



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

August 13, 2018

The Honorable Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

Re: OSC File No. DI-18-1683/DI 18-1827

Dear Mr. Kerner:

I am responding to your February 21, 2018, letter to the Secretary regarding allegations made by an anonymous whistleblower at the Orlando Department of Veterans Affairs (VA) Medical Center, Orlando, Florida, that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. VA conducted a site visit to Orlando on March 12-15, 2018. I have signed the enclosed report and will take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Executive in Charge directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. We substantiated all three of the whistleblowers' allegations, including that Veteran wait times exceed 30 days from the clinically indicated date for endoscopy procedures; however, Orlando has a robust process for ensuring high-risk Veterans get appropriate intervention in a timely manner. We also substantiated that the Acting Chief of Medicine instructed some Gastroenterology personnel not to utilize the Care in the Community (CITC) program. Orlando determined that the contractor for the Veterans Choice Program (VCP) was unable to meet requirements; however, the facility continues to use other CITC programs and uses VCP eligibility rules to determine when to offer Veterans these services. Further, we substantiated that Orlando failed to offer Veterans access to community care when wait times exceed 30 days, in violation of the Veterans Access, Choice, and Accountability Act of 2014. We make five recommendations to Orlando.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink, reading "Robert L. Wilkie", is positioned below the word "Sincerely,".

Robert L. Wilkie

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-18-1683 and DI-18-1827**

**Department of Veterans Affairs (VA)
Orlando VA Medical Center
Orlando, Florida**



Report Date: July 16, 2018

TRIM 2018-D-1000

Executive Summary

The Executive in Charge, Office of the Under Secretary for Health, 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 Orlando VA Medical Center (Orlando), in Orlando, Florida. Persons (the whistleblowers), who chose to remain anonymous, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. VA conducted a site visit to Orlando on March 12–15, 2018.

Specific Allegations of the Whistleblower

1. *Approximately 453 Veteran patients at the Orlando VA Medical Center (VAMC) are awaiting endoscopy procedures at the facility, with wait times exceeding 30 days of the clinically indicated date (CID);*
2. *Acting Chief of Medicine **Employee 1** specifically instructed gastroenterology personnel not to utilize community care, such as the Veterans Choice Program, to alleviate the backlog; and*
3. *Failure to offer Veterans access to community care when wait times exceed 30 days may be a violation of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act).*

We **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, we make the following conclusions and recommendations.

Conclusions for Allegation 1

- We **substantiate** that Veteran wait times exceed 30 days from the CID for endoscopy procedures; however, Orlando has a robust process for ensuring high-risk Veterans get appropriate intervention in a timely manner.
- The rate of colonoscopy screening for higher-than-average-risk Veterans with positive fecal immunochemical test (FIT) screening in 180 days or less appears to be declining, which may increase the risk of delays in diagnosis and treatment of colorectal cancer.
- Although there is no accepted clinical standard or guideline directing timeframes for performing screening colonoscopy, the wait between initial evaluation and colonoscopy appears to be increasing. This interval increases the potential for other

medical conditions to worsen, complicating the ability to actually complete the colonoscopy.

Recommendations to Orlando

1. Formalize the process for reviewing consults in the gastrointestinal (GI) department in a standard operating procedure.
2. Review the Veterans Health Administration (VHA) Support Service Center data on Fecal Occult Blood Test-positive Veterans' access to colonoscopy at 60 days to determine root causes and a corrective action to ensure timely intervention for these higher-than-average-risk Veterans.
3. Provide guidelines for determining wait times from initial assessment to procedure dates to monitor for inadvertent increase in wait times potentially influenced by appointment availability rather than clinical indication.

Conclusions for Allegation 2

- We **substantiate** that the Acting Chief of Medicine instructed some GI personnel not to utilize care in the community (CITC). Orlando determined that the third party administrator for the Veterans Choice Program (VCP) was unable to meet requirements; however, the facility continues to use other CITC programs and uses VCP eligibility rules to determine when to offer Veterans these services.
- Although Orlando offered CITC to 222 Veterans on the list provided, they failed to follow VHA policy and Choice Act rules to offer CITC to 285 Veterans. As a result of our investigation, 127 additional Veterans have been contacted and offered CITC. Efforts are underway to contact the remaining 128 Veterans to offer CITC if they desire.

Recommendations to Orlando

4. Conduct scheduled formal meetings at least monthly with all GI staff members to review challenges affecting their ability to provide timely care.
5. Conduct ongoing leadership reviews of Health Administration Service procedures in GI to ensure compliance with the Choice Act, VHA Directive 1230, VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016, and Medical Center Policy 136-16. Document compliance and education in formal meeting minutes.

Conclusion for Allegation 3

- We **substantiate** that Orlando failed to offer Veterans access to community care when wait times exceed 30 days.

Recommendation to Orlando

See Recommendation 5 above.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Orlando 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 has provided a legal review, VHA Human Resources has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VA and VHA policy, and note that a substantial and specific danger to public health and safety exists at Orlando.

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I. Introduction

The Executive in Charge, Office of the Under Secretary for Health, 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 Orlando VA Medical Center (Orlando), in Orlando, Florida.

Persons (the whistleblowers), who chose to remain anonymous, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. VA conducted a site visit to Orlando on March 12–15, 2018.

II. Facility Profile

Part of Veterans Integrated Service Network (VISN) 8, Orlando, serves more than 110,000 Veterans in a state-of-the-art 134-bed acute inpatient health care facility, which was fully activated in September 2017 (opened all services), including complex medical, surgical, mental health, specialty care, emergency services and advanced diagnostic services, and a large multispecialty outpatient clinic. Orlando also serves Central Florida with a 120-bed Community Living Center, two Mental Health Residential Rehabilitation Treatment Programs/Domiciliaries (60 beds located at the Lake Nona Campus and 58 beds at the Lake Baldwin Campus), one Health Care Center in Viera, two large multispecialty Satellite Outpatient Clinics in Orlando (Lake Baldwin campus) and Daytona Beach, and four Community-Based Outpatient Clinics located in Clermont, Kissimmee, Orange City, and Tavares, Florida.

III. Specific Allegations of the Whistleblower

- 1. Approximately 453 Veteran patients at the Orlando VAMC are awaiting endoscopy procedures at the facility, with wait times exceeding 30 days of the clinically indicated date (CID);*
- 2. Acting Chief of Medicine, Employee 1 specifically instructed gastroenterology personnel not to utilize community care, such as the Veterans Choice Program, to alleviate the backlog; and*
- 3. Failure to offer veterans access to community care when wait times exceed 30 days may be a violation of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act).*

IV. Conduct of Investigation

The VA team conducting the investigation consisted of the Medical Inspector and a Clinical Program Manager, both of OMI. We reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured the Gastroenterology department, and held entrance and exit briefings with the following members of the Orlando leadership team:

Entrance briefing:

- The Associate Director
- The Acting Associate Director Patient Care Services (ADPCS)
- The Acting Chief of Staff (CoS)
- The Assistant Director
- The Administrative Officer (AO) to the ADPCS
- The AO to the CoS
- The AO to the Director
- The Associate Director

Exit briefing:

- The Medical Center Director (MCD)
- The ADPCS
- The CoS
- The Assistant Director
- The Chief of Medicine
- The AO to the ADPCS
- The AO to the CoS
- The AO to the Director
- The AO to the Associate Director

We were unable to interview the whistleblowers as they chose to remain anonymous. We interviewed the following Orlando employees in person:

- The CoS
- The Chief of Medicine
- The Chief, Integrated Health Service (IHS)
- Gastroenterologists (7)
- The Chief, Quality Management
- Nurse Practitioners (NP), Gastroenterology (5)
- A Physician Assistant (PA), Gastroenterology
- An RN, Gastroenterology
- The Patient Safety Manager
- An RN, IHS
- A Health Technician, Gastroenterology

VI. Findings, Conclusions, and Recommendations

Allegation 1

Approximately 453 Veteran patients at the Orlando VAMC are awaiting endoscopy procedures at the facility, with wait times exceeding 30 days of the clinically indicated date (CID)¹.

Background

Endoscopy procedures include a variety of different interventions including, but not limited to, colonoscopy, upper gastrointestinal endoscopy, and specialty procedures such as endoscopic retrograde cholangiopancreatography (ERCP). Each intervention has different indications, and the determination of when the specific endoscopy procedure varies is based on these clinical indications. Some procedures require immediate intervention such as active bleeding, and others such as average risk-screening procedures, are scheduled more than 30 days in the future, as these are not related to a known or suspected dysfunction.

VHA) Directive 1015, outlines policy on providing colon cancer screening for Veterans: “It is VHA policy to recommend CRC [colorectal cancer] screening for average risk individuals [Veterans between the age of 50-75 with neither a family history of CRC nor other risk factors or symptoms that warrant surveillance or diagnostic colonoscopy] in accordance with VHA guidance, coordinated by the VHA National Center for Health Promotion and Disease Prevention (NCP) and to assure that positive screening tests are followed up by appropriate evaluation.”² The Directive also provides recommendations for optimizing CRC screening in practice including the use of group clinics to prepare patients for colonoscopy; use of telemedicine to inform Veterans about screening options and preparation; establishing mandatory view alerts for positive Fecal Occult Blood Test (FOBT) results that includes fecal immunochemical test (FIT); use of service agreements and consult templates to help ensure appropriate consults for procedures; systematic review of consult requests prior to the procedure for appropriateness and the length of time since the last colonoscopy; use of a tracking system to ensure each Veteran’s screening is completed and followed up as indicated; use of a nurse to coordinate screening schedules, procedures, and flow of information between the different entities.^{3,4}

¹ We will use CID throughout the report as it is in the allegation. However on June 5, 2017, the Deputy Undersecretary for Health for Operations and Management (10N) issued a memorandum, “Scheduling and Consult Policy Updates,” to Network Directors indicating the nomenclature for scheduling would combine CID and Preferred Date (PD) into “Patient Indicated Date” (PID). (Reference VAIQ#7798804)

² Veterans Health Administration Directive 1015, Colorectal Cancer Screening, December 30, 2014.

³ Data definitions for CRC screening: Positive FOBT to Follow-Up Colonoscopy from VSSC website and laboratory reporting of FOBT update November 15, 2010 expanding FOBT (guaiac-based) to include FIT.

⁴ A case control study on 4,964 VA patients with previously diagnosed CRC after age 49 found that patients who had a screening colonoscopy had an overall reduced mortality of 61 percent. These results were despite a higher number of risk factors and higher number of comorbidities in VA patients compared to the normal patient population at large. Kahi, C, et al (2017). Colonoscopy and Colorectal Cancer Mortality in the Veterans Affairs Health Care System. *Annals of Internal Medicine*. Doi: 10.7326/M17-0723

The American College of Gastroenterology (ACG) published updated guidelines for CRC screening in June 2017.⁵ ACG differentiates screening and surveillance: screening is the use of tests or procedures to detect early stage disease in asymptomatic individuals without a previous history of disease; surveillance is the use of colonoscopy to monitor individuals with known risk factors (previously detected CRC, precancerous polyps, inflammatory bowel disease, etc.).⁶ ACG recommends that clinicians offer CRC screening beginning at age 50, and offering multiple screening options including FIT and colonoscopy, the later of these options has the benefit of both detection and removal of advanced and non-advanced adenomas.⁷ Their recommendations to clinicians are:

1. We recommend colonoscopy every 10 years or annual FIT as first-tier options for screening the average-risk persons for colorectal neoplasia (strong recommendation; moderate quality evidence).
2. We recommend that physicians performing screening colonoscopy measure quality, including the adenoma detection rate (strong recommendation, high-quality evidence).
3. We recommend that physicians performing FIT monitor quality (strong recommendation, low-quality evidence).
4. We recommend computed tomography (CT) colonography every 5 years or FIT-fecal DNA every 3 years (strong recommendation, low-quality evidence) or flexible sigmoidoscopy every 5 to 10 years (strong recommendation, high-quality evidence) in patients who refuse colonoscopy and FIT.
5. We suggest that capsule colonoscopy (if available) is an appropriate screening test when patients decline colonoscopy, FIT, FIT-fecal DNA, CT colonography, and flexible sigmoidoscopy (weak recommendation, low-quality evidence).
6. We suggest against Septin9 for CRC screening (weak recommendation, low-quality evidence).⁸

VHA Directive 1232 (1), defines the different status of consults:⁹

- *Active*: This status occurs when a consult is “received” and efforts are underway to fulfill a consult. A consult may also revert to “active” in other scenarios such as when an appointment is canceled or no-showed.
- *Pending*: This status designates requests that have been sent, but not yet acted on by the receiving service.
- *Scheduled*: This indicates that an appointment has been made and linked to the consult request. Scheduled status automatically sends an alert to the sending provider. The consult status should not be manually changed to “scheduled” in

⁵ Rex, D., Boland, R., Dominitz, J., Giardiello, F., Johnson, D., Kaltenbach, T., Levin, T., Lieberman, D., Robertson, D. (2017). Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. *Am J Gastroenterology* advance online publication, 6 June 2017; doi: 10.1038/ajg.2017.174

⁶ *ibid*

⁷ *ibid*

⁸ *ibid*, page 9.

⁹ VHA Directive 1232(1) *Consult Processes and Procedures*, Amended September 23, 2016

the consult package, but should be linked to appointments so that the consult status changes when the appointment status is changed.

- *Partial Result*: This status designates partial but not complete resolution of the consult request.
- *Complete*: This status designates completion of the requested service.

VHA Directive 1230 states “Unless otherwise specified by provider, the CID is defined to mean the patient can be scheduled within 30 calendar days of that CID.”¹⁰ VHA Directive 1230 further states: “If VA is not able to offer an appointment within 30 days of the CID/ [preferred date] PD, the patient may be eligible for the [Veterans Choice Program, or VCP]. In this case, the scheduler must ask the patient if they would prefer to make an appointment in the community or wait beyond 30 days for a VA appointment.” There are specific instructions on how to document a Veteran’s preference on either the Veterans Choice List (VCL) if they choose to make an appointment in the community, or by documenting “#COO#” in the comment section of the pending appointment if the Veteran chooses to opt out of using Choice.

VHA Support Service Center (VSSC) provides a series of metrics relevant to consults, and combines the definitions above into two categories:¹¹

- *Closed* - consists of consults with CPRS Status of Cancelled, Complete, Discontinued, and Discontinued/Edit
- *Open* - consists of consults with CPRS Status of Active, Partial Results, Pending, Renewed, Scheduled, Unreleased, and Not Recorded.

Findings

During interviews with the CoS, Acting Chief of Gastroenterology, and gastrointestinal (GI) providers, all described a process intended to address the difficulties meeting the 30-day requirement for consults from primary care providers (PCP). Orlando developed both a telemedicine clinic and a group colorectal screening class in December 2016, staffed by an NP, Case Manager (CM), and Health Administration Service (HAS), where 20 to 30 Veterans attend to discuss endoscopy procedures, preparation, and options for care, including Care in the Community (CITC), as recommended in VHA Directive 1015. The group appointment includes discussion about the various options available for CRC screening, specific instructions on the different types of prep required for each option, and either an appointment for the procedure, or a consult for CITC, if selected by the Veteran. The telemedicine clinic is similar, but the appointment process involves additional phone calls to HAS by the Veteran to schedule the procedure. The result of these efforts is that the GI department meets the CID requirements from the PCP, but the process generates a backlog of risk-screened Veterans awaiting endoscopy procedures.

¹⁰ VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016.

¹¹ VSSC data definitions for Consult Cube metrics.

If the Veteran elects to stay within the VHA system (i.e., opt out of the VCP or other CITC programs), the NP generates a consult for endoscopy with a CID based upon the clinical needs of the Veteran. If the Veteran's assessment reveals more than average risk during the initial evaluation such as a positive FIT, or concerning history, the NP can consult the direct access clinic. This access clinic allows scheduling for the above average risk Veteran within days. This same clinic capability is available to other GI providers not involved in the group appointments.

We reviewed the VSSC data relative to GI services, which combine all endoscopy procedures including colonoscopy, upper gastrointestinal endoscopy, and specialty procedures such as ERCP. As of March 16, 2018, there were 1,341 consults for GI (stop code 321) in an "open" status between 31 and 180 days (see definition above). VSSC also provides a more refined breakdown in line with VHA Directive 1232(1) including "scheduled," and we found 1,302 consults in this status. Since this is a subset and derived from "open" consults, it indicates that the facility is tracking consults and has a plan to meet patient demand. Per VHA Directive 1232(1) consults requiring completion more than 90 days into the future must include the *earliest* appropriate date in the consult. Scheduling future consults is possible up to 365 days from the current date, so these types of future consults would be included in the "scheduled" data. VSSC does not provide a way to determine which of these are for screening or surveillance colonoscopies or other types of endoscopy consults.

The GI Department triages consults from a referring PCP into seven different categories for screening within 48 hours: general GI concerns screened by physicians; high-risk screening, screened by physicians; FIT positive, screened by NP/PA; average risk screening, screened by NP/PA; pancreatic/biliary, screened by hepatic team; irritable bowel disease, screened by physician; hepatic, screened by hepatic team. Once screened, a consult toolbox provides guidance for scheduling for routine, within 1 week, within 2 weeks or 1 month. High-risk Veterans are handled individually with the HAS staff. If an appointment cannot be made within 30 days, the Veteran has the option to pursue CITC. Specifically for endoscopy, the GI provider submits a consult request for a clinical procedure indicating the CID based upon the GI provider's clinical judgment. In compliance with VHA Directive 1015, a CM, in addition to their GI provider, also follows high-risk Veterans throughout their episodes of care. This is a longstanding internal policy; however, there is no standard operating procedure (SOP) or Medical Center Memorandum (MCM) outlining the process.

Several providers expressed concern that longer wait times for procedures could impact the ability to complete them. Because the Veteran population has multiple risk factors, their medical condition could change making them too high risk for the facility's capability. This could result in cancellation of the procedure at the last minute, leading to a potential delay in diagnosis, a wasted procedure appointment, and frustration for the Veteran. Providers could not recall any specific Veterans impacted as a result of this type of delay, and we found no evidence of potential delay in diagnosis resulting from cancellations due to a change in medical condition.

The facility identified positive FIT screening as representing a higher risk to the patient in the triage/screening process described above. In order to identify potential risk to Veterans resulting from extended wait times, we reviewed VSSC data on the percentage of them having a follow-up colonoscopy within 60 days of a positive FIT screening result.¹² In fiscal year (FY) 2017, we found that 20 percent of Veterans with a positive FIT screening had a colonoscopy at 60 days, increasing to 47 percent at 180 days. In the combined first 2 quarters of FY 2018, only 12 percent of Veterans had a colonoscopy, which increased to 21 percent at 180 days in the same time period. These results indicate that at 180 days, 79 percent of these higher than average risk Veterans remain unscheduled for a colonoscopy in FY 2018.

Orlando provided an Excel worksheet with the names of 507 Veterans awaiting endoscopy procedures (all types) more than 30 days (discussed in detail in Allegation 2). These data indicate an average wait time of 54.3 days from the CID exceeding the 30-day requirement in VHA Directive 1230. The GI NP/PA provider staff indicated that they discussed CIDs for average risk colonoscopies and agreed that 4 months was a reasonable expectation from initial screening to procedure, and reiterated that there was no guideline for this procedure from specialty organizations except as indicated in the Background section above. The gastroenterologists we interviewed indicated that they were not aware of wait times from the screening appointment until the procedure date because they had no reason to know this information. Their procedure schedules were always full and they simply responded to that demand. NP and PA providers indicated that they could always get a high-risk or urgent patient scheduled for a procedure within a week. They also indicated that there was an open procedure appointment available on the schedule each day for urgent/high-risk Veterans. They would simply call the HAS staff who would use this open appointment for urgent patients. They also indicated that they received emails from HAS indicating the approximate length of time until the next available procedure slot (currently 4 months), and only one expressed belief that this email process was intended to influence their CIDs. One NP stated that approximately 1 year ago, she was using 2 months as a CID as opposed to the 4 months currently in use.

One gastroenterologist indicated difficulty in scheduling specialty procedures such as ERCP due to a low number of available procedure appointments (there are only three to four specialty procedure slots available weekly). The concern expressed was with only 12 specialty procedures per month, the facility could not meet the potential demand. There are 20 to 30 specialty procedure consult requests per week, and although a physician triages/screens all of these consults to determine the most urgent, the backlog continues to build. Gastroenterologists indicated that they were currently short two providers, and as a result of this and limitations in the number of anesthesia staff available, they can currently use only three of the eight procedure rooms. Each gastroenterologist does approximately 11 procedures per day, 4 days per week. Facility

¹² FIT has a one-time sensitivity for detecting cancer of 79%, and fair sensitivity for advanced adenomas of 30% and poor sensitivity for serrated class precursor lesions. From: Rex, D., Boland, R., Dominitz, J., Giardiello, F., Johnson, D., Kaltenbach, T., Levin, T., Lieberman, D., Robertson, D., "Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer." *Am J Gastroenterology* advance online publication, 6 June 2017; doi: 10.1038/ajg.2017.174.

leadership indicated that they recently recruited and hired two providers for the remaining open positions, one for a gastroenterologist with advanced procedure training, and a permanent Chief of GI. These providers started working at Orlando no later than June 2018.

Conclusions for Allegation 1

- We **substantiate** that Veteran wait times exceed 30 days from the CID for endoscopy procedures; however, Orlando has a robust process for ensuring high-risk Veterans get appropriate intervention in a timely manner.
- The rate of colonoscopy screening for higher-than-average-risk Veterans with positive FIT screening in 180 days or less appears to be declining, which may increase the risk of delays in diagnosis and treatment of colorectal cancer.
- Although there is no accepted clinical standard or guideline directing timeframes for performing screening colonoscopy, the wait between initial evaluation and colonoscopy appears to be increasing. This interval increases the potential for other medical conditions to worsen, complicating the ability to actually complete the colonoscopy.

Recommendations to Orlando

1. Formalize the process for reviewing consults in the GI department in an SOP.
2. Review the VSSC data on FOBT-positive Veterans' access to colonoscopy at 60 days to determine root causes and a corrective action to ensure timely intervention for these higher-than-average-risk Veterans.
3. Provide guidelines for determining wait times from initial assessment to procedure dates to monitor for inadvertent increase in wait times potentially influenced by appointment availability rather than clinical indication.

Allegation 2

Acting Chief of Medicine **Employee 1** specifically instructed gastroenterology personnel not to utilize community care, such as the Veterans Choice Program, to alleviate the backlog.

Background

On August 7, 2014, the *Veterans Access, Choice, and Accountability Act of 2014 (Choice Act)* was signed into law. Part of this law included the creation of the Veterans Choice Program (VCP).¹³ VCP allows Veterans enrolled in VA health care to receive

¹³ Amendments to the Choice Act were made on September 26, 2014, by the Department of Veterans Affairs Expiring Authorities Act of 2014 (Public Law (P.L.) 113-175); on December 16, 2014, by the Consolidated and

health care in their community, while still having access to their regular VA health care. In general, Veterans who have to wait more than 30 days or travel over 40 miles for an appointment are eligible to receive care through VCP.

In order to provide care through VCP, VA modified the existing Patient Centered Community Care (PC3) contract that had been set up the previous year to create a network of community providers for VA to use when care could not feasibly be provided within VA. The modified contract required a third party administrator (TPA) to create a network of providers eligible to provide care under VCP. These TPAs are Health Net (the TPA for Orlando), and TriWest Healthcare Alliance. In order to participate in the VCP networks managed by the TPAs, non-VA providers must accept VCP's terms of participation agreement and join the TPA's network of providers.

VA also has authority to enter into agreements, known within VA as Choice Provider Agreements, directly with individual providers. These agreements could only be entered into when VA's existing contracts and acquisition authorities were not sufficient to procure the necessary care.

To be eligible to receive care under the VCP, Veterans must be enrolled in VA health care and meet at least one of the following criteria:

- The Veteran needs care that his or her local VA medical facility does not offer;
- The VA medical facility is not able to schedule an appointment for the Veteran's care within the wait-time goals of VHA or, with respect to care and services that are clinically necessary, the period VA determines necessary for such care or services if such period is shorter than the wait-time goals of VHA. (VHA defined its wait-time goals as "a date not more than 30 days from either:
The date that an appointment is deemed clinically appropriate by a VA health care provider. In the event a VA health care provider identifies a time range when care must be provided (e.g., within the next 2 months), VA will use the last clinically appropriate date for determining whether or not such care is timely; or, if no such clinical determination has been made, the date that a veteran prefers to be seen for hospital care or medical services.")
- The Veteran lives more than 40 miles driving distance from the closest VA medical facility with a full-time PC provider; (Choice 40);
- The Veteran lives in a state or territory without a full-service VA medical facility and more than 20 miles from such a facility in another state;
- The Veteran resides in a location other than Guam, American Samoa, or the Republic of the Philippines and needs to travel by air, boat, or ferry to the nearest VA medical facility;

Further Continuing Appropriations Act of 2015 (Pub. L. 113-235); on May 22, 2015, by the Construction Authorization and Choice Improvement Act (P.L. 114-19); and on July 31, 2015, by the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 (P.L. 114-410; and on April 19, 2017 by an act to amend the Choice Act to modify the termination date for the VCP, and other purposes (P.L. 115-26).

- The Veteran faces an unusual or excessive burden in traveling to a VA medical facility based on geographic challenges, environmental factors, or a medical condition that affects the ability to travel, or other factors as determined by VA.

In order to optimize community care funds, on June 21, 2017, VA issued a memorandum to Network Directors, *Options for Providing Community Care*, which rescinded the previous memorandum, *VA Care in the Community and Use of the Veterans Choice Program*, dated October 1, 2015. The June, 2017 memorandum instructed Network Directors to:

- Continue to send Veterans with eligibility for the VCP as identified in the Choice Act—those eligible based on residence (40 miles from their residence to the closest VA medical facility), wait times (30 days from the clinically indicated date), or other criteria (such as special criteria for residents of Alaska, Hawaii, and New Hampshire) – to the VCP contractors.
- Medical facilities must now follow their usual referral patterns and refer Veterans to other VA medical facilities, Department of Defense medical facilities, or to other traditional community care providers when services are unavailable at their medical facility and the Veteran does not qualify for VCP under the eligibility criteria identified above.

In addition to VCP, VA has other mechanisms for the provision of CITC, including what is referred to as traditional non-VA care and the PC3 contract among others. Traditional non-VA care provides payment authorization for eligible Veterans to obtain routine outpatient or inpatient medical services through community providers. An authorization may be granted when it has been determined that direct VA services are either geographically inaccessible or VA facilities are not available to meet a Veteran's needs. All community services must be preauthorized before a Veteran receives treatment.¹⁴ PC3 is a VHA nationwide program that utilizes health care contracts to provide eligible Veterans access to primary care, inpatient/outpatient specialty care, mental health care, limited emergency care, and limited newborn care for enrolled female Veterans following the birth of a child. In instances where primary and specialty care is not readily available through a VA health care facility, VA uses the PC3 contract to purchase care. The facility's clinical and Non-VA care teams coordinate to determine if the care is available at the local facility, a nearby facility, or another health care partner. If care is not available, the facility may use the PC3 contract to buy care.¹⁵

Findings

Orlando leadership indicated during interviews that the facility has been in the process of changing from ambulatory care only to a full hospital at the new facility. Starting in 2016, there was a concerted effort to recapture workload that was previously outside

¹⁴ Preauthorized Non-VA Inpatient/Outpatient Medical Care
https://www.va.gov/COMMUNITYCARE/programs/veterans/preauth_care.asp.

¹⁵ Patient-Centered Community Care (PC3)
<https://www.va.gov/COMMUNITYCARE/programs/veterans/pccc/index.asp>.

the scope of the ambulatory care facility, or limited by the resources in the specialty area, including staff. GI was one of these areas that expanded with the opening of the new facility. This did impact referral patterns to the community across all the different CITC programs including Choice; it reduced the need for CITC referrals as more care could be delivered in the facility. Additionally, the CoS stated that prior to the Choice Act, Orlando already had a robust IHS program that managed non-VA care and as a result had well-established relationships with community providers and referral patterns. The CoS also stated that after Choice Act implementation, the contractor (Health Net) did a poor job of managing these Veterans, and they no longer use Health Net to manage CITC. Orlando adopted the rules associated with VCP to refer Veterans to CITC (e.g., greater than 30 days until an available appointment and the other criteria listed in the background section).

We reviewed the VSSC data on Non-VA Care Choice consults for Orlando. In FY 2017, Orlando completed 4,811 Choice consults, and for FY 2018 (as of March 12), there were 19 total. This is consistent with information provided by the CoS. In November 2017, Orlando changed from a system using multiple different consults for CITC to the One Consult process where all consults are in one single system/form. As a result, there is no differentiation between the different types of CITC consults in the VSSC data (NVCC, Choice, etc.). Consistent with the change to the One Consult system, these data indicate an upward trend from November 15, 2017, to March 15, 2018. There are nearly 6,000 total open consults (all specialties) for CITC from Orlando. As indicated in Allegation 1, open consults include active, partial results, pending, renewed, scheduled, unreleased, and not recorded, thus the 6,000 consults do not indicate inaction or inattention on the part of Orlando. There are no data available on open CITC consults from either gastroenterology (stop code 307) or gastroenterology procedure (stop code 321) in this time period. We assess that these data indicate an ongoing use of CITC at Orlando in general, despite the lack of specific data on the GI department.

The Acting Chief of Gastroenterology provided us with an Excel worksheet previously mentioned under Allegation 1, which included 507 Veteran names. This worksheet provides evidence that 159 Veterans opted out of VCP, and 1 Veteran opted into it. We reviewed Veterans Information Systems and Technology Architecture (VistA) documentation on the Veteran opting into VCP, and found this was for another specialty, so the data were in error. As a result of this finding, we reviewed a selection of 17 Veterans (every 10th name on the list) opting out of VCP and found appropriate documentation of this discussion in VistA as required in VHA Directive 1230. VA requested the facility review the remaining 348 Veteran names (this number excludes those that opted out of VCP already on the spreadsheet). We found CITC offered to an additional 63 Veterans for a total of 222 out of 507. Orlando found that CITC was not offered to the remaining 285 Veterans on this list. As of March 29, 2018, Orlando contacted 127 additional Veterans: 30 opted in to VCP; 95 opted out; 2 declined the procedure/consult. As of this same date, Orlando has not contacted the remaining 128 Veterans.

The Acting Chief of Gastroenterology provided us with a series of emails indicating discussions concerning CITC in March 2018. There is evidence of requests for additional information about specific Veterans during the CITC review and approval process and evidence of approval of CITC for these Veterans. We reviewed VSSC data on open community care consults using the One Consult system and found 30 open colonoscopy consults for CITC (current as of March 27, 2018) two of which were open for 61–90 days consistent with the One Consult implementation dates in mid-November 2017 and these email discussions.

The Acting Chief of Gastroenterology also provided action plans from November 2016 and October 2017, indicating ongoing efforts to match supply with demand including recruiting for additional providers and implementation of colorectal screening class/group appointment described in Allegation 1. We also reviewed the email listed as “Exhibit 1” attached to the charge letter from OSC. This September 1, 2017, email, indicates a discussion about the backlog of procedure appointments, with instructions to review the 20 oldest appointments to assess their status. This email also indicates a backlog of 416 Veterans awaiting endoscopy. There is a statement from the Acting Chief: “Perhaps better CID dates for these procedures as we go forward,” and further statement of, “If majority are non-urgent appointments (as I would likely guess from the list), then we could alleviate it by choosing a better CID—understanding that missed opportunities will always be an issue—we should work on that part separately.” When questioned about CIDs, the Acting Chief stated that the previous chief sent out guidance about CIDs and specifically stated that this guidance recommended a CID of 60 days for routine/asymptomatic Veterans requiring colonoscopy. She denied making any changes to this guidance by the former Chief, as it was outside of her specialty training.

We interviewed GI provider staff, and all indicated that no one in leadership had instructed them to change CIDs. Staff in the GI department also stated that there were discussions with the Acting Chief of Gastroenterology on or about August 2017, related to funding for VCP, but there was no discussion or instruction to stop referring Veterans for CITC. There is no evidence that these discussions resulted in any decrease in CITC referrals. Staff did indicate that they were sometimes required to provide additional justification for these referrals, which might delay the CITC referral. We reviewed an email from the Acting Chief of Gastroenterology addressed to all GI providers requesting additional information in the CITC referrals including access, urgency, and complexity. The Acting Chief added clarification in the email that the additional information was not required if the Veteran opted in for VCP. In another email dated March 5, 2018, between IHS staff and the Acting Chief, there is evidence of approval for four different Veterans because of access issues, and one for Veteran complexity beyond Orlando capability. None of the GI staff interviewed could recall adverse patient outcomes related to these delays. Of note, the GI department staff could not recall the last time there was a formal meeting to discuss issues in the department, which they indicated made communication flow difficult.

An email of March 13, 2018, titled: "Routine, Non-Urgent, and Urgent Procedure Update," from a staff member involved in scheduling for endoscopies, indicates that there were no routine or non-urgent procedure appointments until mid-July 2018, and that urgent procedures can be scheduled on a case-by-case basis. It further states: "HAS is a little frustrated we're writing CIDs for 2 months and the reality is 4 months." The writer of this email is not in the supervisory chain and offered no recommendations to change CIDs. Of particular interest is a reply email from the Acting Chief of Gastroenterology specifically stating: "Please use your clinical judgement, please do what is appropriate for patient needs. If the patient has symptoms/FIT positive, notify **REDACTED** and myself for the patients to be accommodated. If unable to be accommodated immediately, notify me for community care consult." The final statement on this email is, "DO NOT change CIDs."

We reviewed Medical Center Policy 136-16, *Business Rules for Appointment Scheduling, No-Shows, Patient Cancellations, Clinic Cancellations and Late Arrivals for Appointments*, May 4, 2017, which provides the following guidance in compliance with VHA Directive 1230:

- If VA is not able to offer an appointment within 30 days of the CID/PD, the patient may be eligible for VCP. In this case, the scheduler must ask the patient if they would prefer to make an appointment in the community or wait beyond 30 days for a VA appointment.
- If the patient chooses the community referral, the scheduler must enter the request on the Veterans Choice List (VCL).
- Schedulers must transcribe the CID located in CPRS order into the CID/PD field of VistA scheduling. Do not change the CID or PD unless the patient cancels and reschedules the appointment.

We reviewed Patient Advocate Tracking System reports and found 2,360 reports from fiscal year (FY) FY 2015 to FY 2018 (through present). Only two related to delays in scheduling or concerns about re-scheduling appointments for procedures in GI. We also reviewed electronic Patient Event Reports (ePER), finding 3 out of 3,300 total Orlando ePERs related to the GI department. One related to inability to contact an on-call provider, one documented an adverse event related to anesthesia, and one documented concerns about transfer of a patient out of the intensive care unit; none related to delays in scheduling endoscopies. Lastly, we reviewed Tort Claims for Orlando from FY 2015 through FY 2018 and found 4 out of 59 related to GI; none related to delays for endoscopic procedures.

Conclusions for Allegation 2

- We **substantiate** that the Acting Chief of Medicine instructed some GI personnel not to utilize CITC. Orlando determined that the TPA for VCP was unable to meet requirements; however, the facility continues to use other CITC programs and uses VCP eligibility rules to determine when to offer Veterans these services.

- Although Orlando offered CITC to 222 Veterans on the list provided, it failed to follow VHA policy and Choice Act rules to offer CITC to 285 Veterans. As a result of our investigation, 127 additional Veterans have been contacted and offered CITC. Efforts are underway to contact the remaining 128 Veterans to offer CITC if they desire.

Recommendations to Orlando

4. Conduct scheduled formal meetings at least monthly with all GI staff members to review challenges affecting their ability to provide timely care.
5. Conduct ongoing leadership reviews of HAS procedures in GI to ensure compliance with the Choice Act, VHA Directive 1230, and Medical Center Policy 136-16. Document compliance and education in formal meeting minutes.

Allegation 3

Failure to offer Veterans access to community care when wait times exceed 30 days may be a violation of the Veterans Access, Choice, and Accountability Act of 2014 (Choice Act).

Findings

We found wait times exceeding 30 days past the CID. There were issues with funding on or about August 2017, which potentially caused Orlando to limit access to VCP, but did not impact other CITC programs. Orlando determined that their TPA (Health Net) was unable to meet Veteran needs, but its leadership maintains the same rules set forth by the Choice Act in determining when to offer CITC (e.g., more than 30 days from CID). There is evidence that over half of the Veterans were not offered CITC in accordance with policy (see Allegation 2). Because these requirements are not present in other CITC programs, there is no central collection of data for compliance in VSSC as there is with the VCP, which makes tracking performance difficult for these referrals.

Conclusion for Allegation 3

- We **substantiate** that Orlando failed to offer Veterans access to community care when wait times exceed 30 days.

Recommendation to Orlando

See Recommendation 5 above.

VI. Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Orlando 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 has provided a legal review, VHA Human Resources has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VA and VHA policy and note that a substantial and specific danger to public health and safety exists at Orlando.

Attachment A

Documents in addition to the Electronic Medical Records reviewed:

VHA Directive 1015 *Colorectal Cancer Screening*, December 30, 2014.

VHA Directive 1232(1) *Consult Processes and Procedures*, Amended September 23, 2016.

VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016.

VHA Support Service Center (VSSC).

Medical Center Policy 136-16, *Business Rules for Appointment Scheduling, No-Shows, Patient Cancellations, Clinic Cancellations and Late Arrivals for Appointments*, May 4, 2017.

Adverse and Sentinel Events related to CRC from 2015 to present.

Peer reviews related to gastroenterology from 2015 to present.

Action plans related to the GI department from 2016 to present.

Current recruiting documents related to GI department.

Emails related to discussions related to endoscopy between members of the GI department.

Spreadsheet with 507 Veteran Names with scheduled appointments longer than 30 days from the CID.