Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1081.02
Transmittal Sheet
October 29, 2020

MANAGEMENT OF BIOLOGICAL AND NON-BIOLOGICAL IMPLANTS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy and standards for the management of biological and non-biological implantable devices.

2. SUMMARY OF CONTENT: This directive outlines the requirements, roles and responsibilities necessary for managing biological and non-biological implantable devices.

3. RELATED ISSUES: VHA Directive 1048, Prosthetic and Sensory Aids Service (PSAS) Specific Purpose Funding, dated July 30, 2014; VHA Directive 1081, Procurement Process for Individual Prosthetic Appliances and Sensory Aids Devices Above the Micro-Purchase Threshold, dated March 25, 2014; VHA Directive 1081.01(1), Procurement of Surgical Implants Under 38 U.S.C. § 8123, dated October 29, 2018; VHA Directive 1116(2), Sterile Processing Services (SPS), dated March 23, 2016; and VHA Directive 1761(2), Supply Chain Inventory Management, dated October 24, 2016.

4. RESPONSIBLE OFFICE: The Procurement and Logistics Office (P&LO, 19PLO) is responsible for the contents of this directive. Questions may be addressed to vhacopaq@va.gov.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY THE DIRECTION OF THE UNDER SECRETARY FOR HEALTH:

/s/ Deborah E. Kramer
Acting Assistant Under Secretary for Health for Support

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

DISTRIBUTION: Emailed to the VHA Publications Distribution List on October 30, 2020.

CONTENTS

MANAGEMENT OF BIOLOGICAL AND NON-BIOLOGICAL IMPLANTS

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for the procurement and management of biological and non-biological implantable devices within the Department of Veterans Affairs (VA). **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b), § 8123.

2. BACKGROUND

The Food and Drug Administration (FDA), through the Center for Biologics Evaluation and Research (CBER), regulates Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) under Title 21 Code of Federal Regulations (C.F.R) 1270 and 1271. For the purpose of this directive, HCT/Ps will be referred to as biological implants. CBER also regulates xenotransplantation but does not regulate the transplantation of vascularized human organs such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs. Human organs and vascularized composite allografts for transplantation are not covered by this directive.

3. DEFINITIONS

a. **Allograft.** An allograft is the transplant of an organ or tissue from one human to another human.

b. **Autograft.** An autograft (autotransplant) is tissue or bone that is taken from part of a person's own body and transplanted into another part of the person's own body.

c. **Biological Implantable Device.** A biological implantable device (BID) is tissue from a human (allograft) or animal (xenograft) or is artificially manufactured (bio-implant), that is implanted into or grafted onto the body to replace damaged tissue. Examples are bone, skin, corneas, ligaments, tendons, dura mater, heart valves and hematopoietic stem and progenitor cells derived from peripheral and cord blood.

d. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Health Information System Technology Architecture (VistA) and Cerner platforms. ***NOTE:*** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

e. **Non-Biological Implantable Device.** A non-biological implantable device (NBID) is an artificial device implanted in a human to replace, support or substitute for deformed or weakened anatomical parts of the body.

f. **Prosthetic and Sensory Aids Service Implant.** For purposes of this directive, a Prosthetic and Sensory Aids Service (PSAS) implant is designed to permanently stay in the body, which replaces, supports or substitutes for deformed or weakened anatomical parts of the body and is not intended to be extracted or removed within a year from the date of implantation. Implants such as whole organs, bone marrow and blood-derived stem cells are not PSAS implants.

g. **Surgical Implant.** Surgical implant means any biological or non-biological material which is manufactured or processed to be placed or injected in the body or into a surgically or naturally formed cavity on the human body; is covered with tissue and has the potential to be covered with tissue or is permanently embedded in tissue. Surgical implants are implanted by surgeons and specialty services including but not limited to: Cardiac Surgery, Thoracic Surgery, Cath Lab, General Surgery, Gynecology, Neurosurgery, Ophthalmology Orthopedic Surgery, Otolaryngology, Plastic Surgery, Podiatry, Urology, Vascular Surgery, Cardiology, Dental, Dermatology, Gastrointestinal, Interventional Pain/Pain Management, Interventional Radiology, Pulmonary or Women's Health Specialty Services.

h. **Xenograft.** A xenograft is a graft from a different species, such as when animal tissue is grafted into human tissue.

i. **Xenotransplantation.** Xenotransplantation is any procedure that involves the transplantation, implantation or infusion into a human recipient of either:

(1) Live cells, tissues or organs from a nonhuman animal source; or

(2) Human body fluids, cells, tissues; or

(3) Organs that have had ex vivo (artificial environment outside the living organism) contact with live nonhuman animal cells or tissues.

4. POLICY

It is VHA policy that biological and non-biological implants used in the delivery of medical services to Veterans are procured, stored and utilized consistently with Federal law and prevailing medical standards.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Support.** The Assistant Under Secretary for Health for Support is responsible for:

(1) Overseeing the VHA Procurement and Logistics Office (P&LO).

(2) Ensuring resources are adequate to implement VHA Supply Chain Management.

(3) Establishing this directive for the management of biological and non-biological implants.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Providing assistance to VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards and applicable regulations.

d. **Executive Director, VHA Procurement and Logistics Office.** The Executive Director, VHA P&LO is responsible for:

(1) Overseeing the Supply Chain Management (SCM) program within VHA as required by VHA Directive 1761(2), Supply Chain Inventory Management, dated October 24, 2016.

(2) Providing oversight for PSAS supply inventories to include adhering to VHA Directive 1761(2) and establishing performance measures. For SCM, performance measures and reports are currently published and tracked on the Supply Chain Common Operating Picture (SCCOP) intranet website, located at https://app.powerbigov.us/home. ***NOTE:*** *These is an internal VA website that is not available to the public.*

e. **National Program Director, Prosthetic and Sensory Aids Service.** The National Program Director, PSAS is responsible for:

(1) Collaborating with VHA P&LO and the VA Office of Acquisition and Logistics to identify and pursue national strategic sourcing initiatives for biological and non-biological implants. A listing of available national strategic sourcing contracts can be found at: https://vaww.pclo.infoshare.va.gov/PCLO/MMStrategicPlan/PEO/Lists/National%20ContractBPABOA/AllItems.aspx?InitialTabId=Ribbon.ListItem&VisibilityContext=WSSTabPersistence%20-%20InplviewHash77848c5d-1425-4351-a045-0ccc5b091048=FilterField1%3DCPO-FilterValue1%3DProsthetics#InplviewHash77848c5d-1425-4351-a045-0ccc5b091048. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(2) Maintaining VHA's EHR for implant consults and procurement requests.

f. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Maintaining VISN level SCM and PSAS programs that effectively meet VHA policy, reporting and operational requirements.

(2) Ensuring that all VA medical facilities within the VISN comply with this directive informing leadership when barriers to compliance are identified.

g. **VHA Directors of Contracting.** The Director of Contracting (DOC) are responsible for:

(1) Ensuring Network Contracting Officers are awarding contracts and establishing consignment agreements under contracts, as outlined in paragraph 6.a.

(2) Ensuring contracts and consignment agreements for implants include guidelines for the sterile processing of implants and implant instrument trays contained in VHA Directive 1116(2), Sterile Processing Services (SPS), dated March 23, 2016. Contracts for human tissue implants should include confirmation from the manufacturer that the product meets FDAs definition of HCT/Ps (e.g., minimally modified and for homologous use).

(3) Ensuring Network Contracting Officers comply with this directive.

h. **Veterans Integrated Service Network Chief Logistics Officer.** The VISN Chief Logistics Officer (VCLO) is responsible for:

(1) Ensuring compliance with VA Handbook 7002, Logistics Management Procedures, dated January 8, 2020; VHA Directive 1761(2); VHA Directive 1081.01(1), Procurement of Surgical Implants Under 38 U.S.C. § 8123, dated October 29, 2018; VA Financial Policy, Volume XVI, Chapter 1B, Government Purchase Card for Micro-Purchases, dated October 22, 2019, available at: https://www.va.gov/finance/docs/VA-FinancialPolicyVolumeXVIChapter01B.pdf and established supply chain benchmarks. For VHA, benchmarks and reports are currently published and tracked on the Supply Chain Common Operating Picture (SCCOP) intranet site, located at https://app.powerbigov.us/home. ***NOTE:*** *These are internal VA websites that are not available to the public.*

(2) Ensuring VA medical facility SCM organizations establish and manage facility implant inventories in the VHA-approved inventory management system (currently, General Inventory Package (GIP)), as required, for any biological and non-biological items maintained in the VA medical facility.

i. **Network Contracting Officers.** The Network Contracting Officers are responsible for:

(1) Awarding contracts and establishing consignment agreements under contracts as outlined in paragraph 6.a.

(2) Utilizing the PSAS's graphical user interface (GUI) interface/Advanced Prosthetics Acquisition Tool (APAT) and the government purchase card to document

and pay for open market surgical implants over the micro-purchase threshold submitted by PSAS personnel in accordance with VHA Directive 1081.01(1).

(3) Ensuring COR designations are identified and delegation letters are issued clearly identifying functions and responsibilities of the assigned COR as related to the consignment agreement. Examples of pertinent VHA COR assigned responsibilities for consignment agreements are in paragraph 5.p.

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

(1) Maintaining compliance with this directive.

(2) Ensuring a VA medical facility implant coordinator is assigned to and oversight is provided by a clinical service line. ***NOTE:*** *The VA medical facility implant coordinator will coordinate and be responsible for all aspects of the facility implant program*.

(3) Reporting all adverse events in accordance with guidance in VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

k. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (COS) is responsible for:

(1) Ensuring all clinical areas have space available for storing implants and that this space meets storage requirements for each implant in inventory.

(2) Ensuring clinical service members (including medical professionals, medical assistants or others) in any clinical specialty assigned to implant procedures submit actionable patient-specific consults and EHR entries within 2 business days for prescribed implants used, including wasted implants or implants contaminated during surgery in accordance with VHA Directive 1081.01(1).

(3) Ensuring clinical service members (including medical professionals, medical assistants or others) in any clinical specialty assigned to implant procedures complete necessary documentation for implant tracking in the current manual or automated implant tracking system (for biologicals) and patient records (for biological and non-biological implants). If a manual implant tracking system is used, paper copies must be returned to staff members responsible for implant tracking and management.

(4) Approving written early release waivers to authorize release of implants during quarantine. Non-biological implants sterilized in SPS must be quarantined until the biological indicator is read as negative and the instrument set has sufficient time to cool down. ***NOTE:*** *An early implant release waiver must be requested of and approved by the VA medical facility COS in the event that a sterilized implant must be released prior to obtaining the negative rapid reading of the biological indicator. The early implant release waiver is to be initiated by the Operating Room (OR) Nurse Manager, signed by the COS or Acting COS and received in SPS prior to the release. SPS must record the reading of the biological indicator on the early implant release waiver when the reading is obtained*.

l. **VA Medical Facility Chief, Pharmacy Service.** The VA medical facility Chief, Pharmacy Service is responsible for the provision of injectable implant devices and other implants to clinical providers as recommended by the National Pharmacy, Prosthetics, Logistics Committee (NPPLC). NPPLC minutes and decisions can be found at: https://dvagov.sharepoint.com/sites/VHAPBM/Formulary/Other%20Documents%20and%20Resources/Forms/AllItems.aspx?viewid=3eb3a32a%2D44df%2D4d3e%2Da842%2D18514609cb65&id=%2Fsites%2FVHAPBM%2FFormulary%2FOther%20Documents%20and%20Resources%2FPharmacy%2DProsthetics%2DLogistics%20%28PPL%29%20Workgroup. ***NOTE:*** *This is an internal VA website that is not available to the public.*

m. **VA Medical Facility Chief, Prosthetic and Sensory Aids Service.** The VA medical facility Chief, PSAS is responsible for:

(1) Coordinating and collaborating with the VA medical facility implant coordinator to manage the VA medical facility's implant program as it pertains to consult processing and implant procurement.

(2) Ensuring that only authorized prosthetic surgical implants are purchased utilizing PSAS specific purpose funds, as described in VHA Directive 1048, Prosthetic and Sensory Aids Service Specific Purpose Funding, dated March 17, 2020.

(3) Ordering or paying for surgical implants once an actional patient-specific consult is received from a clinical service.

(4) Ensuring that implants requested by Specialty Care Services are processed and consistent with requirements contained in VHA Directive 1232(2), Consult Processes and Procedures, dated August 24, 2016 and VHA Directive 1081.01(1).

(5) Ensuring that requirements for open market implant consults above the micro-purchase threshold of $10,000 are submitted to contracting through the FORCE planning module and are also processed consistent with current business practice guidelines for consult management as outlined in VA Financial Policy, Volume XVI, Chapter 1B, Government Purchase Card for Micro-Purchases, dated October 22, 2019.

(6) Ensuring that the PSAS's GUI APAT and government purchase cards are utilized to document and pay for surgical implants for individual patient orders.

(7) Ensuring that serial numbers, lot numbers and catalog numbers are entered into the Veteran's Prosthetic Record in the National Prosthetics Patient Database (NPPD) for purchase orders created within the authority of the PSAS purchase card holder as outlined in VHA Directive 1081.01(1).

(8) Notifying the VA medical facility COS, the VA medical facility implant coordinator and the VA medical facility Chief Supply Chain Officer (CSCO) of instances of noncompliance in receiving EHR consults or inventory concerns upon identification.

(9) Ensuring no PSAS employees are involved in the receipt or storage of implant inventory.

(10) Ensuring 38 U.S.C. § 8123 Procurement of Prosthetic Appliances is annotated by authorized PSAS staff on purchase orders for all mandatory implant purchases greater than $10,000.

n. **VA Medical Facility Sterile Processing Service Chief.** The VA medical facility SPS Chief is responsible for:

(1) Confirming that non-sterile non-biological implants and instrumentation received by or delivered to clinical areas are correctly processed according to manufacturer instructions, as directed in VHA Directive 1116(2). SPS does not have responsibility for delivery, receipt or verification of sterility of implants.

(2) Supporting staff members responsible for decontaminating and sterilizing instruments by ensuring:

(a) Non-sterile non-biological implants contained in loaner instrument trays, not part of the VA medical facility's inventory, are received in the VA medical facility at least 48 hours prior to use in order to provide adequate time for reprocessing (e.g., decontamination, sterilization and cooling of the instrument set(s). ***NOTE:*** *Failure to bring the implantable devices into the VA medical facility in advance is not a valid reason to release the implants early from quarantine. Immediate-use steam sterilization (IUSS) is not allowed for trays arriving late to the VA medical facility.*

(b) Annotating the biological reading on the approved early release waivers received from the VA medical facility COS to authorize release of implants during quarantine.

(c) Notification of the area nurse manager and provider when loaner instrument trays have not been received or cannot be reprocessed in time for a planned procedure.

(d) Retention of itemized inventory count sheets until completion of procedure and vendor has removed loaned instrument sets from the facility. ***NOTE:*** *Vendors conducting business with VA for loaner instrument sets and implants must comply with the requirement to provide an itemized inventory count sheet and manufacturer's instructions for use with each instrument set.*

o. **VA Medical Facility Chief Supply Chain Officer.** The VA medical facility CSCO is responsible for:

(1) Coordinating with the VA medical facility implant coordinator to manage the VA medical facility's non-consignment implant inventories.

(2) Ensuring that SCM personnel are not involved in the consult process or working within EHR. ***NOTE:*** *Accessing patient records and EHR is outside the scope of SCM core duties, standardized job descriptions and assigned functional categories. SCM personnel are reviewed at least every six months by automated data processing*

application coordinators (ADPACs) to validate appropriate menu assignments, as required in VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015. Menu reviews are approved by the VA medical facility Service Chiefs.

(3) Ensuring that non-consignment implants entering the VA medical facility through SCM Service are received by SCM warehouse personnel upon arrival at the VA medical facility.

(4) Ensuring that new requirements for standard and emergency clinical items are reviewed and approved in accordance with VHA Directive 1761(2).

(5) Ensuring that all VA-owned implants and implant-related consumable inventories are purchased with facility funds and are maintained in the VHA-approved inventory management system with appropriate normal stock levels set, in accordance with VHA Directive 1761(2).

(6) Ensuring that VHA-owned inventory is reviewed weekly by SCM inventory management personnel or supply technicians to ensure that items are not past their expiration dates, there is no damage to product and product and storage areas are clean, in accordance with VHA Directive 1761(2). Inventory must be returned to the vendor or otherwise disposed of if it cannot be utilized prior to expiration.

(7) Facilitating the establishment of VA medical facility consignment agreements by collaborating with applicable subject matter experts from the using service, VA medical facility implant coordinator, clinical service, SPS, SCM, PSAS and the Network Contracting Office to generate complete consignment requirements packets, in accordance with the VA Acquisition Manual, Part M816.770, Consignment Agreements, available at: https://www.va.gov/oal/library/vaam/vaamM816.asp#M816770 and VHA Procurement Manual, Part 816.770, Consignment Agreement Standard Operating Procedure (SOP), available at: https://vaww.pclo.infoshare.va.gov/PCLO/PMWeb/VHAPM_Part_816.770.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

(8) Ensuring a Contracting Officer's Representative (COR) nomination is sent from the applicable service or department to the Contracting Officer for consignment agreements.

(9) Completing physical inventories (cycle counts) of all VA-owned implants, in accordance with VHA Directive 1761(2), utilizing GIP or other VHA-approved inventory management system. This includes implants in the OR as well as all specialty areas, including but not limited to:

(a) Interventional Radiology;

(b) Cardiac Catheterization Laboratory (Cath Lab);

(c) Dental;

(d) Gastro-Intestinal (GI); and

(e) Women's Clinic.

(10) Initiating VA Form 2237, Request, Turn-In and Receipt for Property or Services, for any unused inventory requiring turn-in. VA Form 2237 may be submitted manually or electronically in the Integrated Funds Distribution, Control Point Activity, Accounting and Procurement (IFCAP) system or VA-approved purchasing and accounting system.

(11) Notifying the VA medical facility implant coordinator, COS and the VA medical facility Chief, PSAS of any inventory concerns. After initial inventory is established, whether hospital-owned or consignment inventory, replacement of implants only occurs as a result of inventory evaluation after receiving a consult from a clinician.

p. **VA Medical Facility Implant Coordinator.** The VA medical facility implant coordinator is responsible for:

(1) Ensuring that VA and VHA policies governing the management of implants are followed. ***NOTE:*** *The VA medical facility implant coordinator must have access to EHR and other menu options as needed, to investigate issues associated with the implant process.*

(2) Ensuring a system (manual or automated) is implemented for tracking all biological implants, from vendor or distributor to the recipient at implantation and that all necessary staff have access to local training on the system.

(3) Coordinating all aspects of implant management by working with SCM, PSAS, SPS, the VHA CO and all clinical areas using implants.

(4) Ensuring biological and non-biological implants are entered into the EHR by clinical service personnel upon implantation.

(5) Reconciling implants used with VA-owned inventory and vendor consignment stock or list by ensuring that adequate stock is available, while accounting for items used ordered and identified in submitted consults.

(6) Coordinating with all applicable services to ensure implant availability, input of consults, replacement of used stock and payment for used stock.

(7) Assisting respective clinical services in developing all requirements and documents needed for consignment agreements. ***NOTE:*** *For further information on consignment agreements, see paragraph 6.a.*

(8) Reporting any known issues with consigned inventory, such as expired implants or inadequate inventory levels or consignment vendors to the assigned service CORs.

(9) Ensuring that biological implants are stored, tracked and continuously monitored in accordance with manufacturer requirements (as applicable, to exclude autografts) and VHA policy.

(10) Monitoring the processing of PSAS consults to ensure the timely procurement of needed implants and/or the payment for or replacement of used implants.

(11) Ensuring that clinical service submission of the prosthetic post-procedure surgical implant consults, consistent with VHA Directive 1081.01(1) and within 2 business days, contains the following information:

(a) Date of procedure;

(b) Reorder or bill only;

(c) Vendor name;

(d) Complete description of implant, including size and usage (e.g., coronary, skin graft, biliary, esophageal, carotid, peripheral, renal);

(e) Reference, model and catalog number, if available, of implant(s);

(f) Serial number(s) and lot number(s), if available; and

(g) Quantity.

(12) Coordinating with the SCM inventory manager, purchasing agents for PSAS orders and the clinical service nurse manager, as appropriate, for the delivery of implants by sales representatives.

(13) Serving as a VA medical facility point of contact, along with the Patient Safety Manager, to the National Center for Patient Safety (NCPS) for patient and provider notification in the event of a recall or safety notice potentially affecting Veterans with implants.

q. **VHA Contracting Officer Representative.** VHA CORs are responsible for completing all functions delegated by the VHA CO in the COR delegation letter. CORs are nominated by the VA medical facility as the VHA CO's point of contact for all matters related to the consignment agreement. Examples of pertinent VHA COR assigned responsibilities for consignment contracts are:

(1) Submitting reports and feedback as required to the VHA CO.

(2) Monitoring to ensure consignment vendors are performing par level maintenance, expiration date checks, inventory level checks and proper handling procedures, following any procedures identified in the contract and reporting any inventory discrepancies to the VHA CO.

(3) Collecting reports of any discrepancies from the consignment vendors and submitting reports and feedback as required to the VA implant coordinator.

(4) Ensuring only items contained in the consignment agreement are a part of the consignment inventory.

(5) Notifying the CO if additional items need to be added to the consignment agreement prior to adding them to the consignment inventory.

6. PROCUREMENT AND INVENTORY MANAGEMENT

a. **Consignment Agreement.** In accordance with VAAR subsection 816.770, consignment agreement shall only be established under a contract and by a Contracting Officer. A consignment agreement is defined as a delivery method for a specified period of time in which a contractor provides an item(s) for Government use and the contractor receives reimbursement only if and when the item is used by the Government. Consignment agreements are allowable and shall be considered in those instances when the requirement for an item is immediate and on-going and when it is impossible to predetermine the type or model of a particular item until the need is established and it is determined to be in the best interest of the VA, as noted in the VA Acquisition Manual, https://www.va.gov/oal/library/vaam/vaamM816.asp#M816770, and VHA Procurement Manual, Part 816.770, Consignment Agreement Standard Operating Procedure (SOP), available at: https://vaww.pclo.infoshare.va.gov/PCLO/PMWeb/VHAPM_Part_816.770.aspx. ***NOTE:*** *Consignment agreements established under a contract and signed by a Contracting Officer (CO) are the preferred method to manage implantable stock.*

b. **Generic Inventory Package.** The GIP portion of the Integrated Funds Distribution, Control Point Activity, Accounting and Procurement (IFCAP) system is used to manage the receipt, distribution and maintenance of supplies utilized throughout the VA medical facility.

c. **Indefinite Delivery/Indefinite Quantity Contract.** An Indefinite Delivery/Indefinite Quantity (IDIQ) contract is a type of contract that provides for an indefinite quantity of items or services over a specific period of time.

d. **Just-In-Time.** Just-in-time (JIT) is a method of inventory control to increase efficiency and decrease waste by receiving supplies only as they are needed, thereby reducing inventory costs.

e. **Payment Only.** Payment only" implants are brought in by the vendor on the day of surgery (JIT) and do not need to be replenished.

f. **VA-Owned Inventory.** VA-owned inventory refers to items purchased by the VA and accounted for in GIP or its successor inventory system.

g. **Initial Funding and Inventory.** The initial purchase of stock implant devices and VA-owned implantable procedure sets must be paid with VA medical facility general

purpose funds, not with PSAS specific purpose funds. Each VA medical facility will determine the minimal amount of commonly used trays/instrument sets and implants for purchase to have available for procedures.

h. **Use of Indefinite Delivery/Indefinite Quantity Contracts.** A wide variety of implants are available on IDIQ contracts. If implants are available from IDIQs, IDIQs should be considered priority sourcing unless patient-specific needs dictate otherwise.

i. **Prosthetic and Sensory Aids Service Reimbursement.** VA medical facilities will request the replacement of implanted PSAS VA Central Office (VACO)-approved implants through PSAS when prescribed by a VA physician/clinician using the electronic Prosthetic Implant Consults/Order via the EHR or approved VA patient record system. PSAS funding is applicable only for PSAS implants as reference in paragraph 3.f.

j. **Biological Implants and FDA Registration.** VA medical facilities must establish a process to confirm that both manufacturers and suppliers of biological implants are registered with the FDA and licensed by State agencies, if required, prior to purchasing products. Biological implants must be purchased from FDA-registered establishments, a listing of which can be found at: http://www.fda.gov/BiologicsBloodVaccines/ucm133672.htm. FDA tissue bank regulations extend only to establishments or persons engaged in the recovery, screening, testing, processing, storage or distribution of human tissue and do not apply to institutions that only receive and implant biological implants within the same physical address (see 21 CFR 1270-71). However, a VA medical facility that routinely ships biological implants to other VA medical facilities at different physical locations must register with the FDA as a distributor of biological implants; FDA registration can be completed electronically at: http://www.fda.gov/cber/tissue/tisreg.htm. VA medical facilities may qualify their vendors by requesting a copy of their FDA registration and state license (if required) and keeping them on file. FDA registration of the vendor and source facility may be verified by using the FDA's online website, located at: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/human-cell-and-tissue-establishment-registration-hcters-public-query-application. Warranty/registration cards must be completed by the clinical service implanting the device and returned to the vendor when requested. ***NOTE:*** *Biological implants cannot be stored or processed in any way in SPS (packaged or sterilized).*

k. **Receipt, Storage, Distribution and Tracking.**

(1) Transportation, handling, storage, implantation, disposal and documentation of implants must be in accordance with the vendor's written directions. This must be done in a manner appropriate for sterile surgical procedures and which meets VA and VHA requirements. Refrigerators and freezers used to store tissue will be at a controlled temperature and continuously monitored. Daily temperature logs will document that tissues are stored in a controlled environment are stored at required temperatures. Tissue requiring no greater control than ambient temperature, defined as the temperature of the immediate environment, for storage do not require temperature monitoring.

(2) Proper storage and inventory systems must be in place to ensure that unused or unopened VA-owned and consigned implants (biological and non-biological) are promptly returned to the assigned storage location, if the return is permitted by the manufacturer. Implants unable to be returned to storage or that are expired should be returned to the vendor, if allowed by the contract or vendor or discarded and documented accordingly in the inventory system (GIP or its successor inventory system) if VA-owned.

(3) If a patient-specific implant (biological or non-biological) is unused, the clinical service should coordinate and return the implant(s) to the vendor, if the clinical service arranged the delivery of the implant or contact PSAS personnel to assist if a purchase order has already been provided to the vendor. All unused patient-specific implants must be returned to the vendor.

l. **Recalls and Adverse Events.** FDA recalls can be queried through the NCPS Product Recall Office (PRO). VHA Directive 1068, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014, must be adhered to in the event of a recall of a biological or non-biological implant. In cases where patient notification is a part of the recall process for an implant due to the potential for an adverse event, VA medical facilities are required to implement current VHA policy regarding the disclosure of adverse events to patients (see VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018 and VHA Handbook 1050.01).

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. TRAINING

The following training is recommended:

(1) For the VA medical facility implant coordinator: Looking for Consult/Referrals in CPRS, TMS #3857502.

(2) For the VA medical facility implant coordinator and those involved with the implant process in clinical and administrative services: Purchasing Surgical Implants Under Limited 38 U.S.C. § 8123 Authority, TMS #38280.

9. REFERENCES

a. 38 U.S.C. § 7301(b).

b. 21 U.S.C. § 321(h).

c. 21 C.F.R. § 1270 and §1271.

d. VA Acquisition Manual (VAAM), Subpart M816.7 – Agreements, M816.770 Consignment Agreements.

e. VA Acquisition Regulation (VAAR) Subsection 816.770.

f. VA Handbook 6500, Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program, dated March 10, 2015.

g. VA Handbook 7002, Logistics Management Procedures, dated January 8, 2020.

h. VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018.

i. VHA Directive 1048, Prosthetic and Sensory Aids Service Specific Purpose Funding, dated March 17, 2020.

j. VHA Directive 1068, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014.

k. VHA Directive 1081.01(1), Procurement of Surgical Implants Under 38 U.S.C. § 8123, dated October 29, 2018.

l. VHA Directive 1116(2), Sterile Processing Services (SPS), dated March 23, 2016.

m. VHA Directive 1169, National Pharmacy, Prosthetics and Logistics Committee, dated April 14, 2017.

n. VHA Directive 1232(2), Consult Processes and Procedures, dated August 24, 2016.

o. VHA Directive 1761(2), Supply Chain Inventory Management, dated October 24, 2016.

p. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

q. VA Form 2237 Request, Turn-In and Receipt for Property or Services.

r. VA Financial Policy, Volume XVI, Chapter 1B, Government Purchase Card for Micro-Purchases, dated October 22, 2019, available at: https://www.va.gov/finance/docs/VA-FinancialPolicyVolumeXVIChapter01B.pdf.

s. VHA Procurement Manual, SOP Quick Reference Guide, Consignment Agreements SOP, available at: https://vaww.pclo.infoshare.va.gov/PCLO/PMWeb/VHAPM_TOC.aspx. ***NOTE:*** *This is an internal VA website that is not available to the public.*

t. U.S. Food and Drug Administration: Tissue & Tissue Products, available at: http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/.

u. Supply Chain Common Operating Picture (SCCOP) intranet site, located at: https://app.powerbigov.us/home. ***NOTE:*** *This is an internal VA website that is not available to the public.*