

December 2, 2023

DELEGATION OF AUTHORITY AND OVERSIGHT FOR VHA ADVANCED MANUFACTURING

1. In accordance with VA Directive 0000, Delegations of Authority, dated November 14, 2018, and VHA Directive 0000, Delegation of Authority for Signature, Oversight and Management of VHA National Policy, dated October 11, 2023, the Under Secretary for Health has delegated to the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks the interim authority for signature, oversight and decisional authority over all Veterans Health Administration (VHA) Advanced Manufacturing activities while a directive is being prepared, with the exception of those functions and duties which, by statute or regulation, may not be delegated. **NOTE:** *This notice replaces VHA Notice 2022-11, Delegation of Authority and Oversight for VHA Advanced Manufacturing, dated October 5, 2022. The policy content in this notice remains unchanged.*
2. The Department of Veterans Affairs (VA) Puget Sound Health Care System is registered with the U.S. Food and Drug Administration (FDA) as an advanced manufacturing facility. **NOTE:** *The Central Virginia VA Health Care System and the Ralph H. Johnson VA Medical Center are no longer registered with the FDA as advanced manufacturing facilities.* The Office of Healthcare Innovation and Learning, a VHA Office of Discovery, Education and Affiliate Networks (DEAN)-affiliated program office, oversees VHA Advanced Manufacturing activities (e.g., 3D printing, digital manufacturing and point-of-care manufacturing) for medical devices furnished to Veterans for clinical care and service, in accordance with FDA registration and the quality management system established by DEAN, as required by FDA Quality System Regulation (21 C.F.R. Part 820).
3. The Office of Healthcare Innovation and Learning will coordinate with the National Program Office for Sterile Processing to ensure necessary adherence to standards and policies for sterile processing as well as those related to reusable medical devices, where applicable.
4. All inquiries concerning this action should be addressed to the VHA Office of Discovery, Education and Affiliate Networks (14) at VHA14HILFrontOffice@va.gov.
5. This VHA notice will expire and be archived on December 31, 2024.

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

/s/ Shereef Elnahal, MD, MBA
Under Secretary for Health

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