surgeons.  
for your center.**

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## Foreword

The American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) are pleased to offer the latest Standards for the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP®), a nationwide accreditation and quality improvement program for the treatment of metabolic and bariatric patients. The MBSAQIP builds upon the rich history of these organizations in advancing surgical patient care, and the previous success of their individual accreditation and quality improvement programs.

Through their collaborative efforts, the ACS and the ASMBS are confident that by working together with the facilities, physicians, and health care professionals who provide care to the more than 18 million people in the United States who are affected by obesity, they are able to answer the call to action to address obesity as a national public health priority and serve as the medical home for all patients with obesity.

Currently, there are more than 900 MBSAQIP-Accredited centers in the United States and Canada, and multiple international centers participating as Data Collection Centers. More than 200,000 bariatric cases are captured annually in the MBSAQIP Registry.

Multiple studies have examined patient safety in metabolic and bariatric surgery and support the value of accreditation. An article in *Surgical Endoscopy* (July 2013) found that in-hospital mortality rates at accredited centers were more than three times lower than the mortality rates at non-accredited centers (0.06% vs. 0.22%). University of California Irvine researchers conducting this study analyzed 277,760 metabolic and bariatric procedures performed between 2006 and 2010. Additionally, an October 2012 publication in the *Journal of the American College of Surgeons* showed nearly the same differences in mortality rates between accredited and non-accredited academic metabolic and bariatric surgery centers (0.06% vs. 0.21%, respectively).

The *Optimal Resources for Metabolic and Bariatric Surgery* outlines requirements for facilities to follow when seeking accreditation. MBSAQIP Accreditation provides guidance for facilities aiming to build the structure and outcomes expertise necessary to provide safe, efficacious, and high-quality care to all metabolic and bariatric patients.

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## Background on ACS and ASMBS

### About the American College of Surgeons

The American College of Surgeons (ACS) is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and improve the quality of care for all 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 82,000 members and is the largest organization of surgeons in the world. For more information, visit [facs.org](http://facs.org).

### About the American Society for Metabolic and Bariatric Surgery

The American Society for Metabolic and Bariatric Surgery (ASMBS) is the largest organization for metabolic and bariatric surgeons in the world, with more than 4,200 members. It is a not-for-profit organization that works to advance the science of metabolic and bariatric surgery. The ASMBS is committed to educating medical professionals and the lay public about metabolic and bariatric surgery, including the associated risks and benefits, as a treatment option for obesity. The ASMBS encourages its members to investigate and discover new advances in metabolic and bariatric surgery while maintaining a steady exchange of experience and ideas that may lead to improved surgical outcomes for patients with obesity. For more information, visit [asmbs.org](http://asmbs.org).

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## Acknowledgments

This 3rd version of the MBSAQIP Standards Manual is dedicated to Ronald “Ronnie” Clements, MD, FACS, FASMBS.

As Co-Chair of the MBSAQIP Standards Committee, he was instrumental in developing the inaugural version of the *Optimal Resources for Metabolic and Bariatric Surgery*. Memories of his warm personality, clinical excellence, and indomitable spirit will continue as an inspiration to all who care for patients with obesity.

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These Standards are intended solely as qualification criteria for MBSAQIP Accreditation. They do not constitute a standard for care and are not intended to replace the medical judgment of the surgeon or health care professional in individual circumstances.

In order for a center to be found compliant with the MBSAQIP Standards, the center must be able to demonstrate compliance with the entire Standard as outlined in the **Definition and Requirements**, **Documentation**, and **Measure of Compliance** sections under each Standard. The **Documentation** and **Measure of Compliance** sections under each Standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the **Definition and Requirements**.

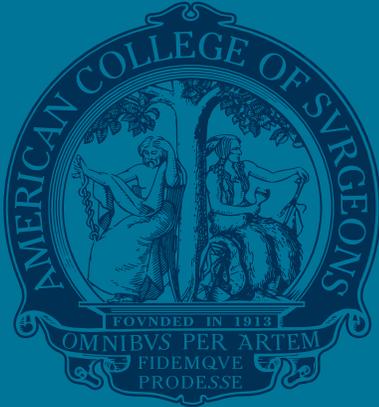
In addition to verifying compliance with the Standards as written in this manual, the MBSAQIP may consider other factors not stated herein when reviewing a center for accreditation and reserves the right to withhold accreditation on this basis.





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## MBSAQIP Designations and Accreditation Pathways

This section provides a list of all designations offered by the MBSAQIP® as well as pathways to achieve full MBSAQIP accreditation.

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## Designations

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### Data Collection Center (not accredited)

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### Accredited Inpatient Center

MBSAQIP Comprehensive Center

MBSAQIP Comprehensive Center with Adolescent Qualifications

MBSAQIP Comprehensive Center with Obesity Medicine Qualifications

MBSAQIP Comprehensive Center with Adolescent and Obesity Medicine Qualifications

MBSAQIP Low Acuity Center

MBSAQIP Adolescent Center

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### Accredited Outpatient Center

MBSAQIP Ambulatory Surgery Center

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## Designation Requirements Overview

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### Data Collection Center

Participation as a Data Collection Center is only available to international centers and is not available to centers within the United States and Canada. Centers within the United States and Canada must apply for MBSAQIP Accreditation.

Please see the MBSAQIP website for more information regarding Data Collection Center eligibility and participation: [facs.org/quality-programs/mbsaqip](https://facs.org/quality-programs/mbsaqip)

1. The MBS Director and program stakeholders must review the MBSAQIP International Data Collection Center Webinar.
2. A Metabolic and Bariatric Surgery (MBS) Clinical Reviewer is identified by the center and the MBS Clinical Reviewer successfully completes training.
3. The MBS Clinical Reviewer enters data into the MBSAQIP Registry.
4. Center is not required to demonstrate compliance with Standards.
5. No minimum annual case volume is required.

**Applicable Standards:** None, not accredited

---

### Accredited Inpatient Center

#### MBSAQIP Comprehensive Center

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 50 bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Approved to perform all ASMBS-endorsed procedures.
4. Only approved to provide care to patients 18 years of age and older.

**Applicable Standards:**

- Standard 1
- Standard 2.1; 2.4–2.7
- Standard 3
- Standard 4.1–4.12
- Standard 5.1–5.3
- Standard 6.1–6.3
- Standard 7
- Standard 8

#### MBSAQIP Comprehensive Center with Adolescent Qualifications

MBSAQIP Adolescent Qualifications are required for facilities that provide care to patients who are younger than 18 years of age. This qualification is separate and distinct from adult accreditation and is awarded to adult inpatient facilities to become MBSAQIP Comprehensive Centers with Adolescent Qualifications.

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 50 bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Approved to perform all ASMBS-endorsed procedures.
4. Approved to provide care to patients of all ages.

**Applicable Standards:**

- Standard 1
- Standard 2.1; 2.4–2.7
- Standard 3
- Standard 4.1–4.14
- Standard 5.1–5.3
- Standard 6.1–6.3
- Standard 7
- Standard 8

#### MBSAQIP Comprehensive Center with Obesity Medicine Qualifications

MBSAQIP Obesity Medicine Qualifications are separate and distinct from surgical and procedural accreditation.

Only MBSAQIP Comprehensive Centers and MBSAQIP Comprehensive Centers with Adolescent Qualifications are eligible to seek MBSAQIP Obesity Medicine Qualifications.

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 50 bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Approved to perform all ASMBS-endorsed procedures.
4. Only approved to provide care to patients 18 years of age and older.

**Applicable Standards:**

- Standard 1
- Standard 2.1; 2.4–2.8
- Standard 3
- Standard 4.1–4.12
- Standard 5.1–5.3; 5.6
- Standard 6
- Standard 7
- Standard 8

### **MBSAQIP Comprehensive Center with Adolescent and Obesity Medicine Qualifications**

MBSAQIP Adolescent Qualifications are required for facilities that provide care to patients who are younger than 18 years of age. This qualification is separate and distinct from adult accreditation and is awarded to adult inpatient facilities to become MBSAQIP Comprehensive Centers with Adolescent Qualifications.

MBSAQIP Obesity Medicine Qualifications are separate and distinct from surgical and procedural accreditation.

Only MBSAQIP Comprehensive Centers and MBSAQIP Comprehensive Centers with Adolescent Qualifications are eligible to seek MBSAQIP Obesity Medicine Qualifications.

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 50 bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Approved to perform all ASMBS-endorsed procedures.
4. Approved to provide care to patients of all ages.

#### **Applicable Standards:**

- Standard 1
- Standard 2.1; 2.4–2.8
- Standard 3
- Standard 4.1–4.14
- Standard 5.1–5.3; 5.6
- Standard 6
- Standard 7
- Standard 8

### **MBSAQIP Low Acuity Center**

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 25 bariatric procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Center follows the Low Acuity Center Patient and Procedure Selection criteria outlined in Standard 2.2.
4. Only approved to provide care to patients 18 years of age and older.

#### **Applicable Standards:**

- Standard 1
- Standard 2.1, 2.2; 2.4–2.7
- Standard 3
- Standard 4.1–4.12
- Standard 5.1–5.3
- Standard 6.1–6.3
- Standard 7
- Standard 8

### **MBSAQIP Adolescent Center**

MBSAQIP Adolescent Qualifications are required for facilities that provide care to patients who are younger than 18 years of age. This qualification is separate and distinct from adult accreditation and is awarded to children's hospitals to become MBSAQIP Adolescent Centers.

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 15 stapling procedures annually, otherwise a MBSAQIP Verified Surgeon must be present as a co-surgeon on each case, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Approved to perform all ASMBS-endorsed procedures.
4. Approved to provide care to adolescent patients.

#### **Applicable Standards:**

- Standard 1
- Standard 2.1; 2.4–2.7
- Standard 3
- Standard 4
- Standard 5.1–5.3
- Standard 6.1–6.3
- Standard 7
- Standard 8

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## **Accredited Outpatient Center**

### **MBSAQIP Ambulatory Surgery Center**

MBSAQIP Accreditation for Ambulatory Surgery Centers is separate and distinct as an outpatient facility designation that provides care for metabolic and bariatric patients 18 years of age and older.

1. Center demonstrates compliance with all applicable MBSAQIP Standards and successfully completes a site visit.
2. Center performs a minimum of 25 bariatric procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Registry.
3. Center follows the Ambulatory Surgery Center Patient and Procedure Selection criteria outlined in Standard 2.3.
4. Only approved to provide care to patients 18 years of age and older.

#### **Applicable Standards:**

- Standard 1
- Standard 2.1; 2.3–2.7
- Standard 3.1–3.2
- Standard 4.1–4.12
- Standard 5.1–5.5
- Standard 6.1–6.3
- Standard 7
- Standard 8

## Accreditation Pathways

\*The applicable Standards for each designation level are found in the Designation Requirements Overview.

### Data Collection Center

- Only available to international centers outside the United States and Canada
- Compliance with Standards not required
- No minimum annual case volume required
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Center is not accredited

### MBSAQIP Comprehensive Center

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 50$  bariatric stapling procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Approved to perform all ASMBS-endorsed procedures
- Adult patients only
- Site Visit required

### MBSAQIP Comprehensive Center with Adolescent Qualifications

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 50$  bariatric stapling procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Approved to perform all ASMBS-endorsed procedures
- Adult and adolescent patients
- Site Visit required

### MBSAQIP Comprehensive Center with Obesity Medicine Qualifications

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 50$  bariatric stapling procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Approved to perform all ASMBS-endorsed procedures
- Adult patients only
- Site Visit required

### MBSAQIP Comprehensive Center with Adolescent and Obesity Medicine Qualifications

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 50$  bariatric stapling procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Approved to perform all ASMBS-endorsed procedures
- Adult and adolescent patients
- Site Visit required

### MBSAQIP Low Acuity Center

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 25$  bariatric procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Center follows the Low Acuity Center Patient and Procedure Selection criteria
- Adult patients only
- Site Visit required

### MBSAQIP Adolescent Center

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 15$  bariatric stapling procedures annually or utilizes a MBSAQIP Verified co-surgeon
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Approved to perform all ASMBS-endorsed procedures
- Approved to provide care to adolescent patients
- Site Visit required

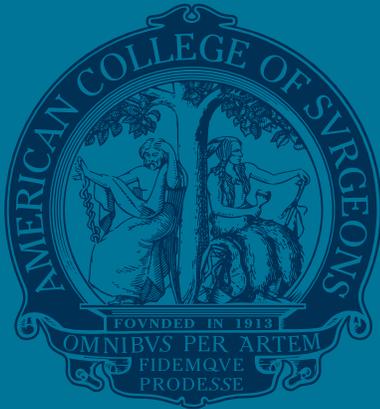
### MBSAQIP Ambulatory Surgery Center

- Center demonstrates compliance with all applicable MBSAQIP Standards
- Performs  $\geq 25$  bariatric procedures annually
- MBS Clinical Reviewer completes training and enters data into the MBSAQIP Registry
- Center follows the Ambulatory Surgery Center Patient and Procedure Selection criteria
- Adult patients only
- Site Visit required



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## **STANDARD 1**

# Institutional Administrative Commitment

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## **Rationale**

Full support and continuous commitment from institutional leadership is vital to maintaining a MBSAQIP-Accredited center. Resource allocation (such as equipment, personnel, and administrative support), a commitment to patient safety, and an enduring focus on continuous quality improvement are the hallmarks of strong institutional administrative support which help facilitate the success of MBSAQIP-Accredited centers.

## 1.1 Administrative Commitment

### Definition and Requirements

Centers seeking MBSAQIP Accreditation must provide a letter from facility leadership (Chief Executive Officer or equivalent) demonstrating the institution's current and continuous administrative commitment to the MBSAQIP-Accredited center. The letter must address, at a minimum, the following topics:

- A high-level description of the metabolic and bariatric surgery program at the facility
  - a. Metabolic and bariatric program leadership
  - b. Annual volume of metabolic and bariatric procedures
  - c. Metabolic and bariatric procedure mix
  - d. Commitment to multidisciplinary care
- All quality improvement initiatives, specific to metabolic and bariatric patient care, implemented in the most recent 12 months
- Involvement and support from facility leadership for the metabolic and bariatric surgery program
- Current and future financial investments in the metabolic and bariatric surgery program

Only one letter of institutional commitment must be provided for each triennial accreditation cycle. The letter of institutional commitment must be written and signed within the most recent 12 months. Letters of commitment from previous calendar years or previous accreditation cycles do **not** meet the measure of compliance for this Standard.

### Documentation

- A letter written and signed by facility leadership demonstrating the institution's current and continuous administrative commitment to the MBSAQIP-Accredited center.

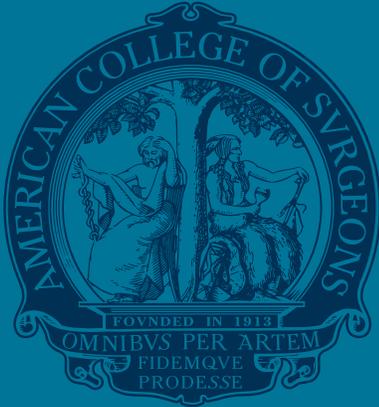
### Measure of Compliance

- Provides documentation of a letter written and signed by facility leadership (Chief Executive Officer or equivalent) demonstrating the institution's current and continuous administrative commitment to the MBSAQIP-Accredited center as outlined above.



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## **STANDARD 2**

# Program Scope and Governance

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## Rationale

All MBSAQIP-Accredited centers must maintain sufficient annual case volume based on their designation level, as outlined below in Standard 2.1. Additionally, accredited centers must follow any patient and procedure selection criteria specific to their designation level.

Every metabolic and bariatric procedure (open, laparoscopic, hand-assisted, robotic, or endoscopic) performed for the treatment of metabolic or obesity-related diseases at a MBSAQIP-Accredited center must be entered into the MBSAQIP Registry. Please refer to Standard 6.1 for further details.

The facility and its medical staff provide the structure, process, and personnel to obtain and maintain the quality standards of the MBSAQIP in caring for metabolic and bariatric patients. The administrative and medical staff must commit to broad cooperation in order to improve the quality of metabolic and bariatric patient care provided at the center.

## 2.1 Volume Criteria

### Definition and Requirements

All centers seeking MBSAQIP Accreditation must maintain sufficient annual case volume based on their designation level, as outlined below.

All centers must follow the requirements outlined in Standard 6.1 regarding data entry into the MBSAQIP Registry, and the requirements for Institutional Review Board (IRB) approval or exemption for primary procedures that are not endorsed by the American Society for Metabolic and Bariatric Surgery (ASMBS). The ASMBS list of endorsed procedures is available on the ASMBS website, [asmbs.org](http://asmbs.org).

Primary procedures that are not endorsed by the ASMBS are eligible to count toward the center’s annual accreditation volume as long as the requirements for IRB approval or exemption are followed. These requirements are outlined in Standard 6.1

Emerging evidence from the MBSAQIP Registry suggests that both surgeon and facility volume are significantly related to 30-day postoperative outcomes in bariatric surgery. To emphasize the importance of annual case volume for procedures with the highest degree of surgical complexity and technical difficulty, the MBSAQIP recommends that centers performing anastomotic procedures for the treatment of metabolic or obesity-related diseases maintain a minimum volume of 25 anastomotic procedures per year. **This recommendation is not a requirement for Standards compliance.**

#### Terminology

**Stapling Procedures:** MBSAQIP defines a stapling procedure as any procedure involving the use of a surgical stapler for the anastomosis or resection of any part of the gastrointestinal (GI) tract performed for the treatment of metabolic or obesity-related diseases. Procedures involving a hand-sutured anastomosis are also included in this procedure category.

**Adult Patients:** Any metabolic and bariatric patient 18 years of age and older.

**Adolescent Patients:** Although adolescence is a recognizable phase of life, an upper age limit is not easily demarcated and varies depending on the individual patient. MBSAQIP defines adolescent patients as those younger than 18 years of age for the sole purpose of determining when additional adolescent-specific care providers must be involved in the medical management of this patient group. MBSAQIP Adolescent Qualifications are required for centers that provide care to patients younger than 18 years of age.

This qualification is separate and distinct from adult accreditation.

MBSAQIP recognizes that under certain circumstances patients older than 18 years of age may undergo metabolic and bariatric treatment at a MBSAQIP Adolescent Center. MBSAQIP Adolescent Centers must review all patients over 21 years of age within the MBS Committee to determine whether or not care is to be deferred to a facility with a MBSAQIP Comprehensive Center designation.

Designation	Volume Criteria
<b>Data Collection Center</b>	No volume requirement—not accredited
<b>Designations For Inpatient Centers</b>	
<b>Comprehensive Center</b>	A minimum of 50 stapling procedures annually—adult patients only
<b>Comprehensive Center with Adolescent Qualifications</b>	A minimum of 50 stapling procedures annually—adult and adolescent patients
<b>Comprehensive Center with Obesity Medicine Qualifications</b>	A minimum of 50 stapling procedures annually—adult patients only
<b>Comprehensive Center with Adolescent and Obesity Medicine Qualifications</b>	A minimum of 50 stapling procedures annually—adult and adolescent patients
<b>Low Acuity Center</b>	A minimum of 25 bariatric procedures annually and must adhere to Low Acuity Center Patient and Procedure Selection (Standard 2.2)—adult patients only
<b>Adolescent Center</b>	A minimum of 15 stapling procedures annually—approved to provide care to adolescent patients  Centers performing fewer than 15 stapling procedures annually require a co-surgeon present for each case, as outlined in Standard 4.15
<b>Designation For Outpatient Centers</b>	
<b>Ambulatory Surgery Center</b>	A minimum of 25 bariatric procedures annually and must adhere to Ambulatory Surgery Center Patient and Procedure Selection (Standard 2.3)—adult patients only

**INITIAL APPLICANTS** must meet all applicable Standards for the designation level being sought within the most recent 12 months prior to applying for accreditation. This includes compliance with the volume requirement for the designation level being sought. Initial Applicants are not required to wait 12 months to apply if the center meets the application criteria sooner. For any Standard that requires 3 years of documentation, Initial Applicants are only required to document compliance within the most recent 12 months.

**RENEWAL APPLICANTS** must maintain continuous compliance with all applicable Standards. Continuous compliance with the MBSAQIP Standards will be evaluated every three years with a site visit as a component of the triennial reaccreditation cycle. Renewal Applicants are allowed to demonstrate compliance with the annual case volume requirements by averaging their annual case volume over the triennial reaccreditation cycle to meet the minimum requirements outlined above.

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## Documentation

- Operative logs from the facility and/or physician records for all metabolic and bariatric procedures performed at the applicant center.

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## Measure of Compliance

- Provides documentation of an administrative data file, operative logs, and/or physician records to verify that the center meets the volume requirements for the designation level sought.
- Provides proof that the center follows the patient and procedure selection criteria for their designation level.

## 2.2 Low Acuity Center Patient and Procedure Selection

### Definition and Requirements

Low Acuity Centers must comply with the **Low Acuity Center** patient and procedure selection criteria outlined below.

#### Patient Selection Criteria

1. Age  $\geq$  18 and  $<$  65 years
2. Males with a BMI  $<$  55 and females with a BMI  $<$  60
3. Patients **without**:
  - a. Organ failure (for example, severe congestive heart failure, end-stage renal disease, severe liver disease, etc.)
  - b. An organ transplant
  - c. Significant cardiac or pulmonary impairment
4. Patients must **not** be a candidate on a transplant list
5. Patients must be ambulatory

#### Procedure Selection

Low Acuity Centers are approved to perform **primary** metabolic and bariatric procedures. All patients must have **no** previous surgical history for the treatment of metabolic or obesity-related diseases.

Low Acuity Centers are only approved to perform the revisional metabolic and bariatric surgical procedures outlined below, and revisional metabolic and bariatric surgical procedures classified as an **emergent case**.<sup>\*</sup> Revisional metabolic and bariatric surgical procedures include any procedure performed for the purposes of weight loss at any time frame following a previous metabolic and bariatric surgical procedure. Low Acuity Centers are approved to perform the following revisional procedures:

- a. Adjustable gastric banding, replacement, repositioning, or removal
- b. Port revision or removal

**\*Emergent case definition:** An emergent case is usually performed within a short interval of time between patient diagnosis or the onset of related preoperative symptomatology. It is understood that the patient's well-being and outcome is potentially threatened by unnecessary delay and the patient's status could deteriorate unpredictably or rapidly. The principal operative procedure must be performed during the hospital admission for the diagnosis. Patients who are discharged after diagnosis and return for an elective, semi-elective, or urgent procedure related to the diagnosis are not considered to have had an emergent case.

#### Introducing New Metabolic and Bariatric Procedures

Low Acuity Centers introducing new metabolic and bariatric procedures must conduct specific education for all personnel (including surgeons covering call) involved in the care of metabolic and bariatric patients prior to performing any new procedure. Education must be tailored specifically to the new metabolic and bariatric procedure being introduced to the center. This education must include, at minimum:

1. Formal training regarding a basic understanding of the procedure being introduced, including the risks and benefits of the procedure
2. Signs and symptoms of postoperative complications
3. A basic understanding of the management and care of metabolic and bariatric patients by a review of the center's clinical pathways and protocols

### Documentation

- Operative logs, chart review during a site visit, and/or MBSAQIP data validation confirming appropriate patient and procedure selection.
- Staff education for newly introduced metabolic and bariatric procedures.

### Measure of Compliance

- Provides proof that patient and procedure selection fall within the Low Acuity Center requirements outlined above.
- Provides documentation that the education for center personnel, as outlined above, is provided prior to performing new metabolic and bariatric procedures.

## 2.3 Ambulatory Surgery Center Patient and Procedure Selection

### Definition and Requirements

Ambulatory Surgery Centers must comply with the **Ambulatory Surgery Center** patient and procedure selection criteria outlined below.

#### Patient Selection Criteria

1. Age  $\geq$  18 and  $<$  65 years
2. Males with a BMI  $<$  55 and females with a BMI  $<$  60
  - a. Patients **without**:
  - b. Organ failure (for example, severe congestive heart failure, end-stage renal disease, severe liver disease, etc.)
  - c. An organ transplant
3. Significant cardiac or pulmonary impairment
4. Patients must **not** be a candidate on a transplant list
5. Patients must be ambulatory

#### Procedure Selection

Ambulatory Surgery Centers are approved to perform **primary** metabolic and bariatric procedures.

Ambulatory Surgery Centers are only approved to perform the revisional metabolic and bariatric surgical procedures outlined below, and revisional metabolic and bariatric surgical procedures classified as an **emergent case**.<sup>\*</sup> Revisional metabolic and bariatric surgical procedures include any procedure performed for the purposes of weight loss at any time frame following a previous metabolic and bariatric surgical procedure. Ambulatory Surgery Centers are approved to perform the following revisional procedures:

- a. Adjustable gastric banding, replacement, repositioning, or removal
- b. Port revision or removal
- c. Adjustable gastric band to sleeve gastrectomy

To emphasize the importance of annual case volume for procedures with a higher degree of surgical complexity, Ambulatory Surgery Centers performing adjustable gastric band to sleeve gastrectomy revisions must perform a minimum of 50 stapling procedures per year.

**\*Emergent case definition:** An emergent case is usually performed within a short interval of time between patient diagnosis or the onset of related preoperative symptomatology. It is understood that the patient's well-being and outcome is potentially threatened by unnecessary delay and the patient's status could deteriorate unpredictably or rapidly. The principal operative procedure must be performed during the hospital admission for the diagnosis.

Patients who are discharged after diagnosis and return for an elective, semi-elective, or urgent procedure related to the diagnosis are not considered to have had an emergent case.

#### Introducing New Metabolic and Bariatric Procedures

Ambulatory Surgery Centers introducing new metabolic and bariatric procedures must conduct specific education for all personnel (including surgeons covering call) involved in the care of metabolic and bariatric patients prior to performing any new procedure. Education must be tailored specifically to the new metabolic and bariatric procedure being introduced to the center. This education must include, at minimum:

1. Formal training regarding a basic understanding of the procedure being introduced, including the risks and benefits of the procedure
2. Signs and symptoms of postoperative complications
3. A basic understanding of the management and care of metabolic and bariatric patients by a review of the center's clinical pathways and protocols

### Documentation

- Operative logs, chart review during a site visit, and/or MBSAQIP data validation confirming appropriate patient and procedure selection.
- Staff education for newly introduced metabolic and bariatric procedures.

### Measure of Compliance

- Provides proof that patient and procedure selection fall within the Ambulatory Surgery Center requirements outlined above.
- Provides documentation that the education for center personnel, as outlined above, is provided prior to performing new metabolic and bariatric procedures.
- Provides documentation of an administrative data file, operative logs, and/or physician records to verify that the center performs a minimum of 50 stapling procedures per year, if the center is performing adjustable gastric band to sleeve gastrectomy revisions.

## 2.4 Metabolic and Bariatric Surgery (MBS) Committee

### Definition and Requirements

The center must establish a single, unified MBS Committee consisting of, at a minimum, the following members:

- The MBS Director
- The MBS Coordinator
- The MBS Clinical Reviewer
- All surgeons and/or proceduralists at the center providing treatment for metabolic or obesity-related diseases
- Representative(s) of the facility's administration who are involved in the care or oversight of metabolic and bariatric patients

If a center is accredited with Adolescent Qualifications, the center must establish a Pediatric Medical Advisor (PMA). The PMA must be a member of the MBS Committee. The responsibilities of the PMA and their involvement in the MBS Committee are outlined in Standard 4.13.

MBSAQIP recognizes that under certain circumstances patients older than 18 years of age may undergo metabolic and bariatric treatment at a MBSAQIP Adolescent Center. MBSAQIP Adolescent Centers must review all patients over 21 years of age within the MBS Committee to determine whether or not care is to be deferred to a facility with a MBSAQIP Comprehensive Center designation.

If a center is accredited with Obesity Medicine Qualifications, the center must establish an Obesity Medicine Director (OMD). The OMD must be a member of the MBS Committee. The responsibilities of the OMD and their involvement in the MBS Committee are outlined in Standards 2.8, 5.6, and 6.4.

The MBS Committee is the primary forum for continuous quality improvement, as outlined in Standard 7. The MBS Committee provides a confidential setting for sharing best practices, responding to adverse events, and fostering a culture to improve patient care. All surgical practices performing metabolic and bariatric procedures at the center must participate in these initiatives in a collaborative manner, focusing on improved quality of care for metabolic and bariatric patients. Official meeting minutes are required to document that the MBS Committee has reviewed and discussed adverse events and patient outcomes. Specific details of these discussions are not mandatory to fulfill this requirement and meeting minutes must be kept in accordance with all laws regarding confidentiality and HIPAA compliance.

There must be a minimum of three MBS Committee meetings each year. At least one of these MBS Committee meetings must be an annual comprehensive review meeting to evaluate the following:

- Quality improvement initiatives (Standard 7.2)
- Procedural volumes (Standard 2.1)
- Patient education pathways (Standard 5.1)
- Patient care pathways (Standard 5.2)
- Procedural outcomes (Standards 6.3 and 7.1)
- Compliance with all applicable MBSAQIP Standards

At minimum, all surgeons and/or proceduralists providing treatment for metabolic or obesity-related diseases are required to attend the annual comprehensive review meeting, unless a written excuse is provided to the MBS Director. Excuses must be kept on file for review by the MBSAQIP to determine reasonableness (for example, patient, family, or personal emergency).

For surgeons seeking Metabolic and Bariatric Surgeon Verification, as outlined in Standard 4.2, the annual comprehensive review meeting of the MBS Committee is allowed to count as one of the two required annual quality meetings. Only one annual comprehensive review meeting per year is allowed to count as a quality meeting for each surgeon seeking verification. All other MBS Committee meetings do not count as quality meetings for the purposes of surgeon verification.

For the remaining meetings that are not the annual comprehensive review meeting, the committee members required to attend depend on the subject matter of the meeting. At a minimum, the attending surgeon or proceduralist must be in attendance if any aspect of care regarding one of their patients is discussed at a meeting. Accordingly, the MBS Committee will determine additional attendance requirements for all active metabolic and bariatric surgeons and proceduralists. A metabolic and bariatric surgeon and/or proceduralist from each practice must serve as a representative for their practice group at each of the three required MBS Committee meetings and attend the meeting either in-person, virtually, or via teleconference in accordance with the MBS Committee requirements.

The MBS Committee must carry out all the duties enumerated here, in addition to any other responsibilities outlined in other Standards.

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## Documentation

- Official minutes for all MBS Committee meetings.
- Proof of attendance for all metabolic and bariatric surgeons and proceduralists at the annual comprehensive review meeting.

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## Measure of Compliance

- Provides documentation of meeting minutes, including date, agenda, and attendance records, for the minimum of three MBS Committee meetings.
- Provides documentation that all actively participating metabolic and bariatric surgeons and proceduralists attended the annual comprehensive review meeting, unless excused by the MBS Director.

## 2.5 Metabolic and Bariatric Surgery (MBS) Director

### Definition and Requirements

The MBS Director must be an actively practicing metabolic and bariatric surgeon and have full privileges and credentials to perform metabolic and bariatric surgery at the accredited center. A single individual must fill the position of MBS Director at a MBSAQIP-Accredited center. In conjunction with the MBS Committee and the institution's administration, the MBS Director organizes, integrates, and leads all metabolic and bariatric surgery-related services throughout the accredited center. The MBS Director must be a MBSAQIP Verified Surgeon as described in Standard 4.2.

If a center loses or changes its MBS Director for any reason, the center must notify the MBSAQIP within 30 days. In this event, the center must establish a new MBS Director. The new MBS Director must be appointed within 12 months of the previous MBS Director's departure. The center must notify the MBSAQIP any time a new MBS Director is appointed.

Specific responsibilities of the MBS Director include:

1. The MBS Director chairs the MBS Committee and must attend at least two of the three required meetings, one of which must be the annual comprehensive review meeting, as well as the majority of all other meetings.
2. The MBS Director, in conjunction with the MBS Committee, is responsible for:
  - Overseeing the accreditation process and ensuring continuous compliance with all applicable MBSAQIP Standards.
  - Contacting the MBSAQIP within 30 days if the center falls out of compliance with any MBSAQIP Standard or there is any substantive change in the center.
  - Providing a response to MBSAQIP inquiries within 30 days.
3. The MBS Director, in conjunction with the MBS Committee, must ensure compliance with outcomes data collection for all metabolic and bariatric procedures performed at the center, as well as leading quality improvement initiatives. The MBS Director, in conjunction with the MBS Committee, is responsible for:
  - Development of quality standards
  - Evaluation of surgical and procedural outcomes
  - Development of specific quality improvement initiatives in response to adverse events while consistently improving the structure, process, and outcomes of the center
4. The MBS Director, in conjunction with the MBS Committee, is also responsible for overseeing the education of relevant staff in the various aspects of metabolic and bariatric patient care with a focus on patient safety and recognition of complications. The MBS Director leads the standardization and integration of metabolic and bariatric patient care throughout the center, as determined by the MBS Committee. Formal education and written protocols to nursing staff, surgeons, and proceduralists detailing the rapid communication and basic response to critical patient findings is specifically required to minimize delays in the diagnosis and treatment of serious adverse events.
5. The MBS Director, in conjunction with the MBS Committee, is responsible for determining the inclusion and exclusion criteria, including weight and/or BMI limits, for metabolic and bariatric patients who receive care at the center. These criteria include the types of procedures performed and the acuity and risk of all patients relative to the services the center can safely provide. These recommendations must be provided to the appropriate institutional body responsible for medical oversight (for example, credentialing, department of surgery, medical staff). Furthermore, if necessary, the MBS Director submits recommendations from the MBS Committee to the appropriate institutional administrative body relative to the scope of metabolic and bariatric practice of each individual surgeon and proceduralist based on that provider's experience, training, and outcomes.
6. The MBS Director is responsible for overseeing the process (as determined by the MBS Committee) by which emerging technologies and procedures will be safely introduced at the center, with adequate patient protection, oversight (including Institutional Review Board [IRB] approval or IRB exemption when indicated), and associated outcomes reporting.
7. The MBS Director is responsible for institution-wide communication of metabolic and bariatric-related policies established by the MBS Committee. Communication with all appropriate personnel through formal metabolic and bariatric team meetings is a basic quality and safety improvement effort.
8. The MBS Director, representing the decision of the MBS Committee, is responsible for reporting to the appropriate institutional entities (for example, chief of surgery, credentialing committee, medical staff, risk management, etc.) significant ethical and/or quality deviations by surgeons and proceduralists performing metabolic and bariatric procedures at the center and, when appropriate, plans for remediation or formal recommendations to limit or redact privileges.

9. The institution's organizational framework must incorporate the MBS Director position. The MBS Director must have a job description, contract, or agreement that provides the authority and resources to fulfill the duties listed above.
10. The MBS Director must be present and actively participate in each MBSAQIP site visit for their current center(s).

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## Documentation

- Metabolic and bariatric surgery privileges and credentials of the MBS Director.
- MBS Committee meeting attendance records for the MBS Director.
- The MBS Director qualifies as a MBSAQIP Verified Surgeon. (Surgeon verification is confirmed during the site visit by demonstrating compliance with Standard 4.2).
- MBS Committee meeting minutes that document the MBS Director is leading the design and implementation of quality improvement initiatives.
- A job description, contract, or agreement for the MBS Director position.

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## Measure of Compliance

- Provides documentation of the MBS Director's privileges and credentials.
- Provides documentation of meeting minutes confirming that the MBS Director has attended at least the minimum number of required MBS Committee meetings as outlined above.
- Provides proof that the MBS Director is a MBSAQIP Verified Surgeon (see Standard 4.2 for full details).
- Provides documentation of MBS Committee meeting minutes that prove the MBS Director is leading the design and implementation of quality improvement initiatives.
- Provides a job description, contract, or agreement for the MBS Director documenting that the MBS Director position is fully integrated into the institution's organizational framework and has the authority and resources to fulfill all duties as outlined in items 1–10 above.

## 2.6 Metabolic and Bariatric Surgery (MBS) Coordinator

### Definition and Requirements

MBSAQIP-Accredited centers must have a designated MBS Coordinator who assists and works directly with the MBS Director. The MBS Coordinator must be a licensed or registered health care professional.\* The center is allowed to have multiple MBS Coordinators, but a single individual must serve as a liaison between the center and the MBSAQIP. The MBS Coordinator is also allowed to fill the role of the MBS Clinical Reviewer (see Standard 2.7) as long as this individual does not document in patients' medical records. If a center loses or changes its MBS Coordinator for any reason, the center must notify the MBSAQIP within 30 days. In this event, the center must establish a new MBS Coordinator.

The MBS Coordinator administrates the MBS Committee and must attend at least two of the three required meetings, one of which must be the annual comprehensive review meeting, as well as the majority of all other meetings. The MBS Coordinator assists in program development, managing the accreditation process, ensuring continuous compliance with MBSAQIP Standards, maintaining relevant pathways and protocols, patient education, monitoring outcomes data and collection, quality improvement initiatives, and the education of relevant staff with a focus on metabolic and bariatric patient safety. The MBS Coordinator supports the development of written protocols and education of nursing staff detailing the rapid communication and basic response to critical patient findings that are specifically required to minimize delays in the diagnosis and treatment of serious adverse events.

The MBS Coordinator serves as the liaison between the facility and all metabolic and bariatric proceduralists at the center and any general surgeons providing call coverage. The MBS Coordinator assists in maintaining the documentation of the call schedule provided by all covering surgeons, as well as providing access to the call schedule to all departments of the facility that provide care for metabolic and bariatric patients.

If the MBS Coordinator and MBS Clinical Reviewer are separate individuals, they must work closely together to ensure timely submission of outcomes data to the MBSAQIP Registry.

The center's organizational framework must incorporate the MBS Coordinator position. The MBS Coordinator must have a job description or contract documenting the authority and resources to fulfill the above listed duties.

The MBS Coordinator must be present and actively participate in each MBSAQIP site visit for their current center(s).

### Documentation

- A job description or contract for the MBS Coordinator position.
- MBS Committee meeting minutes documenting participation by the MBS Coordinator.
- The health care license or registration of the MBS Coordinator.\*

### Measure of Compliance

- Provides a job description or contract documenting that the MBS Coordinator position is fully integrated into the organizational framework and has the authority and resources to fulfill all the duties as outlined above.
- Provides documentation of meeting minutes confirming that the MBS Coordinator has attended at least the minimum number of required MBS Committee meetings as outlined above.
- Provides documentation that the MBS Coordinator is a licensed or registered health care professional.\*
- MBS Coordinator is present and actively participates in each MBSAQIP site visit for their current center(s).

*\*The requirement for the MBS Coordinator to be a licensed or registered health care professional applies to individuals hired into the role of MBS Coordinator on or after May 1, 2015. All non-licensed MBS Coordinators hired into the role of MBS Coordinator prior to May 1, 2015 are exempt from this requirement.*

## 2.7 Metabolic and Bariatric Surgery (MBS) Clinical Reviewer

### Definition and Requirements

Timely and accurate data entry is essential for quality improvement and monitoring of patient safety. Each center is required to establish a MBS Clinical Reviewer to enter data into the MBSAQIP Registry. Designated MBS Clinical Reviewers are not approved to provide direct patient care. The MBS Clinical Reviewer is required to fulfill case abstraction duties, complete ongoing training and recertification requirements, retrieve and enter long-term follow-up data on all patients, and fulfill requests for outcomes data and reports from the MBS Committee and other appropriate personnel. If a center loses or changes its MBS Clinical Reviewer for any reason, the center must notify the MBSAQIP within 30 days. In this event, the center must establish a new MBS Clinical Reviewer.

During the initial stages of a center's participation in MBSAQIP, it is acceptable for the MBS Clinical Reviewer to take on limited additional administrative duties (that do not involve direct patient care) as long as all of their responsibilities as MBS Clinical Reviewer are fulfilled and given the highest priority. The number of Full Time Equivalents (FTEs) needed to fulfill all required MBS Clinical Reviewer duties must be commensurate with the center's annual case volume and follow-up census. Please see the MBSAQIP website [facs.org/quality-programs/mbsaqip/resources](https://facs.org/quality-programs/mbsaqip/resources) for further information regarding the MBS Clinical Reviewer role.

The MBS Clinical Reviewer must be provided with the appropriate resources and access to data and information systems at both the center and the physicians' offices. The MBS Clinical Reviewer must work closely with the center and clinicians to ensure that appropriate short term and long-term data elements are available in the medical records.

#### Training and Maintenance of MBS Clinical Reviewer Certification

The MBS Clinical Reviewer must be an individual with appropriate clinical knowledge and expertise to collect the required data. A sample job description for the MBS Clinical Reviewer role is available on the MBSAQIP website. Satisfactory completion of online initial training, as well as ongoing maintenance of certification, is required of the MBS Clinical Reviewer. Maintenance of certification as a MBS Clinical Reviewer is based upon participation in ongoing educational webinars, satisfactory completion of a yearly certification exam, as well as compliance with MBSAQIP data integrity audits when necessary.

#### MBS Clinical Reviewer Access to Systems and Records Requirements

In addition to MBSAQIP Registry access, it is required that the MBS Clinical Reviewer have open and unrestricted access to electronic and/or paper medical records for all patient-related data from the center and physicians' offices. If participating metabolic and bariatric surgeon(s) and any associated practice(s) do not provide the MBS Clinical Reviewer unrestricted access to all patient-related data, the center will be in violation of this Standard. If any personnel are no longer authorized to have access to the MBSAQIP Registry, the center is required to immediately terminate that individual's access to the MBSAQIP Registry using the Data Platform Contacts page through the MBSAQIP Quality Portal, <https://qualityportal.facs.org/Qport>.

#### MBS Clinical Reviewer Workspace and Equipment Requirements

Ensuring the confidentiality of protected health information is imperative while the MBS Clinical Reviewer engages in the data abstraction process. It is essential to provide the MBS Clinical Reviewer with an appropriate workspace to protect patient confidentiality.

#### Requirements for Timely Data Entry

Data entry to the MBSAQIP Registry is time sensitive, and it is the responsibility of the MBS Clinical Reviewer to ensure that procedure and follow-up data are entered into the MBSAQIP Registry within the prescribed data entry timeframes (as defined by MBS Clinical Reviewer training and the MBSAQIP Registry Operations Manual) to optimize data entry.

#### MBS Clinical Reviewer Participation and Integration

The MBS Clinical Reviewer must work closely with both clinical and administrative staff and must participate in at least two MBS Committee meetings annually, one of which must be the annual comprehensive review meeting.

The center's organizational framework must incorporate the MBS Clinical Reviewer position. The MBS Clinical Reviewer must have a job description or contract documenting the authority and resources to fulfill the above listed duties.

The MBS Clinical Reviewer must be present and actively participate in each MBSAQIP site visit for their current center(s).

### Outsourced MBS Clinical Reviewers

MBSAQIP allows accredited centers to outsource the MBS Clinical Reviewer role. Outsourced MBS Clinical Reviewers are not directly employed by the center, its physicians, or associated practices, but must still fulfill **all** of the requirements outlined above, including open and unrestricted access to medical records and participation in the required MBS Committee meetings. Outsourced MBS Clinical Reviewers must also be present and actively participate in each MBSAQIP site visit for their current center(s).

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## Documentation

- Maintenance of certification for the MBS Clinical Reviewer.
- A job description or contract for the MBS Clinical Reviewer position.
- MBS Committee meeting minutes documenting participation by the MBS Clinical Reviewer.

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## Measure of Compliance

- Provides documentation of maintenance of MBS Clinical Reviewer certification as verified by MBSAQIP.
- Provides a job description or contract documenting that the MBS Clinical Reviewer position is fully integrated into the organizational framework and has the authority and resources to fulfill all the duties outlined above, including timely data entry to the MBSAQIP Registry with full and unrestricted access to medical records.
- Provides documentation of the MBS Committee meeting minutes proving that the MBS Clinical Reviewer has participated in at least two meetings annually, one of which must be the annual comprehensive review meeting.
- MBS Clinical Reviewer is present and actively participates in each MBSAQIP site visit for their current center(s).

## 2.8 Obesity Medicine Director (OMD)

### Definition and Requirements

MBSAQIP Obesity Medicine Qualifications are separate and distinct from surgical and procedural accreditation. Only MBSAQIP Comprehensive Centers and MBSAQIP Comprehensive Centers with Adolescent Qualifications are eligible to seek MBSAQIP Obesity Medicine Qualifications. Centers seeking Obesity Medicine Qualifications must establish the position of the Obesity Medicine Director (OMD).

The Obesity Medicine Director (OMD) must be a physician who actively practices in the field of obesity medicine and is credentialed to practice medicine at the center. The OMD must also organize, integrate, and lead all obesity medicine services provided at the center. A single individual must fill the position of the OMD. Optimal care of obesity medicine patients is enhanced by specialized training, education, and experience, which may include certification as a Diplomate of the American Board of Obesity Medicine (ABOM®). However, such certifications are not a requirement for Standards compliance for the OMD.

The center's MBS Director is eligible to fill the role of the OMD, provided they meet all the requirements enumerated here and in Standard 2.5. The OMD must work in conjunction with the MBS Director, MBS Coordinator and MBS Clinical Reviewer as a member of the MBS Committee. Specific responsibilities of the OMD include:

1. The OMD is responsible for standardizing and integrating obesity medicine patient care.
2. The OMD is responsible for the integration of care for obesity medicine patients with other physicians and advanced practice providers at the center.
3. The OMD is responsible for determining the patient selection criteria for obesity medicine treatment.
4. The OMD is responsible for the development and review of care pathways for obesity medicine patients, as outlined in Standard 5.6.
5. The OMD is responsible for maintaining data collection and outcomes monitoring for obesity medicine patients as outlined in Standard 6.4.
6. The OMD is responsible for the development of quality standards and the evaluation of obesity medicine outcomes for patients with obesity.
7. The OMD is responsible for overseeing the process by which emerging medications and treatment options will be safely introduced to the center with adequate patient protection and oversight (including Institutional Review Board [IRB] approval or IRB exemption when indicated).

8. The institution's organizational framework must incorporate the OMD position. The OMD must have a job description, contract, or agreement that provides the authority and resources to fulfill the duties listed above.
9. The OMD must be an actively participating member of the MBS Committee and attend, at a minimum, the annual comprehensive review meeting.
10. The OMD must be present and actively participate in each MBSAQIP site visit for their current center(s).

### Documentation

- OMD's credentials to practice medicine at the center.
- MBS Committee meeting minutes documenting participation by the OMD.
- A job description, contract, or agreement for the OMD position.

### Measure of Compliance

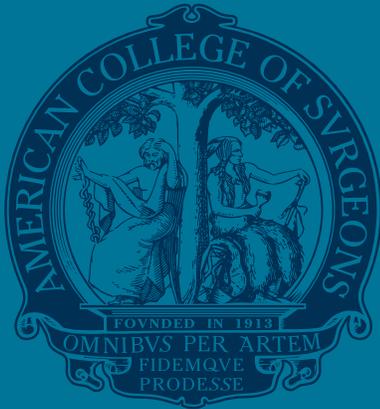
- Provides documentation of the OMD's credentials to practice medicine at the center.
- Provides documentation that the OMD attends, at a minimum, the annual comprehensive review meeting of the MBS Committee.
- Provides a job description, contract, or agreement for the OMD documenting that the OMD position is fully integrated into the institution's organizational framework and has the authority and resources to fulfill all duties as outlined in items 1–10 above.





**MBSAQIP**<sup>®</sup>

METABOLIC AND BARIATRIC SURGERY  
ACCREDITATION AND QUALITY IMPROVEMENT PROGRAM



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

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## **STANDARD 3**

# Facilities and Equipment Resources

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## **Rationale**

The center must maintain appropriate facilities and equipment for the care of metabolic and bariatric patients. This includes furniture, wheelchairs, operating room tables, appropriately weight-rated or reinforced toilets, beds, radiology capabilities, surgical instruments, and necessary facility requirements for the safe delivery of care to patients with obesity.

## 3.1 Health Care Facility Accreditation

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### Definition and Requirements

Health care facility accreditation ensures that care for metabolic and bariatric patients is provided in a safe environment. The applicant facility must be licensed by the appropriate state licensing authority, if required by state law, and/or by one of the following:

- The Joint Commission (TJC)
- State Health Department
- Det Norske Veritas (DNV)
- American Osteopathic Association (AOA)
- Healthcare Facilities Accreditation Program (HFAP)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Institute for Medical Quality (IMQ)
- Center for Improvement in Healthcare Quality (CIHQ)

A comprehensive list of qualifying health care facility accreditations that meet the measure of compliance for this Standard will be updated and maintained as needed on the MBSAQIP website, [facs.org/quality-programs/mbsaqip/resources](https://www.facs.org/quality-programs/mbsaqip/resources).

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### Documentation

- Health care facility accreditation certificate or documentation.

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### Measure of Compliance

- Provides documentation of the health care facility accreditation certificate or letter from an accrediting agency demonstrating current accreditation status.

## 3.2 Facilities, Equipment, and Furniture

### Definition and Requirements

The center must have facilities, equipment, and furniture to accommodate all prospective metabolic and bariatric patients who are within the weight limits of the patient selection criteria established by the MBS Committee.

A written or electronic system to ensure that weight-appropriate equipment is available and used for all metabolic and bariatric patients is required. Staff must be aware of the weight capacities and locations of equipment used for metabolic and bariatric patients. Equipment weight capacities must be documented using the manufacturer's specifications, and this information must be readily available to relevant staff. Stickers and/or labels may be used to identify the weight capacity of bariatric equipment and furniture, but are **not** a requirement for compliance with this Standard.

The center must also have a rental or lease agreement for any necessary equipment that is not available on-site. This agreement must indicate a guaranteed delivery timeframe for the unavailable equipment. The delivery timeframe is established at the discretion of the facility. A rental or lease agreement is not required if all necessary equipment is available at the facility.

Centers do **not** need to have weight appropriate equipment and furniture in every area of the facility. The requirements of this Standard only apply to those areas of the facility where metabolic and bariatric patients receive care. These areas include, but are not limited to: operating rooms, emergency department, radiology suite, endoscopy suite, intensive care unit, designated metabolic and bariatric surgery unit, and all associated waiting areas where metabolic and bariatric patients receive care.

Appropriate patient mobilization and transfer systems must also be located wherever metabolic and bariatric patients receive care. Staff must be trained to use this equipment and capable of mobilizing patients without injury to themselves or the patient (see Standard 4.4 regarding staff education on patient mobilization and transfer).

MBSAQIP requires facilities to have a full line of equipment and furniture for the care of metabolic and bariatric patients. This includes, but is not limited to, the following equipment that must accommodate patients with obesity:

- Examination tables
- Operating room tables
- Radiology equipment
- Fluoroscopy equipment
- Medical imaging equipment
- Surgical instruments (staplers, retractors, long instruments, etc.)
- Intensive care unit (ICU) equipment
- Crash carts
- Blood pressure cuffs
- Sequential compression devices
- Scales
- Gowns
- Wheelchairs
- Walkers

The facility must also have the following amenities to accommodate patients with obesity:

- Chairs
- Beds
- Doorways
- Showers
- Weight-rated or supported toilets\*†
  - a. Weight-rated floor mounted
  - b. Weight-rated wall mounted
  - c. Supported floor mounted
  - d. Supported wall mounted

*\*Toilets must be weight rated or supported to accommodate all prospective metabolic and bariatric patients who fall within the weight limits of the patient selection criteria established by the MBS Committee.*

*†Bedside commodes can be made available for patients with obesity, but **cannot** be used as a replacement for weight-appropriate toilets.*

MBSAQIP does not specify minimum physical dimensions for doorways, hallways, patient rooms, bathrooms, shower rooms, or other such areas of the facility. However, these areas must be able to accommodate all prospective metabolic and bariatric patients who are within the weight limits of the patient selection criteria established by the MBS Committee.

The center's patient selection criteria for metabolic and bariatric surgery must take into account the weight limits of existing equipment. The center must document a care pathway for patients that exceed equipment weight limits. This care pathway must specifically address how the center manages and/or refers care for patients presenting to the metabolic and bariatric surgery program who exceed the weight limits of existing equipment and/or patient selection criteria. The exact details of care management and/or patient referral outlined by the pathway are at the discretion of the MBS Committee. The care pathway does not need to address all patients that exceed the weight limits of existing equipment who present to the facility for general medical or surgical care. The care pathway is only required to address patients presenting for metabolic and bariatric care.

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## Documentation

- Weight appropriate facilities, equipment, and furniture.
- A written or electronic system for clearly defining the weight limits of equipment and furniture.
- Rental or lease agreement for equipment that is not available on-site.
- Care pathway for patients who exceed equipment weight limits.

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## Measure of Compliance

- Provides proof that weight appropriate facilities, equipment, and furniture are provided in the areas where metabolic and bariatric patients receive care.
- Provides documentation of a written or electronic system defining the weight limits of equipment and furniture.
- Provides documentation of a rental or lease agreement for equipment and furniture that is not available on-site that indicates a guaranteed delivery timeframe. This is not required for centers that have all required equipment on-site.
- Provides documentation of a care pathway for patients who exceed equipment weight limits.

## 3.3 Designated Bariatric Unit

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### Definition and Requirements

There must be a designated area in the facility for metabolic and bariatric patients where care is provided in a safe environment. The facility must have a dedicated metabolic and bariatric surgery unit or designated cluster of beds maintained in a consistent area of the facility.

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### Documentation

- Designated bariatric unit or cluster of beds.

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### Measure of Compliance

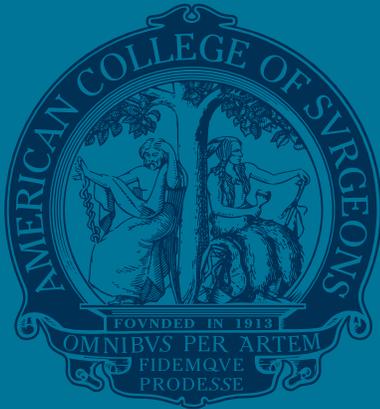
- Provides proof that a designated area in the facility exists for the care of metabolic and bariatric patients, with a dedicated metabolic and bariatric surgery unit or designated cluster of beds in a consistent area of the facility.





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## **STANDARD 4**

# Personnel and Services Resources

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## Rationale

If metabolic and bariatric patients require critical care services, centers and their associated surgeons must ensure that patients receive appropriate care. The facility must maintain various on-site and consultative services required for the care of metabolic and bariatric patients, including the immediate on-site availability of personnel capable of administering advanced cardiovascular life support. Consultants must be available within the specified time as determined by institutional policy.

The responsibility is upon the center, the metabolic and bariatric surgeon, and—ultimately—the MBS Committee and MBS Director, to appropriately select patients and develop selection criteria for the center relative to the center's available resources and experience. For example, patients who are at risk for specific and predictable complications (renal failure, airway compromise, heart failure, etc.) must be managed in a facility where access to all reasonable medical subspecialty care is available.

All MBSAQIP Comprehensive Center designations must be able to provide CCU and/or ICU services, endoscopy services, and diagnostic and interventional radiology services on-site (additional specialty services outlined in Standard 4.12 may be provided through a transfer agreement). Centers accredited under all other designation levels are eligible to provide these services either on-site or through a transfer agreement.

## 4.1 Credentialing Guidelines for Metabolic and Bariatric Surgeons

### Definition and Requirements

**MBSAQIP-Accredited centers must have credentialing requirements for metabolic and bariatric surgery that are separate and distinct from the institution's general surgery credentialing requirements.**

Credentialing policy details the institution's requirements for granting metabolic and bariatric surgical privileges to an applicant physician. These requirements speak to a physician's competency to provide safe, efficacious treatment to all patients and carry out their duties as mandated by the institution's credentialing body.

The credentialing requirements for metabolic and bariatric surgery must be formally documented in alignment with hospital policy. The center's credentialing requirements for metabolic and bariatric surgery must also be approved and officially recognized by the institution's credentialing body.

The institution's credentialing requirements must address the maintenance and renewal of metabolic and bariatric surgery privileges, as well as the frequency at which privileges must be renewed for physicians with current credentials.

All providers must adhere to all metabolic and bariatric surgery credentialing requirements set forth locally by the institution, both at the time of initial application for privileges and at each renewal interval.

The center must have at least one actively practicing surgeon with metabolic and bariatric privileges at all times.

All credentialed metabolic and bariatric surgeons and proceduralists must adhere to all patient and procedure selection criteria established by the MBSAQIP Standards, and locally by the MBS Committee.

The institution's credentialing requirements must adhere to current nationally recognized credentialing guidelines for metabolic and bariatric surgery. **These credentialing requirements must be separate and distinct from the institution's general surgery credentialing requirements.** Examples of nationally recognized credentialing guidelines include those produced by the American Society for Metabolic and Bariatric Surgery (ASMBS), the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), the American College of Surgeons (ACS), and the Society for Surgery of the Alimentary Tract (SSAT). These nationally recognized guidelines are summarized in the next section.

### Guidelines for Metabolic and Bariatric Surgeon Credentialing

1. Completion of an accredited general surgery residency.
2. Certified or eligible to be certified by the American Board of Surgery or equivalent (American Osteopathic Board of Surgery, Royal College of Physicians and Surgeons of Canada). Exceptions to the board certification requirement are allowed on a case-by-case basis.
3. State medical licensure in good standing.
4. Formal didactic training in bariatric surgery, which includes completion of an accredited bariatric surgery fellowship and/or documentation of previous bariatric surgery experience. Supporting documentation, including an operative log or bariatric surgery training certificate, must be provided to allow the credentialing body to assess the applicant surgeon's bariatric surgery experience.
5. Participation within a structured metabolic and bariatric center that provides or coordinates comprehensive, multidisciplinary care of metabolic and bariatric patients.
6. Commitment to use bariatric surgery clinical pathways.
7. Privileges to perform gastrointestinal surgery.
8. Privileges to perform advanced laparoscopic procedures if laparoscopic bariatric surgery privileges are being requested.
9. Privileges to perform endoluminal therapeutic procedures, if endoluminal privileges are being requested.
10. The surgeon must actively participate in the MBSAQIP and adhere to its Standards by implementing changes in practice in accordance with feedback from the MBSAQIP or an equivalent regional or national quality improvement program.

### Guidelines for Surgeons with Limited or No Experience in Bariatric Surgery or Advanced Laparoscopy

1. Applicant surgeon must complete a structured training curriculum in bariatric surgery and advanced laparoscopic surgery as reviewed and approved by the MBS Director.
2. The applicant surgeon must have completed a general surgery residency.
3. The applicant surgeon's initial cases must be performed with a co-surgeon who is a fully credentialed bariatric surgeon. The absolute number of proctored cases is determined by the local credentialing committee. The local credentialing committee may also wish to delineate separate requirements for those procedures which require gastrointestinal stapling versus those that do not.

4. It is advisable that the first cases be of lower technical difficulty with lower risk patients as determined by the MBS Director.
5. The surgeon must actively participate in the MBSAQIP and adhere to its Standards by implementing changes in practice in accordance with feedback from the MBSAQIP or an equivalent regional or national quality improvement program.
4. The surgeon must demonstrate continued critical assessment of their surgical outcomes as determined by the periodic review of outcomes from an acceptable regional or national outcomes registry.
5. The chief of surgery or their designee must verify that these criteria have been met.

### Types of Procedures

The following procedures qualify as bariatric procedures (open or laparoscopic) under these credentialing guidelines:

1. Adjustable gastric banding
  2. Biliopancreatic diversion with duodenal switch
  3. Biliopancreatic diversion without duodenal switch
  4. Roux-en-Y gastric bypass
  5. Sleeve gastrectomy
  6. Single Anastomosis Duodeno-ileostomy with Sleeve (SADI-S)
  7. Revisional or conversional bariatric surgery
- Investigational procedures must be performed under IRB approval or IRB exemption.
  - Local credentialing bodies may wish to delineate separate requirements for those procedures that require gastrointestinal stapling versus those that do not.

### Guidelines for Surgeons and Non-Surgeon Proceduralists Performing Endoluminal Therapeutic Procedures for the Treatment of Metabolic or Obesity-Related Diseases

Individuals performing endoluminal therapeutic procedures for the treatment of metabolic or obesity-related diseases must be credentialed under endoscopic privileges that adhere to current nationally recognized guidelines, such as *SAGES Granting Privileges for Gastrointestinal Endoscopy*. All providers performing endoluminal therapeutic procedures for the treatment of metabolic or obesity-related diseases must be active members of the MBS Committee.

### Guidelines for Maintenance and Renewal of Privileges

1. Privileges to perform bariatric surgery must be renewed commensurate to each institution's credentialing requirements.
2. Continuous certification by the American Board of Surgery or its equivalent.
3. Continued active participation within a structured bariatric surgery center. Ongoing participation with the MBSAQIP or an equivalent regional or national quality improvement program.

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## Documentation

- Metabolic and bariatric surgery credentialing requirements.
- Metabolic and bariatric surgery privileges for all actively practicing metabolic and bariatric surgeons at the center.
- Gastrointestinal endoscopy privileges for all non-surgeons performing metabolic and bariatric procedures at the center.

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## Measure of Compliance

- Provides documentation of the required metabolic and bariatric surgery privileges for all actively practicing metabolic and bariatric surgeons at the center.
- Provides documentation of the required gastrointestinal endoscopy privileges for all non-surgeons performing metabolic and bariatric procedures at the center.
- Provides documentation to demonstrate compliance with current nationally recognized credentialing guidelines.

## 4.2 MBSAQIP Surgeon Verification

### Definition and Requirements

MBSAQIP surgeon verification ensures the presence of experienced and consistent surgical leadership within the accredited center at all times. Surgeon verification is only a component of MBSAQIP Standards compliance.

The center's MBS Director must be a MBSAQIP Verified Surgeon in order for the center to achieve MBSAQIP Accreditation. Only the MBS Director is required to meet the criteria outlined below for surgeon verification. All other surgeons at the center are eligible, but not required, to seek surgeon verification if they meet the criteria outlined below. The MBSAQIP will verify the MBS Director and any additional surgeons seeking verification at each MBSAQIP site visit. All surgeons who meet criteria will receive documentation from the MBSAQIP stating that they have met the qualifications for a "MBSAQIP Verified Surgeon" as of the date of the site visit. Surgeon verification must be renewed during every triennial reaccreditation cycle. **Surgeons seeking MBSAQIP verification must be present and actively participate in each MBSAQIP site visit for their current center(s).**

If a center loses or changes its MBS Director for any reason, the center must notify the MBSAQIP within 30 days. The new MBS Director must be appointed within 12 months of the previous MBS Director's departure. The center must notify the MBSAQIP any time a new MBS Director is appointed. If necessary, the MBSAQIP will review documentation submitted by the center to confirm the new MBS Director meets criteria for surgeon verification to ensure continuous compliance with Standard 4.2.

All surgeons, including MBSAQIP Verified Surgeons, must adhere to the designation level of the MBSAQIP-Accredited center where they are providing care and follow all patient and procedure selection criteria established for that designation level by the MBSAQIP Standards. Surgeons must also adhere to all patient and procedure selection criteria established by the MBS Committee.

The annual volume documentation for surgeon verification can be accomplished using the surgeon's procedure volume from any MBSAQIP-Accredited center. Procedure volume from a center that is in the process of applying but has not yet achieved MBSAQIP Accreditation can also be counted, but is limited to procedure volume from the most recent 12 months.

The following criteria must be met to achieve surgeon verification:

1. **MBSAQIP Participation:** The surgeon's center must be in full compliance with all MBSAQIP Standards and actively participate in the MBSAQIP.
2. **Quality Meetings:** The surgeon must attend at least two quality meetings annually.
  - a. MBSAQIP defines a quality meeting as any local, regional, or national meeting where quality initiatives are discussed, allowing the verified surgeon to bring new ideas and information to an accredited center. Quality meetings do not need to be metabolic or bariatric-specific, but must provide the verified surgeon an opportunity to learn about quality improvement and apply that knowledge to their leadership of a MBSAQIP-Accredited center.
  - b. The annual comprehensive review meeting of the MBS Committee (discussed in Standard 2.4) is allowed to count as one of the two required annual quality meetings for surgeons seeking verification. Only one annual comprehensive review meeting per year is allowed to count toward the quality meeting requirement for surgeon verification. All other MBS Committee meetings do not count as quality meetings.
  - c. Examples of quality meetings include, **but are not limited to**, departmental quality meetings, institutional quality committee meetings, SAGES, ASMBS State Chapter meetings, ACS State Chapter meetings, ASMBS Week, ASMBS Weekend, ACS Quality and Safety Conference, ACS Clinical Congress, and any additional quality based educational programs offered by the ACS or ASMBS.
  - d. Morbidity and Mortality Conferences (M&Ms) and similar peer review meetings do **not** count as quality meetings.
3. **Lifetime Volume Documentation:** The surgeon must present an operative log to document a minimum of 100 lifetime stapling procedures.
  - a. The surgeon can count up to 75 stapling procedures from an accredited fellowship toward the lifetime volume requirement. These procedures must be documented by an operative log and a letter from the fellowship director.
  - b. The surgeon must perform a minimum of 25 stapling procedures after fellowship for a total of at least 100 lifetime stapling procedures.

4. **Annual Volume Documentation:** The surgeon must submit an operative log from the MBSAQIP Registry verifying that, at minimum, an **average** of 25 stapling procedures **per year** were performed during the triennial reaccreditation cycle.
  - a. The annual volume documentation can be accomplished using the surgeon's procedure volume from any MBSAQIP-Accredited center. Procedure volume from a center that is in the process of applying but has not yet achieved MBSAQIP Accreditation can also be counted, but is limited to procedure volume from the most recent 12 months.
5. **Board Certification:** The surgeon must be board certified or in the process of becoming board certified by the American Board of Surgery (or equivalent). Foreign-trained surgeons are eligible for exemption from the board certification requirement and will be evaluated on an individual basis.
6. **CME:** The surgeon is required to complete, at minimum, an **average** of 8 metabolic and bariatric-specific *AMA PRA Category 1* CME credit hours **per year** during the triennial reaccreditation cycle.

**Non-Stapling Verification:** If the center is only performing non-stapling procedures for the treatment of metabolic or obesity-related diseases, verification will follow all of the criteria listed above, except the annual volume documentation will apply to non-stapling procedures only: an **average** of 25 non-stapling procedures **per year**. **Non-stapling surgeon verification is a separate and distinct form of surgeon verification.**

**Adolescent Center Verification:** This requirement applies only to children's hospitals seeking accreditation as a MBSAQIP Adolescent Center. For surgeons seeking verification at an Adolescent Center, verification will follow all of the criteria listed above, except that the annual volume documentation requirement is an **average** of 15 stapling procedures **per year**. The annual volume requirements for Adolescent Centers are discussed further in Standard 4.15. **Adolescent surgeon verification is a separate and distinct form of surgeon verification.**

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## Documentation

- The MBS Director and each additional surgeon seeking verification must document the following:
  1. Participation in the MBSAQIP.
  2. Participation in at least two quality meetings annually.
  3. At least 100 lifetime stapling procedures (or 100 lifetime non-stapling procedures for centers exclusively performing non-stapling procedures).
  4. A minimum average of 25 stapling procedures per year (or 25 non-stapling procedures for centers exclusively performing non-stapling procedures).
  5. Board certification, or in progress board certification.
  6. A minimum average of 8 metabolic and bariatric-specific CME per year.

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## Measure of Compliance

- Provides proof that the MBS Director, and each additional surgeon(s) seeking verification, meets the above criteria for surgeon verification. Only the MBS Director is required to be a verified surgeon.
- The MBS Director and each additional surgeon(s) seeking verification must be present and actively participate in each MBSAQIP site visit for their current center(s).

## 4.3 Metabolic and Bariatric Surgery Call Coverage

### Definition and Requirements

It is the responsibility of MBSAQIP-Accredited centers to provide call coverage for all metabolic and bariatric patients presenting to the facility, whether or not the center performed the patient's principal metabolic and bariatric procedure(s). Call coverage must be provided twenty-four hours a day and 365 days per year. All surgeons performing metabolic and bariatric surgery at the center must have qualified call coverage at all times by a colleague who is responsible for the emergency care of metabolic and bariatric patients in the absence of the primary surgeon. This must include call coverage for the full range of complications associated with metabolic and bariatric surgery. All surgeons providing call coverage must be available within the timeframe determined by institutional policy. It is the responsibility of the MBS Committee to ensure that continuous call coverage is provided. The call coverage schedule must be documented and available to all relevant staff.

Transfer agreements can be used to help facilitate full call coverage, but accredited centers cannot use transfer agreements as a substitute for a call schedule. Furthermore, it cannot be regular practice or a matter of policy to utilize transfer agreements as a substitute for managing metabolic and bariatric patients otherwise unaffiliated with, or unassigned to, the applicant center.

If the center's call coverage involves one or more general surgeons who are not privileged to perform metabolic and bariatric surgery, then the general surgeon(s) covering call must be credentialed with general surgery privileges and must have undergone adequate education and training as determined by the center's MBS Committee, which must include, at minimum, formal training regarding a basic understanding of:

- Metabolic and bariatric procedures commonly performed at the center
- Signs and symptoms of postoperative complications
- Management and care of patients by a review of the center's clinical pathways and protocols

Surgeons covering call for the center must be available for discussion or consultation for patients with a prior history of metabolic and bariatric surgery, inclusive of patients who are unaffiliated with or unassigned to the applicant center. A protocol that has been endorsed by the MBS Committee must address the care of unassigned or unaffiliated metabolic and bariatric patients presenting to the applicant center.

### Documentation

- Call schedule for at least the past three months.
- Roster of surgeons who provide metabolic and bariatric surgery call coverage.
- General surgery privileges for each surgeon.
- Education of general surgeons who provide metabolic and bariatric surgery call coverage.
- Protocol outlining the care of unassigned or unaffiliated patients.

### Measure of Compliance

- Provides documentation of the metabolic and bariatric surgery call schedule for at least the past three months.
- Provides documentation of the roster of surgeons who provide metabolic and bariatric surgery call coverage with documentation of general surgery privileges for each surgeon.
- Provides proof of education of general surgeons who provide metabolic and bariatric surgery call coverage in alignment with the education requirements as outlined above.
- Provides documentation of a protocol outlining the care of unassigned or unaffiliated metabolic and bariatric patients presenting to the applicant center.

## 4.4 Staff Training

### Definition and Requirements

There must be well-established, properly managed, and ongoing education programs for the metabolic and bariatric team and all relevant staff. The educational programs must ensure a basic understanding of metabolic and bariatric surgery and patient care, including the risks and benefits for all procedures performed at the center and the appropriate management and care of metabolic and bariatric patients.

All appropriate personnel caring for metabolic and bariatric patients are required to complete the following training sessions:

#### Training Level 1

**Course Name:** Sensitivity Training

**Course Description:** Education must support a culture where all staff members are prepared to manage patients with obesity, (whether or not metabolic and bariatric surgery is the indication for medical care), with the understanding and compassion to appreciate the burdens of patients with obesity.

**Required Staff:** All staff and licensed health care providers that have, or potentially have, direct contact with metabolic and bariatric patients.

**Minimum Frequency:** At initial hire and repeated within each triennial reaccreditation cycle.

#### Training Level 2

**Course Name:** Patient Transfer and Mobilization

**Course Description:** Education must address the safe transfer and mobilization of patients with obesity, to protect the safety of both patients and staff. This training is also beneficial when providing care for the increasing number of patients with obesity who present for other types of medical care.

**Required Staff:** All staff and licensed health care providers who may need to mobilize or transfer metabolic and bariatric patients.

**Minimum Frequency:** At initial hire and repeated within each triennial reaccreditation cycle.

#### Training Level 3

**Course Name:** Signs and Symptoms of Postoperative Complications

**Course Description:** Education must ensure that those caring for metabolic and bariatric patients are able to recognize the potential signs and symptoms of common metabolic and bariatric surgery complications (for example, pulmonary embolus, anastomotic leak, infection, bowel obstruction, etc.) to ensure that patients can be managed appropriately.

**Required Staff:** All licensed health care providers who have direct contact with metabolic and bariatric patients.

**Minimum Frequency:** At initial hire and annually thereafter.

### Documentation

- Course materials for each training level.
- Records of training completion for relevant staff.

### Measure of Compliance

- Provides documentation of educational materials for each training level outlined above.
- Provides documentation of training completion for relevant staff at the required training intervals as outlined above.

## 4.5 Multidisciplinary Team

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### Definition and Requirements

The center must establish a multidisciplinary team capable of providing an integrated health approach to metabolic and bariatric patients. Optimal care of metabolic and bariatric patients requires specialized training, education, and experience, which may include Certified Bariatric Nurse (CBN®) certification. The center must provide access or referral to the following disciplines, as needed, for preoperative, perioperative, and postoperative care.

- a. Consistent operating room staff or operating room team
- b. Registered nurses, advanced practice nurses, or other advanced practice providers
- c. Registered dietitians
- d. Psychologists, psychiatrists, social workers, or other licensed behavioral health care providers
- e. Physical or exercise therapists

If a center is accredited to perform metabolic and bariatric surgery on adolescent patients, a psychologist, psychiatrist, or other qualified and licensed behavioral health care provider with specific training and credentialing in pediatric and adolescent care must perform the behavioral assessment. This requirement is discussed further in Standard 4.14.

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### Documentation

- Credentials, privileges, licensure, or certification for the multidisciplinary team members listed above.

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### Measure of Compliance

- Provides documentation of a multidisciplinary, integrated health team for metabolic and bariatric patients, as outlined above.

## 4.6 Advanced Cardiovascular Life Support (ACLS)

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### Definition and Requirements

An ACLS-qualified physician, ACLS-qualified advanced practice provider, or other licensed health care provider who is capable of administering ACLS (including cardiac defibrillation, drug administration, advanced airway management, etc.) must be on-site at all times when metabolic and bariatric patients are present. This requirement ensures that a qualified provider is available to perform patient resuscitations at any time when anesthesia is not being administered. Centers with an emergency department can fulfill this requirement with a credentialed emergency department physician, as long as hospital policy dictates that such a physician is available at all times.

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### Documentation

- Credentials for an ACLS-qualified licensed health care provider who is on-site at the facility at all times.

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### Measure of Compliance

- Provides documentation that an ACLS-qualified physician, advanced practice provider, credentialed emergency department physician, or other licensed health care provider who is capable of administering ACLS, as well as advanced airway management, is on-site at the facility at all times when metabolic and bariatric patients are present.

## 4.7 Patient Stabilization

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### Definition and Requirements

All MBSAQIP-Accredited centers must have the ability to stabilize critically ill metabolic and bariatric patients. The facility must have the ability to intubate and manage a difficult airway, and ventilators and hemodynamic monitoring equipment must be immediately available.

If the center is unable to manage the patient on-site, the center must have the ability to stabilize a critically ill metabolic and bariatric patient until the patient can be transferred to a higher level of care (see Standard 5.3 regarding written transfer agreements).

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### Documentation

- Difficult airway cart, ventilator, and hemodynamic monitoring equipment available onsite.

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### Measure of Compliance

- Provides proof of the ability to stabilize critically ill metabolic and bariatric patients by providing physical proof of a difficult airway cart, ventilator, and hemodynamic monitoring equipment.

## 4.8 Critical Care Unit (CCU) / Intensive Care Unit (ICU) Services

### Definition and Requirements

CCU/ICU requirements:

1. CCU/ICU equipment that accommodates patients with obesity.
2. Physician, surgeon, or intensivist who has met credentialing criteria by the facility to manage critically ill patients, who must be available twenty-four hours a day and 365 days per year.
  - a. If a physician, surgeon, or intensivist is not available, an off-site CCU/ICU monitoring system is acceptable only if the center has all of the other critical care requirements in Standards 4.6-4.12 available on-site.
3. Trained critical care nurses who have met the center's credentialing criteria must be available twenty-four hours a day and 365 days per year.
4. All MBSAQIP Comprehensive Center designations must have critical care unit capability on-site. Centers seeking all other designation levels (Low Acuity, Ambulatory, and Adolescent Centers) that do not have critical care unit capability on-site must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric patients to another facility that fully meets all the above requirements.

### Documentation

- CCU/ICU services available on-site.
- Credentials for at least one physician, surgeon, or intensivist approved to manage critically-ill patients.
- Job description and licensure for at least one credentialed critical care nurse.

### Measure of Compliance

- Provides proof of access to critical care services that meet the above requirements.
- Provides documentation of credentials for a physician, surgeon, or intensivist approved to manage critically-ill patients.
- Provides documentation of a job description and licensure for at least one credentialed critical care nurse.

## 4.9 Anesthesia Services

### Definition and Requirements

Anesthesiology requirements for perioperative management of metabolic and bariatric patients:

Anesthesia providers must be approved by the center's credentialing body. Anesthesia providers must also adhere to local and state laws governing their scope of practice.

Accredited centers must have an anesthesia protocol specific to the care of metabolic and bariatric patients that is approved by the MBS Committee. A general surgery anesthesia protocol alone is not sufficient to meet the measure of compliance for this Standard. The metabolic and bariatric anesthesia protocol must address the following, at a minimum:

1. Basic guidelines for the anesthesia management of metabolic and bariatric patients
2. Hemodynamic monitoring
3. Fluid intake and management
4. Mobilization and positioning of patients with obesity while under sedation
5. Difficult airway management

### Documentation

- Anesthesia protocol specific to the care of metabolic and bariatric patients.
- Credentials for at least one approved anesthesia provider.

### Measure of Compliance

- Provides documentation of an anesthesia protocol specific to metabolic and bariatric patients, which is approved by the MBS Committee, as outlined above.
- Provides documentation of the credentials for anesthesia providers who care for metabolic and bariatric patients that adhere to local and state laws governing their scope of practice.

## 4.10 Endoscopy Services

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### Definition and Requirements

Endoscopy services requirements:

1. Physician who has met credentialing criteria by the center to perform diagnostic and therapeutic endoscopy.
2. Trained nursing staff responsible for assisting endoscopists in performing gastrointestinal (GI) endoscopy.
3. All MBSAQIP Comprehensive Center designations must have endoscopy services on-site. Centers seeking all other designation levels (Low Acuity, Ambulatory, and Adolescent Centers) that do not have endoscopy capability on-site must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric patients to another facility that fully meets all the above requirements.

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### Documentation

- Endoscopy services available on-site.
- Credentials for at least one physician approved to provide endoscopy services.

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### Measure of Compliance

- Provides proof of access to endoscopy services that meet the above requirements.
- Provides documentation of credentials for at least one physician approved to perform diagnostic and therapeutic endoscopy as outlined above.

## 4.11 Diagnostic and Interventional Radiology Services

### Definition and Requirements

Diagnostic and interventional radiology services requirements:

1. A physician who meets credentialing criteria by the facility to perform imaging, percutaneous drainage, and other radiology procedures.
  - a. A fully equipped interventional radiology suite is not required for compliance with this Standard. The center's interventional radiology services must be able to perform basic interventional procedures on site. Basic equipment and associated capabilities **may include, but are not limited to:**
    - i. Computed tomography (CT)
    - ii. Fluoroscopy
    - iii. Ultrasound
2. All MBSAQIP Comprehensive Center designations must have diagnostic and interventional radiology services onsite. Centers seeking all other designation levels (Low Acuity, Ambulatory, and Adolescent Centers) that do not have interventional radiology capability on-site must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric patients to another facility that fully meets all the above requirements.

### Documentation

- Diagnostic and interventional radiology services available on-site.
- Credentials for at least one physician approved to provide radiology services.

### Measure of Compliance

- Provides proof of access to diagnostic and interventional radiology services that meet the above requirements.
- Provides documentation of credentials for at least one physician approved to perform diagnostic and interventional radiology services as outlined above.

## 4.12 Specialty Services

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### Definition and Requirements

Accredited centers must have available for consultation, twenty-four hours a day and 365 days per year, credentialed consultants capable of managing the full range of metabolic and bariatric surgery complications:

1. Pulmonology and/or critical care
2. Cardiology
3. Nephrology

All centers must have the above specialty services available on-site or must have a signed written transfer agreement that details the transfer plan for metabolic and bariatric patients to another facility that can provide the specialty services listed above.

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### Documentation

- Credentials for the consultants for all additional specialty services.
- A written transfer agreement for any specialty service listed above that is not provided on-site.

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### Measure of Compliance

- Provides documentation of credentials for at least one physician who provides consultative coverage for each of the additional specialty services listed above.
- Provides proof of access to all the additional specialty services listed above twenty-four hours a day and 365 days per year.
- Provides documentation of a signed, written transfer agreement for any specialty service listed above that is not provided on-site.

## 4.13 Pediatric Medical Advisor (PMA)

### Definition and Requirements

MBSAQIP Adolescent Centers and Comprehensive Centers with Adolescent Qualifications must establish a Pediatric Medical Advisor (PMA). The PMA must be a member of the MBS Committee (as outlined in Standard 2.4).

#### Pediatric Medical Advisor (PMA)

Every adolescent patient requires a pediatrician or equivalent provider who participates in their preoperative and postoperative care. All MBSAQIP-Accredited centers that provide care for adolescent metabolic and bariatric patients must establish a PMA, and the PMA must be a member of the MBS Committee.

#### In MBSAQIP Adolescent Centers, the PMA must fit one of the following physician descriptions:

- A physician with educational training who is credentialed in general pediatrics and/or pediatric sub-specialty training (for example, endocrinology, cardiology, gastroenterology, adolescent medicine, etc.).
- An internal medicine physician or family practitioner with specific training and experience in adolescent medicine.

A pediatric surgeon is **not** eligible to serve as the center's PMA.

#### In MBSAQIP Comprehensive Centers with Adolescent Qualifications, the PMA must fit one of the following physician descriptions:

- A physician with educational training who is credentialed in general pediatrics and/or pediatric sub-specialty training (for example, endocrinology, cardiology, gastroenterology, adolescent medicine, etc.).
- An internal medicine physician or family practitioner with specific training and experience in adolescent medicine.
- If no qualifying individual exists in a Comprehensive Center with Adolescent Qualifications, a specific individual who meets the training qualifications outlined above must be identified within the local medical community to serve as the PMA.

A pediatric surgeon is **not** eligible to serve as the center's PMA.

The responsibilities of the PMA are to provide documented ongoing general pediatric medical oversight in addition to assisting in the utilization of adolescent-specific sub-specialty consultations when needed (for example: sleep medicine, gastroenterology, endocrinology, hematology, nephrology, behavioral health, etc.). Additionally, the PMA must assist in the development of comorbid-specific treatment plans in conjunction with the patient's primary care provider in order to optimize perioperative health. At minimum, the PMA must attend the annual comprehensive review meeting of the MBS Committee and any MBS Committee meeting where pediatric patients are discussed.

The Pediatric Medical Advisor must be present and actively participate in each MBSAQIP site visit for their current center(s).

### Documentation

- A qualified PMA must be established.
- Privileges and credentials of the PMA.
- MBS Committee meeting minutes documenting participation by the PMA.

### Measure of Compliance

- Provides proof that the center has identified an individual to serve as the PMA who meets the qualifications outlined above.
- Provides documentation of the privileges and credentials of the PMA.
- Provides documentation that the PMA attended the annual comprehensive review meeting and any additional MBS Committee meeting where pediatric patients were discussed.
- The PMA is present and actively participates in each MBSAQIP site visit for their current center(s).

## 4.14 Pediatric Behavioral Specialist

### Definition and Requirements

MBSAQIP Adolescent Centers and Comprehensive Centers with Adolescent Qualifications must provide access to a pediatric behavioral specialist for all adolescent patients.

The adolescent patient and their family must be able to demonstrate awareness of the general risks and benefits of metabolic and bariatric surgery as well as awareness of the dietary and physical activity requirements following a metabolic and bariatric procedure. A psychologist, psychiatrist, or other qualified and licensed behavioral health care provider with specific training and credentialing in pediatric or adolescent care must perform this assessment. The pediatric behavioral specialist must have experience in treating obesity and eating disorders as well as experience evaluating adolescent patients and their families. If a qualified pediatric behavioral specialist is not present in a MBSAQIP-Accredited center that provides care for adolescent metabolic and bariatric patients, a specific individual with the aforementioned training must be identified by the MBS Committee. Evaluation by a pediatric behavioral specialist is critical to ensuring that full assent to the proposed care plan can be obtained.

Documentation of the following behavioral assessment elements must be obtained in order to consider an adolescent patient for any metabolic and bariatric procedure:

- Evidence for mature decision making and awareness of potential risks and benefits of the proposed procedure.
- Documentation of the adolescent's ability to provide surgical assent.
- Evidence of appropriate family and social support mechanisms (engaged and supportive family members, care takers, etc.).
- If behavioral disorders are present (depression, anxiety, etc.), there must be evidence that these conditions have been satisfactorily treated.

Evidence must be provided that the family and patient have the ability and motivation to comply with recommended treatments preoperatively and postoperatively, including consistent use of recommended nutritional supplements. Evidence may include a history of reliable attendance at office visits for weight management and compliance with other medical care plans.

### Documentation

- A qualified pediatric behavioral specialist with experience.
- Privileges and credentials of the pediatric behavioral specialist.

### Measure of Compliance

- Provides documentation that the center has identified an individual to serve as the pediatric behavioral specialist who meets the qualifications outlined above.
- Provides documentation of the privileges and credentials of the pediatric behavioral specialist.

## 4.15 Children's Hospital Service Requirements

### Definition and Requirements

This Standard applies only to children's hospitals performing metabolic and bariatric procedures. A children's hospital can only be accredited as a MBSAQIP Adolescent Center.

MBSAQIP defines adolescent patients as any metabolic and bariatric patient younger than 18 years of age. Although adolescence is a recognizable phase of life, an upper age limit is not easily demarcated and varies depending on the individual patient. MBSAQIP defines adolescent patients as those younger than 18 years of age for the sole purpose of determining when additional adolescent-specific care providers must be involved in the medical management of this patient group.

Recognizing that adolescent volume is more difficult to achieve due to a number of unique factors, the volume requirements for Adolescent Centers (outlined in Standard 2.1) must be met in one of the following ways:

1. Adolescent Centers performing a minimum of 15 stapling procedures annually will be unrestricted and do not require a bariatric co-surgeon.
2. Adolescent Centers performing fewer than 15 stapling procedures annually require a bariatric co-surgeon present for all stapling cases. The co-surgeon must be a MBSAQIP Verified Surgeon (outlined in Standard 4.2) who has credentials at a facility with a MBSAQIP Comprehensive Center designation. The MBS Director or another surgeon at the Adolescent Center can fulfill the co-surgeon requirement if they are verified and credentialed at a facility with a MBSAQIP Comprehensive Center designation. The co-surgeon is not required to be present for non-stapling bariatric procedures performed on adolescent patients.

MBSAQIP recognizes that under certain circumstances patients older than 18 years of age may undergo metabolic and bariatric treatment at a MBSAQIP Adolescent Center. MBSAQIP Adolescent Centers must review all patients over 21 years of age within the MBS Committee to determine whether or not care is to be deferred to a facility with a MBSAQIP Comprehensive Center designation.

### Documentation

- Operative log documenting at least 15 stapling procedures annually.
- MBS Committee meeting minutes confirming review of all patients over 21 years of age.
- If applicable, the credentials of the co-surgeon.
- If applicable, proof the co-surgeon is a MBSAQIP Verified Surgeon.
- If applicable, operative logs documenting the co-surgeon's presence during required cases.

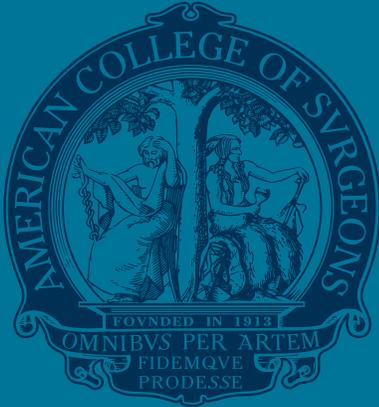
### Measure of Compliance

- Provides documentation of a minimum of 15 stapling procedures annually to meet the volume requirement for a MBSAQIP Adolescent Center. Volume data will be verified with an operative log and by chart review during the site visit.
- Provides documentation of MBS Committee meeting minutes confirming review of all patients over 21 years of age.
- Provides documentation of the co-surgeon's credentials at a facility with a MBSAQIP Comprehensive Center designation, if a co-surgeon is required as outlined above.
- Provides documentation that the co-surgeon is a MBSAQIP Verified Surgeon, if a co-surgeon is required as outlined above.
- Provides documentation of the co-surgeon's presence at required cases, if a co-surgeon is required as outlined above.



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## **STANDARD 5**

# Patient Care: Expectations and Protocols

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## Rationale

The center must utilize comprehensive clinical pathways that facilitate the standardization of patient care for metabolic and bariatric procedures. Pathways are a sequence of orders and therapies describing the routine care for metabolic and bariatric patients from initial evaluation through long-term follow-up. MBSAQIP requires that patient care pathways are thoroughly documented and followed appropriately by both surgeons and advanced practice providers treating metabolic and bariatric patients. Clinical pathways are allowed to be documented in a variety of formats, including tables, algorithms, process maps, and paragraph form. All staff caring for metabolic and bariatric patients must be aware of the pathways pertinent to their area of practice.

MBSAQIP Obesity Medicine Qualifications provide an additional designation level for facilities that offer non-procedural treatment for patients who are overweight and patients with Class I, II, and III obesity. Centers with Obesity Medicine Qualifications employ therapeutic interventions including nutritional intervention, physical activity, behavioral change, and pharmacotherapy. These centers must utilize a comprehensive approach to providing care for patients with obesity as described in the Obesity Medicine Standards (Standards 2.8, 5.6, and 6.4), including the use of additional specialists such as dietitians, exercise specialists, behavioral health professionals, obesity medicine specialists, advanced practice providers, and bariatric surgeons to achieve optimal results. Additionally, obesity medicine practitioners function as an effective resource for providing both pre- and post-operative care for metabolic and bariatric patients, while advocating for all patients with obesity.

## 5.1 Patient Education Pathways

### Definition and Requirements

All metabolic and bariatric surgeons and proceduralists at the center must utilize patient education pathways that provide a comprehensive overview of pre- and post-operative care for metabolic and bariatric patients. The patient education pathways for each surgeon or proceduralist must be approved by the center's MBS Committee. The pathways must be reviewed **and revised** annually by the MBS Committee with updated procedural volumes and outcomes data. At a minimum, the following patient education pathways are required:

1. Indications and contraindications for metabolic and bariatric procedures.
2. All procedure options provided by the center and the center's case volume specific to each procedure, as well as the expected outcomes of each procedure. There must be a clear explanation of the goals, risks, benefits, and alternatives of each procedure in order to demonstrate an informed consent process.
3. Instructions regarding diet, exercise, vitamin and mineral supplementation, and lifestyle changes.
4. The expected course of the perioperative care must be explained as well as a thorough explanation of discharge instructions that include activities, diet, follow-up appointments, medications, and signs and symptoms of complications such as tachycardia, fever, shortness of breath, excessive abdominal pain, and vomiting.

### Documentation

- Patient education pathways for each surgeon or proceduralist.
- MBS Committee meeting minutes documenting annual review and revision of the patient education pathways.

### Measure of Compliance

- Provides documentation of the patient education pathways for each metabolic and bariatric surgeon or proceduralist, which meet the requirements outlined above and have been approved by the MBS Committee.
- Provides documentation of MBS Committee meeting minutes confirming annual review and revision of patient education pathways with updated procedural volumes and outcomes data.

## 5.2 Patient Care Pathways

### Definition and Requirements

Each center must utilize patient care pathways outlining the process for evaluating patients seeking metabolic and bariatric surgery. The pathways must be reviewed regularly (annually, at a minimum) by the MBS Committee and revised if indicated by the review of the center's outcomes data. The following pathways are required and must be approved by the center's MBS Committee:

1. Defined patient selection criteria based on available resources, including equipment weight limits, and the expertise of the center
2. Psychosocial-behavioral evaluation
3. Algorithms for preoperative system clearance
4. Preoperative and postoperative nutrition regimen

Each practicing metabolic and bariatric surgeon or proceduralist at the center must use a standardized order set, specific to metabolic and bariatric procedures. This order set must address:

1. Dietary progression
2. Deep vein thrombosis prophylaxis
3. Respiratory care
4. Physical activity
5. Pain management
6. Parameters for notifying the attending physician

There must be a defined process for the early recognition and management of warning signs of complications, including tachycardia, fever, shortness of breath, excessive abdominal pain, and vomiting.

### Documentation

- Patient care pathways for each surgeon or proceduralist.
- Standardized order sets for each surgeon or proceduralist.
- MBS Committee meeting minutes documenting annual review of the patient care pathways.

### Measure of Compliance

- Provides documentation of the patient care pathways for each metabolic and bariatric surgeon or proceduralist, inclusion and exclusion patient selection criteria, and evaluation process, including psychological evaluation, preoperative clearance, nutrition regimens, and metabolic and bariatric standardized order sets, addressing all of the requirements outlined above.
- Provides documentation of MBS Committee meeting minutes confirming, at minimum, annual review of patient care pathways, which indicate any revisions driven by the review of the center's outcomes data.

## 5.3 Written Transfer Agreement

### Definition and Requirements

MBSAQIP-Accredited centers must be able to reasonably recognize and treat patients with metabolic and bariatric surgery complications. Transfer agreements cannot be used as a substitute for the standard and usual care of metabolic and bariatric patients.

If the center is unable to manage the full range of metabolic and bariatric surgery complications, they must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric patients to other emergency or critical care facilities that have the capability of managing the full range of metabolic and bariatric surgery complications. Centers must have the staff and equipment needed to transfer patients with obesity to an inpatient facility capable of providing a higher level of care.

To address metabolic and bariatric patients requiring emergent care, surgeons performing metabolic and bariatric procedures at Low Acuity Centers and Ambulatory Surgery Centers must have admitting privileges or a written transfer agreement as outlined below in this Standard.

To address long-term surgical complications requiring inpatient diagnosis and treatment, but not emergent care, all surgeons performing metabolic and bariatric procedures at Low Acuity Centers and Ambulatory Surgery Centers must have admitting privileges or a written transfer agreement in place with a facility with a MBSAQIP Comprehensive Center designation.

Transfer requirements:

1. A plan for safe transfer of metabolic and bariatric patients requiring **emergent care** to a full-service facility must be implemented, from the time of the transfer decision to the initiation of care at the accepting facility.
2. A plan for safe transfer of metabolic and bariatric patients requiring **non-emergent care** to a facility with a MBSAQIP Comprehensive Center designation must be implemented, from the time of the transfer decision to the initiation of care at the accepting facility.
3. Facilities must have adequate staff available to provide emergency support, including the time during transfer, until the receiving facility assumes the patient's care.
4. An ACLS-certified individual must accompany the patient during the transfer.

### Documentation

- A signed written transfer agreement, if applicable.

### Measure of Compliance

- Provides documentation of a signed written transfer agreement that details the transfer plan in place for both emergent and non-emergent metabolic and bariatric patients as outlined above, if patient transfer is part of the care pathway.

## 5.4 Inpatient Admitting Privileges

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### Definition and Requirements

This Standard only applies to outpatient facilities accredited as MBSAQIP Ambulatory Surgery Centers.

To address metabolic and bariatric patients requiring **emergent** care, all surgeons performing metabolic and bariatric procedures at Ambulatory Surgery Centers must have admitting privileges at an inpatient facility with the capability to manage the full range of metabolic and bariatric surgery complications.

To address metabolic and bariatric patients requiring **non-emergent** care, all surgeons performing metabolic and bariatric procedures at Ambulatory Surgery Centers must have admitting privileges at a facility with a MBSAQIP Comprehensive Center designation with the capability to address long-term surgical complications requiring inpatient diagnosis and treatment.

All Ambulatory Surgery Centers must have a signed written transfer agreement that meets all the requirements outlined in Standard 5.3, documenting the transfer process for critically ill or emergent metabolic and bariatric patients. The signed written transfer agreement must also cover the transition of care for non-emergent metabolic and bariatric patients if the requirement for admitting privileges at a facility with a MBSAQIP Comprehensive Center designation cannot be met for any reason.

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### Documentation

- Inpatient admitting privileges for all bariatric surgeons.
- Inpatient admitting privileges at a facility with a MBSAQIP Comprehensive Center designation for all bariatric surgeons.
- Signed written transfer agreement.

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### Measure of Compliance

- Provides documentation of inpatient admitting privileges for all metabolic and bariatric surgeons.
- Provides documentation of inpatient admitting privileges for all metabolic and bariatric surgeons at a facility with a MBSAQIP Comprehensive Center designation.
- Provides documentation of the transfer process for critically ill or emergent metabolic and bariatric patients, including the signed written transfer agreement.

## 5.5 Risk Assessment Protocol

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### Definition and Requirements

This Standard only applies to outpatient facilities accredited as MBSAQIP Ambulatory Surgery Centers.

Facilities designated as an Ambulatory Surgery Center must adhere to the patient and procedure selection criteria outlined in Standard 2.3.

To further ensure patient safety, Ambulatory Surgery Centers must develop a risk assessment protocol for treating metabolic and bariatric patients in an outpatient setting. The risk assessment protocol must be endorsed by the MBS Committee. The risk assessment protocol must be inclusive of the patient and procedure selection criteria outlined in Standard 2.3, as well as any additional criteria and safety measures that are deemed necessary by the MBS Committee. The members of the MBS Committee must follow the risk assessment protocol for all discussions regarding patient selection in an Ambulatory Surgery Center. Ambulatory Surgery Centers must review the risk assessment protocol once per year, at a minimum, during the annual comprehensive review meeting of the MBS Committee. The center's compliance with the protocol must also be reviewed annually.

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### Documentation

- A risk assessment protocol.
- MBS Committee meeting minutes documenting a review of the risk assessment protocol and compliance against the risk assessment protocol.

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### Measure of Compliance

- Provides documentation that a risk assessment protocol has been endorsed by the MBS Committee.
- Provides documentation of review of the risk assessment protocol during the annual comprehensive review meeting of the MBS Committee, including a review of the center's compliance with the risk assessment protocol.

## 5.6 Obesity Medicine Services

### Definition and Requirements

MBSAQIP Obesity Medicine Qualifications are separate and distinct from surgical and procedural accreditation. Only MBSAQIP Comprehensive Centers and MBSAQIP Comprehensive Centers with Adolescent Qualifications are eligible to seek MBSAQIP Obesity Medicine Qualifications.

MBSAQIP-Accredited centers with Obesity Medicine Qualifications must be able to provide comprehensive, multidisciplinary obesity medicine services. The medical treatment of patients with obesity must be implemented using care pathways developed by the Obesity Medicine Director (OMD), in conjunction with the MBS Committee. Care pathways for obesity medicine services must be reviewed annually, at a minimum, by the OMD and the MBS Committee. The pathways must be revised when indicated by emerging research and outcomes data in the field of obesity medicine.

The center is required to offer all of the following obesity medicine services utilizing care pathways developed by the OMD:

1. Comprehensive medical examination
2. Evaluation for medical complications related to obesity
3. Assessment of personal and family history of obesity
4. Laboratory testing
5. Nutrition counseling
6. Fitness and exercise counseling
7. Behavior and lifestyle counseling
8. Anti-obesity medication
9. Evaluation and treatment for abnormal weight gain

When obesity medicine services are provided by other physicians or advanced practice providers within the center, those individuals must work collaboratively with the Obesity Medicine Director (OMD) to coordinate patient care. These individuals must also undergo education and training in obesity medicine, as directed by the OMD, which must include, at minimum:

- Obesity medicine treatment options available at the center
- Management and care of obesity medicine patients using the center's care pathways
- Anti-obesity medication prescribing practices

Advanced practice providers are allowed to coordinate care for obesity medicine patients, but only under the oversight and supervision of the OMD.

### Documentation

- Care pathways for all of the required obesity medicine services.
- MBS Committee meeting minutes documenting annual review of the care pathways.
- Education of other physicians and advanced practice providers.

### Measure of Compliance

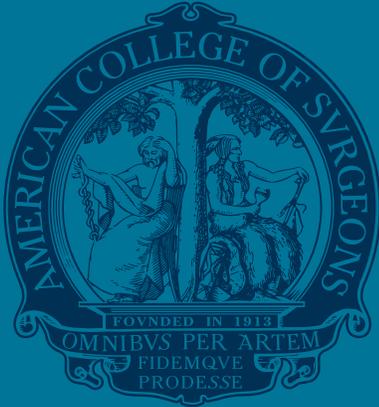
- Provides documentation of established care pathways for all of the required obesity medicine services listed above.
- Provides MBS Committee meeting minutes documenting, at minimum, annual review of the obesity medicine care pathways, which indicate any revisions driven by emerging research and outcomes data in the field of obesity medicine.
- Provides documentation that all other physicians and advanced practice providers caring for obesity medicine patients have undergone education and training in obesity medicine as outlined above, as directed by the OMD.





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## **STANDARD 6**

# Data Surveillance and Systems

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## Rationale

High-quality data is critical to inform quality improvement and measure the performance of metabolic and bariatric surgery programs.

All procedures performed for the treatment of metabolic or obesity-related diseases must be entered into the MBSAQIP Registry, including all metabolic and bariatric procedures performed by endoscopists, gastroenterologists, and general surgeons.

Data collection is ultimately the responsibility of the MBS Director working collaboratively with the MBS Clinical Reviewer, physician offices, and institutional departments to ensure accurate short and long-term results.

The MBSAQIP Registry collects prospective, risk-adjusted, clinically rich data based on standardized definitions. Data variables to be collected are provided via the MBSAQIP Registry. Data variables are periodically updated, refined, added, or deleted to optimize the information entered into the MBSAQIP Registry while minimizing the data collection burden. Centers have the opportunity to submit and track additional data elements as desired using custom fields within the MBSAQIP Registry.

Data are validated through multiple mechanisms that are continuously updated to optimize the quality of the data collected. The MBSAQIP Registry was developed to minimize the potential to submit inaccurate data and to prevent missing data. Centers are required to intermittently submit administrative or other corroborating data as an audit against the data entered. Data are validated in a systematic fashion as part of MBSAQIP site visits. MBS Clinical Reviewers are trained data abstractors who are not directly involved in patient care. Ongoing training and assessment of the MBS Clinical Reviewer's processes and knowledge is monitored as another means to validate data entry (see Standard 2.7 for more information). Additional data integrity audits, information, or clarifications may be required by the MBSAQIP.

Data is collected at 30 days, six months, one year, and annually thereafter. Follow-up data is used to assess morbidity and mortality, as well as clinical effectiveness concerning changes in weight and weight-related comorbidities. Risk-adjusted metrics have been developed for quality assessment and improvement.

## 6.1 Data Entry

### Definition and Requirements

Every metabolic and bariatric procedure (open, laparoscopic, hand-assisted, robotic, or endoscopic) performed for the treatment of metabolic or obesity-related diseases must be entered into the MBSAQIP Registry, including:

- Primary metabolic and bariatric procedures
- Reoperations subsequent to a metabolic and bariatric procedure (regardless of where the primary metabolic and bariatric procedure occurred), including:
  - Non-elective reoperations, revisions and conversions 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 procedures for the treatment of metabolic or obesity-related diseases

All endoluminal therapeutic procedures for the treatment of metabolic or obesity-related diseases performed at an accredited center must be done with the oversight of the MBS Director and the MBS Committee, and all such procedures must be entered into the MBSAQIP Registry. The data from all metabolic and bariatric procedures performed on patients of any body mass index must be entered into the MBSAQIP Registry. Any primary, revisional, or conversion procedure, whether surgical or non-surgical, performed for the treatment of metabolic or obesity-related diseases requires entry into the MBSAQIP Registry. FDA preapproval trials are the only exception to this rule.

The ASMBS publishes a list of endorsed metabolic and bariatric procedures on the ASMBS website, *asmbs.org*. Accredited centers must receive approval from an Institutional Review Board (IRB) in order to perform primary procedures that are not endorsed by the ASMBS. The IRB approval must be for performing the procedures, and not solely for data collection of outcomes from these procedures. In the event that an Institutional Review Board determines a study protocol unnecessary for a primary procedure that is not endorsed by the ASMBS, a letter of exemption from the Institutional Review Board is required. Procedures and devices used for reoperative purposes do not require IRB approval or IRB exemption.

The MBS Committee is responsible for overseeing the process through which emerging technologies, new procedures, and variations of existing ASMBS-endorsed procedures may be safely introduced at the center, ensuring adequate patient protection, oversight (including IRB approval or IRB exemption when indicated), and outcomes reporting.

### Data Collection for Emergency Department Visits, Readmissions, and Patient Transfers

All MBSAQIP-Accredited centers are required to collect necessary data elements in an effort to monitor patient safety and improve the quality of care provided to metabolic and bariatric patients. This includes monitoring emergency department visits, readmissions, and patient transfers to any inpatient facility during the 30-day postoperative period. The center must provide a written protocol for how it will monitor the data entry and patient follow-up associated with emergency department visits, readmissions, and patient transfers to other institutions. This protocol must be endorsed by the MBS Committee.

### Documentation

- A letter of attestation, signed by the MBS Director and MBS Clinical Reviewer, confirming 100 percent data entry into the MBSAQIP Registry.
- Operative logs from hospital and/or physician records for all metabolic and bariatric procedures.
- IRB approval or IRB exemption for all primary procedures not endorsed by the ASMBS.
- Written protocol for monitoring emergency department visits, readmissions, and patient transfers to other institutions.

### Measure of Compliance

- Provides documentation of a letter of attestation signed by the MBS Director and the MBS Clinical Reviewer confirming 100 percent data entry into the MBSAQIP Registry as outlined above.
- Provides documentation of an administrative data file, operative logs, and/or physician records to verify that 100 percent of metabolic and bariatric procedures are submitted and that data do not deviate from the cases entered into the MBSAQIP Registry.
- Provides documentation of IRB approval or IRB exemption if the center performs any primary metabolic and bariatric procedures that are not endorsed by the ASMBS.
- Provides documentation of a written protocol, endorsed by the MBS Committee, for monitoring emergency department visits, readmissions, and patient transfers to other institutions.

## 6.2 30-Day and Long-Term Follow-Up

### Definition and Requirements

Long-term follow-up is essential to evaluate outcomes of metabolic and bariatric procedures. Accurate follow-up data enables the comparison of outcomes data between sites and at the national level. The center must document a protocol to follow the long-term progress of all of their metabolic and bariatric patients.

It is mandatory that all patients are followed through the 30 day, six month, and one year follow-up timeframes. Centers must attempt to follow patients annually until the patient does not have an assessment completed for two consecutive follow-up timeframes. If a patient does not have a scheduled assessment within a follow-up timeframe, the center must contact the patient. Patients designated as lost to follow-up must have a minimum of two attempts to contact the patient for each follow-up timeframe. Contact attempts must be documented in the MBSAQIP Registry. Once an appointment for an assessment has been made within the follow-up timeframe, no additional follow-up contact attempts are required for that follow-up timeframe. The center may cease attempts to contact patients after the patient is lost to follow-up or a no-show for two consecutive follow-up timeframes (for example, a patient who does not return for year two and year three visits).

Methods to obtain follow-up information include, but are not limited to:

- Physician assessment
- Nurse practitioner assessment

- Physician assistant assessment
- Clinical nurse specialist with experience, training, or certification in the care of metabolic and bariatric patients
- Supervised registered nurse with experience, training, or certification in the care of metabolic and bariatric patients
- Patient or patient’s family
- Death certificates
- Internet sources (such as death index, patient locator software, obituary listings)
- Communication with other medical facilities

### Documentation

- Long-term follow-up protocol.
- Documentation of the required contact attempts for each patient.

### Measure of Compliance

- Provides documentation of a long-term follow-up protocol, including a protocol for maintaining or re-establishing contact with metabolic and bariatric patients.
- Provides proof that a minimum of two contact attempts per follow-up period are documented for patients who are lost to follow-up (this is not required for patients who remain lost to follow-up after two consecutive follow-up time periods).

### Requirements for Follow-Up Attempts\*

Patient IDN	30-Day	6-Month	1-Year	2-Year	3-Year	4-Year	5-Year	6-Year
00001	No assessment	No assessment	No assessment	x	x	x	x	x
00002	Assessment	No assessment	No assessment	x	x	x	x	x
00003	Assessment	Assessment	No assessment	No assessment	x	x	x	x
00004	Assessment	Assessment	Assessment	No assessment	No assessment	x	x	x
00005	Assessment	No assessment	Assessment	No assessment	No assessment	x	x	x
00006	Assessment	No assessment	Assessment	No assessment	Assessment	No assessment	No assessment	x
00007	Assessment	No assessment	Assessment	No assessment	Assessment	No assessment	No assessment	x
00008	Assessment	Assessment	Assessment	No assessment	Assessment	Assessment	Assessment	Assessment

Assessment	Patient is contacted and receives scheduled clinical assessment
No assessment	Patient is not seen for scheduled clinical assessment or Patient has no appointment scheduled; two attempts to contact patient must be documented
x	No further attempts to contact patient are required

\*The table above provides an example of possible follow-up scenarios. Attempts to follow patients annually must continue beyond the six-year follow-up period until the patient is not assessed for two consecutive follow-up periods.

## 6.3 Data Review

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### Definition and Requirements

All centers are required to monitor their data. Ongoing review of the semiannual risk-adjusted reports (SAR) and unadjusted outcomes data is critical for continuous quality improvement. Semiannual risk-adjusted reports (SAR) are released twice a year to participating centers that maintain a complete 30-day follow-up rate of greater than or equal to 80 percent. Unadjusted outcomes reports are available to all centers via the MBSAQIP Registry. Reports from the MBSAQIP Registry provide site-specific data for participating centers and the ability to benchmark outcomes against aggregate national comparison data. Online reports must be reviewed by the MBS Committee a minimum of three times annually, two of which must be reviews of the semiannual risk-adjusted reports (SAR).

Centers are exempt from demonstrating compliance with this Standard at their initial accreditation site visit, unless they have already received at least one semiannual risk-adjusted report (SAR). Once a center has received their first semiannual risk-adjusted report (SAR), full compliance with this Standard is required.

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### Documentation

- MBS Committee meeting minutes documenting review of data from the MBSAQIP Registry.
- Copies of the center's semiannual risk-adjusted reports (SAR).

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### Measure of Compliance

- Provides documentation that the MBS Committee reviewed reports from the MBSAQIP Registry a minimum of three times annually, two of which must be reviews of the semiannual risk-adjusted reports (SAR).

## 6.4 Obesity Medicine Data Collection

### Definition and Requirements

MBSAQIP Obesity Medicine Qualifications are separate and distinct from surgical and procedural accreditation. Only MBSAQIP Comprehensive Centers and MBSAQIP Comprehensive Centers with Adolescent Qualifications are eligible to seek MBSAQIP Obesity Medicine Qualifications.

Data collection and outcomes monitoring for obesity medicine patients is a critical component of tracking patient progress and identifying successful treatment strategies. However, only surgical and non-surgical **procedures** performed for the treatment of metabolic or obesity-related diseases are eligible to be captured in the MBSAQIP Registry. Patients receiving non-procedural obesity medicine treatment at a MBSAQIP-Accredited center with Obesity Medicine Qualifications **cannot** be captured in the MBSAQIP Registry, and instead must be captured using an independent, local level data collection method.

All MBSAQIP-Accredited centers with Obesity Medicine Qualifications must commit to independent, local level data collection and outcomes monitoring for obesity medicine patients. The data collection method utilized must be accessible for basic reporting and data analysis to help improve patient care.

#### Required Variables

The following patient variables must be captured for data collection and outcomes monitoring for obesity medicine patients:

- Patient information (Name, ethnicity, demographic information, etc.)
- Height and weight at initial presentation
- Body mass index (BMI) at initial presentation
- Body fat percentage at initial presentation
- Comorbidities at initial presentation
- Weight percentage change over time
- BMI change over time
- Body fat percentage change over time
- Comorbidity change over time
- Anti-obesity medications
- Complications and side effects of obesity medicine treatment

Capturing additional variables related to patient health and satisfaction, and obesity medicine treatment is encouraged, but not required. Identifying additional variables for data capture, beyond the required variables outlined above, is at the discretion of the Obesity Medicine Director (OMD).

#### Data Collection Methods

Independent data collection for obesity medicine patients must be accomplished using one of the following methods. Only one method of data collection is required. The choice of data collection method is at the discretion of the Obesity Medicine Director (OMD).

1. **EMR Data Collection-** Accredited centers with Obesity Medicine Qualifications must document data collection and outcomes monitoring for obesity medicine patients using an electronic medical record system. All required variables for data collection, as outlined above, must be recorded during each patient appointment and documented in the patient's electronic medical record within 90 days of patient contact. The EMR must be accessible for basic reporting and data analysis to help improve patient care.
2. **MBSAQIP Obesity Medicine Patient Tracker-** Accredited centers with Obesity Medicine Qualifications must document data collection and outcomes monitoring for obesity medicine patients using the MBSAQIP Obesity Medicine Patient Tracker. The MBSAQIP Obesity Medicine Patient Tracker is a spreadsheet designed for data collection for obesity medicine patients. All required variables for data collection, as outlined above, must be recorded during each patient appointment and documented in the MBSAQIP Obesity Medicine Patient Tracker within 90 days of patient contact. The MBSAQIP Obesity Medicine Patient Tracker is available on the MBSAQIP website, [facs.org/quality-programs/mbsaqip/resources](https://facs.org/quality-programs/mbsaqip/resources).
3. **Alternative Written or Electronic Method for Data Collection-** Accredited centers with Obesity Medicine Qualifications are allowed to design their own method to document data collection and outcomes monitoring for obesity medicine patients. The center-designed system for data collection must provide reliable and easily accessible patient data in either a written or electronic format for basic reporting and data analysis to help improve patient care. All required variables for data collection, as outlined above, must be recorded during each patient appointment and documented within 90 days of patient contact.

#### Obesity Medicine Data Capture

The Obesity Medicine Director (OMD) must ensure that obesity medicine data capture is executed as outlined above. The OMD is allowed to delegate the actual data capture process to a member(s) of the obesity medicine program capable of maintaining data capture as outlined above. There is no requirement for a designated individual with specialized training (such as a MBS Clinical Reviewer) to document and capture obesity medicine patient data.

If the center chooses to have the current MBS Clinical Reviewer also capture data for the obesity medicine program, the center must provide a letter of attestation stating that the MBS Clinical Reviewer is supported with sufficient time and resources to complete all of their responsibilities for data capture to the MBSAQIP Registry, and for the obesity medicine program. The letter of attestation must be signed by the MBS Director, the OMD, and the MBS Clinical Reviewer.

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## Documentation

- Written or electronic records of data collection and outcomes monitoring for obesity medicine patients.
- Identified member(s) of the obesity medicine program capable of maintaining data capture.
- If applicable, a letter of attestation signed by the MBS Director, the OMD, and the MBS Clinical Reviewer.

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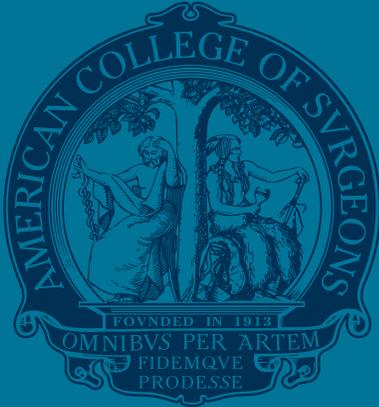
## Measure of Compliance

- Provides documentation of written or electronic records for data collection and outcomes monitoring for obesity medicine patients.
- Provides documentation that all required patient variables outlined above are being recorded for obesity medicine patients.
- Provides proof that an approved data collection method is in use for data collection and outcomes monitoring for obesity medicine patients, which is accessible for basic reporting and data analysis to help improve patient care.
- Provides proof that an identified member(s) of the obesity medicine program is maintaining data capture as outlined above.
- Provides documentation, if applicable, of a letter of attestation signed by the MBS Director, the OMD, and the MBS Clinical Reviewer stating that the MBS Clinical Reviewer is supported with sufficient time and resources to complete all of their responsibilities for data capture to the MBSAQIP Registry and for the obesity medicine program, if the MBS Clinical Reviewer is also responsible for data capture for the obesity medicine program.



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## **STANDARD 7**

# Quality Improvement

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## Rationale

Processes for identifying adverse events and implementing subsequent corrective action plans, measurable through patient outcomes, are inherent cornerstones of continuous quality improvement. Problem resolution, outcomes improvement, and assurances of patient safety (“loop closure”) must be readily identifiable through structured quality improvement initiatives.

In support of these efforts, the MBS Director and the MBS Committee at each center must develop a culture of collaboration in order to report, analyze, and implement strategies based on data to drive improvement in the quality of care offered to metabolic and bariatric patients. While major quality improvement initiatives such as decreasing surgical site infections, leaks, or venous thromboembolism prophylaxis are important, equally important is the examination of pathways of care in order to maximize the patient experience and effectiveness of metabolic and bariatric procedures. Continuous quality improvement must be reflected in the results of such efforts by the MBS Committee. Please see the MBSAQIP website, [facs.org/quality-programs/mbsaqip/resources](https://facs.org/quality-programs/mbsaqip/resources) for further information and resources regarding quality improvement.

## 7.1 Adverse Event Monitoring

### Definition and Requirements

Patient safety and adverse event monitoring must be implemented by all MBSAQIP-Accredited centers through the MBS Committee, and led by the MBS Director. For the purposes of patient safety and adverse event monitoring, it is the responsibility of the MBS Committee to:

1. Establish and maintain a protocol for notifying surgeons and proceduralists of adverse events and to review and discuss the patient's care within the MBS Committee when an adverse event occurs. **Examples of adverse events include, but are not limited to:** complications, readmissions, reoperations, prolonged length of stay, postoperative morbidity, unplanned admission to ICU, and mortality.
2. Review all mortalities occurring within the first 90-day postoperative period. Such mortalities must be reviewed within 60 days of discovery. This review must occur for all mortalities occurring within 90 days of surgery, without exception.
3. Review outcomes data on a regular basis, as outlined in Standard 6.3.
  - This review of outcomes data must be based on data from the MBSAQIP Registry. However, the review of additional data may also help in determining root causes for adverse events.

The MBS Committee meeting minutes must document when adverse event monitoring and review occurs. The meeting minutes must be completed in a HIPAA-compliant manner and with respect for the protected, peer review process.

### Documentation

- Protocol for adverse event notification and review.
- MBS Committee meeting minutes documenting the review of adverse events.

### Measure of Compliance

- Provides documentation of a protocol for the notification of adverse events and the subsequent review process.
- Provides documentation in a HIPAA-compliant manner of the minutes of all MBS Committee meetings indicating that all of the following were reviewed:
  1. All adverse events as part of a protected, peer review process
  2. All 90-day mortalities, if any, within 60 days of discovery
  3. Semiannual risk-adjusted reports (SAR)

## 7.2 Quality Improvement Initiatives

### Definition and Requirements

The goal for MBSAQIP-Accredited centers is to provide safe, efficacious, and high-quality care to each patient at all times. To achieve this goal, it is imperative to develop a culture of collaboration and safety among all MBS Committee members at the center. Quality improvement (QI) emphasizes a continuous, multidisciplinary effort to improve the process of care and its outcome. Thus, QI must be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identify opportunities for improvement at the center. The semiannual risk-adjusted reports (SAR), non-risk-adjusted reports, and other data sources (for example, patient experience scores) are valuable tools to evaluate areas for improvement for the center and must be used to identify pertinent QI initiatives. **All QI initiatives must be based on an existing problem identified by a reliable data source.** These initiatives must change structure, processes, and/or clinical pathways within the center.

With oversight from the MBS Director, all MBSAQIP-Accredited centers must measure, evaluate, and improve their performance through at least one quality improvement initiative each year. The timeline for completion of each QI initiative is variable depending on the scope of the project, and must be determined by the MBS Committee. However, a new QI initiative must be implemented each year, even if a previous initiative is still underway.

Centers must adopt a consistent methodology for quality improvement initiatives. The methodology may vary from center to center depending on the unique needs and expectations of each. Various QI methodologies can be adopted to support quality improvement initiatives. Further information about QI methodologies can be found on the MBSAQIP website, [facs.org/quality-programs/mbsaqip/resources](https://facs.org/quality-programs/mbsaqip/resources).

Renewal centers must first review their risk-adjusted and non-risk-adjusted clinical outcomes data provided by the MBSAQIP Registry to identify quality improvement initiatives, and must prioritize QI initiatives that focus on improving surgical outcomes. **Centers found to be a high outlier on the semiannual risk-adjusted report (SAR) must develop a QI initiative designed to address the high outlier status.** If the center is a high outlier in more than one model on the semiannual risk-adjusted report (SAR), the MBS Committee must prioritize these clinical issues and the next QI initiative must address the greatest risk to patient safety. Although only one QI initiative is required each year,

the MBSAQIP encourages the use of multiple QI initiatives to address issues related to clinical outcomes and patient safety when warranted. If further investigation reveals a QI initiative addressing a high outlier status is unwarranted (for example, concurrent data shows subsequent resolution of the issue), the center may select an alternative QI initiative driven by other data or process reviews. However, the center must provide written justification to support this decision.

Initial centers, and renewal centers that do not have a high outlier status on the semiannual risk-adjusted report (SAR), must develop quality improvement initiatives prioritizing other issues related to clinical outcomes and patient safety. If no such issues are readily identifiable, QI initiatives must target other areas for improvement, including, **but not limited to:** internal processes, clinical pathways, patient education, patient experience, or other relevant issues related to providing safe, efficacious, and high-quality care to metabolic and bariatric patients.

### Quality Improvement Outline

These 6 steps outline the basic process for completing a quality improvement initiative that satisfies the requirements outlined above. **Further information about quality improvement, including a detailed review of this 6 step process, can be found on the MBSAQIP website, [facs.org/quality-programs/mbsaqip/resources](https://facs.org/quality-programs/mbsaqip/resources).**

1. **Review Data**
  - a. Semiannual risk-adjusted reports (SAR)
  - b. Non-risk-adjusted reports
  - c. Internal data
2. **Identify the Problem**
  - a. High outlier status
  - b. Other areas for improvement
3. **Propose Intervention**
  - a. Discuss contributing factors
  - b. Root cause analysis
4. **Choose Quality Improvement Methodology**
  - a. MBSAQIP-Accredited centers are able to use any consistent quality improvement methodology that satisfies their unique needs
  - b. Establish a timeline for review and metrics to track progress
5. **Implement Intervention & Monitor Data**
  - a. Consistently implement the intervention
  - b. Monitor data
6. **Present Results**
  - a. Gather all documentation and data
  - b. Review progress
  - c. Summarize the findings and results of the quality improvement initiative

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## Documentation

- At least one QI initiative per year, implemented using a consistent quality improvement methodology.
- MBS Committee meeting minutes documenting review of QI initiatives.

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## Measure of Compliance

- Provides documentation for at least one QI initiative per year, which outlines how the center measured, evaluated, and improved their performance through the implementation of a consistent quality improvement methodology.
- Provides proof that any high outlier status identified on the semiannual risk-adjusted report (SAR) was prioritized for a quality improvement initiative.
- Provides documentation of MBS Committee meeting minutes which review how the MBS Committee members identified, implemented, and monitored QI initiatives.

## 7.3 Annual Compliance Reports (ACRs)

### Definition and Requirements

Centers are exempt from demonstrating compliance with this Standard at their initial accreditation site visit. Once a center has achieved MBSAQIP Accreditation, full compliance with this Standard is required.

The MBS Director and MBS Coordinator are required to submit an Annual Compliance Report (ACR) to the MBSAQIP in the second and third years of the triennial reaccreditation cycle. The ACR is due during the anniversary month in which the center was first accredited by the MBSAQIP. An ACR is not required for years when the center is due for a site visit.

#### Sample Schedule for Site Visits and ACR Submission

<b>April 2015</b>	Site Visit	<b>April 2018</b>	Site Visit
<b>April 2016</b>	ACR	<b>April 2019</b>	ACR
<b>April 2017</b>	ACR	<b>April 2020</b>	ACR

The ACR contains an attestation of compliance with all applicable Standards for the center's designation level, as well as mandatory information about data entry, procedure volumes, and other questions pertaining to the MBSAQIP Accreditation.

All accredited centers are notified by the MBSAQIP before the ACR must be submitted. This notification contains all the necessary information on how to submit the ACR to MBSAQIP.

The center must retain all complete ACRs submitted to MBSAQIP. The ACRs must be presented for review during the next accreditation site visit to demonstrate compliance with this Standard.

### Documentation

- Copies of the Annual Compliance Reports that were submitted to the MBSAQIP.

### Measure of Compliance

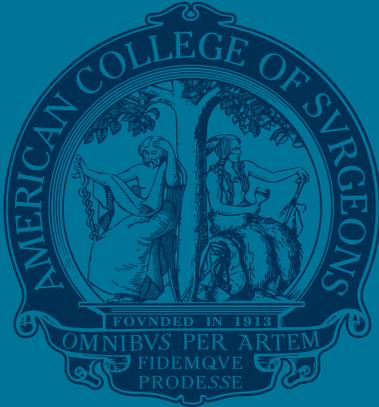
- Provides documentation that complete Annual Compliance Reports were submitted to the MBSAQIP within the accreditation anniversary month in the second and third year of the triennial reaccreditation cycle.





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## **STANDARD 8**

# Education: Professional and Community Outreach

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## **Rationale**

Continuous outreach to metabolic and bariatric patients through regularly scheduled, organized, and supervised support groups is critical for maintaining long-term patient engagement and success. Support groups create an environment for both health care providers and patients to offer ongoing education and encouragement.

## 8.1 Support Groups

### Definition and Requirements

MBSAQIP-Accredited centers must provide regularly scheduled, organized, and supervised support groups for metabolic and bariatric patients. Regularly scheduled support groups must be made available a minimum of every two months. Support group meetings cannot be pre-recorded; they must be hosted in-person, virtually, or via teleconference. The surgical practice(s) and/or center are allowed to organize support groups, but the entity responsible for administering each support group must be clearly identified. A licensed health care provider must be present to supervise all support groups. The center's MBS Committee must determine the required credentials for health care providers supervising support groups. The center must provide patients with information regarding all of their options for support groups.

All support group activities must be documented, including group location, meeting time, supervisor, curriculum, and number of people in attendance. Other activities, including online forums, exercise instruction, and clothing sales must be noted but do not require full documentation.

### Documentation

- Support group meeting schedule.
- Support group meeting documentation: time, location, agenda, attendance, and supervisor.
- Credentials of the support group supervisor.

### Measure of Compliance

- Provides documentation that support groups are held at least every two months (in-person, web-based, or teleconferenced), with proper documentation of the meeting time, location, agenda, attendance, and supervisor.
- Provides documentation of the credentials for the licensed health care provider who is present to supervise support groups.

## Accreditation Definitions

Accreditation Status	Definition
<b>Accredited</b>	The center has completed a site visit and demonstrated full compliance with all applicable Standards for their designation level, as outlined in the <i>Optimal Resources for Metabolic and Bariatric Surgery</i> , and has provided all requisite documentation to support compliance.
<b>Accredited— Corrective Action Required</b>  <i>Renewal Applicants Only</i>	<p>The center is non-complaint with one or more applicable Standards.</p> <p>The center will receive an Accreditation Report documenting all non-compliant Standards and will be given a corrective action timeframe to provide all necessary data and documentation required to verify full compliance with all applicable Standards. The timeframe for corrective action is dependent on the non-compliant Standard(s).</p> <p>During the corrective action timeframe, the center will continue to be recognized as a MBSAQIP-Accredited center. The center must continue to submit clinical data to the MBSAQIP Registry.</p>
<b>Not Accredited— Corrective Action Required</b>  <i>Initial Applicants Only</i>	<p>The center is non-complaint with one or more applicable Standards. Accreditation is pending until the center resolves all non-compliant Standards identified during the application process or at the time of the site visit.</p> <p>The center will receive an Accreditation Report documenting all non-compliant Standards and will be given a corrective action timeframe to provide all necessary data and documentation required to verify full compliance with all applicable Standards. The timeframe for corrective action is dependent on the non-compliant Standard(s).</p> <p>During the corrective action timeframe, the center will <b>not</b> be recognized as a MBSAQIP-Accredited center. The center must continue to submit clinical data to the MBSAQIP Registry.</p>
<b>Not Accredited</b>	<p>The center is unable to demonstrate compliance with the required Standards applicable to the MBSAQIP designation level sought.</p> <p>The center must submit a new Pre-Review Questionnaire (PRQ) if they wish to continue pursuing MBSAQIP Accreditation.</p>

## Accreditation Process Overview

### MBSAQIP Accreditation Process for Initial Applicants

Application
<ul style="list-style-type: none"><li>Review MBSAQIP Standards to determine eligibility and appropriate designation level for your center</li><li>Submit online application available at <a href="https://facs.org/mbsaqip">facs.org/mbsaqip</a></li><li>Upon approval of application, center will be sent login information for the online accreditation portal</li></ul>
Pre-Review Questionnaire (PRQ)
<ul style="list-style-type: none"><li>Log in to online accreditation portal and complete and submit PRQ</li><li>Center pays annual participation fee and executes contracts prior to PRQ submission</li><li>Center must meet all applicable Standards at the time of PRQ submission</li><li>MBS Clinical Reviewer is registered for training</li></ul>
Site Visit
<ul style="list-style-type: none"><li>Center is assigned a surgeon Site Visit Reviewer and must complete a site visit within 6 months of PRQ submission</li><li>MBS Clinical Reviewer must successfully complete online training modules and begin data entry to MBSAQIP Registry prior to site visit</li></ul>
Outcome
<ul style="list-style-type: none"><li>Center will be notified of accreditation decision and receive the Accreditation Report approximately 8-12 weeks after the site visit</li><li>Center's accreditation is effective retroactive to the date of the site visit and remains accredited for a 3-year term</li><li>Center submits Annual Compliance Report (ACR) at the first and second anniversary of initial accreditation and submits renewal application at 3 years</li></ul>

### MBSAQIP Reaccreditation Process for Renewal Applicants

Pre-Review Questionnaire (PRQ)
<ul style="list-style-type: none"><li>Review MBSAQIP Standards to confirm ongoing eligibility and appropriate designation level for your center</li><li>Renewal PRQ becomes available 6 months prior to accreditation anniversary date</li><li>Log in to online accreditation portal to complete and submit PRQ and confirm center information is up to date</li><li>Center pays any outstanding annual participation fees and executes renewal contracts prior to PRQ submission</li><li>Center must meet all applicable Standards at the time of PRQ submission</li></ul>
Site Visit
<ul style="list-style-type: none"><li>Center is assigned a surgeon Site Visit Reviewer after PRQ submission and must complete a site visit within 30 days of accreditation anniversary date</li></ul>
Outcome
<ul style="list-style-type: none"><li>Center will be notified of accreditation decision and receive the Accreditation Report approximately 8-12 weeks after the site visit</li><li>If accredited, the center is renewed for a new 3-year term from the date of initial accreditation</li><li>Center submits Annual Compliance Report (ACR) at the first and second anniversary of initial accreditation and submits renewal application at 3 years</li></ul>







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