

NATIONAL CARDIAC DEVICE SURVEILLANCE PROGRAM

1. SUMMARY OF MAJOR CHANGES: This Veterans Health Administration (VHA) directive:

a. Updates the title of the Deputy Under Secretary for Health for Operations and Management to the Chief Operating Officer (COO).

b. Updates the title of the Deputy Under Secretary for Health for Policy and Services to Assistant Under Secretary for Health for Clinical Services as the signatory authority of the directive.

c. Updates the title of the Chief of Specialty Care Services to Chief Officer, Specialty Care Program Office (SPCO).

d. Updates the title of the National Program Director for Cardiology to the Executive Director, National Cardiology Program.

e. Updates the title of the Director of the VA National Cardiac Device Surveillance Program (NCDSP) to the Executive Director, VHA NCDSP.

f. Assigns new and updated responsibilities in paragraph 2 to the COO; the Assistant Under Secretary for Health for Clinical Services; the Chief Officer, SPCO; the Executive Director, National Cardiology Program; the Executive Director, VHA NCDSP; the Associate Director of Engineering and Recalls, VHA National Center for Patient Safety (NCPS); the Veterans Integrated Services Network (VISN) Director; the Department of Veterans Affairs (VA) medical facility Director; the VA medical facility Chief of Cardiology; and VA medical facility health care providers.

g. Adds paragraph 3, Oversight and Accountability.

h. Incorporates Terms of Service (TOS) that establish the VHA NCDSP as a Nationally Designated Telehealth Hub (NDTH) and adds a link to the NCDSP TOS in paragraph 5.

2. RELATED ISSUES: VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023; VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020; VHA Directive 1915, Enterprise Clinical Resource Sharing through Telehealth from Nationally Designated Telehealth Hubs, dated January 5, 2023.

3. POLICY OWNER: The Specialty Care Program Office (11SPEC) is responsible for the content of this VHA directive. Questions may be addressed to NCDSPSF@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: There are no local document creation requirements in this directive.

5. RESCISSIONS: VHA Directive 1189, National Cardiac Device Surveillance Program, dated January 13, 2020, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of January 2030. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

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

/s/ Erica Scavella, M.D., FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services and Chief Medical
Officer

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 April 17, 2025.

CONTENTS

NATIONAL CARDIAC DEVICE SURVEILLANCE PROGRAM

1. POLICY 1

2. RESPONSIBILITIES 1

3. OVERSIGHT AND ACCOUNTABILITY 5

4. TRAINING 5

5. BACKGROUND 5

6. DEFINITIONS 6

7. RECORDS MANAGEMENT 7

8. REFERENCES 7

NATIONAL CARDIAC DEVICE SURVEILLANCE PROGRAM

1. POLICY

It is Veterans Health Administration (VHA) policy that all Veterans with cardiac implantable electronic devices (CIED) who receive ongoing follow-up care for their CIED at any Department of Veterans Affairs (VA) medical facility must have their CIEDs registered with the VHA National Cardiac Device Surveillance Program (NCDSP) in order to facilitate VA's response to United States (U.S.) Food and Drug Administration (FDA) and manufacturer product alerts and recalls. In addition, it is VHA policy that all Veterans registered with the NCDSP who are willing and able to participate in remote monitoring be enrolled in a remote monitoring program under the authority of the VHA NCDSP. **NOTE:** *This directive focuses on CIED registration and remote monitoring; for policy related to defective medical devices and FDA recalls, see VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.* **AUTHORITY:** 38 U.S.C. §§ 1730C, 7301(b).

2. RESPONSIBILITIES

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

b. **Chief Operating Officer.** The Chief Operating Officer (COO) is responsible for:

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

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

(3) Overseeing VISNs to ensure the effectiveness of and compliance with this directive.

c. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO) is responsible for:

(1) Supporting the Specialty Care Program Office (SPCO) with implementation and oversight of this directive.

(2) Supporting the development of mitigation or corrective actions to address noncompliance with this directive.

d. **Chief Officer, Specialty Care Program Office.** The Chief Officer, SCPO is responsible for supporting the Executive Director, VHA NCDSP in executing their responsibilities as outlined in this directive.

e. **Executive Director, Cardiology National Program.** The Executive Director, Cardiology National Program is responsible for:

(1) Appointing the Executive Director, VHA NCDSP.

(2) Providing oversight and guidance to the Executive Director, VHA NCDSP to ensure their responsibilities are fulfilled as outlined in this directive.

(3) Working with the Associate Director of Engineering and Recalls, VHA National Center for Patient Safety (NCPS) and the Executive Director, VHA NCDSP to determine the appropriate VHA response to FDA and device manufacturer product recalls and safety alerts involving CIEDs.

f. **Executive Director, VHA National Cardiac Device Surveillance Program.** The Executive Director, VHA NCDSP is responsible for:

(1) Managing the VHA NCDSP staff to complete the following requirements:

(a) Ensuring that requests for Veteran registration with the VHA NCDSP and enrollment in remote monitoring are processed according to the Cardiology-Specialty Supplement, available on the VHA NCDSP SharePoint site at:

<https://dvagov.sharepoint.com/sites/OITEPMOEPMDDES/Projects/559/Clinicalsite/SOPs%20%20Guides/Forms/AllItems.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(b) Ensuring that remote transmissions with alerts on CIED manufacturer websites are reviewed by VHA NCDSP staff (e.g., NCDSP nurses and medical instrument technicians) within 1 business day and the remainder are reviewed within 3 business days of transmission.

(c) Ensuring that responsible VA CIED clinics are notified immediately by telephone or email by VHA NCDSP staff when critical clinical findings are discovered upon review of remote monitoring transmissions in accordance with the Clinic Notification and Patient Welfare Check SOP, available at:

<https://dvagov.sharepoint.com/sites/OITEPMOEPMDDES/Projects/559/Clinicalsite/SOPs%20%20Guides/Forms/AllItems.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Maintaining a secure database of CIEDs and their associated leads that are implanted in Veterans who are followed by VA CIED clinics in compliance with VA and VHA data security best practices, updating the database every business day as needed, and maintaining that data for the life of the Veteran.

(3) Working with the Associate Director of Engineering and Recalls, VHA NCPS and the Executive Director, Cardiology National Program to determine the appropriate VHA response to FDA and device manufacturer product recalls and safety alerts involving CIEDs.

(4) Promoting compliance with registration of Veterans with CIEDs with the VHA NCDSP by providing VA medical facilities with lists of Veterans who have been seen for CIED-related care, but who are not registered with the VHA NCDSP, every 4 months.

(5) Tracking and making reports available every 4 months to VA CIED clinics on both the percentage of Veterans followed by a local VA CIED clinic who are actively enrolled in remote monitoring through the VHA NCDSP and, among the Veterans enrolled, the percentage of Veterans who are adherent to remote monitoring.

(6) Notifying responsible VA health care providers who provide frontline clinical care for Veterans with CIEDs regarding VA recommended responses to FDA and manufacturer product recalls and alerts, and assisting them with identifying affected Veterans.

(7) Establishing the VHA NCDSP as a Nationally Designated Telehealth Hub (NDTH) and maintaining a current telehealth Terms of Service (TOS) agreement signed by the hosting VISN Director(s). **NOTE:** See *VHA Directive 1915, Enterprise Clinical Resource Sharing through Telehealth from Nationally Designated Telehealth Hubs, dated January 5, 2023, for additional information on telehealth hubs.*

(8) Maintaining a publicly viewable list of VHA NCDSP staff authorized to read remote transmissions.

g. Associate Director of Engineering and Recalls, VHA National Center for Patient Safety. The Associate Director of Engineering and Recalls, VHA NCPS is responsible for:

(1) Working with the Executive Director, Cardiology National Program and the Executive Director, VHA NCDSP to determine the appropriate VHA response to FDA and device manufacturer product recalls and safety alerts involving CIEDs.

(2) Consulting with the Executive Director, Cardiology National Program and Executive Director, VHA NCDSP when a safety vulnerability is identified through adverse event reporting that could affect additional Veterans and may require the development of a Patient Safety Alert, Patient Safety Advisory, or Patient Safety Notice (see VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023).

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

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing the Assistant Under Secretary for Health for Clinical Services and the COO when barriers to compliance are identified.

(2) Overseeing corrective actions to address operational noncompliance at the VISN and VA medical facilities within the VISN.

(3) Working with the Executive Director, VHA NCDSP to maintain the TOS agreement if they are the hosting VISN Director.

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

(1) Ensuring overall VA medical facility compliance with this directive and taking corrective action if noncompliance is identified.

(2) Providing adequate resources for VA medical facility staff to comply with this directive.

j. **VA Medical Facility Chief of Cardiology.** *NOTE: The VA medical facility Chief of Medicine is the recommended designee if there is not a VA medical facility Chief of Cardiology at a VA medical facility.* The VA medical facility Chief of Cardiology or designee (e.g., Chief of Medicine) is responsible for:

(1) Ensuring that VA health care providers register all Veterans for whom they provide ongoing follow-up care for their CIEDs with the VHA NCDSP.

(2) Establishing local procedures for responding to clinical alerts generated by remote monitoring in a clinically appropriate time frame.

(3) Establishing local procedures to monitor and promote Veterans' adherence with key aspects of remote monitoring (i.e., maintaining the ongoing connectivity of their home transmitter and making transmissions as scheduled).

k. **VA Medical Facility Health Care Providers.** VA medical facility health care providers who follow Veterans for the expressed purpose of monitoring their CIEDs are responsible for:

(1) Registering all Veterans with CIEDs who receive ongoing follow-up care for their CIED at any VA medical facility with the VHA NCDSP. *NOTE: VA health care providers are not required to register Veterans with CIEDs with the VHA NDCSP if no aspect of CIED clinical care is provided at the health care providers' VA medical facility.*

(2) Offering remote monitoring to all Veterans with CIEDs, informing Veterans about the benefits and responsibilities of participating in remote monitoring, and notifying the VHA NCDSP of Veterans who consent and are willing and able to enroll in the remote monitoring program. *NOTE: Enrollment in remote monitoring external to the VHA NCDSP is prohibited.*

(3) Following local procedures for responding to clinical alerts generated by remote monitoring in a clinically appropriate time frame.

(4) Following local procedures to monitor and promote Veterans' adherence with key aspects of their remote monitoring program.

(5) Identifying affected Veterans with CIEDs and implementing recommended actions related to FDA and manufacturer product recalls and alerts involving implanted CIEDs. **NOTE:** For remove-from-use actions related to products that are not currently implanted, consult VHA Directive 1068.

(6) Adhering to the TOS when delivering telehealth services to Veterans.

3. OVERSIGHT AND ACCOUNTABILITY

a. **Internal Controls.** The internal controls in this directive are:

(1) Leadership oversight by the Chief Officer, SCPO; Executive Director, Cardiology National Program; Executive Director, VHA NCDSP; VISN Director; and VA medical facility Director as outlined in paragraph 2 of this directive.

(2) Compliance with applicable TOS and national and local procedures.

b. **Metrics.** The metrics in this directive that assess the directive or program effectiveness are:

(1) The Executive Director, VHA NCDSP provides VA medical facilities with lists of Veterans who have received CIED-related care, but who are not registered with the NCDSP, every 4 months.

(2) The Executive Director, VHA NCDSP provides VA CIED clinics with reports every 4 months on the percentage of Veterans followed by each VA CIED clinic who are enrolled with the VHA NCDSP and participating in remote monitoring; and the percentage of Veterans adherent to remote monitoring among the participating Veterans.

(3) The Executive Director, VHA NCDSP ensures processes are in place so that remote transmissions with alerts on CIED manufacturer websites are reviewed within 1 business day and the remainder are reviewed within 3 business days of transmission.

(4) Immediate email notification to VA CIED clinics by the VHA NCDSP staff when critical clinical findings are discovered upon review of remote monitoring transmissions.

4. TRAINING

There are no formal training requirements associated with this directive.

5. BACKGROUND

a. The VHA NCDSP has monitored Veterans with CIEDs through a Patient Care Services clinical program since 1980.

b. The VHA NCDSP serves four primary roles:

(1) Administrative tracking of CIEDs implanted in Veterans.

(2) Facilitating the remote monitoring of Veterans with CIEDs.

(3) Providing subject matter expertise, information on potentially affected Veterans, and guidance to VHA program offices and VA medical facilities in the event of U.S. FDA or manufacturer safety notification or recalls affecting CIEDs.

(4) Providing clinical support to VA health care providers who follow Veterans with CIEDs by informing them about critical findings discovered via remote monitoring.

c. The VHA NCDSP activities as a NDTH are covered by the NCDSP TOS, available at: <https://vaww.telehealth.va.gov/resources/1915/index.asp>. **NOTE:** *This is an internal VA website that is not available to the public.*

6. DEFINITIONS

a. **Cardiac Implanted Electrical Device.** A CIED is a device implanted in a patient with the purpose of electrical stimulation of the heart or monitoring the electrical activity of the heart. Examples of CIEDs include pacemakers, implanted cardiac defibrillators, cardiac resynchronization devices, cardiac contractility modulation therapy devices, and implanted heart rhythm monitors. This definition does not include cardiac stents, valves, occlusion devices, external heart monitors, or devices implanted solely to monitor congestive heart failure.

b. **Nationally Designated Telehealth Hubs.** NDTHs are telehealth hubs that have been designated by the COO to manage the provision of cross-VA medical facility telehealth services, delivered by NDTH telehealth health care professionals from one or more host VA medical facilities to any VA medical facility VHA-wide.

c. **Remote Monitoring.** Remote monitoring is a form of telemedicine in which patients with CIEDs transmit clinical and device data from their CIED at home to secure central servers, where it can be reviewed by health care providers. **NOTE:** *Remote monitoring reduces the time it takes to identify critical clinical events, improves a wide range of clinical outcomes, and reduces the need for in-person clinical follow-up visits. As a result, it is recognized by international cardiology societies as the standard of care in the management of patients with CIEDs.*

d. **Telehealth.** Telehealth is the use of electronic information or telecommunications technologies to support clinical health care, patient and professional health-related education, public health, and health administration. **NOTE:** *In accordance with 38 C.F.R. 17.417, VA health care providers reviewing CIED remote monitoring data for clinical purposes may provide those telehealth services within their scope of practice, functional statement, or privileges rated by the facility irrespective of the state or location within a state where the VA health care provider or Veteran is located.*

e. **Telehealth Hub.** A telehealth hub is a clinical and administrative organization at a national, consortium, regional, VISN, or VA medical facility level that facilitates and supports the sharing of telehealth services across VA medical facilities by health care

professionals from one or more host VA medical facilities. Examples include Clinical Resource Hubs, Tele-Critical Care Hubs, and VISN-level Clinical Contact centers.

f. **Terms of Service.** For the purposes of this directive, TOS define the clinical, technical, and business requirements for a telehealth clinical service delivered from a NDTH along with the service's contingency plans and emergency handoff procedures.

NOTES: (1) TOS have similar content to a TSA. The main difference is that a TOS, once established for a NDTH, define the NDTH service and standard requirements for every participating site without requiring a unique agreement or signature from each site. This is unlike a TSA which is a unique, signed agreement with each participating site. (2) To exemplify the value of a TOS, a telehealth hub that intends to serve Veterans at any VA medical facility would only need to develop one TOS in place of developing unique, signed TSAs with numerous VA medical facilities.

7. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

8. REFERENCES

- a. 38 U.S.C. §§ 1730C, 7301(b).
- b. 38 C.F.R. § 17.417.
- c. VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.
- d. VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food From VA Medical Facilities, dated June 19, 2020.
- e. VHA Directive 1915, Enterprise Clinical Resource Sharing through Telehealth from Nationally Designated Telehealth Hubs, dated January 5, 2023.
- f. VHA NCDSP SharePoint site. SOPs & Guides:
<https://dvagov.sharepoint.com/sites/OITEPMOEPMDDES/Projects/559/Clinicalsite/SOPs%20%20Guides/Forms/AllItems.aspx>. **NOTE:** This is an internal VA website that is not available to the public.
- g. VHA Office of Connected Care. VHA Telehealth Services website. NCDSP TOS.
<https://vaww.telehealth.va.gov/resources/1915/index.asp>. **NOTE:** This is an internal VA website that is not available to the public.