XTRAwise

a publication for the medical community

Sizewise Special Report

Becoming an ASMBS Bariatric Surgery Center of Excellence:

Hints & Suggestions from the Surgical Review Corporation

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XTRAwise 11.1 Extended Edition provided by SIZEWISE

A Recipe for BSCOE® Site Inspection

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I love to cook for my family and friends. One of my favorite recipes is Pecan Praline French Toast. To ensure excellent results every time, it's important to have the right utensils and fresh ingredients. Experience has helped improve the recipe, and following the same pathway (umm, recipe) each time, ensures excellent outcomes (umm, results). So whether I make French toast just for me or for guests, I prepare it the same way. The presentation for guests may be a little different – a special garnish, decorative tablecloth or some other means to present my dish in a favorable light, but basically, it's the same French toast!

Preparing for a site inspection should be similar to making your favorite recipe. You meet the 10 requirements every day to ensure excellent outcomes. The only real difference during the inspection is that you're demonstrating the specific elements of your excellent program to the site inspector. Getting ready means pulling together the documents needed to present your program — sort of like the garnish for my French toast.

Requirement 1 is about credentialing documents. Your site inspector will want to see the board certification documents and general and bariatric privileges for all of your co-applicant surgeons. She will also ask to see the staff education records related to sensitivity, training in how to recognize the signs and symptoms of complications and prevention of staff and patient injury through training in safe mobility and transfers.

Requirement 2 is all about volumes. The inspector will verify the number of primary bariatric cases performed at your facility. She will also verify the number of bariatric cases performed by each co-applicant surgeon. You will be expected to provide HIPAA compliant lists of this data for the date range specified on your application.

The interdisciplinary team and the bariatric medical director are the focus of Requirement 3. The program must have an officially appointed medical director who is involved in the administrative decisions of the program and a bariatric team that meets regularly and has representatives ranging from the co-applicant surgeons and bariatric coordinator to representatives from administration, the operating room, patient care floors and nutritional services.

Does your program have the means to provide responsive critical care should an emergency arise with a bariatric patient? To meet Requirement 4 you must have an ACLS certified physician 24/7 when a bariatric patient is in the house. Consultants must also be available for anesthesia, critical care, endoscopy and interventional radiology.

Requirement 5 outlines the rules for equipment. Inspectors will tour your facility and the co-applicant surgical practices to ensure that appropriate equipment is available in all patient care areas, operating room, radiology, and emergency room. They will also verify that hemodynamic monitoring equipment and ventilators are available on site should the need arise in an emergency.

Each co-applicant surgeon must document that he/she has qualified call coverage for Requirement 6. Coverage can be provided by a bariatric surgeon or a general surgeon that has assisted on specified numbers of bariatric procedures, depending on the procedures routinely performed by the applicant. All applicants and covering surgeons must be board certified and meet CME requirements as well as be available on-site within 30 minutes.

Clinical pathways are the focus of Requirement 7. These written plans describe the routine care and path that a bariatric patient follows through the entire continuum of care. They are discussed in more detail on page 3.

Requirement 8 dictates the need for a bariatric coordinator who is a licensed health care provider. The coordinator acts as the program's liaison between the hospital and the surgical practice(s). This key program staff member should not only coordinate the program, but also be involved in program development, patient and staff education and participate in oversight of BSCOE compliance.

For Requirement 9 the inspector will verify that the applicant program provides patient support groups supervised by a licensed health care professional. The activities of the support group should be documented including group locations, meeting times, supervisor and curriculum.

Finally, and in many ways most importantly, Requirement 10 addresses outcomes monitoring. All surgeons are required, within 90 days of Provisional Status designation, to begin submitting outcomes data to SRC's Bariatric Outcomes Longitudinal Database™ (BOLD™) (see BOLD Will Answer Complex Questions About Bariatric Surgery on page six). All primary bariatric cases –100 percent– must be entered. The program must also demonstrate that it has a goal and plan in place to follow-up on 75 percent of its patients at five years post bariatric surgery.

Once the site inspection is scheduled, applicants receive a detailed pre-site inspection checklist that is designed to assist with preparation. This checklist is the recipe for a successful inspection. If followed precisely, the prepared documentation, along with your already excellent program, should ensure a successful outcome — just like my French toast!

clin • i • cal path • ways:

WHAT THEY ARE . . . WHAT THEY AREN'T . . . AND WHAT'S ALL THE FUSS?

Judy Crouch, R.N., M.S.N., A.P.R.N., B.C., C.B.N.
Senior Site Inspector
Surgical Review Corporation

Surgical Review Corporation's (SRC) Support Center receives numerous questions each week from bariatric centers across the country about clinical and surgical pathways. Clinical and surgical pathways are extremely important to the ASMBS Bariatric Surgery Centers of Excellence® (BSCOE®) program. To meet Requirement 7, BSCOE applicants must have documented use of clinical pathways and orders that facilitate the standardization of perioperative care. In addition, each surgeon must standardize the operative process and delineate in a surgical pathway each step he or she takes during the operative process.

WHAT IS A CLINICAL PATHWAY?

Clinical pathways are not unique to bariatric surgery. They have been utilized for a number of years as an established method to improve surgical outcomes, especially after complex procedures. A clinical pathway is a written plan describing the routine care of the uncomplicated patient for a specific condition over a given period of time. These plans document the sequence and timing of actions necessary to decrease treatment variation, guide the standardization of care and achieve optimal outcomes and efficiency. Clinical pathways aim to improve, in particular, the continuity and coordination of care across different disciplines and service lines.

In addition, pathways outline a process for the multidisciplinary team to deliver safe and effective health care, provide cost savings, improve quality of care and allow for monitoring and analysis of variances.

Bariatric surgery clinical pathways describe the path that a patient follows through the entire continuum of care, including the preadmission phase (from initial contact with the program to hospital admission), the acute care phase and the long-term post-discharge phase (until at least five years postop). Because bariatric clinical pathways cross this extensive continuum of care, the surgical practice, as well as the hospital, must present clinical pathways of care.

WHAT IS NOT A CLINICAL PATHWAY?

Clinical pathways are NOT standardized orders, policies and procedures, protocols and/or practice guidelines. However, these documents are the basis for the pathways and should be referenced in the pathway along with available evidence. Clinical pathways differ from practice guidelines, protocols and policies because they are utilized by a multidisciplinary team and focus on the quality and coordination of care.

WHAT ARE THE RULES FOR PATHWAY DESIGN & IMPLEMENTATION?

The format of the pathway is not as important as the content. A variety of formats are acceptable, including tables, algorithms, flowcharts, bulleted and numbered lists, narrative, or any

CONT. PAGE FOUR

R7 **REQUIREMENT 7:**

" The applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure. In addition, all bariatric procedures are standardized for each surgeon."

THESE PATHWAYS ARE REQUIRED FOR BARIATRIC SURGERY CENTER OF EXCELLENCE DESIGNATION:

- Anesthesia
- DVT Prophylaxis
- Perioperative care and airway management
- Instruction in the warning signs of complications

Plus 10 of the following 11 pathways must be included as well:

- Patient evaluation
- Initial patient instructions
- Laboratory studies
- Pain management
- Indications for surgery
- Contraindications for surgery
- Admission work up
- Patient Education/Consent
- Imaging studies
- Wound management
- Pre - and postoperative dietary regimen

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combination of these formats.

To meet the requirement for the ASMBS BSCOE designation, clinical and surgical pathways must have been formally adopted and implemented at the time of the site inspection. Failure to provide documentation or other evidence at the site inspection that pathways have been adopted and are being implemented is grounds for denial of the application for Full Approval. The applicant also must present evidence that staff have been educated on the pathways.

WHAT SHOULD I REMEMBER ABOUT PATHWAYS?

- A clinical pathway and surgical pathway must be implemented for each bariatric surgical procedure for every bariatric surgeon
- All required clinical pathways must be present at the site inspection
- Clinical pathways must be approved and implemented
- Staff must be educated regarding the clinical pathways
- Standardized preoperative, postoperative and discharge orders are required
- Pathways are required for the hospital and the surgical practice
- Think "seamless continuum of care" when writing pathways

For further assistance with pathways, please call the SRC Support Center toll-free at 1.866.790.4772.

Interpretive Guidelines Clarify the 10 Requirements for the BSCOE Designation

Julia Hanline
BSCOE Program Coordinator
Surgical Review Corporation

Since the American Society for Metabolic and Bariatric Surgery (ASMBS) Bariatric Surgery Center of Excellence® (BSCOE®) program began, 368 facilities and 634 surgeons have been designated as an ASMBS BSCOE. That's quite an achievement given that the program is the most rigorous in the industry. But as consumer confidence in the surgery grows, so will the need for excellence!

Excellent bariatric surgery requires competent surgeons and well-prepared facilities. Surgical Review Corporation (SRC) is dedicated to assessing and improving the efficacy, efficiency and safety of surgical and related health care. SRC's Bariatric Surgery Review Committee (BSRC) reviews applications and determines whether the 10 Requirements (see page eight)have been met and grants or denies the BSCOE designation. The Committee clarifies the requirements with interpretive guidelines and recommends additional requirements or changes as needed.

To clarify the requirements about which we receive the most questions, SRC offers these guidelines:

Requirement 2 deals with surgical volumes. The BSRC defines "bariatric surgical cases" as primary operations and/or revisions formally recognized by the ASMBS. For a list of these procedures, go to www.surgicalreview.org/pcoe/tertiary/tertiary_provisional.aspx. The BSRC has determined that applicants experiencing a temporary drop in volume may use a "volume averaging" option, which allows them to average surgical volumes for the most recent three years. If that average meets or exceeds the minimum of 125 for facilities or 50 for surgeons, Requirement Two is met.

Another option to help applicants meet the volume requirement is "Fast Tracking." This option is useful for hospital applicants that have a BSCOE surgeon linked to their program. Fast Tracking allows them to submit a Full Approval application once volumes reach roughly half the required volume or 63 within a six-month period. Fast Track applicants must successfully complete a site inspection and meet all other requirements. Full Approval may be granted if circumstances indicate that the 125 minimum number of surgeries is probable by the end of one year.

Requirement 4 focuses on patient care and safety. SRC's BSRC requires that hospital applicants have a full-time staff with experience managing critically ill, morbidly obese patients with ventilators and invasive hemodynamic monitoring technologies that can support the management of a critically ill patient until he or she is sufficiently stable to leave the facility. An ACLS-qualified physician must be immediately available on-site to perform patient resuscitations. Senior residents may provide ACLS coverage if immediately available on site 24-hours per day. Bariatric surgeons, covering surgeons and specialists in anesthesia, interventional radiology, critical care and endoscopy must be available on site within 30 minutes.

Requirement 5 emphasizes the need for improved patient safety, as well as comfort, dignity and respect. Many of the first centers did not have floor-mounted toilets on the bariatric ward and in the practice. The BSRC dictates that furniture and equipment be strong enough and extra wide to accommodate the severely obese. This includes requiring floor-mounted or floor-supported toilets in facilities and practices.

Requirement 6 interpretive guidelines address the surgeon's experience and require that all applicant bariatric surgeons be certified by the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC). In order for the applicant surgeon to demonstrate significant experience in managing bariatric patients and their complications, he or she must have no less than twenty-four (24) hours of Category 1 Continuing Medical Education (CME) in bariatric surgery every three years. In addition, the surgeon must show evidence of bariatric surgical expertise in accordance with the guidelines of the American Society for Metabolic and Bariatric Surgery (ASMBS).

Center of Excellence
BARIATRIC SURGERY

The BSRC defines qualified coverage as the coverage required for the full care of a bariatric patient in the absence of the primary surgeon. The covering bariatric surgeon must be certified (or eligible for certification) by the ABS, AOBS, and/or RCPSC, have significant experience in the care of the type of bariatric surgical patients he or she is covering and be capable of managing the full range of complications associated with surgery of the morbidly obese. Within ten (10) years of the application date, covering bariatric surgeons must have assisted on at least five (5) non-stapling gastric procedures if covering for non-stapling gastric procedures, and/or ten (10) gastric stapling and/or anastomotic procedures if covering for stapling procedures. A surgeon covering a gastric sleeve patient must have assisted on at least five (5) gastric sleeve cases, or have performed or assisted on ten (10) gastric bypass or duodenal switch cases within the past ten (10) years. A surgeon covering gastric bypass cases must have performed or assisted on at least ten (10) gastric bypass cases within the past ten (10) years. In order for the covering general surgeon to demonstrate significant experience in managing bariatric patients and their complications, he or she must have at least twelve (12) hours of Category 1 Continuing Medical Education (CME) in bariatric surgery every three years, and have assisted on at least five (5) non-stapling gastric procedures and/or ten (10) gastric stapling and/or anastomotic procedures, depending on the covering arrangement, within the previous three years. These requirements apply only to general surgeons who cover bariatric cases and do not apply to coverage by a bariatric surgeon. In addition, the covering call surgeon must be available on-site within thirty (30) minutes of request.

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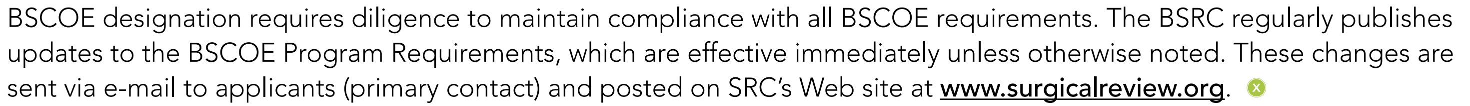
R8 Requirement 8 guidelines clarify the responsibilities of the Bariatric Coordinator as both clinical and administrative. The coordinator must be a licensed health care professional whose duties include care coordination and development of the bariatric surgery program, patient and staff education, oversight of ongoing BSCOE compliance and ongoing multidisciplinary team meetings for the bariatric surgery program. The coordinator is a liaison between the hospital and surgical practice(s); may be employed by either the hospital or surgeon; and may share the duties with another bariatric coordinator. The program must have a full time bariatric coordinator when the volume reaches 150 or greater in a 12-month period.

R9 Requirement 9 clarifications ensure that support groups are led by qualified professionals. The BSRC determined that a licensed health care professional must facilitate the programs support groups.

BSCOE designation requires diligence to maintain compliance with all BSCOE requirements. The BSRC regularly publishes updates to the BSCOE Program Requirements, which are effective immediately unless otherwise noted. These changes are sent via e-mail to applicants (primary contact) and posted on SRC's Web site at www.surgicalreview.org.



BOLD™ WILL ANSWER COMPLEX QUESTIONS about bariatric surgery

Catherine Wild, Manager
SRC Support Services

In 2003, the American Society for Metabolic and Bariatric Surgery (ASMBS) founded Surgical Review Corporation (SRC) and the Bariatric Surgery Centers of Excellence® (BSCOE) program to answer questions about the meaning of excellence in bariatric surgery. Operating as a completely independent organization governed by industry stakeholders, SRC administers the rigorous evaluation process that distinguishes whether a bariatric surgery center meets the 10 requirements (page eight) for the BSCOE designation.

The creation of the ASMBS BSCOE program has done much to change negative perceptions of bariatric surgery and help improve coverage by health insurers. However, SRC's mission doesn't stop there. There has long been a need to collect outcomes data for bariatric surgery, and we have taken the next logical step to demonstrate what we know already that bariatric surgery is safe and provides durable weight-loss with full, long-term remission of diabetes and other comorbidities of severe obesity and to answer the more complex questions such as:

- How do we distinguish patient risk factors?
- How does surgery type impact resolution of diabetes and other comorbidities?
- What is the return on investment for payors that cover bariatric surgery?
- Should BSCOE requirements for excellence change in the future?

SRC expects our Bariatric Outcomes Longitudinal Database™ (BOLD™) to provide the central source to answer these questions. BOLD is an innovative Web-based patient database developed by SRC using data elements and data definitions common with the National Institutes of Health Longitudinal Assessment of Bariatric Surgery (LABS) program and other national databases.

BOLD captures detailed information on each patient such as comorbidities, surgical procedure type, adverse events, weight loss progress and outcomes. BOLD serves three major purposes:

1. To offer Centers a real-time tool to monitor their compliance with the BSCOE requirements.

All BSCOE program data must be entered into BOLD to monitor the program's compliance with their signed BSCOE agreement and with the BSCOE program requirements. Each program can retrieve and organize this data in BOLD's reports functionality for use in Full Approval applications, Renewal applications or progress reports.

2. To provide SRC with credible data that can be used to demonstrate the value and efficacy of bariatric surgery to consumers, employers, medical professionals and payors.

There are now more than 100,000 patients entered into the database. Only patients who sign an approved Institutional Review Board (IRB) informed consent form will have their data de-identified (first and last name removed and DOB converted to age) and shared with the research reporting database to join the dataset for aggregate data analysis. Program coordinators can help increase the size of the research dataset by presenting patients with the research consent form in a positive manner and

explain the relative lack of risk to them personally and the enormous benefits to future patients.

3 To collect the information needed to improve patient outcomes.

BOLD is a unique platform for evidence-based medicine, tracking complications and improvement or resolution of comorbidities in an effort to develop risk stratification guidelines that will promote improved patient care and outcomes. Each program is able to analyze their own data to set internal benchmarks and identify areas for improvement. In much the same way, the aggregate data will help the bariatric community recognize trends, predict outcomes, develop global benchmarks, guide surgeons in choosing the right operation for patients, improve the patient experience and establish criteria for best practices.

There are many expectations of BOLD and SRC believes that it will provide the answers to many important and complex questions. However, without consistent and accurate data entry, BOLD has little value. It is incumbent upon all BSCOE participants to make BOLD a success. The rewards will benefit the whole bariatric community, and more importantly, the patients whose lives are forever changed through bariatric surgery.

INTERFACE WITH THIRD-PARTY SOFTWARE

To accommodate Centers with existing patient databases, SRC has developed an interface designed to import data from interested third-party software systems. This minimizes or eliminates duplicate data entry. For details about third-party vendors currently interfaced with BOLD, go to http://www.surgicalreview.org/paperless.aspx

For BOLD support or information contact the SRC Support Center at: 1.866.790.4772 or srcsupport@surgicalreview.org

BOLD™ Training Opportunities

SRC provides two one-hour online training sessions each week to help you understand how to use BOLD.
The Webinars cover:

- the initial administrative setup of the database,
- how to use the Patient Encounter forms to facilitate fast and accurate data entry,
- virtual demo of entering patient data from first preoperative visit through surgery to first postoperative visit, and
- description of the reports.

To register for the BOLD Training Webinar, go to surgicalreview.org/support.aspx

Requirements for American Society for Metabolic and Bariatric Surgery (ASMBS) Bariatric Surgery Centers of Excellence® (BSCOE) Designation

Centers and surgeons applying for the Bariatric Surgery Center of Excellence® designation must meet these 10 requirements for Provisional Status:

1. a. An institutional commitment at the highest levels of the applicant medical staff and the institution's administration to excellence in the care of bariatric surgical patients as documented with an ongoing, regularly scheduled, in-service education program in bariatric surgery.

b. An institutional commitment that is also demonstrated by employing credentialing guidelines for bariatric surgery.

Interpretative Notes for Requirement 1:

This requirement refers to a culture in which the staff is prepared to manage morbidly obese patients and manage these individuals with understanding and compassion and appreciate the burdens of the comorbidities of the disease. The staff should be aware of the basic concepts of bariatric surgery through in-service programs. Those directly caring for these patients should be able to recognize the early signs of the common complications including pulmonary embolus, anastomotic leak, infection and bowel obstruction so that these can be managed promptly. Sensitivity training is included as an aspect of in-service training. Applicants are required to provide written acknowledgement during the site inspection for Full Approval that sensitivity training is provided to relevant staff at least once every three years. In addition, all Centers (applicants and existing BSCOEs) must provide sensitivity training upon hiring to all new employees who will have contact with bariatric patients. All Centers (applicants and existing BSCOEs) must provide patient mobility and transfer training upon hiring to all new employees who care for bariatric patients. New applicants to the BSCOE program are required to train all bariatric personnel in the patient care areas in the potential signs and symptoms of complications in the bariatric patient. All Centers (applicants and existing BSCOEs) are required to provide all new employees upon hiring with training in the potential signs and symptoms of complications. All Centers (applicants and existing BSCOEs) are required to have a system in place to ensure the ongoing competencies of staff in recognizing the potential signs and symptoms of complications in the bariatric patient.

2. a. The reasonable expectation that the applicant institution will perform at least 125 bariatric surgical cases per year.

b. The reasonable expectation that each applicant surgeon will have performed at least 125 total bariatric cases lifetime, with at least 50 cases performed in the preceding 12-month period.

Interpretative Notes for Requirement 2:

"Bariatric surgical cases" are defined as primary operations and/or revisions.

"Performed" is defined as conducting a significant part of the operation as primary surgeon. Applicants may not include cases in which they served as the assisting surgeon.

Applicants may include up to 75 operations performed during their fellowship in the total lifetime count.

NOTE: Provisional Status applicants that have performed at least 50 percent of the required minimum number of surgeries at the time of Provisional Status application will be approved, since there is a reasonable expectation that they will be able to achieve the minimum number during the two-year Provisional Status term prior to applying for Full Approval. Applicants for Full Approval must be able to demonstrate that they have actually performed the minimum number of required surgeries.

Qualifying procedures: Only bariatric surgical procedures formally recognized by the ASMBS are counted in determining whether an applicant meets the applicable volume requirements. This standard applies to both surgeon and hospital applicants. The following procedures, whether performed open or laparoscopic, are recognized as of March 2009:

- Vertical Banded Gastroplasty
- Gastric Banding
- Duodenal Switch
- Biliopancreatic Diversion
- Sleeve Gastrectomy
- Gastric Bypass (short or long limbed, transected or not transected, banded or not banded)

Within the context of the surgical procedures recognized by ASMBS, the repair of a slipped gastric band is a bariatric procedure which is counted toward the volume requirements.

In addition, repairs of jejuno-jejunostomy, colonic mesentery, Peterson hernias and hernias forming around an adhesion

are bariatric procedures that are counted toward the volume requirements when performed on a post-bariatric surgery patient.

Port revisions, tubing repairs, gastric band removals and repairs of inguinal, incisional, umbilical and port site hernias are not primary bariatric procedures and are not counted toward the volume requirements.

Abdominal wall hernias and exploratory procedures used to make a diagnosis that do not result in the repair of an internal hernia do not count toward the volume requirements.

3. The applicant maintains a designated physician Medical Director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution.

Interpretative Notes for Requirement 3:

The position of Bariatric Surgery Medical Director shall be filled by a qualified bariatric surgeon who is appointed through the administrative/medical staff process with hospital minutes documenting his or her participation in the bariatric program decisions. Regularly scheduled meetings to address the bariatric program in the institution which involve medical staff, nursing, administration and operating room personnel are required. Attendance of an applicant hospital's central supply and business departments at bariatric program staff meetings is optional.

4. The applicant hospital maintains, within 30 minutes of request, a full complement on staff of the various consultative services required for the care of bariatric surgical patients, including the immediate availability of an ACLS-qualified physician on-site who can perform patient resuscitations.

Interpretative Notes for Requirement 4:

The facility must have a full-time staff with experience managing critically ill, morbidly obese patients with ventilators and invasive hemodynamic monitoring technologies that can support the management of a critically ill patient until he or she is sufficiently stable to leave the facility.

For Provisional Status, the failure to have an ACLS-qualified physician on site who can perform patient resuscitations does not automatically disqualify the applicant, because the requirement can be met during the period of Provisional Status. However, this requirement is considered critical, so the failure to have an ACLS-qualified physician on site may warrant Monitoring Status until such time as the requirement is met.

The failure to have an ACLS-qualified physician on-site is grounds for denial of the application for Full Approval. ACLS coverage may be provided by a Senior Resident who is immediately available on site 24-hours per day. The failure to have available within 30 minutes of request all of the following consultative staff (i.e., all of these consultants must be available on-site within 30 minutes) is grounds for denial of the application for Full Approval:

- anesthesiologist/CRNA,
- internist with critical care expertise,
- endoscopist, and
- radiologist with interventional capability.

Failure to have all of these staff does not automatically disqualify the applicant for Provisional Status, but may warrant Monitoring Status until such time as the requirements are met.

Use of an off-site electronic ICU monitoring system (i.e., live video feed and vital sign monitoring at a remote location) without having an intensivist or other recognized consultative staff member either on-site or immediately available does not satisfy Requirement 4.

5. The applicant maintains a full line of equipment and instruments for the care of bariatric surgical patients including furniture, wheelchairs, operating room tables, floor-mounted or floor-supported toilets, beds, radiologic capabilities, surgical instruments and other facilities suitable for morbidly obese patients.

Interpretative Notes for Requirement 5:

Furniture, floor mounted or floor supported toilets, beds, scales, wheel chairs, operating room tables and litters, strong enough and extra wide to accommodate the severely obese according to the weight limits established by the institution, must be available for those patients who need this specialized equipment. Toilets not directly mounted to the floor must be floor supported. Patient movement/transfer systems for morbidly obese patients must be in place throughout the institution wherever the morbidly obese receive care. Ambulances serving the institution should also be equipped to manage these large patients with appropriate stretchers, straps, and transfer devices. Finally, and perhaps most important, the staff must be trained to use the equipment and be capable of moving these large individuals without injury either to the patients or the staff.

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6. The applicant has a bariatric surgeon who spends a significant portion of his or her efforts in the field of bariatric surgery and who has qualified coverage and support for patient care.

Interpretative Notes for Requirement 6:

The applicant surgeon must be certified by the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC). In order for the applicant surgeon to demonstrate significant experience in managing bariatric patients and their complications, he or she must have no less than twenty-four (24) hours of Category 1 Continuing Medical Education (CME) in bariatric surgery every three years. In addition, the surgeon must show evidence of bariatric surgical expertise in accordance with the guidelines of the American Society for Metabolic and Bariatric Surgery (ASMBS).

Qualified coverage is defined as the coverage required for the full care of a bariatric patient in the absence of the primary surgeon. The covering bariatric surgeon must be certified (or eligible for certification) by the ABS, AOBS, and/or RCPSC, have significant experience in the care of the type of bariatric surgical patients he or she is covering and be capable of managing the full range of complications associated with surgery of the morbidly obese. Within ten (10) years of the application date, covering bariatric surgeons must have assisted on at least five (5) non-stapling gastric procedures if covering for non-stapling gastric procedures, and/or ten (10) gastric stapling and/or anastomotic procedures if covering for stapling procedures. A surgeon covering a gastric sleeve patient must have assisted on at least five (5) gastric sleeve cases, or have performed or assisted on ten (10) gastric bypass or duodenal switch cases within the past ten (10) years. A surgeon covering gastric bypass cases must have performed or assisted on at least ten (10) gastric bypass cases within the past ten (10) years.

In order for the covering general surgeon to demonstrate significant experience in managing bariatric patients and their complications, he or she must have at least twelve (12) hours of Category 1 Continuing Medical Education (CME) in bariatric surgery every three years, and have assisted on at least five (5) non-stapling gastric procedures and/or ten (10) gastric stapling and/or anastomotic procedures, depending on the covering arrangement, within the previous three years. These requirements apply only to general surgeons who cover bariatric cases and do not apply to coverage by a bariatric surgeon.

In addition, the covering call surgeon must be available on-site within thirty (30) minutes of request.

Note: The applicant and covering surgeon must meet all of the requirements noted above, as well as board certification, in order to obtain Full Approval, but do not need to have met all requirements at the time of the application for Provisional Status. An applicant or covering surgeon may be board eligible and receive Provisional Status designation, but must be board certified in order to obtain Full Approval.

7. The applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure. In addition, all bariatric surgical procedures are standardized for each surgeon.

Interpretative Notes for Requirement 7:

It is the surgeon's responsibility and duty to select which primary operation(s) he or she will perform, and it is the expectation of SRC that the procedure(s), no matter what the choice, will be done in a standardized manner. Similarly, the surgeon should determine the details of the planned perioperative care. These details will be documented so that each member of the surgeon's team is aware of the care plan and is prepared to follow the process as outlined by the surgeon. Unless such a process is followed, outcomes cannot be evaluated.

The following specific clinical pathways are required for Full Approval (i.e., the pathways must have been formally adopted and implemented at the time of the site inspection):

- Anesthesia including monitoring and airway management.
- Perioperative care including monitoring and airway management.
- DVT management.
- Instructions for the management of warning signs of complications such as tachycardia, fever, and hemorrhage.

In addition, at least 10 of the following additional clinical pathways must have been formally adopted and implemented at the time of the site inspection:

- Indications
- Contraindications
- Initial patient instruction
- Patient evaluation
- Laboratory studies
- Imaging studies
- Patient education/consent
- Admission workup and evaluation
- Wound care management

- Preoperative and postoperative dietary regimen
- Pain management

Nurses, physician assistants, residents, applicant surgeons and other applicable staff must be aware of these protocols and follow them.

The clinical pathway protocols, i.e., a sequence of orders and therapies describing the routine care of the uncomplicated patient, must be available for review during the site inspection for Full Approval.

8. The applicant utilizes designated nurse or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients.

Interpretative Notes for Requirement 8:

The hospital should have a subset of nurses who routinely care for the bariatric patients and receive regular in-service education on their care, preferably assigned to a designated bariatric floor or wing. There should be a Bariatric Coordinator designated to supervise the bariatric program.

Effective December 1, 2007, an applicant's bariatric surgical coordinator must meet the following criteria: The coordinator must be a licensed health care professional, whose duties include care coordination of the bariatric surgery program, bariatric surgery program development, patient and staff education, oversight of ongoing BSCOE compliance, oversight of ongoing multidisciplinary team meetings for the bariatric surgery program, and acting as a liaison between the hospital and surgical practice(s). The coordinator may be employed by either the hospital or surgeon, and the duties do not necessarily have to be performed by one person.

Applicant centers performing more than 150 bariatric surgeries annually are required to have a full-time bariatric coordinator. Centers performing 150 surgeries or less per year may employ a part-time bariatric coordinator. This provision is effective June 1, 2007, for renewing BSCOE centers and for new applicants whose site inspections occur on or after that date.

The physician's practice should also have nursing and physician extenders who provide continuing education and care to the bariatric patients in the practice. This should be outlined in the practice portfolio if it is a split practice that still performs significant general surgery. A physician extender is defined as any health care provider who assists a bariatric surgeon or practice.

Limited Waiver for Coordinator. Centers that were designated as BSCOEs prior to December 1, 2007, whose bariatric coordinators are not licensed health care professionals, may be considered for approval on renewal of their initial BSCOE term provided the coordinator meets one of the following:

- The bariatric coordinator has been continuously employed by the applicant as a bariatric coordinator performing the required duties for at least three (3) years prior to the application; or
- The bariatric coordinator has been continuously employed as a bariatric coordinator in a bariatric surgery practice or institution performing the required duties for at least five (5) years prior to the application; or
- The bariatric coordinator has a bachelor's degree from an accredited institution and at least three (3) years of clinical work experience in the field of bariatric surgery.
- Centers designated as BSCOEs prior to December 1, 2007, may only rely on the preceding exception for renewal of their initial term.

9. The applicant makes available organized and supervised support groups for all patients who have undergone bariatric surgery at the institution.

Interpretative Notes for Requirement Number 9:

The activities of the support group should be documented including group locations, meeting times, supervisor, curriculum, and attendance. For example, such activities as on-line chat rooms, Web-based support groups, exercise, instruction and clothing sales should be noted. A licensed health care professional must either lead or be present at support group meetings. A qualifying licensed health care professional includes a surgeon, physician, physician's assistant, nurse, dietician, nutritionist, psychologist, psychiatrist, licensed practical nurse, physical therapist or licensed clinical social worker. Applicant centers must hold support group meetings on at least a quarterly basis. This requirement applies to the program's primary support group meetings, but not to auxiliary or outlying meetings held in remote locations.

10. The applicant provides documentation of a program dedicated to a goal of long-term patient follow-up of at least 75 percent for bariatric procedures at five years with a monitoring and tracking system for outcomes, and agreement to provide annual outcome summaries to SRC in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.

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Interpretative Notes for Requirement 10:

This requirement is based on the observation that a significant number of patients develop nutritional deficiencies, internal and external hernias, return of previous emotional disorders as well as other late complications. There is no requirement that the surgeon provide the follow-up personally, only that he or she is aware of the long-term status of the patient. Accordingly, the follow-up data can be gathered during group sessions, reunions, or through visits at other physicians' offices. The applicant agrees to enter all patients who undergo bariatric surgery in the group or individual practice into the Bariatric Outcomes Longitudinal Database™ (BOLD™); no patients will be excluded.

Outsourcing patient follow-up to third parties is acceptable provided that the outsourcing agent can be site inspected and the surgeon and/or hospital maintains adequate communications with the outsourcing agent to track patient outcomes on an ongoing basis. Follow-up performed by the patient's primary care physician is also acceptable provided the surgeon or hospital maintains adequate communications with the primary care physician to track outcomes.

Prior to applying for Full Approval status, the Center must first have been granted Provisional Status. The Full Approval application process to become an ASMBS Bariatric Surgery Center of Excellence involves the following steps:

1. **The center and its surgeons continue to meet the criteria required for Provisional Status and fully comply with the 10 requirements for Provisional Status.**
2. **Any deficiencies noted during the Provisional Status review have been corrected.**
3. **A complete and accurate description of changes in the institution or the staff (since the Provisional Status application) has been submitted to the BSRC.**
4. **A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.**
5. **The surgeon must be, or must have been, board certified by either the American Board of Surgery (ABS), the American Osteopathic Board of Surgery (AOBS), and/or the Royal College of Physicians and Surgeons of Canada (RCPSC).**
6. **Outcomes data for bariatric surgery are reported in accordance with HIPAA regulations. Outcomes data must be reported for all bariatric surgery patients in the Bariatric Outcomes Longitudinal Database (BOLD).**

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Surgical Review Corporation (SRC) is an independent, non-profit organization dedicated to assessing and improving the efficacy, efficiency and safety of surgical and related health care worldwide. SRC administers the domestic Bariatric Surgery Center of Excellence® (BSCOE®) program on behalf of the American Society for Metabolic and Bariatric Surgery (ASMBS). This program is endorsed by the Centers for Medicare and Medicaid Services (CMS) and most major health insurers. SRC has certified nearly 640 surgeons as well as more than 360 hospitals and freestanding clinics in the United States alone. SRC also developed the Bariatric Outcomes Longitudinal Database™ (BOLD™) to accelerate development of clinical pathways and research for obese and diabetic patient populations.
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