



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Alleged Issues in the  
Cardiology Department at  
the Richard L. Roudebush  
VA Medical Center

Indianapolis, Indiana



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## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations concerning delays in interpreting and reporting patient cardiology tests and scheduling patients for cardiology procedures, deficiencies in pacemaker data recordkeeping, and supervisory concerns in the Device Clinic at the Richard L. Roudebush VA Medical Center (facility), Indianapolis, Indiana.<sup>1</sup>

Specifically, the allegations included the following:

1. Electrocardiogram (ECG), cardiac event, and Holter monitor tracings reports are not interpreted timely.<sup>2</sup>
2. Patients in need of cardiac surgery procedures are not scheduled for over a year.
3. Pacemaker data records (tracings) are not scanned into the electronic health record (EHR).
4. A cardiologist lacked appropriate credentials to supervise the Device Clinic in October 2018.
5. Registered nurses (nurses) “run” the Device Clinic unsupervised by cardiologists.
6. Cardiologist turnover has been high at the facility.

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<sup>1</sup> The Device Clinic is an area within the facility’s Cardiology Department for cardiac-related testing procedures, including surveillance devices such as electrocardiograms, Holter monitors, and cardiac event monitors. Invasive procedures are not performed in the Device Clinic.

<sup>2</sup> American Heart Association. An ECG (or EKG) is a test that measures the electrical activity of the heart. With each beat, an electrical impulse or “wave” travels through the heart. An electrocardiograph creates a tracing during the heartbeat that shows the timing of the upper and lower chambers of the heart. <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/electrocardiogram-ecg-or-ekg>. (The website was accessed on March 21, 2019.) Zio Patch National Institutes of Health (NIH) Director’s Blog. An event monitor records the heart’s electrical activity when a patient has symptoms (event), such as an abnormally fast or slow heartbeat. <https://directorsblog.nih.gov/tag/zio-patch/>. (The website was accessed on March 28, 2019.) Merriam-Webster, *Medical Definition of Holter monitor*. A Holter monitor is a portable device that logs a continuous record of the heart’s activity to detect abnormal heart rhythm. <https://www.merriam-webster.com/medical/Holtermonitor> and My HealtheVet, [http://www.veteranshealthlibrary.org/Search/142,83074\\_VA](http://www.veteranshealthlibrary.org/Search/142,83074_VA). (The websites were accessed on March 21, 2019.) For purposes of this report, the OIG inspection team considered the time frame at issue to be the time elapsed between the time of the test to the completion of the initial interpretation.

During the hotline inspection, the OIG team reviewed an additional allegation that Surgery Service maintained an unauthorized wait list of 19 patients for an electrophysiology procedure (Maze procedure) yet to be offered at the facility.<sup>3</sup>

The OIG substantiated that cardiologist turnover has been high at the facility. Since October 2016, six of eight cardiologists left the facility. Former Veterans Health Administration (VHA) cardiologists cited “hostile working environment,” workload, and salary as reasons for leaving. Facility leaders credited internal strife, time and attendance issues, and resentment over not being able to work at the university affiliate on VA time as reasons for the cardiologists’ high turnover. The OIG did not find evidence of adverse clinical outcomes resulting from staff turnover.

The OIG substantiated that from July to December 2018, the facility’s Cardiology Department and Surgery Services staff did not utilize the required consult process and maintained an unauthorized wait list of 19 patients for a Maze procedure. Documentation suggests that as early as October 2018, facility leaders initiated an action plan through a Cardiology-Cardiovascular Collaboration Workgroup to offer the Maze procedure and were actively discussing a list of patients who “opted” for the procedure at the facility, once available. Prior to the planning phases of the Maze procedure, a cardiologist and a cardiac surgeon discussed the procedure option with patients and developed the list of candidates who chose to undergo the procedure at the facility (with no predetermined start date) rather than using the required consult process to refer patients to another VA or non-VA care.<sup>4</sup>

In November 29, 2018, the Cardiology-Cardiovascular Collaboration Workgroup discussed that the approval for Maze procedure equipment was stalled at the Veterans Integrated Service Network so the growing list of patients waiting for the procedure would be sent out to the community. In January 2019, leaders ensured the Maze procedure candidates received appropriate referrals. The OIG did not find evidence of adverse clinical outcomes resulting from the use of the unauthorized wait list.<sup>5</sup>

The OIG did not substantiate that

- ECG, cardiac event, and Holter monitor tracings reports were not interpreted timely;
- Patients in need of cardiac surgery procedures were not scheduled for over a year;

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<sup>3</sup> VHA Directive 1230(1), *Outpatient Scheduling Process and Procedures*, July 15, 2016, amended July 12, 2019. VHA permits an electronic wait list as the official list to track patients who have been waiting over 90 days for an appointment. The additional allegation was added to the OIG inspection on May 22, 2019. Mayo Clinic, *Maze Procedures*. The Maze procedure is a minimally invasive surgical treatment that combines electrophysiology (electrical mapping of the heart) and cardiac surgery treatments to help restore a normal heart rhythm. <https://www.mayoclinic.org/tests-procedures/maze-procedure/proc-20384973>. (The website was accessed on June 26, 2019.)

<sup>4</sup> VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016.

<sup>5</sup> For the purposes of this report, the OIG considered an adverse clinical outcome to be death, an unexpected progression of disease, suboptimal treatment, or a need for higher level care.

- A cardiologist lacked appropriate credentials to supervise the Device Clinic in October 2018; and
- Nurses ran the Device Clinic unsupervised.

Pacemaker tracings were not scanned into the EHR; however, the facility's practice of entering tracings into EHR notes was acceptable according to the VA Director of the National Cardiology Program within the Office of Specialty Care Services. The National Cardiology Program Director recognized the lack of a policy, handbook, or directive governing this type of documentation; commented on the impracticability of cutting, pasting, and scanning multiple paper pacemaker strips into the EHR; and explained that it was common practice for staff to incorporate critical information from the tracing into a standardized note. Following the OIG's site visit, the Cardiology Department initiated a process to scan pacemaker reports into the EHR despite the lack of requirement to do so.

After reviewing the Cardiology Department and Surgery Services staff's compliance with VHA requirements related to consults, the OIG found that electrophysiology providers were not using the VHA consult process for electrophysiology procedures prior to February 2019. Due to the low volume of electrophysiology procedures, cardiologists used view alerts to schedule them as opposed to the required consult process.<sup>6</sup> VHA requires staff to use the consult process to ensure consistency and provide the ability to manage timely and appropriate care, which is not possible when using the view alert process alone.<sup>7</sup>

Of the 33 unique patients' EHRs reviewed that used a view alert, the OIG found that 10 patients waited more than the required 30 days for an appointment but did not find evidence of adverse clinical outcomes related to waiting beyond the required timeframe.

The OIG made four recommendations related to cardiology staffing recruitment and retention, staff understanding of authorized and unauthorized patient wait lists, and the training of staff on consult process and wait list policies.

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<sup>6</sup> In February 2019, the Chief of Cardiology directed cardiologists to use the consult process for electrophysiology procedures.

<sup>7</sup> VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016.

## Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A and B). Recommendations 1–4 will remain open and the OIG will follow up on the planned actions until they are completed.



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## Abbreviations

ECG	electrocardiogram
EHR	electronic health record
OIG	Office of Inspector General
PID	patient indicated date
SOP	standard operating procedure
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations concerning delays in interpreting and reporting patient cardiology tests and scheduling patients for cardiology procedures, deficiencies in pacemaker data recordkeeping, and supervisory concerns in the Device Clinic at the Richard L. Roudebush VA Medical Center (facility), Indianapolis, Indiana.<sup>1</sup> Additionally, the OIG team reviewed the Cardiology Department and Surgery Services staff's compliance with Veterans Health Administration (VHA) requirements related to consults and wait lists.

## Background

The facility is part of Veterans Integrated Service Network (VISN) 10. As a tertiary care facility in Indiana, referrals are received from VHA facilities at Fort Wayne and Marion, Indiana, and Danville, Illinois. The facility operates 10 community clinics.<sup>2</sup> VHA classifies the facility as Level 1a, a high complexity facility. Between October 1, 2017, and September 30, 2018, the facility served 62,763 patients and had a total of 209 hospital operating beds, including 159 inpatient beds, and 50 domiciliary beds.<sup>3</sup> The facility provides acute inpatient medical, surgical, psychiatric, neurological, and rehabilitation care, as well as both primary and specialized outpatient services. Specialized services include comprehensive cardiac care, radiation oncology treatment, and community-based extended care.<sup>4</sup>

The facility is affiliated with the Indiana University School of Medicine. Physician residents and fellows pursue clinical training under the supervision of VA physicians in 22 accredited medical specialties.<sup>5</sup>

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<sup>1</sup> The Device Clinic is an area within the facility's Cardiology Department that is responsible for the cardiac-related testing procedures, including surveillance devices such as electrocardiograms (ECGs), Holter monitors, and cardiac event monitors. Staff do not perform invasive procedures in the Device Clinic.

<sup>2</sup> Specifically, the facility operates four community based outpatient clinics in Bloomington, Martinsville, Terre Haute, and West Lafayette, Indiana; two mental health clinics in Bloomington and Terre Haute, Indiana; a YMCA VA Clinic in Indianapolis, Indiana; and, three community clinics in Edinburgh, Indianapolis, and Shelbyville, Indiana.

<sup>3</sup> The VHA Facility Complexity Model categorizes medical facilities by complexity levels 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex. VHA Office of Productivity, Efficiency and Staffing. <http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx>. (The website was accessed on June 27, 2019, and is an internal VA website not publicly accessible.)

<sup>4</sup> About the Veteran Health Indiana, <https://www.indianapolis.va.gov/about/index.asp>. (The website was accessed on July 21, 2019.)

<sup>5</sup> Richard L. Roudebush VA Medical Center. <https://www.va.gov/directory/guide/facility.asp?id=62>. (The website was accessed on July 23, 2019.)

## Allegations and Related Concern

On January 28, 2019, the OIG's Comprehensive Healthcare Inspection Program team conducted a routine inspection of the facility and received allegations about the Cardiology Department that were subsequently submitted to the OIG Hotline division. On February 5, 2019, the OIG Hotline Working Group reviewed the referral and opened a hotline inspection on February 12 to evaluate the allegations:

1. Electrocardiogram (ECG), cardiac event, and Holter monitor tracings reports are not interpreted timely.<sup>6</sup>
2. Patients in need of cardiac surgery procedures are not scheduled for over a year.
3. Pacemaker data records (tracings) are not scanned into electronic health records (EHRs).
4. A cardiologist lacked appropriate credentials to supervise the Device Clinic in October 2018.
5. Registered nurses (nurses) "run" the Device Clinic unsupervised by cardiologists.
6. Cardiologist turnover has been high at the facility.

During the hotline inspection, the OIG Hotline Triage team received and reviewed an additional hotline referral involving an allegation that Surgery Services maintained an unauthorized wait list of 19 patients for an electrophysiology procedure (Maze procedure) yet to be offered at the facility.<sup>7</sup> The allegation was added to the hotline inspection.

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<sup>6</sup> American Heart Association Website. "An electrocardiogram (ECG or EKG) is a test that measures the electrical activity of the heartbeat. With each beat, an electrical impulse (or "wave") travels through the heart." An electrocardiograph creates a tracing during the heartbeat. A normal heartbeat on ECG will show the timing of the top and lower chambers of the heart. <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/electrocardiogram-ecg-or-ekg>. (The website was accessed on July 16, 2019.) Zio Patch-NIH Director's Blog. An event monitor records the heart's electrical activity when a patient has symptoms (events), such as an abnormally fast or slow heartbeat. <https://directorsblog.nih.gov/tag/zio-patch/>. (The website was accessed on March 28, 2019.) Merriam-Webster Medical Dictionary, *Medical Definition of Holter monitor*. A Holter monitor is a portable device that logs a continuous record of the heart's activity to detect abnormal heart rhythm. <https://www.merriam-webster.com/medical/Holtermonitor> and My HealtheVet, [http://www.veteranshealthlibrary.org/Search/142.83074\\_VA](http://www.veteranshealthlibrary.org/Search/142.83074_VA). (These websites were accessed on March 21, 2019.) For purposes of this report, the OIG inspection team defined timely as the time elapsed between the time of the test to the completion of the initial interpretation.

<sup>7</sup> VHA Directive 1230(1), *Outpatient Scheduling Process and Procedures*, July 15, 2016, amended July 12, 2019. VHA permits an electronic wait list as the official list to track patients who have been waiting over 90 days for an appointment. The OIG originally received the separate referral on January 14, 2019. Allegation 7 was added to the OIG inspection on May 22, 2019. Mayo Clinic, *Maze Procedures*. The Maze procedure is a minimally invasive surgical treatment that combines electrophysiology (electrical mapping of the heart) and cardiac surgery treatments to help restore a normal heart rhythm. <https://www.mayoclinic.org/tests-procedures/maze-procedure/pyc-20384973>. (The website was accessed on July 18, 2019.) Heart Surgery for Atrial Fibrillation (MAZE) | Cleveland Clinic, <https://my.clevelandclinic.org/health/treatments/17086-heart-surgery-for-atrial-fibrillation-maze>. (The website was accessed on June 13, 2019.)

During interviews, the OIG identified a related concern that electrophysiology providers were not using the VHA consult process prior to February 2019.

## Scope and Methodology

The OIG initiated the inspection on February 21, 2019, and conducted a site visit from April 23, 2019, through April 25, 2019. During the site visit, members of the OIG team conducted a physical inspection of the Device Clinic office.

The OIG team conducted interviews with facility leaders; managers; employees including nurses, schedulers, and formerly employed cardiologists; and other relevant staff with knowledge of identified issues. Other interviewees included the VA Directors of the National Cardiac Device Surveillance Program and the National Cardiology Program within the Office of Specialty Care Services to clarify program requirements or expectations related to Device Clinic supervision, procedure scheduling, pacemaker tracing recordkeeping, and staffing.

The OIG team reviewed relevant VHA directives and handbooks, VISN and facility policies, standard operating procedures (SOPs), and patient EHRs. Other relevant documents included available meeting minutes between October 2017–April 2019 of the following: Acute Care Committee, Cardiology Huddle, Cardiology-Cardiovascular Collaboration Committee, Professional Standards Board Committee, and the Executive Committee of the Medical Staff. The OIG also reviewed facility internal quality reviews, incident and safety reports, and June 2016–June 2019 Cardiology Department staffing data. To evaluate the facility’s practice of scheduling cardiac surgery patients, the OIG team queried the VA Corporate Data Warehouse specifically for cardiac surgery view alerts issued from October 1, 2017, through May 30, 2019.<sup>8</sup>

Within the context of this report, the OIG considered an adverse clinical outcome to be death, an unexpected progression of disease, suboptimal treatment, or a need for higher level care. This report focuses on patient harm in terms of adverse clinical outcomes.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take

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<sup>8</sup> VHA Directive 1088, *Communication of Test Results to Providers and Patients*, October 7, 2015. View Alerts are EHR notifications to providers about clinical information. VA Corporate Data Warehouse, *Health Services Research & Development*. The VA Corporate Data Warehouse collects data from VHA sources, such as the patient EHR, creates data sets, and allows access or query of VHA historical data that is updated daily. Warehouse data contains demographic and clinical characteristics, as well as healthcare utilization data. [https://www.hsrd.research.va.gov/for\\_researchers/vinci/cdw.cfm](https://www.hsrd.research.va.gov/for_researchers/vinci/cdw.cfm). (The website was accessed on August 14, 2019.)

place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## Inspection Results

### 1. Allegation: Untimely Interpretation of ECG, Cardiac Event, and Holter Monitor Tracings Reports

The OIG did not substantiate that ECG, cardiac event, and Holter monitor tracings reports were not interpreted timely.

#### ECG Reports

The OIG found that ECG machines contain embedded software allowing for immediate interpretation of tracings that produced initial results.<sup>9</sup> The ordering provider was responsible for reviewing and notifying patients of the results, and consulting with a cardiologist if the provider had questions or concerns about the ECG reports.<sup>10</sup>

While the Chief of Cardiology directed facility cardiologists to confirm (overread) the ordering providers' ECG findings, the OIG found no VHA or facility policy requiring cardiologists to routinely perform this practice or to do so within a certain timeframe.<sup>11</sup> According to interviews, if there was a discrepancy between the ordering provider's and cardiologist's interpretations, the cardiologist would notify the ordering provider.

While the OIG did not find untimely interpretations of ECGs, a backlog of ECG quality assurance confirmations (overreads) was identified in May 2018 and August 2018. Facility staff cited reasons for the backlog included technology issues related to duplicate reports,

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<sup>9</sup> American Heart Association, *Cardiac Event Recorder*. <https://www.heart.org/en/health-topics/arrhythmia/prevention--treatment-of-arrhythmia/cardiac-event-recorder>. (The website was accessed on October 30, 2019.) Anandic Medical Systems, *MUSE Cardiology Information System*. A tracing is a graphical representation of electrical activity of the heart. The MUSE Cardiology Information System is an ECG database management system that manages the flow of cardiac information from acquisition devices such as Holter and event monitors to cardiologists. MUSE users can pull ECG data from the acquisition device, analyze and confirm data, distribute results, and access the patient's EHR. <https://www.anandic.com/en/Clinical-Information-Systems/MUSE/page35073.htm>. (The website was accessed on March 27, 2019.) The facility's Chief of Cardiology estimated that the initial (machine/computer) ECG results are approximately 97–99 percent accurate, while the facility interventional cardiologist estimated 99 percent machine accuracy, and a VISN subject matter expert noted the rate to be 95 percent.

<sup>10</sup> VHA Directive 1088.

<sup>11</sup> The Chief of Cardiology directed the facility cardiologists to confirm ordering providers' ECG findings and tasked administrative staff to assign ECGs through the Muse software program. The ECG machine computer software provided an immediate ECG interpretation (first reading/interpretation). Then, the ordering provider reviewed the ECG and the computer-generated ECG report (second reading/interpretation). Finally, facility cardiologists provided an additional interpretation (commonly referred to as an "overread") for quality assurance purposes (third reading/interpretation).

cardiologists being overwhelmed with clinical work, and facility cardiologists overreading ECGs to assist two additional VA medical centers—a practice that concluded at the end of 2018.

Of the patient EHRs reviewed during the hotline inspection, the OIG found no adverse clinical outcomes related to a backlog of ECG overreads.

## **Cardiac Event and Holter Monitor Tracings Reports**

At the time of the inspection, the facility contracted with a cardiac surveillance device vendor and required 24 hours a day, 7 days a week (real-time) cardiac event recording, and the submission of a daily summary report from the vendor to the Cardiology Department.<sup>12</sup> Holter monitoring was also contracted through an event monitoring service that did not require real-time monitoring.

While the OIG found no VHA or facility policy requiring cardiologists to interpret cardiac event and Holter monitor tracings reports within a defined timeframe, the facility's Cardiology Department established clinical criteria for the vendor to contact the patient and facility cardiology staff about significant findings. The vendor was required to provide the facility with the data and results within 24 hours unless the results indicated a life-threatening event, in which case the notification was required to be immediate. At the completion of cardiac event and Holter monitor studies, the facility had access to the preliminary vendor report, and administrative staff uploaded the report to the patient's EHR and assigned a cardiology fellow or a cardiology attending physician or both to confirm the results.<sup>13</sup> In instances when significant findings were noted in the initial Holter monitor tracings reports, health technicians were required to verbally notify the cardiology fellow or attending physician for further action.<sup>14</sup>

The facility established a process for ensuring real-time cardiac event monitoring but there were no time requirements for cardiologists to confirm the results of ECGs, cardiac events, or Holter monitor tracings report interpretations. The OIG found that facility cardiologists confirmed the cardiac surveillance device vendor's real-time results.

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<sup>12</sup> The contract for cardiac event monitoring services required the vendor to provide the necessary technology to transmit cardiac events from the patient's device through wireless, cell phone, or trans-telephonic technology.

<sup>13</sup> Medline Plus, *Holter heart monitor*. A Holter monitor study requires a patient to wear a Holter monitor device to record the heart's electrical activity. <https://medlineplus.gov/ency/imagepages/8810.htm>. (The website was accessed on November 27, 2019.)

<sup>14</sup> Indianapolis VA Cardiology Unit, *Standard Operating Procedure for Charting Holter Reports in MARS and CPRS*, May 31, 2018.

## 2. Allegation: Delays in Scheduling Cardiac Surgery Procedures

The OIG did not substantiate that patients in need of cardiac surgery procedures were not scheduled for over a year.

Clinical consults include a patient indicated date (PID), which is the date the provider deems an appointment clinically appropriate. The PID is based upon the needs of the patient and should be at the soonest appropriate date.<sup>15</sup> VHA's timeliness goal for consults specifies scheduling an appointment within 30 calendar days or less from the PID.<sup>16</sup>

Four names were submitted with the allegation. The OIG used the PID in the patients' EHRs to determine if delays occurred. The OIG found two of the four patients experienced no delay and the other two experienced delays due to administrative scheduling issues. Neither of the two patients waited over a year for care nor did they experience adverse clinical outcomes from the delays.

## 3. Allegation: Pacemaker Tracings Not Scanned into the EHR

The OIG substantiated that pacemaker tracings were not scanned into EHRs. However, the facility's practice of entering tracings data into EHR notes was acceptable according to the VA Director of the National Cardiology Program within the Office of Specialty Care Services.

VHA requires that patient health information is captured and stored in the EHR to increase healthcare practitioner access to patient data.<sup>17</sup> Facility Device Clinic nurses reviewed and entered the pacemaker tracing information into an EHR note, then stored the paper tracings in a locked cardiology office, accessible to electrophysiology providers. OIG team members inspected the locked office and observed pacemaker tracings filed in individually-labeled patient folders.

Device Clinic nurses reported that to cut the paper tracings, and then arrange and affix them to standardized paper in order to scan the tracings into the EHR, was time consuming. Depending on the pacemaker manufacturer, report tracings may vary in size and could not be printed on standard size paper. Rather, tracings are printed on continuous paper strips, as illustrated in figure 1, and a single report can be several feet in length.

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<sup>15</sup> VHA Memorandum, *Scheduling and Consult Policy Update* (VAIQ#7798804) June 5, 2017; VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016. PID includes earlier definitions of the clinically indicated date (CID) and preferred date (PD). The PID is determined by the date the provider requests an appointment for a patient and by the date when the provider decides an appointment is clinically appropriate.

<sup>16</sup> VHA Directive 1230.

<sup>17</sup> VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.



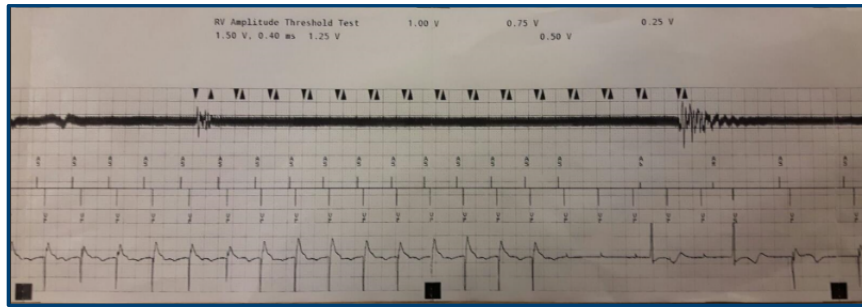


Figure 1. Example of a pacemaker tracing

Source: <https://www.cardiocases.com/en/pacingdefibrillation/forum/forum-tracings/interesting-pacemaker-strip-1>

The National Cardiology Program within the Office of Specialty Care Services recognized the burden imposed on VA medical centers to scan paper tracings into the EHR and accepted EHR nursing notes as primary source documentation. Although not required by the national program office, following the OIG site visit, a facility program manager reported that the Cardiology Department initiated a process to scan pacemaker reports into the EHR.

#### **4. Allegation: A Cardiologist Lacked Credentials to Supervise the Device Clinic**

The OIG did not substantiate that a cardiologist lacked appropriate credentials to supervise the Device Clinic in October 2018. Credentialed cardiologists are not required to possess additional specific credentials to supervise the Device Clinic.

Credentialing is the systematic process of screening and evaluating a clinical provider's qualifications to practice medicine in a facility.<sup>18</sup> Neither VHA nor the Heart Rhythm Society require specific credentials for cardiologists to supervise a device clinic.<sup>19</sup> Supervising cardiologists are generally not required to be physically present in a device clinic but are to be available as needed. Typically, on-site nurses or technicians managed the daily operations of the clinic.

The OIG team interviewed key staff, spoke with the VA National Device Surveillance Program Director, and reviewed the credentials of all facility cardiologists who supervised the Device Clinic in October 2018. The OIG found that the cardiologists were credentialed and, therefore, were able to supervise the Device Clinic.

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<sup>18</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was scheduled for recertification on or before the last working day of October 2017 and has not been recertified.

<sup>19</sup> Heart Rhythm Society, *About Us*. Heart Rhythm Society is an international non-profit organization that serves as a leading resource on cardiac pacing and electrophysiology for cardiac rhythm specialists. <https://www.hrsonline.org/>. (The website was accessed on July 8, 2019.)

## 5. Allegation: Lack of Device Clinic Nurse Supervision

The OIG did not substantiate that nurses “run” the Device Clinic unsupervised by cardiologists. The OIG determined that allowing nurses to operate the Device Clinic, without a cardiologist physically present, was in alignment with the facility’s SOP. Furthermore, the OIG found that neither VHA nor the Heart Rhythm Society issued requirements related to how nurses manage a device clinic.

According to the facility’s SOP, the Device Clinic is physically staffed and operated by two nurses who are responsible for testing cardiac devices, entering tracing data into the EHR, and informing a cardiologist of abnormal findings for further clinical evaluation. The OIG team reviewed the facility’s SOP, interviewed Device Clinic staff, the Chief of Cardiology, and the Deputy Chief of Staff and determined the Device Clinic nurses followed required facility procedures.<sup>20</sup> Additionally, the Director of the VISN 10 Cardiology Advisory Group confirmed that the facility’s Device Clinic procedures aligned with standard practice – that Device Clinic nurses performed the day-to-day activities and were to notify a cardiologist with unexpected results or concerns.<sup>21</sup>

## 6. Allegation: High Cardiologist Turnover

The OIG substantiated that cardiologist turnover had been high at the facility.<sup>22</sup> The OIG found that since October 2016, six of eight cardiologists left the facility.<sup>23</sup> Of the patient EHRs reviewed during the hotline inspection, the OIG did not find evidence of adverse clinical outcomes resulting from staff turnover.

High clinical staff turnover is linked to increased healthcare costs, decreased productivity, and increased prevalence of adverse clinical outcomes.<sup>24</sup> VHA has not established a standardized staffing methodology for specialty care services, such as cardiology. According to a 2017

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<sup>20</sup> Indianapolis VA Cardiac Device Clinic Standard Operating Procedure, *n.d.*, *Cardiac Device Clinic Operations/Scheduling*.

<sup>21</sup> Indianapolis VA Cardiac Device Clinic Standard Operating Procedure, *n.d.*, *Cardiac Device Clinic Operations/Scheduling*.

<sup>22</sup> Leonard, Kimberlee and Thompson, Jayne, *The Definition of High Turnover Rate*, February 4, 2019. “Average turnover rate for all employment is 3.5 percent.” <https://smallbusiness.chron.com/definition-high-turnover-rate-11272.html>. (The website was accessed on August 12, 2019.)

<sup>23</sup> Between October 2016 and April 2019, two of the six vacancies were filled (between September and October 2018). However, three additional cardiologists left VA employment (between September 2018–January 2019). As of June 2019, the Cardiology Department employed a total of four cardiologists and Human Resources was actively recruiting for four vacant cardiologist positions.

<sup>24</sup> Kabdiyeva, Aigerim, *Physician Turnover and Productivity in the Veterans Health Administration*, June 2, 2019. US Government Accountability Office, GAO 18-124, Veterans Health Administration, *Better Data and Evaluation Could Help Improve Physician Staffing, Recruitment, and Retention Strategies*, October 2017.

Government Accountability Office report on physician staffing and the VA national program directors for the Cardiology and Cardiac Device Surveillance Programs, VHA managers and facility leaders balance patient care needs with facility financial resources when staffing specialty areas, such as cardiology departments.

Facility leaders allotted a maximum of 8.0 full-time equivalent staff cardiologist positions for the Cardiology Department, including the Chief of Cardiology. The facility estimated that since October 2016, six cardiologists, including a previous service chief, left the facility.<sup>25</sup> As of June 2019, four of the eight (50 percent) full-time equivalent cardiologist positions remained vacant.

The OIG team reviewed available cardiologists' exit interviews and spoke with cardiologists who left the facility and were no longer employed by VHA.<sup>26</sup> The most common reasons former VHA cardiologists cited for leaving included "hostile working environment," high staff turnover with resulting increased workload, and lower salary than the private sector.<sup>27</sup> The Deputy Chief of Staff attributed infighting, time and attendance issues, and anger over not being able to work at the university affiliate on VA time as reasons for the cardiologists turnover.<sup>28</sup>

The OIG team interviewed cardiologists at the facility, and they expressed that they had been working more than anticipated and felt unable to take leave due to the lack of adequate staff. One cardiologist expressed not being aware of harm resulting from a staffing shortage, but that the potential exists; and if the Cardiology Department continued to be understaffed, the cardiologist would give notice and leave.

The Cardiology Department was actively recruiting cardiologists. The facility's Human Resources Department was assisting the Cardiology Department with recruitment efforts, including providing guidance on the use of incentives.

## **7. Allegation: Unauthorized Patient Wait List for the Maze Procedure**

The OIG substantiated that from July through December 2018, the facility's Cardiology Department and Surgery Services maintained an unauthorized wait list of 19 patients for a Maze

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<sup>25</sup> During an interview, the facility's Cardiology Human Resource Specialist estimated that since 2016, at least five cardiologists separated from the facility. However, the documentation the Human Resource Specialist later provided revealed that six cardiologists separated from the facility.

<sup>26</sup> The Deputy Chief of Staff, Acting Chief of Cardiology, and Human Resource Managers conducted exit interviews with cardiologists separating from the facility. They documented two exit interviews.

<sup>27</sup> For the purposes of this report, the OIG found these human resource issues outside the scope of this inspection and will make no recommendations on those matters. The OIG notified the Director of the issues noted by the former cardiologists.

<sup>28</sup> The Deputy Chief of Staff was reportedly notified that several cardiologists were "putting time in" at the affiliate during scheduled VA work hours. Additionally, the Deputy Chief of Staff stated those cardiologists became angry when they were notified this was not appropriate and they would not be permitted to continue this practice.

procedure not yet offered at the facility. The OIG determined that none of the patients experienced an adverse clinical outcome due to waiting for the procedure.

The Maze procedure is a minimally invasive surgical procedure, which is a collaborative effort between the Cardiology Department and Surgery Services that combines electrophysiology (electrical mapping of the heart) and cardiac surgery treatments to help restore a normal heart rhythm.<sup>29</sup> Cardiologists consider it an elective surgery, reserved for a small number of patients in which other medical treatments and procedures have failed.

VHA policy requires staff to use the electronic wait list for new patient appointment requests; staff are not to utilize any other wait list formats, such as an Excel spreadsheet, a log book, or a paper list.<sup>30</sup> When an appointment or treatment is not available at a VA facility, VHA policy requires the use of a non-VA care consult for established patients to request the needed care in the community. When a non-VA care consult is used, facility staff monitor the consult to ensure transparent, clinically appropriate, and timely care.<sup>31</sup>

The OIG found that in July 2018, before facility leaders were prepared to offer the Maze procedure, a cardiologist and a cardiac surgeon prematurely discussed the procedure with patients and developed a list of candidates. Through interviews, the OIG team discovered that a cardiologist and a cardiac surgeon offered patients the choice to wait until the procedure was available at the facility or be referred to another VA or a non-VA provider that offered the procedure. The OIG team learned that a cardiology nurse practitioner, at the cardiologist's request, maintained an Excel spreadsheet for those patients who expressed interest in waiting to undergo the procedure at the facility. The cardiologist was aware that the procedure could not yet be performed at the facility and there was no predetermined start date at the time the patients were added to the unauthorized wait list. While unclear as to the exact date when facility leaders officially decided to offer the Maze procedure to cardiology patients, documentation suggests that in October 2018, facility leaders created an action plan to offer the Maze procedure, and were aware of patients who "opted" for the procedure at the facility.

According to the December 6, 2018, Cardiology-Cardiovascular Collaboration meeting minutes, 12 of the 19 patients on the unauthorized list were referred through non-VA care and seven patients elected to delay the Maze procedure. Additionally, the Deputy Chief of Staff authored a formal memo to facility leaders dated January 15, 2019, indicating that human resources staff discovered a list of patients waiting for the Maze procedure on an administrative staff member's

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<sup>29</sup> Heart Surgery for Atrial Fibrillation (MAZE) | Cleveland Clinic, <https://my.clevelandclinic.org/health/treatments/17086-heart-surgery-for-atrial-fibrillation-maze>. (The website was accessed on June 13, 2019.)

<sup>30</sup> VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016.

<sup>31</sup> VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016.

computer.<sup>32</sup> The Deputy Chief of Staff's memo outlined the actions taken by facility leaders to address the patients waiting for the Maze procedure. Although the OIG identified contradictory information when facility leaders were made aware of the Maze procedure wait list (October 2018 versus January 2019), documentation supports that patient needs were addressed. As of September 2019, facility leaders and Cardiology Department and Surgery Services staff had not yet offered the procedure.

The OIG conducted an EHR review of the 19 patients on the Maze procedure wait list and found that, of the 19 patients

- Twelve patients were interested in the Maze procedure and received a consult to another VA or for non-VA care;
- Six patients received information, were not clinically ready, or were undecided about the Maze procedure; and
- One patient's EHR did not contain documented discussions related to the Maze procedure. The patient was followed by another VA facility and received cardiology care in the community.

After the facility leaders addressed the unauthorized wait list, the average time it took for facility staff to enter a consult for the 12 patients who were interested in the Maze procedure was 66 days (range 0–153 days) from the date they were placed on the unauthorized list.

The OIG found that facility staff initially kept an unauthorized list for the Maze procedure and did not timely submit consults for VA or non-VA community care when a patient requested the procedure.<sup>33</sup> Maintaining an unauthorized wait list rather than utilizing a consult prohibited Cardiology Department and Surgery Services staff from ensuring that patients received timely care through the consult tracking mechanism. The OIG determined that the 19 patients did not experience adverse clinical outcomes while on the unauthorized list.

## 8. Related Concern: Use of Consults

The OIG found that prior to February 2019, cardiologists did not use the consult process to order electrophysiology procedures, reportedly because of low patient volume. Instead, electrophysiology providers used view alerts to request scheduling for electrophysiology procedures.

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<sup>32</sup> This memorandum addressed the same patients that had already been discussed in the Cardiology-Cardiovascular Collaboration meeting during November and December 2018.

<sup>33</sup> VHA Directive 1601, *Non-VA Medical Care Program*, January 23, 2013. This directive was scheduled for recertification on or before the last working day of January 2018 and has not been recertified. VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016.

View alerts are notifications clinical staff use to communicate patient information within the EHR. VHA requires clinical staff to monitor the alerts and take action as appropriate.<sup>34</sup>

VHA requires staff to use the consult process to ensure consistency and provide the ability to manage timely and appropriate care.<sup>35</sup> VHA's timeliness goal for consults specifies scheduling an appointment within 30 calendar days or less from the PID.<sup>36</sup>

Prior to February 2019, the electrophysiology providers used view alerts to notify the Cardiology Case Manager of the need for a procedure.<sup>37</sup> Upon receipt of the view alert, a case manager acknowledged receipt and coordinated an appointment with the provider and the patient, outside of the consult process.<sup>38</sup>

To determine if there were delays or adverse clinical outcomes, the OIG team requested all the view alerts that the Cardiology Case Manager received between February 2016 and September 2018. Because a consult was not used, the OIG could not refer to a PID to determine if a delay existed. Instead, the OIG team evaluated the timeliness of appointments using the date the provider specified in the view alert. In the absence of a specified date, the OIG used the date the provider entered the view alert.

The OIG found that cardiologists generated 121 view alerts to notify a scheduler to coordinate electrophysiology procedures for 33 unique patients.<sup>39</sup> The OIG reviewed the 33 unique patients' EHRs and determined 10 patients waited beyond the required 30 days for an appointment, per the VHA consult process. The OIG found no evidence of an adverse clinical outcome for the 10 patients who experienced delays in scheduling.

## Conclusion

The OIG did not substantiate that ECG, cardiac event, and Holter monitor tracings reports were not interpreted timely. ECG machines provided immediate, computer-generated results that were interpreted by the ordering provider. A contracted service provided interpretation of cardiac

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<sup>34</sup> Office of the Deputy Under Secretary for Health for Operations and Management, Memorandum for View Alerts Optimization Program, March 8, 2017. VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

<sup>35</sup> VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016.

<sup>36</sup> VHA Memorandum, *Scheduling and Consult Policy Update* (VAIQ#7798804) June 5, 2017; VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016. PID includes earlier definitions of the clinically indicated date (CID) and preferred date (PD). The PID is determined by date the provider requests an appointment for a patient and by the date when the provider decides an appointment is clinically appropriate.

<sup>37</sup> In February 2019, the Chief of Cardiology directed cardiologists to use the consult process for electrophysiology procedures.

<sup>38</sup> Specifically, the case manager acknowledged receipt of the view alert, added a note to the electronic calendar in Share Point, entered the information on note paper in three-ring binder, contacted the patient to coordinate a date, and then entered the appointment in the facility's electronic scheduling system.

<sup>39</sup> The term "unique" refers to the number of patients after duplicates are removed.

event and Holter monitor tracings reports. The facility had an established process for ensuring real-time cardiac event monitoring but there were no time requirements for cardiologists to confirm the results of the ECG or Holter and cardiac event report interpretations.

The OIG did not substantiate that patients in need of cardiac surgery procedures were not scheduled for over a year. Two of four reviewed patients experienced delays due to administrative issues. Neither of the two patients waited over a year for care nor did they experience adverse clinical outcomes from the delay.

Pacemaker tracings were not scanned into EHRs; however, the facility's practice of entering the tracings into an EHR note was acceptable according to the VA Director of the National Cardiology Program within the Office of Specialty Care Services. Although not required by the National Cardiology Program within the Office of Specialty Care Services, following the OIG site visit, the facility leaders initiated a process to incorporate pacemaker tracings into the EHR.

The OIG did not substantiate that a cardiologist lacked appropriate credentials to supervise the Device Clinic in October 2018. The OIG found that credentialed cardiologists are not required to possess additional specific credentials to supervise the Device Clinic.

The OIG did not substantiate that nurses ran the Device Clinic unsupervised. The OIG determined that nurses operated the Device Clinic, without a cardiologist physically present in alignment with the facility's SOPs related to supervision. Furthermore, the OIG found that neither VHA nor the Heart Rhythm Society have issued requirements related to how nurses manage a device clinic.

The OIG substantiated that cardiologist turnover was high at the facility. Since October 2016, six of eight allotted cardiologists separated from the facility. Of the patient EHRs reviewed during this inspection, the OIG did not find evidence of adverse clinical outcomes resulting from staff turnover.

From July to December 2018, the facility's Cardiology Department and Surgery Services staff did not utilize the required consult process and maintained an unauthorized wait list of 19 patients for a Maze procedure not yet offered at the facility. The OIG determined that none of the patients experienced an adverse clinical outcome due to waiting for the procedure.

The OIG identified that electrophysiology providers were not using the required VHA consult process for electrophysiology procedures prior to February 2019. Instead, they relied solely on the use of view alerts. The OIG reviewed the 33 unique patient EHRs and determined 10 patients waited beyond the required 30 days for an appointment. The OIG found no evidence of an adverse clinical outcome for the 10 patients who experienced delays in scheduling.

## **Recommendations 1–4**

1. The Richard L. Roudebush VA Medical Center Director reviews and develops cardiology recruitment and retention processes to reach the approved staffing level.
2. The Richard L. Roudebush VA Medical Center Director explores the possible reasons for difficulties recruiting and retaining cardiologists and takes action to resolve identified issues.
3. The Richard L. Roudebush VA Medical Center Director ensures that facility staff understand the Veterans Health Administration policy regarding authorized and unauthorized patient wait lists, and monitors compliance.
4. The Richard L. Roudebush VA Medical Center Director ensures facility managers train staff regarding the consult process and wait list policies, and monitors compliance.



## Appendix A: VISN Director Memorandum

### Department of Veterans Affairs Memorandum

Date: January 9, 2020

From: Director, VA Healthcare System (10N10)

Subj: Healthcare Inspection—Alleged Issues in the Cardiology Department at the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana

To: Director, Office of Healthcare Inspections (54HL07)  
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed the draft report of the Healthcare Inspection – Alleged Issues in the Cardiology Department at the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana.
2. I concur with the responses and action plans submitted by the Richard L. Roudebush VA Medical Center Director.
3. Thank you for the opportunity to respond to this report

*(Original signed by:)*

Lisa A. Pyle, Quality Management Officer  
for  
RimaAnn O. Nelson

## Appendix B: Facility Director Memorandum

### Department of Veterans Affairs Memorandum

Date: January 7, 2020

From: Acting Director, Richard L. Roudebush VA Medical Center (583/00)

Subj: Healthcare Inspection—Alleged Issues in the Cardiology Department at the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana

To: Director, VA Healthcare System (10N10)

1. I have reviewed the VA OIG's draft report of the Alleged Issues in the Cardiology Department conducted at the Richard L. Roudebush VA Medical Center in Indianapolis Indiana. I concur with the OIG's recommendations.
2. I am submitting my plan to comply with the recommendations to include timeline for completion and sustainment of improvements.
3. I appreciate the OIG's partnership in our continuous improvement efforts.

*(Original signed by:)*

Laura E. Ruzick, FACHE  
Acting Director

## Facility Director Response

### Recommendation 1

The Richard L. Roudebush VA Medical Center Director reviews and develops cardiology recruitment and retention processes to reach the approved staffing level.

Concur.

Target date for completion: September 30, 2020

### Director Comments

The facility has been monitoring the recruitment and retention for the Cardiology Service since July 2018. The facility employs a dedicated full-time physician recruiter, with special emphasis placed on hard-to-recruit positions such as cardiology. The Physician Recruiter advertises and recruits for well-qualified applicants utilizing attendance at national conferences and career fairs, and posts positions in online journals. Over the last year, the Physician Recruiter has provided a total of forty-nine (49) cardiology physician applicants for review and consideration for hire (fourteen (14) electrophysiology; twenty-six (26) interventional cardiology; and, nine (9) general cardiology). The Recruiter and the Chief, Cardiology Section, review the candidates and then move to the interview process. The Cardiology Section has an approved staffing level of 12; 7 FTEE (Full Time Equivalent Employee) physician, 1 FTEE Chief and 4 FTEE Advance Practice Nurses. Staffing will be monitored until we can sustain 50% staffing level for 6 months and achieve 75% (9) staffing of all vacant positions (12) by September 30, 2020. Staffing will be reported at Quality Safety and Value Committee.

### Recommendation 2

The Richard L. Roudebush VA Medical Center Director explores the possible reasons for difficulties recruiting and retaining cardiologists and takes action to resolve identified issues.

Concur.

Target date for completion: September 30, 2020

### Director Comments

The reasons for difficulties recruiting and retaining cardiologists have been explored since the facility began tracking candidates in July 2018. One of the most challenging issues is the significant disparity in physician/cardiology salaries. In the past our facility has been able to collaborate with our academic affiliate in co-recruitment, however, the affiliate is currently experiencing similar difficulties in recruitment. The facility will be completing a salary survey as

well as exploring other options to increase staffing within the Cardiology Section. The full range of recruitment incentives has always been a part of the process.

The Cardiology Section has an approved staffing level of 12; 7 FTEE physician, 1 FTEE Chief and 4 FTEE Advance Practice Nurses. Staffing will be monitored until we can sustain 50% staffing level for 6 months and achieve 75% (9) staffing of all vacant positions (12) by September 30, 2020. Staffing will be reported at Quality Safety and Value Committee.

### **Recommendation 3**

The Richard L. Roudebush VA Medical Center Director ensures that facility staff understand the Veterans Health Administration policy regarding authorized and unauthorized patient wait lists, and monitors compliance.

Concur.

Target date for completion: April 30, 2020

### **Director Comments**

All employees are required to complete annual VA Privacy and HIPAA (Health Insurance Portability and Accountability Act) which fully describes the policy regarding authorized and unauthorized patient wait lists as referenced in the section “Logbooks” (from the training: Paper logbooks contain a written list of patients with specific identifiers which is maintained over time. Employees should never keep paper log books. VHA Directive 1605.01, Privacy and Release of Information prohibits the use of physical (paper) log books and they are not allowed unless there is a specific regulation that requires a paper log book). Any employee who is non-compliant in the completion of the training will have their computer access removed until the training is completed. Facility will maintain 100% compliance in the completion of the VA Privacy and Security Awareness Training Module for six months. Compliance will be monitored by the Quality Safety and Value Committee until 100% compliance is maintained for six consecutive months.

### **Recommendation 4**

The Richard L. Roudebush VA Medical Center Director ensures facility managers train staff regarding the consult process and wait list policies, and monitors compliance.

Concur.

Target date for completion: April 30, 2020

## **Director Comments**

All employees were required to complete training modules related to the implementation of the MISSION (Maintaining Internal Systems and Strengthening Integrated Outside Networks) Act by June 1, 2019. These training modules included the consult process and wait list policies. Facility will maintain 100% compliance in the completion of the Eligibility 101, Urgent Care 101, MISSION Act: Decision Support Tool (DST) Webinar, and Eligibility 201 (detailed Process Training) modules. Compliance will be monitored by the Quality Safety and Value Committee until 90% compliance is maintained for six consecutive months.

## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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