

FACILITY PROCEDURE COMPLEXITY DESIGNATION REQUIREMENTS TO PERFORM INVASIVE PROCEDURES IN ANY CLINICAL SETTING

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy and guidance regarding the infrastructure requirements for Department of Veterans Affairs (VA) medical facilities performing invasive procedures in any clinical setting, and the complexity of the invasive procedures being performed, as well as the method for monitoring compliance. This VHA directive also establishes the Procedure Infrastructure Matrix (PIM) assigning VA medical facility infrastructure requirements to perform a procedure and the Invasive Procedure Complexity Matrix (IPCM) assigning a complexity designation to Current Procedural Terminology (CPT) codes, which together define the Invasive Procedure Complexity Model. The intent of the Invasive Procedure Complexity Model is to ensure that the VA medical facility infrastructure matches the complexity of the invasive procedures performed in any clinical setting.

2. SUMMARY OF MAJOR CHANGES: Major changes to this VHA directive include:

- a. Responsibilities regarding the infrastructure requirements for VA medical facilities performing invasive procedures in any clinical setting are updated; and
- b. Multiple levels of Invasive Procedure Complexity designations are established defining the requirements to perform the most basic outpatient invasive procedure in the clinic to the most complex surgical procedures in an operating room (OR).

3. RELATED ISSUES: VHA Directive 1073, Moderate Sedation by Non-Anesthesia Providers, dated December 31, 2014; VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016 and VHA Directive 1157(1), Out of Operating Room Airway Management, dated June 14, 2018.

4. RESPONSIBLE OFFICE: The Office of Specialty Care Services (10P11) and the National Surgery Office (10NC2) are responsible for the content of this VHA Directive. Questions may be directed to the Department of Veterans Affairs (VA) Office of Specialty Care Services (10P11) at 202-461-7120 or the National Surgery Office (10NC2) at 202-461-7130.

5. RESCISSIONS: VHA Directive 2011-037, Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center, dated October 14, 2011, and VHA Directive 2010-018 Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures, dated May 6, 2010, are rescinded.

6. RECERTIFICATION: This VHA Directive is scheduled for recertification on or before the last working day of May 2024. This VHA directive will continue to serve as national policy until it is recertified or rescinded.

CERTIFIED BY:

**BY DIRECTION OF THE UNDER
SECRETARY FOR HEALTH:**

/s/ Renee Oshinski
Acting Deputy Under Secretary for Health
for Operations and Management

/s/ Renee Oshinski
Acting Under Secretary for Health
for Operations and Management

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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FACILITY PROCEDURE COMPLEXITY DESIGNATION REQUIREMENTS TO PERFORM INVASIVE PROCEDURES IN ANY CLINICAL SETTING

1. PURPOSE

This Veterans Health Administration (VHA) directive updates policy and guidance regarding the infrastructure requirements for VA medical facilities performing invasive procedures in any clinical setting and the complexity of the procedures being performed, as well as the method for monitoring compliance. This VHA directive also updates the Procedure Infrastructure Matrix (PIM) assigning VA medical facility infrastructure requirements to perform a procedure and the Invasive Procedure Complexity Matrix (IPCM) assigning a complexity designation to Current Procedural Terminology (CPT) codes, which together define the Invasive Procedure Complexity Model. The intent of the Invasive Procedure Complexity Model is to ensure that the VA medical facility infrastructure matches the complexity of the invasive procedures performed in any clinical setting. **AUTHORITY:** Title 38 United States Code (U.S.C). 501 and 7301(b).

2. BACKGROUND

a. In 2010, the PIM was first published to ensure VA medical facilities with an approved VHA Inpatient Surgery Program were designated as Standard, Intermediate, or Complex based upon defined infrastructure criteria. Correspondingly, the Operative Complexity Matrix (OCM) was developed to assign a surgical complexity designation to each surgical procedure CPT code as Standard, Intermediate, or Complex.

b. In 2011, the PIM and OCM were expanded to VA medical facilities with an Ambulatory Surgery Center (ASC), thereby establishing the ASC Basic and ASC Advanced operative complexity designations.

c. For Fiscal Year (FY) 2017, the National Surgery Office (NSO) identified the incidence of a VHA Surgery Program performing an invasive procedure in an Operating Room (OR) beyond the operative complexity designation of the VA medical facility to be 0.1 percent.

d. In August 2017, the acting VHA Under Secretary for Health chartered a Work Group to develop policy and guidance that effectively modifies the PIM and the OCM to address all invasive procedures performed in any clinical setting.

3. DEFINITIONS

a. **Advanced Practice Provider.** Advanced Practice Providers (APPs) are qualified health care providers that work under the supervision of a licensed independent provider credentialed and privileged by the VA medical facility. APPs may include a Certified Registered Nurse Anesthetist (CRNA), a Nurse Practitioner (NP), or a Physician Assistant (PA). **NOTE:** *While NPs and CRNAs may practice as LIPs when permitted by state licensing requirements and the VA medical facility, they may also work under a scope of practice. This definition applies only to those NPs and CRNAs who are working under a scope of practice.*

b. **Ambulatory Procedure Center.** An Ambulatory Procedure Center (APC) within a VA medical facility may be established:

(1) As either Health Care Center (HCC) or other Outpatient Services Site per VHA Site Classifications and Definitions policy. **NOTE:** See paragraph 10, References, for details.

(2) Within a VA hospital or medical facility without an established VHA Inpatient Invasive Procedure Program. **NOTE:** See paragraph 10, References, for details.

(3) At a VA hospital or medical facility campus with an Inpatient Surgery Program if community paramedics are used to respond to emergencies, according to current VHA policy on Out-of-Operating Room Airway Management.

c. **Ambulatory Procedure Center Advanced.** APC Advanced is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

d. **Ambulatory Procedure Center Basic.** An APC Basic is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

e. **Board-Eligible Physician.** A board-eligible 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. Physicians who are no longer eligible to sit for the certifying examination are not board-eligible. **NOTE:** Physicians trained outside the United States may have credentials equivalent to board-eligibility, a fact to be considered and evaluated by the VA medical facility credentialing and privileging the provider. **NOTE:** See paragraph 10, References, for details.

f. **Inpatient Complex.** Inpatient Complex is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

g. **Inpatient Intermediate.** Inpatient Intermediate is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

h. **Inpatient Standard.** Inpatient Standard is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

i. **Intensivist.** An intensivist is a licensed independent practitioner (LIP) who specializes and is credentialed in the care of critically ill patients. An intensivist may have certification in a variety of surgical and medical-based specialties including anesthesia, critical care, emergency medicine, internal medicine and its subspecialties, and surgery and its subspecialties.

j. **Invasive Procedure.** For the purpose of this policy, invasive procedures are those procedures that require signature informed consent and involve a skin incision or puncture, or endoscopy, and includes but is not limited to: open surgical procedures, percutaneous aspiration, selected injections, biopsy, percutaneous cardiac and vascular diagnostic or interventional procedures, laparoscopies, and endoscopies. **NOTE:** *This policy applies to invasive procedures performed in and outside of the operating room but does not apply to venipuncture or intravenous therapy in any setting. See paragraph 10, References, for details.*

k. **Licensed Independent Practitioner.** A licensed independent practitioner (LIP) is any individual credentialed and privileged by the VA medical facility to provide patient care services independently, i.e., without supervision or direction, within the scope of the individual's license, and in accordance with individually-granted clinical privileges.

l. **Memorandum of Understanding.** For the purpose of the PIM, a Memorandum of Understanding (MOU) merely states the protocol for transfer between the VA medical facility and the facility performing a procedure. The MOU must not contain language specific to the ordering of services and thereby cannot obligate the VA to a payment for purchased services. The MOU must be in writing and signed by the VA medical facility Director and the Chief Officer of the outside facility.

m. **Operating Room.** An Operating Room (OR) is a room that meets the criteria for operating room design and construction as specified in the VA Construction and Facilities Management Surgical and Endovascular Services Design Guide and is actively being used for patient care and treatment to include the performance of invasive procedures. **NOTE:** *See paragraph 10, References, for details.*

n. **Outpatient Basic.** Outpatient Basic is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

o. **Outpatient Intermediate.** Outpatient Intermediate is an Invasive Procedure Complexity designation of a VA medical facility meeting all the necessary infrastructure requirements specified by the PIM for this designation, as certified by the VISN Network Director and approved by the VHA Under Secretary for Health.

p. **Post-Anesthesia Care Unit.** The Post Anesthesia Care Unit (PACU) is an area dedicated to receiving patients following general anesthesia, regional anesthesia, or monitored anesthesia care for Phase I and Phase II recovery. 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 next level of care or home. Phase I PACU and Phase II PACU may be combined.

q. **Procedure Room.** A procedure room is a room that does not meet the criteria for operating room design and construction as specified in the VA Construction and Facilities Management Surgical and Endovascular Services Design Guide and is actively being used for patient care and treatment to include the performance of invasive procedures.

r. **Surgical or Procedural Assistant.** Surgical or procedural assistants are appropriately trained personnel who provide aid in exposure, hemostasis, closure, and other intra-procedural technical functions that help the LIP to efficiently and safely carry out an invasive procedure.

s. **Surgical Procedure.** A surgical procedure is an invasive procedure performed by qualified providers in an OR when staffed or supported by OR nursing staff. This includes surgical or invasive diagnostic procedures performed outside of the surgical suite when routinely supported by operating room nursing staff (examples include: interventional radiology, cystoscopy suite, procedure room).

t. **VA Surgical Quality Improvement Program Eligible Procedure.** A VA Surgical Quality Improvement Program (VASQIP) eligible procedure is an invasive procedure, identified by a CPT code, which is associated with a measurable morbidity or mortality outcome such that the invasive procedure contributes to a model for risk assessment as determined by the NSO.

4. POLICY

It is VHA policy that each VA medical facility performing invasive procedures in any clinical setting has an Invasive Procedure Complexity designation and that the scheduled (non-emergent) procedures performed do not exceed the infrastructure capabilities of the facility. ***NOTE: This policy does not interfere with performance of an emergency or unplanned invasive procedure where the patient's best interest is served by care and treatment onsite rather than through transfer to a more complex facility.***

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Assigning an Invasive Procedure Complexity designation to each VA medical facility performing invasive procedures based upon the PIM.

b. **Deputy Under Secretary for Health Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN director has sufficient resources to fulfill the terms of this directive in all the VA medical facilities within that VISN; and

(3) Providing oversight of VISNs to assure compliance with all applicable statutes, regulations, and VA and VHA policies.

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for:

(1) Collaborating with Deputy Under Secretary for Health for Operations and Management regarding communication of the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Collaborating with Deputy Under Secretary for Health for Operations and Management regarding oversight of VISNs to assure compliance with all applicable statutes, regulations, and VA and VHA policies.

d. **Chief Officer, Specialty Care Services and National Director of Surgery.** The Chief Officer, Specialty Care Services (COSCS) and National Director of Surgery (NDS) are responsible for:

(1) Assigning facility infrastructure requirements, to the following VA medical facility Invasive Procedure Complexity designations in the PIM:

- (a) Outpatient Basic,
- (b) Outpatient Intermediate,
- (c) APC Basic,
- (d) Inpatient Standard,
- (e) APC Advanced,
- (f) Inpatient Intermediate, and
- (g) Inpatient Complex.

(2) Verifying the content of the IPCM.

(3) Reviewing the PIM and IPCM annually. In performing this review, the COSCS and NDS consider the standard of care, outcomes data, the emergence of new technology, modifications to the CPT codes, and input from the Specialty Care Services Field Advisory Committees (FACs) and the NSO Surgical Advisory Boards (SABs).

(4) Providing notification to the Office of the Deputy Under Secretary for Health for Operations and Management and VISN Leadership located within the VISN offices of any modification to the PIM and the IPCM.

(5) Monitoring and reporting to the VISN and VA medical facility any invasive procedure performed beyond the Invasive Procedure Complexity designation of the VA facility.

(6) Reviewing all information submitted for a VA medical facility infrastructure waiver request and providing approval when a component of VA medical facility PIM requirements is provided onsite at the VA medical facility. **NOTE:** *The COSCS and NDS must both approve and sign off on all waiver requests to be final.*

e. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that each VA medical facility in the VISN performing invasive procedures has an Invasive Procedure Complexity designation based upon analysis of the PIM requirements.

(2) When a change in VA medical facility Invasive Procedure Complexity designation is anticipated or realized, ensuring compliance with VHA policy regarding Restructuring of VHA Clinical Programs with regards to appropriate documentation and procedures. **NOTE:** *For example, an Inpatient Intermediate program adding additional resources may request an Inpatient Complex designation. Alternatively, the loss of key medical staff members may require an Inpatient Intermediate facility to request a change in Invasive Procedure Complexity designation to Inpatient Standard.*

(3) Submitting reviewed and endorsed waiver requests to both the Office of Specialty Care Services (SCS) and the NSO for approval when a component of PIM requirements is not provided onsite at the VA medical facility.

(a) Waivers to the PIM may be granted in the following circumstances:

1. When any of the following infrastructure requirements are provided offsite: Interventional Cardiology, Interventional Neuroradiology, Magnetic Resonance Imaging and Magnetic Resonance Angiography, Non-vascular Interventional Radiology, or Vascular Interventional Radiology; or

2. When any deficient component of the PIM has undergone risk assessment with the determination that the benefit outweighs the risk using the Healthcare Failure Mode Effect Analysis (HFMEA) process as described by National Center of Patient Safety, <http://vaww.ncps.med.va.gov/index.html>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(b) Waivers must be signed by the VISN Network Director and must include each of the following six components:

1. The component of the PIM for which the waiver is requested;
2. The name of the facility performing the procedure;

3. The travel distance between the VA medical facility and the facility performing the procedure if applicable;

4. A copy of the document in which protocol for transfer between the VA medical facility and the facility performing the procedure, if applicable, is established. The protocol for transfer must be agreed to in writing between the VA medical facility and the facility performing a procedure, and may exist in a MOU or a contract. The agreement must be signed by the VA medical facility Director and the Chief Officer of the outside facility. Where the agreement takes the form of a MOU the facility must also have a federal acquisition-based contract in place in order to authorize and purchase the services contemplated by the MOU using community care. Where the agreement on protocol for transfer is stated in a contract, this document can stand alone without an MOU. **NOTE:** *VA medical facilities should utilize national contracts available for purchasing this care. If the care is not available on the national contract and a local contract is needed, the VA medical facility must work through the network contracting office to follow the appropriate process for local contracts.*

5. A plan for monitoring and reviewing the quality of care being provided; and

6. A detailed analysis of the Risk Assessment, if applicable.

(4) Certifying an annual review of VA medical facility Invasive Procedure Complexity Designations for each VA medical facility performing invasive procedures in relationship to available infrastructure (i.e. PIM).

f. **Chief Medical Officer, Veterans Integrated Service Network Chief Surgical Consultant and Veterans Integrated Service Network Specialty Care Medicine Lead.** The Chief Medical Officer (CMO), VISN Chief Surgical Consultant (VCSC) and VISN Specialty Care Medical Lead (VSCML) are responsible for facilitating compliance with this policy through the following:

(1) Providing notification to the Office of SCS and the NSO of any VA medical facility non-compliant with PIM requirements commensurate with the VA medical facility Invasive Procedure Complexity designation.

(2) Ensuring that the VA medical facility with a PIM deficiency has an action plan and timeline for resolution.

(3) Reviewing at least quarterly the details of any invasive procedure performed beyond the Invasive Procedure Complexity designation of the VA medical facility.

(4) Certifying an annual review of VA medical facility Invasive Procedure Complexity designations for each VA medical facility performing invasive procedures in relationship to available infrastructure (i.e. PIM).

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that the infrastructure requirements for the VA medical facility, as identified by the PIM, are accounted for and communicated to the VISN Network Director.

(2) Ensuring that the scope of the invasive procedures being performed in the VA medical facility is within the approved Invasive Procedure Complexity designation and infrastructure requirements of the VA medical facility.

(3) Ensuring that the VISN Director is notified if, and when, there is a failure to maintain the infrastructure appropriate for the Invasive Procedure Complexity designation of the VA medical facility.

(4) Initiating a request to modify the Invasive Procedure Complexity designation in accordance with current VHA policy regarding Restructuring of VHA Clinical Programs, when the VA medical facility infrastructure significantly changes. **NOTE:** *A deficiency in any component of the PIM requirements must have an action plan and timeline for resolution of less than 6 months from the time the deficiency was identified.*

(5) Establishing a local guidance document or standard operating procedure for identifying and documenting Invasive Procedure Complexity designation if the VA medical facility has required infrastructure for the highest complexity available only on a scheduled basis less than 24/7 (see responsibilities of Service Chiefs below).

(6) Certifying an annual review of VA medical facility Invasive Procedure Complexity Designations for each VA medical facility performing invasive procedures in relationship to available infrastructure (i.e. PIM).

h. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for:

(1) Ensuring that all scheduled (non-emergent) invasive procedures performed are within the scope of the facility Invasive Procedure Complexity designation for each specific site of care (inpatient facility, HCC, Community Based Outpatient Clinical (CBOC), etc.).

(2) Reviewing any procedure performed beyond the VA medical facility Invasive Procedure Complexity designation.

(3) Reviewing any concern regarding a Veteran having received or requiring a level of care beyond the Invasive Procedure Complexity Designation of the VA medical facility.

i. **VA Medical Facility Service Chiefs.** The VA medical facility Service Chiefs are responsible for:

(1) Ensuring that all scheduled invasive procedures performed within their service line are within the scope of the VA medical facility Invasive Procedure Complexity designation.

(2) Ensuring documentation in the electronic medical record that all infrastructure requirements are met prior to initiation of the invasive procedure if the VA medical facility has an Invasive Procedure Complexity designation but only has required infrastructure for the highest complexity available on a scheduled basis less than 24/7. For example: the VA medical facility designated Inpatient Intermediate complexity which has only the necessary inpatient intermediate infrastructure on a scheduled basis from Monday to Wednesday is required to document in the electronic medical record documentation for all patients receiving an Inpatient Intermediate procedure that all required Inpatient Intermediate infrastructure is available at the time of the procedure.

(3) Reviewing any procedure performed within their service line that is beyond the facility Invasive Procedure Complexity designation.

(4) Notifying the VA medical facility Chief of Staff or designee if applicable, the medical facility Director, and the VCSC or VSCML of any identified deficiencies in relationship to the facility Invasive Procedure Complexity designation.

(5) Ensuring an identified PIM deficiency has an action plan and timeline for resolution, which is variable and can be more than 6 months even when being addressed in good-faith due to contracting, purchasing, hiring, etc.

(6) Notifying the VA medical facility Chief of Staff and the VCSC or VSCML of any concern regarding a Veteran having received or requiring a level of care beyond the Invasive Procedure Complexity designation for the VA medical facility.

(7) Performing and certifying an annual review of VA medical facility Invasive Procedure Complexity Designations for each VA medical facility performing invasive procedures in relationship to available infrastructure (i.e. PIM). **NOTE:** *If the VA medical facility does not have the appropriate Service Chief, these duties are delegated to the Chief of Staff or VA medical facility designee.*

6. INVASIVE PROCEDURE COMPLEXITY MATRIX

a. The Invasive Procedure Complexity Matrix (IPCM) defines the invasive procedures by Current Procedural Terminology (CPT) code that can be performed in a procedure room or an OR in relationship to the VA medical facility Invasive Procedure Complexity designation.

b. The table below identifies the categories assigned by the IPCM and the VA medical facility Invasive Procedure Complexity designations able to schedule elective invasive procedures by CPT code assignment.

c. Invasive Procedure Complexity Matrix (IPCM) table references are as follows:

(1) Outpatient Basic (Outpt Basic)

(2) Outpatient Intermediate (Outpt Inter)

(3) Ambulatory Procedure Center Basic (APC Basic)

- (4) Inpatient Standard (Inpt Std)
- (5) Ambulatory Procedure Center Advanced (APC Adv)
- (6) Inpatient Intermediate (Inpt Inter)
- (7) Inpatient Complex (Inpt Comp)

		Invasive Procedure Complexity Matrix (IPCM)						
		Outpt Basic	Outpt Inter	APC Basic	Inpt Std	APC Adv	Inpt Inter	Inpt Comp
VA Medical Facility Invasive Procedure Complexity Designation	Outpt Basic	X						
	Outpt Inter	X	X					
	APC Basic	X	X	X				
	Inpt Std	X	X	X	X			
	APC Adv	X	X	X	X	X		
	Inpt Inter	X	X	X	X	X	X	
	Inpt Comp	X	X	X	X	X	X	X

d. The current IPCM can be found on the NSO intranet website page entitled Operative Complexity & Current Procedural Terminology (CPT) Lookup: <https://vaww.nso.med.va.gov/apps/VASQIP/SitePages/CPTLookup.aspx>. **NOTE:** This is an internal Web site that is not available to the public.

e. Veterans Affairs Surgical Quality Improvement Program (VASQIP) eligible procedures must be performed in an operating room by a VA medical facility with ASC Basic Procedure Complexity designation or greater. The NSO identifies VASQIP eligible procedures with the Operative Complexity & CPT Lookup available at <https://vaww.nso.med.va.gov/apps/VASQIP/SitePages/CPTLookup.aspx>. **NOTE:** This is an internal Web site that is not available to the public.

f. The following statements and examples assist in understanding the PIM elements that influence an IPCM designation:

(1) **Outpatient Basic (Bedside/Clinic/Minor Procedure).** Outpatient basic procedures are performed at the bedside or in the clinic or other ambulatory setting. A procedure room is not required. Outpatient basic procedures can be performed with minimal sedation and/or application of local anesthetics. Examples: arthrocentesis, acupuncture, paracentesis, thoracentesis, laryngoscopy, cystoscopy, and cryotherapy for dermatologic purposes. **NOTE:** See paragraph 10, References, for details.

(2) **Outpatient Intermediate (Moderate Sedation)**. Outpatient intermediate procedures involve the administration of moderate/conscious sedation but do not require on-site anesthesia support. Examples: colonoscopy, bronchoscopy, and upper endoscopy. **NOTE:** See paragraph 10, References, for details.

(3) **APC Basic**. APC Basic invasive procedures are performed in an ambulatory setting with available anesthesia services and readily available (fewer than 60 min) back-up of observation beds and inpatient invasive services. Available support services including supply processing service, radiology, blood bank and pharmacy. Examples of APC invasive procedures include intra-ocular lens implant procedures, amputation of a digit, breast biopsy, open or laparoscopic inguinal hernia repair, vasectomy, and arteriovenous fistula creation.

(4) **Inpatient Standard**. Inpatient standard invasive procedures are typically performed on a same day basis and require an ICU with the ability to provide hemodynamic monitoring and respiratory support of the patient delayed in recovering from general anesthesia; pharmacy and blood bank during weekday duty hours; an ED; and a physician call schedule to support the invasive services provided. Examples of inpatient standard invasive procedures are amputation lower extremity, appendectomy, tonsillectomy, cholecystectomy and cardiac pacemaker insertion.

(5) **APC Advanced**. APC advanced invasive procedures are performed routinely in an ambulatory setting with a readily available (fewer than 60 min) back-up of inpatient intermediate or complex invasive services; on-site anesthesia and immediately available cardiology and vascular surgery consultation; and on-site pharmacy services. Examples of APC advanced invasive procedures include mastectomy, laparoscopic cholecystectomy, and transurethral resection of prostate.

(6) **Inpatient Intermediate**. Inpatient intermediate invasive procedures require an ICU with a dedicated intensivist to make daily rounds and provide consultative services; the capability to monitor recovering patients on the ward; medical specialists and services available to care for anticipated complications and co-morbid conditions associated with intracavitary procedures and patients receiving these procedures including nephrology and dialysis, infectious disease, hematology/oncology, pulmonary, cardiology, interventional cardiology and interventional radiology; and immediately available clinicians privileged in thoracic and vascular surgery to respond to foreseeable complications. Examples of inpatient intermediate invasive procedures include head and neck cancer resection, pulmonary resection, bariatric surgery, colectomy, joint replacement, nephrectomy, abdominal aortic aneurysm repair, and lumbar laminectomy.

(7) **Inpatient Complex**. Inpatient complex invasive procedures require a dedicated critical care service providing 24/7 coverage and daily multidisciplinary rounds, specialized technology and board-certified specialists depending on the approved invasive programs, dedicated in-house 24/7 coverage of invasive patients and a readily available OR call team for emergency and salvage procedures. Examples of inpatient complex invasive procedures include radical neck dissection, craniotomy, coronary artery bypass grafting, thoracoabdominal aneurysm resection, Whipple's procedure, esophagectomy, and solid organ (e.g. heart, liver, lung and kidney) transplantation.

7. PROCEDURE INFRASTRUCTURE MATRIX REQUIREMENTS

a. VA medical facilities must have a written plan addressing all clinical sites where invasive procedures are performed that identifies the safe and timely transfer of the patient who requires treatment or therapy which the VA medical facility is unable to provide. Every effort must be made to medically stabilize the patient prior to transfer, a process which may include the timely performance of an invasive procedure beyond the scope of the VA medical facility's Invasive Procedure Complexity designation. For procedures performed on an outpatient (same-day) basis, every effort must be made by practitioners to select appropriate patients in relationship to the services provided at the VA medical facility and the distance and timeliness of back-up services.

b. A VA medical facility's invasive procedure complexity designation must be based on the established infrastructure. The complexity of the invasive procedures to be performed must not exceed this designation; however, the VA medical facility has the option and responsibility to limit (downgrade) the complexity of the invasive procedures to be performed when infrastructure components are unavailable on a temporary or scheduled basis. The VA medical facility must have all required infrastructure in accordance with the designation on a scheduled basis no less than one day a week. For example, a VA medical facility that meets all the infrastructure requirements for Inpatient Intermediate complexity but has vascular surgery coverage that is limited to only one day a week could be designated as Inpatient Intermediate complexity. On the one day per week when all Inpatient Intermediate infrastructure is present including vascular surgery, the VA medical facility would function at the intermediate level. The VA medical facility would limit invasive procedures to Inpatient Standard and lesser complexity designation on all other days when vascular coverage is not available.

(1) Outpatient Basic (Bedside/Clinic/Minor Procedure) Invasive Procedure Complexity. The following infrastructure is required for an Outpatient Basic Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation. No minimum infrastructure requirements.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services. No minimum infrastructure requirements.

(c) Physician Provider Staffing. Physician provider staffing is variable depending upon the clinical services offered. Services may be provided by an Advanced Practice Provider (APP) under an approved scope of practice.

(d) Procedure Room.

1. Staffing. No minimum infrastructure requirements.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Bedside/Clinic/Minor Procedure Room. No minimum infrastructure requirements.

4. Equipment Required for the Procedure Area. No minimum infrastructure requirements.

(e) Anesthesia Services. No minimum infrastructure requirements.

(f) Post Anesthesia Care Unit (PACU). No minimum infrastructure requirements

(g) Support Services. No minimum infrastructure requirements

(h) Sterile Processing Service (SPS). Disposable or sterile instrument sets and Reusable Medical Equipment must be available on-site as needed. **NOTE:** See *paragraph 10, References, for details.*

(i) Back-up Observation and Inpatient Services. No minimum infrastructure requirements. Emergency services may be provided by activating community Emergency Medical Services (EMS, 911).

(2) Outpatient Intermediate (Moderate Sedation) Invasive Procedure Complexity. The following infrastructure is required for an Outpatient Intermediate Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation. The following must be available within 60 minutes during hours of operation: Electrocardiogram (EKG).

(b) Pre-procedural Risk Assessment and Post-Procedural Consultation and Services. No minimum infrastructure requirements.

(c) Physician Provider Staffing. Physician provider staffing is variable depending upon the clinical services offered. Services may be provided by APP under an approved scope of practice.

(d) Procedure Room.

1. Staffing. Each Outpatient Intermediate procedure room must have available the following staff:

a. A qualified individual present in the room to monitor the patient in accordance with VHA policy on Moderate Sedation by Non-Anesthesia Providers.

b. Qualified staff to assist with performance of the procedure dependent on the type of procedure being performed.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring including continuous cardiac monitoring, and pulse oximetry.

4. Equipment Required for the Procedure Room Area. There must be a code cart and defibrillator.

(e) Anesthesia Services. No minimum infrastructure requirements.

(f) PACU.

1. Area. A PACU is not required, however an area must be designated to allow the patient to dress and receive discharge instructions prior to discharge to home.

2. Discharge Guidelines. Patients must be discharged based upon a defined protocol.

(g) Support Services.

1. Pharmacy. Necessary medications and supplies are required onsite during the hours of operation. Clinical Pharmacy consultative services must be available within 15 minutes by phone.

2. Social Work. A Social Worker must be available within 15 minutes by phone during hours of operation.

(h) SPS. Sterile instrument sets and Reusable Medical Equipment must be available on-site for all scheduled procedures. **NOTE:** See paragraph 10, References, for details.

(i) Back-up Observation and Inpatient Services. Protocols to transfer patients within 60 minutes to an inpatient VHA acute care facility or equivalent community provider must be established by a MOU. **NOTE:** *Timeliness of patient transfer in any given situation is dictated by the clinical condition of the patient. Emergency services may be provided by activating community EMS (911).*

(3) Ambulatory Procedure Center Basic Invasive Procedure Complexity. The following infrastructure is required for an APC Basic Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation. The following must be available within 60 minutes during hours of operation:

1. EKG.

2. Basic Laboratory.

3. Plain Film Radiography.

4. Radiology Interpretation.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services.

1. Anesthesia Pre-procedural Assessment. Anesthesia pre-procedural assessment must be available during hours of operation, to be provided by Anesthesiologist or APP.

2. Anesthesia Consultative Services. Anesthesia consultative services must be provided by Anesthesiologist or CRNA, within 30 minutes.

(c) Physician Staffing. Physician provider staffing is variable depending upon the clinical services offered.

(d) Procedure Room.

1. Staffing. Each procedure room must have available the following staff:

a. Anesthesia personnel present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthesia care.

b. Qualified staff to assist with performance of the procedure.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring, including continuous telemetry, pulse oximetry, and end-tidal carbon dioxide (CO₂). Anesthesia machine must be present in the procedure room when general anesthesia, regional anesthetics, or monitored anesthetic care is performed. An additional anesthesia machine must be readily available as backup.

4. Equipment Required for the Procedure Room Area. There must be a code cart, defibrillator, and malignant hyperthermia cart readily available. **NOTE: Malignant hyperthermia cart is only required to be readily available where general anesthesia is being performed.**

(e) Operating Room (OR).

1. Staffing. Each VA medical facility OR must meet the minimum staffing requirement to include a RN circulator or scrub person. Written guidelines defining training and competencies consistent with the Association of periOperative Registered Nurses (AORN) standards and Association of Surgical Technicians (AST) must be maintained.

2. Instrument Sets. There must be a duplication of all VA major instrument sets and no less than one vascular set available for emergency use. **NOTE: See paragraph 10, References, for details.**

3. 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 CO₂, and pulse oximetry.

4. Equipment Required for the OR Area. There must be a code cart, defibrillator, an intra-operative c-arm, malignant hyperthermia cart, difficult airway cart, and at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures. An Immediate Use Steam Sterilizer (IUSS) unit may be located in the OR area or in on-site SPS. Personnel trained and competent in the use of IUSS must be available during hours of operation. **NOTE:** See paragraph 10, References, for details about IUSS.

5. Radiology. There must be a Radiologic Technologist available on-site, during hours of operation.

(f) Anesthesia Services.

1. Anesthesia Provider Staff. There must be an Anesthesiologist or CRNA available for all invasive procedures requiring general anesthesia, regional anesthetics, and monitored anesthesia care.

2. Assistance. There must be a written plan for a qualified provider skilled in airway management to assist as needed.

(g) PACU.

1. Area. There must be a designated PACU or equivalent.

2. Phase I PACU Staffing. Minimum staffing of two RNs is required, one of whom is a RN competent in phase I perianesthesia nursing, with a 1-to-1 RN-to-patient ratio when required, consistent with the ASPAN practice recommendations.

3. Phase II PACU Staffing. Minimum staffing of two personnel, one of whom is a RN competent in phase II perianesthesia nursing consistent with ASPAN practice recommendations.

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

(h) Support Services.

1. Pharmacy. Necessary medications and supplies are required onsite during the hours of operation. Clinical Pharmacy consultative services must be available within 15 minutes by phone and within 60 minutes on-site during hours of operation.

2. Blood Bank. Blood Bank services, including blood and blood components, must be available within 60 minutes during hours of operation.

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

(i) SPS. Sterile instrument sets and Reusable Medical Equipment must be available on-site for all scheduled procedures. **NOTE:** See paragraph 10, References, for details.

(j) Back-up Observation and Inpatient Services. Protocols to transfer patients within 60 minutes to a VHA acute care facility with an Inpatient Invasive Procedure Complexity designation or equivalent community provider must be established by a MOU. **NOTE:** *Timeliness of patient transfer in any given situation is dictated by the clinical condition of the patient. Emergency services may be provided by activating community Emergency Medical Services (EMS, 911).*

(4) Inpatient Standard Invasive Procedure Complexity. The following infrastructure is required for an Inpatient Standard Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation. The following services must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes for the following services:

1. EKG.
2. Basic Laboratory.
3. Plain Film Radiography.
4. Radiology Interpretation.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services. The following services must be available on-site weekdays, dayshift; all other times available on-call within 15 minutes by phone and within 60 minutes on-site:

1. Anesthesia Pre-procedural Assessment. To be provided by Anesthesiologist or APP.
2. Anesthesia Consultative Services. Provided by Anesthesiologist or CRNA.
3. General Medicine Consultation.
4. General Surgery Consultation.

(c) Physician Staffing.

1. General Surgeon. There must be one board-certified or board-eligible Full Time Employee Equivalent (FTEE), who may be provided by contract.

2. Specialty Surgeons. Variable depending upon the clinical services offered.

3. Surgical Assistant. On-call 24/7 and available within 60 minutes on-site.

4. Inpatient Coverage. There must be qualified inpatient coverage in house for all inpatients. Specific requirements are addressed in VHA Handbook 1101.04, Medical Officer of the Day, dated February 6, 2019. There must be a formal call schedule with 24/7 coverage by attending surgeon physicians, fellows or residents in surgical discipline training programs, or trained Advanced Practice Providers, available on-call within 15 minutes by phone and within 60 minutes on-site. **NOTE:** Coverage cannot be provided by physician assigned to the Emergency Department or the Medical Officer of the Day.

(d) Procedure Room.

1. Staffing. Each procedure room must have available the following staff:

a. Anesthesia personnel present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthesia care.

b. Qualified staff to assist with performance of the procedure.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring, including continuous telemetry, pulse oximetry, and end-tidal carbon dioxide (CO₂). Anesthesia machine present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthetic care. An additional anesthesia machine must be readily available as backup.

4. Equipment Required for the Procedure Room Area. There must be a code cart, defibrillator, and malignant hyperthermia cart must be readily available. **NOTE:** Malignant hyperthermia cart is only required to be readily available where general anesthesia is being performed.

(e) Operating Room.

1. Staffing. There must be:

a. Minimum staffing to include a RN circulator and a scrub person. Written guidelines defining training and competencies consistent with the AORN standards and the AST must be maintained.

b. Staff competencies for specialty-specific surgery.

c. A written plan for staffing based upon invasive procedure complexity.

d. A written plan for supplemental staffing for intra-operative emergencies.

2. Instrument Sets. There must be a duplication of all VA major instrument sets and no less than one vascular set available for emergency use. **NOTE:** See paragraph 10, References, for details.

3. 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 CO₂, and pulse oximetry.

4. Equipment Required for the OR Area. There must be a code cart, defibrillator, an intra-operative c-arm, malignant hyperthermia cart, difficult airway cart, and at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures. An IUSS unit may be located in the OR area or in on-site SPS. Personnel trained and competent in the use of IUSS must be available whenever the OR is in use.

5. Coverage. There must be:

a. An on-call schedule for OR nursing staff assuring that they will be on-site, within 60 minutes.

b. An OR must be available for use at all times during off hours.

6. Radiology. There must be a Radiologic Technologist available for intra-operative radiography on-site during weekdays, dayshift; all other times available on-call and within 60 minutes on-site.

(f) Anesthesia Services.

1. Anesthesia Provider Staff. There must be a board-certified or board-eligible Anesthesiologist or CRNA available for all invasive procedures requiring general anesthesia, regional anesthetics, and monitored anesthesia care.

2. Assistance. There must be a written plan for a qualified provider skilled in airway management to assist as needed.

3. Coverage. There must be coverage on-site during weekdays, dayshift; all other times available on-call and within 60 minutes on-site.

(g) PACU.

1. Area. There must be a designated PACU. Written guidelines may require patients undergoing specific invasive procedures or requiring after-hours care to be directly transferred to the Intensive Care Unit (ICU).

2. Phase I PACU Staffing. Minimum staffing of two RNs is required, one of whom is a RN competent in Phase I perianesthesia nursing, with a 1-to-1 RN-to-patient ratio when required, consistent with the ASPAN practice recommendations.

3. Phase II PACU Staffing. There must be two competent personnel, one of whom is a RN competent in Phase II perianesthesia nursing consistent with ASPAN practice recommendations.

4. RN Competencies. RN competencies must include ventilator management and physiological monitoring. Patients who are directly transferred from the OR to the ICU and are in need of Phase I recovery must be cared for by RN staff competent in Phase I recovery.

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

(h) Intensive Care Unit.

1. ICU Level. Level 4 or Level 3 without Intensivist.

2. Medical Co-management of Surgical Patients. There must be a written plan in place that identifies the responsibilities of medicine and surgery service lines in the care and treatment of the patient recovering from an invasive procedure in the ICU.

(i) Ward. Nurse competencies must be in alignment with the types of invasive procedures being performed. In addition, there must be:

1. Telemetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by telemetry.

2. Pulse Oximetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by pulse oximetry.

(j) Support Services.

1. Respiratory Therapy. Respiratory therapy must be available on-site during weekdays, dayshift; all other times available on-call and within 60 minutes on-site. Service must be provided by a credentialed respiratory therapist.

2. Pharmacy. Pharmacy services must be available on-site 16 hours a day; all other times available on-call within 15 minutes by phone and within 60 minutes on-site.

3. Blood Bank. Blood Bank services, including blood and blood components, must be available 24/7 within 60 minutes.

4. Physical Therapy. Physical therapy services must be available on-site during weekdays, dayshift; weekends if necessary for specialty-specific recovery.

5. Pathology. There must be a capability for frozen section studies on-site during weekdays, dayshift.

6. Biomedical Engineering. Biomedical engineering must be available on-site during weekdays, dayshift.

(k) SPS. Sterile processing capability must be available on-site and sterile instrument sets and Reusable Medical Equipment must be available for all scheduled invasive procedures.

(l) Emergency Department (ED). The VA medical facility must have 24/7 ED services available on-site.

(5) Ambulatory Procedure Center Advanced Invasive Procedure Complexity. The following infrastructure is required for an APC Advanced Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation. The following must be available within 60 minutes during hours of operation:

1. EKG.
2. Basic Laboratory.
3. Plain Film Radiography.
4. Radiology Interpretation.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services.

1. Anesthesia Pre-procedural Assessment. Anesthesia pre-procedural assessment, to be provided by Anesthesiologist or APP, must be available during hours of operation.

2. Surgical Consultation.

a. General Surgery must be available on-site, during hours of operation.

b. Vascular Surgery must be available within 15 minutes by phone and within 60 minutes on-site, during hours of operation.

3. Medical Consultation. General Medicine must be available within 15 minutes by phone and within 60 minutes on-site, during hours of operation. Cardiology must be available within 15 minutes by phone, and on-site, or virtually, via telemedicine, within 60 minutes, during hours of operation.

4. Anesthesia Consultative Services. Anesthesia Consultative Services must be provided by Anesthesiologist or CRNA, within 30 minutes, during hours of operation.

(c) Physician Staffing.

1. General Surgeon. There must be one board-certified or board-eligible FTEE, who may be provided by contract.

2. Specialty Surgeon. Variable depending upon the clinical services offered.

3. Surgical Assistant. A surgical assistant must be available within 60 minutes on-site, during hours of operation.

(d) Procedure Room.

1. Staffing. Each procedure room must have available the following staff:

a. Qualified anesthesia personnel present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthesia care.

b. Qualified staff to assist with performance of the procedure.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring, including continuous telemetry, pulse oximetry, and end-tidal carbon dioxide (CO₂). Anesthesia machine present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthetic care. An additional anesthesia machine must be readily available as backup.

4. Equipment Required for the Procedure Room Area. There must be a code cart, defibrillator, and malignant hyperthermia cart must be readily available. **NOTE:** *Malignant hyperthermia cart is only required to be readily available where general anesthesia is being performed.*

(e) Operating Room.

1. Staffing. There must be:

a. Minimum staffing to include a RN circulator and a scrub person. Written guidelines defining training and competencies consistent with the AORN standards and the AST must be maintained.

b. Staff competencies for specialty-specific surgery.

c. A written plan for staffing based upon invasive procedure complexity.

d. A written plan for supplemental staffing for intra-operative emergencies.

2. Instrument Sets. There must be a duplication of all VA major instrument sets and no less than one vascular set available for emergency use. **NOTE:** *See paragraph 10, References, for details.*

3. 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 CO₂, and pulse oximetry.

4. Equipment Required for the OR Area. There must be a code cart, defibrillator, an intra-operative c-arm, malignant hyperthermia cart, difficult airway cart, and at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures. An IUSS unit may be located in the OR area or in on-site SPS. Personnel trained and competent in the use of IUSS must be available during hours of operation.

5. Radiology. There must be a Radiologic Technologist available on-site, during hours of operation.

(f) Anesthesia Services.

1. Anesthesia Provider Staff. There must be at least one board-certified or board-eligible Anesthesiologist on site during hours of operation. An Anesthesiologist or CRNA must be available for all invasive procedures requiring general anesthesia, regional anesthetics, and monitored anesthesia care.

2. Assistance. There must be a written plan for a qualified provider skilled in airway management to assist as needed.

(g) PACU.

1. Area. There must be a designated PACU.

2. Phase I PACU Staffing. Minimum staffing of two RNs is required, one of whom is a RN competent in Phase I perianesthesia nursing, with a 1-to-1 RN-to-patient ratio when required, consistent with the ASPAN practice recommendations.

3. Phase II PACU Staffing. There must be two competent personnel, one of whom is a RN competent in Phase II perianesthesia nursing consistent with ASPAN practice recommendations.

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

(h) Support Services.

1. Pharmacy. Pharmacy Services must be available on-site during the hours of operation.

2. Blood Bank. Blood Bank services, including blood and blood components, must be available within 60 minutes during hours of operation.

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

4. Biomedical Engineering. Biomedical engineering services must be available by phone within 30 minutes during weekdays, dayshift.

(i) SPS. Sterile instrument sets and Reusable Medical Equipment must be available on-site for all scheduled procedures.

(j) Back-up Observation and Inpatient Services. Protocols to transfer patients within 60 minutes to a VHA acute care facility with an Inpatient Intermediate or Complex Invasive Procedure Complexity designation or equivalent community provider must be established by a MOU. **NOTE:** *Timeliness of patient transfer in any given situation is dictated by the clinical condition of the patient.*

(6) **Inpatient Intermediate Invasive Procedure Complexity**. The following infrastructure is required for an Inpatient Intermediate Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation.

1. EKG. EKG services must be available on-site 24/7.
2. Basic Laboratory. Basic laboratory services must be available on-site 24/7, including capability to perform an arterial blood gas.
3. Plain Film Radiography. Plain film radiography must be available on-site 24/7.
4. Radiology Interpretation. Radiology interpretation must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes.
5. Cardiac Stress Testing. Cardiac stress testing must be available on-site during dayshift.
6. Pulmonary Function Test (PFT) Studies. PFT studies must be available on-site during dayshift.
7. Computerized Tomography (CT) Scan and Non-Vascular Ultrasound. CT scan and non-vascular ultrasound services must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes.
8. Vascular Ultrasound. Vascular ultrasound services must be available on-site during weekdays, dayshift.
9. Interventional Cardiac Catheterization Laboratory. Interventional cardiac catheterization laboratory services must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes.
10. Vascular Interventional Radiology. Vascular interventional radiology services must be available on-site during dayshift; all other times available on-call within 60 minutes.
11. Non-vascular Interventional Radiology. Non-vascular interventional radiology services must be available on-site during dayshift; all other times available on-call within 60 minutes.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services.

1. Anesthesia Pre-procedural Assessment. Anesthesia pre-procedural assessment must be available on-site during weekdays, dayshift; all other times must be available on-call within 15 minutes by phone and within 60 minutes on-site, to be provided by Anesthesiologist or APP.

2. General Medicine Consultation. General medicine consultation must be available on-site during weekdays, dayshift; all other times available on-call within 15 minutes by phone and within 60 minutes on-site.

3. General Surgery Consultation. General surgery consultation must be available on-site during weekdays, dayshift; all other times available on-call within 15 minutes by phone and within 60 minutes on-site.

4. Specialty Consultants. The following consultants must be available 24/7 within 15 minutes by phone and on-site, or virtually, via telemedicine, within 60 minutes: Cardiology, Gastroenterology, Hematology/Oncology, Interventional Cardiology, Infectious Disease, Non-Vascular and Vascular Interventional Radiology, Nephrology, Neurology, Pathology, and Pulmonary Medicine. As a condition of the telemedicine option, an onsite hospitalist practitioner must be available to assist in communicating information and facilitating aspects of the physical exam. The appropriately privileged specialty consultant must be available on-site within 60 minutes to participate in interventions or perform procedures as indicated.

5. Surgery Consultants. The following consultants must be on staff and available 24/7 within 15 minutes by phone and within 60 minutes on-site: Thoracic Surgery, Urology, and Vascular Surgery. Routine non-procedural consultation may be provided by telemedicine. As a condition of the telemedicine option, an onsite hospitalist practitioner must be available to assist in communicating information and facilitating aspects of the physical exam. The appropriately privileged specialty consultant must be available on-site within 60 minutes to participate in interventions or perform procedures as indicated.

6. Anesthesia Consultative Services. There must be a board-certified or board-eligible anesthesiologist, on-site, weekdays, dayshift. At all other times, they must be available on-call within 15 minutes by phone and within 60 minutes on-site.

(c) Physician Staffing.

1. General Surgeon. There must be two or more FTEE, who may be provided by contract, one of whom must be board-certified or board-eligible.

2. Specialty Surgeons. Variable depending upon the clinical services offered.

3. Surgical Assistant. A surgical assistant must be available on-call 24/7 and available within 15 minutes by phone and within 60 minutes on-site.

4. General Surgery Attending Call Schedule. There must be a formal call schedule for General Surgery attending physicians.

5. Specialty Surgeon Attending Call Schedule. There must be a formal attending call schedule for specialty surgery services provided by the VA medical facility.

6. Inpatient Coverage. There must be qualified inpatient coverage in house for all inpatients. Specific requirements are addressed in VHA Handbook 1101.04, Medical Officer of the Day, dated February 6, 2019. There must be a formal call schedule with 24/7 coverage by attending surgeon physicians, fellows or residents in surgical discipline training programs, or trained APPs, available on-call within 15 minutes by phone and within 60 minutes on-site. **NOTE:** *Coverage cannot be provided by physician assigned to the Emergency Department or the Medical Officer of the Day.*

(d) Procedure Room.

1. Staffing. Each procedure room must have available the following staff:

a. Qualified anesthesia personnel present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthesia care.

b. Qualified staff to assist with performance of the procedure.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring, including continuous telemetry, pulse oximetry, end-tidal carbon dioxide (CO₂). An anesthesia machine must be present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthetic care. An additional anesthesia machine must be readily available as backup.

4. Equipment Required for the Procedure Room Area. There must be a code cart, defibrillator, and malignant hyperthermia cart must be readily available. **NOTE:** *Malignant hyperthermia cart is only required to be readily available where general anesthesia is being performed.*

(e) Operating Room.

1. Staffing. There must be:

a. Minimum staffing to include a RN circulator and a scrub person. Written guidelines defining training and competencies consistent with the AORN standards and the AST must be maintained.

b. Staff competencies for specialty-specific surgery.

c. A written plan for staffing based upon invasive procedure complexity.

d. A written plan for supplemental staffing for intra-operative emergencies.

2. Instrument Sets. There must be a duplication of all VA major instrument sets and no less than one vascular set available for emergency use. **NOTE:** See paragraph 10, References, for details.

3. Equipment Required in Each OR. There must be suction, an electrocautery unit, an anesthesia machine, and the capability for basic and advanced physiological monitoring, including EKG, end-tidal CO₂, pulse oximetry, central venous pressure, and arterial pressure.

4. Equipment Required for the OR Area. There must be a code cart, defibrillator, an intra-operative c-arm, malignant hyperthermia cart, difficult airway cart, cell saver, and at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures. An IUSS unit must be immediately available 24/7 for use by trained and competent personnel whenever the OR is in use. An IUSS unit may be located in the OR area or in on-site SPS.

5. Coverage. There must be:

a. An on-call schedule for OR nursing staff assuring that they will be on-site, within 60 minutes.

b. An OR available for use at all times during off hours.

6. Radiology. There must be a Radiologic Technologist available on-site 24/7.

(f) Anesthesia Services.

1. Anesthesia Provider Staff. There must be a board-certified or board-eligible Anesthesiologist or CRNA available for all invasive procedures requiring general anesthesia, regional anesthetics, and monitored anesthesia care.

2. Chief of Anesthesia. The anesthesia service must be managed by a board-certified or board-eligible anesthesiologist.

3. Assistance. There must be a written plan for backup assistance of a qualified provider skilled in airway management.

4. Coverage. There must be coverage on-site during weekdays, dayshift; all other times there must be coverage available on-call and within 60 minutes on-site.

(g) PACU.

1. Area. There must be a designated PACU. Written guidelines may require patients undergoing specific invasive procedures or requiring after-hours care to be directly transferred to the ICU.

2. Phase I PACU Staffing. Minimum staffing of two RNs is required, one of whom is a RN competent in Phase I perianesthesia nursing, with a 1-to-1 RN-to-patient ratio when required, consistent with the ASPAN practice recommendations.

3. Phase II PACU Staffing. There must be two competent personnel, one of whom is a RN competent in Phase II perianesthesia nursing consistent with ASPAN practice recommendations.

4. RN Competencies. RN competencies must be documented and include ventilator management, physiological monitoring, and recovery of patients undergoing invasive specialty care (ex. Thoracic, Urologic, Vascular Surgery) as applicable. Patients who are directly transferred from the OR to the ICU and are in need of Phase I recovery must be cared for by RN staff competent in Phase I recovery.

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

(h) Intensive Care Unit.

1. ICU Level. The ICU must be Level 2 or Level 3.

2. Intensivist coverage. Intensivist coverage must be available on-site during dayshift; and at all other times must be available on-call within 15 minutes by phone and within 60 minutes on-site. **NOTE:** *Off-hours intensivist coverage may be provided by VA Tele-ICU services, as long as physician specializing and credentialed in the care of the critically ill patient (e.g. hospitalist, anesthesiologist, general surgeon, or pulmonologist) is available within 15 minutes by phone and within 60 minutes on-site to supplement care and treatment as needed.*

3. Medical Co-management of Surgical Patients. There must be a written plan in place that identifies the responsibilities of medicine and surgery service lines in the care and treatment of the patient recovering from a surgical procedure in the ICU.

(i) Ward. Nurse competencies must be in alignment with the types of invasive procedures being performed. In addition, there must be:

1. Telemetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by telemetry.

2. Pulse oximetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by pulse oximetry.

(j) Support Services.

1. Respiratory Therapy. Respiratory therapy services must be available on-site 24/7. This service must be provided by a credentialed respiratory therapist.

2. Pharmacy. Pharmacy services must be available on-site 16 hours a day; at all other times, pharmacy services must be available on-call within 15 minutes by phone and within 60 minutes on-site.

3. Blood Bank. Blood bank services, including blood and blood components, must be available 24/7 within 60 minutes.

4. Physical Therapy. Physical therapy must be available on-site during weekdays, dayshift; it must be available on weekends if necessary for specialty-specific recovery.

5. Dialysis. Dialysis services must be available on-site within 6 hours.

6. Pathology. There must be a capability for frozen section studies on-site (or by telepathology) during weekdays, dayshift; at all other times, these studies must be available on-call and with ability to provide the service within 60 minutes.

7. Biomedical Engineering. Biomedical engineering services must be available on-site during weekdays, dayshift.

(k) SPS. There must be sterile processing on-site; personnel must be on-site during weekdays, dayshift. At all other times sterile equipment and Reusable Medical Equipment must be available within 15 minutes by written protocol to support invasive procedures.

(l) Emergency Department. The medical facility must have 24/7 Emergency Department (ED) services available on-site.

(7) Inpatient Complex Invasive Procedure Complexity. The following Infrastructure is required for an Inpatient Complex Invasive Procedure Complexity designation:

(a) Pre-procedural and Post-procedural Diagnostic Evaluation.

1. EKG. EKG services must be available on-site 24/7.

2. Basic Laboratory. Basic laboratory services must be available on-site 24/7, including capability to perform an arterial blood gas.

3. Plain Film Radiography. Plain film radiography must be available on-site 24/7.

4. Radiology Interpretation. Radiology interpretation must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes.

5. Cardiac Stress Testing. Cardiac stress testing must be available on-site during dayshift.

6. PFT Studies. PFT studies must be available on-site during dayshift.

7. CT Scan and Non-Vascular Ultrasound. CT scans and non-vascular ultrasounds must be available on-site during weekdays, dayshift; all other times available on-call within 60 minutes.

8. Vascular Ultrasound. Vascular ultrasounds must be available on-site during weekdays, dayshift.

9. Interventional Cardiac Catheterization Laboratory. Interventional cardiac catheterization laboratory services must be available on-site during weekdays, dayshift; all other times these services must be available on-call within 60 minutes.

10. Vascular Interventional Radiology. Vascular interventional radiology services must be available on-site during dayshift; at all other times, these services must be available on-call within 60 minutes.

11. Non-vascular Interventional Radiology. Non-vascular interventional radiology services must be available on-site during dayshift, at all other times these services must be available on-call within 60 minutes.

12. Interventional Neuroradiology. Interventional neuroradiology services must be available on-site during dayshift; all other times available, these services must be available on-call within 60 minutes. **NOTE:** *This requirement only applies to VA medical facilities with an approved VHA Neurosurgery Program.*

13. Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA). MRI and MRA services must be available on-site during dayshift; all other times, these services must be available on-call within 60 minutes.

(b) Pre-procedural Risk Assessment and Post-procedural Consultation and Services.

1. Anesthesia Pre-procedural Assessment. Anesthesia pre-procedural assessments must be available on-site during weekdays, dayshift; all other times, these assessments must be available on-call within 15 minutes by phone and within 60 minutes on-site; to be provided by Anesthesiologist or APP.

2. General Medicine Consultation. General medicine consultation must be available on-site during weekdays, dayshift; all other times, these consultations must be available on-call within 15 minutes by phone and within 60 minutes on-site.

3. Medicine Specialty and Surgery Consultants. The following consultants must be available 24/7 within 15 minutes by phone and on-site, within 60 minutes: Cardiology, Gastroenterology, Interventional Cardiology, Thoracic Surgery, Urology, Vascular Surgery and Non-Vascular and Vascular Interventional Radiology. The following consultants must be available 24/7 within 15 minutes by phone and 60 minutes on-site, or virtually, via telemedicine, within 60 minutes: Hematology/Oncology, Infectious Disease, Nephrology, Neurology, and Pulmonary Medicine. As a condition of the telemedicine option, an onsite hospitalist practitioner must be available to assist in

communicating information and facilitating aspects of the physical exam. The appropriately privileged specialty consultant must be available on-site within 60 minutes to participate in interventions or perform procedures as indicated.

4. Anesthesia Consultative Services. There must be a board-certified or board-eligible anesthesiologist on-site weekday, dayshift; at all other times, they must be available on-call within 15 minutes by phone and within 60 minutes on-site.

5. Cardiac Surgery Specialty Consultants. Cardiac surgery specialty consultants must be on staff and available 24/7 within 15 minutes by phone and within 60 minutes on-site, when the VA medical facility has a VHA approved Cardiac Surgery Program.

6. Neurosurgery Specialty Consultants. Neurosurgery specialty consultants must be on staff and available 24/7 within 15 minutes by phone and within 60 minutes on-site, when the VA medical facility has a VHA approved Neurosurgery Program.

(c) Physician Staffing.

1. General Surgeon. There must be two or more board-certified or board-eligible FTEE employees, who may be provided by contract.

2. Specialty Surgeons. Variable depending upon the clinical services offered.

3. Surgical Assistant. A surgical assistant must be available on-call 24/7 and available within 15 minutes by phone and within 60 minutes on-site.

4. Attending Surgeon Call Schedule. There must be a formal call schedule for General Surgery and Specialty Service attending physicians.

5. Inpatient Coverage. There must be qualified inpatient coverage in house for all inpatients. Specific requirements are addressed in the VHA Medical Officer of the Day policy. There must be a formal call schedule with 24/7 coverage by attending surgeon physicians, fellows, or residents in surgical discipline training programs, or trained APPs, available on-call within 15 minutes by phone and within 60 minutes on-site.

NOTE: Coverage cannot be provided by physician assigned to the Emergency Department or the Medical Officer of the Day.

(d) Procedure Room.

1. Staffing. Each procedure room must have available the following staff:

a. Qualified anesthesia personnel present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthesia care.

b. Qualified staff to assist with performance of the procedure.

2. Instrument Sets. No minimum infrastructure requirements.

3. Equipment Required in Each Procedure Room. There must be suction and the capability for basic physiological monitoring, including continuous telemetry, pulse oximetry, and end-tidal carbon dioxide (CO₂). An anesthesia machine must be present in the room throughout the conduct of all general anesthesia, regional anesthetics, and monitored anesthetic care. An additional anesthesia machine must be readily available as backup.

4. Equipment Required for the Procedure Room Area. There must be a code cart, defibrillator, and malignant hyperthermia cart readily available. **NOTE:** *Malignant hyperthermia cart is only required to be readily available where general anesthesia is being performed.*

(e) Operating Room.

1. Staffing. There must be:

a. Minimum staffing to include a RN circulator and a scrub person. Written guidelines defining training and competencies consistent with the AORN standards and the AST must be maintained.

b. Staff competencies for specialty-specific surgery.

c. A written plan for staffing based upon invasive procedure complexity.

d. Written plan for supplemental staffing for intra-operative emergencies.

2. Instrument Sets. There must be a duplication of all VA major instrument sets and no less than one vascular set available for emergency use. **NOTE:** .See *paragraph 10, References, for details.*

3. Equipment Required in Each OR. There must be suction, an electrocautery unit, an anesthesia machine, and the capability for basic and advanced physiological monitoring, including EKG, end-tidal CO₂, pulse oximetry, central venous pressure, and arterial pressure.

4. Equipment Required for the OR Area. There must be a code cart, defibrillator, an intra-operative c-arm, malignant hyperthermia cart, difficult airway cart, cell saver, and at least one functioning anesthesia machine in excess of the number of ORs scheduled for procedures. An IUSS unit must be immediately available 24/7 for use by trained and competent personnel whenever the OR is in use. An IUSS unit may be located in the OR area or in on-site SPS.

5. Coverage. There must be:

a. An on-call schedule for OR nursing staff assuring that they will be on-site, within 60 minutes.

b. An OR available for use at all times during off hours.

6. Radiology. There must be a Radiologic Technologist available on-site 24/7.

(f) Anesthesia Services.

1. Anesthesia Provider Staff. There must be a board-certified or board-eligible Anesthesiologist or CRNA available for all invasive procedures requiring general anesthesia, regional anesthetics, and monitored anesthesia care.

2. Chief of Anesthesia. The anesthesia service must be managed by a board-certified or board-eligible anesthesiologist.

3. Assistance. There must be a written plan for backup assistance of a qualified provider skilled in airway management.

4. Coverage. There must be anesthesia services coverage on-site during weekdays, dayshift; at all other times, these services must be available on-call and within 60 minutes on-site.

(g) PACU.

1. Area. There must be a designated PACU. Written guidelines may require patients undergoing specific invasive procedures or requiring after-hours care to be directly transferred to the ICU.

2. Phase I PACU Staffing. Minimum staffing of two RNs is required, one of whom is a RN competent in Phase I perianesthesia nursing, with a 1-to-1 RN-to-patient ratio when required, consistent with the ASPAN practice recommendations.

3. Phase II PACU Staffing. There must be two competent personnel, one of whom is a RN competent in Phase II perianesthesia nursing consistent with ASPAN practice recommendations.

4. RN competencies. RN competencies must include ventilator management, physiological monitoring, and recovery of patients undergoing invasive specialty care (e.g. Cardiac, Neurosurgery, Vascular Surgery) as indicated. Patients who are directly transferred from the OR to the ICU and are in need of Phase I recovery must be cared for by RN staff competent in Phase I recovery.

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

(h) Intensive Care Unit.

1. ICU Level. ICU must be Level 1 or Level 2.

2. Intensivist coverage. Intensivist coverage must be available on-site during the dayshift; at all other times available, this coverage must be available on-call within 15 minutes by phone and within 60 minutes on-site. **NOTE:** *Off-hours intensivist coverage may be provided by VA Tele-ICU services, as long as a physician specializing and*

credentialed in the care of the critically ill patient (ex. hospitalist, anesthesiologist, general surgeon, or pulmonologist) is available within 15 minutes by phone and within 60 minutes on-site to supplement care and treatment as needed.

3. Medical Co-management of Surgical Patients. There must be a written plan in place that identifies the responsibilities of medicine and surgery service lines in the care and treatment of the patient recovering from a surgical procedure in the ICU.

(i) Ward. Nurse competencies must be in alignment with the types of invasive procedures being performed. In addition, there must be:

1. Telemetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by telemetry.

2. Pulse oximetry. A written plan must be in place to define the criteria for the use of beds remotely monitored by pulse oximetry.

(j) Support Services.

1. Respiratory Therapy. Respiratory therapy services must be available on-site 24/7. This service must be provided by a credentialed respiratory therapist.

2. Pharmacy. Pharmacy services must be available on-site 24/7.

3. Blood Bank. Blood bank services, including blood and blood components, must be available 24/7 within 60 minutes.

4. Physical Therapy. Physical therapy services must be available on-site during weekdays, dayshift; these services must be available on weekends if necessary for specialty specific recovery.

5. Dialysis. Dialysis must be available on-site within 6 hours.

6. Pathology. There must be a capability for frozen section studies on-site weekdays, dayshift; at all other times, these studies must be available on-call and with ability to provide the service within 60 minutes.

7. Biomedical Engineering. Biomedical engineering services must be available on-site during weekdays, dayshift.

(k) SPS. There must be sterile processing on-site; there must be sterile processing services personnel on-site during weekdays, dayshift. At all other times, sterile equipment and Reusable Medical Equipment must be available within 15 minutes by written protocol to support invasive procedures.

(l) ED. The VA medical facility must have 24/7 ED services available on-site.

8. TRAINING

There are no formal training requirements associated with this directive.

9. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If you have any questions regarding any aspect of records management, you should contact your facility Records Manager or your Records Liaison.

10. REFERENCES

- a. 38 U.S.C. 501.
- b. 38 U.S.C. 7301(b).
- c. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated November 2, 2016.
- d. VHA Directive 1073, Moderate Sedation by Non-Anesthesia Providers, dated December 30, 2014.
- e. VHA Directive 1157(1), Out of Operating Room Airway Management, dated June 14, 2018.
- f. VHA Directive 1116(2), Sterile Processing Services, dated March 23, 2016.
- g. VHA Directive 1101.04, Medical Officer of the Day, dated February 6, 2019.
- h. VHA Directive 1102.01, National Surgery Office, dated April 24, 2019.
- i. VHA Handbook 1004.01(2), Informed Consent for Clinical Treatment and Procedures, dated August 14, 2009.
- j. VHA Handbook 1006.02, VHA Site Classifications and Definitions, dated December 30, 2013.
- k. VHA Handbook 1100.19 Credentialing and Privileging, dated October 15, 2012.
- l. Almenoff, P., Sales, A., Rounds, S., Miller, M., et.al. Intensive Care Services in the Veterans Health Administration. *Chest* 2007; 132:1455-1462.
- m. ASPAN <http://www.aspan.org/Clinical-Practice/Position-Statements>.
- n. Association of Perioperative Registered Nurses (AORN). Standards of Perioperative Nursing. <http://www.aornstandards.org/content/1/SEC39.body>.

o. Association of Surgical Technologists (AST).

http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Job%20Descriptions.pdf

NOTE: *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

p. Haupt, M.T., Bekes, C.E., Brilli, R.J., Carl, L.C., Gray, A. W., et.al. Guidelines on critical care services and personnel: Recommendations based on a system of categorization of three levels of care. Critical Care Medicine 2003: 31(11); 2677-2683.

q. Office of Construction & Facilities Management Technical Information Library Surgical and Endovascular Services Design Guide.

<https://www.cfm.va.gov/til/dGuide/dgSurg.pdf>