



**NON-HOSPITAL MEDICAL AND SURGICAL ACCREDITATION
FACILITIES PROGRAM**

College of Physicians and Surgeons of British Columbia

Laparoscopic Adjustable Gastric Banding STANDARD

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Preamble

This document is intended for non-hospital medical/surgical facilities to ensure that best practices are incorporated into facility policies and procedures for the purpose of a bariatric surgery program acceptable to and approved by the College of Physicians and Surgeons of BC. Laparoscopic adjustable gastric banding (LAGB) is the only qualifying bariatric procedure approved for restricted Class 1 non-hospital facilities as specified by the College. This document is reviewed annually and revised periodically. Information in this document is consistent with, or exceeds, hospital practice and recommendations from provincial health authorities, regulatory colleges, the American College of Surgeons Bariatric Surgery Center Network Accreditation Program, the Canadian Anesthesiologists' Society, American Institute of Architecture (AIA), Operating Room Nurses Association of Canada and the Canadian Standards Association.

College's Position

The College recognizes the need for access to bariatric surgery (i.e. LAGB) and that high quality surgical care requires documentation with reliable measurements of outcomes. Laparoscopic adjustable gastric banding must only be performed in non-hospital facilities approved and accredited by the College of Physicians and Surgeons of BC, and only in facilities where the necessary personnel, physical resources, clinical standards, surgeon credentialing standards, data reporting standards and quality assurance program are in place. The purpose of this standard is to allow qualified physicians and other qualified regulated health-care professionals to administer a bariatric program in its entirety in the non-hospital medical/surgical facility setting and to provide patients with the benefits of the laparoscopic adjustable gastric banding procedure while minimizing the associated risks. The College's guidance of non-hospital facilities is to ensure the safety, quality, and consistency of patient care and is not meant to replace the professional judgment of physicians and other health-care professionals but rather incorporate current evidence-based or consensus-based clinical information into a framework for reasonable and acceptable patient care that promotes the best possible patient outcomes.

The decision to recommend surgery for obese patients requires multidisciplinary input to evaluate the indications for operation and to define and manage comorbidities. Facilities must assure commitment, organization, leadership, personnel and physical sources to provide optimal care.

Physicians, other regulated health-care professionals and support personnel, must demonstrate the requisite training, skills, and experience to administer a comprehensive bariatric program.

Non-hospital surgical facilities approved to perform LAGB are required to have a designated inpatient hospital to which patients can be transferred if the need arises. Facilities must be located within a 10-minute drive of a hospital in case of emergency transfer.

Definitions Pertaining to All College Guidelines

- Mandatory:** Required by authority; obligatory, compulsory. A compulsory descriptor identified in NHMSFAP standards. Unfulfilled mandatory descriptors will result in immediate requirements with specified time frames for follow-up.
- Recommendation:** Expression of an action which is advisory in nature.

Requirement: Expression of an action which is essential or mandatory.
Shall or Must: Indicates mandatory requirement and best practice, i.e. the minimum standard.

Definitions for LAGB

Abbreviations

ACLS:	Advanced Cardiac Life Support
BCLS:	Basic Cardiac Life Support (CPR Level Health Professional)
BMI:	Body Mass Index (weight in kilograms divided by the square of the height in metres)
ASA:	American Society of Anesthesiology. Patient's anesthesia physical status classifications according to risk (Appendix B)
CAS:	Canadian Anesthesiologists' Society
CLPNBC:	College of Licensed Practical Nurses of BC
CRNBC:	College of Registered Nurses of BC
CSA:	Canadian Standards Association
LAGB:	Laparoscopic Adjustable Gastric Banding
LPN:	Licensed Practical Nurse
NHMSFs:	Non-Hospital Medical/Surgical Facilities
PACU:	Post-anesthesia care unit
OR:	Operating room
OSA:	Obstructive Sleep Apnea
RN:	Registered Nurse
VTE:	Venous thromboembolism

Glossary of terms

adult:	Persons 19 years of age or older. Confirms the rights of adults to make their own health-care decision, either independently or with support from family and friends. Adults can be given health care only with their consent (<i>BC's Adult Guardianship Laws: Supporting self-determination for adults in British Columbia</i>).
Aldrete Scale:	Clinical scale used as criteria for patient discharge from PACU. The Aldrete scale scores the patient on mobility, respiratory status, circulation, consciousness, and pulse oximetry .
anesthesiologist:	All licensed medical practitioners with privileges to administer anesthetics. The only route to specialist recognition in anesthesia in Canada is through the Royal College of Physicians and Surgeons of

Canada's certification process. Physicians may be required to provide anesthesia services. CAS guidelines are intended to apply to all anesthesiologists in Canada. In the NHMSF setting only Royal College certified anesthesiologists may provide anesthesia services.

appropriateness:	The degree to which service is consistent with requirements and current best practice.
bariatric:	The field of medicine specializing in the treatment of obesity.
best practice:	An approach that has been shown to produce superior results, selected by a systematic process, and judged as exemplary, or demonstrated as successful. A best practice is a technique or methodology that, through experience, research and expert opinion has proven to reliably lead to a desired result.
child:	A patient 14 years of age or less.
class 1 facility:	Provides general anesthesia services.
college:	Professional regulatory body.
committee:	Non-Hospital Medical and Surgical Facilities Accreditation Program Committee.
comorbidity:	Two or more coexisting medical conditions or disease processes that are additional to an initial diagnosis.
competence:	Guarantee that an individual's training, knowledge and skill are appropriate to the service provided and assurance that the training, knowledge and skill levels are regularly evaluated.
consent:	Refer to BC's <i>Health Care (Consent) and Care Facility (Admission) Act</i> : http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96181_01
guideline(s):	An instructional guide or reference to indicate a course of action or appropriate options. They incorporate the most current evidence-based or consensus-based clinical information into a framework that promotes the best patient outcomes. They do not define a standard of care, but may inform the standard of care. They are not intended to replace the professional judgment of physicians.
overnight stay:	Refer to Appendix E.
practitioner:	An individual who practices a learned profession and supplies health-care services (e.g. physician, registered nurse).
policy:	A principle or guideline that governs activities in a facility that employees are expected to follow.
protocol:	Description of the steps to be taken in a procedure. Formal ideas, written plans and expectations concerning the actions of those involved in patient care.

qualified:	Having the education, abilities, qualities, training, or certification to perform a particular job or duties.
regulated health-care professional:	Applies to a health-care professional who is licensed and in good standing with their regulatory College.
standard:	That which is established by authority as a model, criterion, or rule and serves as a basis for comparison. Authoritative statements that describe the responsibilities for which individuals are accountable. Reflect the values and priorities of the profession. An achievable level of performance against which actual performance is compared.
surgeon:	A specialist certified by the Royal College of Physicians and Surgeons of Canada in a relevant surgical discipline.

Bariatric Program Standards

1. Medical director and facility requirements

The medical director must make application in writing to the College for approval to administer a bariatric program for LAGB procedures. Approval is contingent on the completion of an on-site visit and confirmation of the following requirements:

The medical director must make application in writing to the College for approval to administer a bariatric program for LAGB procedures. Approval is contingent on the completion of an on-site visit and confirmation of the following requirements:

1. meet physical space and design requirements as determined by the Canadian Standards Association (CSA Z8000 and Z317.2) and the American Institute of Architects (Design Guidelines for Facilities with Bariatric Patients)
2. review surgery outcome data to confirm patient safety and satisfactory long term patient outcomes:
 - a. monthly for the first six months of a new LAGB program and frequently thereafter
 - b. monthly for the first six months with the addition of any new bariatric surgeon and frequently thereafter
 - c. as part of the surgeon's re-application for privileges
3. ensure the surgeon and facility continue to meet all requirements at time of annual reappointment for privileges, including review of the surgeon's surgical outcome data (documentation of continuing medical education related to bariatric surgery is recommended)
4. provide key staffing and/or referral requirements:
 - a. one qualified bariatric surgeon who is designated as director of the bariatric program and who can provide (represents the credentialing requirements as documented in the guidelines from the American Society of Metabolic and Bariatric Surgeons (ASMBS) Global credentialing requirements in bariatric surgery):
 - documentation that they are working with an integrated program for the care of the morbidly obese patient that provides ancillary service such as specialized nursing care, dietary instruction, band filling, counselling, support groups, exercise training, and psychological assistance as needed
 - documentation that there is a program in place to prevent, monitor and manage short-term and long-term complication including defective bands
 - documentation that there is a system in place to provide and encourage follow-up for all patients
 - follow-up visits should either be directly supervised by the bariatric surgeon of record or other health-care professionals who are appropriately trained in perioperative management of bariatric patients and part of an integrated program

- while applicants can not guarantee patient compliance with follow-up recommendations, they should demonstrate evidence of adequate patient education regarding the importance of follow-up as well as adequate access to follow-up
- b. one physician surgical assist
- c. two qualified anesthesiologists—second anesthesiologist must be on-site during LAGB surgery (e.g. providing anesthesia in second OR and readily available to assist as necessary)
- d. perioperative and post-anesthesia recovery nursing staff who are qualified and experienced in bariatric procedures
- e. all facilities approved to perform LAGB procedures must only perform LAGB when a second room is operating in the facility to ensure additional personnel are available to assist as necessary
- f. bariatric program coordinator (e.g. registered nurse reporting to director of bariatric surgery) to provide comprehensive management of LAGB program, coordination of multidisciplinary teams (dietician, psychological assessment/support) and committed long-term medical management and follow-up to patients including lap-band fills
- g. dietician experienced in bariatric medicine and LAGB procedure
- h. psychologist experienced in the assessment of morbidly obese patients
- i. administrative support staff

II. Practitioners' qualifications

All general surgeons who perform LAGB in a NHMSF must:

- be certified by the Royal College of Physicians and Surgeons of Canada and be licensed and in good standing with the College of Physicians and Surgeons of BC
- hold privileges in a facility approved by the College
- submit to the College an application for approval specific to LAGB procedure
- hold surgical hospital privileges and possess the requisite experience and skills to perform advanced gastrointestinal and biliary laparoscopic surgery:
 - have performed at least 100 laparoscopic procedures (cholecystectomy, nissen fundoplication, bowel resection, hernia repair, appendectomy) operations over previous 24 months or have a Fellowship in Bariatric Surgery and,
 - have experience performing laparoscopic adjustable gastric banding procedures acceptable to the Committee **or** have completed a proctorship training in LAGB surgery which is acceptable to the Committee (e.g. documented 10 cases with satisfactory outcomes under the supervision of an experienced bariatric surgeon)
 - have privileges and coverage available 24/7/365 at designated in-patient hospital to manage laparoscopic gastric band complications

- ensure one qualified bariatric general surgeon and one physician surgical assist are present during LAGB procedures

All anesthesiologists who provide anesthesia for LAGB procedures **must**:

- be certified by the Royal College of Physicians and Surgeons of Canada and be licensed and in good standing with the College of Physicians and Surgeons of BC
- hold privileges in a facility approved by the College
- possess requisite experience in managing morbidly obese patients and complex airway issues
- hold active hospital privileges in the practice of anesthesia **or** hold current ACLS training and have completed an airway management course acceptable to the College if they have not regularly practiced anesthesia in a hospital setting within three years
- adhere to the practice and documentation/charting of anesthesia as recommended by the Canadian Anesthesiologists' Society
- participate in emergency mock drills at least every six months which should include but are not limited to cardiac arrest, difficult airway management, anaphylaxis, hypovolemia, unresponsiveness, acute stroke and seizure

Qualified and regulated health-care professionals (e.g. registered nurses) must:

- be licensed and be in good standing with their professional regulatory agency (e.g. College of Registered Nurses of BC)
- possess perioperative certification and/or have the equivalent in training and experience to work in the operating room or post-anesthesia/critical care certification and/or have the equivalent in training and experience to work in the post-anesthesia recovery unit
- hold current BCLS training
- participate in emergency mock drills at least every six months which should include, but are not limited to cardiac arrest, difficult airway management, anaphylaxis, hypovolemia, unresponsiveness, acute stroke and seizure

III. Staffing requirements

In all areas of patient care delivery, the facility must ensure sufficient personnel are available to assist with patient transferring and/or ambulation as necessary.

a. Operating room

During LAGB procedures the following staffing requirements **must** be met:

1. A minimum of two perioperative registered nurses who are dedicated to the operating room from the start to the finish of every LAGB procedure. One nurse is assigned to the scrub role and the second is assigned to the circulating role. Both nurses must hold perioperative certification and/or possess the equivalent in training and experience to perform their expected duties.

-and-

2. A third perioperative registered nurse or other regulated health-care professional who is dedicated to assist at the start and end of every case and immediately available during the case to assist as necessary.

b. Post-anesthesia recovery unit

During LAGB post-anesthesia recovery phase the following staffing requirements and ratios **must** be met:

i. Phase 1 level of care

Two registered nurses who are post-anesthesia recovery/critical care certified and/or have the equivalent in training and experience must be present in the same room at all times where a patient is receiving phase 1 PAR care.

One registered nurse to one patient:

- at the time of admission, until the critical elements are met:
 - patient has a patent airway without assistance
 - initial assessment is complete
 - patient is hemodynamically stable
- a second nurse must be available to assist as necessary

One registered nurse to two patients:

- two patients are conscious and free of complications

ii. Phase 2 level of care

Two registered nurses, one of whom is PARR/critical care certified and/or has the equivalent in training and experience, must be present in the same room at all times where a patient is receiving phase 2 PAR care.

One registered nurse to one patient:

- patient of any age who become unstable and require transfer to a higher level of care e.g. hospital
- a second nurse must be available to assist as necessary

One registered nurse to two patients:

- initial admission of the patient into post-anesthesia phase 2

iii. Blended levels of care

Perianesthesia units may provide Phase 1 and/or Phase 2 levels of care within the same environment. This may require the blending of patients and staffing patterns. The perianesthesia registered nurse uses prudent judgment based on patient acuity, nursing observations and required interventions to determine staffing needs.

c. Overnight stay unit

Facilities should consider first the interests, well-being and safety of their patients and avoid any situation that may put patients or staff at risk. The following guidelines should assist facilities in meeting the requirements for overnight stay of a LAGB surgical patient:

1. The College must be notified immediately if a patient is required to stay beyond an overnight stay (i.e. 24 hours past end of surgery).
2. There shall be written policy defining the chain of command and facility expectations in the event of an emergency.
3. There must be a documented call rota for anesthesia service and the surgical specialty of any overnight admission.
4. Call **must not** be transferred to another surgeon who was not involved in the LAGB procedure performed.
5. All LABG overnight stay patients shall be 19 years or over.
6. The overnight stay area must meet the same standards as established for the PAR unit. In addition, the overnight stay area must meet the applicable AIA bariatric design guidelines (see Appendix D) and must also receive the necessary approval of city/municipal and fire authorities.
7. Formalized post-operative care plans, discharge criteria, emergency protocols and hospital transfer protocols must be developed for LAGB patients kept in the overnight stay area. Copies must be included in the policy and procedure manual of the facility, and provided to the College prior to program approval.

During LAGB overnight stay the following staffing requirements **must** be met:

1. The **minimum** compliment of nursing staff is:
1-5 patients – 1 registered nurse in charge + 1 registered nurse or 1 licensed practical nurse. Total: 2 Nurses
The decision of assigning the second nurse as a registered or licensed practical nurse should depend on patient acuity and the facility’s administrator and charge nurse’s determination of staffing needs to provide safe patient care.
2. The medical director must ensure that nursing personnel possess competence appropriate to the patient population.
3. Registered nurse qualifications must include critical care or post-anesthesia recovery certification and/or the equivalent in experience and training.
4. At least one registered nurse with current training in advanced cardiac life support and all other members of the nursing staff with current training in cardiopulmonary resuscitation must be on duty at all times when patients are in the facility. The expected level of ACLS intervention must be clearly defined in the facility’s policy manual.

IV. Practice guidelines

a. Medical records

A permanent record of all LAGB procedures will be maintained and **must** include at a minimum:

- name and address of patient
- names of physicians and other health-care professionals directly involved in patient care
- procedure performed
- informed consent
- preoperative history and physical
- consultations as indicated
- preadmission anesthetic record
- record of allergies and medications
- laboratory and/or diagnostic testing as indicated by the patient's medical status, drug therapy or nature of the procedure
- anesthetic record
- operative report
- operative nursing record
- post-anesthesia recovery record
- discharge record

b. Patient selection and screening

Inappropriate patients for LAGB surgery in a NHMSF:

- ASA > 3
- BMI > 50 and/or patients > 400 lbs
- patients with personal or significant family history of malignant hyperthermia
- patient with no responsible escort to drive them home and stay with them overnight
- untreated coagulopathy
- untreated severe OSA and/or patients who are non-compliant with CPAP
- significant cardiac comorbidity (e.g. recent MI, CHF, significant valve disease, ischemic heart disease, valve replacement, significant arrhythmia requiring post-op monitoring)
- significant pulmonary comorbidity (e.g. severe COPD/emphysema, severe restrictive lung disease, poorly controlled asthma)
- complicated cases such as gastric prolapsed, erosions and patients who have had previous bariatric surgery
- poorly controlled diabetes
- portal hypertension
- impaired mobility (wheelchair or walker)
- patients with confounding psychiatric issues (e.g. active psychosis, current moderate-severe untreated depression)

- patients with confounding psychosocial factors (e.g. recent or current substance/alcohol abuse, disturbed eating habits, limited social support, unrealistic expectations of surgery)

Appropriate patients for LAGB surgery in a NHMSF:

- only ASA 1 and 2 patients and selected ASA 3 patients with no significant cardiac or pulmonary comorbidities
- age between 19 and 65 years
- BMI > 30 and < 35 with at least one severe comorbidity related to their obesity (e.g. heart disease, diabetes)
- BMI > 35 and < 50 (maximum weight of 400 lbs)
- patient has been overweight for at least five years
- mild untreated OSA requiring low dose oral opioids post-op
- mild to moderate treated OSA requiring low dose oral opioids post-op
- selected severe OSA appropriately treated and compliant with CPAP
- patient must be ambulatory

Each patient must be carefully screened and the following criteria reviewed prior to surgery by the designated director of the bariatric program and the bariatric nurse coordinator:

1. Indications for surgery, contraindications for surgery, comorbidities and operative risks.
2. History and physical examination must be performed within 90 days of the procedure by a registered physician and should include: outcome of previous weight loss attempts; comorbidities; current diet habit; medications; allergies; previous surgery; previous hospital admissions; family physician information and assessment; next of kin information; smoking habit; alcohol use; occupation; family history of diabetes; heart disease and cancer; current and maximum weight and BMI calculation; and symptoms of obstructive sleep apnea (OSA patients to be instructed to bring CPAP machines to facility day of surgery). History must be documented, dated and signed and be part of the patient's clinical record preoperatively. Examination must be updated if necessary within two weeks of the procedure.
3. ASA physical classification must be assigned by an anesthesiologist and be recorded for each patient (see Appendix B).
4. Anesthesia consult for every LAGB patient. Anesthetic consults must be carried out, documented, dated and signed not more than two weeks before surgery and at minimum, one day prior to surgery. The pre-anesthesia assessment must include:
 - review of the patient's clinical record
 - a medical interview with the patient
 - a physical examination relative to anesthetic aspects of care and review of previous anesthesia records
 - record of blood pressure, heart rate, respiration status and quality, oxygen saturation and temperature

- a review and ordering of diagnostic tests
 - ECG, CBC, electrolytes, liver function tests are mandatory
 - blood gases, pulmonary function tests, sleep study report as indicated
5. Cardio pulmonary (i.e. presence of sleep apnea and upper GI studies to rule out hiatus hernia as indicated).
 6. Psychological screening assessment, completed by a psychologist or registered counselor experienced in the assessment of the morbidly obese, to ascertain the patient's suitability for the LAGB procedure and to evaluate the patient's ability to comply with the post-operative recommendations.
 7. Psychiatric evaluation on individual basis as indicated.
 8. Dietary educational screening, by a registered dietician, to discuss pre- and post-surgery dietary requirements/recommendations and the patient's commitment to dietary modification both after and prior to surgery (e.g. patients to follow a low fat/low carbohydrate diet 2–3 weeks prior to surgery).
 9. Medical consultation on individual basis as indicated (e.g. MIBI scans, internal medicine or cardiology consultation).
 10. The patient or guardian will be informed of risks and benefits of the procedure and written informed consent for laparoscopic adjustable gastric banding is obtained and documented. Refer to BC's *Health Care (Consent) and Care Facility (Admission) Act*: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96181_01

c. Patient admission

The regulated health-care professionals managing the patient care must:

- confirm and document that the patient has a responsible adult to accompany them home and remain with patient 24 hours post-operative (i.e. if the patient does not stay first 24 hours overnight at the facility); if a responsible adult is not available to accompany the patient home post-procedure, the planned procedure will be cancelled
- review and document patient pre-procedure health evaluation including NPO status, allergies, ASA, height, weight, BMI, and any previous medical, anesthesia and surgical problems
- obtain and document baseline data including heart rate and rhythm, respiratory rate and status, blood pressure, pulse oximetry, glucometer reading as indicated, temperature, mental status, ability to ambulate, and pain level
- confirm as indicated VTE and antibiotic prophylactic administration
- confirm as indicated discontinuation of anticoagulant/antiplatelet/anti-inflammatory medications one week prior to surgery
- ensure appropriate bariatric specific fasting guidelines have been followed preoperatively
- provide patient with the appropriate information regarding procedure, nature of medications and post-procedure care

- review patient chart for completeness (e.g. consent, history and physical, diagnostic testing, etc.)
- ensure surgical site verification/markings
- ensure that patient has CPAP machine as indicated – some do not allow for supplemental oxygen delivery and this must be identified and corrected before surgery

d. Operating theatres and equipment

The regulated health-care professionals managing the patient care must ensure:

- OR theatres are large enough to accommodate easy access for staff, equipment and patient
- OR theatres are fully equipped with all appropriate equipment and supplies appropriate to the morbidly obese patient
 - OR table must accommodate up to 400 lbs and have sufficient accessories to safely anesthetize, position and restrain the patient
 - positioning devices must include but are not limited to arm boards, bed extensions, table foot and/or leg attachments, safety straps, transfer board or ceiling lift device, pillows, sandbags
- two complete sterile LAGB laparoscopic sets are available for each LAGB case (one as back-up) with appropriate retractors, long surgical instruments, long trocars and sheaths as indicated
***flash sterilization is not acceptable practice due to lack of inventory**
- two insufflators, two light sources, two cameras and two light cords are available for each case (one for back-up)
- two LAGB bands are available for each case
- a complete sterile laparotomy set is available in case of need to open with appropriate retractors and all other necessary supplies in order to deal with problems of (e.g. intra-abdominal bleeding, bowel injury or other intra-abdominal problems) that may arise
- OR theatre doors are kept closed during surgery
- heating ventilation and air conditioning systems meet CSA standards and documentation is provided to the College
- standard OR lights, suction and temperature controls are in place
- emergency power and lighting is available for minimum of four hours and tested weekly
- that emergency cart and difficult intubation equipment is immediately available
- adequate electrical outlets are available
- non-flammable medical gas piping system complies with BC building codes and is serviced annually
- all equipment is CSA approved and checked annually by a biomedical engineer
- that OR theatre is adequately staffed from the start to finish of each case

- that “surgical safety checklist” (briefing, timeout and debriefing) is completed and recorded on OR record
- that all intraoperative charting and surgical counts are completed and signed by the appropriate health-care professionals
- that all surgeons complete a detailed operative report

e. Post-anesthesia recovery unit

The regulated health-care professionals managing the patient care must ensure:

- there is adequate number of patient stations equipped with monitoring equipment which includes:
 - ECG monitor
 - suction
 - oxygen source with mask and/or nasal cannula
 - bag-valve-mask device
 - intravenous supplies
 - medications and narcotics
 - emergency light source
 - body warming device
- adequate space exists to allow for free movement of staff and emergency equipment access on both sides of the patient stretcher
- during the patient recovery phase a registered nurse qualified and trained in recovery room procedures remains in continuous attendance to the patient
- there is ongoing patient assessment and documentation of every patient which includes:
 - respiration rate and airway patency
 - heart rate evaluation
 - blood pressure
 - oxygen saturation by pulse oximetry
 - colour
 - level of consciousness
 - activity
- hand-washing station and/or alcohol rub dispensers are easily accessible to ensure hand washing between patients

f. Patient discharge

1. Discharge criteria must be met prior to discharge from the patient from the Facility e.g. modified Aldrete score (see Appendix C).

2. The patient and/or guardian/responsible adult will be instructed in the after care of the patient. Verbal and written discharge instructions will be given to the patient and/or responsible adult and must include:
 - when to resume taking medications taken before procedure
 - new prescriptions
 - wound care
 - diet and activity restrictions, additive effects of alcohol and other sedative drugs
 - no driving or operating dangerous machinery for at least 24 hours
 - follow-up care, telephone contact numbers
 - responsible adult to remain with patient for 24 hours
 - written materials applicable to procedure
3. The anesthesiologist or other competent physician **must** remain on the premises until the patient meets predetermined recovery criteria. Discharge from the PACU is the responsibility of the anesthesiologist.
***Post-anesthesia recovery unit and overnight stay equipment must accommodate morbidly obese patients up to 400 lbs:**
 - stretchers to accommodate both weight and width of patient
 - transfer or lifting devices
 - commode
 - wheelchair
 - bathroom sinks and toilets

g. Emergency protocols

1. Overview

In facilities doing LAGB there may be emergencies that relate to the airway, cardiac function and to the management of unexpected findings during the laparoscopy or intra-abdominal injuries that ensue during the procedure. The facility must have appropriately trained personnel to deal with these emergencies and have the appropriate equipment to perform life-saving procedures.

2. Emergency patient care

Protocols for the contact of EMS and patient transfer to a hospital must be published, posted and regularly reviewed.

3. Difficult airway management

Facility must be capable of and appropriately equipped to safely and effectively deal with difficult airway problems. The equipment necessary includes flexible bronchoscope with suction capabilities, glide scope and a difficult intubation tray.

4. Emergency equipment and supplies

- cardiac monitor with display

- defibrillator
- means to monitor body temperature
- emergency and resuscitative medication as per College guidelines for Class 1 facility (see Appendix F)
- two functioning laryngoscopes appropriate for obese patients
- endotracheal tubes, laryngeal masks, stylets, airways and facemasks in a selection of sizes appropriate to the patient
- 100% oxygen source (two E tanks available) and supplies
- positive-pressure breathing device
- portable suction and suction catheters (tonsil and deep)
- cricothyrotomy kit
- pulse oximeter with audible monitor
- CO₂ monitor
- stethoscope
- CPR backboard
- emergency record document
- cardiac algorithms
- IV fluids and supplies
- supply of plasma volume expanders
- Magill forceps

h. Medication management

Controlled substances/narcotics shall be managed in a manner that permits full auditing of the substances from acquisition through to patient administration and wastage.

i. Safety

1. All equipment and supplies must be appropriate, CSA approved and calibrated according to the manufacturer's recommended standards.
2. All equipment must undergo annual inspection and maintenance by qualified personnel i.e. biomedical engineer. Records indicating conformity to regulations and inspection and maintenance must be retained by the facility.
3. Emergency mock drills must be performed at least every six months which should include, but are not limited to, cardiac arrest, difficult airway management, anaphylaxis, hypovolemia, unresponsiveness, acute stroke and seizure. All staff must participate in mock drills with attendance and specified drills practised documented.

j. Physical space

Facilities must meet AIA bariatric design guidelines (see Appendix D) which include:

- corridor widths
- doorway widths
- bathroom toilets and sinks
- adequate space in facility for the health team to deliver safe, private and efficient patient care in all patient areas
- mandatory access to facility by emergency medical services and fire department

k. Infection prevention and control management

- “routine practices” shall be employed in the handling of all patients, care items and medical devices
- sufficient hand-washing sinks shall be available and hand-washing protocol posted as a visible reminder of the importance for staff to wash their hands
- appropriate personal protective devices shall be employed by all staff
- sterile technique shall apply as appropriate to procedure performed
- all sharps devices must be handled appropriately and disposed of in a dedicated biohazard puncture resistant container (see WorksafeBC Guideline at www.worksafebc.com – Reference OSHR 6.36(1))
- single-use medical devices (e.g. syringes) must not be reused
- ensure that potentially infectious materials or agents are not transferred from one patient to another; special attention shall be given to syringes, infusion pump administration sets and multi-dose medication vials

l. Sterile processing management

Facilities are required to verify the following:

1. The Ministry of Health document (Dec 2011), *Best practice guidelines for cleaning, disinfection and sterilization of critical and semi-critical medical devices in BC health authorities* is incorporated into facility policy and followed:
<http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.pdf>
2. Sufficient LAGB instrument inventory is available and on-site.
3. Medical devices must not be flashed on a routine basis. Flash sterilization may only be used in an emergency situation when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization must not be used as a substitute for insufficient instrument inventory. Manufacturer’s sterilization recommendations should be followed prior to flash sterilization of any medical device.
4. All medical devices are appropriately wrapped, placed in steri-peel or metal storage containers prior to full-cycle steam sterilization.
5. All sterile processing staff are appropriately qualified and trained to perform expected duties.

m. Quality improvement program

Non-hospital facilities approved to perform LAGB must have a quality improvement program in place which includes promotion and documentation of the use of best practices and measuring outcomes:

- long-term post-operative follow-up must be established for all patients
- post-operative rehabilitation support should include dietary counseling, exercise counseling and psychological counselling
- patients must be encouraged to participate in ongoing support groups
- improvement in obesity related co-morbidities should be monitored and documented
- follow-up visits must occur frequently, e.g. two weeks post-operatively, four–six weeks post-operatively, three months, six months, one year and every year thereafter
- a patient may be deemed “lost to follow-up” if at least three consecutive and ***different*** contact efforts have been documented including:
 - phone call to patient
 - letter to patient
 - letter to patient’s family physician/general practitioner

Documentation of the quality improvement program is reviewed during the application process for establishing a LAGB program and at time of accreditation.

n. Manuals

1. Policies and procedures pertaining to bariatric medicine and LAGB surgery, including clinical pathways/care algorithms, shall be current, complete and available for staff review.
2. Education materials relevant to the services provided at the facility.

APPENDICES

Appendix A

Specific protocols have been developed by surgeons experienced in operating on morbidly obese patients, along with anesthetists to ensure patient safety. These protocols are outlined below and these are the protocols that we follow.

i. Sleep apnea

All patients would be screened for sleep apnea and those with a STOP-Bang score of ≥ 3 would be sent for a sleep apnea study.^{1, 2, 6}

If a patient has sleep apnea (including those with moderate to severe sleep apnea), s/he is instructed to bring their continuous positive airway pressure (CPAP) machine with them to the facility for use after the procedure.

Additional measures to ensure patient safety include:

- minimizing anesthesia time (note: LAGB usually takes less than one hour)
- using non-narcotics to control pain post-operatively
- extubating when the patient is fully awake and in a semi-upright position

In outpatient facilities following this protocol, complications resulting from sleep apnea have not occurred, not even in those patients with moderate to severe sleep apnea and are super obese (BMI ≥ 50).^{2, 3, 4} The study by Watkins et al. involved 2,411 patients and the study by Montgomery et al. involved 320 super-obese patients.

ii. Preventing nausea and vomiting and minimizing post-operative pain to allow rapid ambulation

To minimize post-operative nausea and vomiting, a scopolamine patch is applied just prior to surgery and during surgery anti-nausea medications are administered intravenously.

To minimize pain post-operatively, a non-narcotic is used during and post-surgery (if needed).

iii. Preventing deep vein thrombosis (DVT) and pulmonary embolism (PE)

The following steps are taken to prevent DVTs or PEs:

- requiring patients to stop estrogen-containing medications one month before surgery
- administering 4,000 U of low molecular heparin subcutaneously one hour prior to anesthesia induction
- placing pneumatic compression devices on the lower extremities of the patients during surgery
- allowing for rapid ambulation post-surgery by minimizing post-operative nausea, vomiting and pain through the administration of appropriate medications, as mentioned earlier

These measures have been shown to greatly reduce risk.^{2,3}

iv. Anesthesia management

Short-acting anesthetics are used and extubation occurs once the patient can lift his/her head, responds to commands and has appropriate vital capacity.

Following extubation, the patient is maintained in a 45-degree heads-up position. This improves the expiratory reserve volume and the functional residual capacity.⁵

By following these guidelines, patients can typically become mobile and leave the clinic as early as two hours after the procedure.^{2,4}

v. Patient support post-procedure

- All patients must be accompanied by an adult companion for the first 24 hours after the procedure.
- If an adult companion is not available, the surgeon must arrange for a nurse to stay with the patient for the first 24 hours.
- Out-of-town patients are asked to stay close to the clinic for two to three days post-procedure and must be seen by either the surgeon or a nurse at the clinic before they travel home.
- All patients are called the following day and their first appointment is booked within four to six weeks.
- Patients are provided with a telephone number so they can reach the surgeon 24 hours per day, seven days a week.

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Appendix B

American Society of Anesthesiologists (ASA)

Physical Status Classification System

Only patients at Categories 1 and 2 risk level as defined by the American Society of Anesthesiologists should normally be accepted in the facility. However, risk level Category 3 patients may be treated there if the patient's disease is not expected to be affected by the anesthetic.

ASA 1 A normal healthy patient

e.g. Healthy patient without any systemic medical problems other than surgical.

ASA 2 A patient with mild systemic disease

e.g. Patient who smokes and has hypertension, which is well controlled.

ASA 3 A patient with severe systemic disease

e.g. Patient with diabetes and angina. Takes medications, including insulin. angina – fairly stable.

ASA 4 A patient with severe systemic disease that is a constant threat to life

e.g. Patient with diabetes, angina and congestive heart failure. Patient has dyspnea on mild exertion and chest pain.

Appendix C

I. Phase I recovery to phase II recovery discharge criteria:

A. Modified Aldrete scoring system

A minimum score of 9/10 (and/or return to similar preop status) is achieved prior to transferring the patient to a Phase II recovery area.

Table One: Modified Aldrete scoring system

Category	Score = 2	Score = 1	Score = 0
Respirations	Breathes, coughs freely	Dyspnea	Apnea
O₂ Saturation	SpO ₂ > 94% on R/A	Supplemental O ₂	SpO ₂ < 94% on O ₂
Circulation	BP +/- 20 mmHg pre-op value	BP +/- 20-50 mmHg pre-op value	BP +/- 50 mmHg pre-op value
LOC	Awake and oriented	Wakens with stimulation	Non-responsive
Movement	Moves 4 limbs spontaneously	Moves 2 limbs spontaneously	Moves 0 limbs spontaneously

B. Post-anesthetic discharge scoring system (PADSS):

A minimum score of 9/10 (and/or return to similar preop status) is achieved prior to transferring the patient to a Phase III recovery area or home.

Table Two: Post-anesthetic discharge scoring system (PADSS)

Category	Description of Status	PADSS Score
Vital Signs	Within 20% range of pre-op value	2
	20–40% range of pre-op value	1
	> 40% range of pre-op value	0
Respiratory Status	O ₂ saturation > 94% on room air	2
	O ₂ saturation > 94% on nasal prongs @ 4 LPM or less	1
	O ₂ saturation > 94% on FM @ 10 LPM or less	0
Nausea & Vomiting	Minimal, treated with po medications	2
	Moderate, treated with parenteral medications	1
	Continues after repeated treatments	0

Category	Description of Status	PADSS Score
Pain	Acceptable to patient (with po medications)	2
	Pain somewhat acceptable to patient	1
	Pain not acceptable to patient	0
Surgical Bleeding	Minimal: no dressing changes required	2
	Moderate bleeding: 1–2 dressing changes	1
	Severe bleeding: intervention required	0

II. Phase II to Phase III recovery/extended observation (or home) discharge criteria:

A minimum score of 9/10 (and/or return to similar pre-op status) is achieved prior to transferring the patient to a Phase III recovery area or home.

Table Three: Post-anesthetic discharge scoring system (PADSS) for ambulatory surgical patients

Category	Description of Status	PADSS Score
Vital Signs	Within 20% range of pre-op value	2
	20–40% range of pre-op value	1
	> 40% range of pre-op value	0
Ambulation	Steady gait/no dizziness	2
	Ambulates with assistance	1
	Not ambulating/dizziness	0
Nausea & Vomiting	Minimal, treated with po medications	2
	Moderate, treated with parenteral medications	1
	Continues after repeated treatments	0
Pain	Acceptable to patient (po medications)	2
	Pain not acceptable to patient	1
Surgical Bleeding	Minimal, no dressing changes required	2
	Moderate bleeding	1
	Severe bleeding	0

Post-operative voiding is not always required. See the National Association of PeriAnesthesia Nurses of Canada *Standards for Practice* for further information.

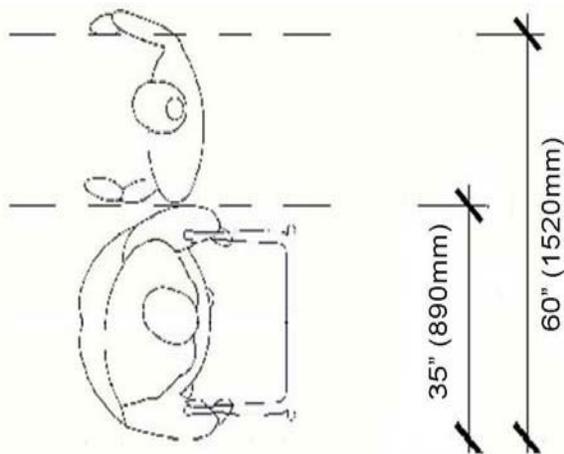
Appendix D

Design guidelines for facilities with bariatric patients

The design of health-care facilities has a direct impact on both worker safety and the quality of patient care. With an increasing number of bariatric patients (patients 100 lbs or more over their ideal body weight or having a Body Mass Index of 40 or more), designing or re-designing facilities is an emerging topic. The following guidelines are some basic numbers based on research by the American Institute of Architecture Academy for Health. It is important to note when applying these numbers into a design that there are many other considerations that need to be taken into account, such as:

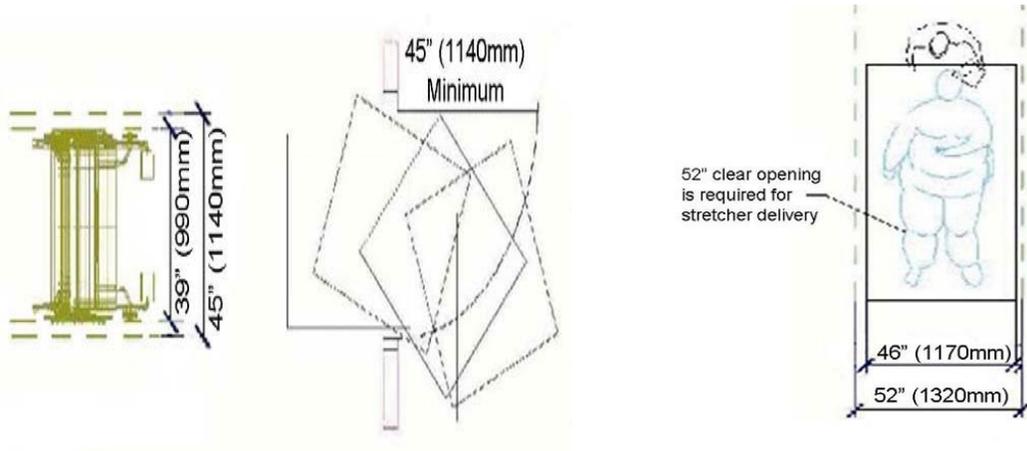
- a description of the patient population – physical and mental capacities, medical conditions;
- the types of procedures being performed and what equipment is required
- how and where patients are transported (patient flow)
- dimensions and storage of equipment

Corridor widths



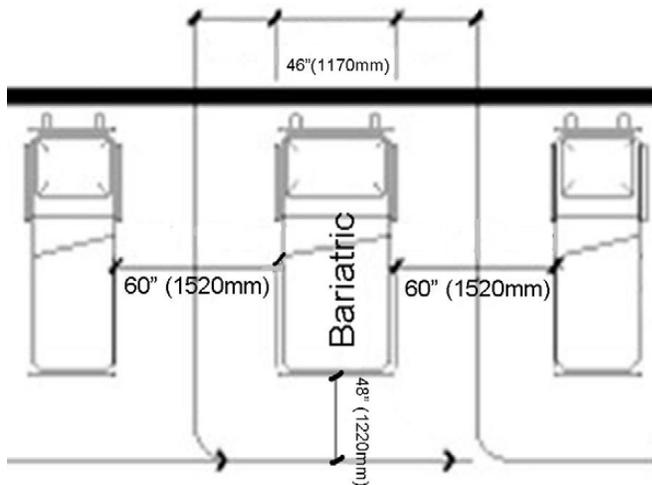
In order to accommodate a patient with a bariatric walker and allow passage for other foot traffic, a minimum of 5 ft (60" or 1,520 mm) is required for the width of a corridor.

Doorway widths



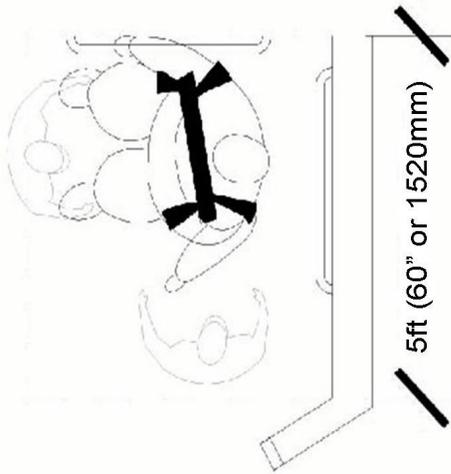
To accommodate bariatric wheelchairs 45" (1,140 mm) doorway openings are required. Where the passage of bariatric stretchers is needed, doorways should be a minimum of 52" (1,320 mm).

Room size



In order to accommodate the larger equipment needed for bariatric patients, the design shall provide a minimum of 80 ft² (7.43 m²) for each patient bed, and for clearance of at least 5 ft (60" or 1,520 mm) between patient beds and 4 ft (48" or 1,220 mm) at the foot of the bed.

Toilet rooms



Provide floor-mounted toilets with a drop weight rating of 700 lbs (to accommodate an impact factor of 1.4 for a 500 lb patient) and a clearance of 5 ft (60" or 1,520 mm). Allow for staff assistance on two sides of the toilet or shower.

Provide wall-mounted sinks with a rating of 300 lbs (floor-mounted sinks interfere with wheelchairs).

Opt for open showers with a floor drain to allow for easier staff assistance and provide wall-mounted grab bars. Ensure any wall with a wall-mounted fixture is re-enforced to meet or exceed the rating.

Source: The American Institute of Architects. (2004). Planning and Design Guidelines for Bariatric Healthcare Facilities. Found online at:

http://www.aia.org/nwsltr_print.cfm?pagename=aah_jrnl_20061018_award_winner

Appendix E

See Overnight Stay Guideline at <https://www.cpsbc.ca/files/pdf/NHMSFAP-Overnight-Stay-Guideline.pdf>.

Appendix F

See the following documents:

- Emergency Cart Medication and Equipment – Class 1 <https://www.cpsbc.ca/files/pdf/NHMSFAP-AS-Emergency-Cart-Class-1.pdf>
- Malignant Hyperthermia Standard <https://www.cpsbc.ca/files/pdf/NHMSFAP-Malignant-Hyperthermia-Standard.pdf>

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Revision History

Version No.	Version Date	Summary of Change
1.7	2019-02	<ul style="list-style-type: none"> Updated Section II Practitioner’s qualifications to be congruent with the change made in 2014-03
1.6	2017-12	<ul style="list-style-type: none"> Program name change
1.5	2014-03	<ul style="list-style-type: none"> Updated Medical Director and Facility Requirements, item 4b from “second qualified general surgeon assisting who is experienced in laparoscopic surgery” to “one physician surgical assist”
1.4	2013-03	<ul style="list-style-type: none"> Document title change, cover page Edits to preamble and College’s position Updated medical director and facility requirements: minimum number of procedures in 12-month period requirement deleted, revised review of surgery outcome data to confirm patient safety Updated patient selection criteria – inappropriate patients: psychiatric issues, psychological factors Updated patient screening and review: review of indications for surgery, contraindications, comorbidities and operative risk; psychological screening; dietary screening Updated Quality Improvement Program Edits to Manuals Updated Appendix A: STOP-Bang screening tool Updated references
1.3	2012-01	<ul style="list-style-type: none"> Edits to physical space requirements to include CSA Z8000, page 5 Edits to points 3 and 4 under Appropriate patients for LABG surgery in a NHMSF, page 11 Edits to Operating Theatres and Equipment requirements, page 14 Changed “Emergency Airway Management” to “Difficult Airway Management”, page 17 Removed introductory paragraph under Sterile Processing Management, page 19 Updated link to Ministry of Health document, page 19 Removed ASA 5 in Appendix B ASA Physical Status Classification System, page 25 Edits to Appendix C Modified Aldrete Scoring System, page 26 Appendix E (hyperlink), page 32 Update to Appendix F, page 33 Edits to References, pages 34-36
1.2	2010-11	Edits to point 3 of screening criteria, page 12 (as directed by the NHMSFAP Committee)
1.1	2010-07	Edits to last sentence, point 5 of screening criteria, page 13
1.0	2009-07	Initial final version