

September 8, 2005

**CRITERIA AND STANDARDS FOR
BARIATRIC SURGERY**

- 1. REASON FOR ISSUE:** This VHA Directive establishes procedures for the Department of Veterans Affairs (VA) Veterans Health Administration (VHA) Bariatric Surgery.
- 2. MAJOR CHANGES:** This is a new Handbook establishing procedures for Bariatric Surgery in VHA.
- 3. RELATED ISSUES:** VHA Directive 1102 (to be published).
- 4. RESPONSIBLE OFFICE:** The Chief Consultant, Medical-Surgical Services (111) is responsible for the contents of this VHA Handbook. Questions may be referred to the National Director of Surgery (111B) 202-273-8505.
- 5. RECISSIONS:** None.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of September 2010.

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CRITERIA AND STANDARDS FOR BARIATRIC SURGERY

1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes procedures to access bariatric surgery and funding policies in the Department of Veterans Affairs (VA) medical centers and outpatient clinics.

2. BACKGROUND

a. Bariatric surgery is surgery intended to produce weight loss in individuals who are excessively obese.

b. Bariatric surgery in VA must be performed as a national referral system. VA has offered bariatric services at several medical centers for the past few years. As of July 2004, more than 800 bariatric operations have been performed at VA medical centers. Recently, the centers that have demonstrated expertise with these operations were organized into a coordinated network that would be able to accommodate eligible veterans. **NOTE:** *For the most recent VA bariatric surgery sites and contact person(s), refer to www1.va.gov/SURGERY and click on bariatric surgery sites.*

3. SCOPE

a. Since it is VHA policy to provide bariatric surgery for eligible veterans, the request for weight loss surgery must originate from the veteran's preferred VA medical center where the patient is enrolled.

b. Eligible veterans meeting pre-operative criteria are considered for surgical intervention.

NOTE: *The Chief, Health Administration Service (HAS), or equivalent, completes the appropriate section of the referral information sheet (see App. A).*

4. FACILITY EVALUATION

The foremost consideration in caring for the bariatric patient is safety for both the patient and the facility staff. Readiness of the facility's physical plant and equipment to care for bariatric patients must be evaluated. This includes developing a plan to provide physical renovations, equipment and supplies intended for these patients to include:

a. **Physical Plant Evaluation.** The physical plant evaluation includes:

(1) Consideration of special bariatric suites;

(2) Identifying physical space limitations of all treatment areas including inpatient areas, operating room (OR) suite, cardiac catheterization laboratory, radiology, etc.; and

(3) Width of passageways and doorways.

(4) A formal psychological evaluation showing the patient is mentally and emotionally stable and is able to:

(a) Control eating-related impulses;

(b) Comply with a restricted diet post-surgery; and

(c) Maintain the frequent and long-term follow-up necessary after these procedures.

b. **Equipment and Supplies.** The equipment and supplies evaluation includes:

(1) Examining weight limit of equipment including beds, chairs, exam tables, commodes, etc.;

(2) Ensuring there are adequate patient lift and/or transfer devices in all patient care areas; and

(3) Ensuring there are adequate-sized gowns, exam supplies, emergency equipment, wound supplies, etc.

c. **Staff Training.** This includes an evaluation of safety training and sensitivity training.

5. PRE-OPERATIVE CRITERIA

a. **Patient Selection – Pre-Bariatric Surgery Treatment and Assessment.** Prior to consideration for bariatric surgery, the Chief of Staff (COS) must ensure the following indications or conditions have been met:

(1) Patients with a body mass index (BMI) of more than (>) 40 may be considered for bariatric surgery. Those with BMI > 35 and less than (<) 40 with significant co-morbid medical conditions offering the potential of improvement by surgically-induced weight loss (e.g., diabetes, hypertension not well controlled by medical therapy, severe sleep apnea, osteoarthritis causing lower extremity pain limiting ambulation, and documented gastroesophageal reflux disease) are also to be considered.

(2) Patients must have demonstrated prior attempts at weight loss and compliance with prior treatment regimens. They must have followed the Managing Overweight/Obesity for Veterans Everywhere (MOVE!) for a period of not less than 3 months (see <http://vaww.nchdpd.med.va.gov/>). Patients must demonstrate compliance with weight loss measures as a predictor of post-operative success. For VA medical facilities that have not yet implemented the MOVE! weight and physical activity program, there must be proof of enrollment for a similar period of time in a similar multi-disciplinary weight management and/or physical activity program with structure comparable to MOVE!.

(3) Patients need to undergo an adequate weight loss as defined by the VA Bariatric Surgery Work Group (VABSWG) prior to surgery not only to improve the chances for successful surgical outcomes, but also to demonstrate the ability to cope with a restrictive lifestyle engendered by the procedure.

NOTE: Selection factors are subject to immediate change based on the most current evidence-based findings.

b. **Guidelines for Contraindications for Bariatric Surgery.** The following are not considered to be candidates for bariatric surgery:

(1) Current tobacco smokers; patients must abstain from smoking for at least 6 weeks prior to surgery.

(2) Patients with oxygen dependent chronic obstructive pulmonary disorder (COPD).

(3) Patients with active hepatitis B or cirrhosis.

(4) Patients with congestive heart failure or pulmonary hypertension unresponsive to treatment.

(5) Patients having had multiple abdominal operations, complicated incisional hernias, or infection resulting in a multiple, diffuse, or severe intra-abdominal infection.

(6) Patients with major psychoses and/or any non-compliance with prescribed treatment regimens.

(7) Patients who were active substance abusers within a period of 1-year prior to the referral.

NOTE: Patients with active hepatitis C receive consideration on an individual basis.

6. REFERRAL AND/OR ASSESSMENT PROCESS

a. **Administrative Considerations.** The following must be certified by the Chief, HAS, or equivalent, prior to initiating the referral of a veteran to any other VA medical center or non-VA facility for bariatric surgery.

(1) The veteran's eligibility to receive VA health care benefits and the associated priority group status must be verified and documented on VA Form 10-0245, Bariatric Surgery Information Package, Part III, Eligibility.

(2) Beneficiary travel eligibility, in accordance with Title 38 United States Code Section 111 and Title 38 Code of Federal Regulations Sections 17.143 through 17.145, must be verified and documented on VA Form 10-0245, Bariatric Surgery Information Package, Part III, Eligibility.

NOTE: Eligibility to receive beneficiary travel assistance is not a condition of eligibility for medical care, and therefore, would not preclude a veteran who is otherwise eligible to receive VA health care benefits from being referred for bariatric surgery. Beneficiary travel eligibility

only determines whether VA will or will not provide travel assistance.

b. Standard Referral Process

(1) The referral originates from a VA physician at a facility with the ability to provide ongoing care for the patient. The referring facility must have the ability, resources, and structured multi-disciplinary program to provide long-term, post-operative care and follow-up for patients undergoing this procedure. These criteria are defined by the VABSWG. The facility must be capable of following the patient for several years post-surgery including pre- and post-operative nursing, dietary and psychological assessments, and assessment of level of care requested on return to the facility.

(2) The VA staff physician making the referral is responsible for ensuring that complete, accurate and current information is included in the referral packet. Required documentation includes:

(a) All reports and laboratory data specific to the procedure;

(b) Current clinical information relevant to decision-making;

(c) A concise referral letter from the requesting VA staff physician citing the anticipated benefit to the patient and plan for post-operative follow-up;

(d) A psychological-sociological evaluation by a professional provider, i.e., a psychiatric or mental health social worker, or advanced practice nurse; or psychiatrist or psychologist as indicated by the VA BSWG. **NOTE:** See <http://vaww.nchdp.med.va.gov/> then click on "VA Bariatric Surgery Resource Center."

(e) A completed VA Form 10-0425, Bariatric Referral Information Package (see App. A). **NOTE:** *The complete medical record is not required.*

(3) The VA staff physician making the referral and the COS, or clinical equivalent, must sign the Referral Information Package and include their telephone and fax number.

(4) Pending development of an electronic format, the Referral Information Package must be typed or printed legibly. A referral packet and disc, the original and one copy, must be mailed via express mail or faxed to a regional referral center. This information is to be entered into the Computerized Patient Record System (CPRS).

(5) When a specific VA Bariatric Surgery Center (VABSC) is requested, it needs to be indicated on the first page of VA Form 10-0425, under "Referring Physician's Notes." **NOTE:** *Every effort needs to be made to accommodate this request.*

NOTE: *A list of approved VABSCs can be found at the following web site:*
<http://www1.va.gov/SURGERY>.

c. **Screening Visit.** Upon receipt of VA Form 10-0425, the VABSC schedules a visit for the patient to the selected VABSC site to:

- (1) Conduct a physical assessment evaluation,
- (2) Review all patient information,
- (3) Complete additional required information as indicated,
- (4) Provide an opportunity for questions and answers, and
- (5) Conduct mental health assessment as needed.

d. **Patient Screening via Telehealth, Teleconferencing, and the Referral Process.** VHA sites with appropriate video teleconferencing (Vtech) equipment and linkages may choose to augment the standard referral process described subparagraph 6a, by conducting a two-part patient screening process facilitated through the use of Vtech and the following sequential telehealth screening processes:

(1) **Initial Screening.** Initial screening is accomplished through a CPRS-based “store and forward” template suitable for organizing clinical information critical for referral decisions.

(2) **Secondary Screening.** Secondary screening (i.e., after the initial screening, but prior to actual travel to the VHA surgical site) is accomplished through live real-time video teleconferencing. Such telehealth visits are restricted to patients meeting initial eligibility criteria (see subpar. 6c(1)). *NOTE: Patients may need to travel to the nearest VA medical center video teleconferencing facility if one is not available locally. All such teleconferences must be scheduled in advance.*

e. **Decision Visit.** At the decision visit (at the VABSC), the physician or Registered Nurse (RN) initiates the multi-disciplinary plan of care.

f. **Education Visit.** At the education visit, the RN initiates nursing, hospital, and community resource consultations as needed.

g. **Emergency Referrals**

(1) An emergency is defined as a referral of a patient with complications from a bariatric operation that requires urgent intervention.

(2) In cases where an emergent referral is required and the patient is not stable enough for transfer to a VABSC, the referring facility may send the patient to a local bariatric surgery center. However, if the patient stabilizes and can be transported, or is discharged from the hospital (either VA medical center or local bariatric surgery center), the regional bariatric center needs to be notified and a reassignment made to a VABSC.

(3) In cases when an emergency referral is required, the regional bariatric center must be notified as soon as the determination is made.

NOTE: Required information must be provided. Incomplete referral information packets will result in a delay in getting the referral to the appropriate VABSC while the missing information is sought from the requesting facility. If there are any questions, or if this is the first time the physician is making a referral, contact the COS's office, or the regional bariatric referral center prior to submitting the referral information packet.

7. RIGHT TO APPEAL AND SECOND OPINIONS

If a patient is rejected by a regional bariatric center, the patient has the right to a second review by another regional bariatric center. If the second center also rejects the patient, the present VHA clinical appeal process may be followed. In Fiscal Year (FY) 2000, VHA instituted an external appeal system, which allows Networks to request prompt, impartial reviews of clinical determination decisions by a professional board external to the agency. In this case, members of the BSWG serve as the independent external reviewers.

8. DISCHARGES AND FOLLOW-UP

a. Discharge Planning

(1) The regional bariatric center is responsible for providing medications for 30 days, when the bariatric surgery patient is discharged back to the referring facility, using the VA National Formulary. After the initial 30 days, the referring facility is responsible for all ongoing medications.

(2) The appropriately trained experts from the following services are to be consulted, as needed, to assist with discharge planning:

- (a) Surgery;
- (b) Nursing (including wound care);
- (c) Psychology;
- (d) Occupational Therapy (OT), Physical Therapy (PT), and/or Recreation Therapy (RT);
- (e) Respiratory;
- (f) Social Service; and
- (g) Dietetic.

b. Patient Follow-up. The VABSC contacts the referring facility's bariatric surgery coordinator for discharge planning and ensuring appropriate and timely patient follow-up.

9. BARIATRIC SURGERY SPECIFIC COMPLICATIONS

- a. Patients with complications from procedures are referred back to the VABSC where the operation was performed, when appropriate.
- b. All complications occurring as a result of this surgery must be recorded appropriately on a risk-adjusted basis to the National Surgical Quality Improvement Program (NSQIP) Coordinator by the regional center coordinator.

10. BARIATRIC SURGERY PROGRAMMATIC SUPPORT STRUCTURE - REFERRING FACILITY

- a. Each referring facility must show that there is a multi-disciplinary weight management and/or physical activity program in place to adequately address the bariatric surgery patient's pre-operative and long-term post-operative medical, nutritional, fitness, and psychological requirements.
- b. Criteria for the structure of this multi-disciplinary weight management program are reflected in the VA National Center for Health Promotion and Disease Prevention (NCP) MOVE! Program, developed in conjunction with the VA BSWG (see <http://vaww.nchpdp.med.va.gov/>).
- c. Evaluations of the adequacy of a facility's weight management program must be in writing or through periodic site visits. *NOTE: Failure to have a structured program as described may result in suspension of referrals from that facility.*

11. FUNDING

The funding follows the patient through the Veterans Equitable Resource Allocation (VERA) methodology via pro-rated person computations.

12. TEMPORARY LODGING

- a. Temporary lodging is used at the time of initial evaluation, for any follow-up evaluations prior to admission, or while on the waiting list, at the time of the bariatric episode, or until discharge to home from the VABSC, and any post-bariatric follow-up visits. There may be instances when the patient must remain in the area of the VABSC while undergoing pre-operative assessments and/or treatments and/or recovering from surgery.
- b. The VABSC funds temporary lodging for the patient and one support person for the operative period or if readmitted for complications. Under certain circumstances an exception may be made for dependent children under 18 years of age.

NOTE: The VABSC will not support lodging if the patient and family decide to permanently relocate to the area in which the VABSC is located.

13. REQUIREMENTS FOR ESTABLISHING A VA BARIATRIC SURGERY CENTER

Veterans Integrated Services Networks (VISNs) desiring to initiate a BSC must demonstrate the following:

a. **Staff.** A surgical team must have at least two appropriately trained surgeons in bariatric surgery procedures, at least one of whom participates in each bariatric surgical operation. Programs must provide appropriately trained personnel or consultants in various disciplines to include, but not limited to:

- (1) Surgeons (preferably one specialized in this procedure),
- (2) House staff,
- (3) Anesthesiologist,
- (4) Operating room nurses,
- (5) Intensive care nurses,
- (6) Dietary staff,
- (7) Mental health staff, and
- (8) Rehabilitation staff.

NOTE: Substitutions may be provided by contract with university and/or affiliate surgeons, anesthesiologists and/or technicians.

b. **Facility Requirements.** Each facility must provide:

- (1) Appropriate equipment for lifting patients with BMI > 35.
- (2) Appropriate OR space with accommodations for patients with BMI >35 and scheduled time to perform procedure.
- (3) Surgical Intensive Care Unit capable of caring for post-operative patient(s).
- (4) Suitable beds and toilet facilities.
- (5) A comprehensive rehabilitation program.

c. **Notification of the VHA Central Office Surgical Program Office.** When a facility wishes to establish a VABSC, the request must be signed by the facility Director and the VISN Director and be forwarded to the VA Central Office Surgical Program Office.

d. **Site Visit.** Once a letter is received, the VA Central Office Surgical Program Office schedules a site visit to the proposed VABSC to ensure the Bariatric Surgery Center is in compliance with VHA policy (i.e., this Handbook).

e. **Approved VABSCs.** Following the site visit, and the Bariatric Surgery Program has been approved, the VABSC is listed on the VA surgical web site at: <http://www1.va.gov/SURGERY>.

14. QUALITY ASSURANCE FOR VA BARIATRIC SURGERY CENTERS

a. Operative Workload Statistics With Morbidity and Mortality Rates

(1) Deaths following Bariatric Surgery within 1 year of surgery, or any death as a direct result of a surgical complication.

(2) Each VABSC must submit to the NSQIP Data Center a complete operative workload with morbidity and mortality statistics for each 6-month period for review by the BSWG.

b. **Indications for Written Evaluation.** Any program that has an overall operative mortality greater than two times the VA national average for a period of 6-months is required to conduct a written review for evaluation by VA Central Office Surgical Program Office (111B), with consultation from the BSWG.

c. Indications for Site Visit

(1) Two consecutive 6-month periods which required written assessment.

(2) Findings from a written assessment that suggest possible deficiencies, which are a source of concern to the BSWG, VA Central Office Surgical Program Office (111B), Director, Deputy Under Secretary for Health, Under Secretary for Health, or VISN Director.

(3) Special requests from a VA medical center Director, VISN Director, or VA Central Office to review the VABSC Program.

d. Indications for Placing Programs on Probation

(1) A BSWG site visit team recommends, and the VABSWG concurs to VA Central Office Surgical Program Office (111B) and the Office of Patient Care Services (11), that serious problems are present at a VABSC which need to be corrected as a matter of some urgency, but are not immediately life threatening or impact negatively on the mortality and morbidity rate. If these problems are not corrected in an established period of time (usually 6-12 months), bariatric surgery at that center could be suspended or closed.

(2) If the recommendation is suspension or closure, the subsequent procedure must be as follows:

(a) The program must be placed on probation for a period of 6-12 months (under unusual

circumstances this period could be extended) and instructed to meet certain requirements and correct specific deficiencies.

(b) Before the end of the probation period, the VISN Director must report progress to VA Central Office Surgical Program Office (111B).

(c) A site visit must be made when deficiencies are reported to have been corrected or, at the latest, at the end of the probationary period, to determine whether:

1. Probation should be lifted.
2. Probation should continue.
3. The program should be closed.

e. **Indications for Placing Programs on Suspension**

(1) The site visit team recommends, and the VABSWG concurs that:

(a) Serious problems are present at a VA medical center that has the potential of becoming life threatening or have reflected negatively on the mortality and/or morbidity rates. As a result, the BSWG determines that immediate action needs to be taken and recommends the suspension of bariatric surgery to the Under Secretary for Health. At the same time, the VABSWG is to notify the VISN Director of the recommendation.

(b) If these problems are deemed uncorrectable within 60 days, bariatric surgery at that center **must** be recommended for closure.

(2) The subsequent procedure must be as follows:

(a) Once suspension has occurred, all bariatric surgery must cease at that center until the specific problem(s) have been corrected.

(b) Before the end of the established timeframe, the VISN Director must report progress to the VABSWG.

(c) Once deficiencies are reported to have been corrected, a site visit must be conducted to re-evaluate the program to determine whether:

1. The suspension should be lifted, or
2. To recommend program closure.

f. **Indications for Program Closure**

(1) At the end of the probationary or suspension period, if specific critical deficiencies identified during the initial site visit have not been corrected, and/or mortality, volume, and other

standards continue to be below accepted criteria, the program must be recommended for closure.

(2) The VABSWG may elect to defer a decision to recommend closure of a program if extraordinary circumstances warrant it.

(Date)

VA FORM 10-0425, BARIATRIC SURGERY INFORMATION PACKAGE

Below is an imbedded copy of Department of Veterans Affairs (VA)Form 10-0425, Bariatric Surgery Information Package. This form can also be found on the VA Forms web site at: <http://vaww.va.gov/vaforms> .



VA Form
10-0425-fill.pdf