



DEPARTMENT OF VETERANS AFFAIRS  
Washington DC 20420

August 03, 2016

The Honorable Carolyn N. Lerner  
Special Counsel  
U.S. Office of Special Counsel  
1730 M Street, NW, Suite 300  
Washington, DC 20036

RE: OSC File No. DI-16-1181

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by an anonymous whistleblower at the Malcolm Randall Veterans Affairs Medical Center, Gainesville, Florida (the Medical Center). The whistleblower alleged that physicians failed to enter blood test orders for patients and that a lab technician fraudulently entered test orders under physicians' names, and that these practices constitute a violation of law, VA directives, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

When this referral was received, the Under Secretary for Health was assigned to review this matter and prepare a report in compliance with § 1213(d)(5) requirements. He, in turn, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report substantiates both allegations and makes six recommendations to the Medical Center. We will send your office follow-up information describing actions that have been taken by the Medical Center and other entities to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

  
Robert D. Snyder  
Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS  
Washington, DC**

**Report to the  
Office of Special Counsel  
OSC File Number DI-16-1181**

**Department of Veterans Affairs  
Malcolm Randall Veterans Affairs Medical Center  
Gainesville, Florida**



**Report Date: June 30, 2016**

**TRIM 2016-D-978**

## Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Malcolm Randall VA Medical Center (VAMC) (hereafter, the Medical Center) located in Gainesville, Florida. A person (hereafter, the whistleblower), who requested that his identity remain confidential, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on April 18–20, 2016.

### Specific Allegations of the Whistleblower

1. Gainesville VAMC surgical service physicians frequently fail to enter pre-operative blood test orders, creating undue delays in care; and
2. In an effort to mitigate these delays, **Employee A** fraudulently enters test orders under providers' names, without the proper authority or credentialing to do so.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

### Conclusions for Allegation 1

- VA **substantiates** that the Medical Center's Surgical Service physicians fail to enter pre-operative blood test orders in up to 1.3-6 percent of cases, creating undue delays in care. However, these delays in care are limited to the time that Veterans spend in the laboratory while Pathology and Laboratory Medicine (PLMS) staff members attempt to determine what tests are required and who should have ordered them. There were no delays in surgical care related to missing or delayed laboratory orders.
- Missing orders are not isolated to the Surgical Service, have a negative impact on PLMS workflow, and create longer wait times for Veterans awaiting specimen collection.
- Despite missing orders, laboratory results are available for surgical staff members when needed.

## **Conclusions for Allegation 2**

- VA **substantiates** that the lead health technician inappropriately entered test orders under providers' names without proper authority or credentialing and, in so doing, violated Veterans Health Administration (VHA) Handbook 1106.01 and Medical Center policy.
- The ordering of laboratory tests by any staff member who lacks the requisite clinical education and training poses a substantial and specific danger to public health and safety.
- In none of the subject cases did the VA team find evidence of patient harm resulting from the lead health technician's inappropriate actions.
- The Medical Center policies and procedures on handling laboratory orders by PLMS contain potentially-conflicting guidance because there are some circumstances where PLMS employees may be required to change, add, or amend orders.

## **Recommendations to the Medical Center**

1. Review the process for addressing missing orders with PLMS and clinic staff members and implement a quality improvement activity to decrease the frequency in which laboratory orders are not entered until Veterans arrive at the phlebotomy clinic.
2. Provide supervisory oversight, training, and education to the lead health technician on the specific limits related to laboratory order entry authorized for phlebotomists, which prohibits them from entering laboratory orders for providers without their requests.
3. Periodically review laboratory test orders written or changed by PLMS staff members to ensure staff are compliant with VHA Handbook 1106.01 and relevant Medical Center policy (as revised per recommendation #5 below).
4. Consider the initiation of progressive discipline for future non-compliance for misuse of Government property (e.g., electronic health record (EHR)) if the lead health technician continues to enter laboratory orders without providers' requests and without appropriate credentials. (5 Code of Federal Regulations § 2635.704).
5. Revise Medical Center policies and procedures pertaining to the handling of laboratory orders by PLMS staff members to eliminate potentially-conflicting guidance.
6. Invite an Ethics Specialty Team attorney to provide all PLMS staff with in-person refresher training on Government ethics.

## **Summary Statement**

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, engaged in gross mismanagement and abuse of authority, or created a substantial and specific danger to public health and safety. In particular, the Office of General Counsel (OGC) has provided a legal review, VHA Human Resources (HR) has examined personnel issues to establish accountability, and the Office of Accountability Review (OAR) has reviewed the report and has or will address potential senior leadership accountability. VA found violations of VA and VHA policy, and notes that a substantial and specific danger to public health and safety exists at the Medical Center.

## Table of Contents

Executive Summary .....	ii
I. Introduction .....	1
II. Facility and VISN Profile .....	1
III. Specific Allegations of the Whistleblower .....	1
IV. Conduct of Investigation .....	1
V. Findings, Conclusions, and Recommendations .....	3
Attachment A .....	11

## **I. Introduction**

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) assemble and lead a Department of Veterans Affairs (VA) team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Malcolm Randall VA Medical Center, (hereafter, the Medical Center) located in Gainesville, Florida. A person (hereafter, the whistleblower), who asked to remain anonymous, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on April 18–20, 2016.

## **II. Facility Profile**

The Medical Center, part of Veterans Integrated Service Network (VISN) 8, is a tertiary care facility with 255 authorized beds and a nursing home care unit of 34 beds. It is also an active teaching hospital, with an extensive array of specialty services, combining a full range of patient care services with state-of-the-art technology enhanced and supported through education and research. It is affiliated with the University of Florida, College of Medicine, training more than 180 of its medical school residents, interns, and students, annually, along with students in dentistry, nursing, physical therapy, health services administration, and pharmacy. The Medical Center also has affiliations with Florida State University, Valdosta State University, Santa Fe Community College, and Lake City Community College in nursing, social work, physical therapy, medical technology, and health care administration. In addition, the Medical Center conducts more than 300 active research projects in all the major branches of VA research.

## **III. Specific Allegations of the Whistleblower**

1. Gainesville VAMC Surgical Service physicians frequently fail to enter pre-operative blood test orders, creating undue delays in care; and
2. In an effort to mitigate these delays, **Employee A** [the lead health technician and a phlebotomist], fraudulently enters test orders under providers' names, without the proper authority or credentialing to do so.

## **IV. Conduct of Investigation**

The VA team conducting the investigation consisted of Erica Scavella, M.D., FACP, FACHE, Medical Investigator (an internist), and Douglas Howard, RN, MS, Clinical Program Manager. VA reviewed the relevant policies, procedures, professional standards, reports, memoranda, and other documents listed in Attachment A. We toured the Medical Center's pre-operative clinic, orthopedic clinic, pre-anesthesia clinic, and phlebotomy clinic, and held entrance and exit briefings with Medical Center leadership.

VA was unable to interview the anonymous whistleblower. We interviewed the following Medical Center employees:

- [REDACTED] Chief, Pathology and Laboratory Medicine (PLMS)
- [REDACTED] Anesthesiologist
- [REDACTED] Surgeon
- [REDACTED] Pharmacist, Anticoagulation Clinic
- [REDACTED] Pre-Anesthesia Clinic (PAC)
- [REDACTED] Surgical Day Stay Unit
- [REDACTED] Operating Room (OR) Nurse
- [REDACTED] Clinical Informatics
- [REDACTED] Support Staff, PAC
- [REDACTED] Support Staff, Surgical Day Stay Unit
- [REDACTED] Administrative Officer, PLMS
- [REDACTED] Supervisor Health Technician, PLMS
- [REDACTED] Lead Laboratory Health Technician, PLMS
- [REDACTED] Ancillary Test Coordinator, PLMS
- [REDACTED] Laboratory Health Technician, PLMS

The team conducted a tour of the Medical Center areas involved in preparing Veterans for surgery (pre-operative, surgical clinics, pre-anesthesia, and phlebotomy clinics) in order to understand workflow through the system. We also interacted with the following Medical Center employees during a facility tour on April 18, 2016:

- [REDACTED] ARNP-C, General Surgery
- [REDACTED] RN, Orthopedic Clinic
- [REDACTED] RN, PAC
- [REDACTED] Acting Nurse Manager, OR
- [REDACTED] Health Technician PLMS

## **VI. Findings, Conclusions, and Recommendations**

### **Allegation 1**

Gainesville VAMC Surgical Service Physicians frequently fail to enter preoperative blood test orders, creating undue delays in care.

### **Findings**

In the general surgery clinic, Veterans are given a pre-operative appointment and a pre-anesthesia appointment, both of which take place within 30 days of the procedure. During the preoperative appointment, the nurse practitioner reviews health history and assess for any changes to the Veteran's condition. The review and ordering of radiology and laboratory studies may also occur during this preoperative appointment, if necessary. During the pre-anesthesia appointment, a nurse reviews elements relevant to anesthesia and coordinates any relevant information with the surgical team. Typically, the pre-anesthesia clinic appointment is on the same day as the pre-operative appointment. The Veteran may be scheduled for a visit in the phlebotomy clinic to draw laboratory studies, as necessary. A default time of 8:00 a.m. is listed on all Veteran's surgery instruction letters for pre surgery clinic appointments.

In order to ensure the most up-to-date information, time-sensitive laboratory orders are collected the morning of the actual surgical procedure (including specimens for blood typing and cross matching, anticoagulation studies, glucose levels, and pregnancy testing). Nursing staff members assigned to the Same Day surgical unit, commonly referred to as an Outpatient Surgery unit outside of VA, perform phlebotomy and specimen collection on the pre-operative same day surgical cases scheduled at 6:00 a.m. PLMS collects specimens on all later surgical cases.

During interviews with staff members in the various surgical clinic areas, none could recall a time that missing laboratory values caused the cancellation of a surgical procedure, although they could recall some delays due to difficult blood draws or pregnancy tests which must be completed on the day of surgery.

PLMS staff members stated that the average workload each day is between 250-450 Veterans. PLMS provides phlebotomy services beginning at 4:00 a.m. on the inpatient units, which does not include same day surgical patients since they are considered outpatients. Outpatient phlebotomy services for patients from all outpatient clinics in the Medical Center, except for same day surgery patients, begin at 6:00 a.m. even though those clinic appointments do not begin until 8:00 a.m. Medical Center policy mandates that routine laboratory studies must be scheduled on the same day as the clinic appointment, but Veterans do not always report to the phlebotomy clinic on the correct date.<sup>1</sup> In order to ensure that Veterans are provided timely phlebotomy services in the event that they do not arrive on the correct date, procedures are in place that allow

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<sup>1</sup> North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-56, Change 2 *Clinical Laboratory Orders*, January 1, 2016.

PLMS staff members to search up to 7 days forward and 30 days backward to find existing laboratory orders.<sup>2</sup> During our tour of the phlebotomy clinic, we observed PLMS staff members as they checked in and processed Veterans with existing laboratory orders, a process that generally took less than 2 minutes.

If laboratory orders are not available when a Veteran presents to the phlebotomy clinic, they must wait until the order has been entered into the computerized patient record system (CPRS) by the provider. PLMS staff members described the process that they must follow in the event that an order cannot be located. First, they try to identify the provider who should have placed the laboratory order, typically by first asking the Veteran, then by looking at the Veteran's most recent clinic appointments. PLMS staff members then notify the ordering provider, designee, or clinic support staff members of the missing order and request a new order. Upon receipt of the order, the Veteran is placed back into the queue. PLMS staff members reported 6 to 15 missing orders from many different outpatient clinics out of 250-450 total visits to the phlebotomy clinic per day (an incidence of 1.3 to 6 percent). Because the steps required to address missing orders require significantly more time (10 minutes or longer), Veterans whose laboratory orders are missing create a backlog at the single check-in window. PLMS staff members have contact information for the various clinics to facilitate the timely entry of laboratory orders. We found that despite this disruption, missing orders do not impact the timeliness with which laboratory results are reported.

The VA Surgical Quality Improvement Program (VASQIP) OR Efficiency Matrix Dashboard includes four key metrics for efficiency including surgical case cancellation rates, utilization rates, lag time between surgical cases (which includes OR cleaning time, configuration of the OR for the next case, and any other logistical preparations needed before the next case can start), and the percentage of each day's first cases that begin on-time.<sup>3</sup> Of these four metrics pertaining to surgical efficiency, cancellation rates and the percentage of first case on-time starts would be expected to be affected by delays in PLMS.

We reviewed Medical Center data related to surgical case cancellations for the 12-month period from January 1, 2015, through December 31, 2015. The data show 182 cancellations due to "patient health status" during this period. "Patient health status" in this context refers to significant changes in the patient's condition that could negatively impact the patient during or after surgery, such as (but not limited to) uncontrolled hypertension, cardiac dysrhythmia, high blood sugar, or infection.

None of the 182 total occurrences of surgery cancellations ascribed to "patient health status" was related to missing laboratory values. Eight cancellations occurred because of abnormal laboratory values that had been ordered preoperatively. The remaining

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<sup>2</sup> Ibid.

<sup>3</sup> VASQIP -

[https://vawww.rtp.portal.va.gov/OQSV/10A4C/SRD/education/sfii/layouts/15/WopiFrame.aspx?sourcedoc=/OQSV/10A4C/SRD/education/sfii/SFII%20Toolkits/SurgFlowImprovelnitHandbookFY14\\_FINAL%20\(Sep%202014\).docx&action=default](https://vawww.rtp.portal.va.gov/OQSV/10A4C/SRD/education/sfii/layouts/15/WopiFrame.aspx?sourcedoc=/OQSV/10A4C/SRD/education/sfii/SFII%20Toolkits/SurgFlowImprovelnitHandbookFY14_FINAL%20(Sep%202014).docx&action=default)

174 cancellations were due to other comorbid conditions that made surgical intervention too risky or, in a small subset of instances, surgical intervention was no longer indicated.

Regarding surgery, the Medical Center has an 84 percent on-time rate for the previous 12 months ending December 31, 2015. If there were significant issues with missing or delayed laboratory results, it would be reflected in this measure.

### **Conclusions for Allegation 1**

- VA **substantiates** that the Medical Center's Surgical Service physicians fail to enter pre-operative blood test orders in up to 1.3-6 percent of cases, creating undue delays in care. However, these delays in care are limited to the time that Veterans spend in the laboratory while PLMS staff members attempt to determine what tests are required and who should have ordered them. There were no delays in surgical care related to missing or delayed laboratory orders.
- Missing orders are not isolated to the Surgical Service, have a negative impact on PLMS workflow, and create longer wait times for Veterans awaiting specimen collection.
- Despite missing orders, laboratory results are available for surgical staff members when needed.

### **Recommendations to the Medical Center**

1. Review the process for addressing missing orders with PLMS and clinic staff members and implement a quality improvement activity to decrease the frequency in which laboratory orders are not entered until Veterans arrive at the phlebotomy clinic.

### **Allegation 2**

In an effort to mitigate these delays, **Employee A** [the lead health technician and a phlebotomist], fraudulently enters test orders under providers' names, without the proper authority or credentialing to do so.

### **Findings**

VHA Handbook 1106.01 states: The Chief or Director of PLMS may delegate selected functions to qualified pathologists (physicians), medical laboratory scientists, laboratory managers, and supervisors.<sup>4</sup> Medical care responsibilities may only be delegated to physicians, unless there are specific protocols and parameters that allow other clinical staff members to intervene. Ordering laboratory and other ancillary studies are part of

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<sup>4</sup> VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

medical care and the responsibility of the physician or credentialed provider as this requires an in-depth knowledge of the specific medical condition and patient. In addition to physicians and credentialed providers, registered nurses can also enter certain laboratory studies using standing protocols approved by the Medical Center. We found evidence that the Medical Center had protocols in place in the PAC outlining the scope of duties of registered nurses to perform, facilitate, and expedite the preoperative evaluation of patients.<sup>5</sup> PAC nurses may place specific laboratory and other ancillary test orders in accordance with specific anesthesia protocols/guidelines. Registered nurses in the Same Day surgery unit also have a standard operating procedure that allows them to order specific laboratory tests for blood product administration (blood type and antibody screen) based on a protocol.<sup>6</sup>

Technical responsibilities, such as processing laboratory specimens, may be delegated to qualified laboratory personnel, as appropriate.”<sup>7</sup>

Several different employee categories in PLMS are germane to this case. Phlebotomists are: “...specialized clinical laboratory technicians who perform blood drawing services and specimen processing. They ensure patient identification, minimize risk of infection or harm during specimen collection and manage proper handling of collected specimens. Phlebotomists play a vital role in the diagnosis and treatment of Veterans.”<sup>8</sup> The individual named in allegation 2 is a phlebotomist. A medical technologist, who receives a higher level of education and training: “...perform[s] analytical testing of patient specimens and confirms test results for physicians to determine the presence and extent of disease. These professionals oversee the technical aspects of laboratory testing and consult with health care professionals on laboratory results. Medical technologists deliver high-quality patient care services to Veterans by providing precise and effective laboratory results.”<sup>9</sup> Medical technologists and phlebotomists can add laboratory tests under specific circumstances.

The Medical Center has standard operating procedures (SOP) in PLMS. Policy dictates that: “Only testing requests submitted by authorized physicians/caregivers will be accepted to be performed on specimens submitted to Pathology and Laboratory Medicine Service”.<sup>10</sup> Adding laboratory tests to specimens that have already been collected also requires orders to be “...requested and signed in the Computerized Patient Record System (CPRSA)/Veterans Health Information Systems and Technology

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<sup>5</sup> North Florida/South Georgia Veterans Health System VA Medical Center Anesthesiology Service Policy/Procedure Manual Policy No. 23, *Nursing Practice Guidelines for the Pre-Anesthesia Clinic (PAC)*, Change 4, August 20, 2014

<sup>6</sup> North Florida/South Georgia Veterans Health System VA Medical Center SOP, *Registered Nurse Ordering of Preoperative Type and Screen*, May 21, 2013.

<sup>7</sup> Ibid

<sup>8</sup> <https://mycareeratva.va.gov/careers/career/064599>

<sup>9</sup> <https://mycareeratva.va.gov/careers/career/064402>

<sup>10</sup> North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-2, Change 6, *Guidelines for Pathology and Laboratory Medicine Service Specimen Labels and Requisitions*, June 26, 2015.

Architecture (VistA) by providers...”<sup>11</sup> All laboratory orders require signature of the ordering provider, and unsigned or verbal orders are not accepted.<sup>12</sup>

An additional Medical Center policy addresses the process for rejecting and discarding mislabeled, unlabeled, partially labeled, illegibly labeled, and mismatching specimen/requisition orders and provides steps for a PLMS technologist to correct the issue in the VistA computer system.<sup>13</sup> The phlebotomy clinic also has a procedure for patient check-in, labeling and accessioning specimens, and canceling laboratory tests. This procedure outlines the process for the phlebotomist in the event that no orders are in VistA for the Veteran. The policy specifically states that the phlebotomist will contact the primary physician or designee for instructions. If the phlebotomist is unable to contact the primary physician or designee, the Veteran is directed to the Emergency Room for further assistance. There are no provisions for the phlebotomist to enter orders in this situation.

We interviewed PLMS staff members regarding the process for reviewing laboratory orders in VistA. The administrative officer for PLMS stated that there are only two individuals, including the health technician named in allegation 2, who are trained to cancel and re-order laboratory studies in the event that the Veteran refuses to have a specimen collected by phlebotomy staff members or there is a “ward collect.” The process as stated by the administrative officer is to cancel the full order, and re-enter the exact order as a “ward collect,” meaning that the nurses on the ward will collect the specimen. This occurs when the Veteran has an intravenous access (a catheter inserted into a vein for the purpose of administering fluids or medications directly into the circulatory system) from which to collect a specimen, and does not want an additional needle stick. PLMS staff members are not authorized to collect specimens from intravenous lines.

The laboratory package in VistA is an independent system that other systems, such as CPRS, use as a data source. Prior to CPRS, physicians used VistA directly to order laboratory studies, and PMLS staff used VistA to determine which studies to collect. CPRS consolidated multiple systems into one user interface but left the functionality of VistA in place for the actual laboratory order process. We interviewed the Clinical Informatics nurse and the Ancillary Test Coordinator (a VistA laboratory package expert) regarding assignment of specific tasks within VistA and CPRS.

According to the Clinical Informatics Nurse, the user profile assigned to phlebotomists does not allow them to enter orders in either CPRS or VistA; he was unfamiliar with the VistA laboratory package (a separate function). The typical flow of orders starts with

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<sup>11</sup> North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-48, Change 2, *Add-On Lab Orders Policy Gainesville and Lake City Divisions*, January 20, 2012.

<sup>12</sup> North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-56, Change 2, *Clinical Laboratory Orders*, January 1, 2016.

<sup>13</sup> North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-36, Change 10, *Specimen Rejection and Discard Policy*, June 26, 2015.

CPRS where the provider enters and signs the order. Once signed, the order will appear in VistA where the phlebotomist takes the appropriate action. Unsigned orders in CPRS (e.g., those entered per protocol by a nurse working in a clinic or inpatient unit), will not appear in VistA until signed by the provider.

All laboratory orders appear in VistA for action by phlebotomists. There are no actions in CPRS for phlebotomists, and few have access to this system. All phlebotomists have access to the laboratory package in VistA and can perform the same functions. In the phlebotomy clinic, Veterans are checked-in using this package, which also displays the active orders assigned for the Veteran. The Ancillary Test Coordinator stated that in the laboratory package it was possible for phlebotomists to order laboratory studies when providers request that tests are added. In the user profile assigned to phlebotomists, there is the ability to both add tests to an existing order and to order new laboratory tests. This functionality exists so that phlebotomists can cancel an order in the event there is some difficulty obtaining the specimen, the Veteran refuses, or if the nursing staff draws the specimen on the inpatient unit (as discussed above). Medical technologists also use this functionality when they receive add-on orders from providers after specimens are collected. The Medical Center does not have a mechanism to monitor laboratory order cancellations, add-ons, or other order entry functions completed by phlebotomists or technologists if they have entered orders outside of permitted parameters.

We interviewed the Administrative Officer, PLMS and the Supervisor Health Technician, both of whom discussed incidents where a phlebotomist entered orders for Veterans using the laboratory package process outlined above. VA reviewed the position descriptions and training records of all PLMS phlebotomists assigned to the Medical Center. Since phlebotomists do not undergo clinical education or training and do not have any type of professional health care license, they do not possess the knowledge and skills required to determine which, if any, laboratory tests a patient should receive. Phlebotomists are not subject to credentialing. The Supervisor Health Technician identified a specific example where a provider in the anticoagulation clinic contacted her about laboratory tests that she did not order. A similar circumstance was described in the letter from OSC; however, some of the details, including the provider's name and position, differed. VA reviewed the clinical facts surrounding both instances of care and found that patients seen in the anticoagulation clinic had orders entered into VistA by the lead health technician. In one instance, someone other than the identified ordering clinical pharmacist called PLMS to voice concerns. In the other instance, the identified ordering clinical pharmacist called PLMS to voice her concerns and to cancel the laboratory orders. The Administrative Officer, PLMS, provided evidence of verbal counseling of the lead health technician on the second incident.

In addition to the above incident, the VA team found substantial evidence to prove that the lead health technician named in allegation 2 had entered laboratory test orders in several different providers' names. However, we were unable to determine if she was re-entering erroneously deleted orders or amending providers' orders at their request, two permissible actions she is trained and authorized to take per above, or if these

orders were entered outside of these parameters. When the VA team interviewed this lead health technician, specifically asking if she ever entered orders in providers' names without their authorization, she denied it.

Our concern about these specific laboratory tests is that they were associated with a clinical pharmacist (PharmD) in the anticoagulation clinic, not a physician. Although evaluation and management of certain laboratory results are within the privileges of this pharmacist, two of the laboratory orders (complete blood count with differential and basic metabolic panel) are not within the privileges of any pharmacist in the anticoagulation clinic. Test results, when ordered without the provider's knowledge or given to the wrong provider, can cause delays to patient care, and when they exceed the provider's expertise, training, and education, may cause potential harm to patients. VA reviewed all incident reports and near miss reports related to preoperative procedures and processes for the past year and found no evidence of harm to any patients.

### **Conclusions for Allegation 2**

- VA **substantiates** that the lead health technician inappropriately entered test orders under providers' names without proper authority or credentialing and in so doing violated VHA Handbook 1106.01 and Medical Center policy.
- The ordering of laboratory tests by any staff member who lacks the requisite clinical education and training poses a substantial and specific danger to public health and safety.
- In none of the subject cases did the VA team find evidence of patient harm resulting from the lead health technician's inappropriate actions.
- The Medical Center policies and procedures on handling laboratory orders by PLMS contain potentially conflicting guidance because there are some circumstances where PLMS employees may be required to change, add or amend orders.

### **Recommendations to the Medical Center**

2. Provide supervisory oversight, training, and education to the lead health technician on the specific limits related to laboratory order entry authorized for phlebotomists, which prohibits them from entering laboratory orders for providers in the absence of documented lab requests by the providers.
3. Periodically review laboratory test orders written or changed by PLMS staff members to ensure staff are compliant with VHA Handbook 1106.01 and relevant Medical Center policy (as revised per recommendation #5 below).
4. Consider the initiation of progressive discipline for future non-compliance for misuse of Government property (e.g., EHR) if the lead health technician continues to enter laboratory orders without providers' requests and without appropriate credentials.

(5 CFR § 2635.704).

5. **Revise Medical Center policies and procedures pertaining to the handling of laboratory orders by PLMS staff members to eliminate potentially conflicting guidance.**
6. **Invite an Ethics Specialty Team attorney to provide all PLMS staff with in-person refresher training on Government ethics.**

## **Attachment A**

Documents in addition to the Electronic Medical Records reviewed.

North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service *Early Morning Laboratory Collection List Procedure*, January 22, 2016.

North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-56, Change 2, *Clinical Laboratory Orders*, January 1, 2016.

North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-2, Change 6, *Guidelines for Pathology and Laboratory Medicine Service Specimen Labels and Requisitions*, June 26, 2015.

North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-48, Change 2, *Add-On Lab Orders Policy Gainesville and Lake City Divisions*, January 20, 2012.

North Florida/South Georgia Veterans Health System VA Medical Center Pathology and Laboratory Medicine Service Memorandum No. 113-36, Change 10, *Specimen Rejection and Discard Policy*, June 26, 2015.

VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013.

VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

North Florida/South Georgia Veterans Health System VA Medical Center Anesthesiology Service Policy/Procedure Manual Policy No. 23, *Nursing Practice Guidelines for the Pre-Anesthesia Clinic (PAC)*, Change 4, August 20, 2014.

North Florida/South Georgia Veterans Health System VA Medical Center SOP, *Registered Nurse Ordering of Preoperative Type and Screen*, May 21, 2013.

Email from Glenda Skinner sent March 11, 2016, at 12:45 p.m. subject: FW: Patient orders.

North Florida/South Georgia Veterans Health System VA Medical Center SOP, *Patient Check-In Accessioning/Labeling Laboratory Test Samples Cancelling Laboratory Test Procedures*, (no date).