DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

July 29, 2016

The Honorable Tim Walz
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Walz:

This is in response to your letter dated December 10, 2015, conveying the concerns of a whistleblower regarding potential quality of care issues and hostile work environment at the St. Cloud VA Medical Center, St. Cloud, Minnesota, (hereafter, the Health System). Specifically, the whistleblower is concerned about a hostile work environment, understaffing of the hospital, and retaliation by management. The Department of Veterans Affairs (VA) found that potential health care problems have been corrected, but substantiated that patient-aligned care teams are understaffed, and that leadership is deficient in certain areas.

The Secretary directed me to ask the Office of the Medical Inspector to assemble and lead a VA team to conduct a review, and upon completion, to provide him with findings on the investigation. VA made nine recommendations for the Health System, three for the Veterans Health Administration, and one for Veterans Integrated Service Network 23.

The full report has been sent to the Chairman, House Veterans' Affairs Committee. Thank you for your interest in the St. Cloud VA Medical Center.

Sincerely,

David J. Shulkin, M.D.

DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

July 29, 2016

The Honorable Amy Klobuchar
United States Senate
Washington, DC 20510

Dear Senator Klobuchar:

This is in response to your letter dated December 10, 2015, conveying the concerns of a whistleblower regarding potential quality of care issues and hostile work environment at the St. Cloud VA Medical Center, St. Cloud, Minnesota, (hereafter, the Health System). Specifically, the whistleblower is concerned about a hostile work environment, understaffing of the hospital, and retaliation by management. The Department of Veterans Affairs (VA) found that potential health care problems have been corrected, but substantiated that patient-aligned care teams are understaffed, and that leadership is deficient in certain areas.

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David J. Shulkin, M.D.

DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

July 29, 2016

The Honorable Al Franken
United States Senate
Washington, DC 20510

Dear Senator Franken:

This is in response to your letter dated December 10, 2015, conveying the concerns of a whistleblower regarding potential quality of care issues and hostile work environment at the St. Cloud VA Medical Center, St. Cloud, Minnesota, (hereafter, the Health System). Specifically, the whistleblower is concerned about a hostile work environment, understaffing of the hospital, and retaliation by management. The Department of Veterans Affairs (VA) found that potential health care problems have been corrected, but substantiated that patient-aligned care teams are understaffed, and that leadership is deficient in certain areas.

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Sincerely,

David J. Shulkin, M.D.

DEPARTMENT OF VETERANS AFFAIRS
Under Secretary for Health
Washington DC 20420

July 29, 2016

The Honorable Tom Emmer
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Emmer:

This is in response to your letter dated December 10, 2015, conveying the concerns of a whistleblower regarding potential quality of care issues and hostile work environment at the St. Cloud VA Medical Center, St. Cloud, Minnesota, (hereafter, the Health System). Specifically, the whistleblower is concerned about a hostile work environment, understaffing of the hospital, and retaliation by management. The Department of Veterans Affairs (VA) found that potential health care problems have been corrected, but substantiated that patient-aligned care teams are understaffed, and that leadership is deficient in certain areas.

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Sincerely,

David J. Shulkin, M.D.

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Department of Veterans Affairs Report

St. Cloud Veterans Affairs Health Care System
St. Cloud, Minnesota

Report Date: May 20, 2016

TRIM 2016-D-176

Executive Summary

The Under Secretary for Health (USH) requested that the Office of the Medical Inspector (OMI) lead a VA investigation to address allegations lodged by employees of the St. Cloud VA Health Care System, St. Cloud, Minnesota (hereafter, the Health System) through Members of Congress. The VA team conducted a site visit to the Health System on January 4-8, 2016.

Specific Concerns of the Complainants

VA received letters from four members of Congress with allegations from eighteen individual letters (including one summarized from interview notes) raising concerns categorized below:

1. Veteran care concerns on the Respiratory Dependency Unit (RDU):
    a. Mass insulin verification by staff;
    b. Over sedation of patients (chemical restraints);
    c. Suprapubic catheter irrigation using unsterile equipment;
    d. Improper skin care resulting in pressure ulcers;
    e. Failing to respond to medical device recalls/alerts;
2. Understaffing of the hospital/panel sizes in primary care too large;
3. Misrepresenting physician workload to VA's Office of the Inspector General (OIG);
4. Management and leadership failing to address identified concerns and employees fearing reprisal and retaliation for expressing concerns;
5. Hostile work environment (already addressed by other investigations).

VA **found evidence** when the facts and findings supported that the alleged events or actions took place and **did not find evidence** when the facts and findings showed the allegations were unfounded. VA was **not able to find evidence** 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 Concern 1

Insulin administration

- We **found evidence** that prior to 2013, nurses gave insulin without a second licensed nurse verifying the dose, route, patient, time, or medication.

- Based on the software prior to 2013, it was possible to administer high-risk medications without a second licensed nurse to verify the dose, patient, route, medication, time, and sign off as a witness, until after the fact.

- Since the upgrade to the Bar Code Medication Administration (BCMA) system revised in 2013, the ability to bypass the verification step is not possible.

Overuse of Sedation

- This investigation **did not find evidence** of overuse of sedation with psychotropic medication.

- There were three instances of narcotic medications used for agitation or anxiety; these uses were appropriately ordered and documented.

- There was evidence of more frequent administration of narcotics on night shift than on day shift; however, this would not be an unusual practice as Veterans are encouraged to take pain medication at night to prevent disrupted sleep cycles.

Suprapubic catheter irrigation

- This investigation **did not find evidence** that a suprapubic catheter was irrigated using non-sterile equipment.

Skin Breakdown

- This investigation **did not find evidence** of improper skin care leading to hospital acquired pressure ulcers (HAPU). There is evidence of a decreasing incidence of HAPU since 2013.

Failure to respond to medical device alerts/recalls

- This investigation **did not find evidence** that Biomedical Engineering (BME) failed to respond to medical device alerts/recalls.

- Although there are over 500 open work orders for a variety of equipment in the BME section, there is evidence of active management to improve the backlog of work orders since October 2015 and of supervisory oversight of high-risk recalls.

- We found a large number of corrective maintenance and preventive maintenance work orders unassigned to a specific BME technician despite recent changes in procedures.

- There is no evidence of Veteran harm as a result of the backlog of work orders.

Recommendations to the Health System

1. Assign corrective maintenance and preventive maintenance to individual BME technicians.

2. Continue to monitor open work order status in BME to ensure that the implemented solution provides proper oversight.

3. Evaluate the current process to close out completed work orders and develop a process that includes the actual completion time.

Conclusions for Concern 2

- There is evidence that the Patient Aligned Care Teams (PACT) are providing quality care to Veterans in the Health System.

- The investigators **found evidence** that some of the PACT panel sizes are so large that primary care providers (PCP) feel an overwhelming sense of responsibility, which adds considerable stress to the work environment. In addition, the distribution of physicians, physician extenders, and part-time providers create a mix that also adds to the sense of responsibility, especially for the full-time physicians.

- The Health System cannot meet current primary care appointment demand, using their existing scheduling template.

- Leadership's efforts to retain PCPs by extending part-time positions and increased recruiting of physician assistants (PA) and advance practice registered nurses (APRN) had an unintended consequence of increasing the full-time PCP physician's workload in oversight and surrogate responsibilities, and simultaneously reducing the Team PCP full-time employee (FTE) (PCP/AP Adjusted).

- The guidance provided by *VHA Handbooks 1101.10 and 1101.02* on Veteran assignment to only one PCP, and the directive that precludes combining part-time PCPs into single, full-time equivalent panels (job sharing) have a negative impact on the Health System's ability to manage the competing priorities of PACT growth, PCP recruitment and retention, and the current PCP's overwhelming sense of responsibility.

Recommendations to the Health System

4. Establish organizational policies to ensure that the ratio of physicians to PAs/APRNs does not adversely impact actual available FTEs.

5. Analyze surrogate and collaborative responsibilities in support of part-time PCPs and adjust for these responsibilities in physician workload.

6. Analyze current appointment needs and consider adjusting scheduling templates to meet requirements.

Recommendation to the Veterans Health Administration (VHA)

1. Consider revising *VHA Handbook 1101.10 (paragraph 7.a. and 7.c.(4)(b)) and 1101.02 (paragraph 11.b.)* to permit combining multiple part-time providers into full-time equivalent PCP panel.

Conclusions for Concern 3

- VA **did not find evidence** of efforts to intentionally misrepresent physician workload.
- There are differences between calculations used to monitor and assign workload which could easily lead to confusion and could explain the observed discrepancy between the OIG investigation and that reported by the complainants (simple average by provider type versus corrected average irrespective of provider type).
- Additional details will be included in the OIG follow-up report.

Recommendations for VHA

2. Establish a single, standardized metric for reporting PACT panel sizes to sources outside the VHA.

Conclusions for Concern 4

- VA **did not find evidence** that management and leadership were failing to respond to identified concerns.
- Leadership has multiple initiatives aimed at improving the working conditions for the Primary and Specialty Medicine (P&SM), but some unintended consequences have impacted the desired effect, resulting in increasing responsibility and stress for providers.
- Leadership has fully implemented the PACT concept and is using team members to the fullest extent of their licensure.
- Leadership's P&SM initiatives were not recognized solutions by the P&SM staff.
- Leadership has attempted to improve communications through its presence at monthly P&SM staff meetings.
- Leadership has successfully recruited Veterans to enroll in PACTs at the Health System.
- The local implementation of the Veterans Choice Act is increasing workload for P&SM.

- This investigation found no evidence of Leadership retaliating against staff for identifying concerns or problems.

- This investigation found evidence of Leadership addressing individual issues and taking appropriate actions.

- There is evidence of overuse of Human Resources (HR) Specialists and Health System's Leadership when addressing HR concerns.

- High performance metrics can impair early identification of undesirable conduct by supervisors and need for the additional leadership training or reassignment.

Recommendations to the Health System

1. Provide middle managers additional training on dealing with performance issues, and handling issues at the lowest possible level.

2. Consider directing a 360 degree review of all current mid-managers and senior managers to identify potential unrecognized opportunities for improvement.

3. Implement recommendations resulting from the mediation with the union.

Recommendation to VISN 23

1. Monitor implementation of recommendations from the mediation with the Union.

Recommendation to VHA

3. Consider mandating the performance evaluation criteria "Leading People" a critical element on all supervisory positions.

Concern 5

Separate HR actions and an OIG investigation in January 2014 reviewed allegations of a hostile work environment in (b)(6) (b)(6) (b)(6)

Table of Contents

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 made by various employees of the St. Cloud Health Care System in St. Cloud, Minnesota (hereafter, the Health System). Allegations were made through eighteen individual letters (including one summarized from interview notes) to Congressional Representatives Tom Emmer and Tim Walz, and Senators Amy Klobuchar and Al Franken. The specific concerns addressed in these letters are:

1. Veteran care concerns on the Respiratory Dependency Unit (RDU):
   a. Mass insulin verification by staff;
   b. Over sedation of patients (chemical restraints);
   c. Suprapubic catheter irrigation using unsterile equipment;
   d. Improper skin care resulting in pressure ulcers;
   e. Failing to respond to medical device recalls/alerts;
2. Understaffing of the hospital/panel sizes in primary care too large;
3. Misrepresenting physician workload to VA's Office of the Inspector General (OIG);
4. Management and leadership failing to address identified concerns and employees fearing reprisal and retaliation for expressing concerns;
5. Hostile work environment (already addressed by other investigations).

The VA team conducted a site visit to the Health System on January 4-8, 2016.

II. Facility Profile

The Health System is a part of Veterans Integrated Service Network (VISN) 23 and is located in St. Cloud, Minnesota. It provides medical care to Veterans in central Minnesota, northern Iowa, northwestern Wisconsin, and eastern North and South Dakota, providing primary and subspecialty medical, urgent, specialty, mental health care, acute psychiatry services, and extended care and rehabilitation (EC&R) services. It offers the specialty outpatient services of audiology, dentistry, endoscopy, ambulatory surgery, laboratory, orthopedics, optometry, podiatry, pulmonology, radiology, urology, otolaryngology, respiratory therapy, rheumatology, hematology/oncology, cardiology, neurology, nephrology, and women Veterans health care. Community-Based Outpatient Clinic (CBOC) services are located in Alexandria, Brainerd, and Montevideo, Minnesota. The Health System does not maintain an inpatient acute care medical unit; the local St. Cloud Hospital (non-VA) and the Minneapolis VA Health System provide these services.

The Health System delivers care to more than 38,000 unique patients. Services are also delivered through: 15 acute psychiatry beds, 225 EC&R beds including 15 RDU beds, and 148 Residential Rehabilitation Treatment Program (RRTP) beds (with 23 more RRTP beds approved and under construction). In fiscal year (FY) 2015, the Health System completed over 589,000 outpatient encounters, treated 319 patients on

the acute psychiatry unit, 1,180 patients in the RRTP, and 679 residents in EC&R units. Sixty-three percent of the total Veteran workload is over the age of 65.

III. Conduct of Investigation

The VA team conducting the investigation included VA Team Member 1 Deputy Medical Inspector and VA Team Member 2 Clinical Program Manager, both from OMI; VA Team Member 3 Employee Relations/Labor Relations Specialist from the (b)(7) and VA Team Member 4 scheduling subject matter expert from the (b)(6) VA Medical Center.

The Investigators reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. They also conducted an announced visit of the Health System's RDU. The VA team conducted an entrance brief on January 5, 2016, and an exit brief on January 7, 2016, with Health System and VISN leadership, which included:

- Director Director
- COS MD, Chief of Staff (CoS)
- Employee 1 Associate Director for Patient Care Services/Nurse Executive (ADPCS/NE)
- Assoc. Director Associate Director
- Employee 2 RN, Director, Quality, Safety and Value
- Acting VISN MD, Acting VISN 23 Network Director (via teleconference)
- Deputy VISN VISN 23 Deputy Network Director (via teleconference)
- Employee 5 MD, VISN Primary and Specialty Medicine (P&SM) Director
- Employee 4 VISN 23 Quality Management Officer (via teleconference)

VA also interviewed the following employees:

- Director Director
- COS MD, CoS
- Employee 6 MD, VISN P&SM Director
- Employee 5 MD, Urologist, P&SM
- Employee 6 MD, P&SM
- Employee 7 MD, P&SM
- Employee 8 MD, P&SM (via teleconference)
- Employee 9 MD, P&SM
- Employee 10 MD, P&SM
- Employee 11 FNP, Nurse Administrator, P&SM
- Employee 1 FNP, ADPCS/NE
- Employee 12 APRN, Geriatric Nurse Practitioner
- Employee 13 RN, EC&R
- Employee 14 RN, EC&R
- Employee 15 RN

- [redacted] Director of Facilities Management
- [redacted] Engineering Technician, Facilities Management
- [redacted] Biomedical Engineering Technician, Facilities Management
- [redacted] Tractor Operator, Facilities Management
- [redacted] RD, Director, NFS
- [redacted]
- [redacted]
- [redacted] Food Service Worker, NFS
- [redacted], Supervisor, NFS
- [redacted]
- [redacted] Compliance and Business
- [redacted] LPN, Mental Health
- [redacted] RN, Risk Manager

VA investigated concerns 1–4 categorized above.

IV. Findings, Conclusions, and Recommendations

Concern 1: Veteran care concerns on the RDU

a. Mass insulin verification by staff
b. Over-sedation of Veterans (chemical restraints)
c. Suprapubic catheter irrigation using unsterile equipment
d. Improper skin care resulting in pressure ulcers
e. Failing to respond to medical device recalls/alerts

Background

The RDU is a specialized unit within the Community Living Center (CLC) that provides specialized care for Veterans with chronic respiratory difficulties, both those on ventilators and off them.[1]

Mass insulin verification by staff: To reduce the risk of adverse events, VA's Bar Code Medication Administration (BCMA) software requires the licensed nurse to scan the Veteran's armband to ensure selection of the correct Veteran and scan at the medication cart to retrieve the correct medication. Medications associated with serious drug effects are considered "high risk" and require additional steps to minimize the possibility of error when administering them. Insulin is "high risk" as it can cause coma or death through an immediate or insidious drop in blood sugar. In November 1999, the Joint Commission adopted a policy requiring two-person verification of "high risk" medications that is now included in their *Health System Memorandum CD 11-110, Medication – High Risk (March 2014).*[2]

[1] St. Cloud VA Health Care System Health Care Memorandum EC-01, Extended Care and Rehabilitation Programs, August, 2015.
[2] Sentinel Event Alert: High-Alert Medications and Patient Safety, November 19, 1999. http://www.jointcommission.org/assets/1/18/sea_11.pdf.

Over sedation of Veterans (chemical restraints): VA uses the Center for Medicare and Medicaid Services (CMS) standardized assessment and treatment instrument for its CLC program as a means of ensuring consistency with national nursing home standards, meeting accreditation standards of the Joint Commission, and facilitating comparisons between VA CLCs and nursing homes in the community and private sector.[3] The guidelines of the CMS require a pharmacist medication review of all long-term care residents on a monthly basis.[4] In addition to this review, the Health System elected to monitor on a quarterly basis all psychotropic medications (sedatives, antipsychotics, etc.), using a more comprehensive method as part of an ongoing performance improvement plan.

Suprapubic catheter irrigation using unsterile equipment: Because the indwelling catheter bypasses normal anatomic structures that protect against infection, microorganisms can colonize suprapubic and other chronic indwelling urinary catheters that are usually replaced every 1–3 months. Microorganisms that normally colonize periurethral skin and other infectious organisms can migrate into the bladder through a mucoid film that forms between the skin and catheter. Chronic urinary tract infections in these patients are typically asymptomatic, a low risk for other complications, and difficult to eradicate. Because the risk of promoting antibiotic resistance is high, and the risk of complications low, providers rarely prescribe antibiotics for such infections associated with long-term indwelling catheters.[5,6,7,8]

Improper skin care resulting in pressure ulcers: VHA Handbook 1180.02 addresses the prevention of pressure ulcers.

> Pressure ulcers are a cause of significant morbidity and mortality among hospitalized, institutionalized, and mobility-compromised individuals (see subpar. 21g). An important indicator of patient safety, pressure ulcer incidence rates and prevalence are now included in many performance measure sets. Pressure ulcer prevention across the continuum of care is a priority for VHA, the largest integrated health care delivery system in the United States. Most pressure ulcers are avoidable; however, unavoidable pressure ulcers may develop and existing ulcers may worsen despite appropriate care in certain high-risk individuals (see subpar. 21d).

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[3] VHA Handbook 1142.03 Requirements for use of the Resident Assessment Instrument (RAI) and Minimum Data Set (MDS), January 4, 2013.
[4] CFR-42 §483.60 (c)(1). Pharmacy Services.
[5] Stamm WE (1991) Catheter-associated urinary tract infections: epidemiology, pathogenesis, and prevention. Am J Med 91 (Suppl 3B): 65S-71S.
[6] Tambyah PA et al. (1999) A prospective study of pathogenesis of catheter-associated urinary tract infections. Mayo Clin Proc 74: 131-136.
[7] Bacterial Biofilms in Patients With Indwelling Urinary Catheters: Catheter Biofilms, 2008 http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjyro_A-97KAhUG3mMKHdVADtwQFgghMAA&url=http%3A%2F%2Fwww.medscape.org%2Fviewarticle%2F582018_2&usg=AFQjCNHYS4XGDkoFgENOXlZa5aE7-VoZ8A.
[8] Tenke P et al. (2008) European and Asian guidelines on management and prevention of catheter-associated urinary tract infections. Int J Antimicrob Agents 31 (Suppl 1): S68-S78.

Failing to respond to medical device recalls/alerts: A medical device is any instrument, apparatus, implement, machine, or similar or related article, intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease, injury, illness, or other condition, and is not a drug, human tissue, or used for sustenance.[9]

Findings

The investigators interviewed the previous Director of EC&R Services who provided a background history for the unit, (b)(6) (b)(6) (b)(6) In December 2011, the new nursing leadership implemented a 35-item action plan to address the failures to follow policy. The Health System documented all of the action items as "complete" as of this site visit.

Mass insulin verification by staff

A nurse, employed at the Health System from October 2011 until June 2013, raised concerns about the lack of two-person verification in her letter, and reiterated her concerns during her interview. Rather than verifying the correct dose, medication, and time with another licensed nurse, some nursing staff on the unit would give their assigned Veterans insulin injections, and only then ask another nurse to verify the medications. This is known as mass verification.

The former Service Line Director indicated that a nurse had erroneously administered too large a dose of short-acting insulin in 2011. At that time, nurses were required to obtain a second licensed nurse to verify the Veteran, time, dose, route, and medication; however, the BCMA software did not restrict forward progress (referred to as a hard stop) to force the administering nurse to obtain verification from a second nurse before proceeding with the dose. The program only required the second nurse to add a comment in a separate field, and this could be done either before or after administration. VA reviewed 23,289 incidences of insulin administration from January 2011 through December 2012, and found evidence of insulin administration by 11 different nurses without a verification signature from a second licensed nurse. These omissions were found in the medication records of many Veterans throughout the two years surveyed. The former Director stated that when VA upgraded the BCMA software in 2013, the Health System had volunteered to serve as a beta site during its initial capability testing in April of that year.

In addition to the former Director, we interviewed the current Director and other RDU providers and nurses and reviewed the current process in BCMA. We found that it was now impossible to bypass the verifier: a hard stop in the program prevented the administering nurse from moving past the insulin documentation screen or move on to another patient without having another nurse sign and verify the medication. All staff on the unit confirmed the appropriate two-person verification for high-risk medications and agreed that there was no way to circumvent the BCMA system.

[9] Health System Memorandum LOG-04, August, 2015.

Over-sedation of Veterans (chemical restraints)

Regarding use of sedation as a chemical restraint, all RDU staff interviewed indicated there were several steps used prior to the administration of sedating medications for restlessness or anxiety. These are outlined in *Health System Memorandum CD 11-56, Restraints and/or Seclusion Policy* (September 2015) that defines a chemical restraint as: "Any drug that is used to sedate a patient as a disciplinary measure or for staff convenience and not required to treat medical symptoms." The policy as written for EC&R Services, of which RDU is a subset, states: "The use of restraints [including chemical restraints] is limited to circumstances where the resident [Veteran] has medical symptoms that warrant restraint usage, and the use of restraints is prohibited for disciplinary or convenience purposes." RDU staff outlined the steps of escalation to modify Veteran behavior and use of restraints was the last resort.

The complainant did not provide specific names of persons alleged to have been chemically restrained; however, the Health System provided the Performance Improvement (PI) plan for psychotropic medications (of which sedation medications are a subset) for review. The PI plan, monitored quarterly, compares documentation of the reasons for administering as needed (prn) and the listed indications in the medication order. Compliance with the PI plan exceeds 95 percent for FYs 2014 and 2015 (goal is 90 percent). The Health System also provided a copy of the *Nursing BCMA Process Standard Operating Procedure (SOP) NSG-04 (November 2014)* that outlines procedures for administration of as needed medications (including sedation medications). The Health System recently began monitoring nurse activity in the pharmacy package. VA was provided all available pharmacy reports for Quarter (Q) 2 FY 2015 to Q1 FY 2016 documenting nurse activity in the pharmacy package in the Electronic Health Record (EHR); we identified 22 instances of sedation medications orders for Veterans. Fifteen of these were one-time medications for a specific procedure, and the remainders were for hospice and palliative care Veterans and appropriately documented in EHR.

The complainant did provide specific medications allegedly used to chemically restrain Veterans. The medications indicated were narcotics (Vicodin, oxycodone, morphine), and typically ordered for pain control either as an as-needed medication, or as a routine, scheduled medication, with additional medication for intermittent increases in the Veteran's report of pain. VA reviewed narcotic medication use for the period from October 2011 through September 2012 (the period of time the complainant was working in the RDU), looking for appropriate justification and monitoring for narcotics on both the day and night shifts. Of the 7,619 doses of narcotics given during this time, 4,693 were prn for 12 Veterans on as-needed narcotics. Three of the 4,693 prn doses were for anxiety or agitation (also symptoms of pain) in two different Veterans, both of whom were long-term ventilator-dependent in the RDU for palliative care and on baseline (routine) narcotics for pain around the clock; only one instance occurred on the night shift, for breakthrough pain or shortness of breath. The second Veteran's narcotic order was written for pain only. All three narcotic doses had follow-up documentation indicating that they had achieved the intended outcome (reduced anxiety, reduced agitation). VA analyzed narcotic administration patterns between day (0700-1900) and

night (1900-0700) shifts and found a distribution of 43 percent day shift, and 57 percent night shift administration of narcotics (3,255 narcotics on day shifts, and 4,364 on night shifts).

Suprapubic catheter irrigation using unsterile equipment

A complainant alleged that a specific nurse irrigated a Veteran's suprapubic catheter using an unsterile container. The complainant did not witness the event, but indicated the Veteran had called her into his room and described the incident. The complainant alleged that a urine culture taken after the alleged event "grew 4 microorganisms and one parasite," and caused the Veteran to have a high fever necessitating antibiotics.

We interviewed the nurse associated with this incident. The nurse indicated that in this particular case, a catheter irrigation kit was not available in the supply room, so she assembled individual pieces of sterile equipment in order to complete the task. All the equipment she used was sterile, but not packaged together in a single kit. VA reviewed the Veteran's EHR around the dates of the complainant's employment, and found four instances of documented urinary tract infection in this Veteran. None had more than three microorganisms and none indicated the presence of a parasite. Three instances occurred while the Veteran was an outpatient. The Veteran had an exacerbation of his chronic obstructive pulmonary disease and was transferred from urgent care at the Health System to a non-VA facility because his medical needs exceeded the Health System's resources. The Veteran returned to the Health System after recovering, and the Vancomycin-resistant Enterococcus (VRE) infection was in a urine culture collected after his return (VRE is associated with both long-term urinary catheters and hospital acquired infection). The nurse alleged to have caused the infection cared for the Veteran for approximately three weeks before the positive culture, and the day after the collection of this culture, making a direct cause-effect relationship unlikely. VA also reviewed the investigation completed by the Health System, which determined she met the standard of care.

Improper skin care resulting in pressure ulcers

A complainant stated that Veterans acquired bed sores and skin breakdowns as a result of night nurses failing to reposition patients every two hours as ordered.

VA reviewed RDU pressure ulcer reports for FY 2013–FY 2015 which encompassed the complainant's period of employment and beyond, and included enough of a sample to allow for trending. VA found 12 hospital acquired pressure ulcers (HAPU), and 5 community acquired pressure ulcers (CAPU) occurring in 9 unique Veterans. These 12 HAPU occurred in 6 unique Veterans, 3 of whom had multiple incidents. The trend for HAPU is downward (8 in FY 2013; 3 each in FY 2014 and FY 2015). During the time of the complainant's employment, there were two HAPUs in one Veteran, and two CAPUs in two different Veterans. VA reviewed the record of the single Veteran with HAPU. There was evidence in the nursing documentation that the Veteran did not comply with the interventions intended to mitigate the risk. There was significant evidence of nursing staff's interventions attempting to mitigate pressure ulcers (turning,

transferring Veteran to wheelchair using a lift, frequent skin assessments, etc.) and evidence of the Veteran refusing these efforts due to anxiety and discomfort.

Failing to respond to medical device recalls/alerts

A complainant indicated during an interview that the Biomedical Engineering (BME) section was not responding to medical device alerts and recalls, stating that there were over 600 outstanding work orders in the system, many of them medical device alerts or recalls.

We reviewed the Health System Procedures for Recall of Potentially Hazardous Products, Safe Medical Device Tracking, and Reporting (*Health System Memorandum LOG-04, August, 2015*). The Facility Recall Coordinator (FRC) serves as the primary point of contact in the Health System for all devices and product recalls (voluntary or otherwise) and manufacturer actions related to their products. The FRC coordinates the facility response and works with the appropriate Facility Designated Area Specialist (FDAS) to implement the program. The BME Supervisor is the FDAS for medical devices and responsible for:

1. Responding to all of the repairable medical devices alerts and recalls on the VA National Center for Patient Safety (NCPS) site upon notification from the FRC within required timelines;
2. Assigning action items to BMEs within the Alert and Recall Management System (ARMS) program located on the NCPS site;
3. Ensuring all actions are completed and posted within prescribed timeframes to the ARMS program;
4. Notifying FRC when action is closed out within ARMS on NCPS site.

There are three general categories of work orders: corrective maintenance, preventive maintenance, and recalls. Corrective maintenance is for medical devices that have an issue reported by the operator (e.g., the device is broken). Preventive maintenance is routine periodic (usually annual) with the intent to keep the medical device functioning at the optimal level. Recalls are alerts from outside agencies (device manufacturer, Food and Drug Administration, etc.) that require either inspection or corrective action on a specific medical device because of a known issue.

The investigators reviewed the Health System's work orders, and found 542 currently in open status. There were 196 corrective maintenance work orders in the Health System as of January 6, 2016. These corrective maintenance work orders are assigned a priority by the end user (low, average, high, emergency) when the device report is filed. BME technicians self-assign corrective maintenance work orders based on their area of specialization (e.g., dental equipment, radiology equipment, etc.) and urgency of the request. Of the 196 corrective maintenance work orders, only 27 had a specific BME technician assigned on the open work order list. Because corrective maintenance work orders might have several different technicians working on the equipment at the same time without anyone having full responsibility, a missing name was not seen by BME leadership as a significant issue. The information would be available after close out of the work order.

There were 325 preventive maintenance work orders as of January 6, 2016. Of these work orders, more than half (225) were opened between December 2015 and January 2016. BME leadership stated that this distribution of preventive maintenance work orders in the winter matched employees' higher availability in the winter versus the summer to avoid traditional vacation scheduling issues. BME leadership stated that prior to December 2015, BME technicians also self-assigned preventive maintenance tasks, but there was a disparity between BME technicians completing these tasks. BME leadership provided a spreadsheet outlining workload statistics for calendar year 2015. The goal for the percentage of work recorded (in work orders for corrective or preventive maintenance) to hours worked is 80 percent, and there was variance between BME technicians from 27.06 percent to 84.4 percent which required management intervention. In December, 2015, the BME technician's supervisor began assigning these preventive maintenance tasks to individual BME technicians to balance workload more equitably.

There were 21 recall work orders, and none of these recalls were identified as critical or required the medical device's removal from service. BME leadership reported that in September 2015, an engineer from the VISN came to assist the Health System with BME at the Health System's request. The VISN engineer identified a gap between recalls, and tracking the actions taken on recalls. The VISN engineer, along with the Health System engineer, developed a solution that required opening a work order on all recalls to improve tracking. This was not the practice prior to this date. BME leadership implemented this solution on November 24, 2015, and reported that a biomedical equipment specialist reviews all recalls to determine whether any impact patient outcomes are critical to patient care. VA reviewed evidence of 21 recalled devices, all with work orders dated November 24, 2015. There were no open work orders for recalls prior to this date. Of the 21 recalls active in January, 2016, none had a BME technician assigned, but all listed the engineer as the point of contact by name. As of February 18, 2016, eight recalls remained open/active.

VA interviewed a BME leader who described a work order tracking process involving multiple computer tracking systems, and that the service (which includes all sections of engineering including BME) section dealt with over 20,000 work orders per year. He also stated that work orders may be held in "open" status after intervention by the BME technician for several reasons (e.g., awaiting parts, a reported problem could not be replicated by the BME technician, etc.), and medical devices may remain in service if the work order is for preventive maintenance.

There were four reports of medical equipment failures and associated impact on Veterans from 2013–2016. Three of these were associated with incorrect use of equipment by clinical staff, and one with a recall notice. The BME staff had responded to the recall notice the month before the incident with the Veteran, and there was no evidence of the defect at the time of the BME inspection. Subsequent to the recall evaluation, the medical equipment failed in the way the recall suggested; the Veteran was not injured in this event.

BME leadership also indicated that a recent change from the National Program Office required an engineer to close out all medical device alerts in the data base. Since the

Health System has only one engineer and hundreds of work orders, the database update lags behind the actual completion of the orders (e.g., many items appear to be in "open" status when they are actually completed).

Conclusions for Concern 1

Insulin administration

- We **found evidence** that prior to 2013 nurses gave insulin without a second licensed nurse verifying the dose, route, patient, time, or medication.
- Based on the software prior to 2013, it was possible to administer high-risk medications without a second licensed nurse to verify the dose, patient, route, medication, time, and sign off as a witness, until after the fact.
- Since the upgrade to the BCMA system revised in 2013, the ability to bypass the verification step is not possible.

Overuse of Sedation

- This investigation **did not find evidence** of overuse of sedation with psychotropic medication.
- There were three instances of narcotic medications used for agitation or anxiety; these uses were appropriately ordered and documented.
- There was evidence of more frequent administration of narcotics on night shift than on day shift; however, this would not be an unusual practice as Veterans are encouraged to take pain medication at night to prevent disrupted sleep cycles.

Suprapubic catheter irrigation

- This investigation **did not find evidence** that a suprapubic catheter was irrigated using non-sterile equipment.

Skin Breakdown

- This investigation **did not find evidence** of improper skin care leading to HAPU. There is evidence of a decreasing incidence of HAPU since 2013.

Failure to respond to medical device alerts/recalls

- This investigation **did not find evidence** that BME failed to respond to medical device alerts/recalls.
- Although there are over 500 open work orders for a variety of equipment in the BME section, there is evidence of active management to improve the backlog of work orders since October 2015 and of supervisory oversight of high risk recalls.
- We found a large number of corrective maintenance and preventive maintenance work orders unassigned to a specific BME technician despite recent changes in procedures.
- There is no evidence of Veteran harm as a result of the backlog of work orders.

Recommendations to the Health System

1. Assign corrective maintenance and preventive maintenance to individual BME technicians.

2. Continue to monitor open work order status in BME to ensure that the implemented solution provides proper oversight.

3. Evaluate the current process to close out completed work orders and develop a process that includes the actual completion time.

Concern 2: Understaffing of the hospital/panel sizes in primary care too large

Background

As outlined in *VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook*, primary care is the provision of integrated, accessible health care services by health care professionals accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Primary care includes, but is not limited to: diagnosis and management of acute and chronic biopsychosocial conditions, health promotion, disease prevention, overall care management, post deployment care, and patient and caregiver education. PCPs are physicians, APRN, and PAs who provide primary care to an assigned panel of patients and in accordance with licensure, privileges, scope of practice, or functional statement. PAs must function as agents of a supervising physician specified by scope of practice and facility policy, consistent with state licensure requirements, and therefore must function in a collaborative relationship with a physician.[10] APRNs have varying degrees of physician oversight depending on their state licensure.

It is VHA policy that Veterans receiving VA primary care are assigned to a PACT for continuity of care over time, and offered services and benefits for which they are eligible as established in the VHA Handbook 1101.10 and as set forth in 38 Code of Federal Regulations 17.38.[11] PACT staff members establish a caring longitudinal relationship with Veterans and personal support persons that persist beyond a single episode of care. Continuity of care means that one team is the point of contact for coordinating its Veterans' current and future VA health care. PACT staff members are required to have access to the EHR, which records and stores all medical details on each Veteran, and is used to order medication changes, laboratory and radiology studies, and specialty consults with other providers. The EHR also provides alerts to the provider when orders need review, consults, radiology and laboratory studies are completed, and when secure messaging from Veterans occurs through My HealtheVet.

[10] VHA Handbook 1101.10: *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014.
[11] Ibid, page 7.

As outlined in *VHA Handbook 1101.10,* each PACT has only one PCP even when the provider is part-time. Specifically: "Several part-time PCPs should not be grouped to form one full-time PACT PCP (i.e., five 0.2 FTE PCPs should not be grouped to form one full-time PACT PCP)."[12] The baseline panel size for a full-time physician provider is 1,200 Veterans, although the facility CoS (or designee) has the authority to assign larger panels based on the capacity available in a VA Medical Center. Support staffing should be sufficient for Veterans to receive comprehensive primary care, and the recommendation is 3.0 Full Time Equivalent (FTE) staff to 1.0 FTE PCP. An FTE is equivalent to 2,080 hours, (8 hours/day, and 5 days/week) or 261 days. Adjusted FTEs for full-time PA or APRN providers are 0.75 FTE when compared to physician panel sizes, and the number of Veterans assigned is 75 percent of the physician panel size (PACT baseline panel size of 900 Veterans). Physicians that provide supervision or collaboration to PAs and APRNs also have their panel sizes reduced to allow for time to provide this oversight. Guidance for the number of Veterans assigned to a PCP are in *VHA Handbook 1101.02.*[13]

The VHA Handbook 1101.10 also addresses access and timeliness as essential components of high quality customer service and supports VHA's goals to provide prompt and appropriate treatment for Veterans' health concerns. PCPs who are not accessible to provide patient care during daily clinic hours (e.g., part-time PCPs) have formalized coverage arrangements with other PCPs or PACTs that ensure Veterans receive continuity of and access to care when a Veteran's designated PCP is not available. Covering PCPs act as surrogates for the assigned PCP, and are responsible for providing appropriate care and follow up on any alerts and secure messages received through the EHR. Appropriate care and follow up may require the Veteran to schedule an appointment with the covering PCP. Providing surrogate coverage for an unavailable PCP is in addition to the surrogate's primary responsibilities. Local service-level officials accountable for PACTs must establish and implement contingency plans for ensuring Veterans receive continuity of and access to appropriate primary care during periods of inadequate resources, extended staff absences, staff turnover, understaffing, and nature-related events (e.g., extreme weather conditions, natural disasters).[14]

Per *VHA Handbook 1101.10,* the responsibilities of the PACT provider are:

- Providing health care commensurate to the PCP's licensure and clinical privileges or scope of practice.
- Ensuring the patient's care plan contains medical recommendations for clinically indicated care.

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[12] Ibid, page 10.
[13] VHA Handbook 1101.02: *Primary Care Management Module (PCMM),* April 21, 2009.
[14] VHA Handbook 1101.10: *Patient Aligned Care Team (PACT) Handbook,* February 5, 2014.

- Offering clinically indicated health care services to patients assigned to the PACT, and providing or arranging for care to which patients consent.
- Providing leadership to the team including shared delegation of appropriate care and care processes to appropriate team members.
- Reviewing available clinical and performance data with the team, focusing on continuous improvement of critical team processes.
- Ensuring the patient has same-day access for face-to-face and telephone care visits during regular clinic hours.
- Collaborating with PACT staff to develop personal health plans that incorporate care management and care coordination appropriate to the patient's needs.
- Communicating with facility leadership regarding the resources needed by the PACT for optimal function.
- Ongoing, continuous care of one or more assigned panel(s) of Veterans [in the role of surrogate or if the provider has a separate panel in a subspecialty area].
- Utilizing all available tools, such as registries, to enable effective and efficient identification and intervention of individual patients and cohorts.
- Ensuring appropriate evaluation and access to patients assigned to the patient panel.
- Functioning at the full extent of the team member's relevant clinical privileges, credentials, scopes of practice, elements of practice, certification, functional statement, position description, or other VHA or local facility approved documentation of competency.
- Participating in team performance improvement and sustainment activities to optimize team efficiency and care delivery to patients.
- Implementing primary care operations management processes, as appropriate.
- Managing communications and facilitating safe transitions of patients between the PACT's site of care and other health care settings, using informal and formal communication methods, as appropriate.
- Providing health education and health coaching on wellness, disease prevention, chronic care management, and self-management skills to patients and personal support persons.
- Engaging patients in using health care, encouraging patients to engage personal support persons, receiving input from patients and personal support persons regarding VA care.
- Using formal and informal communications that are respectful, effective, timely, and bidirectional with all team members

(including the patient and personal support persons) to convey significant, clinically relevant information for the care of the patient.
- Collaborating with informatics technology staff to develop and implement systematized, electronically supported, standardized, tools to support PACT care delivery processes (e.g., pre-visit reminder calls, post-hospitalization follow-up calls, recall scheduling procedures, new patient orientation, disease registries and primary care protocols for chronic disease management).[15]

Ultimately, the responsibility for all aspects of the care of the Veteran falls on the PACT's PCP.

Findings

The Health System has fully implemented the PACT model and has a staffing plan for PACTs that outlines the minimum daily required amount of staff needed to provide care in each area. The details are specified in *Primary and Specialty Medicine Service Line Policy 111-03 (June 2014)* for providers, nurses, respiratory therapists, and clerk staff.

The investigators interviewed six PCPs currently employed by the Health System (one former PCP declined to be interviewed). None of the six could relate any instances where PACT resourcing had negatively impacted Veteran care; however, they all stated that their PACT patient panel sizes were "too large" based on VHA guidance and had been that way for approximately 3 years. Staff turnover requires patient reassignment from the departing PCP to a new PCP in order to comply with VHA Handbook 1101.10, creating turbulence in PACT panels.[16] Staff turnover rates for the Health System were at or below VISN and National rates.[17]

Workload

The Health System sets the full time physician PCP panel size at 1,350 Veterans, although there is variability depending on the number of PCPs employed. In FY 2016, the current average number of primary care visits for each unique Veteran at the Health System is 2.77 per year. PCPs' template currently schedules 12 Veterans per day in 30-minute appointments. Utilizing this template, full time PCPs would have the maximum capacity to see 3,120 appointments per year (assuming 100 percent availability on 261 days/year, i.e., no annual leave, sick leave, holidays or attendance at any continuing education conferences). PCP's earn 26 days of annual leave, 13 days of sick leave, and 10 federal holidays per year and must account for these days. If a PCP is absent on these allowable days that would result in 2,532 available appointments per PCP. Using the Primary Care Demand/Supply Ratio Calculator,

[15] Ibid, pages 60-61.
[16] Ibid. page 14.
[17] OIG Hotline Case Report #2014-00459-HL-044.

which also factors in standard panel turnover (10 percent) and missed opportunity rates (11 percent), the number of available appointments per PCP is 2054. Based on the known use rate at the Health System, a PCP physician panel needs 3,740 appointments to meet their current demand; this is between 620 to 1208 more appointments than on their schedule. The Health System has also attempted to address the shortfall in appointment availability due to manpower issues by utilizing urgent care and adding after-hours clinics on Tuesday evenings and Saturday mornings once per week as outlined in VHA Directive 2013-001.[18] In FY 2015, the Health System had 10,851 urgent care visits. We also found evidence of overbooking in the Clinic Capacity and Utilization report beginning in May of FY 2015 and continuing until the last data published in January of FY 2016.

Another evaluation technique would be to evaluate by the Team PCP FTE (PCP/AP Adjusted). The Team PCP FTE (PCP/AP Adjusted) adjusts PA and APRN PCP panel assignments to that of a full-time physician FTE so comparisons can be made. This technique essentially adds the 0.25 FTE capacity removed in the adjusted FTE calculations. VA reviewed the VHA Support Service Center (VSSC) Patient Aligned Care Teams Compass Facility Performance Summary for the Health System. In December 2015, there were 32,609 Veterans assigned. These Veterans would require 90,327 appointments per year to meet the Health System's population average use rate of 2.77 appointments per Veteran per year. PCP/AP Adjusted, which corrects for PA and APRN panel size, was 22.79 from this same data source. The Team PCP FTE (PCP/AP Adjusted) can provide a maximum of 71,378 appointments per year, a deficit of 18,949 per year. Adjusting the available PCP time to include annual leave and holidays increases the deficit of available appointments to 28,794.

Other aspects of PCP workload, in addition to direct care (i.e., clinic appointments), include care coordination using virtual methods (secure messaging, etc.), and management of EHR alerts for consult results, laboratory and radiology results, medication advisories, etc. The asynchronous nature of receiving alerts (e.g., the order is written, but the laboratory or radiology test is not completed for several hours or days) also impacts the PACT provider workload. Some of these asynchronous results require review immediately upon receipt and must be worked in between Veteran appointments. For reference purposes, one PACT provider stated she managed an estimated average of 60 EHR alerts per day in addition to direct care.

While the addition of PAs and APRNs increases PACT access, it also increases the amount of time that PCPs must devote to supervising PAs and APRNs. Collaboration and oversight activities vary with specialty (PAs require direct supervision by a physician, and APRNs require collaboration with a physician). The Health System Bylaws, Rules, and Regulations of the Medical and Clinical Professional Staff outline responsibilities for collaboration and oversight duties.[19] The Minnesota Board of

[18] VHA Directive 2013-001 Extended Hours Access for Veterans Requiring Primary Care Including Women's Health and Mental Health Services at Department of Veterans Affairs Medical Centers and Selected Community Based Outpatient Clinics. January 9, 2013.
[19] St. Cloud VA Health Care System Bylaws, Rules, and Regulations of the Medical and Clinical Professional Staff, November, 2015.

Nursing does not require collaboration by a physician except for the first 2,080 hours of clinical practice if the APRN graduated after July 1, 2014.[20] In both the PA and APRN panels, the physician is responsible for co-signing all admission orders for Veterans, long-term care orders including community care orders for Veterans in long-term care outside the Health System, recurring orders for Veterans in a variety of facilities outside the Health System, and other types of orders that are outside the scope of practice for PAs and APRNs.[21] The physicians interviewed estimated the volume of these orders and other documents requiring co-signature and review at 50 to 100 hundred per physician per day. CMS generally requires that a physician sign the plan of care for reimbursement by CMS.[22]

Leadership has approved an increased number of providers to work part-time in an effort to retain PCPs. This has helped maintain appointment availability, but also added requirements for management of the part-timers' panels during days these providers are not in clinic. Providing care for Veterans assigned to part-time PCPs needing direct care, reviewing ancillary studies, or the myriad of other asynchronous tasks expected of the PACT provider, becomes the responsibility of the full-time providers assigned as surrogates when the part-timer is not available, a responsibility that is in addition to the full-time provider's assigned PACT responsibilities. This is especially critical at CBOCs where the ratio of part- to full-time providers is higher, and where there is no access to urgent care. The part-time PCP has a team of support staff that can assist in coordinating care with the surrogate PACT provider, but the ultimate responsibility still rests with the surrogate provider. This sense of responsibility, desire to maintain continuity, and the fear of missing something critically important in the Veteran's care was voiced by all the PACT providers, and described by one provider as "a feeling of abject terror."

We reviewed the primary care PACT monthly schedules: between January 2013 and January 2016, PCP staffing increased overall by 40 percent, physician staffing by 35 percent, PAs by 100 percent, and APRNs by 120 percent. Leadership explained that although they had open continuous recruiting for physicians, it was difficult to hire at the site because of its location. Therefore, a conscious decision had been made to hire PAs and APRNs as these professionals were more readily available in the area. Despite higher overall numbers of PCPs, the secondary effect of enabling more part time PCPs, and hiring PAs and NPs in lieu of physicians negatively impacted the FTEs available to provide Veteran care. During the period from 2014–2016, the Team PCP FTE (PCP/AP Adjusted) decreased from 25.78 in FY 2014 to 22.79 in FY 2016 to date.

The proportion of part- time PCPs at the Health System has increased from 18 percent in January 2013 to 33 percent in January 2016. This increase is an effort by leadership to retain existing staff. Review of VSSC data from January 2016 on primary care panel capacity shows 34 providers assigned to the facility and 3 providers assigned to the CBOCs. Of these 34 providers, 12 are part-time (7 work less than 0.5 FTE or half time)

[20] Minnesota Statute § 148.171, sub 5(4), 10(2), 11(4), 13, 21(2).
[21] VHA Handbook 1143.2, VHA Community Nursing Home Oversight Procedures, p. 7.
[22] 42 CFR chapter IV § 409.43 Plan of care requirements.

and assigned 6,941 out of 32,602 Veterans as of January 12, 2016 (21 percent). At the CBOCs, part-time providers make up 33 percent (Montevideo), 40 percent (Brainerd), and 67 percent (Beilke) of the staff; at the St. Cloud facility, the percentage is 29.1 percent. The Health System Leadership attempted to combine these part-time PCPs together to fill a full time FTE, but was instructed that this was against policy.

Quality of Care

The investigators reviewed Healthcare Effectiveness Data and Information Set HEDIS quality indicators for primary care and compared these data to national averages. The Health System exceeded national averages in 23 out of 24 measures (only their Cervical Cancer Screening Women age 21-29 year was below the national average). VA national averages on these measures exceeded commercial, Medicaid and Medicare averages, placing the Health System near the top of all providers in the Nation. VA reviewed FY 2015 measures of Timely Care, Safe Care, Patient-Centered Care, and Effective Care, and the Health System was higher than VA National averages in 87 of 115 measures (75 percent).

Conclusions for Concern 2

- There is evidence that the PACT teams are providing quality care to Veterans in the Health System.

- The investigators **found evidence** that some of the PACT panel sizes are so large that PCPs feel an overwhelming sense of responsibility, which adds considerable stress to the work environment. Also the distribution of physicians, physician extenders, and part-time providers create a mix that also adds to the sense of responsibility, especially for the full-time physicians.

- The Health System cannot meet current primary care appointment demand, using their existing scheduling template.

- Leadership's efforts to retain PCPs (by extending part-time positions) and increased recruiting of PAs and APRNs had an unintended consequence of increasing the full-time PCP physician's workload in oversight and surrogate responsibilities, and simultaneously reducing the Team PCP FTE (PCP/AP Adjusted).

- The guidance provided by *VHA Handbooks 1101.10 and 1101.02* on Veteran assignment to only one PCP, and the directive that precludes combining part time PCPs into single full time equivalent panels (job sharing) has impacts on the Health System's ability to manage the competing priorities of PACT growth, PCP recruitment and retention, and the current PCP's overwhelming sense of responsibility.

Recommendations to the Health System

4. Establish organizational policies to ensure the ratio of physicians to PAs/APRNs does not adversely impact actual available FTEs.

5. Analyze surrogate and collaborative responsibilities in support of part-time PCPs and adjust for these responsibilities in physician workload.

6. Analyze current appointment needs and consider adjusting scheduling templates to meet requirements.

Recommendation to VHA

1. Consider revising *VHA Handbook 1101.10 (paragraph 7.a. and 7.c.(4)(b)) and 1101.02 (paragraph 11.b.)* to permit combining multiple part-time providers into full-time equivalent PCP panel.

Concern 3: Misrepresenting physician workload to OIG

Background

There are several different methods for calculating provider workload, depending on the level of detail required and how the results are used. One way to determine average PACT panel sizes is to divide the total number of Veterans assigned to the facility by the total number of provider FTEs (physicians, PAs, and APRNs) in the facility.

Another method is to use the PCP/AP Adjusted, which calculates an average number of Veterans assigned for an average provider, and then corrects the average upward by 25 percent for each PA or APRN assigned to the team. The intent of this metric is to adjust the PA or APRN's panel size to that of a physician to allow for comparison between panels, and is not an actual average of patients assigned.[23]

There is variance between different providers due to several factors, including the number of days worked per week in the clinic (represented as direct care FTEs) and type of provider. PAs and APRNs have PACT panels assigned at 75 percent of the workload assigned to physicians, regardless of the number of days worked. In order to adjust for this workload difference, the number of Veterans assigned, divided by 0.75 is the PCP/AP Adjusted. For example, if a PA has 1,000 patients assigned, the team adjusted panel size average would be 1,333 (1,000/0.75). If the provider works less than 1.0 FTE, this will also require correction.[24]

Findings

In the January 2014 OIG report, the average PACT panel size in November 2013 was 1,417, and reported as decreased from a high of 1,787 in August 2013. There was

[23] Ibid.
[24] Patient Aligned Care Team Compass Data Definitions update 6/25/2015.

concern expressed in a complaint sent to Senators Klobuchar and Franken regarding the accuracy of these figures and whether they represented actual workload.

We interviewed a member of the VISN team detailed to complete the OIG investigation in January 2014. His explanation for the variance was the different methods to determine the average panel size for the PACT teams. The method the OIG investigation used was the Team PCP Panel Size Average (PCP/AP Adjusted) as recommended by PCMM. This method corrects for smaller PCP panel sizes assigned to PAs and APRNs to an FTE equivalent of a full-time physician. It does not provide separate averages for physicians and PAs/APRNs as reported in an issue brief submitted by the Health System to the VISN in September 2013, which described panel sizes of 1,810 for primary care physicians, and an average mid-level (PA/APRN) panel size of 1,281. He stated that the multiple methods caused confusion between the report and those observed by the complainants.

The metrics are constantly changing with fluctuations in Veteran enrollment, and provider staffing. Because metrics are only available back to October 2013, it is not possible to check the exact timeframe used by the OIG team. However, in October 2013, the PCP/AP Adjusted was 1,587 and dropped to 1,159 in January 2014. This is consistent with the hiring of six additional providers between October 2013 and January 2014.

The investigators also reviewed VSSC data from February 6, 2016, to determine PACT panel sizes for the 34 panels listed. The largest PACT panel was 1,708 Veterans, and the smallest was 10. Twelve PACT panels had more than 1,200 Veterans (34 percent of PACT panels larger than baseline), and 20 out of the 34 were larger than maximum capacity when adjusted for FTE.

Conclusions for Concern 3

- VA **did not find evidence** of efforts to intentionally misrepresent physician workload.
- There are differences between calculations used to monitor and assign workload which could easily lead to confusion and could explain the observed discrepancy between the OIG investigation and that reported by the complainants (simple average by provider type versus corrected average irrespective of provider type).
- Additional details will be included in the OIG follow-up report.

Recommendations for VHA

2. Establish a single, standardized metric for reporting PACT panel sizes to sources outside the VHA.

Concern 4: Management and leadership failing to address identified concerns

Background

One measure of the health of an organization is the All Employee Survey (AES), which is collected annually at each facility. The AES contains details for each specific work section. The Health System has 14 different work sections and one combined score. P&SM is one of the work sections broken out in the survey and includes all the PACTs at the main facility and CBOCs.

Leadership is a performance measure in all employees' annual appraisals. The broad goals set for each employee start with the goals of senior leadership. *VA Directive 5027, Senior Executive Service* states that:

> The performance appraisal system for Senior Executives Service (SES) shall serve as a tool for executing basic management and supervisory responsibilities by:
> (1) Communicating and clarifying organizational goals and objectives.
> (2) Identifying individual accountability for the accomplishment of Department goals and objectives.
> (3) Evaluating and improving individual and organizational accomplishments.
> (4) Providing a basis for SES performance awards and other personnel actions including pay adjustments, executive development, reassignments, reduction-in-force and removals.[25]

VA Handbook 5013 Appendix F covers all non-SES supervisory and management employees in VHA's Executive Career Field (ECF). This handbook also states that: "The executive leadership's performance measures will cascade down to the ECF employees as deemed applicable."[26] The VA Leadership Competency Model includes six core competencies: Leading People; Building Coalitions; Leading Change; Results Driven; Global Perspective; and Business Acumen.[27] Each core competency has five proficiency levels: Novice, Foundational, Intermediate, Advanced, and Expert that are behavioral expectations for various levels of leaders.[28] On the employee's performance plan, these five core competencies are a combined total of 100 percent and can vary based upon the local SES's annual performance goals.

Findings

The FY 2015 AES results show a low direct supervision score (P&SM was the lowest in the Health System), and organization satisfaction (P&SM was second lowest). P&SM job control and information sharing were low (second lowest and lowest, respectively).

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[25] VA Directive 5027, *Senior Executive Service*
[26] VA Handbook 5013, *Performance Management Systems*.
[27] Global Perspective is no longer in use
[28] VA Leadership Competency Model, June, 2011.

Fairness, relationship, and favoritism scores were also lowest in the Health System and intended to describe the employee's perception of how the supervisor treats all staff members. The results from 2015 AES were slightly better than the 2013 results in psychological safety for P&SM; however, both years' results were lower than the average for the Health System.

We interviewed clinical personnel from different specialty areas under P&SM; they alleged that leadership was inattentive to their concerns. P&SM staff expressed concerns over staff turnover, excessive PACT panel sizes with disproportionate workloads, unclear or missing flow of information, and lack of input into decisions directly affecting their practice.

VA interviewed the Director, CoS, VISN P&SM Director, and ADPCS/NE (hereafter Leadership) addressing the allegations expressed by the P&SM staff. Leadership noted that in 2013, five providers resigned, relocated, or retired at approximately the same time (July through September 2013). Since that period, there three additional P&SM providers have been terminated for substandard performance or behavior. Leadership has aggressively attempted to recruit additional providers through:

- Open, continuous advertisements in USAJobs;
- Print and on-line advertisements in major professional journals;
- Special pay rates for physicians;
- Use of VHA National Recruiter and third-party recruiting services;
- Relocation and recruitment incentives for providers;
- Education debt reduction for providers;
- Pay adjustments for PAs and APRNs;
- Hiring new PA and APRN providers coupled with an extended orientation program;
- Established an internal provider recruitment working group.

They have also developed a very strong PACT supportive structure, utilizing all team members to practice to the full extent of their relevant clinical privileges, credentials, scopes of practice, elements of practice, certification, functional statement, position description, or other VHA or local facility-approved documentation of competency. Evidence that the Health System' leadership encouraged this is in *P&SM-61, Medication Reconciliation (March 2015)*.[29] In this P&SM, there are procedures for registered nurse and pharmacy focused office visits in which any medication discrepancies are addressed, and medications can be adjusted by nursing protocol or pharmacist intervention. These office visits can be independent or shared medical appointments with providers. This Reconciliation also outlines expanded responsibilities for telephone and telehealth visits by both nurses and pharmacists.

Leadership has been addressing PACT panel sizes by increasing the number of P&SM providers. They voiced difficulties in recruiting qualified providers secondary to a competitive market and lack of a Health System affiliated physician residency program.

[29] St. Cloud VA Health Care System Standard Operating Procedure P&SM-61, March 2015.

Active recruiting from the surrounding civilian community medical centers and P&SM provider turnover impacted PACT panel sizes. There is an established Health System Growth Committee that sets Veteran recruiting goals annually, but there is a significant lag between adding Veterans to PACTs for care, and recruiting P&SM providers. Leadership resorted to hiring PAs and APRNs in place of physicians secondary to physician extender availability.

Leadership also indicated that using the Veterans Choice Program (Choice) has been challenging because the Choice contractor is unfamiliar with both Veterans and the local area. For example, the contractor scheduled a Veteran for hip replacement in Kentucky, which would impact the Veteran's recovery and family support. In contrast, the PACT providers track their Choice appointments, results, and reports, call Veterans if they miss an appointment, and help them reschedule, ensuring the Veteran is getting appropriate care. Out of concern for their Veterans, the Health System ensures that the Veteran is assigned to a PACT so that the PACT team can help the Veteran navigate the system as described above. This has the undesired effect of increasing panel sizes and PCP responsibilities. For example, the PACT team has had to resort to calling the contractor to assist Veterans in getting care through Choice. This active management of the Choice referral has added to PACT workload, instead of relieving it. The Health System is continuously following up with the contractor to ensure that Veterans are getting needed care.

Leadership succeeded in expanding Veteran enrollment in PACT panels. According to VSSC data on new outpatient visits and unique patient trends, the Health System has grown from 28,544 Veterans serviced in FY 2010 to 32,609 in FY 2015. The number of encounters with the Health System also increased from 102,499 to 138,356 during the same period (a 35 percent increase). In contrast to the average visits above, these encounter figures include traditional appointments, telephone consults, virtual visits, and other asynchronous methods reflecting a use rate of 4.24 encounters per Veteran per year for the Health System.

Leadership indicated that they have renewed efforts to be more visible to P&SM staff through monthly attendance at formal P&SM meetings. The Director and CoS attended 15 out of 22 scheduled meetings from September 2013 to September 2015, and since December 2015, the CoS has attended the 2 of 5 P&SM meetings. Leadership reported also conducting both formal and informal walking rounds periodically; however, there were no records of rounds to review. While there is documented evidence that on multiple occasions leadership discussed recruitment efforts and PACT panel size, and workload concerns at the P&SM meetings, not everyone attends those meetings. When asked about leadership participation at their meetings, the P&SM confirmed their participation and requests for interchange of ideas, but did not recognize this as leadership engagement.

The Health System has a standing Workforce Development Committee with evidence of monthly meetings since November 2014. The HR Officer chairs this Committee and the Associate Director is a member. One of the functions of the Committee is to oversee

action plans related to AES results. There is evidence that the Committee follows these action plans quarterly. VA reviewed action plans for P&SM for FY 2015 that includes improving communications to the CBOCs and improving communication with all staff regarding administrative items. The actions addressing these goals are monthly emails, quarterly site visits to CBOCs, and newsletters to staff. There is also a goal of "Staff stretch assignments, improve participation and decrease feelings of favoritism" with the action item that "Supervisors will ensure equal opportunity for staff to volunteer for stretch assignment including workgroups, committees, and special projects".[30]

Many individuals expressed concern that the HR was overused for routine personnel performance issues, describing the "march to HR" for minor infractions that caused anxiety and embarrassment for the individual being counseled. Leadership indicated that the increased use of HR for arbitration of minor infractions was in response to aggressive union tactics to elevate everything to a "Level 3 Grievance" over the last 3 to 4 years. The week following VA's site visit, the Health System participated in Federal Mediation with the union. The public statement indicates: "We are jointly committed to embracing a productive and cooperative working relationship between AFGE Local 390 and St. Cloud VA management which is essential to achieving our mission and ensuring a quality work environment for all employees." It has scheduled additional meetings in the months ahead to continue this process.

We interviewed leadership regarding actions to correct undesirable conduct by (b)(6) (b)(6) supervisors. (b)(6) had sustained high performance on metrics for their sections. Leadership stated that this performance of their sections gave an impression of supervisor effectiveness, making it difficult to initially recognize their undesirable conduct. Their performance plans and appraisals were written to emphasize results (45 percent) over leading people (20 percent). (b)(6) (b)(6)

[30] Workforce Development Committee St. Cloud VA Agenda and Minutes, June 2015.

Conclusions for Concern 4

- VA **did not find evidence** that management and leadership were failing to respond to identified concerns.

- Leadership has multiple initiatives aimed at improving the working conditions for the P&SM, but some unintended consequences have impacted the desired effect, resulting in increasing responsibility and stress for providers.

- Leadership has fully implemented the PACT concept and is using team members to the fullest extent of their licensure.

- Leadership's P&SM initiatives were not recognized solutions by the P&SM staff.

- Leadership has attempted to improve communications through its presence at monthly P&SM staff meetings.

- Leadership has successfully recruited Veterans to enroll in PACTs at the Health System.

- The local implementation of the Choice Program is increasing workload for P&SM.

- This investigation found no evidence of Leadership retaliating against staff for identifying concerns or problems.

- This investigation found evidence of Leadership addressing individual issues and taking appropriate actions.

- There is evidence of overuse of HR Specialists and Health System's leadership when addressing HR concerns.
- High performance metrics can impair early identification of undesirable conduct by supervisors and need for the additional leadership training or reassignment.

Recommendations to the Health System

1. Provide middle managers additional training on dealing with performance issues, and handling issues at the lowest possible level.

2. Consider directing a 360-degree review of all current mid-managers and senior managers to identify potential unrecognized opportunities for improvement.

3. Implement recommendations resulting from the mediation with the union.

Recommendation to VISN 23

1. Monitor implementation of recommendations from the mediation with the union.

Recommendation to VHA

1. Consider mandating the performance evaluation criteria "Leading People" a critical element on all supervisory positions.

Attachment A

VA Directive 5027, *Senior Executive Service,* April 15, 2002

VA Handbook 5013, *Performance Management Systems,* April 15, 2002

VA *Leadership Competency Model*, June 2011

OIG Hotline Case # 2014-00459-HL-0044 Follow up report

VHA Directive 2013-001 *Extended Hours Access for Veterans Requiring Primary Care Including Women's Health and Mental Health Services at Department of Veterans Affairs Medical Centers and Selected Community Based Outpatient Clinics.* January 9, 2013

VHA Handbook 1143.2 *VHA Community Nursing Home Oversight Procedures,* June 4, 2004

VHA Handbook 1180.02 *Prevention of Pressure Ulcers*, July 1, 2011

VHA Handbook 1101.02 Primary *Care Management Module (PCMM)*, April 21, 2009

VHA Handbook 1101.10 Patient *Aligned Care Team (PACT) Handbook,* February 5, 2014

VHA Handbook 1142.03 Requirements for use of the Resident Assessment Instrument (RAI) and Minimum Data Set (MDS), January 4, 2013

VHA Handbook 1142.01Criteria and Standards for VA Community Living Centers (CLC), August 13, 2008

St. Cloud VA Health Care System, *Health Care Memorandum* EC-01, *Extended Care and Rehabilitation Programs*, August 2015

St. Cloud VA Health Care System, *Bylaws, Rules, and Regulations of the Medical and Clinical Professional Staff,* November 2015

St. Cloud VA Health Care System, *Health Care Memorandum* LOG-04, August 2015

St. Cloud VA Health Care System, *Standard Operating Procedure P&SM-61,* March 2015

St Cloud VA Health Care System, Workforce Development Committee *Agenda and Minutes*, June 2015

St. Cloud VA Health Care System Memorandum HCSM HR-01, August 2014

CFR-42 §483.60 (c)(1). Pharmacy Services. https://www.ssa.gov/OP_Home/comp2?B-CFR-42.html

(page 7): https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/lewingroup.pdf

Department of Health and Human Services, Office of Inspector General,
OIG Supplemental Compliance Program Guidance for Nursing September 24, 2008, in Facilities Federal Register / Vol. 73, No. 190 / Tuesday, September 30, 2008 / Notices page 56838. http://www.ltciorg.org/wp-content/uploads/2013/03/OIG-Supplemental-Program-Guidance-for-Nursing-Facilities.pdf

Sentinel Event Alert: *High-Alert Medications and Patient Safety*, November 19, 1999 http://www.jointcommission.org/assets/1/18/sea_11.pdf

Mediation Public Statement AFGE Local 390 and St. Cloud VA, January 14, 2016