

# STANDARDS MANUA LV2.0

Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016

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

They are dedicated to improving quality, providing value, and achieving excellent outcomes in metabolic and bariatric surgery.

It's better for your patients. for your surgeons. for your center.

# **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®), the only nationwide accreditation and quality improvement program for metabolic and bariatric surgery. The MBSAQIP builds upon the rich history of these organizations in surgical patient care and the successes and extensive experiences both have had in administering their individual accreditation and quality improvement programs.

The previous version of the standards was enhanced based on feedback received from MBSAQIP-accredited centers and site surveyors in order to improve the program's primary goal of patient safety. Additionally, substantive changes were made to the program to incorporate new technology and improve a center's ability to implement the standards.

Metabolic and bariatric surgical procedures have been shown to reduce obesity, improve mortality, and decrease the health risks from chronic diseases, as evidenced in more than 20 years of peer-reviewed publications. As metabolic and bariatric surgery is proven to be effective in the resolution of obesity-related comorbid conditions, an increasing number of hospitals and surgery centers look to provide this service to those affected patients in their communities. Through their collaborative efforts, the MBSAQIP, the ACS, and the ASMBS are confident that by working together with the facilities, physicians, and other health care professionals that provide care to the more than 18 million people in the United States who are suffering from severe 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 the patient with obesity.

Multiple studies have examined patient safety in the metabolic and bariatric surgical patient population and have shown to support the value of accreditation. An article in Surgical Endoscopy (July 2013) found that in-hospital mortality rates at nonaccredited centers were more than three times higher than the mortality rate at accredited centers (0.22% vs. 0.06%). University of California Irvine researchers conducting this study analyzed 277,760 metabolic and bariatric procedures performed between 2006 and 2010. In addition, an earlier October 2012 publication in the Journal of the American College of Surgeons showed nearly the same differences in mortality between nonaccredited and accredited academic metabolic and bariatric centers (0.21% vs. 0.06%, respectively). Furthermore, an Annals of Surgery 2014 article by Stanford University researchers demonstrated significantly less mortality, complications, and failure to rescue at accredited centers versus nonaccredited centers.

Currently, there are more than 700 MBSAQIP-accredited centers in the United States and Canada, and international centers will soon be participating as Data Collection Centers. More than 150,000 bariatric cases are captured annually in the MBSAQIP Data Registry. The inaugural MBSAQIP Standards (published in 2014) served as a catalyst for increased collaboration focusing on quality improvement. In 2015, MBSAQIP launched the D.R.O.P. (Decreasing Readmissions through Opportunities Provided) project with a goal to decrease all-cause 30-day readmission rates within 12 months of implementing process improvement plans. More than 130 MBSAQIP-accredited centers participated in the project by using a standardized, bundled process involving a patient education video, discharge checklists, follow-up phone calls, and nutritional consults. Preliminary reports indicate the project was highly rated by programs and patients alike and resulted in an initial decline in 30-day readmissions.

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Currently, MBSAQIP is planning future projects, which will focus on patient experience and quality of care.

MBSAQIP accreditation is important because it provides an objective and measurable means in which a center can demonstrate that it offers high-quality care in a multidisciplinary format. The personnel and infrastructure required to attain accreditation provide critical support for high-quality operations inherent to patient safety and excellent clinical outcomes. Maintenance of accreditation requires consistent attention to the details of the program on an ongoing basis with periodic review of outcomes, pathways, and protocols to ensure that the center is providing safe and competent metabolic and bariatric surgical care. With the primary tenet of continual monitoring of outcomes data in a reliable, clinically rich, and streamlined format, the MBSAQIP serves to improve quality of care for metabolic and bariatric surgical patients in a systematic and scientific manner. MBSAQIP accreditation ensures the facilities' ongoing commitment to quality of care and serves as a mechanism for reflection of its own processes and protocols.

Under the standards described in the Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016, the MBSAQIP accredits inpatient and outpatient metabolic and bariatric surgery centers in the United States and Canada that have undergone an independent, voluntary, and rigorous peer evaluation in accordance with nationally recognized metabolic and bariatric surgical standards. On-site visits are conducted by a trained MBSAQIP metabolic and bariatric surgeon surveyor. During the visit, metabolic and bariatric surgery centers are verified against set criteria for annual facility and individual surgeon volumes specific to stapling and nonstapling procedures. Oversight of the center's metabolic and bariatric program must be led by a metabolic and bariatric surgery director in conjunction with a multidisciplinary metabolic and bariatric surgery committee. This essential component emphasizes the leadership of surgeons and the engagement of all members of the team charged with the care of metabolic and bariatric surgical patients. In addition, structural needs, appropriate equipment, and appropriate patient care pathways are assessed and must accommodate the specialized needs of morbidly obese patients. Finally, requirements for reporting of 30-day and long-term follow-up outcomes to a national registry with review of associated outcomes serve to inform the center of its performance and help the center identify areas of focus for continuous quality improvement by benchmarking its outcomes to other centers.

The Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016 outlines both the standards and the pathways for facilities to follow when seeking accreditation. MBSAQIP accreditation provides guidance for facilities aiming to build the structure, process, and outcome expertise with a focus on quality and safety as it relates to the care of all metabolic and bariatric surgery patients.

## **Background on ACS and ASMBS**

#### About the American College of Surgeons

The American College of Surgeons is a scientific and educational organization of surgeons that was founded in 1913 to raise the standards of surgical practice and 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 79,000 members and is the largest organization of surgeons in the world. For more information, visit facs.org.

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

The ASMBS is the largest organization for metabolic and bariatric surgeons in the world. It is a not-for-profit organization that works to advance the art and science of metabolic and bariatric surgery and is committed to educating medical professionals and the lay public about metabolic and bariatric surgery as an option for the treatment of morbid obesity, as well as the associated risks and benefits. It encourages its members to investigate and discover new advances in metabolic and bariatric surgery while maintaining a steady exchange of experiences and ideas that may lead to improved surgical outcomes for severely obese patients. For more information, visit asmbs.org.

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#### **ACKNOWLEDGEMENTS**

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

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

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

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# MBSAQIP Designations and Accreditation Pathways for Application

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



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# **Designations**

# **Data Collection Center (not accredited)**

# **Accredited Inpatient Center**

- 1. Comprehensive Center
- 2. Comprehensive Center with Adolescent Qualifications
  - 3. Low Acuity Center
  - 4. Adolescent Center

# **Accredited Freestanding Outpatient Center**

5. Ambulatory Surgery Center

# **Designation Requirements Overview**

#### **Data Collection Center**

- 1. A Metabolic and Bariatric Surgical (MBS) Clinical Reviewer has been identified by the center, and the MBS Clinical Reviewer has successfully completed training and begun data entry to the MBSAQIP Data Registry Platform.
- 2. Center is not required to demonstrate compliance with
- 3. No annual case volume is required.
- 4. Centers in the U.S. and Canada may apply for full accreditation status once they have met all standards and the center case volume threshold, if any, for the designation level they are seeking. International centers are invited to participate as a Data Collection Center; however, accreditation is not currently offered to centers outside of the U.S. and Canada.
- Applicable Standards: None

See the MBSAQIP website for additional details regarding Data Collection Center eligibility and participation.

# **Designations for Accredited Inpatient Centers**

#### Comprehensive Center

- 1. Center has demonstrated compliance with all MBSAQIP Core Standards (Standards 1–7) and successfully completed
- 2. Center performs a minimum of 50 approved bariatric stapling procedures annually (as outlined in Standard 6.1), and the MBS Clinical Reviewer enters data into the MBSAQIP Data Registry Platform.
- 3. May perform all approved procedure types.
- 4. Only approved to provide care to patients 18 years of age and older.
- Applicable Standards: 1.1, 2-7

#### Comprehensive Center with Adolescent Qualifications

- 1. Center has demonstrated compliance with all MBSAQIP Core Standards (Standards 1-7) as well as Standards 9.2 and 9.3 and successfully completed a site visit.
- 2. Center performs a minimum of 50 approved bariatric stapling procedures annually, and the MBS Clinical Reviewer enters data into the MBSAQIP Data Registry Platform.
- 3. May perform all approved procedure types.
- 4. Approved to provide care to patients of all ages when adolescent criteria are met as outlined in Standard 9.
- Applicable Standards: 1.1, 2-7, 9.2, and 9.3

#### Low Acuity Center

- 1. Center has demonstrated compliance with all MBSAQIP Core Standards (Standards 1-7) and successfully completed
- 2. Center performs a minimum annual volume of 25 approved bariatric operations, and the MBS Clinical Reviewer enters data into the MBSAQIP Data Registry Platform (see low acuity restrictions outlined in Standard 1.2).
- 3. May perform approved primary procedures within low acuity restrictions (Standard 1.2).
- 4. Only approved to provide care to patients 18 years of age and older.
- Applicable Standards: 1.1, 1.2, and 2-7

#### Adolescent Center

- 1. Center has demonstrated compliance with all Adolescent Standards (as defined in Standard 9) in addition to MBSAQIP Core Standards (Standards 1-7) and successfully completed a site visit.
- 2. May perform all approved procedure types.
- 3. Centers performing fewer than 25 stapling procedures annually require a MBSAQIP-Verified Bariatric Surgeon as a co-surgeon on each case (as defined in Standard 9).
- Applicable Standards: 1.1, 2–7, and 9

# **Designation for Accredited Freestanding Outpatient Centers**

## **Ambulatory Surgery Center**

- 1. Center has demonstrated compliance with Ambulatory Surgery Center Standards (as defined in Standards 1.2 and 8) in addition to all MBSAQIP Core Standards (Standards 1-7) and successfully completed a site visit.
- 2. Center performs a minimum annual volume of 25 approved bariatric operations, and the MBS Clinical Reviewer enters data into the MBSAQIP Data Registry Platform (see list of qualifying stapling procedures and definition of restrictions as outlined in Standard 1.2).
- 3. Facilities designated as an Ambulatory Surgery Center are only approved to perform stapling procedures on low acuity patients as outlined in Standard 1.2.
- 4. Center is only approved to provide care to patients 18 years of age and older.
- Applicable Standards: 1.1, 1.2, 2-8

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# **Pathways**

# New Center Pathway to MBSAQIP Data Collection Center Option

**New Center to:** 

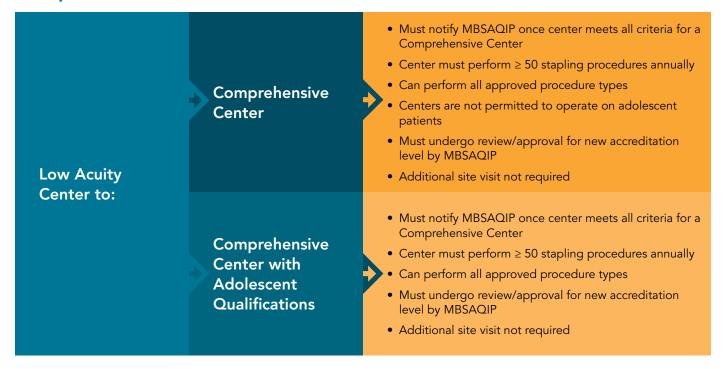
**Data Collection** Center (Not Accredited)

- Open to all Bariatric Centers including International
- Compliance with standards not required
- No minimum annual volume required
  - Requires dedicated data collector (MBS Clinical Reviewer)
  - Data collector must successfully complete training by **MBSAQIP**

## **Accreditation Pathways for New Centers**

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	Comprehensive Center	<ul> <li>Apply for Accreditation once all criteria for a Comprehensive Center are met</li> <li>Must perform ≥ 50 stapling cases annually</li> <li>Can perform all approved procedure types</li> <li>Centers are not permitted to operate on adolescent patients</li> <li>Site visit required</li> </ul>
	Comprehensive Center with Adolescent Qualifications	<ul> <li>Apply for Accreditation once all criteria for a Comprehensive Center with Adolescent Qualifications are met</li> <li>Must perform ≥ 50 stapling cases annually</li> <li>Can perform all approved procedure types</li> <li>Site visit required</li> </ul>
New Center (or Data Collection Center) to:	Low Acuity Center	<ul> <li>Apply for Accreditation once all criteria for a Low Acuity Center are met</li> <li>Must perform ≥ 25 cases annually</li> <li>Center must limit its performance of stapling cases to low acuity patients</li> <li>Site visit required</li> </ul>
	Adolescent Center	<ul> <li>Apply for Accreditation once all criteria for an Adolescent Center are met</li> <li>MBSAQIP Verified co-surgeon is required on all cases for Centers that perform &lt; 25 cases annually</li> <li>Can perform all approved procedure types</li> <li>Site visit required</li> </ul>
	Ambulatory Surgery Center	<ul> <li>Apply for Accreditation once all criteria for a Ambulatory Surgery Center are met</li> <li>Must perform ≥ 25 cases annually</li> <li>Center must limit its performance of stapling cases to low acuity patients</li> <li>Site visit required</li> </ul>

## Low Acuity Center Pathways to Comprehensive Center and Comprehensive Center with Adolescent Qualifications Accreditation



## Comprehensive Center Pathway to Comprehensive Center with **Adolescent Qualifications Accreditation**

• Must notify MBSAQIP once center meets all criteria for a Comprehensive Center Comprehensive • Center must perform ≥ 50 stapling procedures annually Comprehensive Center with • Can perform all approved procedure types Center to: **Adolescent** • Must undergo review/approval for new accreditation Qualifications level by MBSAQIP Additional site visit not required

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# STANDARD 1

# Case Volume, Patient Selection, and Approved Procedures by Designation Level



# 1.1 Volume Criteria by Designation Level

All elective primary and revisional procedures, as well as complications and reoperations (elective and nonelective) related to metabolic and/or bariatric surgery require submission to the MBSAQIP Data Registry Platform.

Stapling Procedure Definition: Procedure involving the use of a surgical stapler for the anastomosis or resection of any part of the GI tract. Procedures involving a hand-sutured anastomosis (for example, gastric bypass) are also included in this procedure category.

## Requirements

	Center Volume Criteria
Data Collection Center	No volume requirement—not accredited
Designations for Inpat	ient Centers
Comprehensive Center	A minimum of 50 stapling procedures annually—approved to perform all approved procedure types
Comprehensive Center with Adolescent Qualifications	A minimum of 50 stapling procedures annually (volume not restricted to adolescent patients only)—approved to perform all approved procedure types
Low Acuity Center	A minimum of 25 bariatric procedures annually—approved to perform all approved primary procedures within low acuity restrictions (1.2)
Adolescent Center	Centers performing fewer than 25 stapling procedures annually require a MBSAQIP-Verified Bariatric Surgeon who has credentials at a MBSAQIP Comprehensive Center as a co-surgeon on each case—approved to perform all approved procedure types
	No co-surgeon required for centers performing greater than or equal to 25 stapling procedures annually—approved to perform all approved procedure types
Designation for Freest	anding Outpatient Centers
Ambulatory Surgery Center	A minimum of 25 bariatric procedures annually—approved to perform all approved primary procedures within low acuity restrictions (1.2)

**INITIAL APPLICANTS** may apply once the center has met all standards, including volume requirements, for the designation level sought within the 12 month period prior to application. However, initial applicants are not required to wait 12 months to apply if the center can meet criteria sooner.

**RENEWAL APPLICANTS** must be able to demonstrate ongoing compliance with standards and volume requirements every three years but may demonstrate compliance with volume criteria if able to meet the minimum volume when averaged over the triennial reporting period.

#### **Documentation**

• Volume will be verified by MBSAQIP and/or by chart review at site visit.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Center meets volume requirements for designation level sought.

# 1.2 Low Acuity Patient and Procedure Selection

## Requirements

Low Acuity and Ambulatory Surgery Centers are only approved to perform primary metabolic and bariatric procedures (i.e., excludes patients who have had a previous surgical intervention(s) performed for the treatment of morbid obesity) on low acuity patients as defined below (these restrictions do not apply to band procedures or endoluminal therapeutic procedures for the treatment of obesity):

#### Low Acuity 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 CHF, 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 and Ambulatory Surgery Centers are only approved to perform revisional intraabdominal procedures when classified as an emergent case.\* Revisional bariatric intraabdominal procedures include any procedure performed at any time frame following a previous surgical intervention performed for the treatment of morbid obesity. These centers are not approved to perform elective revisional intraabdominal procedures, with the exception of the following gastric bandrelated procedures:

- Gastric banding, replacement, and repositioning
- b. Gastric band and/or port removal
- Port revision

\*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 implied 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, semielective, or urgent procedure related to the diagnosis would not be considered to have had an emergent case.

#### **Introducing Stapling Procedures**

As previously stated, Low Acuity and Ambulatory Surgery Centers may perform primary stapling procedures on low acuity patients. However, prior to performing any stapling procedures, the center must notify the MBSAQIP of its intent to perform stapling procedures.

Low Acuity and Ambulatory Surgery Centers introducing stapling procedures must conduct specific education for all personnel, including surgeons covering call, involved in the care of the metabolic and bariatric surgery patient prior to beginning any stapling procedures. Education must be tailored specifically to the new stapling procedure being introduced to the center. This education would include, at minimum:

- 1. Formal training regarding a basic understanding of the bariatric procedures commonly performed with the risks and benefits of the procedure
- 2. Signs and symptoms of postoperative complications
- 3. Basic understanding of management and care of the metabolic and bariatric patient by a review of the center's clinical pathways and protocols

#### **Documentation**

- Data will be verified by MBSAQIP and/or by chart review at the site visit.
- Low Acuity and Ambulatory Surgery Centers introducing stapling procedures must provide documentation that education, as outlined above, is provided prior to performing the first stapling procedure.

## Measure of Compliance

- Patient and procedure selection fall within low acuity requirements.
- For Low Acuity and Ambulatory Surgery Centers introducing stapling procedures, documentation that education, as outlined above, is provided prior to performing the first stapling procedure.

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# STANDARD 2

# **Commitment to Quality Care**

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 surgical patients. The administrative and medical staff commit to broad cooperation in order to improve the quality of metabolic and bariatric surgical care provided at the center.



# 2.1 Metabolic and Bariatric Surgery (MBS) **Committee**

## Requirements

The center must establish a MBS Committee consisting of, at a minimum, the MBS Director, all surgeons and proceduralists (for example, endoscopists, radiologists, and so on) performing metabolic and bariatric procedures at the center, the MBS Coordinator, the MBS Clinical Reviewer, and institutional administration representatives involved in the care of metabolic and bariatric surgical patients.

The MBS Committee is considered the primary forum for Continuous Quality Improvement, as outlined in Standard 7. It provides a confidential setting for sharing best practices, responding to adverse events, and fostering a culture to improve patient care. All surgical practices performing bariatric surgery at the center must participate in these initiatives in a collaborative manner focusing on improved quality of care for the metabolic and bariatric patient. Official meeting minutes are required to acknowledge that the MBS Committee has reviewed and discussed adverse events and outcomes. Specific details of the discussion are not required to fulfill this requirement and should be kept in accordance with laws regarding confidentiality.

There must be a minimum of three meetings each year, at least one of which is a comprehensive review of the center to evaluate quality initiatives, procedural volumes, outcomes, and compliance with the MBSAQIP Standards. At minimum, all metabolic and bariatric surgeons and proceduralists participating in the center 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 MBSAQIP to determine reasonableness (for example, patient, family, or personal emergency). For the remaining meetings that are not the comprehensive review, the members required to attend depend on the subject matter of the meeting. Accordingly, the MBS Committee will determine additional attendance requirements for all active metabolic and bariatric surgeons and proceduralists. A metabolic and bariatric surgeon or proceduralist from each practice must serve as a representative at each of the three required meetings and attend either in person or by remote access in accordance with the MBS Committee requirements.

All practitioners performing therapeutic or interventional metabolic and bariatric procedures must be active participants of the MBS Committee.

If a center elects to perform surgery on adolescents, the center must identify an individual to serve on the MBS Committee as the Pediatric Medical Advisor (PMA). The adult metabolic and bariatric center must meet the PMA requirement as described in Standard 9.2.

#### **Documentation**

- The center maintains official minutes of the MBS Committee meeting, which include the date, agenda, and attendance.
- The center provides documentation that all actively participating metabolic and bariatric surgeons and proceduralists attended the annual comprehensive review meeting, unless excused by the MBS Director.

## Measure of Compliance

- Produces minutes, which include the date, agenda, and attendance, of 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.

# 2.2 Metabolic and Bariatric Surgery (MBS) Director

## Requirements

The MBS Director, as a surgeon, must be actively practicing metabolic and bariatric procedures in the center and have full privileges and credentials to perform metabolic and bariatric surgery. A single individual must fill the position of director of a metabolic and bariatric surgery center. In conjunction with the MBS Committee and the administration of the institution, the MBS Director organizes, integrates, and leads all metabolic and bariatric surgery-related services throughout the designated center. The MBS Director must be a MBSAQIP-Verified Surgeon as described in Standard 2.7. Specific responsibilities of the MBS Director include:

- 1. The MBS Director chairs the MBS Committee and attends at least two of the three required meetings and the majority of other meetings.
- 2. The MBS Director, in conjunction with the MBS Committee, is responsible for:
  - Overseeing the accreditation process and ensuring continuous compliance with MBSAQIP requirements.
  - Contacting the MBSAQIP within 30 days if the center falls out of compliance with any MBSAQIP requirements or there is any substantive change in the center that could affect accreditation.
  - Providing a response to MBSAQIP inquiries within 30
- 3. The MBS Director, in conjunction with the MBS Committee, must ensure compliance with outcomes data collection as well as participate in quality improvement efforts for all metabolic and bariatric surgery and interventions performed in the center. The MBS Director, in conjunction with the MBS Committee, is responsible for the:
  - Development of quality standards
  - Evaluation of surgical and procedural outcomes
  - Development of specific quality improvement initiatives in response to adverse events and to improve 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 the metabolic and bariatric surgery patient with a focus on patient safety and complication recognition. 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 both nurses and all surgeon-providers detailing the rapid communication and basic response to critical vital signs is specifically required to minimize delays in the diagnosis and treatment of serious adverse events.

- 5. The MBS Director, in consultation with the MBS Committee, is also responsible for determining the inclusion and exclusion criteria, including weight and/or BMI limits, for patient selection in the center. This criteria includes the types of procedures performed and the acuity and risk of the patient relative to the services the center can safely offer. These recommendations should be made to the appropriate institutional body (for example, credentialing, department of surgery, medical staff, and so on). Furthermore, if necessary, the MBS Director submits recommendations of 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 practitioner's experience, training, and outcomes.
- 6. The MBS Director is responsible for overseeing the process, as determined by the MBS Committee, in which emerging technologies and procedures may be safely introduced by surgeons and proceduralists into the center with adequate patient protection, oversight (including Institutional Review Board [IRB] approval when indicated), and 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 center 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, and so on) significant ethical and/or quality deviations by surgeons and proceduralists performing metabolic and bariatric procedures 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, and the position must have the authority and resources to fulfill the above listed duties.

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

#### **Documentation**

- The center provides a copy of the metabolic and bariatric surgery privileges and credentials of the MBS Director.
- The center provides documentation that the MBS Director is attending at least the minimum required number of committee meetings.
- The center provides proof that the MBS Director is a MBSAQIP-Verified Surgeon.
- The center provides MBS Committee meeting minutes that document the MBS Director is leading the design and implementation of quality and safety improvement initiatives throughout the institution.
- The center provides a job description for the MBS Director position that illustrates that the MBS Director is fully integrated into the institution's organizational framework and has the authority and resources to fulfill all duties as outlined in items 1-9 above.

## Measure of Compliance

- Provides a copy of MBS Director privileges and credentials.
- Provides proof that the MBS Director is attending at least the minimum required number of committee meetings.
- Provides proof that the MBS Director is a MBSAQIP-Verified Surgeon.
- Provides a copy of MBS Committee meeting minutes that document the MBS Director is leading the design and implementation of quality and safety improvement initiatives throughout the institution.
- Provides documentation indicating 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 1-9 above.

# 2.3 Metabolic and Bariatric Surgery (MBS) Coordinator

## Requirements

Metabolic and bariatric surgery centers must have a designated MBS Coordinator who reports to and assists the MBS Director. It is required that a licensed health care professional or registered dietitian\*\* fills this position. The metabolic and bariatric surgery center can have multiple MBS Coordinators, but a single individual must serve as a liaison between the center and MBSAQIP. The MBS Coordinator may fill the role as the MBS Clinical Reviewer (see Standard 2.4) as long as this individual does not document in the patient's

The MBS Coordinator assists in center development, managing the accreditation process and ensuring continuous compliance with MBSAQIP requirements, maintaining relevant policies and procedures, patient education, outcomes data collection, quality improvement efforts, and education of relevant staff in the various aspects of the metabolic and bariatric surgery patient with a focus on patient safety. The MBS Coordinator supports the development of written protocols and education of nurses detailing the rapid communication and basic response to critical vital signs that is 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 surgeons performing metabolic and bariatric surgery 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.

If the MBS Coordinator and MBS Clinical Reviewer are separate individuals, they must work closely together to ensure timely submission of outcomes data. The center's organizational framework must incorporate the MBS Coordinator position, and the MBS Coordinator must have the authority and resources to fulfill the above listed duties.

#### **Documentation**

- The center provides documentation that the MBS Coordinator position is fully integrated into the organizational framework and has the authority and resources to fulfill all
- The center provides a copy of the health care license or registration of the MBS Coordinator.\*\*

## Measure of Compliance

- Provides documentation that the MBS Coordinator position is fully integrated into the organizational framework and has the authority and resources to fulfill all duties.
- Provides a copy of health care license or registration of the MBS Coordinator.\*\*

<sup>\*\*</sup> The requirement for the MBS Coordinator to be a licensed or registered health care professional applies to MBS Coordinators hired on or after May 1, 2015. All nonlicensed MBS Coordinators hired prior to May 1, 2015, are exempt from this requirement.

# 2.4 Metabolic and Bariatric Surgery (MBS) Clinical Reviewer

## Requirements

Timely and accurate data entry is essential to ensure quality improvement can occur that will ultimately enhance patient safety. Each center is required to provide a MBS Clinical Reviewer to enter data into the MBSAQIP Data Registry Platform. Designated MBS Clinical Reviewers are not approved to be supervising patient care (for example, a surgeon, a physician assistant, or advanced practice nurse). The MBS Clinical Reviewer is not only required to fulfill case abstraction duties, but also fulfill ongoing training and recertification requirements, retrieve and enter long-term follow-up data on a compounding number of patients over time, and fulfill requests for patient data and reports to the MBS Coordinator and appropriate personnel for analysis.

During the initial phase of center participation, the MBS Clinical Reviewer may take on limited additional administrative duties (not involved in supervising patient care) as long as all of his or her responsibilities as MBS Clinical Reviewer are fulfilled and given highest priority. The number of Full Time Equivalents (FTEs) needed to fulfill all required MBS Clinical Reviewer duties must be commensurate to the center's annual case and follow-up census. Please see MBSAQIP website at facs. org/mbsaqip for further information regarding MBS Clinical Reviewer requirements. The MBS Clinical Reviewer must be provided with the appropriate resources and access to data and information systems at both the facility and the physicians' offices. The MBS Clinical Reviewer should work closely with the facility and clinicians to ensure that appropriate short-term and long-term data points are available in the medical records.

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

The MBS Clinical Reviewer should be an individual with appropriate clinical knowledge and expertise to collect the required data. A current job description is available on the MBSAQIP website. Satisfactory completion of online initial training is required, as well as ongoing education and training.

Maintenance of certification as an MBS Clinical Reviewer is required and is based upon satisfactory completion of initial online training, participation in ongoing educational webinars, satisfactory completion of a yearly certifying exam, as well as compliance with data audits.

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

In addition to the MBSAQIP Data Registry Platform access, it is required that the MBS Clinical Reviewer have open and unrestricted electronic and paper medical record access to all patient-related data from the institution and physicians' office(s) that is required to be submitted to MBSAQIP. Should a participating metabolic and bariatric surgeon(s) and any associated practice(s) not provide the MBS Clinical Reviewer unrestricted access to patient-related data, the center will be in violation of this standard. The center is required to immediately notify MBSAQIP if any personnel should no longer have access to the MBSAQIP Data Registry Platform.

#### MBS Clinical Reviewer Workspace and **Equipment Requirements**

Ensuring confidentiality of patient information during data collection is imperative while the MBS Clinical Reviewer engages in the data entry process. It is essential to provide appropriate workspace to protect this confidentiality.

#### Requirements for Timely Data Entry

Data entry to the MBSAQIP Data Registry Platform is time sensitive, and it is the responsibility of the MBS Clinical Reviewer to ensure that case and follow-up data are entered into the platform within prescribed data entry timeframes (as illustrated in the MBS Clinical Reviewer training and data registry technical user manuals) to optimize data capture.

#### MBS Clinical Reviewer Meeting Attendance and Participation

The MBS Clinical Reviewer works closely with both clinical and administrative staff and participates in at least two MBS Committee meetings annually.

#### Documentation

- Maintenance of certification for the MBS Clinical Reviewer is tracked by the MBSAQIP.
- The center demonstrates that the MBS Clinical Reviewer position is fully integrated into the center's organizational framework and has the authority and resources to fulfill all duties, including timely data entry to the MBSAQIP Data Registry Platform with full unrestricted patient-related data access.
- The center provides a copy of the MBS Committee meeting minutes indicating that the MBS Clinical Reviewer has participated in at least two meetings annually.

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

## Measure of Compliance

- Maintenance of MBS Clinical Reviewer certification as verified by MBSAQIP.
- Documentation that the MBS Clinical Reviewer position is fully integrated into the organizational framework and has the authority and resources to fulfill all duties, including timely data entry to the MBSAQIP Data Registry Platform with full unrestricted patient-related data access.
- Copy of the MBS Committee meeting minutes indicating that the MBS Clinical Reviewer has participated in at least two meetings annually.

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Designations	Pathways	1	2	3	4	5	6	7	8	9

# 2.5 Health Care Facility Accreditation

## Requirements

Health care facility accreditation ensures that the care for the metabolic and bariatric surgery patient 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), or the Institute for Medical Quality (IMQ).

#### **Documentation**

• The institution provides a copy of the health care facility accreditation document from the accrediting agency.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Copy of the health care facility accrediting certificate or letter by accrediting agency demonstrating current accreditation status.

# 2.6 Credentialing Guidelines for Metabolic and **Bariatric Surgeons**

## Requirements

The center must have at least one actively practicing, credentialed metabolic and bariatric surgeon. The institution's credentialing body must adhere to current nationally recognized credentialing guidelines, which are separate from general surgery guidelines, such as those produced by ASMBS, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), ACS, and the Society for Surgery of the Alimentary Tract (SSAT) (see http://asmbs.org/resources/jointtask-force-recommendations-for-credentialing-of-bariatricsurgeons).

#### 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 can be made 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 a case log list or bariatric surgery training certificate, should be provided to allow the credentialing committee to assess the applicant surgeon's bariatric surgery experience.
- 5. Participation within a structured bariatric center that provides or coordinates comprehensive, interdisciplinary care of the bariatric patient.
- 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 interventional therapeutic procedures, if endoluminal interventional therapeutic procedures are performed by surgeons at the
- 10. The surgeon will actively participate with 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 No or Limited 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 bariatric medical
- 2. The applicant surgeon must have completed a general surgery residency
- 3. The applicant surgeon's initial cases should be performed with a co-surgeon who is a fully credentialed bariatric surgeon. The absolute number of proctored cases is left up to the local credentialing committee. However, the local credentialing committees may wish to delineate separate requirements for those procedures that require gastrointestinal stapling versus those that do not.
- 4. It is advisable that the first cases be of lower technical difficulty with carefully determined lower risk patients as determined by the bariatric medical director.
- 5. The surgeon will actively participate with the MBSAQIP program 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.

#### 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. Revisional bariatric surgery
- 5. Roux-en-Y gastric bypass
- 6. Sleeve gastrectomy
- 7. Vertical banded gastroplasty
  - Investigational procedures should be performed under an IRB-approved protocol.
  - Local credentialing committees may wish to delineate separate requirements for those procedures that require gastrointestinal stapling versus those that do not.

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Designations	Pathways	1	2	3	4	5	6	7	8	9

#### Guidelines for Surgeons and Nonsurgeon Proceduralists Performing Endoluminal Therapeutic Procedures for the Treatment of Obesity

Individuals performing endoluminal bariatric procedures must be credentialed under endoscopic privileges that adhere to current nationally recognized guidelines (for example, SAGES Granting Privileges for Gastrointestinal Endoscopy; see http:// www.sages.org/publications/guidelines/granting-of-privilegesfor-gastrointestinal-endoscopy/). Practitioners performing endoluminal bariatric procedures should be credentialed to perform metabolic and bariatric surgery, and if they are not, they must be an active participant of the MBS Committee in an accredited metabolic and bariatric surgery center.

#### Guidelines for Maintenance and Renewal of **Privileges**

- 1. Privileges to perform bariatric surgery should be renewed commensurate to your center's facility accreditation quidelines.
- 2. Maintenance of 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 program or an equivalent regional or national quality improvement program.
- 4. The surgeon must demonstrate continued critical assessment of his or her outcomes as determined by the composite outcomes measures or periodic review of outcomes from an acceptable regional or national outcomes
- 5. The chief of surgery or his or her designee should verify that these criteria have been met.

#### **Documentation**

- The center provides a copy of required metabolic and bariatric surgery privileges for all actively practicing metabolic and bariatric surgeons at the institution.
- The center provides a copy of required gastrointestinal endoscopy privileges for all practitioners performing endoluminal metabolic and bariatric procedures at the institution.
- The center provides documentation to demonstrate compliance with current nationally recognized credentialing guidelines.

## Measure of Compliance

- Provides a copy of separately required metabolic and bariatric surgery privileges for all actively practicing metabolic and bariatric surgeons at the institution.
- Provides a copy of required gastrointestinal endoscopy privileges for all practitioners performing endoluminal metabolic and bariatric procedures at the institution.
- Provides documentation to demonstrate compliance with current nationally recognized credentialing guidelines.

# 2.7 Metabolic and Bariatric Surgeon Verification

There must be at least one verified surgeon performing metabolic and bariatric surgery at the center in order for the center to achieve accreditation. If a center loses its only verified surgeon, it must notify the MBSAQIP within 30 days. The annual volume requirement for verification must be accomplished at one accredited center. If the surgeon wishes to be the verified surgeon at more than one center, the annual volume requirement must be met at each center. The MBSAQIP will verify surgeons at the time of the center's site inspection, and those surgeons who meet the criteria will receive a document from the MBSAQIP stating that they have been verified as having met the qualifications for a "Metabolic and Bariatric-Verified Surgeon" as of the date of the site visit.

The surgeon verification:

- 1. Recognizes a surgeon's specialized skills and active practice in metabolic and bariatric surgery (MBS)
- 2. Ensures that accredited centers have at least one verified
- 3. Allows surgeons to "transport" their verification status to other MBSAQIP-accredited centers
- 4. Allows surgeons who desire to start a new center an opportunity to demonstrate and bring their specialized skills to a new facility

The following criteria must be met to achieve surgeon

- 1. The surgeon's center must be in full compliance with all MBSAQIP standards and actively participating in the
- 2. The surgeon must attend at least two quality meetings annually (hospital, regional, and/or national).
- 3. The surgeon must document at least 100 lifetime stapling
  - a. The surgeon can count up to 75 stapling cases from an accredited fellowship documented by a letter from the fellowship director and a case log (from training center if fellowship completed after 2013).
  - b. Additionally, the surgeon needs to perform at least 25 stapling cases after fellowship for a total of 100 lifetime stapling cases.

- 4. Annual volume documentation: The surgeon must submit a case log from the MBSAQIP Data Registry verifying that a minimum of 75 stapling cases (an average of 25 cases annually per three-year accreditation cycle) were performed per three-year re-accreditation cycle at the center seeking accreditation.
  - a. Verification volume will only be considered for a single MBSAQIP-accredited center; surgeons may elect to become verified at additional MBSAQIP-accredited centers but must meet the verification volume requirement for each MBSAQIP-accredited center.
  - b. Only MBSAQIP-approved cases will count toward volume.
  - c. If the center is only performing bands and/or endoluminal therapeutic procedures for the treatment of obesity, verification will follow the same criteria listed above, except that the volume requirement will apply to nonstapling procedures only: 100 nonstapling cases lifetime, 75 nonstapling cases per three-year re-accreditation cycle (25 nonstapling cases per year). Nonstapling surgeon verification is separate and distinct from stapling surgeon verification.
- 5. The surgeon must be board certified or in the process of becoming certified by the American Board of Surgery (or equivalent). There will be a waiver process for foreigntrained surgeons or surgeons with substantial contributions to the field as discussed in the surgeon credentialing Standard 2.6.
- 6. The surgeon is required to complete a minimum of 24 metabolic and bariatric-specific AMA PRA Category 1 CME credit hours per three-year re-accreditation cycle or 8 CME credit hours per year (see http://www.ama-assn.org/ama/ pub/education-careers/ama-cme-credit-system.page).

#### Portability of Surgeon Verification

The verified surgeon who moves to another center that does not have a verified surgeon at that location has 24 months to achieve the annual surgeon verification volume requirement to maintain verification status.

1. Verified surgeons transferring from a MBSAQIP Comprehensive Center to another MBSAQIP Comprehensive Center are not required to limit their initial cases to "low acuity" patients.

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

- 2. Verified surgeons transferring from a MBSAQIP Comprehensive Center to a MBSAQIP Low Acuity Center must limit the center's practice to "low acuity" patients until all requirements for a comprehensive center are met.
- 3. Verified surgeons transferring from a MBSAQIP Low Acuity Center to a MBSAQIP Comprehensive Center are not required to limit the practice to "low acuity" patients, but the scope of practice and patient selection criteria will be determined by the center's MBS Committee and credentialing body.
- 4. Verified surgeons transferring from a MBSAQIP Low Acuity Center to another MBSAQIP Low Acuity Center must limit the center's practice to "low acuity" patients until all requirements for a comprehensive center are met.
- 5. Surgeon verification has no effect on a center that is new to MBSAQIP or just beginning its bariatric program until the center applies for accreditation, at which time the facility standards take precedence over surgeon verification.

#### **Documentation**

- The center must show it has at least one participating surgeon who can document the following:
  - 1. Proof that the surgeon has participated in at least two quality meetings annually (hospital, regional, and/or national).
  - 2. Proof that the surgeon has performed at least 100 lifetime stapling (or 100 lifetime nonstapling cases, for Low Acuity and Ambulatory Surgery Centers not performing stapling cases).
  - 3. Proof from the MBSASQIP Data Registry showing that the surgeon has performed a minimum of 25 stapling cases (or 25 nonstapling cases, for Low Acuity and Ambulatory Surgery Centers not performing stapling cases) per year at the center seeking accreditation.
  - 4. Proof that the surgeon is board certified, or in the process of becoming board certified, by the American Board of Surgery (or equivalent).
  - 5. Proof that the surgeon completed at least 8 hours of metabolic and bariatric-specific AMA PRA Category 1 CME credit hours per year.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides proof of at least one participating surgeon who is verified meeting the above criteria.

# 2.8 Qualified Metabolic and Bariatric Surgery Call Coverage

## Requirements

It is the responsibility of accredited centers to provide call coverage for ALL patients presenting to the center whether the center performed the patient's principal metabolic and bariatric procedure(s) or not. This call coverage must be provided 24/7 and 365 days/year. All surgeons performing metabolic and bariatric surgery at the center must have qualified coverage at all times by a colleague who is responsible for the emergency care of a metabolic and bariatric surgery patient—including the full range of complications associated with metabolic and bariatric surgery—in the absence of the primary surgeon. All covering surgeons 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 either by qualified local coverage or through transfer agreements to a facility with qualified surgical emergency coverage.

Transfer agreements cannot be a substitute for a call schedule. Furthermore, it should not 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 covering general surgeon must be credentialed with general surgery privileges and must have undergone adequate education and training as determined by the center's MBS Committee, which would 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 the patient by a review of the center's clinical pathways and protocols

Covering surgeons 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 policy or protocol (inclusive of transfer agreement to an MBSAQIP-Accredited Comprehensive Center, if transfer is part of the call coverage plan), which has been endorsed by the MBS Committee, must address the care of the unassigned or unaffiliated metabolic and bariatric patients presenting to the applicant center.

#### **Documentation**

- The center provides a copy of the call schedule.
- The center provides a copy of the roster of surgeons who provide metabolic and bariatric surgery call coverage with documentation of general surgery privileges for each surgeon.
- The center provides proof of education of general surgeons covering bariatric emergency care in alignment with the education requirements as outlined above.
- The center provides a copy of the protocol outlining the care of the unassigned or unaffiliated metabolic and bariatric patient presenting to the applicant center.

## Measure of Compliance

- Copy of the metabolic and bariatric surgery call schedule.
- Copy 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 covering bariatric emergency care in alignment with the education requirements as outlined above.
- Provides a copy of the protocol outlining the care of the unassigned or unaffiliated metabolic and bariatric patient presenting to the applicant center.

# 2.9 Designated Area of Facility, with Knowledgeable and Consistent Nursing Staff, for Postoperative **Metabolic and Bariatric Surgery Patients**

## Requirements

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

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

Centers must also have a system in place to ensure the ongoing competencies of staff in recognizing these signs and symptoms.

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

#### Training Session 1

Course Name: Signs and Symptoms of Postoperative Complications

Course Description: In-service education must help 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, and bowel obstruction) so the patient can be managed promptly.

Required Staff: All staff that has, or potentially has, direct contact with metabolic and bariatric patients

Minimum Frequency: At initial hire and annually thereafter

## **Training Session 2**

Course Name: Sensitivity Training

Course Description: In-service education must support a culture where all staff members are prepared to manage severely obese patients, whether or not metabolic and bariatric surgery is the reason for admission, with understanding and compassion to appreciate the burdens of the comorbidities of severe obesity.

Required Staff: All staff that has, or potentially has, direct contact with metabolic and bariatric patients

Minimum Frequency: At initial hire and repeated within each accreditation renewal cycle

#### **Training Session 3**

Course Name: Patient Transfer and Mobilization

Course Description: In-service education must address the safe transfer and mobilization of severely obese patients, which is for the benefit of the patient as well as the staff. This is important not only for the metabolic and bariatric surgery patients the staff encounters, but also for the benefit of the increasing number of severely obese individuals in the facility for other reasons.

Required Staff: All staff that has, or potentially has, direct contact with metabolic and bariatric patients

Minimum Frequency: At initial hire and repeated within each accreditation renewal cycle

#### **Documentation**

- The center provides documentation that metabolic and bariatric surgery care is provided in a specific area(s) designated within the facility.
- The center must provide documentation that in-service training is provided as outlined above.

## Measure of Compliance

- Provides document indicating designated specific area(s) for care of the metabolic and bariatric surgery patient.
- Provides documents that in-service training modules are provided as outlined above.

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

# 2.10 Designated Personnel

## Requirements

The center must have a procedure in place that involves an integrated health approach to the metabolic and bariatric surgery patient. The optimal care of the metabolic and bariatric surgery patient requires specialized training, education, and experience that can include Certified Bariatric Nurses (CBN®) certification. The center must provide access or referral to the following disciplines, as needed, for both preoperative and postoperative care.

- a. Registered nurses, advanced practice nurses, or other physician extenders
- b. Registered dietitians
- c. Psychologists, psychiatrists, social workers, or other licensed behavioral health care providers
- d. Physical or exercise therapists

If a center elects to perform metabolic and bariatric surgery on adolescents, a psychologist, psychiatrist, or other qualified and independently licensed behavioral health care provider with specific training and credentialing in pediatric and adolescent care must perform the behavioral assessment. The adult metabolic and bariatric center must meet the behavioral specialist requirements as outlined in Standard 9.3.

#### **Documentation**

• The center provides documentation that an integrated health team is caring for the metabolic and bariatric surgery patient.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation showing an integrated health team is caring for the metabolic and bariatric surgery patient.

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

# STANDARD 3

# **Appropriate Equipment and Instruments**

The center must maintain appropriate equipment and instruments for the care of metabolic and bariatric surgical patients. This includes furniture, wheelchairs, operating room tables, floor-mounted or floor-supported toilets, beds, radiologic capabilities, surgical instruments, and other facilities required for the safe delivery of care to patients with morbid obesity.



# 3.1 Facilities, Equipment, and Instruments **Accreditation**

## Requirements

Furniture and equipment must be able to accommodate patients who are within the patient weight limits established by the metabolic and bariatric center. A written system to ensure that weight-appropriate equipment is available and used for all metabolic and bariatric surgery patients is required. Weight capacities must be documented by the manufacturer's specifications, and this information must be readily available to relevant staff. Appropriate patient movement and transfer systems must also be located wherever metabolic and bariatric surgery patients receive care. Personnel must be trained to use the equipment and be capable of moving patients without injury to the patient or themselves (see Standard 2.9 regarding in-service education on patient transfers and mobilization).

MBSAQIP requires facilities to have a full line of equipment and instruments for the care of patients who undergo metabolic and bariatric surgery. This list includes, but is not limited to, the following equipment that can accommodate morbidly obese patients appropriate for the facility's patient population:

- Examination tables
- Operating room tables
- Radiological tables and facilities
- Fluoroscopic technologies
- Medical imaging equipment for diagnostic purposes
- Surgical instruments (staplers, retractors, long instruments, and so on)
- Intensive care unit (ICU) equipment
- Crash carts
- Blood pressure cuffs
- Sequential compression device sleeves

The facility must also have the following additional facility requirements to accommodate morbidly obese patients:

- Doorways
- Chairs
- Beds
- Scales
- Gowns
- Floor-Mounted or Floor-Supported Toilets
- Shower Rooms
- Wheelchairs
- Walkers

Patient selection criteria for metabolic and bariatric procedures must take into account the weight limits of the existing equipment. A center must document a patient care pathway for patients that exceed equipment weight limits. Centers do not need to change all of the equipment, furniture, and instruments throughout the entire facility. This requirement only applies to those areas where patients undergoing metabolic and bariatric surgery receive care, including the operating room, emergency department, radiology suite, designated metabolic and bariatric unit, and waiting areas. Metabolic and bariatric care may occur within several areas of the facility, and additional equipment required to care for the morbidly obese patient may be located off-site.

#### **Documentation**

- Evidence that weight- and size-appropriate facilities, equipment, and instruments are provided in the areas where metabolic and bariatric patients are treated.
- Rental or lease agreement for equipment that is not available on-site that indicates a guaranteed delivery timeframe (not required for centers that have all required equipment onsite).
- The center demonstrates its written system of clearly defining the weight limits of equipment.
- The center provides documentation of a care pathway for patients who exceed equipment weight limits.

## Measure of Compliance

- Provides evidence that weight- and size-appropriate facilities, equipment, and instruments are provided in the areas where metabolic and bariatric patients are treated.
- Provides rental or lease agreement for equipment that is not available on-site that indicates a guaranteed delivery timeframe (not required for institutions that have all required equipment on-site).
- Provides documentation of written system defining weight limits.
- Provides documentation of a care pathway for patients who exceed equipment weight limits.

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Designations	Pathways	1	2	3	4	5	6	7	8	9

# STANDARD 4

# **Critical Care Support**

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



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Designations	Pathways	1	2	3	4	5	6	7	8	9

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

# 4.1 Advanced Cardiovascular Life Support (ACLS)-**Qualified Provider Accreditation**

## Requirements

An ACLS-qualified physician, ACLS-qualified physician extender, or other licensed health care provider who is capable of administering ACLS (defibrillation, drug administration, and so on), as well as advanced airway management, must be onsite at all times when metabolic and bariatric surgery patients are present. This requirement ensures that a qualified provider is available to perform patient resuscitations at any time in cases where anesthesia is not being administered. Centers with an emergency department can fulfill this requirement with a credentialed emergency room physician, as long as the hospital's policies dictate that this physician is available at all times.

#### **Documentation**

• The center provides documentation that an ACLS-qualified physician, physician extender, credentialed emergency room physician or other licensed health care provider who is capable of administering ACLS (defibrillation, drug administration, and so on), as well as advanced airway management, is on-site at the facility at all times when metabolic and bariatric surgical patients are present.

# Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation that an ACLS-qualified physician, physician extender, credentialed emergency room physician, or other licensed health care provider who is capable of administering ACLS (defibrillation, drug administration, and so on), as well as advanced airway management, is on-site at the facility at all times when metabolic and bariatric surgical patients are present.

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

# 4.2 Ability to Stabilize Patients and Transfer

## Requirements

When necessary, the center must have the ability to stabilize patients and transfer to a higher level of care if the center is unable to manage this metabolic and bariatric surgery patient on-site (see Standard 4.3 regarding written transfer agreements). Facilities that do not have an ICU on-site must have the ability to support the stabilization of a critically ill patient until the patient can be transferred. The facility must have immediately available ventilators and hemodynamic monitoring equipment as well as have the capacity to manage a difficult airway and intubation.

#### **Documentation**

• The center demonstrates the ability of stabilizing a critically ill metabolic and bariatric surgery patient by providing physical proof of a difficult airway cart, ventilator, and hemodynamic monitoring equipment.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides physical proof of a difficult airway cart, ventilator, and hemodynamic monitoring equipment.

# 4.3 Written Transfer Agreement

## Requirements

An accredited center should be able to reasonably recognize and treat patients with metabolic and bariatric surgery complications. Transfer agreements should not be used as a substitute for standard and usual care of metabolic and bariatric surgery 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 surgery 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 for transferring severely obese patients to that inpatient facility.

To address metabolic and bariatric surgery 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 above.

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 at a MBSAQIP-accredited Comprehensive Center or a written transfer agreement in place with a metabolic and bariatric surgeon at a MBSAQIP-accredited Comprehensive Center.

#### Transfer requirements:

- 1. A plan for safe transfer of a metabolic and bariatric surgery patient 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 a metabolic and bariatric surgery patient requiring nonemergent care to a MBSAQIP-Accredited Comprehensive Center 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**

• The center provides documentation of the transfer process for both emergent and nonemergent metabolic and bariatric surgery patients, if patient transfer is part of the care pathway.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation of the transfer process for both emergent and nonemergent metabolic and bariatric surgery patients, if patient transfer is part of the care pathway.

# 4.4 Required Available Services

Comprehensive Centers must be able to provide anesthesia services, CCU and/or ICU services, comprehensive endoscopy services, and comprehensive diagnostic and interventional radiology services on-site (additional required services outlined in 4.4-5 may be provided through a transfer agreement). Centers accredited under all other designation levels may provide the following services either on-site or through a transfer agreement.

#### 4.4-1 Anesthesia Services

## Requirements

Anesthesiology requirement for perioperative management of the metabolic and bariatric surgery patient:

The center must have an anesthesia protocol specific to the care of the metabolic and bariatric surgery patient that is endorsed by the MBS Committee. Anesthesia providers must adhere to local and state laws governing their scope of practice, which is approved by the center's credentialing body and is further endorsed by the center's MBS Committee.

#### **Documentation**

- The center provides documentation of their protocol for anesthesia care of the metabolic and bariatric patient, which is endorsed by the local level MBS Committee.
- The center provides documentation of their credentialing policy for the anesthesia providers who provide care to the metabolic and bariatric patient that adheres to local and state laws and governs their scope of practice.

## **Measure of Compliance**

Compliance: The center fulfills the following criteria:

- Provides documentation of their protocol for anesthesia care of the metabolic and bariatric patient, which is endorsed by the local level MBS Committee and approved by the center's credentialing body.
- Provides documentation of their credentialing policy for the anesthesia providers who provide care to the metabolic and bariatric patient that adheres to local and state laws and governs their scope of practice.

# 4.4-2 Critical Care Unit (CCU) / Intensive Care Unit (ICU) Services

## Requirements

CCU/ICU requirements:

- 1. Required personnel
  - a. Physician, surgeon, or intensivist who has met credentialing criteria by the institution to manage critically ill patients 24/7
  - b. Trained critical care nursing staff who have met the center's credentialing criteria 24/7
- 2. ICU must be equipped for patients with morbid obesity (see Standard 3).
- 3. Comprehensive Centers 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 must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric surgery patients to another facility that fully meets all the above requirements.
- 4. An off-site ICU monitoring system is acceptable only if the center fully meets all other requirements in Standard 4.

#### **Documentation**

• The center demonstrates access to critical care services and meets all of the above requirements.

## Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation of access to critical care services and meets all of the above requirements.

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#### 4.4-3 Comprehensive **Endoscopy Services**

#### Requirements

Comprehensive endoscopy services requirements:

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

#### **Documentation**

• The center demonstrates access to endoscopy services and meets the above requirements.

#### Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation that access to endoscopy services is available and meets the above requirements.

#### 4.4-4 Comprehensive Diagnostic and Interventional Radiology Services

#### Requirements

Comprehensive diagnostic and interventional radiology services requirements:

- 1. Physician who has met credentialing criteria by the facility to perform imaging, percutaneous drainage, and other radiology procedures.
- 2. Comprehensive Centers must have comprehensive 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 must have a signed written transfer agreement that details the transfer plan of metabolic and bariatric surgery patients to another facility that fully meets all the above requirements.

#### **Documentation**

• The center demonstrates access to diagnostic and interventional radiology services and meets the above requirements.

#### Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides proof of access to diagnostic and interventional radiology services and meets the above requirements.

#### 4.4-5 Access to Additional **Required Services**

#### Requirements

The center must have available for consultation, at all times, credentialed consultants capable of managing the full range of metabolic and bariatric surgery complications:

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

#### **Documentation**

- The center demonstrates that all additional required services are available at all times.
- The center provides a copy of the signed written transfer agreement for any service listed above that is not provided on-site.

#### Measure of Compliance

- Provides documentation of access to all of the additional required services listed above.
- Provides a copy of the signed, written transfer agreement for any service listed above that is not provided on-site.

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

# STANDARD 5

# **Continuum of Care**

The center utilizes clinical protocols that facilitate the standardization of perioperative care for the relevant procedure. Protocols are a sequence of orders and therapies describing the routine care of the metabolic and bariatric patient from initial evaluation through long-term follow-up. Centers are required to use comprehensive protocols outlining the continuum of care of the metabolic and bariatric surgery patient.



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	Pathways	1	2	3	4	5	6	7	8	9			

MBSAQIP requires that metabolic and bariatric procedures are standardized and perioperative care details are well documented and followed appropriately. Clinical protocols can be documented in a variety of formats, including tables, algorithms, process maps, and paragraph form. All staff caring for the metabolic and bariatric patient must be educated about the protocols pertinent to their area of practice.

# 5.1 Patient Education Pathways

#### Requirements

The preoperative education pathways from each surgeon performing metabolic and bariatric surgery in the center must outline a process by which the patient is educated in detail, and said pathways must be approved by the center's MBS Committee. Required pathways include:

- 1. Indications and contraindications for metabolic and bariatric surgery.
- 2. Various interventional options provided by the center and the center's volume specific to each procedure, as well as 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 should be explained as well as a thorough explanation of discharge instructions that include activities, diet, followup appointments, medications, and signs and symptoms of complications such as tachycardia, fever, shortness of breath, excessive abdominal pain, and vomiting.

#### **Documentation**

• The center demonstrates each surgeon's preoperative educational pathways whether written, video, web-based, slide show, etc.

#### Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation of each surgeon's preoperative educational pathways, addressing each element stated above.

# 5.2 Perioperative Care Pathways

#### Requirements

Each center must utilize perioperative care pathways outlining the process for evaluating the patient seeking metabolic and bariatric surgery. Pathways should be reviewed regularly (at minimum annually) and revised if indicated by the review of the center's outcomes data (see Standard 7.2). The following pathways are required and must be approved by the center's MBS Committee:

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

Each practicing metabolic and bariatric surgeon in 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 surgeon

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

#### **Documentation**

- The center provides copies of each surgeon's perioperative care pathways, inclusion and exclusion patient selection criteria and evaluation process, including psychological evaluation, preoperative clearance, nutrition regimens, and metabolic and bariatric standardized order-sets.
- The center provides MBS Committee meeting minutes documenting, at minimum, annual review of perioperative care protocols, which indicate any revisions driven by the review of the center's outcomes data.

#### Measure of Compliance

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

# 5.3 30-Day and Long-Term Follow-Up

#### Requirements

Centers must document each surgeon's plan to follow the long-term progress of their metabolic and bariatric surgery patients.

Documented processes should be in place to achieve long-term follow-up of metabolic and bariatric surgery patients. Follow-up should be provided by a physician, nurse practitioner, clinical nurse specialist, physician assistant, or supervised registered nurse with experience, training, or certification in the care of the metabolic and bariatric surgery patient. Patients lost to follow-up must have a minimum of two efforts to contact the patient (including one phone call and one letter) for each follow-up period (defined as 30 days, six months, one year, and annually thereafter). Patient contact attempts must be documented in the patient record for all patients. It is mandatory that all patients are followed through the first year following surgery (in other words, 30 days, six months, and one year). The center may cease attempts to contact patients after the patient is lost to follow-up for two consecutive follow-up periods (in other words, a patient who does not return for six-month and one-year visits may be considered lost to follow-up).

#### **Documentation**

- The center provides copies of its long-term follow-up plan, including a protocol for maintaining or re-establishing contact with metabolic and bariatric surgery patients.
- The center provides documentation of a minimum of two attempts per follow-up period for patients who are lost to follow-up (not required for patients who remain lost to followup after two consecutive follow-up time periods).

#### Measure of Compliance

Compliance: The center fulfills the following criteria:

- Long-term follow-up plan and protocol are provided.
- A minimum of two attempts per follow-up period are documented for patients who are lost to follow-up (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 show	no show	no show	Χ	Χ	X	Χ	X
00002	assessment	no show	no show	Χ	Χ	X	Χ	X
00003	assessment	assessment	no show	no show	Χ	X	Χ	X
00004	assessment	assessment	assessment	no show	no show	X	Χ	X
00005	assessment	no show	assessment	no show	no show	X	Χ	X
00006	assessment	no show	assessment	no show	assessment	no show	no show	X
00007	assessment	assessment	assessment	no show	assessment	assessment	assessment	assessment

assessment	patient is contacted and receives scheduled clinical assessment; documentation of contact attempts is not required
no show	patient did not show up for scheduled clinical assessment or a clinical assessment was not scheduled; 2 attempts to contact the patient must be documented
X	patient did not show up for scheduled clinical assessment or a clinical assessment was not scheduled for 2 consecutive follow-up timeframes; no further attempts to contact the patient are required

<sup>\*</sup>Please note that the table above provides a snapshot of possible follow-up scenarios. Attempts to follow patients annually should continue beyond the six-year follow-up period until the patient fails to show up for two consecutive follow-up periods.

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Designations	Pathways	1	2	3	4	5	6	7	8	9		

# 5.4 Support Groups

#### Requirements

The center must provide regularly scheduled organized and supervised support groups to metabolic and bariatric surgery patients. Regularly scheduled support groups must be made available a minimum of every quarter and can be in-person, Web-based, or teleconferenced. The practice and/or facility can organize support groups, but the entity responsible for administering each support group must be clearly identified. A licensed health care provider must provide support group oversight. The center's MBS Committee will determine credentials for health care providers supervising the support groups. Patients must have knowledge of their support group options.

All in-person 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 should be noted but do not require full documentation.

#### **Documentation**

- The center provides a copy of the, at minimum, quarterly in-person, Web-based, or teleconferenced support group meetings schedule, including time, location, agenda, and supervisor.
- The center provides the credentials of the health care provider who offers support group oversight.

#### Measure of Compliance

- Provides the minimum quarterly support group documentation (in-person, Web-based, or teleconferenced).
- Provides the credentials of the health care provider who offers support group oversight.

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

# STANDARD 6

# **Data Collection**

High-quality data is critical to inform quality improvement and to determine accreditation.



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Designations	Pathways	1	2	3	4	5	6	7	8	9	

All metabolic and bariatric surgical procedures, including those performed by non-metabolic and bariatric surgery credentialed general surgeons, must be entered into the MBSAQIP Data Registry Platform. Documentation of each hospitalization and surgical procedure is required to obtain valid outcomes data.

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

The MBSAQIP Data Registry collects prospective, risk-adjusted, clinically rich data based on standardized definitions. Data variables to be collected are listed in the online workstation. Data variables are periodically updated, refined, added, or deleted to optimize information captured to inform quality improvement and assessment while minimizing the data collection burden. Centers have the opportunity to submit and track additional data elements as they wish with custom fields.

Data is validated with multiple mechanisms that are continuously updated to optimize the quality of the data collected. The workstation was developed to minimize the ability to submit inaccurate data and to prevent missing data. Centers are required to intermittently submit administrative or other corroborating data as an audit of data entered (see Standard 6.1 for documentation and compliance measures). Data are validated in a systematic fashion as part of scheduled site visits. Ongoing training and assessment of the MBS Clinical Reviewers processes and knowledge is monitored as another means to validate data entered (see Standard 2.4 for documentation and compliance measures). Additional data audits, information, or clarifications may be required by MBSAQIP.

MBS Clinical Reviewers are audited, trained data reviewers who are not directly involved in patient care. All metabolic and bariatric operations and interventions must be submitted via the online MBSAQIP Data Registry Platform. Follow-up data is used to assess morbidity and mortality, as well as clinical effectiveness concerning changes in weight and weight-related comorbidities. Data is collected at 30 days, six months, one year, and yearly thereafter. Riskadjusted metrics have been developed for quality assessment and improvement.

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

#### Requirements

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

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

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

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

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

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

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

#### **Documentation**

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

#### Measure of Compliance

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

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

# 6.2 Data Reports, Quality Metrics, and Quality **Monitoring**

#### Requirements

All centers are expected to monitor their data. Ongoing review of risk-adjusted and unadjusted outcomes and processes is critical for continuous quality improvement. Risk-adjusted reports are available on a semiannual basis 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 centers via the MBSAQIP Data Registry Platform in real time. Documentation in the workstation of the required minimum attempts to contact the patient for follow-up at 30 days is anticipated for 100 percent of cases. See Standard 5.3 for further details regarding patient followup requirements. The unadjusted online reports provide site-specific and surgeon-specific data for that center and the ability to benchmark outcomes against aggregate, national comparison data.

MBSAQIP reports must be accessed and reviewed by the MBS Committee and/or the MBS Clinical Reviewer at least three times annually. The MBS Committee is able to see the results of all surgeons at the center and determines the distribution of data that can compare individual surgeon results at that center.

#### **Documentation**

• The center must document that it has accessed the data on the workstation at least three times a year, of which two must be a review of the risk-adjusted reports.

#### Measure of Compliance

Compliance: The center fulfills the following criterion:

• Provides documentation that the MBS Committee and/ or the MBS Clinical Reviewer accessed the reports on the workstation at least three times a year, of which two must be a review of the risk-adjusted reports.

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Designations	Pathways	1	2	3	4	5	6	7	8	9

# STANDARD 7

# **Continuous Quality Improvement**

Inherent to continuous quality improvement, the center must develop processes of identifying adverse events, which in turn result in the development of corrective action plans and measurement of patient outcomes. Problem resolution, outcome improvements, and assurance of safety ("loop closure") must be readily identifiable through methods of monitoring, reevaluation, and documentation. MBSAQIP® ACCREDITED CENTER QUALITY PROGRAM METABOLIC

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Designations	Pathways	1	2	3	4	5	6	7	8	9

To support these efforts, the MBS Director and other team members of the MBS Committee at each center must develop a culture of collaboration in order to report, analyze, and implement strategies based on the data and effect improvements in the quality of care offered to metabolic and bariatric patients. While major quality improvement projects such as decreasing surgical site infections, leaks, or DVT/PE are important, equally important is the examination of pathways of care in order to maximize the patient experience and effectiveness of the operations. A continuous quality improvement process must reflect the result of such efforts through the center's MBS Committee. Please see the MBSAQIP website at facs.org/mbsagip for further information and resources regarding quality improvement.

#### 7.1 Institutional Collaborative

#### Requirements

Each center is required to establish and maintain an institutional collaborative consisting of all surgeons who practice metabolic and bariatric surgery within the center. The collaborative is the MBS Committee, chaired by the MBS Director. Specifically, the collaborative:

- 1. Establishes and maintains a process to notify surgeons of an adverse event and to give the surgeons a chance to review the data and discuss the case with the MBS Committee. Examples of adverse events may include, but are not limited to, ED visits, reoperations, readmissions, prolonged LOS, bleeding, postoperative morbidity, unplanned admission to ICU, etc.
- 2. Reviews the data from the center on a regular basis, as outlined in Standard 6.2. Each surgeon reviews his or her own data to determine how results compare within the institutional collaborative and to national comparison data.
  - This review is based on data from the real-time online reports available via the MBSAQIP Data Registry Platform or patient experience feedback. The online reports contain granular data that may help the group determine root causes of adverse outcomes.
- 3. Review the semiannual risk-adjusted report (SAR) with the MBS Committee.

#### **Documentation**

- The center provides documentation of the process for notification of adverse events and the subsequent review process.
- The center maintains minutes of the MBS Committee meetings indicating that all of the following were reviewed:
  - 1. All adverse events as part of protected, peer review
  - 2. Semiannual risk-adjusted report (SAR)

#### Measure of Compliance

- Provides documentation of the process for notification of adverse events and the subsequent review process.
- Provides the minutes, in a HIPAA-compliant manner, of all MBS Committee meetings indicating that all of the following were reviewed:
  - 1. All adverse events as part of protected, peer review process
  - 2. Semiannual risk-adjusted report (SAR)

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# 7.2 Quality Improvement Process

#### Requirements

Within metabolic and bariatric surgical care, the goal is to provide safe, efficacious, and high-quality care to every patient at all times. It is imperative to develop a culture of collaboration and safety among all MBS Committee members at your center to achieve this goal. Under the stewardship of the MBS Director, all MBS centers must measure, evaluate, and improve their performance through at least one quality improvement initiative or project each year.

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 report (SAR), non-risk-adjusted real-time reports, and other data sources (for example, patient experience scores) are valuable tools to evaluate areas for improvement at your center and must be used to identify pertinent QI projects. These projects should change structure, processes, and/or clinical pathways within the center.

Preferably, a center should adopt a consistent methodology for these improvement projects. The methodology may vary from center to center depending on the unique needs and expectations of each. There are various process improvement methodologies and tools that centers can adopt. Further information can be found on our website at facs.org/mbsaqip.

Renewal centers must first look at their center's risk-adjusted

and non-risk-adjusted clinical outcomes data provided via the MBSAQIP Data Registry to identify QI initiatives and prioritize QI initiatives that focus on improving surgical outcomes. At minimum, centers found to be a high outlier must investigate the factors contributing to the high outlier status as an opportunity for QI. If further investigation reveals a related QI initiative is unwarranted (in other words, 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. Centers are encouraged not to limit QI efforts to a single initiative based on a single data source and must prioritize QI initiatives related to safety and clinical outcomes over internal process or patient

satisfaction-related initiatives.

#### **Documentation**

- The center provides documentation for at least one QI initiative per year, which outlines how the center has measured, evaluated, and improved their performance through implementation of a process improvement methodology.
- The center provides MBS Committee minutes documenting discussion regarding how the committee members identified, implemented, and monitored the QI initiative.

#### Measure of Compliance

- Provides documentation for at least one QI initiative per year, which outlines how the center has measured, evaluated, and improved their performance through implementation of a quality improvement methodology.
- Provides MBS Committee minutes documenting discussion regarding how the committee members identified, implemented, and monitored the QI initiative.

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Designations	Pathways	1	2	3	4	5	6	7	8	9		

# 7.3 Ongoing Monitoring of Safety Culture

#### Requirements

Safety and outcomes monitoring will be implemented for all centers. Examples of adverse events for safety and outcomes monitoring can include, but are not limited to, complications, readmissions, reoperations, unplanned admissions to ICU, postoperative morbidity, prolonged length of stay, and emergency department (ED) visits. At minimum, in-hospital or 30-day mortalities initiating within the first 30-day postoperative period must be reported to the MBS Committee and reviewed within 60 days of the occurrence.

In addition to reporting all mortalities, the MBS Director and members of the MBS Committee will be required to submit an annual report to MBSAQIP during the anniversary month in which they were accredited in the second and third year of the three-year accreditation cycle. The report will contain an attestation of compliance with all applicable standards. Additionally, the report will require confirmation from the MBS Director that the MBS Committee reviewed any mortality that occurred within the annual reporting period, if any, and brought forth to the institution's committee or board responsible for overseeing patient safety.

#### **Documentation**

- The center provides proof that all mortalities, if any, were reported and reviewed by the MBS Committee within 60 days of occurrence.
- The center provides a copy of annual reports submitted to MBSAQIP within the accreditation anniversary month in the second and third year of the three-year accreditation cycle.

#### Measure of Compliance

- Provides proof that all mortalities, if any, were reported and reviewed by the MBS Committee within 60 days of the occurrence.
- Provides proof that complete annual reports were submitted to MBSAQIP within the accreditation anniversary month in the second and third year of the three-year accreditation cycle. Reports must properly address all mortalities, if any, within the previous year.

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

# STANDARD 8

# **Ambulatory Surgery Centers**

The accreditation for an Ambulatory Surgery Center is separate and distinct from the fully accredited inpatient metabolic and bariatric comprehensive and low acuity centers. Ambulatory Surgery Center accreditation is awarded to outpatient surgery centers that partner with an inpatient MBSAQIP-accredited center to ensure the continuum of care. Accredited Ambulatory Surgery Centers must meet the MBSAQIP core standards (Standards 1–7) in addition to the criteria outlined in Standard 8.



# 8.1 Inpatient Admitting Privileges

#### Requirements

To address metabolic and bariatric surgery patients requiring emergent care, surgeons performing metabolic and bariatric procedures at Ambulatory Surgery Centers must have admitting privileges at an inpatient center that is capable of handling the full range of surgical emergency complications. A written transfer agreement must be in place with an inpatient MBSAQIP-accredited center if, after stabilization of the patient, the hospital does not have the capability to further treat the patient's condition.

To address nonemergent surgical complications requiring inpatient diagnosis and treatment, all surgeons performing metabolic and bariatric procedures at Ambulatory Surgery Centers must have admitting privileges for metabolic and bariatric surgery at a MBSAQIP-accredited center or a written plan or protocol in which the surgeon assumes the responsibility to transfer the patient's care to the appropriate specialist to a center capable of treating the patient's condition.

#### **Documentation**

- For all metabolic and bariatric surgeons at Ambulatory Surgery Centers, the center provides a copy of inpatient admitting privileges.
- The center provides documentation of the transfer process of a critically ill, emergent, metabolic and bariatric surgery patient, including the written transfer agreement.
- The center provides admitting privileges for metabolic and bariatric surgery at a MBSAQIP-accredited center or a written plan or protocol in which the surgeon assumes the responsibility to transfer the patient's care to the appropriate specialist to a center capable of treating the patient's condition.
- The center provides documentation of the transfer process of a nonemergent metabolic and bariatric surgery patient requiring inpatient treatment to a metabolic and bariatric surgeon at a MBSAQIP-Accredited Comprehensive Center, including the signed written transfer agreement.

#### Measure of Compliance

- Provides, for all metabolic and bariatric surgeons, a copy of inpatient admitting privileges.
- Provides admitting privileges for metabolic and bariatric surgery at a MBSAQIP-accredited center or a written plan or protocol in which the surgeon assumes the responsibility to transfer the patient's care to the appropriate specialist at a center capable of treating the patient's condition.
- Provides documents of the transfer process of a critically ill or emergent, metabolic and bariatric surgery patient, including the signed written transfer agreement.
- Provides documents of the transfer process of a nonemergent metabolic and bariatric surgery patient requiring inpatient treatment to a metabolic and bariatric surgeon at an MBSAQIP-Accredited Comprehensive Center, including the signed written transfer agreement.

# 8.2 Stapling Procedures in Ambulatory **Surgery Centers**

Ambulatory Surgery Centers seeking MBSAQIP accreditation that wish to perform stapling procedures must restrict patient and procedure selection in accordance with the low acuity restrictions outlined in Standard 1.2. Results on short length of stay patients need to be monitored by the MBS Committee closely for safety and will be additionally monitored during triennial site visits.

8.2-2 Additional Data Collection and Monitoring for Quality **Improvement: Emergency** Department Visits, Readmissions, and Transfers to Other Facilities

#### 8.2-1 Risk Assessment Protocol

#### Requirements

Facilities designated as an Ambulatory Surgery Center must restrict patient and procedure selection as defined in Standard 1.2.

To further ensure patient safety, a risk assessment protocol must be created and reviewed at a minimum during the required MBS Committee meetings as stipulated in Standard 2.1 to discuss appropriate patient selection at the ambulatory surgery center; compliance against this protocol must be measured a minimum of annually during the center's annual comprehensive review meeting.

#### **Documentation**

- The center must provide documentation (meeting minutes) that a risk assessment protocol has been developed and reviewed a minimum of annually.
- Meeting minutes from each MBS Committee meeting that demonstrate a review of compliance against the risk assessment protocol.

#### Measure of Compliance

Compliance: The program fulfills the following criteria:

- Provides documentation (meeting minutes) that a risk assessment committee meets on a schedule determined by the MBS Committee.
- Demonstrates review at every MBS Committee meeting and compliance with the established risk assessment protocol.

#### Requirements

Quality improvement and safety monitoring must be conducted as outlined in Standards 7.2 and 7.3. Ambulatory Surgery Centers performing stapling procedures are required to collect additional data elements in an effort to monitor patient safety and improve quality of care being administered to the metabolic and bariatric surgery patient in the ambulatory surgery setting. This will include monitoring of 30-day, postprincipal, operative procedure emergency department visits; readmissions; and patient transfers. The center will need to provide a written plan for how it will monitor ED visits and readmissions to other hospitals.

#### **Documentation**

- The center provides documentation that it is monitoring additional data elements as outlined above and is monitoring and discussing quality improvement at the MBS Committee meetings.
- The center provides a written plan for how the center will monitor ED visits and readmissions to other hospitals.

#### Measure of Compliance

- Provides documentation that the center is monitoring additional data elements as outlined above and is monitoring and discussing quality improvement at the MBS Committee meetings.
- The center provides a written plan for how the center will monitor ED visits and readmissions to other hospitals.

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

# STANDARD 9

## **Adolescent Center Accreditation**

The prevalence of childhood obesity and numerous obesity-related comorbidities has risen exponentially over the past several decades. In addition, a mounting body of scientific evidence demonstrating a high propensity for severely obese adolescents to become severely obese adults has led to an increase in the consideration and utilization of surgical weight reduction procedures in this emerging population.





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

MBSAQIP adolescent accreditation is required for facilities that provide care to patients who are less than 18 years of age. This accreditation is separate and distinct from the adult accreditation and is awarded to Comprehensive Centers and Children's Hospitals that meet the MBSAQIP Core Standards (Standards 1–7) as well as those enumerated in this standard.

# 9.1 Co-Surgeon Requirement for **Children's Hospitals**

#### Requirements

The adolescent patient who has surgery within a comprehensive center is addressed within the structure of the standards elsewhere. Standard 9.1 applies only to a Children's Hospital with a pediatric metabolic and bariatric surgeon.

Recognizing that adolescent volume is more difficult to achieve due to a number of unique reasons, volume requirements can be met in the following ways:

- 1. A Children's Hospital performing fewer than 25 stapling procedures annually requires a MBSAQIP-Verified Bariatric Surgeon who has credentials at a MBSAQIP Comprehensive Center as a co-surgeon on each case, unless the MBS Director or other surgeon at the Children's Hospital is also verified at an MBSAQIP Comprehensive Center. MBS verification volume can be fulfilled by the co-surgeon covering the center.
- 2. A Children's Hospital performing equal to or more than 25 stapling procedures annually will be unrestricted and does not require a bariatric co-surgeon.

#### **Documentation**

- The adolescent center identifies the co-surgeon and verifies credentials at a MBSAQIP Comprehensive Center, if a cosurgeon is needed to meet the requirement.
- The adolescent center documents co-surgeon's presence at required cases.
- The adolescent center meets volume requirement for designated level. Volume data will be verified by MBSAQIP and/or by chart review at the site visit.

#### Measure of Compliance

Compliance: The adolescent center fulfills the following criteria:

- Provides the qualified co-surgeon's name and credentials at a MBSAQIP Comprehensive Center, if a co-surgeon is needed to meet the requirement.
- Provides documentation of co-surgeon's presence during the key portions of the case, if a co-surgeon is needed to meet the requirement.
- Meets volume requirement for designated level. Volume data will be verified by MBSAQIP and/or by chart review at the site visit.

# 9.2 Addition to Metabolic and Bariatric Surgery (MBS) Committee

#### Requirements

The metabolic and bariatric center within a children's hospital setting must establish and maintain a MBS Committee that governs all aspects of the center. The MBS Committee must be the same in composition and function as in a comprehensive center (Standard 2.1), with the addition of the Pediatric Medical Advisor.

#### Pediatric Medical Advisor (PMA)

Every adolescent patient requires a pediatrician or equivalent provider who participates in the preoperative and postoperative care of the adolescent patient. In a center located within a children's hospital, a PMA must be an individual with educational training and accreditation in general pediatrics and/or pediatric sub-specialty training (in other words, endocrinology, cardiology, gastroenterology, adolescent medicine) or an internist or family practitioner with specific training and experience in adolescent medicine and must participate in the pediatric MBS Committee.

In an adolescent center located within a comprehensive metabolic and bariatric center, the center must identify an individual to serve as the PMA. This individual must fit one of the following descriptions:

- An individual with educational training and credentialed in general pediatrics and/or pediatric sub-specialty training (in other words, endocrinology, cardiology, gastroenterology, adolescent medicine).
- An internist or family practitioner with specific training and experience in adolescent medicine who agrees to participate on the adult MBS Committee. Note: A pediatric surgeon may not serve as the center's PMA.
- If no specific individual exists in the same center as the adult center providing metabolic and bariatric surgery in adolescents, a specific individual with the aforementioned training qualifications should be identified within the local medical community who is willing and available to serve on the MBS Committee.

Responsibilities of the PMA or pediatric member of the MBS Committee are to provide documented ongoing general pediatric medical oversight in addition to assisting in utilization of adolescent-specific sub-specialty consultation when needed (in other words, sleep medicine, gastroenterology, endocrinology, hematology, nephrology, behavioral health, and so on). In addition, responsibilities include assistance in the development of comorbid-specific treatment plans in conjunction with the patient's primary care provider in order to optimize perioperative health.

#### **Documentation**

- The center identifies an individual who serves as the PMA and meets the above listed qualifications.
- The center provides a copy of the privileges and credentials
- The center provides documentation that the PMA attended the required number of MBS Committee meetings per year.

#### Measure of Compliance

- Provides a copy of the privileges and credentials of the PMA.
- Provides proof that the PMA attended the required number of MBS Committee meetings per year.

Standards Designations **Pathways** 5

# 9.3 Behavioral Specialist

The adolescent patient and family must be able to demonstrate awareness of the general risks and benefits of metabolic and bariatric surgery as well as the dietary and physical activity requirements following a metabolic and bariatric procedure. A psychologist, psychiatrist, or other qualified and independently licensed provider with specific training and credentialing in pediatric and adolescent care must perform this assessment. The practitioner must have experience in treating obesity and eating disorders as well as experience evaluating adolescent patients and families. If no specific individual exists in the adult center providing metabolic and bariatric surgery in adolescents, a specific individual with the aforementioned training should be identified and the work outsourced to that individual for the adolescent patient at the discretion of the local MBS Committee. This step is critical to ensuring that full assent to the surgery can be ascertained. Documentation of the following behavioral assessment elements must be obtained in order to consider an adolescent for metabolic and bariatric surgical intervention:

- Evidence for mature decision-making and awareness of potential risks and benefits of the proposed operation.
- Documentation of the adolescent's ability to provide surgical assent.
- Evidence of appropriate family and social support mechanisms (for example, engaged and supportive family members, care takers, and so on).
- If behavioral disorders are present (for example, depression, anxiety, and so on), they 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 needs.

#### **Documentation**

- The center identifies an individual who serves as the behavioral specialist with pediatric experience.
- The center provides a copy of the privileges and credentials of the behavioral specialist with pediatric experience.

#### Measure of Compliance

- Identifies an individual who serves as the behavioral specialist with pediatric experience.
- Provides a copy of the privileges and credentials of the behavioral specialist with pediatric experience.

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

# **APPENDIX**



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# Appendix A: Overview of Designation Levels and Award Definitions

# **Designation Levels**

Adolescent Center	Ambulatory Surgery Center	Low Acuity Center	Comprehensive Center with Adolescent Qualifications	Comprehensive Center	Data Collection Center	Designation Level
Children's hospital that is recognized for offering all requisite resources to perform complex primary and revisional bariatric stapling procedures on patients at all acuity levels. These centers are designated to care for patients at all levels of obesity, age, and comorbid conditions.	Center is recognized for offering all requisite resources, either on-site or through transfer to an MBSAQIP-Accredited Inpatient Center, to perform primary and revisional bariatric procedures on a minimum volume of low acuity patients (see definition in Standard 1.2). These centers are restricted from performing elective revisional intraabdominal procedures with the exception of emergent cases.	Center is recognized for offering all requisite resources to perform primary and revisional bariatric stapling and band procedures on a minimum volume of low acuty patients (see definition in Standard 1.2). These centers are restricted from performing elective revisional intraabdominal procedures with the exception of emergent cases.	Center is recognized for offering all requisite resources to perform complex primary and revisional bariatric stapling and nonstapling procedures on a high volume of patients at all acuity levels. These centers are designated to care for patients at all levels of obesity, age, and comorbid conditions.	Center is recognized for offering all requisite resources to perform complex primary and revisional bariatric stapling and nonstapling procedures on a high volume of patients at all acuity levels. These centers are designated to care for patients 18 years of age and older at all levels of obesity and comorbid condition.	Center elects to participate in the MBSAQIP Data Registry only and is not recognized as an MBSAQIP-accredited Center	Definition
U.S. and Canada only	U.S. and Canada only	U.S. and Canada only	U.S. and Canada only	U.S and Canada only	Domestic and International Centers are invited to participate provided they employ a dedicated Metabolic and Bariatric Surgical Clinical Reviewer who can meet all requirements	Domestic/International
No facility volume requirement for designation; however, restrictions do apply for centers performing < 25 MBSAQIP approved stapling procedures annually (see Standard 9.1)	A minimum of 25 MBSAQIP-approved cases annually	A minimum of 25 MBSAQIP- approved stapling cases annually	A minimum of 50 MBSAQIP- approved stapling cases annually	A minimum of 50 MBSAQIP- approved stapling cases annually	n/a	Facility Volume
At minimum, one surgeon must have 100 lifetime MBSAQIP-approved stapling cases and 75MBSAQIP-approved stapling cases over the previous 3 years (25 per year)	At minimum, one surgeon must have 100 lifetime cases and 75 cases over the previous 3 years (25 per year)	At minimum, one surgeon must have 100 lifetime MBSAQIP- approved stapling cases and 75 MBSAQIP-approved stapling cases over the previous 3 years (25 per year)	At minimum, one surgeon must have 100 lifetime MBSAQIP-approved stapling cases and 75 MBSAQIP-approved stapling cases over the previous 3 years (25 per year)	At minimum, one surgeon must have 100 lifetime MBSAQIP-approved stapling cases and 75 MBSAQIP-approved stapling cases over the previous 3 years (25 per year)	n/a	Surgeon Volume
1.1, 2-7, and 9	1.1, 1.2, 2-8	1.1, 1.2, 2-7	1.1, 2-7, 9.2, and 9.3	1.1, 2-7	n/a	Required Standards
All patients	Restricted to Low Acuity patients (see Standard 1.2 for definition) 18 years of age and older	Restricted to Low Acuity patients (see Standard 1.2 for definition) 18 years of age and older	All patients	All patients 18 years of age and older	n/a	Patient Selection
100% of metabolic and bariatric procedures performed at the center must be entered	100% of metabolic and bariatric procedures performed at the center must be entered	100% of metabolic and bariatric procedures performed at the center must be entered	100% of metabolic and bariatric procedures performed at the center must be entered	100% of metabolic and bariatric procedures performed at the center must be entered	100% of metabolic and bariatric procedures performed at the center must be entered	Data Registry
Yes, every 3 years	Yes, every 3 years	Yes, every 3 years*	Yes, every 3 years*	Yes, every 3 years*	2	On-site visit Required?

<sup>\*</sup>See pathways on pages 10 and 11 for exceptions to site visit requirements when converting status from another designation level prior to your three-year renewal.

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

#### **Award Definitions**

Award Status	Definition
Fully Approved	Center has demonstrated full compliance with all standards for their designation level at the time of the site visit and has provided requisite documentation to support their compliance. Center adheres to the requirements stated in the Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016 for their designation level at the time of their site visit.
Delayed Pending Approval— Initial Applicants Only	Full approval is pending until the center resolves any noncompliant or partially compliant standards noted during the application process or at the time of the site visit. Center will be notified of deficiencies and be given a deadline to provide data and documentation demonstrating compliance in deficient areas. Timeframe for resolution (i.e., 3, 6, or 12 months) is dependent on deficient area. Prior to resolution of deficiencies and full approval, center will not be recognized as an "accredited center" by the MBSAQIP but must continue to submit clinical data via the MBSAQIP Data Registry.
Probationary	Center is deficient with one or more standards. Center is required to re-submit data and documentation to show full compliance with the requirements stated in the Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016. Centers will be notified of deficiencies and be given a deadline to provide data and documentation demonstrating compliance in deficient areas. Timeframe for resolution (i.e., 3, 6, or 12 months) is dependent on deficient area. Centers that fail to resolve deficiencies within the prescribed timeframe will be denied approval and have to reapply to the program. During the probation period, centers will continue to be recognized as an "accredited center" by the MBSAQIP as long as the center continues to submit clinical data via the MBSAQIP Data Registry.
Denied	Center has failed to meet the required standards specific to the level of designation they are seeking. Center will have to reapply to the program but may choose to participate as a Data Collection Center.

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

# **Appendix B: Accreditation Process Overview**

# MBSAQIP Accreditation Process (For Initial Applicants Only)

Pre-Application	Application	Site Visit	Award
<ul> <li>Review Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016 to determine eligibility and appropriate designation level for your center</li> <li>Submit online Pre- Application (available at facs.org/mbsaqip)</li> <li>Upon approval of Pre- Application, center will be sent login information for the online application portal</li> </ul>	<ul> <li>Log in and complete application via online application portal</li> <li>Center remits annual participation fee and executes contracts prior to application submission</li> <li>Center must meet all Standards criteria at the time of application submission</li> <li>MBS Clinical Reviewer is registered for training</li> </ul>	<ul> <li>Center will be assigned a Surgeon Surveyor and must complete site visit within 6 months of application submission</li> <li>MBS Clinical Reviewer must successfully complete online training modules and begin data entry to MBSAQIP Clinical Data Registry prior to site visit</li> </ul>	<ul> <li>Center will be notified of award decision and receive the Surveyor's Performance Report approximately 8 weeks following the date of the site visit</li> <li>Center's designation is effective retroactive to the date of the site visit and remains designated for a 3-year term</li> <li>Center submits annual compliance attestation at the first and second anniversary of initial accreditation date and submits renewal application at 3 years</li> </ul>

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

# **Appendix C: Accreditation Process Overview**

### MBSAQIP Accreditation Renewal Process (For Renewing Applicants Only)

Application	Site Visit	Award
<ul> <li>Review Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016 to confirm ongoing eligibility and appropriate designation</li> </ul>	<ul> <li>Center is assigned a Surgeon Surveyor prior to renewal application availability and must complete site visit within 30 days of accreditation expiration date</li> </ul>	<ul> <li>Center will be notified of award decision and receive the Surveyor's Performance Report approximately 8 weeks following the date of the site visit</li> </ul>
<ul><li>level for your center</li><li>Renewal application becomes available 6 months prior to renewal date</li></ul>		<ul> <li>If approved, the center is renewed for a new 3-year term from the date of initial accreditation</li> </ul>
• Log in to online application portal to complete and submit renewal application and confirm center's data is current on Center Profile		<ul> <li>Center submits annual compliance attestation at first and second anniversary of initial accreditation date and submits renewal application at 3</li> </ul>
Center executes renewal contracts prior to application submission		years
• Center must meet all Standards criteria at the time of application		

# STANDARDS MANUAL Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient 2016