

October 14, 2011

**FACILITY INFRASTRUCTURE REQUIREMENTS TO PERFORM INVASIVE
PROCEDURES IN AN AMBULATORY SURGERY CENTER**

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy and procedures regarding the infrastructure requirements for VHA facilities providing surgical services in an Ambulatory Surgery Center (ASC) in relationship to the complexity of the surgical procedures being performed, as well as the method for monitoring compliance. *NOTE: This Directive does not impact or supersede in any way VHA Directive 2010-018.*

2. BACKGROUND

a. VHA Directive 2010-018 established the facility infrastructure requirements to perform standard, intermediate, or complex surgical procedures by inpatient VHA Surgical Programs.

b. Approximately 80 percent of all surgical procedures performed by VHA are done so on a same day or outpatient basis. In accordance with the demand for outpatient services, VHA has plans to expand the number of free standing ASCs.

c. **Definitions**

(1) **Ambulatory Surgery.** Ambulatory surgery refers to surgical or invasive diagnostic procedures performed by qualified providers in an inpatient surgical suite or ASC with pre-procedural and immediate post-procedure care completed on the same day, or observation without hospitalization.

(2) **Ambulatory Surgery Center (ASC).** An ASC is a free standing VHA facility separate from an inpatient VHA Surgery Program. Outpatient (same day) surgery performed in a separate building on a VHA campus with an inpatient VHA Surgery Program would be considered an ASC if community paramedics are used to respond to emergencies according to current VHA policy on Out-of-Operating Room Airway Management.

(3) **Post-anesthesia Care Unit (PACU).** The PACU is an area dedicated to receive patients following general anesthesia, regional anesthesia, or monitored anesthesia care. Phase I requires close monitoring, including airway, ventilator, and hemodynamic support. Phase II allows preparations to be made to progress the patient towards discharge to home. Phase I PACU and Phase II PACU may be combined.

(4) **Ambulatory Surgery Program.** An Ambulatory Surgery Program provides surgical procedures on an outpatient basis in an ASC; distinguishable from an inpatient VHA Surgery Program performing surgical procedures on an a same-day or outpatient basis at a VA medical center.

THIS VHA DIRECTIVE EXPIRES OCTOBER 31, 2016

VHA DIRECTIVE 2011-037

October 14, 2011

(5) **VHA Facility.** A VHA facility includes any one of the following: VA medical center, community based outpatient clinic, long-term care facility, or Ambulatory Surgery Center. *NOTE: Invasive procedures performed outside the inpatient surgical suite or ASC (i.e., clinics, procedure rooms), utilizing local anesthesia or moderate sedation, are not defined as ambulatory surgery. For specific guidelines refer to VHA's current policy on Moderate Sedation by Non-Anesthesia Providers.*

3. POLICY: It is VHA policy that each Department of Veterans Affairs (VA) medical facility with an ASC must possess a surgical complexity designation of either basic or advanced, based on the facility's infrastructure and will only perform surgical procedures that do not exceed the infrastructure capabilities of the facility.

4. ACTION

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for designating the surgical complexity of each VHA medical facility with an Ambulatory Surgery Program.

b. **National Director of Surgery (NDS).** The NDS is responsible for:

(1) The content of the Ambulatory Surgery Center Infrastructure Matrix (ASCIM) and the Ambulatory Surgery Complexity Matrix (ASCM), and for ensuring that both documents are reviewed on an annual basis. In performing this review, the NDS must consider modifications of the Current Procedure Terminology (CPT) codes, the standard of care, the clinical outcomes data from the Veterans Affairs Surgical Quality Improvement Program, the emergence of new technology, and the opinion of the Surgical Advisory Boards within the National Surgery Office (NSO). *NOTE: For information regarding these forms see Attachments A and B.*

(2) Providing timely notification to the Office of the Deputy Under Secretary for Health for Operations and Management and the Veterans Integrated Service Network (VISN) Chief Surgical Consultants located within the VISN offices, of any modification to the ASCIM and ASCM.

(3) Providing oversight to the NSO, which:

(a) Monitors all surgical procedures performed by a VHA Ambulatory Surgery Program by complexity designation of the facility,

(b) Reports all surgical procedures performed beyond facility complexity designation, and

(c) Notifies the VISN and the facility whenever a surgical procedure has been performed by a VHA Ambulatory Surgery Program beyond the complexity designation of the facility.

c. **Veterans Integrated Service Network (VISN) Director.** The VISN Director is responsible for:

(1) Ensuring that each VHA medical facility in the VISN with an Ambulatory Surgery Program has an ASC Complexity Designation based upon an analysis of the ASCIM requirements.

(2) Providing the Deputy Under Secretary for Health for Operations and Management and the NDS with appropriate notification and documentation of any future request by a VA medical facility to modify the surgical complexity designation of an ASC consistent with current VHA policy on restructuring VHA clinical programs. *NOTE: In this manner, a basic ASC adding additional resources may request an advanced designation. Alternatively, the loss of key infrastructure may require an advanced ASC to request a change to basic designation.*

(3) Submitting all waiver documentation to the Deputy Under Secretary for Health for Operations and Management and the NDS for concurrence when any component of the ASCIM is provided outside the VA medical facility. The waiver must include:

- (a) The component of the ASCIM for which the waiver is requested;
- (b) The name of the facility performing the procedure;
- (c) The travel distance between the ASC and the facility performing the procedure;
- (d) The process by which the Veteran patient receives care and treatment;
- (e) A copy of either the Memorandum of Understanding or a contractual agreement between the VA medical facility performing the services; and
- (f) A plan to monitor and review the quality of care provided.

(4) Ensuring that all appropriate documentation is submitted and procedures followed, according to current VHA policy regarding restructuring VHA clinical programs, anytime a significant increase or decrease in surgical services is anticipated or realized at any given facility sufficient to result in a change in the facility surgical complexity designation.

d. **Facility Director.** The facility Director is responsible for:

(1) Ensuring that the infrastructure requirements for the facility, as identified by the ASCIM, are accounted for and communicated to the VISN Director;

(2) Ensuring that the VISN Director is notified if, and when, there is a failure to maintain the infrastructure appropriate for the surgical complexity designation of the ASC;

(3) Initiating the request for a change in clinical services to the VISN Office according to current VHA policy regarding restructuring VHA clinical programs, anytime the facility infrastructure significantly changes, resulting in a decrease or increase in the services being provided; and

VHA DIRECTIVE 2011-037

October 14, 2011

(4) Ensuring that the scope of surgical and invasive procedures being performed is within the capabilities of the ASC.

e. **Facility Chief of Surgery.** The facility Chief of Surgery is responsible for:

(1) Ensuring that the scheduled surgical procedures performed by the ASC are within the scope of the facility ambulatory surgery complexity designation.

(2) A timely review of any surgical procedure performed beyond the ambulatory surgery complexity designation.

(3) Ensuring that all surgical procedures performed by the ASC are entered into the Veterans Health Information Systems and Technology Architecture (VistA) Surgical Package. **NOTE:** *The facility may choose whether or not to enter non-surgical procedures into the VistA Surgical Package, e.g., colonoscopy.*

(4) Timely notification of the VISN Chief Surgical Consultant within the VISN Office of any concern regarding a Veteran having received or requiring a level of care beyond the surgical complexity designation of the ASC.

5. REFERENCES: American Society of Anesthesiologists, Standard for Post anesthesia care (2009), available at www.asahq.org/

6. FOLLOW-UP RESPONSIBILITY: The National Surgery Office (10NC2), Office of the Deputy Under Secretary for Health and Operations and Management is responsible for the contents of this directive. Questions may be referred to the National Director of Surgery at (202) 461-7148.

7. RESCISSIONS: None. This VHA Directive expires October 31, 2016.

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DISTRIBUTION: CO: E-mailed to VHA Publications Distribution List on 10/20/2011

ATTACHMENT A

AMBLATORY SURGERY CENTER INFRASTRUCTURE MATRIX

Veterans Health Administration (VHA) facilities with an Ambulatory Surgery Center (ASC) must have a written plan or policy for the safe and timely transfer of the patient who requires treatment or therapy which the facility is unable to provide or perform. Every effort must be made to select appropriate patients who are suitable to have their procedure performed in an ASC. Patients must be discharged from the ASC according to an established protocol, or must be transferred to a facility with 24 hour observation and inpatient surgical services.

1. DEFINITION OF BOARD ELIGIBLE. Board eligible implies that a physician has completed a training program approved by the specialty specific Residency Review Committee and is eligible to sit for that specialty's certifying examination. Individuals who are no longer eligible to sit for the certifying examination are not board eligible. *NOTE: Individuals trained outside the United States may have credentials equivalent to board eligibility, a fact to be considered and evaluated by the facility credentialing and privileging the provider.*

2. ASC FACILITY COMPLEXITY DESIGNATION REQUIREMENTS

a. **Basic Surgical Complexity.** A facility is designated a basic VHA ASC Program when the following infrastructure is readily available:

(1) Pre-operative and Post-operative Diagnostic Evaluation

- (a) Electrocardiogram (EKG). Available within 30 minutes during hours of operation.
- (b) Basic Laboratory. Available within 30 minutes during hours of operation.
- (c) Basic Radiology. Available within 30 minutes during hours of operation.

(2) Pre-operative Risk Assessment and Post-operative Consultation and Services

(a) Anesthesia Pre-operative Assessment. Available during hours of operation, may be provided by Certified Registered Nurse Anesthetist (CRNA), or appropriately trained advanced nurse practitioner or physician assistant.

(b) Post-operative General Surgery Surgical Consultation. Available within 15 minutes by phone and 60 minutes in person, during the hours of operation.

(3) Surgical Physician Staffing

(a) General Surgeon. One Full-Time Equivalent (FTE) employee, board eligible or certified, who may be provided by contract.

(b) Specialty Surgeon. Variable depending upon the clinical services offered.

VHA DIRECTIVE 2011-037

October 14, 2011

(4) Operating Room (OR)

(a) Staffing. Each facility OR must meet the minimum staffing requirement to include a circulating Registered Nurse (RN), scrub technician or Registered Nurse (RN). A policy or protocol defining training and competencies consistent with the Association of Operating Room Nurses (AORN) and the Association of Surgical Technicians (AST) must be maintained.

(b) Instrument Sets. There must be a duplication of all major instrument sets, including one vascular set available for emergency use.

(c) Equipment required in each OR. There must be suction, an electrocautery unit, an anesthesia machine, and the capability for basic physiological monitoring including EKG, end-tidal carbon dioxide (CO₂), and pulse oximetry. At all times, there must be at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures.

(d) Equipment required for the OR Area. There must be a code cart and defibrillator, flash sterilizer, and intra-operative c-arm in the OR.

(e) Radiology. There must be a Radiology Technician on call, available within 30 minutes during the hours of operation.

(5) Anesthesia Services

(a) Provider. Anesthesiologist or CRNA.

(b) Assistance. There must be a written plan or policy for the physician provider skilled in airway management, as necessary.

(c) Coverage. Coverage must be available within 30 minutes during the hours of operation.

(6) Post Anesthesia Care Unit (PACU)

(a) Area. There must be a designated PACU or equivalent.

(b) Phase I PACU Staffing: Minimum staffing of two licensed providers with a 1 to 1 provider to patient ratio as required, consistent with the American Society of Peri-Anesthesia Nursing (ASPAN) guidelines.

(c) Phase II PACU Staffing: There must be a registered nurse with demonstrated competencies available, consistent with ASPAN guidelines.

(d) Discharge Guidelines. Patients must be discharged from the Phase I PACU and Phase II PACU based upon a defined protocol.

(7) **Support Services**

(a) Pharmacy. Pharmacy Services must be available within 15 minutes by phone, and within 60 minutes on site during the hours of operation.

(b) Blood Bank. There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes during the hours of operation.

(c) Social Work. Social Work must be available within 15 minutes by phone, and within 60 minutes on site during hours of operation.

(8) **Supply, Processing, and Distribution (SPD)**

(a) Availability. Sterile instrument sets must be available on site for all scheduled procedures.

(b) Equipment. There must be a flash sterilizer available with competent personnel during hours of operation.

(9) **Back-up 23 Hour Observation and In-patient Surgical Services**. Protocols to transfer patients within 60 minutes to a VHA acute care facility with an Inpatient Surgery Program or community provider must be established through Memorandums of Understanding. **NOTE:** *Timeliness of patient transfer in any given situation is dictated by the clinical condition of the patient.*

b. **Advanced Surgical Complexity**. A facility is designated an advanced VHA Ambulatory Surgery Program when the following infrastructure is made available:

(1) **Pre-operative and Post-operative Diagnostic Evaluation**

(a) Electrocardiogram (EKG). Available within 30 minutes during the hours of operation.

(b) Basic Laboratory. Available within 30 minutes during the hours of operation.

(c) Basic Radiology. Available within 30 minutes during the hours of operation.

(d) Radiology Interpretation. Available within 30 minutes during the hours of operation.

(2) **Pre-operative Risk Assessment and Post-operative Consultation and Services**

(a) Anesthesia Pre-operative Assessment. Available during the hours of operation, may be provided by Certified Registered Nurse Anesthetist (CRNA) or appropriately trained advanced nurse practitioner or physician assistant.

(b) General Surgery Surgical Consultation. Available on-site during the hours of operation.

VHA DIRECTIVE 2011-037

October 14, 2011

(c) Medical Consultation. Available within 15 minutes by phone, and within 60 minutes in person during the hours of operation.

(d) Specialty Consultation. Cardiology and Vascular Surgery within 15 minutes by phone and within 60 minutes in person, during the hours of operation.

(3) **Surgical Physician Staffing**

(a) General Surgeon. There must be two or more FTE employees, who may be provided by contract. At least one must be board eligible or certified.

(b) Specialty Surgeon. Variable depending upon the clinical services offered.

(c) Surgical Assistant. Available within 60 minutes during the hours of operation.

(4) **Operating Room (OR)**

(a) Staffing. There must be:

1. There must be a minimum staffing to include a circulating Registered Nurse (RN) and scrub technician or RN. A policy or protocol defining training and competencies consistent with the AORN and the AST must be maintained.

2. Staff competencies for specialty specific surgery.

3. A plan or policy for staffing based upon procedural complexity.

4. A plan or policy for supplemental staffing for intra-operative emergencies.

(b) Instrument Sets. There must be a duplication of all major instrument sets, including one vascular set available for emergency purpose.

(c) Equipment required in each OR. There must be suction, an electrocautery unit, an anesthesia machine, the capability for basic physiological monitoring including EKG, end-tidal carbon dioxide (CO₂), and pulse oximetry. There must be at all times at least one functioning anesthesia machine in excess to the number of operating rooms scheduled for procedures.

(d) Equipment required for the OR Area. There must be a code cart and defibrillator, flash sterilizer, and an intraoperative c-arm.

(e) Radiology. There must be a Radiology Technician on call, available within 30 minutes during the hours of operation.

(5) **Anesthesia Services**

(a) Anesthesiologist. There must be one or more FTE employees, board eligible or certified anesthesiologist on site during hours of operation.

(b) Provider. There must be an Anesthesiologist or CRNA available for all cases.

(6) Post Anesthesia Care Unit (PACU)

(a) Area. There must be a designated PACU or equivalent.

(b) Phase I PACU Staffing. Minimum staffing of two licensed providers with a 1 to 1 provider to patient ratio as required, consistent with the ASPAN guidelines.

(c) Phase II PACU Staffing: There must be a RN with demonstrated competencies available, consistent with ASPAN guidelines.

(d) Discharge Guidelines. Patients must be discharged from the Phase 1 PACU and Phase II PACU based upon a defined protocol.

(6) Support Services

(a) Pharmacy. Pharmacy Services must be available on site during the hours of operation.

(b) Blood Bank. There must be packed red blood cells, fresh frozen plasma, and platelets available within 60 minutes during hours of operation.

(c) Social Work. A Social Worker must be available within 15 minutes by phone, and within 60 minutes on-site during the hours of operation.

(7) Supply, Processing, and Distribution (SPD)

(a) Availability. Sterile instrument sets must be available on site for all scheduled procedures.

(b) Equipment. There must be a flash sterilizer available with competent personnel during the hours of operation.

(8) Back-up 23 hour Observation and In-patient Surgical Services. Transfer to VHA acute care facility with an intermediate or complex inpatient Surgical Program (see current VHA policy) or equivalent community provider through established memorandum of understanding within 60 minutes. ***NOTE:** Timeliness of patient transfer in any given situation is dictated by clinical condition of the patient.*

ATTACHMENT B

AMBULATORY SURGERY COMPLEXITY MATRIX

1. The Ambulatory Surgery Complexity Matrix (ASCM) is the assignment of each surgery procedure by Current Procedure Terminology (CPT) code to an operative complexity designation of basic or advanced. Alternatively, the National Surgery Office has made available a Web-based tool, the CPT Look-Up, to allow any individual with Intranet access to identify the complexity assignment for any individual surgical procedure, available at:

<http://vaww.medicalsurgical.va.gov/surgery/index.asp>. **NOTE:** *This tool identifies procedures that must not be performed in an ASC. This is an internal Web site and is not available to the public.*

2. To provide a visual framework for classification of surgical procedures to operative complexity category, the following table is included in this document. **NOTE:** *Only samplings of surgical procedures are identified by surgical specialty.*

Procedure Category	Basic	Advanced
Amputation - Basic	Amputation, upper extremity, forearm, hand or digit; lower extremity, foot and digit	
Breast - Basic	Aspiration, cyst; drainage, abscess; biopsy or excision, breast lesion	
Breast - Advanced	Mastectomy	
Ear, Nose, and Throat (ENT) - Basic	Biopsy, soft tissue lesion or lymph node, head and neck; Biopsy throat; Excision, intranasal polyps or lesions or turbinates; septoplasty; repair of nasal defects; treatment of nasal fractures; treatment of nosebleeds; sinus surgery; nasal or sinus endoscopy with biopsy, polypectomy, debridement; laryngoscopy with biopsy or foreign body removal; drainage, biopsy, excision, repair of lip or mouth or tongue or gum or salivary, submaxillary, sublingual glands or external ear; excision neck cyst; construction of tracheoesophageal fistula for speech prosthesis; cleft lip repair; partial thyroidectomy; mastoidectomy; reconstruction of the external ear; tympanic membrane repair; myringoplasty	
ENT - Advanced	Drainage, deep abscess, neck; radiofrequency ablation base of tongue; sinus surgery--obliteration; palate reconstruction; oral vestibuloplasty-posterior; hemiglossectomy; uvulopalatopharyngoplasty; radical parotidectomy	
Eye - Basic	Blepharoplasty, corneal biopsy, cataract removal with lens insertion, vitrectomy, repair of ectropion	
Eye - Advanced	Enucleation of eye, insertion of ocular implant, repair of retinal detachment, strabismus surgery	
Facial - Basic	Treatment of nasal fracture, closed	
Facial - Advanced	Arthrotomy, Temporomandibular Joint and Muscle Disorders (TMJ); excision of tumor, benign or malignant, facial bones; preparation, facial prosthesis; Maxillofacial fixation; repair or revision or reconstruction, facial bones; Treatment of nasal fracture, open; treatment of complex fracture, nasal or maxillary or zygomatic arch or orbit, open or closed; Treatment of fracture,	

VHA DIRECTIVE 2011-037

October 14, 2011

Procedure Category	Basic	Advanced
	palatal or maxillary or mandibular; Arthroscopy, jaw; Complex surgery, nose	
Foot - Basic	Incision; Excision; Repair; Revision; Reconstruction; Fracture; Dislocation; Arthrodesis; or Amputation of the foot and ankle	
General Surgery (GS) -Basic	Biopsy skin or soft tissue or muscle or nerve or lymph nodes; Hernia repair, inguinal, femoral or umbilical, open or laparoscopic; drainage, rectal abscess	
GS - Advanced	Gastrostomy, jejunostomy, open or laparoscopic; laparoscopic cholecystectomy; open or laparoscopic ventral hernia repair	
General Urology (GU) - Basic	Kidney biopsy, percutaneous; Cystoscopy and renal endoscopy; Ureteral endoscopy, procedures or treatment; lithotripsy; placement of suprapubic catheter; urodynamics; cystoscopy, procedures or treatment; Urethral surgery, dilatation or repair or treatment of lesions; biopsy or excision or repair of penis; circumcision; penile prosthesis, placement or removal; orchiectomy; biopsy or exploration or removal of the testes, epididymis, scrotum; vasectomy; hydrocele, drainage or repair or excision prostate, biopsy or ultrasound	
GU - Advanced	Transurethral resection prostate; laparoscopic orchiectomy	
Gynecology - Basic	Pelvic exam under anesthesia; vaginal biopsy or excision or destruction of lesion; placement of Intrauterine Device (IUD), I & D perineal abscess; colposcopy; hysterosalpingography; hysteroscopy; amniocentesis; treatment of the cervix, including dilatation; superficial abscess or lesion; laser or chemical destruction of vulvar lesion; biopsy or excision vulva	
Gynecology - Advanced	Vulvectomy, anterior or posterior colporrhaphy, fallopian tube ligation or transaction, oophorectomy	
Hand - Basic	Incision; excision; repair; revision; reconstruction; fracture; dislocation; arthrodesis, forearm or wrist or hand or digits	
Ortho - Basic	Debridement skin or muscle or bone; bone biopsy, open or excisional or percutaneous; injection, tendon or ligament; drainage or injection, joint, bursa; placement or removal, fixation device; removal, implant or wire or pin or rod (except for long bone implants); Harvest of tendon or cartilage for transplant; I & D, shoulder: biopsy or excision, soft tissue lesion shoulder; excision or curettage, bone lesion or foreign body; muscle transfer or tenotomy, shoulder; humerus, nailing or plating or pinning or wiring; clavicular fracture, closed treatment; treatment, humerus fracture; treatment shoulder dislocation, closed; surgery of the arm or elbow; surgery of tendons or ligaments, upper extremity; Fractures of the upper extremity; soft tissue surgery of the hip; hip dislocation, closed reduction; Soft tissue surgery, thigh; Surgery knee, not including arthroplasty; Curettage, femur; Thigh fracture, closed treatment; treatment of patellar and knee fracture; treatment of fracture or dislocation of the leg and ankle; Casting or splint	
Ortho - Advanced	Ablation of bone tumor; clavectomy; Open repair of proximal humeral fracture; open treatment of shoulder dislocation; arthroplasty radial head; ligamentous reconstruction of the knee	

VHA DIRECTIVE 2011-037
October 14, 2011

Procedure Category	Basic	Advanced
Plastic-Basic	Breast implant placement, local skin flaps <5cm; skin grafting <100 sq. cm	
Plastic or Reconstructive - Advanced	Fascia or muscle graft for face nerve palsy; excision excessive skin or subcutaneous tissue, face or trunk or extremity, including liposuction	
Proctology - Basic	Treatment of pilonidal cyst, rectal lesion, rectal abscess, anal fissure, hemorrhoids, anal fistula; anoscopy	
Skin or Subcutaneous Tissue - Basic	Incision, drainage, removal, abscess or foreign body or hematoma; debridement, skin, subcutaneous tissue, muscle, bone; paring callus; biopsy, skin lesion; Remove, skin tags; shave, skin lesions; excision, skin lesion, benign or malignant; excision, hidradentiis, axillary or inguinal or perineal; Excision, skin lesion, benign or malignant; Surgery of the nails or nail bed; Introduction or removal, tissue expanders; Insertion or removal, drug delivery system; Simple or complex or layer closure, wounds; Skin grafts, autografts or allografts or xenograft; dermabrasion, chemical peel, simple facial plastic surgery; Removal excessive skin; destruction lesion, laser or electrosurgery or cryosurgery or chemosurgery; Incision, abscess	
Spine - Advanced	Incision or drainage, deep abcess, cervical, thoracic, lumbar spine; excision or osteotomy, cervical, thoracic, lumbar spine; spinal fracture, closed or open treatment; vertebroplasty; kyphoplasty; arthrodesis, cervical, thoracic, lumbar spine; laminectomy for exploration or decompression or excision; Implantation or removal of spinal catheter or neurostimulator	
Thoracic- Basic	Bronchoscopy; chest tube placement; thoracentesis; percutaneous pleural biopsy	
Thoracic - Advanced	Pacemaker placement; implantable defibrillator placement	
Vascular- Basic	Central venous access; arteriovenous fistula, primary or graft; endovenous ablation; sclerotherapy	
Vascular-Advanced	Venous excision	