Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1189
Transmittal Sheet
January 13, 2020

NATIONAL CARDIAC DEVICE SURVEILLANCE PROGRAM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive provides policy to ensure that all VA patients with cardiovascular implantable electronic devices (CIEDs) are registered with the VHA National Cardiac Device Surveillance Program (NCDSP) and that when appropriate they are enrolled in a remote monitoring program.

2. SUMMARY OF CONTENT: This policy provides the requirements that Veterans Affairs (VA) patients with CIEDs be registered with the NCDSP, that willing and eligible patients with CIEDs be offered remote monitoring via the NCDSP, that processes are in place at the NCDSP and local clinics so that important clinical findings discovered on remote monitoring are acted on in a clinically timely manner, and that processes are in place for the VA to effectively respond to US Food and Drug Administration (FDA) and Manufacturer CIED alerts and recalls.

3. RELATED ISSUES: VHA Directive 1068 Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014.

4. RESPONSIBLE OFFICE: The Office of Specialty Care Services (10P11) is responsible for the content of this VHA Directive. Questions may be referred to 202- 461 - 7120.

5. RECISSIONS: None.

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 This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Heath
for Policy and Services

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 Publication Distribution List on January 15, 2020.

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1. PURPOSE

This Veterans Health Administration (VHA) directive provides policy for VHA National Cardiac Device Surveillance Program (NCDSP) to monitor the safety of cardiovascular implantable electronic devices (CIEDs) and provide VA medical facilities with clinical information necessary to treat Veterans with CIEDs. This policy provides the requirements for the registration of patients with CIEDs with the NCDSP and for the enrollment of patients in a remote monitoring program in coordination with VHA National Cardiac Device Surveillance Program. **AUTHORITY:** Title 38 United States Code (U.S.C.) 1730C, 7301(b).

2. BACKGROUND

a. The VHA National Cardiac Device Surveillance Program (NCDSP) has monitored patients with cardiac implanted electrical devices (CIEDs) through a Patient Care Services Clinical Program since 1980.

b. The NCDSP serves four primary roles:

(1) Administrative tracking of CIEDs implanted in Veterans.

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

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

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

3. DEFINITIONS

a. **Cardiac Implanted Electrical Device.** A cardiac implanted electrical device (CIED) is a device implanted in a patient with the purpose of monitoring and/or treating the patient's heart rhythm. Examples include pacemakers, implanted cardiac defibrillators, 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. **Remote Monitoring.** Remote monitoring is a form of store and forward telemedicine in which patients with CIEDs transmit clinical and device data from their CIED from home to secure central servers where it can be reviewed by clinical providers. ***NOTE:*** *Remote monitoring reduces the time to the recognition of important clinical events, improves a wide range of clinical outcomes, reduces the need for in-*

person clinical follow-up visits and as a result is recognized by international cardiology societies as the standard of care in the management of patients with CEIDs.

c. **Telehealth.** Telehealth is 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 Title 38 Code of Federal Regulations 17.417, clinical 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 healthcare provider or patient is located*.

4. POLICY

It is VHA policy that all Veterans who receive care for their CIEDs at any VA medical facility must have their medical devices registered with VA NCDSP in order to facilitate the VA response to FDA and manufacturer product alerts and recalls, and that Veterans with CIEDs who are willing and able to participate in remote monitoring will be enrolled in a remote monitoring program under the auspices of the NCDSP. ***NOTE:*** *VA health care providers must register CIEDs for remote monitoring through NCDSP. Enrollment in remote monitoring external to the NCDSP is prohibited. However, providers are not required to register Veterans with CIEDs through NDCSP if no aspect of CIED clinical care is provided at the providers' VA medical facility*. ***NOTE:*** *This directive focuses on CIED registration and remote monitoring; for policy related to defective medical devices and FDA recalls, see VHA Directive 1068 Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014.*

5. RESPONSIBILITIES

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

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

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

(2) Ensuring that each VISN Director has sufficient resources to fulfill the terms of this directive in all VA health facilities within that VISN.

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

c. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for communicating to the Deputy Under Secretary for Health and Operations and Management administrative guidance and programmatic information to the field for distribution.

d. **Chief of Specialty Care Services and National Program Director for Cardiology.** The Chief of Specialty Care Services and National Program Director for Cardiology is responsible for:

(1) Ensuring that the NCDSP has sufficient resources to fulfill the terms of this directive.

(2) Appointing the Director of the NCDSP.

e. **Director of the VA National Cardiac Device Surveillance Program.** The Director of the VA National Cardiac Device Surveillance Program is responsible for managing the NCDSP staff to achieve the following:

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

(a) Ensuring processes are in place so that requests for patient registration with the NCDSP and enrollment in remote monitoring are processed according the NCDSP Standard Operating Procedures. ***NOTE:*** *Please contact the NCDSP for current SOPs.*

(b) Ensuring processes are in place so that remote transmissions with high priority findings are reviewed within 1 business day and the remainder are reviewed within 3 business days of transmission.

(c) Ensuring that local VA referring clinics are notified immediately by email by the NCDSP staff when critical clinical findings are discovered on review of remote monitoring transmissions.

(2) Maintaining a database of CIEDs and their associated leads that are implanted in VA patients.

(3) Working with the National Center for Patient Safety to determine the appropriate VHA response to FDA and device manufacturer recalls and safety alerts.

(4) Notifying responsible VHA health care providers who provide front-line clinical care for Veterans with CIEDs regarding VA recommended response to FDA and manufacturer recalls and alerts and assisting them with identifying affected patients.

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

(1) Providing oversight of VA medical facilities to assure compliance with this directive, relevant standards, and applicable regulations.

(2) Communicating the contents of this directive to each of the VA medical facility Directors.

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

(1) Providing adequate resources for local clinic staff to comply with this directive.

(2) Providing oversight to ensure compliance with the directive.

h. **VA Medical Facility Chief of Cardiology.** The VA medical facility Chief of Cardiology or designee is responsible for: ***NOTE:*** *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*.

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

(2) Establishing local procedures to monitor and promote the compliance of patients with key aspects of remote monitoring to include maintaining the ongoing connectivity of their home transmitter and making scheduled transmissions as scheduled.

i. **VA Health Care Providers.** VA health care providers who follow patients for the expressed purpose of monitoring their CIEDs are responsible for:

(1) Registering all their patients with CIEDs with the NCDSP.

(2) Offering remote monitoring to all patients who have CIEDs and registering patients who are willing and able to participate in remote monitoring with the NCDSP.

(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 the compliance of patients with key aspects of their remote monitoring program.

NOTE: *For the purposes of this directive, the VA health care provider refers to the provider who follows Veterans for the express purpose of monitoring their CIEDs*.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., 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. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

a. 38 U.S.C 1730C.

b. 38 U.S.C. 7301(b).

c. 38 CFR 17.417.

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

e. VHA Handbook 1050.01, VHA National Center for Patient Safety Improvement Handbook, dated March 4, 2011.