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Comprehensive Healthcare Inspection of the North Florida/South Georgia Veterans Health System

Gainesville, Florida

CHIP REPORT | **REPORT #19-00010-237** | **SEPTEMBER 27, 2019**

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Figure 1. *North Florida/South Georgia Veterans Health System, Gainesville, FL (Source: https://vaww.va.gov/directory/guide/, accessed on May 21, 2019)*

Abbreviations

ADPCS	associate director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
FPPE	focused professional practice evaluation
FY	fiscal year
LIP	licensed independent practitioner
MST	military sexual trauma
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
SAIL	Strategic Analytics for Improvement and Learning
TJC	The Joint Commission
UCC	urgent care center
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Report Overview

This Office of the Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the North Florida/South Georgia Veterans Health System (the facility), which includes Malcom Randall VA Medical Center (VAMC) and Lake City VAMC. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

CHIP inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The reviews are performed approximately every three years for each facility. The OIG selects and evaluates specific areas of focus each year.

The OIG team looks at leadership and organizational risks as well as areas affecting quality patient care. At the time of the review, the clinical areas of focus were

1. Quality, safety, and value;
2. Medical staff privileging;
3. Environment of care;
4. Medication management (specifically the controlled substances inspection program);
5. Mental health (focusing on military sexual trauma follow-up and staff training);
6. Geriatric care (spotlighting antidepressant use for elderly veterans);
7. Women's health (particularly abnormal cervical pathology result notification and follow-up); and
8. High-risk processes (specifically the emergency department and urgent care center operations and management).

This unannounced visit was conducted during the week of January 14, 2019. The OIG held interviews and reviewed clinical and administrative processes related to areas of focus that affect patient care outcomes. Although the OIG reviewed a broad spectrum of clinical and administrative processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this facility's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this facility and other Veterans Health Administration (VHA) facilities to identify areas of vulnerability or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results and Inspection Impact

Leadership and Organizational Risks

At the time of the OIG's visit, the facility leadership team consisted of the director, acting chief of staff, associate director for Patient Care Services (ADPCS), and the deputy director, associate director (Lake City), and assistant director (all three are primarily nonclinical). Organizational communications and accountability were managed through a committee reporting structure, with the Executive Leadership Council having oversight for several working groups. The director and deputy director were co-chairs of the Quality Executive Council, which was responsible for tracking, identifying trends, and monitoring quality of care and patient outcomes.

The facility's leadership team had been working together for almost two months, although several team members had served in their position for years. The director and associate director were permanently assigned in June and November 2012, respectively. The ADPCS, deputy director, and assistant director positions have been filled since November 2018, August 2016, and November 2015, respectively. Of note, at the time of the OIG on-site visit, the deputy chief of staff had been the acting chief of staff since the position became vacant July 27, 2018.

The OIG noted that selected employee satisfaction survey results indicated that facility leaders were engaged and promoted a culture of safety where employees feel safe bringing forward issues and concerns. However, opportunities exist for the chief of staff to improve employee satisfaction. Three of four selected patient experience survey scores for facility leaders were similar to or better than the VHA average. Facility leaders had implemented processes and plans to maintain positive patient experiences; for example, robotic pet therapy was initiated to improve behavioral and emotional well-being during residential stays.

Additionally, the OIG reviewed accreditation agency findings, sentinel events,[1] disclosures of adverse patient events, and patient safety indicator data and did identify organizational risk factors. The quality management staff should review the current process used for tracking and monitoring accreditation survey information and institutional disclosures to ensure facility leaders have accurate information to make decisions to mitigate future clinical and administrative risks.

The OIG recognizes that the Strategic Analytics for Improvement and Learning (SAIL) model has limitations for identifying all areas of clinical risk but is "a way to understand the similarities

[1] The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

and differences between the top and bottom performers" within VHA.[2] Although the leadership team members were knowledgeable within their areas of responsibility about selected SAIL metrics and community living centers (CLC) measures, the leaders should continue to take actions to sustain and improve performance of the quality of care metrics and measures likely contributing to the facility's SAIL "3-star,"[3] Malcom Randall VAMC CLC "2-star," and Lake City VAMC CLC "1-star" quality ratings.[4]

The OIG noted findings in all eight of the clinical areas reviewed as well as incidental findings and issued 28 recommendations that are attributable to the director, deputy director, and chief of staff. These are briefly described below.

Quality, Safety, and Value

The OIG found there was general compliance with requirements for protected peer review and patient safety. However, the OIG identified noncompliance with interdisciplinary reviews of utilization management[5] data, inclusion of required elements in root cause analyses, and committee review of all resuscitation episodes.

Medical Staff Privileging

The facility generally complied with requirements for credentialing and privileging. However, the OIG identified noncompliance with defining focused professional practice evaluation criteria in advance, establishing ongoing professional practice evaluation criteria specific to the

[2] VHA's Office of Operational Analytics and Reporting developed a model for understanding a facility's performance in relation to nine quality domains and one efficiency domain. The domains within SAIL are made up of multiple composite measures, and the resulting scores permit comparison of facilities within a Veterans Integrated Service Network or across VHA. The SAIL model uses a "star rating" system to designate a facility's performance in individual measures, domains, and overall quality. http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 6, 2019 but is not accessible by the public.)

[3] Based on fiscal year 2018, quarter 3 ratings at the time of the site visit.

[4] Based on fiscal year 2018, quarter 4 ratings at the time of the site visit.

[5] The definition of utilization management can be found within VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018). Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria." This directive was in effect at the time of the review but was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019); this directive expired on July 31, 2019.

service/section, and using OPPE results in the service chief's determination to recommend continuance of current privileges.[6]

Environment of Care

The facility generally complied with requirements for safety and privacy at the parent facility and the representative clinic (The Villages VA Clinic). The OIG did not find any issues with the availability of medical equipment and supplies. However, the OIG identified noncompliance with environmental cleanliness, infection prevention, and emergency management testing of generators.

Medication Management

Overall, the facility complied with requirements for some of the performance indicators evaluated, including the completion of controlled substances coordinator reports, the controlled substances inspectors having no conflicts of interest, and completing annual competency assessments. However, the OIG noted concerns with monthly inspections, rotation of controlled substance inspectors, completion of physical inventory count on the day initiated, verification of controlled substances orders, security and verification of drugs held for destruction, accountability of prescription pads, verification of hard copy prescriptions, and verification of completion of the twice weekly inventories.

Mental Health

The OIG team found that the facility complied with many of the mental health performance indicators, including the designation of a military sexual trauma (MST) coordinator, tracking of MST-related data, and referral for MST-related care. The OIG noted a concern however, with providers completing MST mandatory training.

[6] The definitions of ongoing professional practice evaluation and focused professional practice evaluations can be found within Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility." A focused professional practice evaluation for cause is "a time-limited period during which the medical staff leadership assesses the provider's professional performance to determine if any action should be taken on the provider's privileges."

Geriatric Care

For geriatric patients, clinicians documented reasons for prescribing medications. However, the OIG identified concerns with the patient and/or caregiver education and medication reconciliation processes.

Women's Health

The OIG found compliance with many of the selected performance indicators, including requirements for a designated women veterans program manager, clinical oversight of the women's health program, communication of abnormal results to patients, and follow-up care when indicated. However, the OIG identified noncompliance with the Women Veterans Health Committee membership and tracking of cervical cancer screening data.

High-Risk Processes

The facility generally complied with many of the performance indicators used to assess the operations and management of the emergency department. However, the OIG identified a lack of availability of social work support services and inadequate directional signage.

Incidental Findings

At the time of the OIG visit, the facility had a current scanning backlog of 2,045 inches for Malcom Randall VAMC with the oldest documents dated October 2017 and 134 inches for Lake City VAMC with the oldest documents dated November 2017. The contracted vendor started on January 7, 2019, but at the time of the OIG visit had not started scanning. The OIG also identified deficiencies with medical equipment inspection and labeling and oxygen storage.

Summary

In reviewing key healthcare processes, the OIG issued 28 recommendations for improvement directed to the facility director, acting chief of staff, and deputy director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this facility. The intent is for facility leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address system issues as well as other less-critical findings that, if left unattended, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network director and facility director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes F and G, pages 101–102, and the responses within the body of the report for the full text of the directors' comments.) The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to provide oversight of healthcare services to veterans. This focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the North Florida/South Georgia Veterans Health System (the facility) is accomplished by examining a broad overview of key clinical and administrative processes associated with quality care and positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and facility leaders so that informed decisions can be made on improving care.

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting the quality agenda; and promoting a culture to sustain positive change.[7] Investments in a culture of safety and quality improvement with robust communications and leadership significantly contribute to positive patient outcomes in healthcare organizations.[8] Figure 2 shows the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

To examine risks to patients and the organization when core processes are not performed well, the OIG focused on the following nine areas of clinical and administrative operations that support quality care at the facility:

1. Leadership and organizational risks
2. Quality, safety, and value (QSV)
3. Medical staff privileging
4. Environment of care
5. Medication management (specifically the controlled substances inspection program)
6. Mental health (focusing on military sexual trauma follow-up and staff training)
7. Geriatric care (spotlighting antidepressant use for elderly veterans)
8. Women's health (particularly abnormal cervical pathology results notification and follow-up)

[7] Anam Parand, Sue Dopson, Anna Renz, and Charles Vincent, "The role of hospital managers in quality and patient safety: a systematic review," *British Medical Journal*, 4, no. 9 (September 5, 2014): e005055. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4158193/. (The website was accessed on January 24, 2019.)

[8] Institute for Healthcare Improvement, "How risk management and patient safety intersect: Strategies to help make it happen," March 24, 2015. http://www.npsf.org/blogpost/1158873/211982/How-Risk-Management-and-Patient-Safety-Intersect-Strategies-to-Help-Make-It-Happen. (The website was accessed on January 24, 2019.)

9. High-risk processes (specifically the emergency department and urgent care center operations and management).[9]

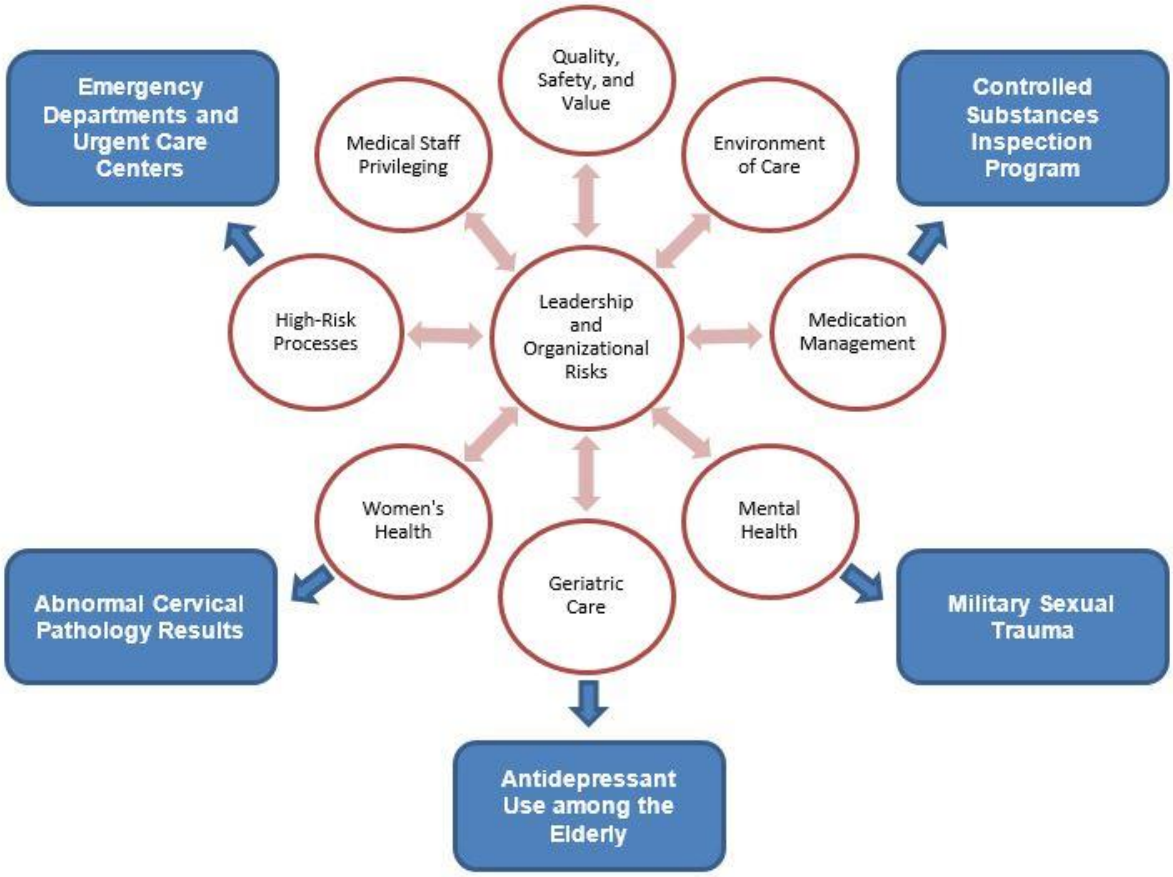

Figure 2. *Fiscal Year (FY) 2019 Comprehensive Healthcare Inspection of Operations and Services*
Source: VA OIG

[9] See Figure 2. CHIP inspections address these processes during FY 2019 (October 1, 2018, through September 30, 2019); they may differ from prior years' focus areas.

Methodology

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports;[10] physically inspected OIG-selected areas; and discussed processes and validated findings with managers and employees. The OIG also interviewed members of the executive leadership team.

The inspection period examined operations from April 25, 2015, through January 18, 2019, the last day of the unannounced week-long site visit.[11] While on site, the OIG did not receive any complaints beyond the scope of the CHIP review.

This report's recommendations for improvement target problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the facility completes corrective actions. The facility director's comments submitted in response to the report recommendations appear within each topic area.

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

[10] The OIG did not review VHA's internal survey results, instead focusing on OIG inspections and external surveys that affect facility accreditation status.

[11] The range represents the time period from the last Combined Assessment Program review, which was performed prior to the comprehensive healthcare inspection, to the completion of the unannounced week-long CHIP site visit.

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare facility. Leadership and organizational risks can impact the facility's ability to provide care in all of the selected clinical areas of focus.[12] To assess the facility's risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation and/or for-cause surveys and oversight inspections
5. Factors related to possible lapses in care
6. VHA performance data

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this facility's reported organizational structure. The facility has a leadership team consisting of the director, acting chief of staff, associate director for Patient Care Services (ADPCS), and the deputy director, associate director (Lake City) and assistant director (all three are primarily nonclinical). The acting chief of staff, ADPCS, deputy director, and associate director oversee patient care, which requires managing service directors and chiefs of programs and practices.

[12] L. Botwinick, M. Bisognano, and C. Haraden, "Leadership Guide to Patient Safety," *Institute for Healthcare Improvement*, Innovation Series White Paper. 2006. www.IHI.org. (The website was accessed on February 2, 2017.)

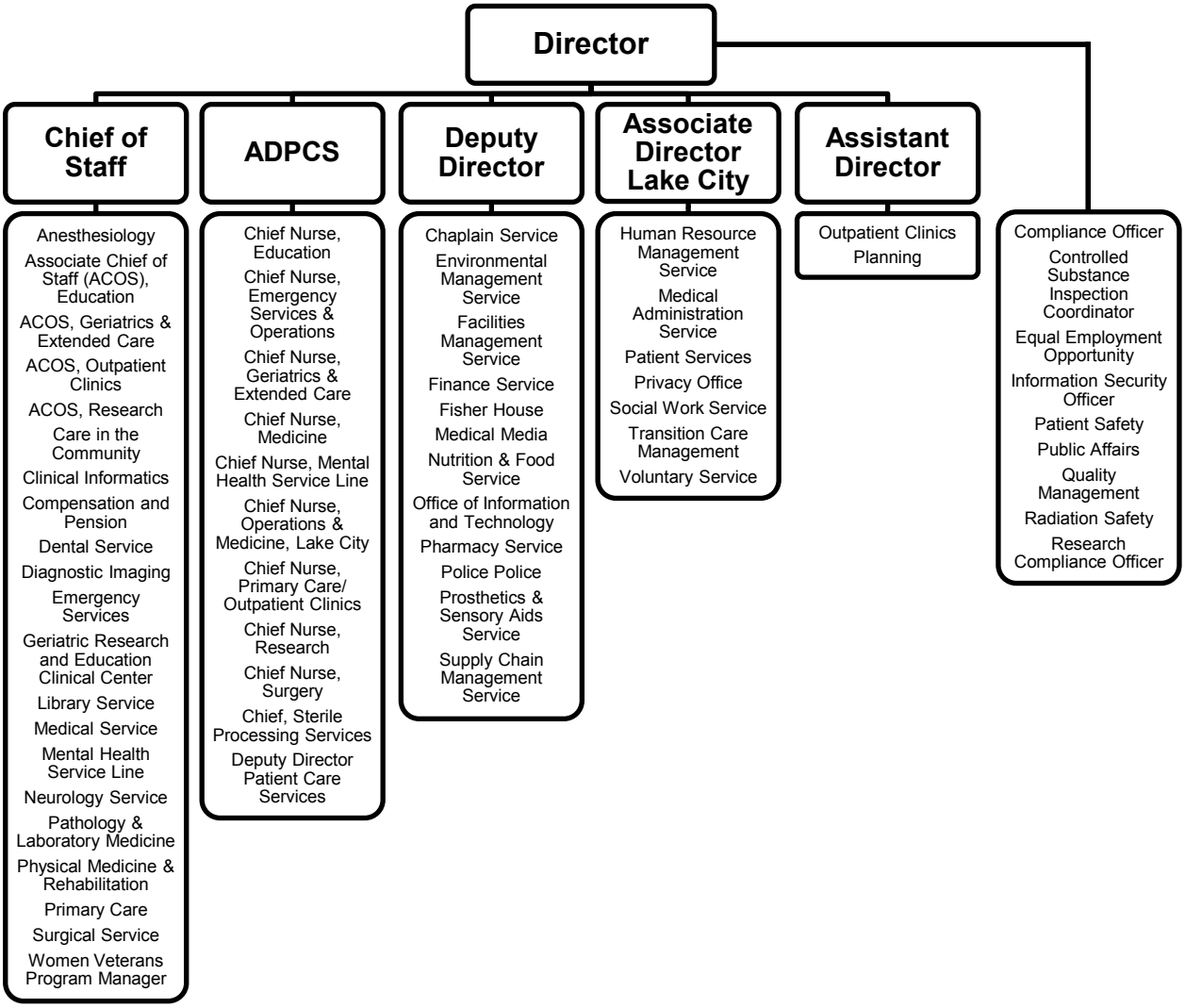

Figure 3. *Facility Organizational Chart*[13]
Source: North Florida/South Georgia Veterans Health System (received January 14, 2019)

At the time of the OIG site visit, the executive team had been working together for almost two months, although several team members have been in their position for many years (see Table 1).

[13] At this facility, the director is responsible for the Compliance Officer, Controlled Substance Inspection Coordinator, Equal Employment Opportunity, Information Security Officer, Patient Safety, Public Affairs, Quality Management, Radiation Safety, and the Research Compliance Officer.

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Facility director	June 2, 2012
Chief of staff	July 27, 2018 (acting)
Associate director for Patient Care Services	November 25, 2018
Deputy director	August 21, 2016
Associate director	November 18, 2012
Assistant director	November 1, 2015

Source: North Florida/South Georgia Veterans Health System human resources officer (received January 15, 2019)

To help assess facility executive leaders' engagement, the OIG interviewed the director, acting chief of staff, ADPCS, deputy director, and associate director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance.

In individual interviews, these executive leadership team members generally were able to speak knowledgeably about actions taken during the previous 12 months to maintain or improve performance, as well as employee and patient survey results. In addition, the executive leaders were generally knowledgeable within their scope of responsibilities about selected Strategic Analytics for Improvement and Learning (SAIL) metrics and community living centers (CLC) measures. These are discussed in greater detail below.

The director serves as the chairperson of the Executive Leadership Council, with the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Executive Leadership Council oversees various working groups, such as the Administrative Executive Committee, Environment of Care Committee, and Medical Executive Committee.

These leaders are also engaged in monitoring patient safety and care through the Quality Executive Council, for which the director and deputy director are co-chairs. The Quality Executive Council is responsible for tracking, identifying trends, and monitoring quality of care and patient outcomes and reports to the Executive Leadership Council. See Figure 4.

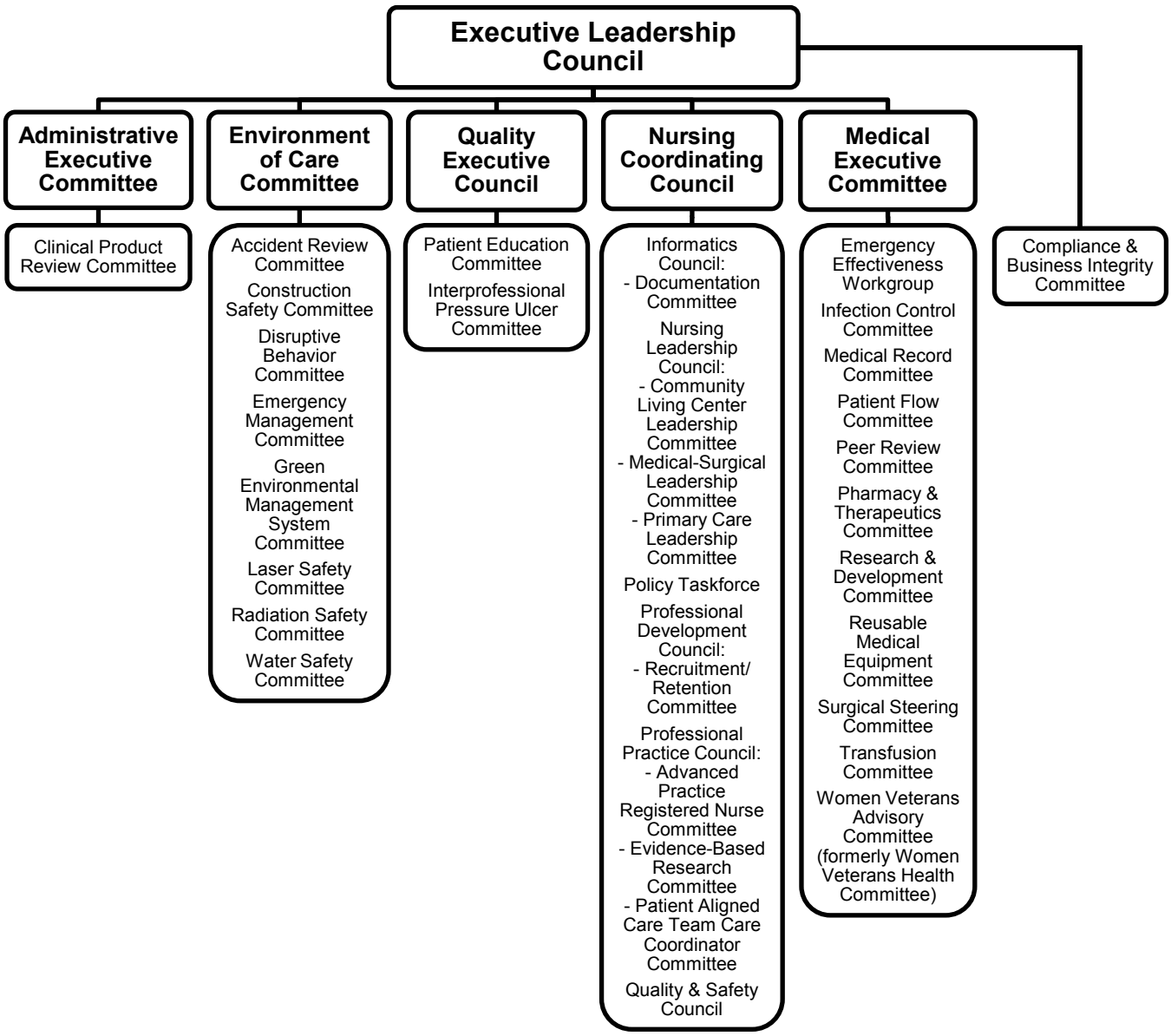

Figure 4. *Facility Committee Reporting Structure*[14]
Source: North Florida/South Georgia Veterans Health System (January 17, 2019)

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential." Since 2001, the instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health. Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point

[14] The Executive Leadership Council directly oversees the Compliance and Business Integrity Committee.

for discussions, indicate areas for further inquiry, and be considered along with other information on facility leadership.

To assess employee attitudes toward facility leaders, the OIG reviewed employee satisfaction survey results that relate to the period of October 1, 2017, through September 30, 2018.[15] Table 2 provides relevant survey results for VHA, the facility, and selected facility executive leaders. It summarizes employee attitudes toward these selected facility leaders as expressed in VHA's All Employee Survey. The OIG found the facility average for the selected survey leadership questions was similar to or lower than the VHA averages.[16] The members of the executive leadership team averages were better than the VHA and facility averages, except for the chief of staff who had lower averages for all survey questions.[17] In all, employees appear generally satisfied with facility leaders.

Table 2. Survey Results on Employee Attitudes toward Facility Leadership (October 1, 2017, through September 30, 2018)

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Deputy Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Servant Leader Index Composite*[18]	0–100 where HIGHER scores are more favorable	71.7	70.4	89.6	95.9	66.4	87.7	86.8	88.0

[15] Ratings are based on responses by employees who report to or are aligned under the director, deputy director, chief of staff, ADPCS, associate director, and assistant director.

[16] The OIG makes no comment on the adequacy of the VHA average for each selected survey element. The VHA average is used for comparison purposes only.

[17] It is important to note that the 2018 Employee Survey results are not reflective of employee satisfaction with the current chief of staff as the position was vacant at the time of the OIG visit and covered by an acting chief of staff since July 27, 2018.

[18] According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, Servant Leader Index "is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others' contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others' needs before their own."

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Deputy Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.3	3.3	4.2	4.8	3.2	3.6	4.3	4.4
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.5	3.5	4.4	4.9	3.4	3.6	4.6	4.8
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.5	4.5	4.9	3.3	4.1	4.3	4.8

Source: VA All Employee Survey (accessed December 17, 2018)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. Note that the facility and executive leadership team averages for the selected survey questions were generally similar to or better than the VHA average. Facility leaders appear to be maintaining an environment where employees feel safe bringing forth issues and concerns.

Table 3. Survey Results on Employee Attitudes toward the Workplace (October 1, 2017, through September 30, 2018)

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Deputy Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.8	4.3	4.8	3.3	3.9	4.7	4.8

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Deputy Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.6	4.1	4.8	3.6	3.8	4.4	4.2
All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?*	0 (Never) – 6 (Every Day)	1.5	1.4	1.2	1.1	1.2	1.5	0.7	1.8

Source: VA All Employee Survey (accessed December 17, 2018)

Patient Experience

To assess patient attitudes toward facility leaders, the OIG reviewed patient experience survey results that relate to the period of October 1, 2017, through August 31, 2018. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experiences of Patients (SHEP) program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides

relevant survey results for facility leadership and compares the results to the overall VHA averages.[19]

VHA collects SHEP survey data from Patient-Centered Medical Home, Specialty Care, and Inpatient Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients' attitudes toward facility leaders (see Table 4). For this facility, three of four patient survey results reflected similar or higher care ratings compared to the VHA average. Patients appeared generally satisfied with the leadership and care provided. Facility leaders also supported programs to improve patients' behavioral and emotional well-being. An example is the patient use of robotic pet therapy. With this therapy program, veterans in a residential setting adopt an interactive dog or cat to experience the positive benefits of pet ownership. The facility has noted a reduction in aggressive behavior and increase in social behavior, leading to successful discharges for patients who participate in the program.

Table 4. Survey Results on Patient Attitudes toward Facility Leadership (October 1, 2017, through August 31, 2018)

Questions	Scoring	VHA Average	Facility Average
Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	66.9	71.2
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.3	84.8
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.2	76.0
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.4	74.4

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed December 17, 2018)

[19] Ratings are based on responses by patients who received care at this facility.

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys, including those conducted for cause, by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[20] Table 5 summarizes the relevant facility inspections most recently performed by the OIG and The Joint Commission (TJC).[21] Indicative of effective leadership, the facility has closed all recommendations for improvement.[22]

In addition, the OIG noted the facility's current accreditation status with the Commission on Accreditation of Rehabilitation Facilities. [23] However, in reviewing the facility's College of American Pathologists (CAP)[24] survey reports, the OIG noted that the Malcom Randall VAMC's Pathology & Laboratory Medicine Service was given probationary accreditation status May 3, 2017. On January 10, 2018, a nonroutine CAP survey was conducted at the facility; and, on March 13, 2018, the CAP accreditation committee removed the probationary accreditation status due to the significant improvement made at the facility. Other survey results included the Long Term Care Institute's inspections of the Malcom Randall VAMC and the Lake City VAMC CLCs.[25]

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[20] The Joint Commission (TJC) conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization.

[21] According to VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017, TJC provides an "internationally accepted external validation that an organization has systems and processes in place to provide safe and quality-oriented health care." TJC "has been accrediting VA medical facilities for over 35 years." Compliance with TJC standards "facilitates risk reduction and performance improvement."

[22] A closed status indicates that the facility has implemented corrective actions and improvements to address findings and recommendations, not by self-certification, but as determined by the accreditation organization or inspecting agency.

[23] According to VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs,* May 9, 2017, the Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term joint collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs.

[24] According to the College of American Pathologists, for 70 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." College of American Pathologists. https://www.cap.org/about-the-cap. (The website was accessed on February 20, 2019.) In accordance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

[25] The Long Term Care Institute states that it has been to over 4,000 healthcare facilities conducting quality reviews and over 1,145 external regulatory surveys since 1999. The Long Term Care Institute is "focused on long-term care quality and performance improvement; compliance program development; and review in long-term care, hospice, and other residential care settings." Long Term Care Institute. http://www.ltciorg.org/about-us/. (The website was accessed on March 6, 2019.)

Although the quality management staff provided the requested accreditation survey information, the OIG noted the survey summary did not include at least two Long Term Care Institute survey reports and discrepancies between the total number of JC recommendations in the official report and the total number reported by the facility. The quality management staff have an opportunity to improve how accreditation survey information is tracked and monitored as part of the facility's continuous survey readiness process.

Table 5. Office of Inspector General Inspections/The Joint Commission Survey

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Combined Assessment Program Review of the North Florida/South Georgia Veterans Health System, Gainesville, Florida, Report No. 15-00601-376, June 25, 2015*)	April 2015	15	0
OIG (*Review of Community Based Outpatient Clinics and Other Outpatient Clinics of North Florida/South Georgia Veterans Health System, Gainesville, Florida, Report No. 15-00143-372, June 11, 2015*)	April 2015	8	0
TJC Hospital Accreditation	August 2016	35	0
TJC Nursing Care Center Accreditation		8	0
TJC Behavioral Health Care Accreditation		0	0
TJC Home Care Accreditation		4	0
TJC For Cause	July 2018	2	0

Sources: OIG and TJC (Inspection/survey results verified with the chief of Quality Management on January 14, 2019)

Factors Related to Possible Lapses in Care

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. The OIG was provided the requested institutional disclosure data; however, upon review, discrepancies were noted. For instance, the initial list of disclosures included seven individual patient events that met criteria for disclosure but did not identify the patient involved; an incorrect social security number was provided for one patient; and the facility did not provide any information for five patient events that were identified by the OIG prior to the site visit. The discrepancies were discussed with the chief of Quality Management who provided an updated list. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. Table 6 lists the reported patient safety events from April 25, 2015 (the prior comprehensive OIG inspection), through January 18, 2019.[26]

[26] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the North Florida/South Georgia Veterans Health System is the highest complexity (1a) affiliated facility as described in Appendix B.)

Table 6. Summary of Selected Organizational Risk Factors (April 25, 2015, through January 18, 2019)

Factor	Number of Occurrences
Sentinel Events[27]	25
Institutional Disclosures[28]	66
Large-Scale Disclosures[29]	0

Source: North Florida/South Georgia Veterans Health System's patient safety manager provided sentinel events data on January 15, 2019, chief of Quality Management provided institutional and large-scale disclosure data on February 4, 2019, and January 14, 2019 respectively

The OIG also reviewed patient safety indicators developed by the Agency for Healthcare Research and Quality within the U.S. Department of Health and Human Services. These provide information on potential in-hospital complications and adverse events following surgeries and procedures.[30] The rates presented are specifically applicable for this facility, and lower rates indicate lower risks. Table 7 summarizes patient safety indicator data from October 1, 2016, through September 30, 2018.

[27] The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

[28] According to VHA Directive 1004.08, *Disclosure of Adverse Events To Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or [his or her] personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."

[29] According to VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018, VHA defines large-scale disclosures of adverse events (sometimes referred to as "notifications") as "a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue."

[30] Agency for Healthcare Research and Quality. https://www.qualityindicators.ahrq.gov/. (The website was accessed on December 11, 2017.)

Table 7. Patient Safety Indicator Data
(October 1, 2016, through September 30, 2018)

Indicators	Reported Rate per 1,000 Hospital Discharges			
	VHA	VISN 8	Malcom Randall	Lake City
Pressure ulcer	0.74	0.60	0.41	0.69
Death among surgical inpatients with serious treatable conditions	113.42	173.25	241.76	200.00
Iatrogenic pneumothorax[31]	0.17	0.18	0.05	0.00
Central venous catheter-related bloodstream infection	0.16	0.30	0.00	0.00
In-hospital fall with hip fracture	0.09	0.06	0.06	0.00
Perioperative hemorrhage or hematoma	2.61	2.93	3.83	0.00
Postoperative acute kidney injury requiring dialysis	0.89	1.00	2.17	0.00
Postoperative respiratory failure	4.54	3.90	4.23	0.00
Perioperative pulmonary embolism or deep vein thrombosis	2.97	3.02	1.53	0.00
Postoperative sepsis	3.55	4.09	5.63	0.00
Postoperative wound dehiscence (rupture along incision)	0.82	0.18	0.00	0.00
Unrecognized abdominopelvic accidental puncture or laceration	1.00	0.97	2.10	0.00

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.

For the facility's Lake City VA VAMC division's FY 2018 quarter 4 results, the patient safety indicator measure for pressure ulcer showed a higher reported rate than VISN 8. The measure for death among surgical inpatients with serious treatable conditions also showed a higher reported rate than VISN 8 and VHA. For the Malcolm Randall VAMC, five patient safety indicator measures (death among surgical inpatients with serious treatable conditions, perioperative hemorrhage or hematoma, postoperative acute kidney injury requiring dialysis, postoperative sepsis, and unrecognized abdominopelvic accidental puncture/laceration) showed a higher reported rate than VISN 8 and/or VHA, and the postoperative respiratory rate reported higher than VISN 8.

[31] According to Northwestern Memorial Hospital, "A Pneumothorax is a type of lung injury that allows air to leak into the area between the lungs and the chest wall, which causes mild to severe chest pain and shortness of breath. An Iatrogenic Pneumothorax is one which was caused by medical treatment, often as an incidental event during a procedure such as a pacemaker insertion." Northwestern Medicine. http://www.nmh.org/nm/quality-lung-injury-due-to-medical-care. (The website was accessed on March 6, 2019.)

The OIG also reviewed patient safety indicator data for FY 2018, quarter 4 (the most recent data) and the previous four quarters to identify any potential trends that may impact patient safety or increase the risk for patient harm. It is important to note that although the data are collected and reported by quarter, each set of quarterly data represents potential complications or patient safety events over an eight-quarter or two-year period. Further, it is possible for a facility measure to exceed the VHA rate due to a single incident and for that measure to vary above or below the VHA rate over time due to differences in the number of patients treated. Figure 5 illustrates the time frames covered by the data reviewed.

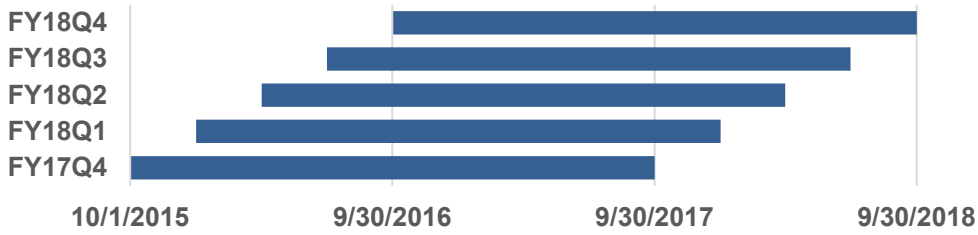

Figure 5. *Associated Time Frames for Quarterly Patient Safety Indicator Data*
Source: VA OIG
FY18Q4 = fiscal year 2018, quarter 4
FY18Q3 = fiscal year 2018, quarter 3
FY18Q2 = fiscal year 2018, quarter 2
FY18Q1 = fiscal year 2018, quarter 1
FY17Q4 = fiscal year 2017, quarter 4

Table 8 summarizes patient safety indicator data for FY 2017, quarter 4 (FY17Q4) through FY 2018, quarter 4 (FY18Q4), which includes potential complications from October 1, 2015, through September 30, 2018.

Table 8. Patient Safety Indicator Data Trending October 1, 2015, through September 30, 2018)

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Pressure ulcer	VHA	0.60	0.88	–[32]	0.76	0.74
	Malcom Randall	0.44	0.85	–	0.49	0.41
	Lake City	0.83	0.62	–	0.73	0.69

[32] According to VHA's Inpatient Evaluation Center, pressure ulcer data are not available for the time frame of April 1, 2016, through March 31, 2018.

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Death among surgical inpatients with serious treatable conditions	VHA	100.97	118.96	113.92	114.89	113.42
	Malcom Randall	175.82	207.92	213.48	228.26	241.76
	Lake City	n/a	333.33	333.33	200.00	200.00
Iatrogenic pneumothorax	VHA	0.19	0.19	0.17	0.15	0.17
	Malcom Randall	0.05	0.05	0.00	0.05	0.05
	Lake City	0.00	0.00	0.00	0.00	0.00
Central venous catheter-related bloodstream infection	VHA	0.15	0.14	0.15	0.16	0.16
	Malcom Randall	0.09	0.08	0.09	0.09	0.00
	Lake City	0.00	0.00	0.00	0.00	0.00
In-hospital fall with hip fracture	VHA	0.08	0.09	0.08	0.09	0.09
	Malcom Randall	0.19	0.15	0.17	0.18	0.06
	Lake City	0.00	0.00	0.00	0.00	0.00
Perioperative hemorrhage or hematoma	VHA	1.94	2.58	2.62	2.59	2.61
	Malcom Randall	2.86	3.75	3.69	4.31	3.83
	Lake City	n/a	0.00	0.00	0.00	0.00
Postoperative acute kidney injury requiring dialysis	VHA	0.88	0.80	0.65	0.96	0.89
	Malcom Randall	1.07	0.96	1.10	2.19	2.17
	Lake City	n/a	0.00	0.00	0.00	0.00
Postoperative respiratory failure	VHA	5.55	5.34	5.11	4.88	4.54
	Malcom Randall	3.70	3.25	1.60	4.26	4.23
	Lake City	n/a	0.00	0.00	0.00	0.00
Perioperative pulmonary embolism or deep vein thrombosis	VHA	3.29	3.26	3.09	3.05	2.97
	Malcom Randall	0.86	1.15	1.11	0.88	1.53
	Lake City	n/a	0.00	0.00	0.00	0.00
Postoperative sepsis	VHA	4.00	3.96	3.72	3.70	3.55
	Malcom Randall	4.49	4.00	4.20	5.32	5.63
	Lake City	n/a	0.00	0.00	0.00	0.00
Postoperative wound dehiscence (rupture along incision)	VHA	0.52	1.04	1.00	0.93	0.82
	Malcom Randall	1.11	1.42	0.82	0.81	0.00
	Lake City	0.00	0.00	0.00	0.00	0.00

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Unrecognized abdominopelvic accidental puncture or laceration	VHA	0.53	1.21	1.02	1.07	1.00
	Malcom Randall	0.82	1.84	1.42	1.73	2.10
	Lake City	0.00	0.00	0.00	0.00	0.00

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.
n/a = not applicable

Five measures (death among surgical inpatients with serious treatable conditions, perioperative hemorrhage or hematoma, postoperative acute kidney injury requiring dialysis, postoperative sepsis and unrecognized abdominopelvic accidental puncture or laceration) are higher than the VHA averages for all quarters reviewed. Of note, Lake City VAMC had six measures (death among surgical inpatients with serious treatable conditions, perioperative hemorrhage or hematoma, postoperative acute kidney injury requiring dialysis, postoperative respiratory failure, perioperative pulmonary embolism or deep vein thrombosis, and postoperative sepsis) that were not applicable to the facility in FY 2017 quarter 4.

Twenty-two deaths at Malcom Randall VAMC and one death at Lake City VAMC resulted in the most recently reported rates for death among surgical inpatients with serious treatable conditions. The Malcom Randall VAMC reported rates were higher than VHA for all five quarters and showed an apparent upward trend. Nine events occurred in the last FY with one death in the first quarter, two deaths in the second and fourth quarters, and four in the third quarter of FY 2018.

All cases were individually reviewed by the quality management specialist and a clinician from the associated treating service. The cases were then reviewed during the system inpatient Morbidity and Mortality Workgroup meeting. The facility noted that a procedure (bronchial brushing and washing) was not documented appropriately, causing patients from both medical centers to be incorrectly included in this metric. A standardized history and physical template was implemented to improve documentation and patient risk factors prior to procedures, and the facility has not had a patient meet this criteria since October 2018.

For FY 2018 quarter 4, the reported rate for perioperative hemorrhage or hematoma was based on 17 patients. In FY 2018, there were two new patients in the first, second, and fourth quarters and four in the third quarter of FY 2018. All events were individually reviewed by the quality management specialist and a clinician from the associated treating service. In addition, all cases were reviewed at the system inpatient Mortality and Morbidity Workgroup meeting where no trends were identified.

Although the OIG noted a trend above VHA average in FY 2017 quarter 4 through FY 2018 quarter 3 for patients who experienced a hip fracture after a fall, this was due to falls prior to FY 2018.

Six patients met criteria for inclusion in the postoperative acute kidney injury requiring dialysis measure for FY 2018 quarter 4. The OIG noted an upward trend that was largely due to events reported during FY 2017 quarter 4 and FY 2018 quarter 1 and that there was only one additional patient identified in FY 2018 quarter 3. All individual cases were reviewed by the quality management specialist and a clinician from the associated service. The cases were also reviewed as an aggregate at the monthly Surgical morbidity and mortality meeting and the system inpatient Morbidity and Mortality Workgroup meetings. An opportunity for improvement was identified, and the facility changed the type of intravenous (IV) fluid that will be used to treat these types of cases.

Eight patient events resulted in the most recently reported rates for postoperative respiratory failure, with five events occurring in quarter 3 of FY 2018. The quality management specialist and a clinician from the associated service reviewed each case individually. The cases were then reviewed at the system inpatient Morbidity and Mortality Workgroup meeting. Because of the reviews, the facility formed an Aspiration Precaution Workgroup and developed compliance monitoring audits. Facility-wide nursing education on risk identification and protocol implementation was also conducted.

For FY 2018, quarter 4, the reported rate for postoperative sepsis was based on 15 patients. For FY 2018, there were six new patients—one in quarters 2 and 4 and four in quarter 3. All cases were individually reviewed by the quality management specialist and a clinician from the associated treating service. The cases were also reviewed a at the system inpatient Morbidity and Mortality Workgroup meeting and the Sepsis Review Committee. Facility actions included implementation of a sepsis alert initiative with a targeted focus on improved bedside identification. The facility also implemented modified early warning (MEW) scores and expedited delivery of targeted antibiotics.

Six patients met criteria for inclusion in the unrecognized abdominopelvic accidental puncture/laceration measure for FY 2018 quarter 4—five of the six events occurred in FY 2018, with one patient in first, third, and fourth quarters and two in the second quarter. All cases were individually reviewed by the quality management specialist and a clinician from the associated treating service. The system inpatient Morbidity and Mortality Workgroup also reviewed the cases and identified a single provider who received additional training with the daVinci robot.[33]

[33] The daVinci robot is a robotic-assisted surgical system used by surgeons to perform complex surgical procedures that are less invasive with precision and accuracy, https://uchealth.com/services/robotic-surgery/patient-information/davinci-surgical-system/. (The website accessed on April 8, 2019.)

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adapted the SAIL Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[34]

VA also uses a star-rating system where facilities with a "5-star" rating are performing within the top 10 percent of facilities and "1-star" facilities are performing within the bottom 10 percent of facilities. Figure 6 describes the distribution of facilities by star rating.[35] As of June 30, 2018, the facility was rated as "3-star" for overall quality.

[34] VHA Support Service Center (VSSC), The Strategic Analytics for Improvement and Learning (SAIL) Value Model, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 7, 2019 but is not accessible by the public.)

[35] According to the methods established by the SAIL Model, this is based on normal distribution ranking of the quality domain for 130 VA Medical Centers.

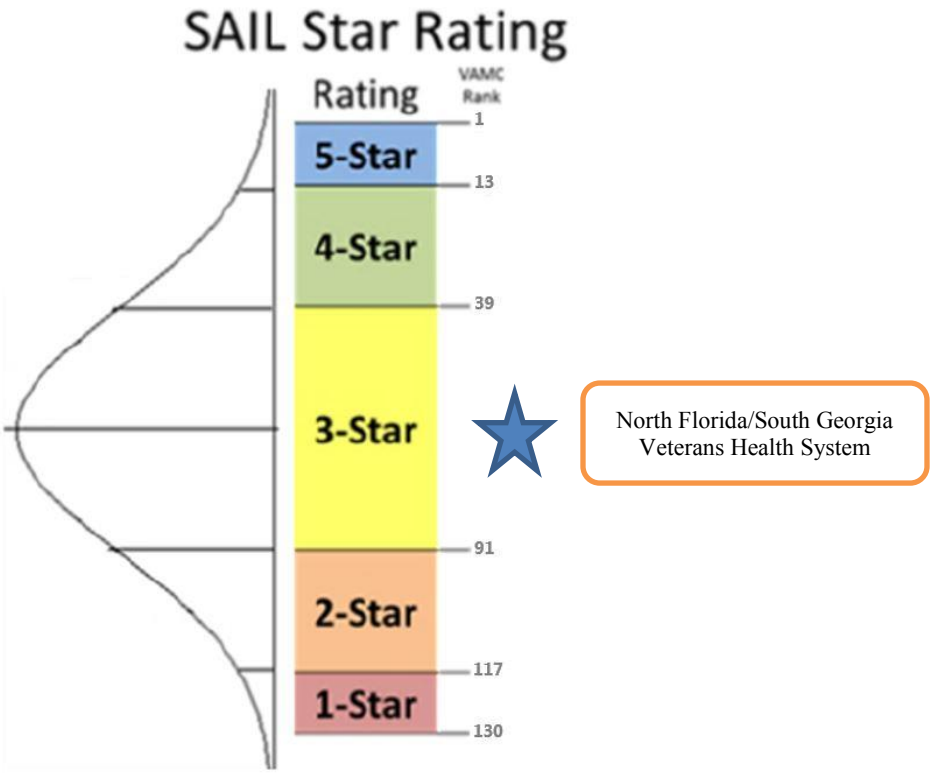

Figure 6. *Strategic Analytics for Improvement and Learning Star Rating Distribution (as of June 30, 2018)*
Source: VA Office of Informatics and Analytics Office of Operational Analytics and Reporting (accessed December 17, 2018)

Figure 7 illustrates the facility's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2018. Of note, the figure uses blue and green data points to indicate high performance (for example, in the areas of complications, health care (HC) associated infections, and adjusted length of stay (LOS). Metrics that need improvement are denoted in orange and red (for example, best place to work, call responsiveness, and admit reviews met).[36]

[36] For information on the acronyms in the SAIL metrics, please see Appendix D.

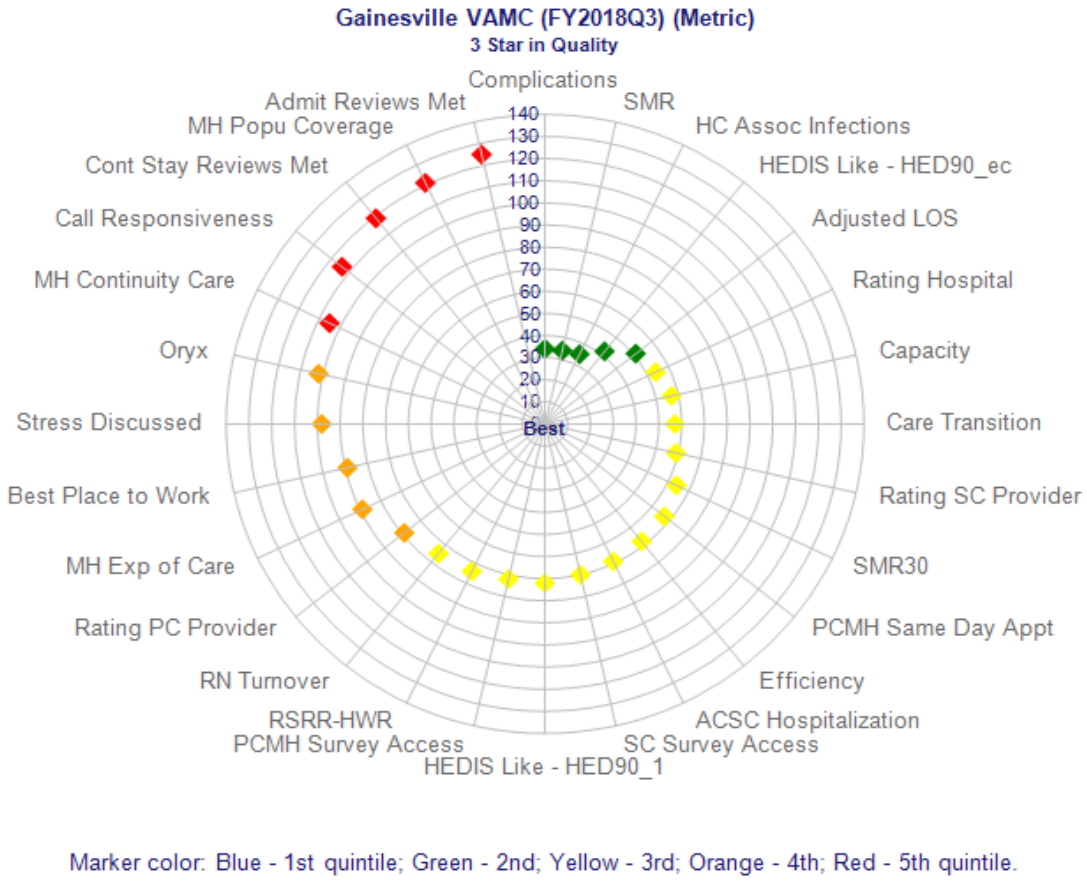

Figure 7. *Facility Quality of Care and Efficiency Metric Rankings (as of June 30, 2018)*
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. Also see Appendix C for sample outpatient performance measures that feed into these data points (such as wait times, discharge contacts, and where patient care is received). Data definitions are provided in Appendix D.

The SAIL Value Model also includes "SAIL CLC," which is a tool to summarize and compare the performance of CLCs in the VA. The SAIL model leverages much of the same data used in The Centers for Medicare & Medicaid Services' (CMS) *Nursing Home Compare*.[37] The SAIL CLC provides a single resource to review quality measures and health inspection results. It

[37] According to the Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, November 19, 2018, "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

includes star ratings for an unannounced survey, staffing, quality, and overall results.[38] Tables 9 and 10 summarize the rating results for the Malcom Randall and Lake City VAMC CLCs as of September 30, 2018. Although the Malcom Randall VAMC's CLC has an overall "5-star" rating, its rating for quality is "2-star." Further, the Lake City VAMC's CLC has an overall "2-star" rating, while its quality rating is "1-star."

Table 9. Malcom Randall VA Medical Center CLC Star Ratings (as of September 30, 2018)

Domain	Star Rating
Unannounced Survey	4
Staffing	5
Quality	2
Overall	5

Source: VHA Support Service Center

Table 10. Lake City VA Medical Center CLC Star Ratings (as of September 30, 2018)

Domain	Star Rating
Unannounced Survey	2
Staffing	5
Quality	1
Overall	2

Source: VHA Support Service Center

In exploring the reasons for the "2-star" quality rating for the Malcom Randall VAMC and the "1-star" quality rating for the Lake City VAMC CLCs, the OIG considered the radar diagram showing CLC performance relative to other CLCs for all 13 quality measures. Figures 8 and 9 illustrate the facility's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2018. Figure 8 uses blue and green data points and Figure 9 has blue data points to indicate high performance (for example, in the areas of physical restraints long-stay (LS) and newly received antipsychotic medications short-stay (SS) at Malcom Randall VA Medical Center, and physical restraints (LS) at Lake City VA Medical Center. Metrics that need improvement and were likely contributing reasons for the quality star rating are denoted in

[38] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated November 19, 2018). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on March 6, 2019, but is not accessible by the public.)

orange and red (for example, falls with major injury (LS) at the Malcom Randall VA Medical Center and receive antipsychotic medications long stay (LS) at Lake City VA Medical Center).[39]

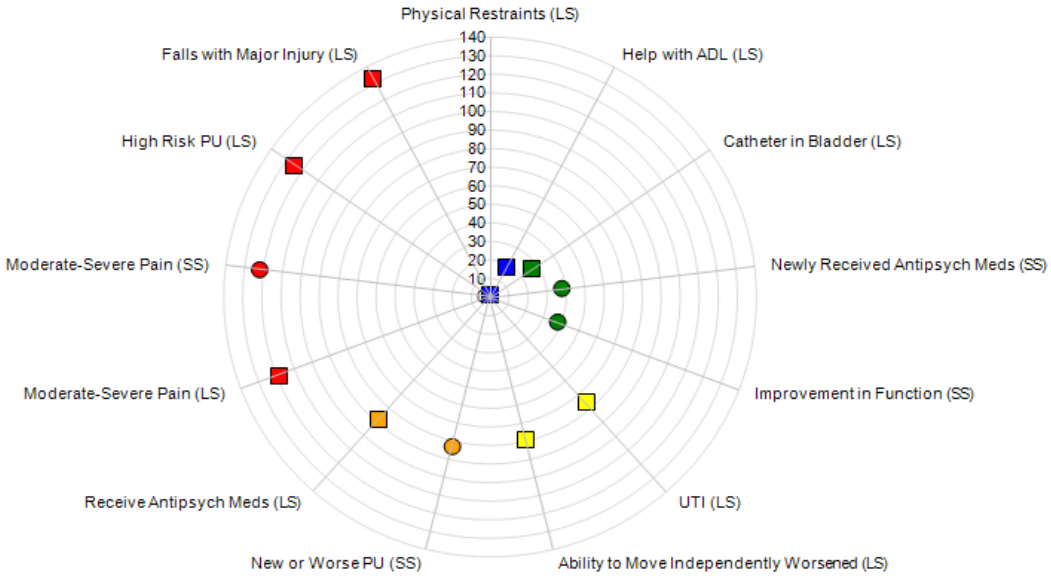

Figure 8. *Malcom Randall VA Medical Center CLC Quality Measure Rankings (as September 30, 2018)*
LS = Long-Stay Measure SS = Short-Stay Measure
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix E.

[39] For data definitions of acronyms in the SAIL CLC measures, please see Appendix E.

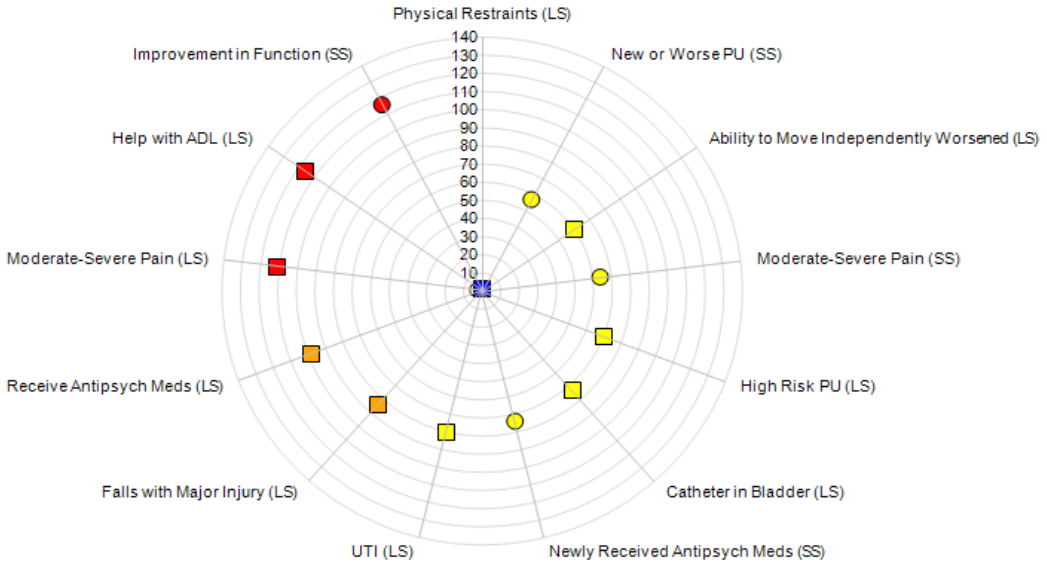

Figure 9. *Lake City VA Medical Center CLC Quality Measure Rankings (as September 30, 2018)*
LS = Long-Stay Measure SS = Short-Stay Measure
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix E.

Leadership and Organizational Risks Conclusion

The facility's executive leadership team appeared relatively stable, with four of the six positions permanently filled for over one year prior to the OIG's on-site visit. Selected survey scores related to employee satisfaction and trust in the facility's executive leaders were generally similar to or higher than VHA averages with the exception of the chief of staff. In review of patient experience survey data, three of the four survey scores were similar to or above VHA averages. Facility leaders were engaged with employees and patients while actively working to sustain and further improve employee and patient engagement and satisfaction. Organizational leaders appeared to support efforts related to patient safety, quality care, and other positive outcomes (such as implementing processes to improve quality care and initiating plans to maintain positive perceptions of the facility through active stakeholder engagement). However, the presence of organizational risk factors identified in this report, as evidenced by missing institutional disclosure information, conflicting survey report information, and the patient safety indicator data may contribute to future issues of noncompliance and/or lapses in patient safety unless corrective processes are implemented and continuously monitored. The leadership team was knowledgeable about selected SAIL metrics but should continue to take actions to improve care and performance of selected quality of care metrics that are likely contributing to the SAIL "3-star," the Malcom Randall VAMC CLC "2-star," and the Lake City VAMC CLC "1-star" quality ratings.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care that involves coordinating care among members of the healthcare team. To meet this goal, VHA must foster a culture of integrity and accountability in which personnel are vigilant and mindful, proactively risk-aware, and committed to consistently providing quality care, while seeking continuous improvement.[40] VHA also strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.[41] VHA requires that its facilities operate a quality, safety, and value (QSV) program to monitor the quality of patient care and performance improvement activities.[42]

In determining whether the facility implemented and incorporated several OIG-selected key functions of VHA's Enterprise Framework for QSV into local activities, the inspection team evaluated protected peer reviews of clinical care,[43] utilization management (UM) reviews,[44] patient safety incident reporting with related root cause analyses,[45] and cardiopulmonary resuscitation (CPR) episode reviews.[46]

When conducted systematically and credibly, protected peer reviews reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and

[40] VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. (This VHA directive was scheduled for recertification on or before the last working day of August 2018 and has not been recertified.)

[41] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

[42] VHA Directive 1026.

[43] The definition of a peer review can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a critical review of care, performed by a peer, to evaluate care provided by a clinician for a specific episode of care, to identify learning opportunities for improvement, to provide confidential communication of the results back to the clinician, and to identify potential system or process improvements.

[44] According to VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018), UM reviews include evaluating the "appropriateness, medical need, and efficiency of health care services according to evidence-based criteria." This directive was in effect at the time of the review but was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019); this directive expired on July 31, 2019.

[45] The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. (This VHA Handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.) A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

[46] VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.

nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[47]

The UM program, a key component of VHA's framework for quality, safety, and value, provides vital tools for managing the quality and the efficient use of resources. It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[48]

Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the facility.[49]

VHA has also issued guidance to support its strategic priority of providing personalized, proactive, patient-driven care and to ensure that the provision of life-sustaining treatments, including CPR, is aligned with patients' values, goals, and preferences. VHA requires that each facility establishes a CPR Committee or equivalent that fully reviews each episode of care in which resuscitation was attempted. The ongoing review and analysis of high-risk healthcare processes is essential for ensuring patient safety and the provision of high-quality care. VHA also has established requirements for basic life support and advanced cardiac life support training and certification for clinicians responsible for administering life-sustaining treatments.[50]

The OIG interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents. Specifically, OIG inspectors evaluated the following performance indicators:[51]

- Protected peer reviews
    - Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
    - Implementation of improvement actions recommended by the Peer Review Committee
    - Completion of final reviews within 120 calendar days

[47] VHA Directive 1190.

[48] VHA Directive 1117(1).

[49] VHA Handbook 1050.01.

[50] VHA Directive 1177, VHA Handbook 1004.03, *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017.

[51] For CHIP reviews, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

  - Quarterly review of Peer Review Committee's summary analysis by the Medical Executive Committee
  - Peer review of all applicable deaths within 24 hours of admission to the hospital
  - Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[52]
- UM
  - Completion of at least 75 percent of all required inpatient reviews
  - Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database
  - Interdisciplinary review of UM data
- Patient safety
  - Annual completion of a minimum of eight root cause analyses[53]
  - Inclusion of required content in root cause analyses (generally)
  - Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
  - Provision of feedback about root cause analysis actions to reporting employees
  - Submission of annual patient safety report to facility leaders
- Resuscitation episode review
  - Evidence of a committee responsible for reviewing resuscitation episodes
  - Confirmation of actions taken during resuscitative events being consistent with patients' wishes
  - Evidence of basic or advanced cardiac life support certification for code team responders
  - Evaluation of each resuscitation episode by the CPR Committee or equivalent

[52] VHA Directive 1190.

[53] According to VHA Handbook 1050.01, "the requirement for a total of eight [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of [root cause analyses] is driven by the events that occur and the [Safety Assessment Code] SAC score assigned to them. At least four analysis per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses]."

Quality, Safety, Value Conclusion

The OIG found general compliance with requirements for protected peer reviews and patient safety; however, the OIG identified concerns with the lack of evidence of Advanced Cardiac Life Support or Basic Life Support certification for 1 of 10 physician code leaders—a resident physician[54] who functioned as the leader—and scanning of all 10 resuscitation records reviewed (see Incidental Finding on page 74). Additionally, the OIG noted noncompliance with the facility's interdisciplinary review of UM data, root cause analyses (RCAs), and committee review of all resuscitation episodes that warranted recommendations for improvement.

Specifically, VHA requires interdisciplinary review of UM data. This process must include but not be limited to representatives from UM, medicine, nursing, social work, case management, mental health, and chief Business Office revenue utilization review.[55] From January 2018 through October 2018, the Patient Flow Committee that reviews UM data lacked representation from mental health and the chief Business Office revenue utilization review. As a result, the Patient Flow Committee performed reviews and analyses of UM data without the perspectives of key mental health and utilization review colleagues. The committee chair had not reviewed the VHA directive in detail prior to October 2018 when the facility started an annual review of all policies. Facility managers stated the reason for noncompliance as the lack of knowledge of VHA policy.

Recommendation 1

1. The chief of staff ensures all required representatives participate in the interdisciplinary review of utilization management data and monitors representatives' compliance.

[54] VHA Directive 1400.01, *Resident Supervision*, December 19, 2012, defines resident as "an individual who is engaged in an accredited graduate training program for physicians, dentists, optometrists, and podiatrists, and who participates in patient care under the direction of supervising practitioners." This VHA Handbook was scheduled for recertification on or before the last working day of December 2017 and has not been renewed

[55] VHA Directive 1117(1).

Facility concurred.

Target date for completion: April 30, 2020

Facility response: The Chair, Patient Flow Committee is responsible to ensure all required members are invited/notified to all meetings.

System mental health leadership and VISN Chief Business Office Revenue Utilization were reminded by the Chair, Patient Flow Committee of attendance requirements. For the past two quarters, a Mental Health representative has attended each meeting. Discussion was held with the Facility Revenue Manager regarding committee attendance requirements. A VISN Chief Business Office Revenue Utilization representative has attended three out of the last six months, VISN Consolidated Patient Account Center management was notified when not in attendance.

Chair, Patient Flow Committee will report attendance issues to the Medical Executive Committee monthly. Target compliance rate of 90% for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% then a new action plan will be developed, and reporting will resume monthly until target of 90% compliance is reached.

The Chief, Quality Management Service will monitor monthly reports from the Patient Flow Committee at the Medical Executive Committee.

To ensure credibility, VHA requires root cause analysis to include several factors, such as participation by leadership, "analysis of the underlying systems through a series of 'why' questions to determine where redesigns might reduce risk," exclusion of individuals involved in the event under review, consideration of relevant literature, and identification of at least one root cause with a corresponding action and outcome measure.[56] Of the five individual root cause analyses reviewed, the OIG found that three did not include a review of the underlying systems through a series of "why" questions, and two did not include a literature review. This resulted in insufficient evaluation of patient safety events and limited the analysis of system vulnerabilities that may lead to patient harm. The patient safety manager believed the series of "why" questions were evident in the root cause statement and stated that literature reviews are not always completed if the RCA involves standards and policies that are unique to VHA.

Recommendation 2

2. The facility director makes certain that the patient safety manager or designee includes all required components in each root cause analysis and monitors patient safety manager's compliance.

[56] VHA Handbook 1050.01.

Facility concurred.

Target date for completion: August 31, 2019

Facility response: The Patient Safety Coordinator is responsible to ensure all components required in a root cause analysis are complete.

On February 2, 2019, an in-service was conducted by the Patient Safety Coordinator with all Patient Safety Managers. The in-service included a tab-by-tab review of the Patient Safety database and discussed approaches for standardization. A Standard Operating Procedure was developed and implemented on February 6, 2019. Six Root Cause Analyses have been completed for two quarters (February – July 2019) and have included all required components to include a review of the underlying systems through a series of "why" questions, and literature reviews.

All Root Cause Analyses now require Patient Safety Coordinator approval to ensure all components are completed prior to finalization.

The Director will monitor monthly Patient Safety reports at the Quality Executive Council.

For resuscitation episode reviews, VHA requires that the facility establish a committee for reviewing each resuscitative episode under the facility's responsibility.[57] The OIG reviewed 10 resuscitation episodes and found no evidence of committee review. This likely resulted in missed opportunities for the identification of errors or deficiencies in technique or procedures; availability or malfunction of equipment; and clinical issues or patient care issues, such as failure to rescue, that can contribute to the occurrence of a cardiopulmonary event. Although the Emergency Effectiveness Workgroup, which reports through the Medical Executive Committee, reviews resuscitative episodes; there was no documentation to support the reviews or evidence of committee evaluation. The medical co-chair of the Emergency Effectiveness Workgroup stated a lack of awareness of the requirement as reason for noncompliance.

Recommendation 3

3. The facility director ensures that the identified committee reviews all resuscitative episodes and monitors the committee's compliance.

[57] VHA Directive 1177(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: Chair, Emergency Effectiveness Workgroup is responsible to ensure all resuscitative episodes are monitored at the committee and documented appropriately in the minutes.

A new co-chair of the Emergency Effectiveness Workgroup was appointed March 2019. Episodes were being reviewed by committee but not documented in minutes. The agenda was revised and implemented at August 27, 2019 meeting. The revised format ensures appropriate documentation of all events to include tracking, trending and opportunities for improvement.

Target compliance rate of 100% of episodes are reviewed and documented in minutes for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Chief, Quality Management Service or designee will monitor monthly Emergency Effectiveness Workgroup minutes. Quarterly data will be presented to the Medical Executive Committee.

Medical Staff Privileging

VHA has defined procedures for the clinical privileging of all healthcare professionals who are permitted by law and the facility to practice independently—"without supervision or direction, within the scope of the individual's license, and in accordance with individually granted clinical privileges." These healthcare professionals are also referred to as licensed independent practitioners (LIPs).[58]

Clinical privileges need to be specific, based on the individual's clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo re-privileging prior to their expiration.[59]

VHA defines the Focused Professional Practice Evaluation (FPPE) as "a time-limited period during which the medical staff leadership evaluates and determines the practitioners' professional performance. The FPPE typically occurs at the time of initial appointment to the medical staff or the granting of new, additional privileges." "The on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation[s] (OPPE), [are] essential to confirm the quality of care delivered."[60]

According to TJC, the "FPPE for Cause" should be used when a question arises regarding a privileged provider's ability to deliver safe, high-quality patient care. The "FPPE for Cause" is limited to a particular time frame and customized to the specific provider and related clinical concerns.[61] Federal law requires VA facilities to report to the National Practitioner Data Bank when facilities take adverse clinical privileging actions, accept the surrender of clinical privileges, or restrict clinical privileges when the action is related to professional competence or professional conduct of LIPs.[62]

To determine whether the facility complied with requirements for privileging, the OIG interviewed key managers and selected and reviewed the privileging folders of several medical staff members:

[58] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (This VHA Handbook was scheduled for recertification on or before the last working date of October 2017 and has not been recertified.)

[59] VHA Handbook 1100.19.

[60] VHA Handbook 1100.19.

[61] Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2).

[62] VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. (This VHA Handbook was scheduled for recertification on or before the last working date of December 2014 and has not been recertified.)

- Five solo or few practitioners (less than two in a specialty) hired within 18 months before the site visit or were privileged within the prior 12 months[63]
- Eleven LIPs hired within 18 months before the site visit
- Nineteen LIPs re-privileged within 12 months before the visit
- One provider who underwent a FPPE for Cause within 12 months prior to the visit

The OIG evaluated the following performance indicators:

- Privileging
  - Privileges requested by the provider
    - Facility-specific
    - Service-specific
    - Provider-specific[64]
  - Approval of privileges for a period of less than, or equal to, two years
- Focused professional practice evaluations
  - Criteria defined in advance
  - Use of required criteria in FPPEs for selected specialty LIPs
  - Results and time frames clearly documented
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's consideration of FPPE results in its decision to recommend continuing the initially granted privileges
- Ongoing professional practice evaluations
  - Criteria specific to the service or section
  - Use of required criteria in OPPEs for selected specialty LIPs

[63] The 18-month period was from August 11, 2017, through January 11, 2019. The 12-month review period covered January 11, 2018, through January 11, 2019; VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers "few practitioners" as being fewer than three providers in the facility that are privileged in a particular specialty.

[64] According to VHA Handbook 1100.19, facility-specific means that privileges are granted only for procedures and types of services performed at the facility; service-specific refers to privileges being granted in a specific clinical service, such as neurology; and provider-specific means that the privileges should be granted to the individual provider based on their clinical competence and capabilities.

  - Service chief's determination to recommend continuation of current privileges was based in part on the results of OPPE activities
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's decision to recommend continuing privileges based on OPPE results
- Focused professional practice evaluations for cause
  - Clearly defined expectations/outcomes
  - Time-limited
  - Provider's ability to practice independently not limited for more than 30 days
  - Shared with the provider in advance
- Reporting of privileging actions to National Practitioner Data Bank

Medical Staff Privileging Conclusion

The OIG found general compliance with requirements for credentialing and privileging. However, the OIG identified noncompliance with defining FPPE criteria in advance, establishing OPPE criteria specific to the service/section, and the using OPPE results in the service chief's determination to recommend continuance of current privileges that warranted recommendations for improvement.

Specifically, VHA requires the "criteria for the FPPE process to be defined in advance, using objective criteria accepted by the practitioner."[65] In 3 of 11 licensed independent practitioner profiles reviewed, the OIG noted lack of evidence that the FPPE process was defined in advance with the providers. This could potentially result in unclear and ill-defined expectations for the medical staff leaders performing the evaluation as well as the providers who are being evaluated. Facility managers reported that two credentialing staff members were on extended sick leave without any cross coverage, which resulted in lack of oversight of the FPPE process.

Recommendation 4

4. The chief of staff ensures that clinical managers clearly define focused professional practice evaluation criteria in advance with providers and monitors clinical managers' compliance.

[65] VHA Handbook 1100.19.

Facility concurred.

Target date for completion: May 30, 2020

Facility response: Clinical Service Chiefs are responsible for defining service specific FPPE criteria to be communicated/accepted by the practitioner prior to appointment.

The Clinical Service Chiefs will collaborate with providers and define new service/section specific FPPE criteria. Administrative Officers for each section will send the FPPE forms with an acknowledgement of receipt form to on-boarding providers. Receipt of review and acknowledgement signed form is required prior to firm offer being made.

The Chief of Staff's office will review 90% of FPPE forms for service/section specific criteria and acknowledgement by provider monthly for six months to ensure sustainability. Target compliance rate of 90% for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% then a new action plan will be developed, and reporting will resume monthly until target of 90% compliance is reached.

The Chief of Staff will monitor monthly reports at the Medical Executive Committee.

Additionally, VHA requires at the time of reprivileging that each service chief establishes criteria for clinical privileges consistent with the needs of the service and the facility as well as the available resources to provide these services. Clinical privileges must be based on evidence of an individual's current competence.[66]

For 8 of 19 provider profiles used to support the renewal of practitioners' privileges, the OIG found that OPPE criteria were not specific to the service/section. This impacts the ability to thoroughly evaluate the quality of the care delivered by providers. The deputy chief of staff reported there were two credentialing staff on extended sick leave, with no cross coverage in their absence, which contributed to a lack of oversight for the OPPE process.

Recommendation 5

5. The chief of staff confirms that clinical managers include service/section-specific criteria in ongoing professional practice evaluations and monitors compliance.

[66] VHA Handbook 1100.19.

Facility concurred.

Target date for completion: April 30, 2020

Facility response: Clinical Service Chiefs are responsible for establishing service/section specific OPPE criteria.

The Clinical Service Chiefs will collaborate with providers and define service/section specific OPPE criteria.

The Chief of Staff's office will review 90% of submitted OPPE forms monthly for inclusion of service/section specific OPPE for six months to ensure sustainability. Target compliance rate of 90% for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% then a new action plan will be developed, and reporting will resume monthly until target of 90% compliance is reached.

The Chief of Staff will monitor monthly reports at the Medical Executive Committee.

VHA requires that the service chief's determination to continue licensed independent practitioners' current privileges should be based in part on results of OPPE activities, such as electronic health record reviews, outcome data, and direct observation.[67] For 8 of 19 LIP profiles, the OIG noted a lack of evidence that the service chiefs' determinations to continue privileges were based on results of OPPE activities. This impacts the facility's ability to identify professional practice trends that impact the quality of the care and patient safety. The facility's clinical managers stated that a VISN 8 annual quality management review conducted in August 2018 identified opportunities to improve the OPPE process and presented the action plan to the OIG team. The deputy chief of staff reported there were two credentialing staff on extended sick leave, without cross coverage in their absence, which contributed to the lack of oversight of the OPPE process.

Recommendation 6

6. The chief of staff makes certain that service chiefs' determination to recommend continuation of privileges be based in part on results of ongoing professional practice activities and monitors service chiefs' compliance.

[67] VHA Handbook 1100.19

Facility concurred.

Target date for completion: April 30, 2020

Facility response: The Chief of Staff will ensure recommendations for continuation of privileges includes results of ongoing professional practice activities.

Clinical services began providing two years of FPPE/OPPE data for providers who are due to be re-privileged at the August 28, 2019 Medical Executive Committee meetings.

The Chief of Staff's office will review all of service chief recommendations for inclusion of FPPE/OPPE for two quarters to ensure sustainability. Target compliance rate of 90% for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% then a new action plan will be developed, and reporting will resume monthly until target of 90% compliance is reached.

The Chief of Staff will monitor monthly reports at the Medical Executive Committee.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct environment of care inspection rounds and resolve issues in a timely manner. The goal of the environment of care program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.[68]

The purpose of this facet of the OIG inspection was to determine whether the facility maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the facility met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the locked inpatient mental health unit. The inspection team also looked at facility compliance with emergency management processes.[69]

VHA requires its facilities to have the "capacity for [providing] mental health services for veterans with acute and severe emotional and/or behavioral symptoms causing a safety risk to self or others, and/or resulting in severely compromised functional status. This level of care is typically provided in an inpatient setting;" however, for facilities that do not have inpatient mental health services, that "capacity" could mean facilitating care at a nearby VA or non-VA facility.[70]

VHA requires managers to establish a comprehensive emergency management program to ensure the continuity of patient care and hospital operations in the event of a natural disaster or other emergency. This includes conducting a hazard vulnerability analysis and developing an emergency operations plan. These requirements are meant to support facilities' efforts to identify and minimize harm from potential hazards, threats, incidents, and events related to healthcare and other essential services.[71] Managers must also develop utility management plans to increase reliability and reduce failures of electrical power distribution systems in accordance with TJC,

[68] VHA Directive 1608, *Comprehensive Environment of Care (CEOC) Program*, February 1, 2016.

[69] Applicable requirements for high-risk areas and emergency management include those detailed in or by various VHA Directives, Joint Commission hospital accreditation standards, Occupational Safety and Health Administration, American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), and National Fire Protection Association (NFPA).

[70] VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013. (This VHA Handbook was scheduled for recertification on or before the last working date of September 2018 and has not been recertified.)

[71] VHA Directive 0320.01, *Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures*, April 6, 2017.

Occupational Safety and Health Administration,[72] and National Fire Protection Association standards.[73] The provision of sustained electrical power during disasters or emergencies is critical to healthcare facility operations.[74]

In all, the OIG team inspected eight areas at the Malcom Randall VA Medical Center—surgical intensive care unit/cardiothoracic intensive care unit, CLC, emergency department, medical (unit 4W), primary care clinic, post anesthesia care unit, surgical (unit 2E), and inpatient mental health (unit 5W). In addition, the OIG team inspected six areas at the Lake City VA Medical Center—intensive care unit (4S), CLC (Serenity Place 3S), emergency department, outpatient clinic-orange, post-anesthesia care unit, and surgical (unit 3N). The OIG also inspected The Villages VA Clinic and reviewed the emergency management program. The inspection team reviewed relevant documents and interviewed key employees and managers. The OIG evaluated the following location-specific performance indicators:

- Parent facility
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies
- Community based outpatient clinic
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies
- Locked inpatient mental health unit

[72] The Occupational Safety and Health Administration (OSHA) is part of the US Department of Labor. OSHA's mission is to assure safe and healthy working conditions "by setting and enforcing standards and by providing training, outreach, education, and assistance." https://www.osha.gov/about.html. (This website was accessed on June 28, 2018.)

[73] The National Fire Protection Association (NFPA) is a global nonprofit organization "devoted to eliminating death, injury, property, and economic loss due to fire, electrical, and related hazards." https://www.nfpa.org/About-NFPA. (This website was accessed on June 28, 2018.)

[74] TJC. Environment of Care standard EC.02.05.07.

  - Mental health environment of care rounds
  - Nursing station security
  - Public area and general unit safety
  - Patient room safety
  - Infection prevention
  - Availability of medical equipment and supplies
- Emergency management
  - Hazard vulnerability analysis (HVA)
  - Emergency operations plan (EOP)
  - Emergency power testing and availability

Environment of Care Conclusion

Generally, the facility complied with safety requirements and privacy measures at the parent facility and the representative CBOC. The OIG did not identify any issues with the availability of medical equipment and supplies. However, the OIG found supplies, needles, syringes, and equipment in an unattended procedure room that was accessible to the public and adjacent to the Malcom Randall emergency department waiting room. The OIG also noted deficiencies with environmental cleanliness, infection prevention, and emergency management testing of generators that warranted recommendations for improvement.

Specifically, VHA requires that all VA medical facilities provide a safe, clean, functional, and high-quality environment for patients, staff, and visitors.[75] TJC requires hospitals to identify environmental deficiencies, hazards, and unsafe practices and keep furnishings and equipment safe and in good repair.[76]

At the Malcom Randall VA Medical Center, of the eight patient care areas inspected, two had dirty/dusty ventilation grills and unrepaired wall damage and one had a dirty/dusty sprinkler head.[77] At the Lake City VA Medical Center, six patient care areas were inspected. Of these, five had dirty/dusty ventilation grills and dirty floors, four had unrepaired wall damage, three had missing/ill fitted/stained ceiling tiles, and one had a dirty/dusty sprinkler head.[78] These

[75] VHA Directive 1608, *Comprehensive Environment of Care Program*, February 1, 2016.

[76] TJC. Environment of Care standard EC.02.06.01.

[77] Malcom Randall VA Medical Center—surgical intensive care unit/cardiothoracic intensive care unit, CLC, ED, medical (unit 4W), primary care clinic, post-anesthesia care unit, surgical (unit 2E), and inpatient mental health (unit 5W).

[78] Lake City VA Medical Center—intensive care unit (4S), CLC (Serenity Place 3S), emergency department, outpatient clinic-orange, post-anesthesia care unit, and surgical (unit 3N).

conditions potentially affect the safety and physical well-being of patients, staff, and visitors. The chief of facility management service stated lack of attention to detail and oversight as the reasons for noncompliance.

Two bedside shelving units in the surgical intensive care unit and one in the cardio-thoracic intensive care unit had damage to laminate surfaces, revealing exposed particle board. When facility staff are unable to properly clean shelving units, this leads to an increased risk of contamination and/or pathogen exposure to patients and staff. The facility and environmental management service chiefs and nurse manager for the area stated a lack of attention to detail as the reason for not identifying the need for repair or replacement.

Recommendation 7

7. The deputy director confirms that facility managers maintain a safe and clean environment throughout the healthcare system and monitors compliance.

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Chief, Facilities Management Service is ultimately responsible for ensuring the facility complies with safety requirements.

The Chief, Facilities Management Service ensured conditions affecting safety and the physical environment were remedied during the survey. Check boxes were added to the Environment of Care rounds form March 29, 2019, in Performance Logic regarding cleanliness of sprinkler heads. Environment of care rounds includes a review of cleanliness and safety with the addition of sprinkler head cleanliness. Beginning September 2019, the number of sprinkler heads inspected per area during Environment of Care rounds will be noted along with the number of sprinkler heads requiring maintenance.

Target compliance rate of 90% cleanliness of sprinkler heads for six consecutive months. Dirty sprinkler heads will be addressed and cleaning completed within 14 days. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% then reporting will resume monthly until target of 90% compliance is reached. Compliance with cleanliness and safety, with the addition of sprinkler head cleanliness is monitored weekly through Environment of Care rounds and entered in Performance Logic. The weekly data from Environment of Care rounds is collated and presented to Environment of Care Committee.

Recommendation 8

8. The deputy director ensures the furnishings in the intensive care units are repaired or replaced and monitors compliance.

Facility concurred.

Target date for completion: October 15, 2019

Facility response: The Chief, Facilities Management Service is ultimately responsible for ensuring the facility complies with safety requirements.

The Chief, Facilities Management Service removed the exposed particle board in the Cardio Thoracic Intensive Care Unit on January 18, 2019. The exposed particle board in the Surgical Intensive Care Unit was sealed July 18, 2019.

Replacement project is currently underway. Personnel assigned to the project ensure that the seal is intact and the integrity of the sealant is not compromised. If the sealant is found to be compromised then corrective action is taken immediately. This will continue until project completion. Estimated date of completion October 15, 2019. Once the replacement surface has been installed, continued monitoring for compliance will be through monthly Environment of Care rounds.

Further, TJC requires that hospitals minimize the risk of infection when storing and disposing of infectious waste.[79] The OIG found one medical biohazardous waste storage room (surgical unit, 2E) with a damaged, unsecured door. The area is in the nurse's station and not readily accessible to patients or visitors; however, this lack of security presents the potential for patient, staff, and visitor exposure to contaminated materials. A work order was placed on December 19, 2018; however, the door had not been repaired.

A medical biohazardous waste storage room in the CLC lacked signage, an area for staff to clean their hands, and vetting prior to being used as a medical biohazardous waste storage room. When biohazard storage rooms are not easily identifiable or properly evaluated prior to their use, patients, staff, and visitors may potentially be at risk for exposure to infectious material. The chiefs of environmental and facilities management stated the reason for the unsecured waste storage rooms was lack of oversight by facility managers.

Recommendation 9

9. The deputy director makes certain that medical biohazardous waste storage rooms are secured and properly identified and monitors compliance.

[79] TJC. Infection Prevention and Control standard IC.02.01.01.

Facility concurred.

Target date for completion: March 31. 2020

Facility response: The Chief, Facilities Management Service is ultimately responsible for ensuring the facility complies with safety requirements.

The Chief, Facilities Management Service ensured signage for the biohazardous waste room in the Community Living Center was corrected during survey on January 18, 2019 (picture available). The electronic work order dated December 19, 2018 for the medical biohazardous waste storage room on Unit 2E was completed on December 19, 2018, however the original copy of the work order request was not removed from the door. The door was subsequently noted to have been damaged again on January 16, 2019. It was repaired for a second time on January 17, 2019. Work orders have been placed to conduct a monthly preventative maintenance check of the door on Unit 2E to ensure appropriate latching.

Compliance is monitored through work order process for two consecutive quarters. Data is presented monthly to Environment of Care Committee.

VHA also requires that facilities have an electrical distribution system that operates safely, reliably, and efficiently.[80] VHA requires that all essential electrical systems, such as "automatic transfer switches and emergency generators, be inspected weekly."[81] The OIG found that from June 1, 2018, to December 31, 2018, the facility[82] lacked four weeks of documentation for two generators.[83] This could result in lack of assurance of operational readiness and reliability of the generators when needed. The operations supervisor stated he was confident the weekly testing was completed but the documentation was not filed; the reason for noncompliance was lack of oversight in filing documentation.

Recommendation 10

10. The deputy director makes certain that facility management service managers conduct weekly generator testing as required and monitors managers' compliance.

[80] VHA Directive 1028, *Electrical Power Distribution Systems*, July 25, 2014.

[81] VHA Directive 1028.

[82] Generator 4 ambulatory care addition and Generator 8 CLC.

[83] Weeks lacking documentation were: 1st week, July 2018; last week, September 2018; and 3rd and 4th weeks in November 2018.

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Chief, Facilities Management Service is responsible for ensuring generator testing documentation is completed and available for review.

The Chief, Facilities Management Service implemented an electronic data file on January 17, 2019 to back-up paper files. All paper documents are now maintained in a centralized location in the Facilities Management Service.

Generator testing documentation has been completed and compliant for the last two (February – July 2019) quarters. Testing is documented utilizing a Generator Operational Checklist. Items inspected include: oil level, radiator water level, fuel tank level, battery voltage, exit light battery, and generator in auto position. Any additional comments by the operator may be added.

Chief, Facilities Management Service will monitor electronic file weekly to ensure documentation is uploaded. Any deficiencies will be presented monthly to the Environment of Care Committee. Compliance will be monitored for two consecutive quarters.

Medication Management: Controlled Substances Inspections

The Controlled Substances Act divides controlled drugs into five categories based on whether they have an accepted medical treatment use in the United States, their relative potential for abuse, and the likelihood of causing dependence if abused.[84] Diversion of controlled substances by healthcare workers—the transfer of legally prescribed controlled substances from the prescribed individual to others for illicit use—remains a serious problem that can increase patient safety issues and elevate the liability risk to healthcare facilities.[85]

VHA requires that facility managers implement and maintain a controlled substances inspection program to minimize the risk for loss and diversion and to enhance patient safety. Requirements include the appointment of controlled substances coordinator(s) and controlled substances inspectors, implementation of procedures for inventory control, and inspections of the pharmacy and clinical areas with controlled substances.[86]

To determine whether the facility complied with requirements related to controlled substances security and inspections, the OIG team interviewed key managers and reviewed inspection reports; monthly summaries of findings, including discrepancies, provided to the facility director; inspection quarterly trend reports for the prior two completed quarters;[87] and other relevant documents. The OIG evaluated the following performance indicators:

- Controlled substances coordinator reports
  - Monthly summary of findings to the director
  - Quarterly trend reports to the director
  - Quality Management Committee's review of monthly and quarterly trend reports
  - Actions taken to resolve identified problems
- Pharmacy operations
  - Staff restrictions for monthly review of balance adjustments[88]
- Requirements for controlled substances inspectors

[84] Drug Enforcement Agency Controlled Substance Schedules. https://www.deadiversion.usdoj.gov/schedules/. (The website was accessed on March 7, 2019.)

[85] American Society of Health-System Pharmacists, "ASHP Guidelines on Preventing Diversion of Controlled Substances," *American Journal of Health-System Pharmacists* 74, no. 5 (March 1, 2017): 325-348.

[86] VHA Directive 1108.02(1), *Inspection of Controlled Substances*, November 28, 2016 (amended March 6, 2017).

[87] The two quarters were from April 1, 2018, through September 30, 2018.

[88] Controlled substances balance adjustment reports list transactions in which the pharmacy vault inventory balance was manually adjusted.

  - No conflicts of interest
  - Appointed in writing by the director for a term not to exceed three years
  - Hiatus of one year between any reappointment
  - Completion of required annual competency assessment
- Controlled substances area inspections
  - Completion of monthly inspections
  - Rotations of controlled substances inspectors
  - Patterns of inspections
  - Completion of inspections on day initiated
  - Reconciliation of dispensing between pharmacy and each dispensing area
  - Verification of controlled substances orders
  - Performance of routine controlled substances inspections
- Pharmacy inspections
  - Monthly physical counts of the controlled substances in the pharmacy
  - Completion of inspections on day initiated
  - Security and verification of drugs held for destruction[89]
  - Accountability for all prescription pads in pharmacy
  - Verification of hard copy controlled substances prescriptions
  - Verification of 72-hour inventories of the main vault
  - Quarterly inspections of emergency drugs
  - Monthly checks of locks and verification of lock numbers
- Facility review of override reports[90]

Medication Management Conclusion

The OIG found general compliance with requirements for some of the performance indicators evaluated, including the controlled substances coordinator reports, the controlled substances

[89] According to VHA Directive 1108.02(1), The Destructions File Holding Report "lists all drugs awaiting local destruction or turn-over to a reverse distributor." Controlled substances inspectors "must verify there is a corresponding sealed evidence bag containing drug(s) for each destruction holding number on the report."

[90] When automated dispensing cabinets are used, nursing staff can override and remove medications prior to the pharmacists' review of medications ordered by the providers.

inspectors having no conflicts of interest, and completing annual competency assessments. However, the OIG identified deficiencies with monthly inspections, rotation of controlled substances inspectors, completion of physical inventory count on the day initiated, verification of controlled substances orders, security and verification of drugs held for destruction, accountability of prescription pads, verification of hard copy prescriptions, and verification of completion of 72-hour inventories that warranted recommendations for improvement.

Specifically, VHA requires controlled substances inspectors to conduct monthly inspections of controlled substances storage areas.[91] VHA also requires that the controlled substances coordinator retain records to include inspector worksheets and supporting documentation.[92] In 5 of the 10 non-pharmacy areas selected for review, the OIG found that the controlled substances inspectors did not complete monthly inventory inspections but did document inventory completion on the inspection worksheet. As a result, all required elements of the monthly review were not completed, which impacts the ability to identify potential drug diversion activities and discrepancies with controlled substances. This also resulted in a loss of integrity of the program when inspectors documented work that was not completed. The controlled substances coordinator stated that the inspectors were aware of the requirements, but the coordinator does not have a process to validate inventory completion or other elements of the inspections.

The OIG also found that all 10 non-pharmacy areas and two of five pharmacy areas selected for review did not have evidence that the inventory count was completed the day initiated, although the inspectors documented a date of completion on the worksheet. This resulted in missed opportunities to identify potential drug diversion activities and any discrepancies related to controlled substances. The controlled substances coordinator does not have a process to validate inventory completion or other elements of the inspections. It was observed by the OIG that the non-pharmacy area inspection forms have only one location to document a date but is used to document inspections for several dispensing cabinets locations, and the controlled substance coordinator explained that the inspectors cannot do all in one day.

Recommendation 11

11. The facility director makes certain that controlled substances inspectors complete the monthly controlled substances inspections and physical inventory counts on the day initiated and that the controlled substances coordinator evaluates and maintains supporting documentation and monitors inspectors' and coordinator's compliance.

[91] VHA Directive 1108.02(1).
[92] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator is responsible for ensuring inspectors complete the monthly controlled substances inspections and physical inventory counts on the day initiated and maintaining supporting documentation.

Controlled substance forms were updated May 1, 2019 to include spaces to input the date inspection was initiated and completed on the same day.

Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports is maintained by the Controlled Substance Coordinator and documents corrective actions taken. Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100% for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

VHA also requires that although a controlled substances inspector is assigned to assist in the monthly inspection process, the inspector may not inspect the same controlled substance storage area two months consecutively.[93] The OIG found that for the non-pharmacy area reviews, one inspector completes the inventory inspection and another inspector verifies the five dispensing activities. In 2 of 10 non-pharmacy areas, a controlled substance inspector conducted, in the same area, two or more consecutive months of verifications for dispensing activities. This resulted in missed opportunities to identify potential drug diversion activities and discrepancies with controlled substances. The controlled substances coordinator acknowledged the lack of process validation and the lack of oversight as the reason for noncompliance.

Recommendation 12

12. The facility director ensures controlled substances inspectors do not inspect the same area for two or more consecutive months and monitors inspectors' compliance.

[93] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator is responsible to ensure inspectors are not inspecting the same controlled substance storage area consecutively for two months.

Controlled Substance Coordinator assigns monthly rotations to ensure consistency with the directive. An annual schedule has been developed (August 16, 2019) and has been provided to the Controlled Substance Inspectors (August 16, 2019). Controlled Substance Coordinator monitors reports to ensure the same inspectors are not monitoring the same area consecutively for two months. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports is maintained by the Controlled Substance Coordinator and documents corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor reports sent to Quality Executive Council to ensure completeness and identify trends in noncompliance. The Quality Manager will work with Controlled Substance Coordinator to develop a new plan if issues regarding inspectors reviewing the same areas consecutively for two months arise.

VHA requires that during controlled substances area inspections, controlled substances inspectors verify that there is evidence of a written or electronic controlled substances order for a prescribed number of randomly selected patients.[94] The OIG found that controlled substances inspectors did not verify controlled substances orders (electronic or written) for five randomly selected dispensing activities in 5 of 10 areas reviewed. Failure to verify orders may result in missed opportunities to identify potential drug diversion activities and any discrepancies related to controlled substances. The controlled substance coordinator stated the reason for noncompliance was related to a lack of process validations.

Recommendation 13

13. The facility director makes certain the controlled substances coordinator ensures that written and electronic controlled substance orders have been verified and monitors coordinator's compliance.

[94] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator is responsible for ensuring all inspectors verify controlled substances orders and monitor compliance.

Controlled substance forms have been updated as of August 10, 2019 to indicate if no additional patients were available for review. Controlled Substance Inspectors were educated on August 16, 2019. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports is maintained by the Controlled Substance Coordinator and documents corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

Specifically, VHA requires that during controlled substances inspections, the controlled substances inspectors verify there is a corresponding sealed evidence bag containing drug(s) for each medication held for destruction as listed on the "Destructions File Holding Report."[95] For three of five pharmacy areas, the OIG did not find evidence that controlled substances inspectors verified that drugs held for destruction were secure or that each drug had a corresponding destruction number on the report. Failure to verify drugs held for destruction against the holding number on the report may leave the facility vulnerable to loss and theft. The controlled substances coordinator reported a lack of process validation and oversight as the reasons for noncompliance.

Recommendation 14

14. The facility director ensures that controlled substances inspectors verify there is a corresponding sealed evidence bag containing drug(s) for each medication listed on the "Destructions File Holding Report" during monthly inspections and monitors inspectors' compliance.

[95] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator is responsible for ensuring inspectors review corresponding sealed evidence bag containing drug(s) for each medication listed on the "Destructions File Holding Report" during monthly inspections.

As of August 10, 2019, controlled substance forms have been updated. The security of drugs being held for destruction has been included on the updated form. The evidence bag number for each drug being held for destruction is also included on the updated form. The evidence bag numbers are matched against the destruction log. Verification of the matching destruction numbers is verified by two signatures. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports is maintained by the Controlled Substance Coordinator and documents corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

VHA requires that controlled substances inspectors verify the inventory count of prescription pads on the day of the monthly pharmacy inspection.[96] The OIG found that three of five pharmacy area reviews lacked evidence that the controlled substances inspectors verified prescription pad counts each month. This could result in missed opportunities to identify potential drug diversion activities and any discrepancies related to controlled substances. The controlled substances coordinator reported a lack of process validation and the lack of oversight as reasons for noncompliance.

Recommendation 15

15. The facility director ensures that controlled substances inspectors complete pharmacy prescription pad inventories during monthly pharmacy inspections and monitors inspectors' compliance.

[96] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator is responsible for ensuring inspectors complete pharmacy prescription pad inventories monthly.

Controlled Substance Inspectors will submit a copy of the prescription pad log with the monthly report for all areas inspected. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports will be maintained by the Controlled Substance Coordinator including documentation of corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to the Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

VHA requires that during controlled substances area inspections, controlled substances inspectors verify for evidence of a written signature for non-electronic controlled substances orders for the month preceding the inspection.[97] The OIG found that three of five pharmacy areas lacked evidence of verification of written prescriptions for 50 controlled substances orders. When program oversight and process validation are not completed, opportunities to maintain an accurate count of controlled substances and minimize drug diversion activities may be missed, leading to organizational and patient risk. The controlled substances coordinator stated they did not review or maintain the supporting documentation provided by the inspectors and reported a lack of process validation and oversight as the reasons for noncompliance.

Recommendation 16

16. The facility director ensures the controlled substances inspectors verify evidence of written signature for non-electronic controlled substances orders during monthly area inspections and monitors inspectors' compliance.

[97] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator ensures inspectors verify evidence of written signature for non-electronic controlled substances orders monthly.

As of August 31, 2019, Controlled Substance Inspectors will submit a copy of the Pharmacy Prescription List for written prescriptions with their monthly Controlled Substance Inspection report. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports will be maintained by the Controlled Substance Coordinator and documents corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

Additionally, VHA requires that controlled substances inspectors verify and document that pharmacy inventory checks have been completed twice per week.[98] The OIG found that all five pharmacy areas inspected lacked evidence of verification of the pharmacy inventory count. Failure to verify physical inventories could potentially delay identification of discrepancies and potential drug diversions. The controlled substances coordinator stated the lack of process validation and oversight as the reasons for noncompliance.

Recommendation 17

17. The facility director makes certain that controlled substances inspectors complete the verification of the twice weekly pharmacy inventory as required and monitors inspectors' compliance.

[98] VHA Directive 1108.02(1).

Facility concurred.

Target date for completion: March 31, 2020

Facility response: The Controlled Substance Coordinator ensures inspectors complete the verification of the twice weekly pharmacy inventory.

As of August 10, 2019, controlled substance forms have been updated to include a calendar indicating which days of the month a pharmacy inspection was done. Both Controlled Substance Inspectors and Pharmacy staff sign the report. Controlled Substance Coordinator reviews each report monthly for completeness. A database of incomplete/deficient reports is maintained by the Controlled Substance Coordinator and documents corrective actions taken.

Controlled Substance Coordinator will report monthly to Quality Executive Council. Target compliance rate of 100%. Controlled Substance Inspections consisting of 25 individual areas surveyed monthly for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

Mental Health: Military Sexual Trauma Follow-Up and Staff Training

The Department of Veterans Affairs uses the term "military sexual trauma" (MST) to refer to a "psychological trauma, which in the judgment of a mental health professional employed by the Department [of Veterans Affairs], resulted from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while the Veteran was serving on active duty, active duty for training, or inactive duty training."[99] MST is an experience, not a diagnosis or a mental health condition. Although posttraumatic stress disorder is commonly associated with MST, other frequently associated diagnoses include depression and substance use disorders.[100]

VHA requires that the facility director designates an MST coordinator to support national and VISN-level policies related to MST-related care and serve as a source of information; establish and monitor MST-related staff training and informational outreach; and communicate MST-related issues, services, and initiatives with leadership.[101] Additionally, the facility director is responsible for ensuring that MST-related data are tracked and monitored.[102]

VHA requires that all veterans and potentially eligible individuals seen in VHA facilities be screened for experiences of MST with the required MST clinical reminder in the computerized patient record system.[103] Those who screen positive must have access to appropriate MST-related care.[104] VHA also requires that evidence-based mental health care be available to all veterans with mental health conditions related to MST. Patients requesting or referred for mental health services must receive an initial evaluation within 24 hours of the referral to identify urgent care needs and a more comprehensive diagnostic evaluation within 30 days.[105]

The MST coordinator may provide clinical care to individuals experiencing MST and is thus subject to the same mandatory training requirements as mental health and primary care providers.[106] All mental health and primary care providers must complete MST mandatory

[99]VHA Directive 1115, *Military Sexual Trauma (MST) Program*, May 8, 2018.

[100]Military Sexual Trauma. https://www.mentalhealth.va.gov/docs/mst_general_factsheet.pdf. (The website was accessed on November 17, 2017.)

[101] VHA Directive 1115.

[102] VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008 (amended November 16, 2015) (This VHA Handbook was scheduled for recertification on or before the last working date of September 2013 and has not been recertified.)

[103]VHA Directive 1115 states that "MST-related care is not subject to the minimum active duty service requirement set forth in 38 U.S.C. 5303A; Veterans may therefore be able to receive MST-related care even if they are not eligible for VA health care under other treatment authorities."

[104]VHA Directive 1115.

[105] VHA Handbook 1160.01.

[106] VHA Directive 1115

training; for those hired after July 1, 2012, this training must be completed no later than 90 days after assuming their position.[107]

To determine whether the facility complied with the requirements related to MST follow-up and training, the OIG inspection team reviewed relevant documents and staff training records and interviewed key employees. The team also reviewed the electronic health records of 50 outpatients who had a positive MST screen from July 1, 2017, through June 30, 2018. The OIG evaluated the following performance indicators:

- Designated facility MST coordinator
  - Establishes and monitors MST-related staff training
  - Establishes and monitors informational outreach
  - Communicates MST-related issues, services, and initiatives with local leaders
- Evidence of tracking MST-related data
- Provision of clinical care
  - Referral for MST-related care to patients with positive MST screens
  - Initial evaluation within 24 hours of referral for mental health services
  - Comprehensive diagnostic and treatment planning evaluation within 30 days of referral for mental health services
- Completion of MST mandatory training requirement for mental health and primary care providers

Mental Health Conclusion

Generally, the OIG found compliance with many of the performance indicators, including the designation of an MST coordinator, tracking of MST-related data, and referral for MST-related care. However, the OIG found a concern with providers completing MST mandatory training that warranted a recommendation for improvement.

Specifically, VHA requires that all primary care and mental health providers complete MST mandatory training; for those hired before July 1, 2012, evidence of completion must be available and for those hired after July 1, 2012, training must be completed no later than 90 days

[107] VHA Directive 1115.01, *Military Sexual Trauma (MST) Mandatory Training and Reporting Requirements for VHA Mental Health and Primary Care Providers*, April 14, 2017; Deputy Under Secretary for Health for Operations and Management Memorandum, *Compliance with Military Sexual Trauma (MST) Mandatory Training for Mental Health and Primary Care Providers,* February 2, 2016.

after entering their position.[108] The OIG found that for those hired after July 1, 2012, 4 of 13 did not complete the training within 90 days of their hire date and 5 of 13 did not complete training at all. This could potentially prevent clinicians from providing appropriate counseling, care, and service to veterans who experienced MST. The acting chief of staff for mental health services reported a lack of attention to detail and other competing priorities as the reasons for noncompliance.

Recommendation 18

18. The chief of staff confirms that providers complete military sexual trauma mandatory training within the required time frame and monitors providers' compliance.

Facility concurred.

Target date for completion: March 31, 2020

Facility response: Mental Health and Primary Care Supervisors are responsible for ensuring all providers complete Military Sexual Trauma (MST) training.

The MST Coordinator developed a process with Talent Management System administrators to assign MST training to all current and new Primary Care and Mental Health providers. All current Mental Health and Primary Care providers have completed MST training. Talent Management System reports for last two quarters (February – July 2019) indicate all Primary Care (176 of 176 providers) and Mental Health (361 of 361 providers) have received training.

Mental Health and Primary Care Supervisors will ensure all new providers are put into the automated training management system and MST training is completed. The Acting Associate Chief of Staff for Mental Health Service Line will report monthly to Quality Executive Council. Target compliance rate of 90% for six consecutive months. If compliance falls below 90% then a new action plan will be developed, and reporting will resume monthly until target of 90% compliance is reached.

The Quality Manager will monitor monthly reports sent to Quality Executive Council, followed by quarterly reports to ensure completeness and identify if there are any trends in noncompliance.

[108] VHA Directive 1115.01; Department of Veterans Affairs, Deputy Under Secretary for Health for Operations and Management, (10N) Memorandum, February 2, 2016.

Geriatric Care: Antidepressant Use among the Elderly

VA's National Registry for Depression reported that "11 [percent] of veterans aged 65 years and older have a diagnosis of major depressive disorder."[109] The VA/DoD Clinical Practice Guideline (CPG) describes depression as "a common mental disorder that presents with depressed mood, loss of interest or pleasure in regular activities, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration." This can lead to poor quality of life, decreased productivity, and increased mortality from suicide.[110]

According to the Centers for Disease Control and Prevention, older adults are at increased risk for experiencing depression because "80 [percent] of older adults have at least one chronic health condition and 50 [percent] have two or more." Further, "most older adults see an improvement in [their] symptoms when treated with antidepression drugs, psychotherapy, or a combination of both."[111]

The American Geriatrics Society revised the Beers Criteria in 2015 to include lists of potentially inappropriate medications to be avoided. Potentially inappropriate medication use in older adults continues to be associated with confusion, falls, and mortality.[112] The criteria provide guidelines that help to improve the safety of prescribing certain medications including antidepressants for older adults.

TJC requires clinicians to educate patients and families about the "safe and effective use of medications."[113] In 2015, VHA outlined essential medical information "necessary for review, management, and communication of medication information" with patients, caregivers, and their healthcare teams.[114] Further, TJC requires clinicians to perform medication reconciliation by comparing the medication a patient is actually taking to the new medications that are ordered for the patient and resolving any discrepancies.[115] The CPG recommends that clinicians monitor patients monthly after therapy initiation or a change in treatment until the patient achieves

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[109] Hans Peterson, "Late Life Depression," *U.S. Department of Veterans Affairs*, Mental Health Featured Article, March 1, 2011. https://www.mentalhealth.va.gov/featureArticle_Mar11LateLife.asp. (The website was accessed on March 8, 2019.)

[110] VA/DoD *Clinical Practice Guideline for the Management of Major Depressive Disorder*, April 2016. https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf. (The website was accessed November 20, 2018.)

[111] Centers for Disease Control and Prevention, "Depression is Not a Normal Part of Growing Older," January 31, 2017. https://www.cdc.gov/aging/mentalhealth/depression.htm. (The website was accessed on March 8, 2019.)

[112]American Geriatrics Society 2015 Beers Criteria Update Expert Panel, "American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults." http://www.sigot.org/allegato_docs/1057_Beers-Criteria.pdf. (The website was accessed on March 22, 2018.)

[113] TJC. Provision of Care, Treatment, and Services. standard PC 02.03.01

[114] VHA Directive 1164, *Essential Medication Information Standards*, June 26, 2015.

[115] TJC. National Patient Safety Goal standard NPSG.03.06.01.

remission. Monitoring includes assessment of symptoms, adherence to medication and psychotherapy, and any adverse effects. The CPG also recommends that treatment planning includes patient education about treatment options, including risks and benefits.[116]

To determine whether the facility complied with requirements concerning use of antidepressants among the elderly, the OIG inspection team interviewed key employees and managers. The team also reviewed the electronic health records of 47 randomly selected patients, ages 65 and older, who were newly prescribed one of seven selected antidepressant medications from July 1, 2017, through June 30, 2018.[117] The OIG evaluated the following performance indicators:

- Justification for medication initiation
- Evidence of patient and/or caregiver education specific to the medication prescribed
- Clinician evaluation of patient and/or caregiver understanding of the education provided
- Medication reconciliation

Geriatric Care Conclusion

For geriatric patients, clinicians documented reasons for prescribing medications. However, the OIG identified concerns with the patient/caregiver education and medication reconciliation processes that warranted recommendations for improvement.

TJC requires that clinicians educate patients and families about safe and effective use of medications and that the patient's medical record contains information that reflects the patient's care, treatment, and services.[118] The OIG estimated that clinicians provided patient/caregiver education to 77 percent of the patients at the facility, based on electronic health records reviewed.[119] Providing medication education is critical to ensuring that patients or their caregivers have the information they need to manage their own health at home.[120] Facility managers reported that providers lack education on charting requirements, face time constraints with large patient profiles, and existing template deficiencies as the reasons for noncompliance.

[116] VA/DoD Clinical Practice Guidelines for the Management of Major Depressive Disorder.

[117] The seven selected antidepressant medications are Amitriptyline, Clomipramine, Desipramine, Doxepin (>6mg/day), Imipramine, Nortriptyline, and Paroxetine.

[118] TJC. Provision of Care standard PC.02.03.01; TJC. Record of Care, Treatment, and Services standard RC.02.01.01.

[119] The OIG is 95 percent confident that the true compliance rate is somewhere between 63.8 and 87.7 percent, which is statistically significantly below the 90 percent benchmark.

[120] TJC. Provision of Care standard PC.02.03.01.

Recommendation 19

19. The chief of staff makes certain that clinicians provide and document patient/caregiver education about the safe and effective use of newly prescribed medications and monitors clinicians' compliance.

Facility concurred.

Target date for completion: December 15, 2019

Facility response: Chief of Staff ensures clinicians provide and document patient/caregiver education about the safe and effective use of newly prescribed medications.

Chief of Pharmacy developed and implemented an evidence based clinical decision tool on February 28, 2019 to ensure providers are documenting patient/caregiver education. Clinical pharmacist verifies that the clinical decision tool is completed prior to prescribing or dispensing medication. The medication will not be ordered without completion of the clinical decision tool.

Pre and post intervention data on the clinical decision tool will be evaluated quarterly for the first six months. Target compliance rate of 90% for two consecutive quarters. If compliance falls below 90% then a new action plan will be developed, and reporting will resume quarterly until target of 90% compliance is reached.

Chief of Pharmacy will review the quarterly reports to Pharmacy and Therapeutics Committee to ensure the continuous appropriate use of the clinical decision tool and will review areas of noncompliance.

Regarding medication reconciliation, TJC requires that, "a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolves any discrepancies."[121] TJC also requires that patients receive information on the "safe and effective use of medications."[122] Furthermore, VHA requires that clinicians review and reconcile medications relevant to the episode of care.[123]

The OIG estimated that clinicians performed medication reconciliation for 79 percent of the patients at the facility, based on electronic health records reviewed.[124] Failure to maintain and communicate accurate patient medication information and reconcile medications increases the risk of duplications, omissions, and interactions in the patient's actual drug regimen.[125] Facility

[121] TJC National Patient Safety Goal standard NPSG.03.06.01.

[122] TJC. Provision of Care standard PC.02.03.01.

[123] VHA Directive 1164.

[124] The OIG is 95 percent confident that the true compliance rate is somewhere between 66.6 and 89.6 percent, which is statistically below the 90 percent benchmark.

[125] TJC Rationale for standard NPSG.03.06.01.

managers reported that providers lack education on charting requirements, face time constraints with large patient profiles, and existing template deficiencies as the reasons for noncompliance.

Recommendation 20

20. The chief of staff ensures clinicians reconcile medication information and maintain accurate patient medication information in patients' electronic health record and monitors clinicians' compliance.

Facility concurred.

Target date for completion: December 15, 2019

Facility response: Chief of Staff ensures clinicians reconcile medication information and maintain accurate patient medication information.

Chief of Pharmacy developed and implemented an evidence based clinical decision tool on February 28, 2019 to ensure providers are documenting medication reconciliation. Clinical pharmacist verifies that the clinical decision tool is completed prior to prescribing or dispensing medication. The medication will not be ordered without completion of the clinical decision tool.

Pre and post intervention data on the clinical decision tool will be evaluated quarterly for the first six months. Target compliance rate of 90% for two consecutive quarters. If compliance falls below 90% then a new action plan will be developed, and reporting will resume quarterly until target of 90% compliance is reached.

Chief of Pharmacy will review the quarterly reports to Pharmacy and Therapeutics Committee to ensure the continuous appropriate use of the clinical decision tool and will review areas of noncompliance.

Women's Health: Abnormal Cervical Pathology Results Notification and Follow-Up

Each year, about 12,000 women in the United States are diagnosed with cervical cancer.[126] Human papillomavirus (HPV) can be transmitted during sexual contact and is the main cause of cervical cancer.[127] In addition to HPV infection, other risk factors for cervical cancer include smoking, human immunodeficiency virus (HIV) infection, use of oral contraceptives for five or more years, and having given birth to three or more children.[128] Cervical cancer is highly preventable through diligent screening and vaccination efforts. With early detection, it is very treatable and associated with optimal patient outcomes.[129]

VA is authorized to provide "gender-specific services, such as Papanicolaou tests (Pap smears)," to eligible women veterans. Further, VHA requires that all eligible and enrolled women veterans have access to appropriate services and preventative care. That care would include age-appropriate screening for cervical cancer.[130]

VHA requires that each facility have a "full-time Women Veterans Program Manager (WVPM) to execute comprehensive planning for women's health care." VHA also requires a medical director or clinical champion to be responsible for the clinical oversight of the women's health program. Each facility must also have a "Women Veterans Health Committee comprised of appropriate facility leadership and program directors, which develops and implements a Women's Health Program strategic plan." The Women Veterans Health Committee must meet at least quarterly and report to the executive leaders. The facility must also have a process to ensure the collecting and tracking of data related to cervical cancer screenings.[131]

VHA has established time frames for notifying patients of abnormal cervical pathology results. Abnormal cervical pathology results must be communicated to patients within seven calendar days from the date the results are available to the ordering provider. Communication of the

[126] Centers for Disease Control and Prevention. "Cervical Cancer" *Inside Knowledge* fact sheet, December 2016. https://www.cdc.gov/cancer/cervical/pdf/cervical_facts.pdf. (The website was accessed on February 28, 2018.)
[127] Center for Disease Control and Prevention. *Basic Information About Cervical Cancer*. February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on March 8, 2019.)
[128] Centers for Disease Control and Prevention. *What Are the Risk Factors for Cervical Cancer?* February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/risk_factors.htm. (The website was accessed on March 8, 2019.)
[129] Center for Disease Control and Prevention. *Basic Information About Cervical Cancer*. February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on February 28, 2018.)
[130] VHA Directive 1330.01(2), *Health Care Services for Women Veterans,* February 15, 2017 (amended July 24, 2018).
[131] VHA Directive 1330.01(2).

results to patients must be documented. The facility must ensure that appropriate follow-up care is provided to patients with abnormal results.[132]

To determine whether the facility complied with selected VHA requirements for the notification and follow-up care of abnormal cervical pathology results, the OIG inspection team reviewed relevant documents and interviewed selected employees and managers. The team also reviewed the electronic health records of 20 women veteran patients, between ages 21 and 65, who had an abnormal pap smear or test from July 1, 2017, through June 30, 2018. The OIG evaluated the following performance indicators:

- Appointment of a women veterans program manager
- Appointment of a women's health medical director or clinical champion
- Facility Women Veterans Health Committee
  - Core membership
  - Quarterly meetings
  - Reports to clinical executive leaders
- Collection and tracking of cervical cancer screening data
  - Notification of patients due for screening
  - Completed screenings
  - Results reporting
  - Follow-up care
- Communication of abnormal results to patients within required time frame
- Provision of follow-up care for abnormal cervical pathology results, if indicated

Women's Health Conclusion

Generally, the OIG found compliance with many of the performance indicators, including requirements for a designated women veterans program manager, clinical oversight of the women's health program, communication of abnormal results to patients, and follow-up care when indicated. However, the OIG identified noncompliance with the Women Veterans Health Committee membership and data tracking related to cervical cancer screenings that warranted recommendations for improvement.

Specifically, VHA requires that the core membership of the Women Veterans Health Committee includes a women veterans program manager; a women's health medical director;

[132] VHA Directive 1330.01(2).

"representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership."[133] From July 2018 through December 2018, the committee lacked representation from primary care, emergency department, and executive leadership. This resulted in a lack of expertise and oversight in the review and analysis of data to ensure appropriate clinical services are available to women veterans.[134] The women veterans program assistant stated the reason for noncompliance was that the previous women veterans program manager revised the charter and removed several required members due to nonparticipation in monthly meetings.

Recommendation 21

21. The facility director makes certain that the Women Veterans Health Committee includes required core members and monitors committee's compliance.

Facility concurred.

Target date for completion: February 29, 2020

Facility response: Women Veterans Program Manager is responsible to ensure all required members are invited/notified to all meetings.

Women Veterans Program Manager ensured Primary Care, Emergency Department, and Executive Leadership assigned a primary and alternate member to the Women Veterans Advisory Committee. Women Veterans Program Manager will ensure attendance requirements are met.

Women Veterans Program Manager will report attendance issues to the Medical Executive Committee quarterly. Target compliance rate of 100% for two consecutive quarters. After two quarters of compliance is achieved, reporting will be changed to annually. If compliance falls below 100% then a new action plan will be developed, and reporting will resume quarterly until target of 100% compliance is reached.

Chief of Staff will monitor quarterly reports from the Women Veterans Advisory Committee at Medical Executive Committee.

According to VHA, the Women Veterans Heath Committee must report and provide signed minutes to an executive leadership committee.[135] From January 2018 through December 2018, the committee did not report to an executive leadership committee. This resulted in facility

[133] VHA Directive 1330.01(2).
[134] VHA Directive 1330.01(2).
[135] VHA Directive 1330.01(2).

leaders' lack of awareness to potential or actual issues involving care and services provided to women veterans. The women veterans program assistant reported that the facility thought they met the requirement by reporting to the Primary Care and Outpatient Leadership Council; however, this council was not attended by senior leadership.

Recommendation 22

22. The facility director confirms that the Women Veterans Health Committee reports to an executive leadership committee and monitors the committee's compliance.

Facility concurred.

Target date for completion: January 31, 2020

Facility response: Women Veterans Program Manager is responsible to ensure the Women Veterans Advisory Committee presents to an executive leadership committee

Women Veterans Program Manager ensured the Women Veterans Health Committee presented to the Medical Executive Committee on the following dates: January 23, 2019, March 27, 2019, June 26, 2019 and will continue to present quarterly.

Women Veterans Program Manager will ensure the Women Veterans Health Committee attends and presents to the Medical Executive Committee quarterly with a compliance rate of 100% annually.

Chief of Staff will monitor quarterly reports from the Women Veterans Health Committee at Medical Executive Committee.

Additionally, VHA requires each facility to assign care coordination responsibilities to specific individuals to ensure notification of patients who are due for screening, tracking of screening completion, results reporting, and follow-up care.[136] The OIG found that facility staff did not track cervical cancer screening data. Lack of tracking cervical cancer screening data may cause delays in providing appropriate care. The women veterans program assistant reported there was no designated employee assigned to perform required tracking duties and the patient assigned care team staff are not tracking due to workload.

Recommendation 23

23. The chief of staff ensures that staff collect and track cervical cancer screening data and monitors staff compliance.

[136] VHA Directive 1330.01(2).

Facility concurred.

Target date for completion: September 30, 2019

Facility response: Women Veterans Program Manager is responsible for ensuring cervical cancer screening data are collected and tracked appropriately.

Women Veterans Program Manager ensured National Pap Tracker is utilized as of March 11, 2019 and reviewed monthly. Primary Care Providers are notified via email when measures are not being met.

Patient Aligned Care Team Liaison presents cervical cancer screening data monthly (data to include total number of paps with results, total number of timely notification from lab to provider, and total number of timely notifications from provider to Veteran) to the Women Veterans Advisory Committee. Women Veterans Program Manager chairs the committee and monitors for compliance. Analysis of data is reported quarterly to Medical Executive Committee by Women Veterans Program Manager. Target compliance rate of 90% for cervical cancer screening data two consecutive quarters. After two quarters of compliance is achieved, reporting will be changed to annually. If compliance falls below 90% then a new action plan will be developed, and reporting will resume quarterly until target of 90% compliance is reached.

Chief of Staff will monitor quarterly reports from the Women Veterans Advisory Committee at Medical Executive Committee.

High-Risk Processes: Operations and Management of Emergency Departments and Urgent Care Centers

VHA defines an emergency department as a "unit in a VA medical facility that has acute care medical and/or surgical inpatient beds and whose primary responsibility is to provide resuscitative therapy and stabilization in life-threatening situations." An urgent care center (UCC) "provides acute medical care for patients without a scheduled appointment who are in need of immediate attention for an acute medical or mental health illness and/or minor injuries."[137] A variety of emergency services may exist, dependent on "capability, capacity, and function of the local VA medical facility;" however, emergency care must be uniformly available in all VHA emergency departments and UCCs.[138]

Because the emergency department or UCC is often the first point of contact for patients seeking treatment of unexpected medical issues, a care delivery system with appropriate resources and services must be available to deliver prompt, safe, and appropriate care. VHA requires that each emergency department provide "unrestricted access to appropriate and timely emergency medical and nursing care 24 hours a day, 7 days a week." VHA UCCs are also required to provide access and timely care during established operational hours. VHA also requires that "evaluation, management, and treatment [are] provided by qualified personnel with the knowledge and skills appropriate to treat those seeking emergency care."[139]

TJC noted that patient flow problems pose a persistent risk to quality and safety and established standards for the management of the flow of patients in the emergency department and the rest of the hospital. Managing the flow of patients prevents overcrowding, which can "undermine the timeliness of care and, ultimately, patient safety." Effective management processes that "support patient flow [in the emergency department or UCC settings] (such as admitting, assessment and treatment, patient transfer, and discharge) can minimize delays in the delivery of care."[140]

The VHA national director of Emergency Medicine developed the Emergency Medicine Improvement (EMI) initiative to improve the quality of emergent and urgent care provided through VA emergency departments and UCCs. As part of this initiative, all VA emergency departments and UCCs must use the Emergency Department Integration Software (EDIS) tracking program to document and manage the flow of patients.[141]

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[137] VHA Directive 1101.05(2), *Emergency Medicine*, September 2, 2016 (amended March 7, 2017).

[138] VHA Directive 1101.05(2).

[139] VHA Directive 1101.05(2).

[140] TJC. Leadership standard LD.04.03.11.

[141] VHA Directive 1101.05(2); The Emergency Medicine Management Tool (EMMT) uses data collected from EDIS to generate productivity metrics. The use of EDIS and EMMT are key tools in accomplishing EMI initiative goals.

VA emergency departments and UCCs must also be designed to promote a safe environment of care.[142]. Managers must ensure medications are securely stored,[143] a psychiatric intervention room is available,[144] and equipment and supplies are readily accessible to provide gynecologic and resuscitation services. VHA also requires emergency departments to have communication systems available to accept requests by local emergency medical services for transporting unstable patients to VA emergency departments.[145]

The OIG examined the clinical risks of the emergency department/UCC areas by evaluating the staffing; the provision of care, including selected aspects of mental health and women's health; and the reduction of patient safety risks to optimize quality care and outcomes in those areas. In addition to conducting manager and staff interviews, the OIG team reviewed emergency department staffing schedules, committee minutes, and other relevant documents. The OIG evaluated the following performance indicators:

- General
  - Presence of an emergency department or UCC
  - Availability of acute care medical and/or surgical inpatient beds in facilities with emergency departments
  - Emergency department/UCC operating hours
  - Workload capture process
- Staffing for emergency department/UCC
  - Dedicated medical director
  - At least one licensed physician privileged to staff the department at all times
  - Minimum of two registered nurses on duty during all hours of operation
  - Backup call schedules for providers
- Support services for emergency department/UCC
  - Access during regular hours, off hours, weekends, and holidays
  - On-call list for staff required to respond

[142] VHA Directive 1101.05(2).

[143] TJC. Medication Management standard MM.03.01.01.

[144] A psychiatric intervention room is where individuals experiencing a behavioral health crisis, including serious disturbances, agitation, or intoxication may be taken immediately on arrival.

[145] VHA Directive 1101.05(2).

  - Licensed independent mental health provider available as required for the facility's complexity level
  - Telephone message system during non-operational hours
  - Inpatient provider available for patients requiring admission
- Patient flow
  - EDIS tracking program
  - Emergency department patient flow evaluation
  - Diversion policy
  - Designated bed flow coordinator
- General safety
  - Directional signage to after-hours emergency care
  - Fast tracks[146]
- Medication security and labeling
- Management of patients with mental health disorders
- Emergency department participation in local/regional emergency medical services (EMS) system, if applicable
- Women veteran services
  - Capability and equipment for gynecologic examinations
- Life support equipment

High-Risk Processes Conclusion

The facility generally complied with many of the performance indicators used by the OIG team to assess the operations and management of the emergency department. However, the OIG identified a lack of availability of social work support services and directional signage that warranted recommendations for improvement.

Specifically, VHA requires that the emergency department/ UCC must be provided with a list of on-call social work, mental health, and specialty physician staff who are required to respond to assist with patient care.[147] The facility did not have a call schedule for social work service from

[146] The emergency department fast track is a designated care area within the emergency department domain where lower acuity patients are assessed and treated.
[147] VHA Directive 1101.05(2).

Friday 8:00 p.m. to Saturday 7:30 a.m.; Saturday from 6:00 p.m. to Sunday 7:30 a.m.; and Sunday from 6:00 p.m. to Monday 7:30 a.m. This resulted in a lack of social work staff available to assist the emergency department with patient care. The associate chief of Social Work Services stated that social workers were deleted from the on-call schedule because of lack of demand for their services.

Recommendation 24

24. The facility director makes certain that the emergency department has on-call social work staff available to assist with patient care and monitors staff compliance.

Facility concurred.

Target date for completion: January 23, 2020

Facility response: The Chief, Social Work is responsible for developing and implementing an on-call schedule for the emergency department.

A clinical social worker is now available 24 hours a day. The Social Work on call schedule was posted to the on call schedule SharePoint website, June 23, 2019. The schedule is accessible to all Emergency Department staff.

The Chief of Social Work will verify presence of call schedule monthly for two quarters to demonstrate 100% compliance with call schedule availability.

The monitoring results will be reported to the monthly Quality Executive Council.

VHA requires that facilities have appropriate signage at all entrances directing patients to the emergency department.[148] The OIG found that the facility's internal signage at the main entrance directed patients down a corridor that was a dead end with no access to the emergency department. In addition, signage at several intersections on the first floor lacked information directing patients to the emergency department. When directional signage is inaccurate, patients may encounter delays when seeking urgent or emergent care. The chief of Environmental Management Service stated that there was a current contract for evaluation of signage throughout the facility.

Recommendation 25

25. The facility director confirms adequate directional signage leads patients to the emergency department and monitors staff compliance.

[148] VHA Directive 1101.05(2).

Facility concurred.

Target date for completion: July 31, 2019

Facility response: The Chief, Environmental Management Service ensured directional signage to the emergency department was installed on January 23, 2019.

Directional signage to the emergency department was installed on January 23, 2019 at the main hospital entrance as well as several intersections on the first floor providing information directing patients to the emergency department.

As facility changes and/or new construction is made, signage will be evaluated to ensure sustainment. Photographs of the new signage are available.

Deputy Director approved installation of new emergency department signage during the survey. Signage will be monitored for sustainment by weekly Construction Safety Rounds.

Incidental Findings

Patient Safety: Medical Record Scanning Backlog

VHA requires timely filing or scanning of reports into patients' EHRs.[149] The OIG found 2,045 inches of patient reports for Malcom Randall VA Medical Center and 134 inches for Lake City VA Medical Center dating back to October 2017 and November 2017, respectively. This prevented healthcare providers from accessing patient results to perform comprehensive evaluations and provide timely quality care. According to the chief of Health Information Management, the backlog is a result of Malcom Randall VAMC being the primary scanning site for most of the North Florida/South Georgia Veterans Health System, and the Health Information Management staff had difficulties keeping up with the workload. The facility leaders were aware of the backlog and, in May 2018, began seeking a vendor to assist with scanning needs. The contracted vendor started on January 7, 2019, but at the time of the OIG visit, had not started scanning.

Recommendation 26

26. The facility director ensures the chief of Health Information Management facilitates the timely scanning of clinical reports into patients' electronic health records and monitors compliance.

[149] VHA Handbook 1907.07, *Management of Health Records File Room and Scanning*, May 12, 2016.

Facility concurred.

Target date for completion: February 20, 2020

Facility response: The Chief, Health Information Management Service is responsible for timely scanning of clinical reports into electronic health records.

The Chief, Health Information Management Service ensured a vendor was on board January 14, 2019 to assist with timely scanning of clinical reports. Scanning by the vendor started March 1, 2019 and Gainesville documents were scanned by the vendor before July 26, 2019 and converted to electronic documents. The vendor completed indexing the electronic documents into the computerized patient record system August 28, 2019. Lake City completed scanning and indexing of their documents May 17, 2019. Current work is being entered timely into the electronic health record by Health Information Management Staff.

To ensure sustainability, Central Office has secured a national contract NF/SGVHS can utilize to address any potential backlogs.

The Chief, Health Information Management Service will monitor the timely filing/scanning of reports into the Electronic Health Records on an ongoing basis and report monthly to the Medical Record Committee. Any backlog of 60 or greater documents that have not been scanned within five business days of receipt will be reported to Executive Leadership Council on an ad-hoc basis.

Environment of Care: Post-Anesthesia Care Unit

TJC requires that hospitals inspect, test, and maintain all high-risk equipment.[150] The OIG found eight cardiac monitors in the post-anesthesia care unit with blue biomedical engineering stickers, indicating the equipment is not a part of the preventative maintenance program. Proper assessment of equipment to determine the potential physical risks associated with the equipment's use, function, and incident history and performing required maintenance activities per manufacturers' recommendations ensures that critical patient care equipment is safe and reliable and operates at the required level of performance. A biomedical engineering supervisor stated the noncompliance was due to a lack of oversight and staff may be unclear how to properly identify preventive maintenance requirements, as wording on the form used for conducting equipment risk assessments may not be specific enough. The biomedical engineering department has not had a chief since 2016.

[150] TJC. Environment of Care standard EC.02.04.03.

Recommendation 27

27. The deputy director ensures medical equipment is evaluated per manufacturers' recommendations and monitors compliance.

Facility concurred.

Target date for completion: January 31, 2020

Facility response: The Chief, Facilities Management Service is ultimately responsible for ensuring medical equipment is evaluated per manufacturers' recommendations.

The cardiac monitors were in the preventative maintenance program although labeling had not occurred. Labeling was corrected during survey. All Biomed staff were re-educated on appropriate labeling during weekly staff meeting on January 22, 2019.

Target compliance rate of 90% of cardiac monitors being evaluated per manufacturers' recommendations for six consecutive months. Identified cardiac monitors without labeling indicating review completed will be addressed within 14 days. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 90% reporting will resume monthly until target of 90% compliance is reached.

Compliance rate of medical equipment being evaluated per manufacturers' recommendations is monitored weekly through Environment of Care rounds and entered in Performance Logic. The weekly data from Environment of Care rounds is collated and presented to Environment of Care Committee for two consecutive quarters.

TJC requires facilities to physically separate and clearly label full and empty oxygen gas cylinders.[151] The OIG noted two of six oxygen gas cylinders in the post-anesthesia care unit were empty and stored with the full tanks. All six tanks were unlabeled, had regulators attached, and were in transport caddies. This could result in staff assuming that all tanks in the post-anesthesia care unit are full or partially full and available for use. The charge nurse in the post anesthesia care unit, an anesthesia tech, and a logistics staff member were not able to explain the process or ownership of the oxygen tanks and how the tanks get to the location but did state that the area where the tanks were found in the post-anesthesia care unit was used to store oxygen cylinders for patient transport.

Recommendation 28

28. The deputy director ensures that full and empty oxygen gas cylinders are physically separated and clearly labeled and monitors compliance.

[151] TJC. Environment of Care standard 02.05.09.

Facility concurred.

Target date for completion: January 31, 2020

Facility response: The Acting Chief Nurse, Perioperative Services ensured all oxygen tanks were removed from the post-anesthesia care unit during survey.

Full oxygen tanks are now delivered to and stored in the operating room. Full tanks are stored in room E147-1 and empty tanks are stored in center-core room C282a-1. The wall and the storage racks are appropriately labeled in both rooms.

Target compliance rate of 100% gas cylinders being physically separated and clearly labeled for six consecutive months. After six months of compliance is achieved, reporting will be changed to quarterly. If compliance falls below 100% then a new action plan will be developed, and reporting will resume monthly until target of 100% compliance is reached.

Compliance with gas cylinders being physically separated and clearly labeled is monitored weekly through Environment of Care rounds and entered in Performance Logic. The weekly data from Environment of Care rounds is collated and will be presented to Environment of Care Committee for two consecutive quarters. The data includes all deficiencies in the hospitals to be completed within 14 days.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

The intent is for facility leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if left unattended, may potentially interfere with the delivery of quality health care.

Healthcare Processes	Performance Indicators	Conclusion
Leadership and Organizational Risks	• Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation and/or for-cause surveys and oversight inspections • Factors related to possible lapses in care • VHA performance data	Twenty-eight OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the director, deputy director, and chief of staff. See details below.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• Protected peer reviews • UM reviews • Patient safety • Resuscitation episode review	• None	• All required representatives participate in the interdisciplinary review of UM data. • The patient safety manager includes all required components in each root cause analysis. • The identified committee reviews all resuscitative episodes.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	• Privileging • FPPEs • OPPEs • FPPEs for cause • Reporting of privileging actions to National Practitioner Data Bank	• Clinical managers clearly define FPPE criteria in advance with providers. • Clinical managers include service/section-specific criteria in OPPEs. • Service chiefs' use results of OPPE activities when making recommendation to continue privileges.	• None

Environment of Care	• Parent facility
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
	• Community based outpatient clinic
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
	• Locked inpatient mental health Unit
	  ○ Mental health environment of care rounds
	  ○ Nursing station security
		• Intensive care unit furnishings are repaired or replaced.
		• Facility management service managers conduct weekly generator testing as required.
			• A safe and clean environment is maintained throughout the healthcare system.
			• Medical biohazardous waste storage rooms are secured and properly identified.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
	○ Public area and general unit safety ○ Patient room safety ○ Infection prevention ○ Availability of medical equipment and supplies • Emergency management ○ Hazard vulnerability analysis (HVA) ○ Emergency operations plan (EOP) ○ Emergency power testing and availability		
Medication Management: Controlled Substances Inspections	• Controlled substances coordinator reports • Pharmacy operations • Controlled substances inspector requirements • Controlled substances area inspections • Pharmacy inspections • Facility review of override reports	• None	• Controlled substances inspectors complete monthly controlled substances inspections and physical inventory counts on the day initiated and the controlled substances coordinator evaluates and maintains supporting documentation. • Controlled substances inspectors do not inspect the same area for two or more consecutive months. • The controlled substances coordinator ensures that written and electronic controlled substance orders have been verified. • Controlled substances inspectors verify there is a corresponding sealed evidence bag containing drug(s) for each medication listed on the "Destructions File Holding Report"

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
			during monthly inspections. • Controlled substances inspectors complete pharmacy prescription pad inventories during monthly pharmacy inspections. • Controlled substances inspectors verify evidence of written signature for non-electronic controlled substances orders during monthly area inspections. • Controlled substances inspectors complete the verification of the twice weekly inventory as required.
Mental Health: Military Sexual Trauma (MST) Follow-Up and Staff Training	• Designated facility MST coordinator • Evidence of tracking MST-related data • Provision of clinical care • Completion of MST mandatory training requirement for mental health and primary care providers	• None	• Providers complete MST mandatory training within the required time frame.
Geriatric Care: Antidepressant Use among the Elderly	• Justification for medication initiation • Evidence of patient and/or caregiver education specific to the medication prescribed • Clinician evaluation of patient and/or caregiver understanding of the education provided • Medication reconciliation	• Clinicians reconcile medication information and maintain accurate patient medication information in patients' electronic health record.	• Clinicians provide and document patient/caregiver education about the safe and effective use of newly prescribed medications.
Women's Health: Abnormal Cervical	• Appointment of a women veterans program manager	• Staff collect and track cervical cancer screening data.	• The Women Veterans Health Committee includes required core members.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Pathology Results Notification and Follow-Up	• Appointment of a women's health medical director or clinical champion • Facility Women Veterans Health Committee • Collection and tracking of cervical cancer screening data • Communication of abnormal results to patients within required time frame • Provision of follow-up care for abnormal cervical pathology results, if indicated		• The Women Veterans Health Committee reports to an executive leadership committee.
High-Risk Processes: Operations and Management of Emergency Departments and UCCs	• General • Staffing for emergency department/UCC • Support services for emergency department/UCC • Patient flow • General safety • Medication security and labeling • Management of patients with mental health disorders • Emergency department participation in local/regional EMS system • Women veteran services • Life support equipment	• None	• The emergency department has on-call social work staff available to assist with patient care. • Adequate directional signage leads patients to the emergency department.
Incidental	• None	• The chief of Health Information Management facilitates the timely scanning of clinical reports into patients' electronic health records.	• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
		• Medical equipment is evaluated per manufacturers' recommendations. • Full and empty oxygen gas cylinders are physically separated and clearly labeled.	

Appendix B: Facility Profile and VA Outpatient Clinic Profiles

Facility Profile

The table below provides general background information for this highest complexity (1a) affiliated[152] facility reporting to VISN 8.[153]

Table B.1. Facility Profile for North Florida/South Georgia Veterans Health System (573) (October 1, 2015, through September 30, 2018)

Profile Element	Facility Data FY 2016[154]	Facility Data FY 2017[155]	Facility Data FY 2018[156]
Total medical care budget dollars	$1,093,621,720	$1,108,131,046	$1,151,218,428
Number of:			
• Unique patients	136,637	138,651	141,053
• Outpatient visits	1,689,627	1,707,118	1,760,571
• Unique employees[157]	4,900	4,938	4,853
Type and number of operating beds:			
• Community living center	221	221	221
• Domiciliary	74	74	74
• Medicine	170	170	170
• Mental health	48	48	48
• Neurology	4	4	4
• Surgery	69	69	69
Average daily census:			
• Community living center	122	127	129
• Domiciliary	71	70	69
• Medicine	127	124	115

[152] Associated with a medical residency program.

[153] The VHA medical centers are classified according to a facility complexity model; a designation of "1a" indicates facilities with "high volume, high-risk patients, most complex clinical programs, and large research and teaching programs."

[154] October 1, 2015, through September 30, 2016.

[155] October 1, 2016, through September 30, 2017.

[156] October 1, 2017, through September 30, 2018.

[157] Unique employees involved in direct medical care (cost center 8200).

Profile Element	Facility Data FY 2016[154]	Facility Data FY 2017[155]	Facility Data FY 2018[156]
• Mental health	44	41	43
• Neurology	3	3	3
• Surgery	31	31	29

Source: VA Office of Academic Affiliations, VHA Support Service Center, and VA Corporate Data Warehouse
Note: The OIG did not assess VA's data for accuracy or completeness.

VA Outpatient Clinic Profiles[158]

The VA outpatient clinics in communities within the catchment area of the facility provide primary care integrated with women's health, mental health, and telehealth services. Some also provide specialty care, diagnostic, and ancillary services. Table B.2. provides information relative to each of the clinics.

Table B.2. VA Outpatient Clinic Workload/Encounters and Specialty Care, Diagnostic, and Ancillary Services Provided (October 1, 2017, through September 30, 2018)[159]

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
Valdosta, GA	573GA	10,599	4,642	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Cardio thoracic	n/a	Nutrition Pharmacy Prosthetics Social work Weight management

[158] Includes all outpatient clinics in the community that were in operation as of August 15, 2018. The OIG omitted Gainesville 2-98th Street, FL (573QB); Gainesville 4-64th Street (O), FL (573QD); Gainesville 5-64th Street (D), FL (573QE); and Ocala West, FL (573QH), as no data was reported.

[159] The definition of an "encounter" can be found in VHA Directive 2010-049, *Encounter and Workload Capture for Therapeutic and Supported Employment Services Vocational Programs*, October 14, 2010. (This directive expired on October 31, 2015 and has not been updated.) An encounter is a "professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient's condition."

[160] Specialty care services refer to non-primary care and non-mental health services provided by a physician.

[161] Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

[162] Ancillary services include chiropractic, dental, nutrition, pharmacy, prosthetic, social work, and weight management services.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
Ocala, FL	573GD	19,032	8,226	Cardiology Dermatology Endocrinology Hematology/ Oncology Nephrology Eye Podiatry	EKG	Nutrition Pharmacy Social work Weight management
Saint Augustine, FL	573GE	10,009	6,671	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Poly-trauma Podiatry	EKG	Pharmacy Social work Weight management Nutrition
Lecanto, FL	573GG	14,829	7,764	Cardiology Dermatology Hematology/ Oncology Infectious disease Anesthesia	EKG	Pharmacy Social Work Weight management Nutrition
St. Mary's, GA	573GJ	6,548	3,840	Dermatology	EKG	Pharmacy Social work

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
Tallahassee, FL	573GF	30,850	11,823	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Nephrology Neurology Pulmonary/ Respiratory disease Poly-trauma Anesthesia Eye GYN Plastic Podiatry Urology Vascular	Laboratory & Pathology Radiology	Pharmacy Prosthetics Social work Weight management Dental Nutrition
Marianna, FL	573GK	7,092	3,009	Cardiology Dermatology Endocrinology Hematology/ Oncology Infectious disease Anesthesia Podiatry	n/a	Nutrition Pharmacy Prosthetics Social work Weight management

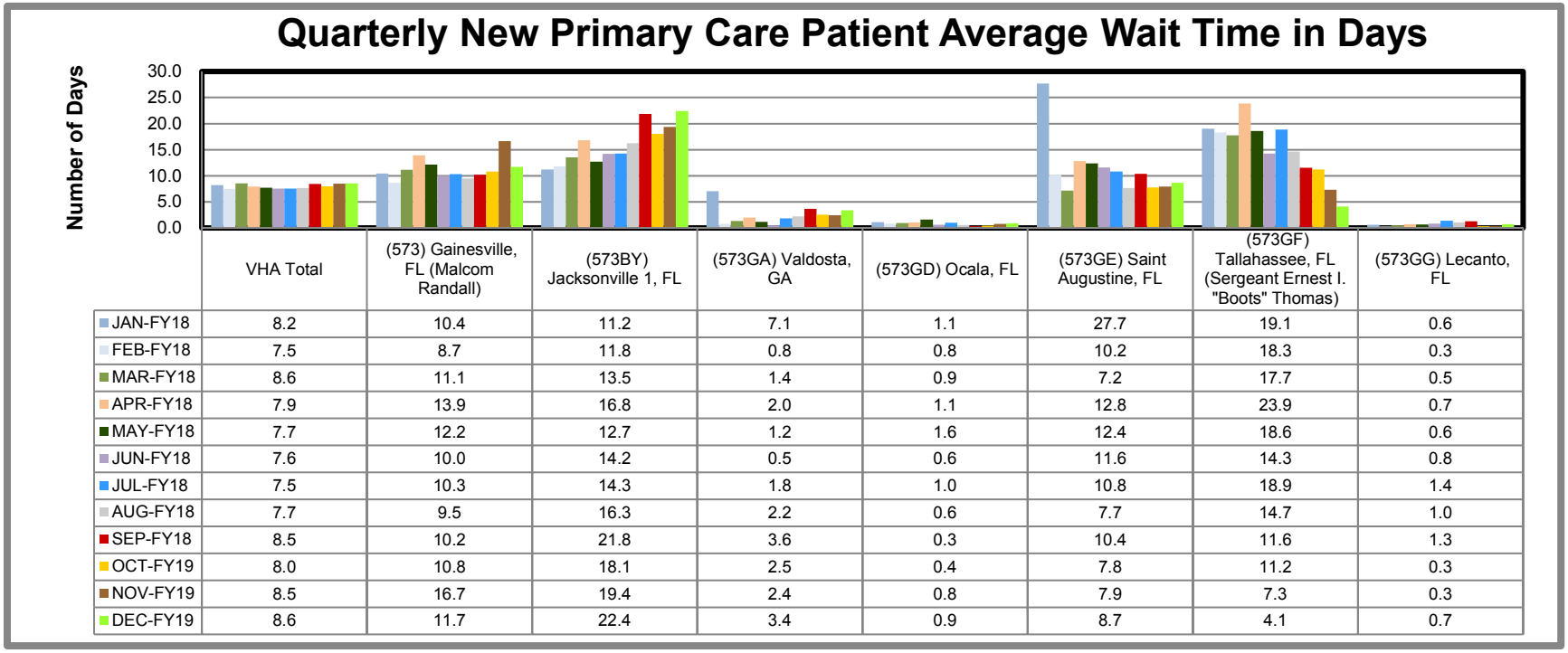
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
The Villages, FL	573GI	28,859	9,821	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Poly-trauma Anesthesia Eye Neurosurgery Podiatry Vascular	EKG Laboratory & Pathology Radiology	Pharmacy Prosthetic Social work Weight management Dental Nutrition
Palatka, FL	573GL	7,069	3,425	Cardiology Dermatology Endocrinology Hematology/ Oncology Rheumatology	EKG	Pharmacy Weight management Nutrition
Waycross, GA	573GM	4,207	2,576	Cardiology Dermatology Hematology/ Oncology Infectious disease Anesthesia	EKG	Pharmacy Social work Weight management Nutrition
Perry, FL	573GN	2,540	161	Cardiology Hematology/ Oncology	n/a	Pharmacy Social work Nutrition

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
Gainesville, FL	573QA	n/a	3,122	n/a	n/a	n/a
Gainesville, FL	573QC	n/a	2,800	Eye	n/a	n/a
Gainesville, FL	573QF	n/a	117	n/a	n/a	n/a
Jacksonville, FL	573QG	17,970	20,550	Endocrinology Poly-trauma Rehab physician Anesthesia	EMG	Nutrition Pharmacy Prosthetics Social work Weight management
Jacksonville, FL	573QJ	15,269	5,906	Nephrology Rheumatology GYN	n/a	Pharmacy Social work

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[160] Provided	Diagnostic Services[161] Provided	Ancillary Services[162] Provided
Jacksonville, FL	573BY	28,642	7,577	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Nephrology Pulmonary/ Respiratory disease Poly-trauma Rehab physician Anesthesia Eye GYN Orthopedics Podiatry Urology Vascular	EKG Laboratory & Pathology Nuclear med Radiology Vascular lab	Nutrition Pharmacy Social work Weight management Dental

Source: VHA Support Service Center and VA Corporate Data Warehouse
Note: The OIG did not assess VA's data for accuracy or completeness.
n/a = not applicable

Appendix C: Patient Aligned Care Team Compass Metrics[163]



	VHA Total	(573) Gainesville, FL (Malcom Randall)	(573BY) Jacksonville 1, FL	(573GA) Valdosta, GA	(573GD) Ocala, FL	(573GE) Saint Augustine, FL	(573GF) Tallahassee, FL (Sergeant Ernest I. "Boots" Thomas)	(573GG) Lecanto, FL
JAN-FY18	8.2	10.4	11.2	7.1	1.1	27.7	19.1	0.6
FEB-FY18	7.5	8.7	11.8	0.8	0.8	10.2	18.3	0.3
MAR-FY18	8.6	11.1	13.5	1.4	0.9	7.2	17.7	0.5
APR-FY18	7.9	13.9	16.8	2.0	1.1	12.8	23.9	0.7
MAY-FY18	7.7	12.2	12.7	1.2	1.6	12.4	18.6	0.6
JUN-FY18	7.6	10.0	14.2	0.5	0.6	11.6	14.3	0.8
JUL-FY18	7.5	10.3	14.3	1.8	1.0	10.8	18.9	1.4
AUG-FY18	7.7	9.5	16.3	2.2	0.6	7.7	14.7	1.0
SEP-FY18	8.5	10.2	21.8	3.6	0.3	10.4	11.6	1.3
OCT-FY19	8.0	10.8	18.1	2.5	0.4	7.8	11.2	0.3
NOV-FY19	8.5	16.7	19.4	2.4	0.8	7.9	7.3	0.3
DEC-FY19	8.6	11.7	22.4	3.4	0.9	8.7	4.1	0.7

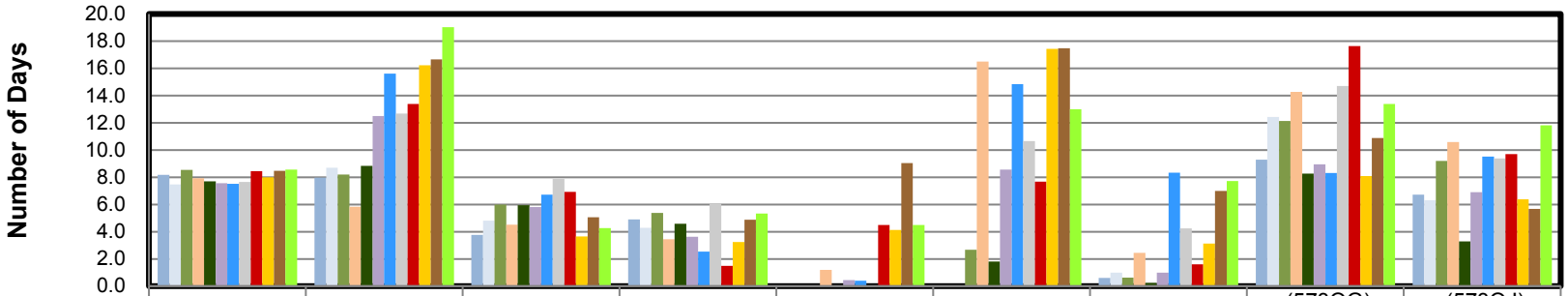
Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. *The OIG omitted Gainesville 1-16th Street, FL (573QA); Gainesville 2-98th Street, FL (573QB); Gainesville 3-64th Street (C), FL (573QC); Gainesville 4-64th Street (O), FL (573QD); Gainesville 5-64th Street (D), FL (573QE); and Ocala West, FL (573QH), as no data were reported.*

Data Definition: "The average number of calendar days between a New Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date." Note that prior to FY15, this metric was calculated using the earliest possible create date.

[163] Department of Veterans Affairs, Patient Aligned Care Teams Compass Data Definitions, accessed September 13, 2018.

Quarterly New Primary Care Patient Average Wait Time in Days (cont.)

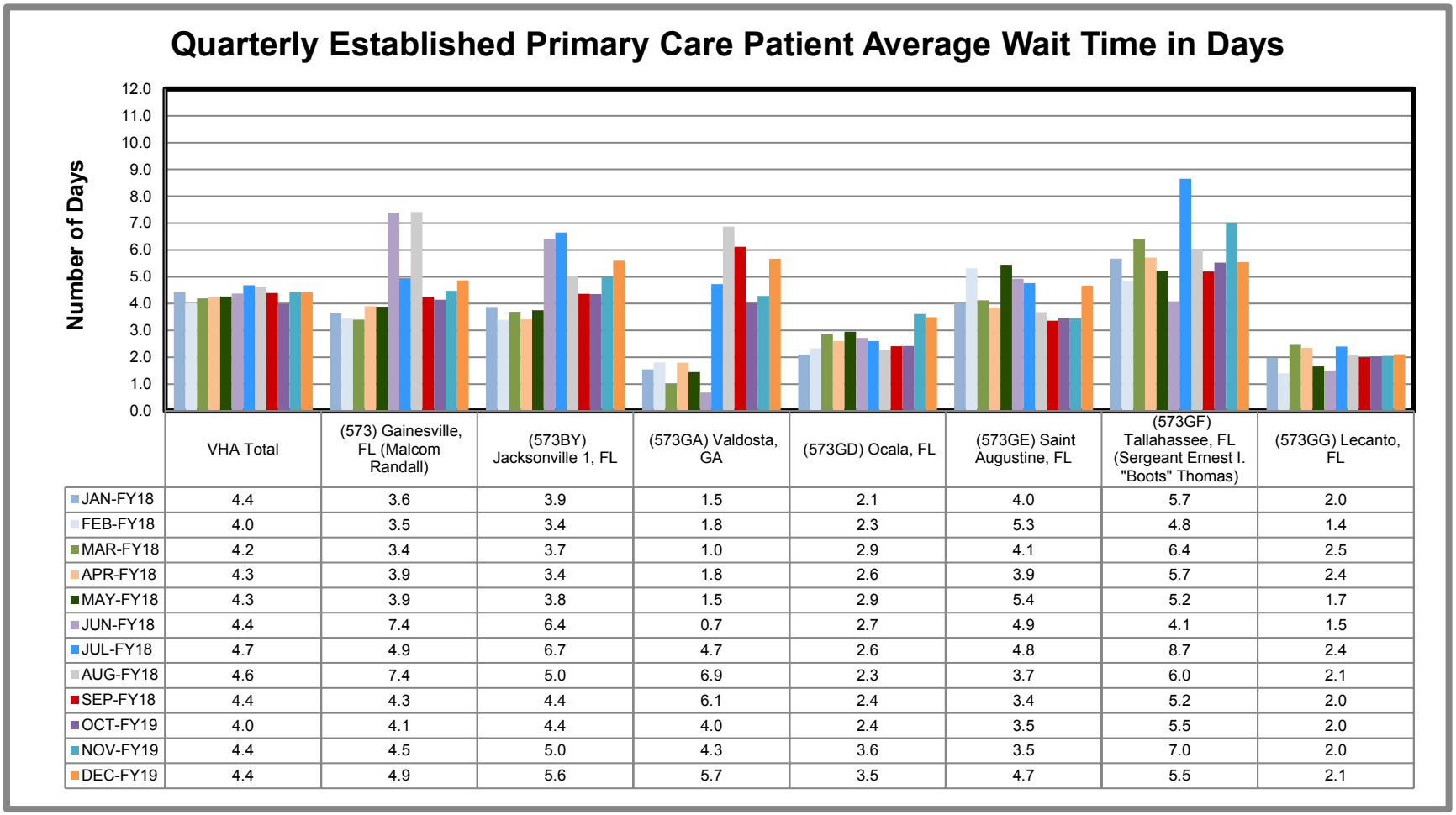


	VHA Total	(573GI) The Villages, FL	(573GJ) St. Marys, GA	(573GK) Marianna, FL	(573GL) Palatka, FL	(573GM) Waycross, GA	(573GN) Perry, FL	(573QG) Jacksonville Southpoint, FL	(573QJ) Jacksonville 2 University Boulevard, FL
JAN-FY18	8.2	8.0	3.8	4.9	0.0	0.0	0.6	9.3	6.7
FEB-FY18	7.5	8.7	4.8	4.3	0.0	0.0	1.0	12.4	6.3
MAR-FY18	8.6	8.2	6.0	5.4	0.0	2.7	0.6	12.1	9.2
APR-FY18	7.9	5.8	4.5	3.5	1.2	16.5	2.4	14.3	10.6
MAY-FY18	7.7	8.8	6.0	4.6	0.1	1.8	0.3	8.3	3.3
JUN-FY18	7.6	12.5	5.8	3.6	0.5	8.6	1.0	9.0	6.9
JUL-FY18	7.5	15.6	6.7	2.5	0.4	14.8	8.3	8.3	9.5
AUG-FY18	7.7	12.7	7.9	6.1	0.0	10.7	4.3	14.7	9.4
SEP-FY18	8.5	13.4	6.9	1.5	4.5	7.7	1.6	17.6	9.7
OCT-FY19	8.0	16.2	3.6	3.3	4.1	17.4	3.1	8.1	6.4
NOV-FY19	8.5	16.7	5.1	4.9	9.1	17.5	7.0	10.9	5.7
DEC-FY19	8.6	19.0	4.3	5.3	4.5	13.0	7.7	13.4	11.8

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. *The OIG omitted Gainesville 1-16th Street, FL (573QA); Gainesville 2-98th Street, FL (573QB); Gainesville 3-64th Street (C), FL (573QC); Gainesville 4-64th Street (O), FL (573QD); Gainesville 5-64th Street (D), FL (573QE); and Ocala West, FL (573QH), as no data were reported.*

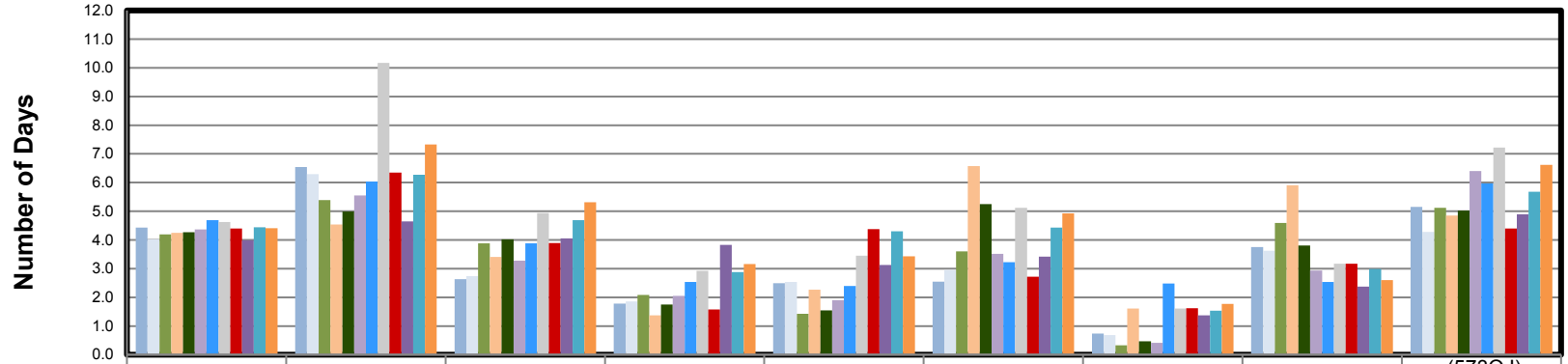
Data Definition: "The average number of calendar days between a New Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date." Note that prior to FY15, this metric was calculated using the earliest possible create date.



	VHA Total	(573) Gainesville, FL (Malcom Randall)	(573BY) Jacksonville 1, FL	(573GA) Valdosta, GA	(573GD) Ocala, FL	(573GE) Saint Augustine, FL	(573GF) Tallahassee, FL (Sergeant Ernest I. "Boots" Thomas)	(573GG) Lecanto, FL
JAN-FY18	4.4	3.6	3.9	1.5	2.1	4.0	5.7	2.0
FEB-FY18	4.0	3.5	3.4	1.8	2.3	5.3	4.8	1.4
MAR-FY18	4.2	3.4	3.7	1.0	2.9	4.1	6.4	2.5
APR-FY18	4.3	3.9	3.4	1.8	2.6	3.9	5.7	2.4
MAY-FY18	4.3	3.9	3.8	1.5	2.9	5.4	5.2	1.7
JUN-FY18	4.4	7.4	6.4	0.7	2.7	4.9	4.1	1.5
JUL-FY18	4.7	4.9	6.7	4.7	2.6	4.8	8.7	2.4
AUG-FY18	4.6	7.4	5.0	6.9	2.3	3.7	6.0	2.1
SEP-FY18	4.4	4.3	4.4	6.1	2.4	3.4	5.2	2.0
OCT-FY19	4.0	4.1	4.4	4.0	2.4	3.5	5.5	2.0
NOV-FY19	4.4	4.5	5.0	4.3	3.6	3.5	7.0	2.0
DEC-FY19	4.4	4.9	5.6	5.7	3.5	4.7	5.5	2.1

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted Gainesville 1-16th Street, FL (573QA); Gainesville 2-98th Street, FL (573QB); Gainesville 3-64th Street (C), FL (573QC); Gainesville 4-64th Street (O), FL (573QD); Gainesville 5-64th Street (D), FL (573QE); and Ocala West, FL (573QH), as no data was reported.
Data Definition: "The average number of calendar days between an Established Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding Compensation and Pension appointments) and the earliest of three possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date."

Quarterly Established Primary Care Patient Average Wait Time in Days (cont.)



	VHA Total	(573GI) The Villages, FL	(573GJ) St. Marys, GA	(573GK) Marianna, FL	(573GL) Palatka, FL	(573GM) Waycross, GA	(573GN) Perry, FL	(573QG) Jacksonville Southpoint, FL	(573QJ) Jacksonville 2 University Boulevard, FL
JAN-FY18	4.4	6.5	2.6	1.8	2.5	2.5	0.7	3.8	5.2
FEB-FY18	4.0	6.3	2.7	1.9	2.5	3.0	0.7	3.6	4.3
MAR-FY18	4.2	5.4	3.9	2.1	1.4	3.6	0.3	4.6	5.1
APR-FY18	4.3	4.5	3.4	1.4	2.3	6.6	1.6	5.9	4.9
MAY-FY18	4.3	5.0	4.0	1.8	1.5	5.2	0.5	3.8	5.0
JUN-FY18	4.4	5.6	3.3	2.1	1.9	3.5	0.4	2.9	6.4
JUL-FY18	4.7	6.0	3.9	2.5	2.4	3.2	2.5	2.5	6.0
AUG-FY18	4.6	10.2	4.9	2.9	3.5	5.1	1.6	3.2	7.2
SEP-FY18	4.4	6.4	3.9	1.6	4.4	2.7	1.6	3.2	4.4
OCT-FY19	4.0	4.6	4.1	3.8	3.1	3.4	1.4	2.4	4.9
NOV-FY19	4.4	6.3	4.7	2.9	4.3	4.4	1.5	3.0	5.7
DEC-FY19	4.4	7.3	5.3	3.2	3.4	4.9	1.8	2.6	6.6

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (573QA) Gainesville 1-16th Street, FL (573QA); Gainesville 2-98th Street, FL (573QB; Gainesville 3-64th Street (C), FL (573QC); Gainesville 4-64th Street (O), FL (573QD); Gainesville 5-64th Street (D), FL (573QE); and Ocala West, FL (573QH), as no data was reported.
Data Definition: "The average number of calendar days between an Established Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding Compensation and Pension appointments) and the earliest of three possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date."

Appendix D: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions[164]

Measure	Definition	Desired Direction
ACSC hospitalization	Ambulatory care sensitive conditions hospitalizations	A lower value is better than a higher value
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
Admit reviews met	Percent acute admission reviews that meet interqual criteria	A higher value is better than a lower value
APP capacity	Advanced practice provider capacity	A lower value is better than a higher value
Best place to work	All employee survey best places to work score	A higher value is better than a lower value
Call responsiveness	Call center speed in picking up calls and telephone abandonment rate	A lower value is better than a higher value
Care transition	Care transition (Inpatient)	A higher value is better than a lower value
Complications	Acute care risk adjusted complication ratio (observed to expected ratio)	A lower value is better than a higher value
Comprehensiveness	Comprehensiveness (PCMH)	A higher value is better than a lower value
Cont stay reviews met	Percent acute continued stay reviews that meet interqual criteria	A higher value is better than a lower value
Efficiency	Overall efficiency measured as 1 divided by SFA (Stochastic Frontier Analysis)	A higher value is better than a lower value
Efficiency/capacity	Efficiency and physician capacity	A higher value is better than a lower value
Employee satisfaction	Overall satisfaction with job	A higher value is better than a lower value

[164] VHA Support Service Center (VSSC), Strategic Analytics for Improvement and Learning (SAIL) (last updated December 26, 2018). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938. (The website was accessed on March 7, 2019, but is not accessible by the public.)

Measure	Definition	Desired Direction
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like	Outpatient performance measure (HEDIS)	A higher value is better than a lower value
HEDIS like – HED90_1	HEDIS-EPRP based PRV TOB BHS	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS-eOM based DM IHD	A higher value is better than a lower value
MH wait time	Mental health care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx	ORYX	A higher value is better than a lower value
PC routine care appt	Timeliness in getting a PC routine care appointment (PCMH)	A higher value is better than a lower value
PC urgent care appt	Timeliness in getting a PC urgent care appointment (PCMH)	A higher value is better than a lower value
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
Physician capacity	Physician capacity	A lower value is better than a higher value
PC wait time	PC wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
PSI	Patient safety indicator (observed to expected ratio)	A lower value is better than a higher value

Measure	Definition	Desired Direction
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RN turnover	Registered nurse turnover rate	A lower value is better than a higher value
RSMR-AMI	30-day risk standardized mortality rate for acute myocardial infarction	A lower value is better than a higher value
RSMR-CHF	30-day risk standardized mortality rate for congestive heart failure	A lower value is better than a higher value
RSMR-COPD	30-day risk standardized mortality rate for COPD	A lower value is better than a higher value
RSMR-pneumonia	30-day risk standardized mortality rate for pneumonia	A lower value is better than a higher value
RSRR-AMI	30-day risk standardized readmission rate for acute myocardial infarction	A lower value is better than a higher value
RSRR-cardio	30-day risk standardized readmission rate for cardiorespiratory patient cohort	A lower value is better than a higher value
RSRR-CHF	30-day risk standardized readmission rate for congestive heart failure	A lower value is better than a higher value
RSRR-COPD	30-day risk standardized readmission rate for COPD	A lower value is better than a higher value
RSRR-CV	30-day risk standardized readmission rate for cardiovascular patient cohort	A lower value is better than a higher value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
RSRR-med	30-day risk standardized readmission rate for medicine patient cohort	A lower value is better than a higher value
RSRR-neuro	30-day risk standardized readmission rate for neurology patient cohort	A lower value is better than a higher value
RSRR-pneumonia	30-day risk standardized readmission rate for pneumonia	A lower value is better than a higher value
RSRR-surg	30-day risk standardized readmission rate for surgery patient cohort	A lower value is better than a higher value

Measure	Definition	Desired Direction
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC routine care appt	Timeliness in getting a SC routine care appointment (specialty care)	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SC urgent care appt	Timeliness in getting a SC urgent care appointment (specialty care)	A higher value is better than a lower value
Seconds pick up calls	Average speed of call center responded to calls in seconds	A lower value is better than a higher value
SMR	Acute care in-hospital standardized mortality ratio	A lower value is better than a higher value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Specialty care wait time	Specialty care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value
Telephone abandonment rate	Telephone abandonment rate	A lower value is better than a higher value

VHA Support Service Center

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Community Living Center (CLC) Measure Definitions[165]

Measure	Definition
Ability to move independently worsened (LS)	Long-stay measure: percentage of residents whose ability to move independently worsened.
Catheter in bladder (LS)	Long-stay measure: percent of residents who have/had a catheter inserted and left in their bladder.
Falls with major injury (LS)	Long-stay measure: percent of residents experiencing one or more falls with major injury.
Help with ADL (LS)	Long-stay measure: percent of residents whose need for help with activities of daily living has increased.
High risk PU (LS)	Long-stay measure: percent of high-risk residents with pressure ulcers.
Improvement in function (SS)	Short-stay measure: percentage of residents whose physical function improves from admission to discharge.
Moderate-severe pain (LS)	Long-stay measure: percent of residents who self-report moderate to severe pain.
Moderate-severe pain (SS)	Short-stay measure: percent of residents who self-report moderate to severe pain.
New or worse PU (SS)	Short-stay measure: percent of residents with pressure ulcers that are new or worsened.
Newly received antipsych meds (SS)	Short-stay measure: percent of residents who newly received an antipsychotic medication.
Physical restraints (LS)	Long-stay measure: percent of residents who were physically restrained.
Receive antipsych meds (LS)	Long-stay measure: percent of residents who received an antipsychotic medication.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

[165] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated November 19, 2018). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on March 6, 2019, but is not accessible by the public.)

Appendix F: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: September 11, 2019

From: Network Director, VISN 8 (10N8)

Subj: Comprehensive Healthcare Inspection of the North Florida/South Georgia Veterans Healthcare System, Gainesville, FL

To: Director, Bay Pines Office of Healthcare Inspections (54CH03)

Director, GAO/OIG Accountability Liaison (VHA 10EG GOAL Action)

1. I have reviewed the OIG's findings and recommendations concerning the Comprehensive Healthcare Inspection of the North Florida/South Georgia Veterans Healthcare system and concur.

2. Additionally, I have reviewed the action plans and timeline for completion as submitted by the Director, North Florida/South Georgia Veterans Healthcare System and concur. VISN 8 will assist with ensuring timely and sustained compliance.

(Original signed by:)

Miguel H. LaPuz, M.D., MBA

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Appendix G: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: September 9, 2019

From: Director, North Florida/South Georgia Veterans Health System (573/00)

Subj: Comprehensive Healthcare Inspection of the North Florida/South Georgia Veterans Health System, Gainesville, FL

To: Director, VA Sunshine Healthcare Network (10N8)

1. I have reviewed and concur with the findings and recommendations in the report of the Comprehensive Healthcare Inspection Review.

2. Corrective action plans have been established with planned completion dates, as detailed in the attached report.

(Original signed by:)

Thomas Wisnieski, MPA, FACHE

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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Other Contributors	Shirley Carlile, BA Limin Clegg, PhD Justin Hanlon, BS LaFonda Henry, MSN, RN-BC Gayle Karamanos, MS, PA-C Yoonhee Kim, PharmD Susan Lott, MSA, RN Scott McGrath, BS Larry Ross, Jr., MS Marilyn Stones, BS Erin Stott, MSN, RN April Terenzi, BA, BS Mary Toy, MSN, RN Robert Wallace, ScD, MPH

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