



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare
Inspection of the Central
Alabama Veterans Health
Care System in Montgomery

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Figure 1. Central Alabama Veterans Health Care System in Montgomery (Source: <https://vaww.va.gov/directory/guide/>, accessed on March 24, 2020)

Abbreviations

ADPCS	Associate Director for Patient Care Services
CBOC	community-based outpatient clinic
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
FPPE	focused professional practice evaluation
FY	fiscal year
HRS	high risk for suicide
LIP	licensed independent practitioner
LST	life-sustaining treatments
LSTD	life-sustaining treatments decision
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
RME	reusable medical equipment
SAIL	Strategic Analytics for Improvement and Learning
SLB	state licensing board
SOP	standard operating procedure
SPC	suicide prevention coordinator
SPS	Sterile Processing Services
TJC	The Joint Commission
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Central Alabama Veterans Health Care System, which includes two divisions, Montgomery–West Campus and Tuskegee–East Campus, and multiple outpatient clinics in Alabama and Georgia. 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 inspections 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 and at the time of the inspection, focused on the following clinical areas:

1. Quality, safety, and value
2. Medical staff privileging
3. Environment of care
4. Medication management (targeting long-term opioid therapy for pain)
5. Mental health (focusing on the suicide prevention program)
6. Care coordination (spotlighting life-sustaining treatment decisions)
7. Women’s health (examining comprehensive care)
8. High-risk processes (emphasizing reusable medical equipment)

The unannounced visit was conducted during the week of February 24, 2020, at the Central Alabama Veterans Health Care System (Montgomery and Tuskegee campuses) and Central Alabama Montgomery VA Clinic. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of 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 healthcare system’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 healthcare system and other Veterans Health Administration (VHA) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

Leadership and Organizational Risks

At the time of the OIG's visit, the healthcare system's leadership team consisted of the acting Director, acting Chief of Staff, acting Associate Director for Patient Care Services (ADPCS)/Nurse Executive, Deputy Director, and acting Associate Director. Organizational communications and accountability were managed through a committee reporting structure with the Medical Center Governing Board overseeing several working groups. The leaders monitor patient safety and care through the Quality Safety Value Council which was responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this inspection, the healthcare system's Deputy Director was the only tenured leader, permanently assigned in November 2017. The system director position had been vacant since October 2019; an acting Director had been assigned since that time. The chief of staff position had been vacant since February 2018, and five individuals had served in an acting capacity. The current acting Chief of Staff was assigned in August 2019. The ADPCS position had been vacant since August 2019, with the current acting ADPCS serving since January 2020. The associate director position had been vacant since April 2019, with the current acting Associate Director serving since November 2019.

The OIG reviewed selected employee satisfaction survey results and found multiple opportunities for improvement. Selected patient experience survey scores generally reflected lower ratings than the VHA average.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and did not identify any substantial organizational risk factors.¹

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (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.²

The executive leaders were generally knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing SAIL measures. However, leaders lacked understanding of Community Living Center (CLC) SAIL measures,

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."

² VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, <https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428>. (The website was accessed on March 6, 2020, but is not accessible by the public.)

despite the healthcare system's generally positive results.³ In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and patient experiences.

The OIG noted opportunities for improvement in all eight clinical areas reviewed and issued 30 recommendations that are directed to the Director, Chief of Staff, ADPCS, Deputy Director, and Associate Director. These are briefly described below.

Quality, Safety, and Value

The healthcare system complied with requirements for establishment of a committee responsible for quality, safety, and value oversight functions. However, the OIG identified significant opportunities for improvement with peer review, utilization management, and root cause analysis processes.⁴

Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluation and provider exit review processes.⁵

Environment of Care

The healthcare system largely met the requirements for general safety, privacy, and accommodation for women veterans. At the time of the site visit, the OIG did not note any issues with the availability of medical equipment and supplies; however, during a subsequent OIG visit to review COVID-19 screening processes and pandemic readiness, healthcare system staff reported an inadequate supply of hand sanitizer.⁶ The OIG identified issues with cleanliness and infection prevention at the Tuskegee campus.

³ According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as Nursing Home Care Units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

⁴ The definition of utilization management can be found within VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria."

⁵ The definitions of focused professional practice evaluation and ongoing 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."

⁶ VA OIG, *Inspection of Veterans Health Administration's COVID-19 Screening Processes and Pandemic Readiness, March 19-24, 2020*, Report No. 20-02221-120, March 26, 2020.

Medication Management

The OIG observed significant concerns with medication management of long-term opioid therapy, including aberrant behavior risk assessments, documented justification for concurrent therapy with benzodiazepines, urine drug testing, informed consent, patient follow-up after therapy initiation, and multidisciplinary Pain Management Committee activities.

Mental Health

The OIG found compliance with requirements for a designated suicide prevention coordinator, patient tracking, monthly outreach activities, and suicide safety plans. However, areas for improvement included completion of at least four mental health visits within 30 days of High Risk for Suicide flag placement and fulfillment of the annual suicide prevention training requirement.

Care Coordination

Generally, the healthcare system met expectations for the Life-Sustaining Treatment Decisions Committee. However, goals of care conversations were not always completed before patients were referred to hospice.

Women's Health

The OIG found the healthcare system complied with many of the provision of care and staffing requirements for women's health. However, the OIG noted concerns with the Women Veterans Health Committee.

High-Risk Processes

The healthcare system met the requirements for a current reusable medical equipment inventory, standard operating procedures, quality assurance monitoring, and most of the reprocessing and storage area physical inspection elements reviewed. The OIG identified deficiencies with the annual risk analysis; airflow monitoring; and staff training, competency, and continuing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 30 recommendations for improvement to the System Director, Chief of Staff, ADPCS, Deputy Director, and Associate Director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this system. The intent is for system 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 not addressed, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and acting System Director agreed with the CHIP review findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 85–86, 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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Contents

Abbreviations	ii
Report Overview	iii
Inspection Results.....	iv
Purpose and Scope.....	1
Methodology	3
Results and Recommendations.....	5
Leadership and Organizational Risks.....	5
Quality, Safety, and Value.....	21
Recommendation 1	23
Recommendation 2.....	24
Recommendation 3.....	25
Recommendation 4.....	26
Recommendation 5.....	26
Recommendation 6.....	27
Recommendation 7.....	28
Medical Staff Privileging.....	29
Recommendation 8.....	31
Recommendation 9.....	32
Recommendation 10.....	32

Environment of Care 34

 Recommendation 11 36

Medication Management: Long-Term Opioid Therapy for Pain 37

 Recommendation 12 39

 Recommendation 13 39

 Recommendation 14 40

 Recommendation 15 41

 Recommendation 16 42

 Recommendation 17 43

 Recommendation 18 44

 Recommendation 19 45

Mental Health: Suicide Prevention Program 47

 Recommendation 20 51

 Recommendation 21 52

Care Coordination: Life-Sustaining Treatment Decisions 53

 Recommendation 22 55

Women’s Health: Comprehensive Care 57

 Recommendation 23 59

 Recommendation 24 60

High-Risk Processes: Reusable Medical Equipment 61

Recommendation 25..... 63

Recommendation 26..... 64

Recommendation 27..... 65

Recommendation 28..... 66

Recommendation 29..... 67

Recommendation 30..... 67

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings 69

Appendix B: Healthcare System Profile 76

Appendix C: VA Outpatient Clinic Profiles..... 78

Appendix D: Patient Aligned Care Team Compass Metrics..... 80

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions 82

Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions..... 84

Appendix G: VISN Director Comments 85

Appendix H: Central Alabama Veterans Health Care System Director Comments 86

OIG Contact and Staff Acknowledgments 87

Report Distribution..... 88



Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities providing healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Central Alabama Veterans Health Care System examines a broad range of key clinical and administrative processes associated with positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and healthcare system leaders so that informed decisions can be made to improve care.

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change.¹ Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes.² Figure 2 illustrates 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, the OIG focused on core processes in the following nine areas of administrative and clinical operations:

1. Leadership and organizational risks
2. Quality, safety, and value (QSV)
3. Medical staff privileging
4. Environment of care
5. Medication management (targeting long-term opioid therapy for pain)
6. Mental health (focusing on the suicide prevention program)
7. Care coordination (spotlighting life-sustaining treatment decisions)
8. Women's health (examining comprehensive care)
9. High-risk processes (emphasizing reusable medical equipment)³

¹ 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 September 25, 2019.)

² Jamie Leviton and Jackie Valentine, "How risk management and patient safety intersect: Strategies to help make it happen," *Institute for Healthcare Improvement and National Patient Safety Foundation (NPSF)*, March 24, 2015.

³ See Figure 2. CHIP inspections address these processes during FY 2020 (October 1, 2019, through September 30, 2020); they may differ from prior years' focus areas.

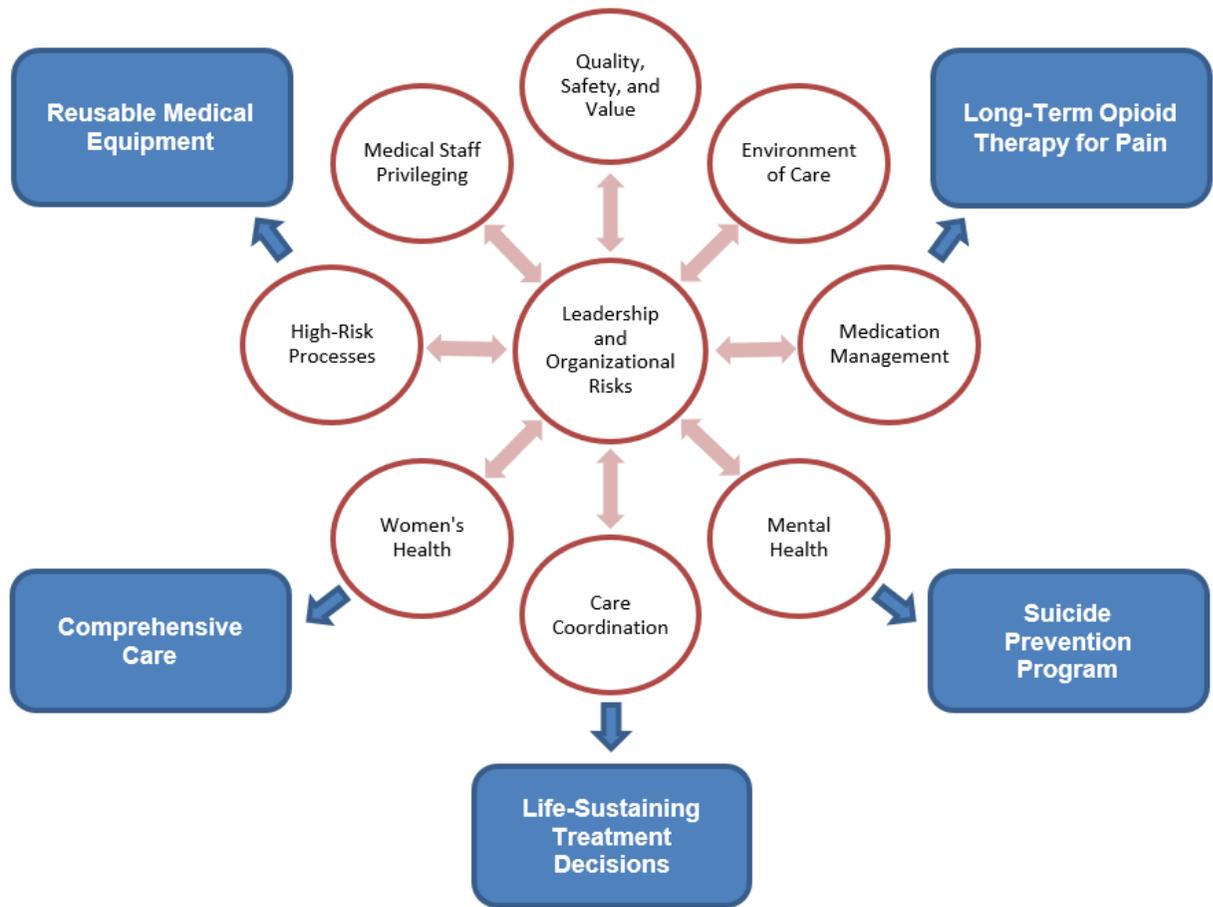


Figure 2. Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services
Source: VA OIG

Methodology

The Central Alabama Veterans Health Care System includes the Montgomery–West Campus, Tuskegee–East Campus, and multiple outpatient clinics in Alabama and Georgia. Additional details about the types of care provided by the healthcare system can be found in Appendixes B and C.

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.⁴

The OIG team also selected and physically inspected the Central Alabama Montgomery VA Clinic and the following areas of the Montgomery–West Campus and Tuskegee–East Campus:

- Montgomery
 - Emergency Department
 - Intensive care unit
 - Medical/surgical inpatient unit
 - Post-anesthesia care unit
 - Specialty clinic
 - Sterile processing services areas
- Tuskegee
 - Acute psychiatric units
 - Community living centers (CLCs)⁵
 - Primary care clinic
 - Rehabilitation-physical therapy/occupational therapy clinic

The OIG inspection team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

⁴ The OIG did not review VHA’s internal survey results, instead focused on OIG inspections and external surveys that affect facility accreditation status.

⁵ According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as Nursing Home Care Units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

The inspection examined operations from June 10, 2017, through February 28, 2020, the last day of the unannounced multiday site visit.⁶ While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leadership, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

This report's recommendations for improvement address problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the healthcare system completes corrective actions. The System Director's responses to the report recommendations appear within each topic area. The OIG accepted the action plans that the system leaders developed based on the reasons for noncompliance.

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

⁶ The range represents the time period from the prior CHIP inspection to the completion of the unannounced, multiday CHIP site visit in February 2020.

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare system. Leadership and organizational risks can impact the healthcare system's ability to provide care in the clinical focus areas.⁷ To assess the healthcare system's risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation surveys and oversight inspections
5. Identified factors related to possible lapses in care and healthcare system response
6. VHA performance data (healthcare system)
7. VHA performance data (CLCs)

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 healthcare system's reported organizational structure. The healthcare system has a leadership team consisting of the acting Director, acting Chief of Staff, acting Associate Director for Patient Care Services (ADPCS)/Nurse Executive, Deputy Director, and acting Associate Director. The acting Chief of Staff and acting ADPCS oversee patient care which requires managing service directors and chiefs of programs and practices.

⁷ 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 November 6, 2019.)

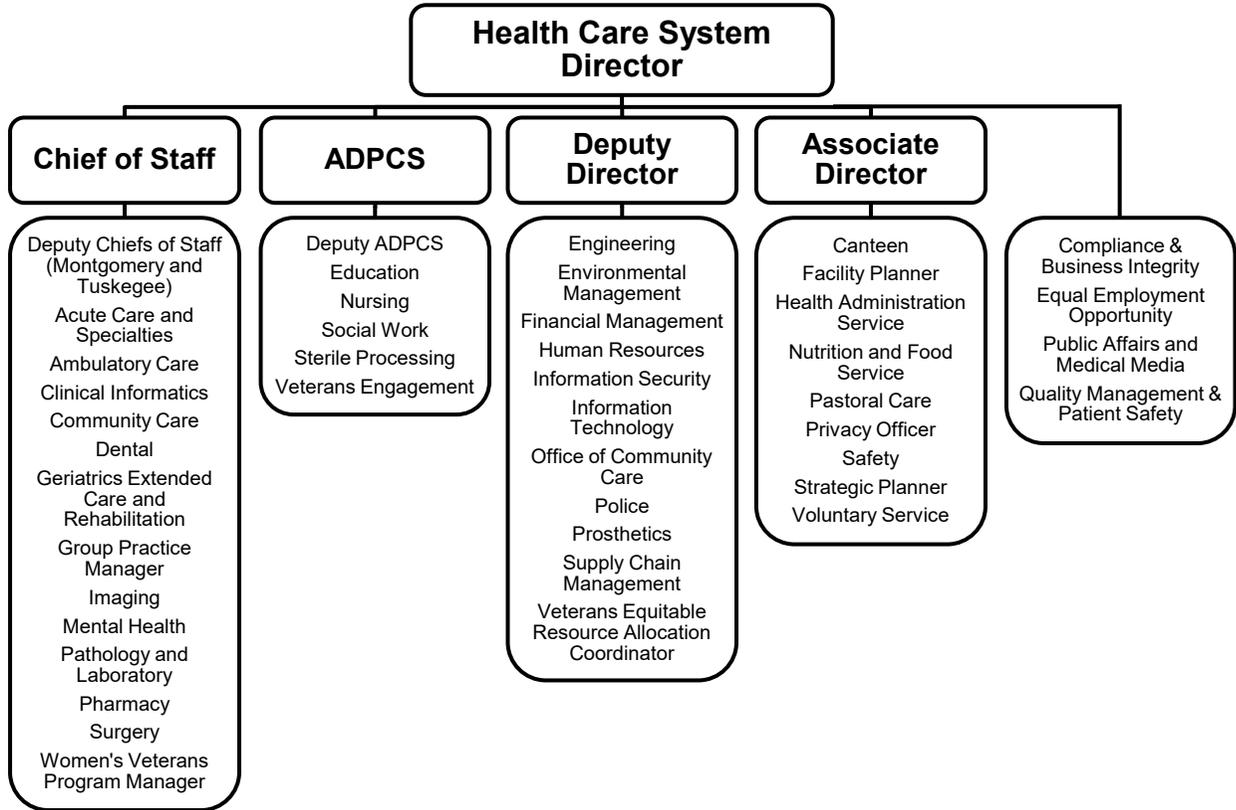


Figure 3. Healthcare System Organizational Chart

Source: Central Alabama Veterans Health Care System (received on February 24, 2020)

At the time of the OIG site visit all members of the executive team were assigned in an acting capacity except the Deputy Director, who had been in the position since November 2017. The system director position had been vacant since October 2019; an acting Director had been assigned since that time. The chief of staff position had been vacant since February 2018, and five individuals had served in an acting capacity. The current acting Chief of Staff was assigned in August 2019, but the acting Director stated that a selection had been made. The ADPCS position had been vacant since August 2019, with the current acting ADPCS serving since January 2020. The associate director position had been vacant since April 2019, with the current acting Associate Director serving since November 2019 (see Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
System Director	October 2, 2019 (acting)
Chief of Staff	August 4, 2019 (acting)
Associate Director for Patient Care Services	January 19, 2020 (acting)
Deputy Director	November 26, 2017
Associate Director	November 3, 2019 (acting)

Source: Central Alabama Veterans Health Care System Human Resources Officer (received on February 24, 2020) and acting Director (received on June 22, 2020)

To help assess the healthcare system executive leaders’ engagement, the OIG interviewed the acting Director, acting Chief of Staff, acting ADPCS, and Deputy Director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance. The acting Associate Director was unavailable due to planned travel.

The executive leaders were generally knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing Strategic Analytics for Improvement and Learning (SAIL) measures. Additionally, most leaders lacked understanding of Community Living Center (CLC) SAIL measures, despite the healthcare system’s generally positive CLC results.⁸ In individual interviews, executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences. These are discussed in greater detail below.

The Director serves as the chairperson of the Medical Center Governing Board, which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The board oversees various working groups such as the Medical Executive, Health Care Excellence, and Resource Executive Councils.

These leaders monitor patient safety and care through the Quality Safety Value Council. The Quality Safety Value Council is responsible for tracking and trending quality of care and patient outcomes and reports to the Medical Center Governing Board. See Figure 4.

⁸ According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as Nursing Home Care Units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

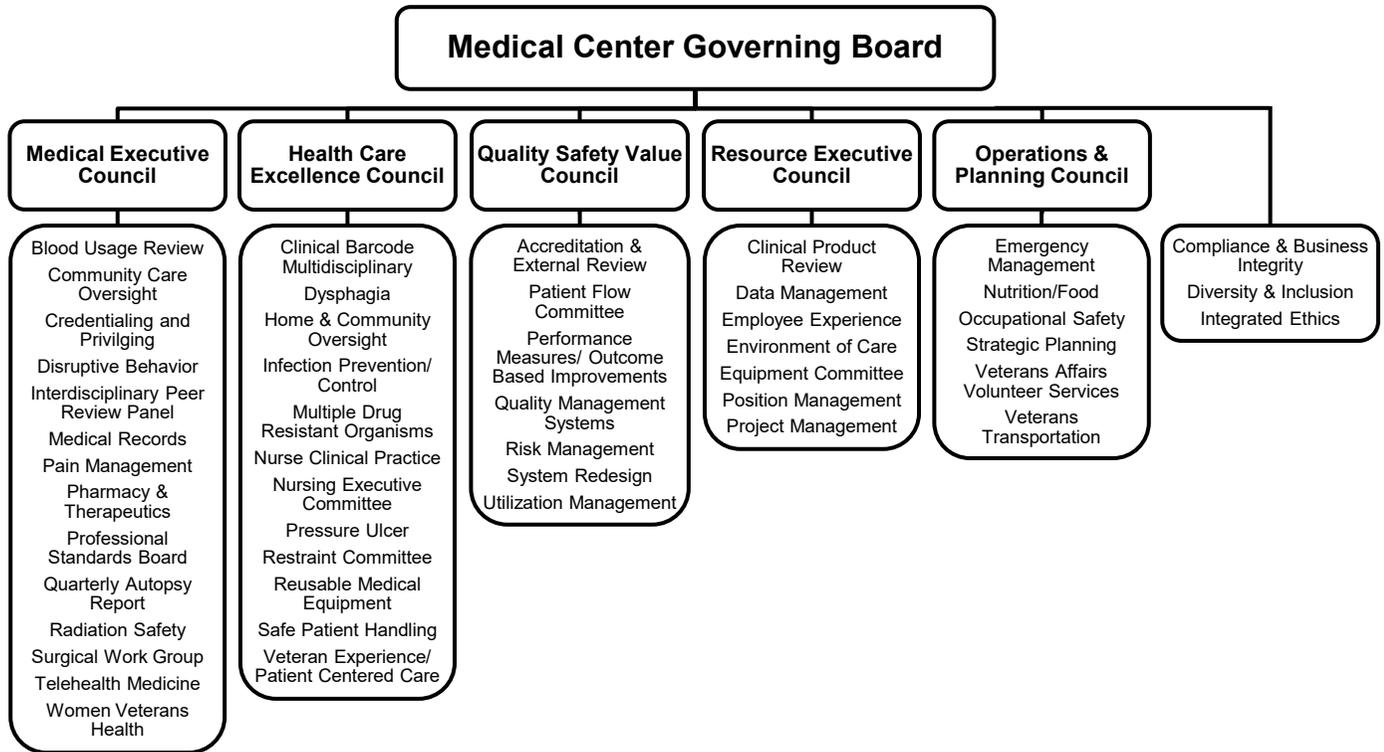


Figure 4. Healthcare System Committee Reporting Structure

Source: Central Alabama Veterans Health Care System (received on February 24, 2020)

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

To assess employee attitudes toward healthcare system leaders, the OIG reviewed employee satisfaction survey results from VHA’s All Employee Survey that relate to the period of October 1, 2018, through September 30, 2019.⁹ Table 2 provides relevant survey results for VHA, the healthcare system, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA’s All Employee Survey. The OIG found the healthcare

⁹ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Associate Director, and Deputy Director. It is important to note that the AES scores are not reflective of the current acting Director, acting Chief of Staff, acting ADPCS, or acting Associate Director.

system average for the selected survey leadership questions was lower than the VHA average.¹⁰ The same trend was noted for the leaders' scores.

Table 2. Survey Results on Employee Attitudes toward Healthcare System Leaders (October 1, 2018, through September 30, 2019)

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Deputy Director Average	Assoc. Director Average
All Employee Survey: <i>Servant Leader Index Composite</i> ¹¹	0–100 where higher scores are more favorable	72.6	67.3	58.0	64.2	67.9	68.2	66.5
All Employee Survey: <i>In my organization, senior leaders generate high levels of motivation and commitment in the workforce.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.4	3.1	3.3	2.9	3.0	3.2	3.2
All Employee Survey: <i>My organization's senior leaders maintain high standards of honesty and integrity.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.3	3.1	3.1	2.9	3.4	3.3
All Employee Survey: <i>I have a high level of respect for my organization's senior leaders.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.4	3.6	3.1	3.0	3.4	3.5

Source: VA All Employee Survey (accessed on January 21, 2020)

¹⁰ 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.

¹¹ According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, the 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.”

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA’s All Employee Survey.¹² Note that the healthcare system average for the selected survey questions was worse than the VHA average. The same trend was generally noted for the leaders’ scores. Opportunities appear to exist for all leaders to improve employee attitudes toward leaders and the workplace.

**Table 3. Survey Results on Employee Attitudes toward the Workplace
(October 1, 2018, through September 30, 2019)**

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Deputy Director Average	Assoc. Director Average
All Employee Survey: <i>I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.5	4.3	3.3	3.2	3.6	3.5
All Employee Survey: <i>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).</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.5	3.4	3.5	3.3	3.4	3.4
All Employee Survey: <i>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)?</i>	0 (Never) – 6 (Every Day)	1.4	1.6	1.1	1.7	2.1	1.7	1.9

Source: VA All Employee Survey (accessed on January 21, 2020)

¹² Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Associate Director, and Deputy Director. It is important to note that the AES scores are not reflective of the current acting Director, acting Chief of Staff, acting ADPCS, and acting Associate Director. It is important to note that the AES scores are not reflective of the current acting Director, acting Chief of Staff, acting ADPCS, or acting Associate Director.

Patient Experience

To assess patient experiences with the healthcare system, which directly reflect on its leaders, the OIG team reviewed patient experience survey results that relate to the period of October 1, 2018, through June 30, 2019. VHA’s Patient Experiences Survey Reports provide results from the Survey of Healthcare Experience 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 VHA and the healthcare system.¹³

VHA also collects SHEP survey data from Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients’ attitudes toward their healthcare experiences (see Table 4). For this system, the patient survey results reflected lower ratings than the VHA average.

**Table 4. Survey Results on Patient Experience
(October 1, 2018, through June 30, 2019)**

Questions	Scoring	VHA Average	Healthcare System Average
Survey of Healthcare Experiences of Patients (inpatient): <i>Would you recommend this hospital to your friends and family?</i>	The response average is the percent of “Definitely Yes” responses.	68.3	53.1
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	84.9	68.4
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	77.3	59.5
Survey of Healthcare Experiences of Patients (outpatient specialty care): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	78.0	64.0

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on December 23, 2019)

¹³ Ratings are based on responses by patients who received care at this healthcare system.

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from 2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.¹⁴ For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients’ experiences by gender (see Tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that the results for both male and female respondents were less favorable than the corresponding VHA averages. Although multiple opportunities appear to exist to improve patient experiences, system leaders appeared to be actively engaged with both male and female patients (for example, using the Service Line Advocacy Program to address veterans’ concerns in real-time, hosting town hall meetings, and using email surveys to learn the perception of their experience after an encounter).

**Table 5. Inpatient Survey Results on Experiences by Gender
(October 1, 2018, through September 30, 2019)**

Questions	Scoring	VHA ¹⁵		Healthcare System ¹⁶	
		Male Average	Female Average	Male Average	Female Average
<i>During this hospital stay, how often did doctors treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	82.3	—
<i>During this hospital stay, how often did nurses treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	83.8	—
<i>Would you recommend this hospital to your friends and family?</i>	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	51.0	—

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on January 21, 2020)

¹⁴ VA National Center for Veterans Analysis and Statistics, *The Past, Present and Future of Women Veterans*, February 2017.

¹⁵ The VHA averages are based on 48,259–48,798 male and 2,342–2,359 female respondents, depending on the question.

¹⁶ The healthcare system averages are based on 99–101 male respondents, depending on the question. Data are not available for the low number of female respondents.

Table 6. Patient-Centered Medical Home Survey Results on Patient Experiences by Gender (October 1, 2018, through September 30, 2019)

Questions	Scoring	VHA ¹⁷		Healthcare System ¹⁸	
		Male Average	Female Average	Male Average	Female Average
<i>In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	32.0	32.7
<i>In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	48.7	33.9
<i>Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	56.2	52.2

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on January 21, 2020)

¹⁷ The VHA averages are based on 79,450–241,828 male and 5,762–13,041 female respondents, depending on the question.

¹⁸ The healthcare system averages are based on 404–1,210 male and 56–113 female respondents, depending on the question.

Table 7. Specialty Care Survey Results on Patient Experiences by Gender (October 1, 2018, through September 30, 2019)

Questions	Scoring	VHA ¹⁹		Healthcare System ²⁰	
		Male Average	Female Average	Male Average	Female Average
<i>In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	37.3	20.6
<i>In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	55.0	47.3	36.4
<i>Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	64.6	66.6

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on January 21, 2020)

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.²¹ Table 8 summarizes the relevant system inspections most recently performed by the OIG and The Joint Commission (TJC).²² Of note, at the time of the OIG visit, the system had closed all

¹⁹ The VHA averages are based on 65,968–208,722 male and 3,460–11,072 female respondents, depending on the question.

²⁰ The healthcare system averages are based on 297–870 male and 20–60 female respondents, depending on the question.

²¹ The Joint Commission 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.

²² 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.”

recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in June 2017. The Quality Management Chief reported that leaders are awaiting the results of an OIG hotline related to electronic health record view alerts that was conducted in December 2019.

At the time of the site visit, the OIG team also noted the system’s current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²³ The Long Term Care Institute’s inspection of the system’s CLCs was conducted in August 2019; the results included 11 findings, two of which remain open.²⁴

Table 8. Office of Inspector General Inspection/The Joint Commission Survey

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (<i>Comprehensive Healthcare Inspection Program Review of the Central Alabama Veterans Health Care System, Montgomery, Alabama, Report No.17-01851-72, February 6, 2018</i>)	June 2017	7	0
TJC Hospital Accreditation	January 2019	48	0
TJC Behavioral Health Care Accreditation		10	0
TJC Home Care Accreditation		8	0

Source: OIG and TJC (inspection/survey results verified with the Quality Management Chief on February 24, 2020)

Identified Factors Related to Possible Lapses in Care and Healthcare System Response

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

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; 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.

²⁴ 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.ltc.org/about-us/>. (The website was accessed on March 6, 2019.)

conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. The OIG identified no concerns related to the potential for patient harm.

Table 9 lists the reported patient safety events from June 5, 2017 (the prior OIG comprehensive healthcare inspection), through February 27, 2020.²⁵

Table 9. Summary of Selected Organizational Risk Factors (June 5, 2017, through February 27, 2020)

Factor	Number of Occurrences
Sentinel Events ²⁶	1
Institutional Disclosures ²⁷	5
Large-Scale Disclosures ²⁸	0

Source: Central Alabama Veterans Health Care System’s Quality Management Chief (received on February 27, 2020)

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted 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

²⁵ 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 Central Alabama Veterans Health Care System is a mid-high complexity (1c) system as described in Appendix B.)

²⁶ 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.”

²⁷ 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 leaders 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.”

²⁸ According to VHA Directive 1004.08, 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.”

“understand the similarities and differences between the top and bottom performers” within VHA.²⁹

Figure 5 illustrates the system’s quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, Figure 5 uses blue and green data points to indicate high performance for the Montgomery VAMC (for example, in the areas of acute care 30-day standardized mortality ratio (SMR30), healthcare associated (HC assoc) infections, and admit reviews met). Metrics that need improvement are denoted in orange and red (for example, mental health (MH) continuity (of) care, call responsiveness, patient-centered medical home (PCMH) same day appointment (appt), capacity, specialty care (SC) survey access, and MH experience (exp) of care).³⁰

²⁹ VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, <https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428>. (The website was accessed on March 6, 2020, but is not accessible by the public.)

³⁰ For information on the acronyms in the SAIL metrics, please see Appendix E.

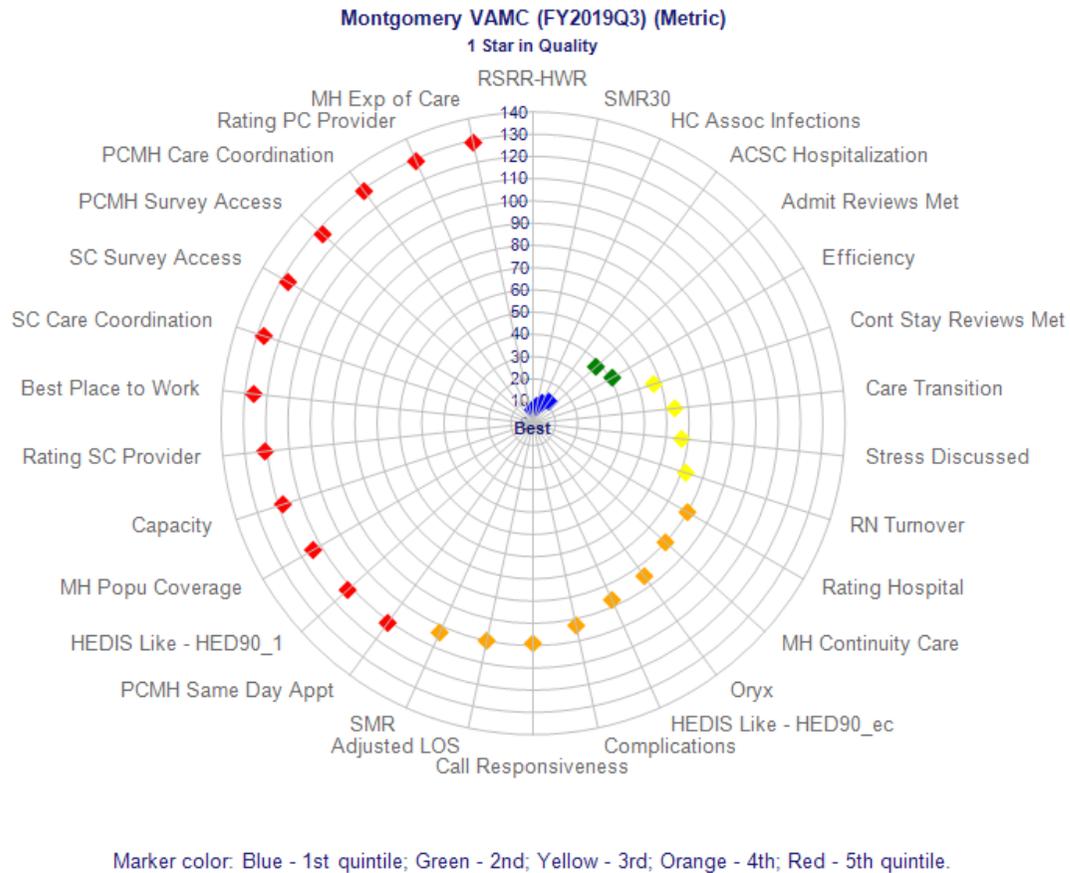


Figure 5. System Quality of Care and Efficiency Metric Rankings (as of January 21, 2020)

Source: VHA Support Service Center

Note: The OIG did not assess VA’s data for accuracy or completeness.

Veterans Health Administration Performance Data for Community Living Centers

The “CLC SAIL” Value Model is a tool to summarize and compare the performance of CLCs in the VA. The model leverages much of the same data used in the Centers for Medicare & Medicaid Services’ (CMS) *Nursing Home Compare* and provides a single resource to review quality measures and health inspection results.³¹

³¹ 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.”

Figure 6 illustrates the system's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2019. Figure 6 uses blue data points to indicate high performance for the Tuskegee CLC (for example, in the areas of urinary tract infections (UTI)–long-stay (LS), new or worse pressure ulcer (PU)–short-stay (SS), and help with activities of daily living (ADL)–LS). Metrics that need improvement are denoted in orange and red (receive antipsychotic (antipsych) medications (meds)–LS and improvement in function–SS).³²

³² For data definitions of acronyms in the SAIL CLC measures, please see Appendix F.

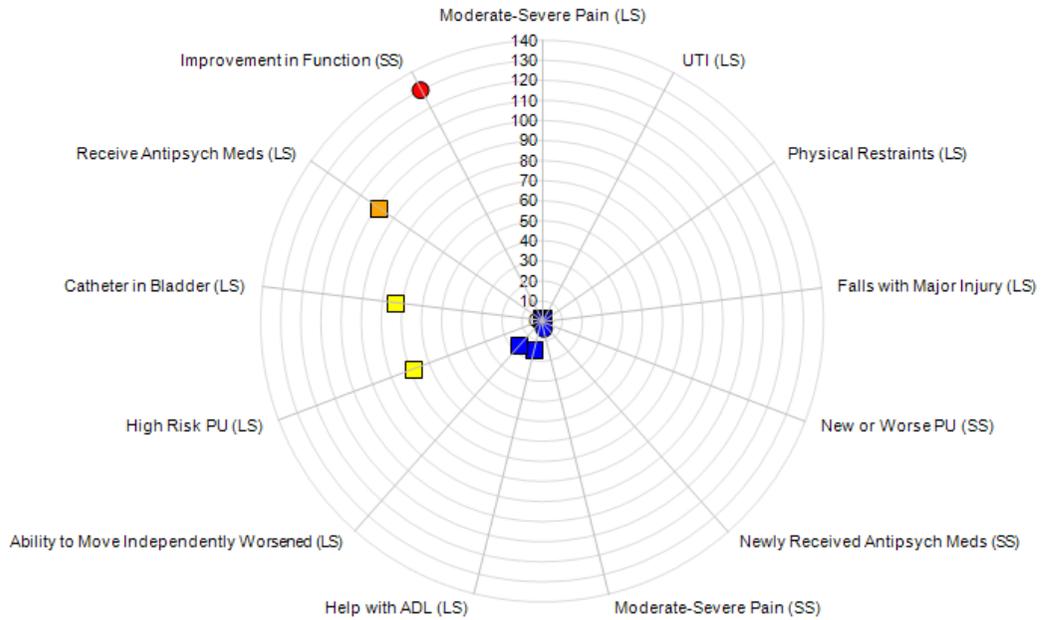


Figure 6. Tuskegee CLC Quality Measure Rankings (as of September 30, 2019)

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.

Leadership and Organizational Risks Conclusion

The system’s executive leadership team had vacancies in four of the five key positions. At the time of OIG’s inspection, the system director, ADPCS, and associate director roles had been vacant for at least six months; the chief of staff position had been vacant for two years. The acting Director stated that a selection had been made for the chief of staff role. Selected survey items related to employees’ attitudes toward leaders and the workplace revealed multiple opportunities for improvement. Further, the OIG found that selected survey results for both female and male respondents were consistently less favorable than those for VHA patients nationally. The OIG’s review of the system’s accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve performance, employee satisfaction, and patient experiences. However, the executive leaders lacked understanding of CLC SAIL measures, despite the healthcare system’s generally positive results, but were generally knowledgeable within their scope of responsibilities about selected VHA data contributing to specific poorly performing SAIL measures. The OIG noted that only 6 of 30 VHA quality metrics showed high performance, which indicates that multiple opportunities exist for improvement.

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.³³ To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and to maintain Joint Commission accreditation.³⁴ Many quality-related activities are informed and required by VHA directives, nationally recognized accreditation standards (such as The Joint Commission), and federal regulations. VHA strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.³⁵

To determine whether VHA facilities have implemented and incorporated OIG-identified key processes for quality and safety into local activities, the inspection team evaluated the healthcare system's committee responsible for quality, safety, and value (QSV) oversight functions; its ability to review data, information, and risk intelligence; and its ability to ensure that key QSV functions are discussed and integrated on a regular basis. Specifically, OIG inspectors examined the following requirements:

- Review of aggregated QSV data
- Recommendation and implementation of improvement actions
- Monitoring of fully implemented improvement actions

The OIG reviewers also assessed the healthcare system's processes for conducting protected peer reviews of clinical care.³⁶ Protected peer reviews, when conducted systematically and credibly, 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 nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.³⁷ The OIG team examined the completion of the following elements:

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)

³³ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

³⁴ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

³⁵ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

³⁶ 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. In the context of protected peer reviews, "protected" refers to the designation of review as a confidential quality management activity under 38 U.S.C. 5705 as "a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or the utilization of health-care resources in VA facilities."

³⁷ VHA Directive 1190.

- 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 unit³⁸
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the healthcare system's utilization management (UM) program, a key component of VHA's framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.³⁹ 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.⁴⁰ Inspectors reviewed several aspects of the UM program:

- Completion of at least 80 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
- Implementation and monitoring of improvement actions recommended by the interdisciplinary UM group

Finally, the OIG reviewers assessed the healthcare system's reports of patient safety incidents with related root cause analyses.⁴¹ 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 healthcare system.⁴² The healthcare system was assessed for its performance on several dimensions:

³⁸ VHA Directive 1190.

³⁹ According to VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019, reviews include evaluating the "appropriateness, medical need, and efficiency of health care services according to evidence-based criteria."

⁴⁰ VHA Directive 1117(2).

⁴¹ The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. 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."

⁴² VHA Handbook 1050.01.

- Annual completion of a minimum of eight root cause analyses⁴³
- Inclusion of required content in root cause analyses
- 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 healthcare system leaders

The OIG reviewers 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.⁴⁴

Quality, Safety, and Value Findings and Recommendations

The healthcare system complied with requirements for establishing a committee responsible for QSV oversight functions. The OIG identified deficiencies in peer review, utilization management, and root cause analysis processes.

VHA requires that final peer reviews are completed within 120 calendar days from the determination that a peer review is needed and that extensions are reviewed and approved in writing by the Healthcare System Director.⁴⁵ For January 2018 through February 2020, the OIG reviewed a sample of 20 peer reviews and found that 5 were not completed within the expected time frame. The OIG observed that the relevant files maintained by the previous Risk Manager were incomplete and lacked documentation of an extension signed by the System Director. This likely prevented timely improvements in patient care. The acting Chief of Staff and Risk Manager cited that inattention to detail and the absence of a tracking process resulted in the peer review due dates being overlooked.

Recommendation 1

1. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that final peer reviews are completed within 120 calendar days from the date a peer review is required, and any necessary extensions are approved in writing by the System Director.

⁴³ 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 analyses per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses].”

⁴⁴ For CHIP inspections, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁴⁵ VHA Directive 1190.

Healthcare system concurred.

Target date for completion: August 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff will ensure the reviews are completed within 120-calendar days. The Risk Manager will track each Peer Review to ensure 120-calendar day completion. Peer Reviews with deemed necessary extensions beyond the 120-calendar day completion will receive approval in writing by the Health Care System Director. The Risk Manager will provide a tracking report for all Peer Reviews nearing 120-calendar days in the monthly Interdisciplinary Peer Review Panel meeting which the Chief of Staff chairs until 90 percent compliance has been achieved for six months.

VHA also requires that Interdisciplinary Peer Review Panel analysis summaries are reviewed quarterly by an executive-level medical committee.⁴⁶ The OIG was informed that from January 1, 2019, through December 31, 2019, the Interdisciplinary Peer Review Panel did not provide a summary report to the Medical Executive Council. The Medical Executive Council's failure to review summary reports may decrease the council's ability to identify clinical practice trends, determine the need for further action, and monitor the effectiveness of quality improvement initiatives. The acting Chief of Staff stated that the Interdisciplinary Peer Review Panel was not included in the previous governance structure reporting schedule for the timeframe reviewed.

Recommendation 2

2. The Chief of Staff determines the reasons for noncompliance and makes certain that the Interdisciplinary Peer Review Panel provides quarterly analysis summaries to the Medical Executive Council.

Healthcare system concurred.

Target date for completion: July 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Risk Manager will provide quarterly analysis summaries to the Medical Executive Council of which the Chief of Staff is chair until 90 percent compliance has been achieved for six months.

⁴⁶ VHA Directive 1190.

VHA requires that physician UM advisors document at least 75 percent of their decisions regarding appropriateness of patient admissions and continued stays in the National UM Integration database.⁴⁷ The OIG found that physician UM advisors documented 49 percent of referred reviews from July 1, 2019, through December 31, 2019. Incomplete documentation of UM decisions may result in a lack of assurance that the appropriate level of care and treatment was provided to patients. The acting Chief of Staff reported that the physician UM advisor duties were not completed because of the responsible provider's abrupt separation of employment.

Recommendation 3

3. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that physician utilization management advisors consistently document their decisions in the National Utilization Management Integration database.

Healthcare system concurred.

Target date for completion: October 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Physician Utilization Management Advisors will consistently document their decisions in the National Utilization Management Integration database. The Chief of Staff will ensure the Physician Utilization Management Advisors report their compliance of reviews quarterly to the Medical Executive Council where the Chief of Staff is chair for six months until 75 percent compliance is achieved.

VHA requires that an interdisciplinary group review UM data on an ongoing basis. This group must include, but not be limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [Chief Business Office Revenue-Utilization Review]."⁴⁸ The OIG found that from January 2019 through January 2020, the Chief Business Office Revenue-Utilization Review representative was not involved in UM data reviews. As a result, the UM Committee performed reviews and analyses without the required interdisciplinary membership. The Deputy ADPCS reported that, prior to receiving guidance from the VISN, staff believed utilization review nurses identified on the committee could serve in the Chief Business Office Revenue-Utilization Review role.

⁴⁷ VHA Directive 1117(2).

⁴⁸ VHA Directive 1117(2).

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that all required representatives consistently participate in interdisciplinary reviews of utilization management data.

Healthcare system concurred.

Target date for completion: September 30, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Committee Charter for the Patient Flow Committee includes all required members per VHA Directive 1117 (2), VHA Utilization Management Directive. The Patient Flow Committee Chair will send a monthly recurring invite to all required members of the Committee for attendance requests. The Chief of Staff will ensure the Patient Flow Committee tracks attendance of required members until 90 percent compliance has been achieved for six consecutive months within the Patient Flow Committee minutes.

To ensure credibility, VHA requires root cause analyses to include several factors, such as participation by leaders, consideration of relevant literature, and identification of at least one root cause with a corresponding action and outcome measure.⁴⁹ Additionally, TJC requires that corrective actions be implemented and monitored⁵⁰ so that performance improvement “effectiveness can be sustained, assessed, and measured.”⁵¹ Further, WebSPOT (the VHA Patient Safety Information System) must be used to document the root cause analysis.⁵² Of the five individual root cause analyses reviewed, the OIG found that one did not have a corresponding outcome measure and three of four lacked evidence that the action items were fully implemented. This likely affected evaluation of patient safety events that could help prevent patient harm. The Patient Safety Manager, who was new to the role, was reportedly unaware that tracking outcome measures was required and stated there was lack of oversight for staff responsible for implementing root cause analysis actions.

Recommendation 5

5. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Patient Safety Manager includes all required elements in root cause analyses and properly documents root cause analyses in the VHA Patient Safety Information System.

⁴⁹ VHA Handbook 1050.01.

⁵⁰ TJC Rationale for Leadership standard LD.03.02.01 and TJC Performance Improvement standard PI.03.01.01.

⁵¹ TJC Leadership standard LD.03.05.01.

⁵² VHA Handbook 1050.01.

Healthcare system concurred.

Target date for completion: December 30, 2020

Healthcare system response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Patient Safety Managers will provide all required elements in the root cause analysis and properly document root cause analysis in the VHA Patient Safety Information System. The Health Care System Director will ensure Patient Safety provides a quarterly report listing each root cause analysis that has been documented in the VHA Patient Safety Information System into the Quality, Safety, Value Council that he co-chairs until 90 percent compliance has been achieved for six months.

VHA requires that root cause analyses be timely and submitted to the National Center for Patient Safety within 45 days of becoming aware that an analysis is required.⁵³ The OIG found that three of five root cause analyses were not submitted on time.⁵⁴ A delay in completing and submitting root cause analyses potentially hinders timely identification and correction of system vulnerabilities that contribute to patient harm events. The Patient Safety Manager reported lack of oversight as the reason for noncompliance.

Recommendation 6

6. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Patient Safety Manager submits each root cause analysis to the National Center for Patient Safety within the required time frame.

⁵³ VHA Handbook 1050.01.

⁵⁴ “VA National Center for Patient Safety: About the National Center for Patient Safety,” VA website, <https://www.patientsafety.va.gov/about/index.asp>. (The website was accessed on May 21, 2020.) The National Center for Patient Safety (NCPS) is the Department of Veterans Affairs National Center for Patient Safety, established to lead VA’s patient safety efforts and develop and nurture a culture of safety throughout Veterans Health Administration. The goal is “nationwide reduction and prevention of inadvertent harm to patients as a result of their care.” NCPS provides a “confidential, non-punitive” electronic reporting system that allows users from around the country to electronically document patient safety information. This centralized database allows for lessons to be learned that can benefit the entire VHA healthcare system.

Healthcare system concurred.

Target date for completion: September 30, 2020

Health Care System response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Patient Safety Managers will complete and submit each root cause analysis to the National Center for Patient Safety within the allotted 45-day time frame. The Health Care System Director will ensure all root cause analysis are completed within the 45-day time frame by tracking completion quarterly within the Quality Safety Value Council where he is co-chair until 90 percent compliance has been achieved for six months.

VHA requires that the Patient Safety Manager or designee provides timely feedback to staff who submit close call and adverse event reports that result in a root cause analysis.⁵⁵ For two of four root cause analyses, the OIG found that the Patient Safety Manager could not provide evidence that feedback was provided to the staff who reported the events or concerns. This may result in missed opportunities to establish employee trust in the system and positively reinforce a culture of safety. The Patient Safety Manager reportedly did not fully understand the feedback requirements.

Recommendation 7

7. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that the Patient Safety Manager or designee provides feedback to staff who submit patient adverse event reports that result in root cause analysis actions.

Healthcare system concurred.

Target date for completion: August 31, 2020

Healthcare system response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Health Care System Director will ensure Patient Safety Managers provide feedback to all staff who submit patient adverse events into the Joint Patient Safety Reporting System that result in root cause analysis actions. Upon completion of each root cause analysis, feedback will be provided via memorandum to all identified reporters. The Health Care System Director will track feedback to all staff who submit patient adverse events into the Joint Patient Safety Reporting System until compliance has been achieved for six months as evidenced in the Quality Safety Value Council minutes, where he is co-chair.

⁵⁵ VHA Handbook 1050.01.

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).⁵⁶

Clinical privileges need to be specific and based on the individual practitioner’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 reprivileging prior to their expiration.⁵⁷

VHA defines the focused professional practice evaluation (FPPE) as “a time-limited period during which the medical staff leadership evaluates and determines the practitioner’s professional performance.” The FPPE process occurs when a provider is hired at the facility and granted initial privileges and before any new clinical privileges are granted. Additionally, VA facilities must continuously monitor the performance of their providers. VHA requirements state that “the on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered.”⁵⁸ The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
 - Establishment of criteria in advance
 - Use of minimum criteria for selected specialty LIPs⁵⁹
 - Clear documentation of the results and time frames
 - Evaluation by another provider with similar training and privileges
- OPPEs
 - Application of criteria specific to the service or section
 - Use of minimum criteria for selected specialty LIPs⁶⁰
 - Evaluation by another provider with similar training and privileges

⁵⁶ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

⁵⁷ VHA Handbook 1100.19.

⁵⁸ VHA Handbook 1100.19.

⁵⁹ VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁶⁰ VHA DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*. August 29, 2016.

The OIG also determined whether service chiefs recommended continuing the LIPs' current privileges based in part on the results of OPPE activities and if the healthcare system's Executive Committee of the Medical Staff decided to recommend continuing privileges based on FPPE and OPPE results.

Further, VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and to subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.⁶¹ Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process. This individual will be the subject matter expert (SME) for the facility...and ensure oversight of the exit review process, including receipt, review, and maintenance of the Provider Exit Review Forms."⁶² The OIG reviewers assessed whether the healthcare system's staff

- Designated an individual and backup responsible for the SLB reporting process,
- Completed forms within the required time frame and with required oversight, and
- Reported results to SLBs when indicated.

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

- Three solo/few practitioners who underwent reprivileging during the previous 12 months⁶³
- Six LIPs hired within 18 months before the site visit
- Twelve LIPs privileged within 12 months before the visit
- Seventeen LIPs who left the healthcare system in 12 months before the visit

Medical Staff Privileging Findings and Recommendations

The OIG identified deficiencies with FPPE, OPPE, and provider exit review processes.

⁶¹ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005.

⁶² VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018.

⁶³ 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 less than three providers in the facility that are privileged in a particular specialty. The 12-month review period was from November 4, 2018, through November 4, 2019.

VHA requires that the competency of LIPs is evaluated by another provider with similar training and privileges.⁶⁴ The OIG found that in two of six FPPE provider profiles and 5 of 15 OPPE provider profiles, including one solo provider, the evaluations were not completed by another similarly trained and privileged provider. As a result, the LIPs continued to deliver care without a thorough evaluation of their competencies, which could have impacted quality of care and patient safety. For one of the cases, the acting Chief of Staff stated that the reviewing provider was unaware of the requirement but did not provide an explanation for the remaining cases reviewed.

Recommendation 8

8. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers with similar training and privileges complete focused and ongoing professional practice evaluations of licensed independent practitioners.

Healthcare system concurred.

Target date for completion: August 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff will ensure that providers with similar training and privileges complete focused and ongoing professional practice evaluations of licensed independent practitioners. A Standard Operating Procedure will be created listing responsibilities and requirements of Ongoing Professional Practice Evaluations (OPPE) and Focused Professional Practice Evaluations (FPPE) completed by another provider with similar training and privileges. The Deputy Chief of Staff will conduct Staff training during the Medical Executive Council meeting for all Provider Service Chiefs and Supervisors. Monitoring reports will be provided by the Credentialing Staff monthly to the Medical Executive Council where the Chief of Staff is chair. The Chief of Staff will monitor compliance of Providers with similar training and privileges completing focused and ongoing professional practice evaluations of licensed independent practitioners until a 90 percent compliance rate is achieved for six months.

VHA requires that reprivileging decisions are based on OPPE data specific to the service or section.⁶⁵ For 13 of 15 practitioners repriviledged within the last 12 months—one was solo and two were few practitioners—the OIG found that service chiefs could not demonstrate that reprivileging decisions were based upon service-specific OPPE criteria. This resulted in incomplete data to support decisions to continue the practitioners' clinical privileges.

⁶⁴ VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*.

⁶⁵ VHA Handbook 1100.19.

Furthermore, the lack of a thorough competency evaluation could potentially impact the quality of care and patient safety. The acting Chief of Staff stated that the healthcare system continued to use nonspecific criteria forms and were awaiting guidance from VHA regarding standardized service-specific criteria.

Recommendation 9

9. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that reprivileging decisions are based on service- or section-specific ongoing professional practice evaluation data.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Deputy Chief of Staff provided service-specific indicators to all Clinical Provider Chiefs and Administrative Officers to be used in completing OPPE. The Chief of Staff will monitor the reports of OPPE service-specific indicators completed compared to the total number of OPPEs submitted monthly through the Medical Executive Council in which he chairs until a compliance rate of at least 90 percent is achieved for six months.

VHA requires that provider exit review forms, which document the review of a provider's clinical practice, are "completed within 7 calendar days of the departure of a licensed health care professional from a VA facility."⁶⁶ The OIG found 9 of 17 exit review forms were not completed within seven days. This may have resulted in delayed reporting of licensed healthcare professionals' potential substandard practices to state licensing boards. The acting Chief of Staff cited that the facility did not have a process to track exit interviews.

Recommendation 10

10. The System Director evaluates and determines any additional reasons for noncompliance and makes certain the licensed healthcare professional's first- or second-line supervisor completes and signs the exit review form within seven calendar days of the professional's departure from the healthcare system.

⁶⁶ VHA Notice 2018-05.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Health Care System Director will ensure the licensed healthcare professional's first or second-line supervisor completes and signs the exit review form within seven calendar days of the professional's departure from the health care system. The exit review form will be added to the employee clearance process. The Health Care System Director will monitor the exit review form completion compared to the total number of providers departing from the health care system through the Quality Safety Value Council where Credentialing will provide a quarterly report until 90 percent compliance is achieved for six months.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct Comprehensive Environment of Care Inspection Rounds and to resolve issues in a timely manner. The goal of the Comprehensive 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.⁶⁷

The purpose of this facet of the OIG inspection was to determine whether the healthcare system maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the healthcare system met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the inpatient mental health unit where patients with active suicidal ideation or attempts are treated. Inspectors reviewed several aspects of the healthcare system's environment:

- Medical centers
 - General safety
 - Special use spaces
 - Environmental cleanliness and infection prevention
 - Privacy
 - Accommodation and privacy for women veterans
 - Logistics
- Inpatient mental health unit
 - General safety
 - Special use spaces
 - Environmental cleanliness and infection prevention
 - Privacy
 - Accommodation for women veterans
 - Logistics
- Community-based outpatient clinic (CBOC)
 - General safety
 - Special use spaces

⁶⁷ VHA Directive 1608, *Comprehensive Environment of Care (CEOC) Program*, February 1, 2016.

- Environmental cleanliness and infection prevention
- Privacy
- Privacy for women veterans
- Logistics

During its review of the environment of care, the OIG team inspected the Montgomery VA Clinic and the following 10 patient care areas of the Montgomery–West Campus and Tuskegee–East Campus:

- Montgomery
 - Emergency Department
 - Intensive care unit
 - Medical/surgical inpatient unit
 - Post-anesthesia care unit
 - Specialty clinic
- Tuskegee
 - Acute psychiatric unit
 - Community living centers (CLC-GB and CLC-1B)⁶⁸
 - Primary care clinic
 - Rehabilitation-physical therapy/occupational therapy clinic

The inspection team reviewed relevant documents and interviewed key employees and managers.

Environment of Care Findings and Recommendations

The inspection team observed general compliance with requirements for the inpatient mental health unit and general safety, privacy, and accommodation for women veterans. At the time of the site visit, the OIG did not note any issues with the availability of medical equipment and supplies; however, during a subsequent OIG visit to review COVID-19 screening processes and pandemic readiness, healthcare system staff reported an inadequate supply of hand sanitizer.⁶⁹

⁶⁸ According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

⁶⁹ VA OIG, *OIG Inspection of Veterans Health Administration's COVID-19 Screening Processes and Pandemic Readiness, March 19-24, 2020*, Report No. 20-02221-120, March 26, 2020.

The OIG identified a deficiency in environmental cleanliness and infection prevention at the Tuskegee campus.

VHA requires hospitals to identify environmental deficiencies and areas for improvement during environment of care rounds and to track them until resolved.⁷⁰ TJC requires hospitals to establish and maintain a safe, functional environment that is clean and suitable for patient care and treatment.⁷¹ The OIG noted soiled floors in three locations at the Tuskegee campus.⁷² Although the environmental management staff immediately addressed the finding, the OIG noted an ineffective process to identify environmental deficiencies during environment of care rounds and track them until resolved. This lack of cleanliness may result in the spread of infection within the patient care environment. The Industrial Hygienist stated that, due to a lack of attention to detail, deficiencies were not always detected and tracked.

Recommendation 11

11. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that healthcare system managers maintain a safe and clean environment by identifying and resolving environmental deficiencies found during environment of care rounds.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Associate Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Associate Director will ensure the health care system managers maintain a safe and clean environment by identifying and resolving environmental deficiencies found during environment of care rounds by utilizing Pro-Logic to notify team members, verify attendance, complete rounds and track deficiencies until resolved. Deficiencies will be corrected immediately during all Environment of Care rounding or within 14 days of deficiency identification. Deficiencies not corrected or completed within 14 days will warrant an action plan. Deficiencies will be tracked by the Associate Director into the Environment of Care committee monthly until 90 percent compliance is sustained for six months.

⁷⁰ VHA Directive 1608.

⁷¹ TJC, Environment of Care standard EC.02.06.01, EP 1 and 20.

⁷² Rehabilitation-physical therapy/occupational therapy clinic (storeroom), primary care clinic (exam room), and a stairwell.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁷³ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁷⁴ Long-term opioid use is of particular concern in the veteran population where there is a high incidence of posttraumatic stress disorder, major depressive disorder, alcohol use, substance abuse, and suicide attempts.⁷⁵ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁷⁶

VHA requires routine assessments of pain and the completion of an opioid risk assessment before initiating patients on long-term opioid therapy and recommends against the therapy for patients with untreated substance use disorders. VHA also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines.⁷⁷ Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.⁷⁸ To achieve VHA's vision of providing patient-driven healthcare, providers are also required to obtain informed consent from patients and to provide education about the risks, benefits, and alternatives prior to initiating long-term opioid therapy.⁷⁹ VHA recommends evaluating patients receiving continued opioid therapy for improvement of pain and opioid-related adverse events at least every three months and more frequently as doses increase.⁸⁰

The OIG reviewers assessed providers' provision of pain management using long-term opioid therapy:

- Completion of initial screening for pain
- Assessment of aberrant behavior risk
- Avoidance of concurrent therapy with benzodiazepines
- Completion of urine drug testing with intervention, when indicated

⁷³ World Health Organization. "Information sheet on opioid overdose," August 2018. https://www.who.int/substance_abuse/information-sheet/en/. (The website was accessed on November 6, 2019.)

⁷⁴ Centers for Disease Control and Prevention. "Opioid Overdose, Understanding the Epidemic," December 19, 2018. <https://www.cdc.gov/drugoverdose/epidemic/>. (The website was accessed on November 6, 2019.)

⁷⁵ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0. February 2017. <https://www.healthquality.va.gov/guidelines/Pain/cot/>. (The website was accessed on November 6, 2019.)

⁷⁶ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁷⁷ According to the U.S. Department of Justice's Drug Enforcement Administration, benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety." https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. (The website was accessed on December 1, 2019.)

⁷⁸ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁷⁹ VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020.

⁸⁰ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

- Documentation of informed consent
- Timely follow-up with patients included required elements

VHA also requires facilities to establish a multidisciplinary pain management committee “to provide oversight, coordination, and monitoring of pain management activities and processes.” Monitoring measures include, but are not limited to, adherence to published clinical practice guidelines, timeliness of treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment, patient satisfaction, and quality of life.⁸¹ The OIG examined the following indicators for program oversight and evaluation:

- Performance of pain management committee activities
- Monitoring of quality measures
- Following the quality improvement process

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 29 selected outpatients who had newly dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The team considered whether providers acted in accordance with guidelines for the provision of pain management and the healthcare system’s oversight process for evaluating pain management outcomes and quality.

Medication Management Findings and Recommendations

The healthcare system addressed the pain screening indicator of expected performance. However, the OIG found deficiencies with aberrant behavior risk assessments, concurrent benzodiazepine therapy, urine drug testing, informed consent, patient follow-up, and pain committee activities.

VA/DoD clinical practice guidelines recommend completion of an aberrant behavior risk assessment that includes the patient’s history of substance abuse, psychological disease, and aberrant drug-related behaviors⁸² prior to initiating long-term opioid therapy.⁸³ The OIG determined that providers assessed 31 percent of patients for history of personal or family substance abuse, 17 percent for psychological disease, and 45 percent for aberrant drug-related behaviors.⁸⁴ This may have resulted in providers prescribing opioids for patients at high risk for

⁸¹ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

⁸² Examples of “aberrant drug related behaviors include lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents.” VHA, *Pain Management, Opioid Safety, VA Educational Guide* (2014), July 2014. https://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Toolkit_Provider_AD_Educational_Guide_7_17.pdf. (The website was accessed on September 17, 2019.)

⁸³ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁸⁴ Confidence intervals are not included because the data represents every patient in the study population.

misuse. The acting Associate Chief of Staff, Ambulatory Care cited a shortage of providers and recruiting challenges due to the healthcare system's rural location as reasons for noncompliance.

Recommendation 12

12. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers complete an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors on patients prior to initiating long-term opioid therapy.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff will ensure providers complete an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors on patients prior to initiating long-term opioid therapy. The Controlled Substance note will capture aberrant behavior risk assessments that includes the patient's history of substance abuse, psychological disease, and aberrant drug-related behaviors prior to initiating long-term opioid therapy. The Chief of Staff will track submitted reports of compliance detailing the provider's completion of the Controlled Substance note for aberrant risk behaviors in the Medical Executive Council where he is chair until compliance of at least 90 percent is achieved for six months.

VA/DoD clinical practice guidelines recommend avoiding co-administration of drugs such as opioids and benzodiazepines that could induce fatal drug-drug interactions.⁸⁵ The OIG found that providers did not document justification for prescribing opioids and benzodiazepines concurrently in all three of the electronic health records reviewed. This may result in an increased risk of harm and potentially fatal drug interactions. The acting Associate Chief of Staff, Ambulatory Care cited frequent provider turnover and lack of effective treatment planning between mental health and primary care providers as the reasons for noncompliance.

Recommendation 13

13. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers document justification for prescribing opioids and benzodiazepines concurrently.

⁸⁵ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff will ensure providers document justification for prescribing opioids and benzodiazepines concurrently. Within the Controlled Substance note the patient assessment will include the provider's justification for prescribing opioids and benzodiazepines concurrently. The Chief of Staff will ensure provider justification for concurrently prescribing opioids and benzodiazepines is documented in the Controlled Substance note and compliance of documentation is reported monthly for six months until a 90 percent compliance rate is achieved through the Medical Executive Council in which he chairs.

VA/DoD clinical practice guidelines recommend that providers “obtain UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter.”⁸⁶ The OIG determined that providers conducted initial urine drug testing in 52 percent of the patients reviewed.⁸⁷ This may have resulted in clinicians' inability to identify the remaining patients' lack of adherence to opioid therapy or potential for drug diversion. The acting Associate Chief of Staff, Ambulatory Care cited staffing shortages, overloaded clinicians' panels, and recruiting challenges due to the healthcare system's rural location as reasons for noncompliance.

Recommendation 14

14. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers consistently conduct urine drug testing for patients on long-term opioid therapy.

⁸⁶ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁸⁷ Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff ensures health care providers consistently conduct urine drug testing for patients on long-term opioid therapy. The Controlled Substance note will now capture the patient's assessment that includes the providers conducting an initial urine drug screen prior to initiating or continuing long-term opioid therapy. The Chief of Staff will monitor the compliance report detailing the consistency of urine drug testing for patients on long-term opioid therapy through the Medical Executive Council which he chairs until compliance of at least 90 percent is sustained for six months.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy.⁸⁸ VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.⁸⁹ The OIG determined that providers completed informed consent for 21 percent of the patients reviewed.⁹⁰ Failure to complete informed consent could result in patients not having a full understanding about the risks, benefits, or alternatives to long-term opioid therapy. The acting Associate Chief of Staff, Ambulatory Care stated that primary care providers were unaware of the requirements for informed consent.

Recommendation 15

15. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers consistently obtain and document informed consent for patients prior to initiating long-term opioid therapy.

⁸⁸ VHA Directive 1005.

⁸⁹ VHA Directive 1005.

⁹⁰ Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Chief of Staff will ensure health care providers obtain and document informed consent consistently for patients prior to initiating long-term opioid therapy. A standard operating procedure will be developed to ensure providers have a clear process for prescribing long-term opioid therapy and detailing guidelines such as usage of the informed consent which includes the risks and benefits of opioid therapy and alternative therapies. Training for the standard operating procedure will be conducted by the Chair of the Pain Committee for all providers who prescribe opioids. Training completion will be reported to the Pain Management Committee once completed. The Chief of Staff will monitor the documentation of informed consent for patients prior to initiating long-term opioid therapy compared to the total number of patients initiated on long-term opioid therapy monthly until a 90 percent compliance rate is achieved for six months in the Medical Executive Council where he serves as chair.

VA/DoD clinical practice guidelines recommend “evaluating benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months.”⁹¹ The OIG determined that providers documented patient follow-ups within three months after initiating long-term opioid therapy in 45 percent of the electronic health records reviewed.⁹² Lack of follow-up could result in missed opportunities to assess patients for adherence to and effectiveness of opioid therapy and any adverse reactions. The acting Associate Chief of Staff, Ambulatory Care cited a shortage of primary care providers which prevented timely follow-ups as the reason for noncompliance.

Recommendation 16

16. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers follow up with patients within the required time frame after initiating long-term opioid therapy.

⁹¹ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁹² Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. A standard operating procedure will be developed to ensure providers complete follow up within the required time frame after initiating long-term opioid therapy. Training will be conducted by the Chair of the Pain Committee for all providers who prescribe opioids. The Chief of Staff will monitor follow up of patients compared to patients initiated on long-term opioid therapy within the required time frame. Data will be tracked monthly through the Medical Executive Council where the Chief of Staff is chair until a compliance rate of 90 percent has been achieved for six months.

Additionally, VHA requires “periodic evaluation of adherence, response to interventions, and achievement of time-limited therapeutic goals in the pain management plan.”⁹³ The OIG determined that 23 percent of patients reviewed had an assessment of adherence to a pain management plan of care.⁹⁴ Lack of patient adherence to the plan of care can result in poor pain control. The acting Associate Chief of Staff, Ambulatory Care cited the absence of a systematic documentation process as the reason for noncompliance.

Recommendation 17

17. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers’ follow-up with patients receiving long-term opioid therapy includes an assessment of adherence to the pain management plan of care.

⁹³ VHA Directive 2009-053.

⁹⁴ Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. Medical record documentation captures the completion of patient assessments that include the provider's evaluation of adherence, response to interventions, and achievement of time-limited therapeutic goals in the pain management plan. A standard operating procedure will be created to ensure that providers follow-up with patients receiving long-term opioid therapy and include an assessment of adherence to the pain management plan of care. Training will be conducted by the Chair of the Pain Committee for all Providers who prescribe opioids. The Chief of Staff will track training completion and monitoring of provider follow-up compared to patients receiving long-term opioid therapy, including assessments of adherence to the pain management plan of care. Data will be tracked monthly through the Medical Executive Council where the Chief of Staff is chair until a compliance rate of 90 percent has been achieved over six months.

VHA requires that providers monitor patients' responses to interventions in the pain management plan.⁹⁵ The OIG determined that providers documented effectiveness of interventions in 23 percent of patients reviewed.⁹⁶ Failure to evaluate and document effectiveness of interventions may result in patients receiving sub-optimal pain management. The Associate Chief of Staff, Ambulatory Care cited the lack of a systematic documentation process as the reason for noncompliance.

Recommendation 18

18. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers' follow-up with patients receiving long-term opioid therapy includes an assessment of intervention effectiveness.

⁹⁵ VHA Directive 2009-053.

⁹⁶ Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. A standard operating procedure will be created to ensure that providers follow up with patients receiving long-term opioid therapy which includes an assessment of intervention effectiveness. Training will be conducted by the Chair of the Pain Committee for all providers who prescribe opioids. The Chief of Staff will track training completion and monitoring of provider follow-up compared to patients receiving long-term opioid therapy and assessments of intervention effectiveness. Data will be tracked monthly through the Medical Executive Council where the Chief of Staff is chair until a compliance rate of 90 percent has been achieved over six months.

VHA requires facilities to have a multidisciplinary pain management committee to monitor the quality of pain assessment and effectiveness of pain management interventions.⁹⁷ TJC also requires that when deficiencies or opportunities for improvement are identified, action plans are implemented.⁹⁸ The OIG found that from October 23, 2019 through January 24, 2020, the Pain Management Committee did not monitor the quality or effectiveness of pain management. This resulted in the committee's inability to identify deficiencies and provide system leaders with recommendations to improve pain management outcomes. The acting Associate Chief of Staff, Ambulatory Care stated the Pain Management Committee was inactive due to frequent changes in staff and system leadership.

Recommendation 19

19. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that the Pain Management Committee monitors the quality of pain assessment and the effectiveness of pain management interventions.

⁹⁷ VHA Directive 2009-053.

⁹⁸ TJC. Leadership Standards LD.03.02.01, LD.03.05.01, and Performance Improvement PI.03.01.01.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found.

The Chief of Staff will ensure the quality of pain assessment and effectiveness of pain management interventions are tracked through the Medical Executive Council which he chairs.

The Chair of the Pain Committee will present the data monthly into the Medical Executive Council until 90 percent compliance is achieved for six months.

Mental Health: Suicide Prevention Program

In 2017, suicide was the 10th leading cause of death, with approximately 47,000 lives lost across the United States.⁹⁹ The suicide rate was 1.5 times greater for veterans than for non-veteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States.¹⁰⁰ Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.¹⁰¹

VHA has identified suicide prevention as a top priority and implemented various evidence-based approaches to reduce the veteran suicide rate. In addition to expanded mental health services and community outreach, VHA has developed comprehensive screening and assessment processes to identify at-risk patients.¹⁰²

VHA requires that each medical center and very large CBOC have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.¹⁰³ The OIG examined various requirements related to SPCs:

- Assignment of a full-time SPC
- Tracking and follow-up of high-risk veterans
 - Patients' completion of four appointments within the required time frame
 - Safety plan completion within the required time frame
 - Mental health teams' contacts with patients for missed appointments
- Provision of suicide prevention training for nonclinical employees at new employee orientation
- Completion of at least five outreach activities per month

VHA also requires that any patient determined to be at high risk for suicide be added to the facility high-risk list and have a High Risk for Suicide (HRS) Patient Record Flag (PRF) placed

⁹⁹ Centers for Disease Control and Prevention. *Preventing Suicide*.

<https://www.cdc.gov/violenceprevention/suicide/fastfact.html>. (The website was accessed on March 4, 2020.)

¹⁰⁰ Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*, September 2018; Department of Veterans Affairs, *National Strategy for Preventing Veteran Suicide 2018-2028*.

¹⁰¹ Veterans who recently used VHA services are defined as having an encounter in the calendar year of death or in the previous year; Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*.

¹⁰² *VA Office of Mental Health and Suicide Prevention Guidebook*, June 2018.

¹⁰³ According to VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015, very large CBOCs are those that serve more than 10,000 unique veterans each year. The Veterans Crisis Line connects veterans with qualified responders through a confidential toll-free hotline, online chat, and text-messaging service to receive confidential support 24 hours a day. Community outreach activities are described in VHA Handbook 1160.01.

in his or her electronic health record “as soon as possible but no later than 1 business day after such determination by the SPC.”¹⁰⁴ According to VHA, “Some studies indicate that up to two-thirds of patients who commit suicide have seen a physician in the month before their death... The primary purpose of the High Risk for Suicide PRF is to communicate to VA staff that a veteran is at high risk for suicide and the presence of a flag should be considered when making treatment decisions.”¹⁰⁵ The HRS PRF is reviewed at least every 90 days and depending on changes to the suicide risk status, will remain active or be removed.¹⁰⁶ Additionally, VHA requires designated high-risk patients to have a completed suicide safety plan and four face-to-face visits with an acceptable provider within the first 30 days of designation.¹⁰⁷

The OIG noted that from July 1, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA required that “Any patient determined to be High Risk for Suicide [by the licensed independent provider] must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination.”¹⁰⁸ However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management (DUSHOM) changed the requirement for the HRS PRF placement to be “as soon as possible but no later than 1 business day after determination by the SPC.”¹⁰⁹ VHA further provided additional clarifying information:

- The “SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list.”
- “The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted.”
- The SPC’s determination process “may be beyond 24 hours after a referral, due to case consultation and review.”¹¹⁰

The OIG is concerned that the updated requirement may result in delayed placement of the HRS PRFs for at-risk patients. Without defined time frames for SPC determination that the HRS PRF

¹⁰⁴ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

¹⁰⁵ VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008.

¹⁰⁶ *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*, January 5, 2018; VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

¹⁰⁷ A safety plan is a written list of coping strategies and support sources for use during or preceding suicidal crises. Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

¹⁰⁸ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

¹⁰⁹ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

¹¹⁰ VHA, *Response to Questions by VA OIG Office of Healthcare Inspections from February 12, 2020*, received on February 19, 2020.

is warranted, patients identified as at-risk for suicide could have flags placed in his or her chart several days after referral. For example, the current requirement would allow for a patient to be identified as high risk for suicide and referred to the SPC on Monday, the SPC to assess the patient for risk and determine the need for an HRS PRF on the following Friday, and the SPC to place an HRS PRF on the subsequent Monday (a week after referral).

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRFs to “occur no earlier than 10 days before and no later than 10 days after the 90-day due date.”¹¹¹

Inspectors examined the completion of several requirements:

- Review of HRS PRFs within the required time frame
- Completion of at least four mental health visits within 30 days of HRS PRF placement
- Appropriate follow-up for no-show high-risk appointments
- Completion of suicide safety plans with the required elements within the required time frame

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training.¹¹² VHA also requires that all staff receive annual refresher training.¹¹³ In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.¹¹⁴

To determine whether the healthcare system complied with OIG-selected suicide prevention program requirements, the inspection team interviewed key employees and reviewed

- Relevant documents;

¹¹¹ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

¹¹² Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym “S.A.V.E” summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for non-clinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

¹¹³ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

¹¹⁴ The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training. VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017.

- The electronic health records of 40 outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The OIG found the healthcare system complied with requirements associated with a designated SPC, patient tracking, monthly outreach activities, and suicide safety plans.

However, the OIG found deficiencies. With VHA’s original requirement that was in place when these patients received care—that “Any patient determined to be High Risk for Suicide must have a HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination”¹¹⁵—the OIG estimated that 58 percent of HRS PRFs were placed by the end of the next day following referral to the SPC.¹¹⁶ Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined timeframe for doing so)¹¹⁷, the OIG further calculated that the average time from referral to HRS flag placement for the patients reviewed was three days (observed range was 0–13 days).

Further, the OIG noted concerns with reviewing HRS PRFs within the required time frame. VHA required that all patients with an HRS PRF be reevaluated at least every 90 days and there is documented justification for continuing or discontinuing the flag.¹¹⁸ The OIG estimated that 45 percent of patients with an HRS PRF were reevaluated at least every 90 days.¹¹⁹ However, based upon the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation¹²⁰, the OIG found that 31 of 40 patients (78 percent) were reviewed within the expected time frame (observed range was 48–101 days).

Additionally, the OIG noted concerns with the completion of follow-up appointments and annual suicide prevention training.

VHA requires a veteran to have four follow-up visits with a qualified provider within 30 days of HRS PRF placement. The follow-up visits should be face-to-face unless the veteran requests a telephonic visit, and there must be documentation identifying the patient’s preference for a

¹¹⁵ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

¹¹⁶ The OIG estimated that 95 percent of the time, the true compliance rate is between 42.1 and 73 percent, which is statistically significantly below the 90 percent benchmark.

¹¹⁷ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

¹¹⁸ *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*. VHA Directive 2008-036; VHA Directive 2010-053, *Patient Record Flags*, December 3, 2010.

¹¹⁹ The OIG estimated that 95 percent of the time, the true compliance rate is between 30 and 60.5 percent, which is statistically significantly below the 90 percent benchmark.

¹²⁰ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

telephone call.¹²¹ The OIG estimated that providers conducted four mental health visits for 55 percent of patients reviewed.¹²² This resulted in insufficient follow-up of high-risk patients. The Associate Chief of Staff of Mental Health reported difficulty with attracting, recruiting, and retaining mental health providers.

Recommendation 20

20. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers conduct four follow-up appointments within the required time frame for patients flagged as high risk for suicide.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Mental Health Suicide Prevention Team and Health Administration Service will create a standard operating procedure for scheduling of the four follow-up appointments within 30 days, for patients flagged as high risk for suicide. The Suicide Prevention Coordinators will train the Health Administration Service and Mental Health providers using the standard operating procedure which outlines appointment scheduling for patients flagged as high risk for suicide. Monthly Electronic Health Record audits will be conducted, and compliance will be reported monthly into the Medical Executive Council which the Chief of Staff chairs for six months until at least 90 percent compliance is achieved.

VHA requires that all employees complete suicide risk and intervention training within 90 days of entering their position. Clinical staff must complete the Suicide Risk Management Training for Clinicians, and nonclinical staff are required to complete Operation S.A.V.E. training. VHA also requires that all staff, clinical and nonclinical, receive annual refresher training thereafter.¹²³ The OIG found that 8 of 18 clinical or nonclinical staff did not complete mandatory annual refresher training. Failure to complete the training could prevent staff from providing optimal treatment to patients with suicidal ideations. The Chief, Quality Management stated that a lack of programmatic oversight contributed to the clinical staff's failure to complete the annual training.

¹²¹ VA's *Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

¹²² The OIG estimated that 95 percent of the time, the true compliance rate is between 39.5 and 70.6 percent, which is statistically significantly below the 90 percent benchmark.

¹²³ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

Recommendation 21

21. The System Director evaluates and determines any additional reasons for noncompliance and ensures clinical and nonclinical staff complete annual suicide prevention refresher training.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Suicide Prevention Coordinators will track completion of annual suicide prevention refresher training through the Talent Management System by all clinical and nonclinical staff monthly. The Suicide Prevention Coordinators will provide this monthly report to Service Chiefs for follow up of non-compliant staff identified and ensure the required Suicide Prevention Refresher training is completed annually. The Health Care System Director will ensure Annual Suicide Prevention Refresher training is tracked by the Suicide Prevention Coordinators monthly through the Medical Center Governing Board until sustained compliance of 90 percent is achieved for six months.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. Life-sustaining treatments may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by “...eliciting, documenting, and honoring patients’ values, goals, and preferences.”¹²⁴

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.¹²⁵ Implementation requirements included initiating conversations about the goals of care. A goals of care conversation is a discussion between a healthcare provider and a patient or surrogate to help define the patient’s values, goals, and preferences for care and, based on the discussion, make choices about starting, limiting, or ceasing LSTs.¹²⁶ VHA requires practitioners to initiate goals of care conversations with high-risk patients—including hospice patients or their surrogates—within a time frame that meets the medical needs of the patient or at the time of a triggering event.¹²⁷

The OIG noted that from July 12, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA policy defined the elements of a goals of care conversation to be documented in an LST progress note in the electronic health record, which included

- Decision-making capacity,
- Identification of a surrogate if the patient loses decision-making capacity,
- Patient or surrogate understanding of the patient’s condition,
- Goals of care,
- Plan of care for the use of LST, including whether cardiopulmonary resuscitation will be attempted in the event of cardiac arrest, and
- Informed consent for the LST plan.

¹²⁴ VHA Handbook 1004.03(1), *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients’ Values, Goals and Preferences*, January 11, 2017, amended March 19, 2020.

¹²⁵ According to VHA Handbook 1004.03(1), the medical facility must fully implement handbook requirements within 18 months of publication.

¹²⁶ According to VHA Handbook 1004.03(1), a surrogate is legally authorized under VA policy to serve as the decision maker on behalf of the patient should the patient lose decision-making capacity.

¹²⁷ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017, defines hospice patients as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. According to VHA Handbook 1004.03(1), triggering events requiring goals of care conversations include those “prior to referral or following admission (e.g., within 24 hours) to VA or non-VA hospice.”

However, on March 19, 2020, VHA amended the requirements related to documenting patients' goals of care. Although the elements of the goals of care conversation are still required, the LST progress note must document at a minimum

- Decision-making capacity,
- Goal(s) of care,
- Plan of care for the use of LST, and
- Informed consent for the LST plan.

The OIG is concerned that VHA's updated requirement could mislead practitioners to only address those goals of care conversation elements that are required to be documented in the LST progress note.

The healthcare system was assessed for its adherence to requirements for goals of care conversations:

- Completion of LSTD notes
- Timely documentation of LSTD
- Inclusion of required elements in LSTD documentation
- Completion of LSTD note/orders by an authorized provider or delegation to a designee met all requirements

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service.¹²⁸ Inspectors examined if the healthcare system established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the healthcare system complied with the OIG-selected requirements related to LSTD for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 17 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

The healthcare system generally complied with requirements for the LSTD committee.

¹²⁸ VHA Handbook 1004.03(1).

Additionally, with VHA's original requirements that were in place when these patients received care,¹²⁹ the OIG found that

- 50 percent of patients' LST progress notes addressed identification of a surrogate if the patient loses decision-making capacity,
- 83 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes, and
- 50 percent of patients' LST progress notes addressed the patient's or surrogate's understanding of the patient's condition.

However, VHA recently deleted requirements for the documentation of these elements in the LST progress note.¹³⁰ The OIG remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

Further, the OIG found a deficiency with providers completing goals of care conversations.

VHA requires that providers complete a goals of care conversation with hospice patients and document life-sustaining treatment decisions before entering a referral to VA or non-VA hospice.¹³¹ The OIG determined that providers completed goals of care conversations prior to a hospice referral for 35 percent of the patients reviewed.¹³² Failure to document the LST plan may prevent patients from having their "values, goals, and preferences regarding the initiation, limitation or discontinuation of LSTs" identified and met.¹³³

The Assistant Chief of Staff, Geriatrics and Extended Care and Rehabilitation stated that, due to frequent staff turnover and provider shortage, there was a delay implementing procedures to meet VHA's LSTD Initiative requirements. This delay limited providers' ability to understand, address, and document LSTD requirements. The Assistant Chief of Staff, Geriatrics and Extended Care and Rehabilitation also cited frequent turnovers at the executive level resulted in inadequate oversight by senior leaders.

Recommendation 22

22. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers complete and document goals of care conversations prior to hospice referrals.

¹²⁹ VHA Handbook 1004.03(1).

¹³⁰ VHA Handbook 1004.03(1).

¹³¹ VHA Handbook 1004.03(1).

¹³² Confidence intervals are not included because the data represents every patient in the study population.

¹³³ VHA Handbook 1004.03(1).

Healthcare system concurred.

Target date for completion: February 28, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found.

Health care practitioners will complete and document goals of care conversations within the life-sustaining treatment note prior to hospice referral in the Patient's medical record. Training on completion and documentation of the goals of care conversations prior to hospice referrals will be provided by the Associate Chief of Staff for Geriatrics and Extended Care to all Clinical Social Workers, Physician Assistants, Registered Nurses, Physicians, Psychologists, Nurse Practitioners and Residents. Audits will be completed by the Associate Chief of Staff of Geriatrics and Extended Care monthly and reported into the Medical Executive Council which the Chief of Staff chairs for six months until 90 percent compliance is achieved.

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹³⁴ According to data released by the National Center for Veterans Analysis and Statistics in May 2019, the total veteran population and proportion of male veterans are projected to decrease while the proportion of female veterans are anticipated to increase.¹³⁵ To help the VA better understand the needs of the growing women's veteran population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."¹³⁶ Additionally, a VA report in 2016 on suicide among veterans pointed out concerning trends in suicide among women veterans and discussed "the importance of understanding suicide risk among women veterans and developing gender-tailored suicide prevention strategies."¹³⁷

VHA requires that all eligible and enrolled women veterans have access to timely, high-quality, and comprehensive healthcare services in a sensitive and safe environment. Facilities must, therefore, ensure availability of appropriate resources, services, and staffing ratios.¹³⁸ VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veteran health committee that "develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."¹³⁹

To determine whether the healthcare system complied with OIG-selected VHA requirements to provide comprehensive healthcare services to women veterans, the inspection team reviewed relevant documents and interviewed selected managers and staff on the following requirements:

- Provision of care requirements

¹³⁴ National Center for Veterans Analysis and Statistics, "VETPOP2016 LIVING VETERANS BY AGE GROUP, GENDER, 2015-2045," Table 1L. https://www.va.gov/vetdata/Veteran_Population.asp. (The website was accessed on November 14, 2019.)

¹³⁵ National Center for Veterans Analysis and Statistics, "Veteran Population," May 3, 2019. https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf. (The website was accessed on September 16, 2019.)

¹³⁶ U.S. Department of Veterans Affairs, "Study of Barriers for Women Veterans to VA Health Care," Final Report, April 2015. https://www.womenshealth.va.gov/docs/Womens%20Health%20Services_Barriers%20to%20Care%20Final%20Report_April2015.pdf. (The website was accessed on September 16, 2019.)

¹³⁷ U.S. Department of Veterans Affairs, Health Services Research & Development, Forum, *Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions*, Suicide Prevention, Spring 2018. <https://www.hsr.d.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5>. (The website was accessed on September 16, 2019.)

¹³⁸ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020.

¹³⁹ VHA Directive 1330.01(3).

- Designated Women’s Health Patient Aligned Care Team established
- Primary Care Mental Health Integration (PCMHI) services available
- Gynecologic care coverage available 24/7
- Gynecology care accessible
- Facility women health primary care providers designated
- CBOC women’s health primary care providers designated
- Emergency contraception accessible
- Oversight of program and monitoring of performance improvement data
 - Women Veterans Health Committee established
 - Quarterly meetings held
 - Core members attend
 - Quality assurance data collected and tracked
 - Reports made to clinical executive leaders
- Assignment of required staff
 - Women Veterans Program Manager
 - Women’s Health Medical Director or clinical champion
 - Maternity Care Coordinator
 - Women’s health clinical liaison at each CBOC

Women’s Health Findings and Recommendations

The healthcare system complied with requirements for most of the provision of care indicators and each of the selected staffing elements reviewed. However, the OIG identified deficiencies with the Women Veterans Health Committee.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership. That membership includes a women veterans program manager; a women’s health medical director; and “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.”¹⁴⁰ The OIG was informed that from January through November 2019, the Women Veterans Health Committee did not report to executive leaders. Failure to report activities to executive leaders has

¹⁴⁰ VHA Directive 1330.01(3).

the potential to impede oversight and support of the women's health program. The acting Chief of Staff reported that the Women Veterans Health Committee reporting schedule was affected by governance changes made through a prior acting Chief of Staff.

The OIG also noted that from January through May 2018, representatives from mental health, medical and/or surgical subspecialties, pharmacy, radiology, business office/Non-VA medical care, social work and care management, nursing, and a member from executive leadership did not attend any scheduled meetings. Furthermore, representatives from primary care, gynecology, and the Emergency Department lacked consistent attendance. This could result in a lack of expertise and oversight in the review and analysis of data as the committee plans and carries out improvements for quality and equitable care for women veterans. The acting Chief of Staff reported that leadership was reviewing all governance charters and that past charters were poorly written or not executed.

Recommendation 23

23. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that all required members consistently attend Women Veterans Health Committee meetings and the committee reports to executive leaders.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Health Care System Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Women Veterans Health Committee charter reflects all required committee members. The Chair of the Women Veterans Health Committee will track attendance of core members within the meeting minutes. The Health Care System Director will ensure attendance for core members will be reported by the Chair of the Women Veteran's Health Committee into the Medical Center Governing Board monthly for six months until 90 percent compliance is achieved.

VHA requires the facility to collect and track quality assurance data related to appropriate and timely follow-up care of abnormal breast cancer screening results, cervical screening results, customer satisfaction initiatives and outcomes; and women veterans who are waiting more than 30 days for a clinic appointment.¹⁴¹ The OIG found that healthcare system staff did not collect or track quality assurance data related to customer satisfaction initiatives and outcomes or wait times. This could prevent the healthcare system from identifying opportunities for practice improvements, ensuring appropriate action is taken, and measuring the effectiveness of those

¹⁴¹ VHA Directive 1330.01(3).

actions on a regular basis. The Women Veterans Program Manager stated that members of the committee failed to report the customer satisfaction data due to competing priorities. Additionally, the Women Veterans Program Manager reported that the Access Committee's discussion of wait time data met the requirement.

Recommendation 24

24. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that healthcare system staff collect and track the required women veterans quality assurance data.

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Chief of Staff attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. A comprehensive quality assurance scorecard was created to collect and track customer satisfaction initiatives and outcomes. The quality assurance scorecard data is reported every other month in the Women Veterans Health Committee. The Chief of Staff will ensure the Women's Health Medical Director will collect and track the required Women Veterans Program quality assurance data and report compliance of at least 90 percent monthly for six months into the Medical Executive Council which he chairs.

High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have a Sterile Processing Services (SPS) “to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment...”¹⁴² The goal of SPS is to “...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections.”¹⁴³ To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME
- Have standard operating procedures (SOPs) that are based on current manufacturer’s guidelines and reviewed at least triennially
- Use CensiTrac[®] Instrument Tracking System for tracking reprocessed instruments¹⁴⁴
- Perform annual risk analysis and report results to the VISN SPS Management Board
- Monitor data for reprocessing and storing RME
- Conduct annual airflow/ventilation system inspections¹⁴⁵

VHA requires strict controls that closely monitor climate, storage, and sterilization parameters and additionally requires that quality assurance documentation of this monitoring be maintained for a minimum of three years.¹⁴⁶ The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.¹⁴⁷

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station, personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME.¹⁴⁸

¹⁴² VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

¹⁴³ Association for Professionals in Infection Control and Epidemiology, *APIC Text of Infection Control and Epidemiology*, Chapter 107: Sterile Processing, April 26, 2019. https://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing#book_section_17348. (The website was accessed on May 14, 2019.)

¹⁴⁴ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.

¹⁴⁵ VHA Directive 1116(2).

¹⁴⁶ VHA Directive 1116(2); VHA DUSHOM Memorandum, *Interim Guidance for Heating, Ventilation and Air Conditioning (HVAC) Requirements Related to Reusable Medical Equipment (RME) Reprocessing and Storage*, September 5, 2017.

¹⁴⁷ VHA Directive 7704(1), *Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment*, February 16, 2016.

¹⁴⁸ VHA Directive 1116(2).

VHA also requires facilities to provide training for staff who reprocess RME; this training must be provided and documented prior to the reprocessing of equipment. The required training includes mandatory initial competencies, continued annual and essential staff competency assessments, and monthly continuing education. This ensures that staff have sufficient aptitude, knowledge, and skills to effectively and safely reprocess and sterilize RME.¹⁴⁹

To determine whether the healthcare system complied with OIG-selected requirements, the inspection team examined relevant documents and training records; conducted physical inspections of the SPS, Gastroenterology SPS, and sterile storage areas; and interviewed key managers and staff on the following:

- Requirements for administrative processes
 - RME inventory file is current
 - SOPs are based on current manufacturer's guidelines and reviewed at least triennially
 - CensiTrac[®] System used
 - Risk analysis performed and results reported to the VISN SPS Management Board
 - Airflow checks made
 - Eyewash station checked
 - Daily cleaning schedule maintained
- Monitoring of quality assurance
 - High-level disinfectant solution tested
 - Bioburden tested
- Physical inspections of reprocessing and storage areas
 - Traffic restricted
 - Airflow monitored
 - Personal protective equipment available
 - Area is clean
 - Eating or drinking in the area prohibited
 - Equipment properly stored
 - Required temperature and humidity maintained

¹⁴⁹ VHA Directive 1116(2).

- Completion of staff training, competency, and continuing education
 - Required training completed in a timely manner
 - Competency assessments performed
 - Monthly continuing education received

High-Risk Processes Findings and Recommendations

The healthcare system met the requirements for a current reusable medical equipment inventory, standard operating procedures, quality assurance monitoring, and most of the reprocessing and storage area physical inspection elements reviewed. However, the OIG identified deficiencies with the annual risk analysis; airflow monitoring; and staff training, competency, and continuing education.

VHA requires that the SPS Chief performs an annual risk analysis and reports the results to the VISN SPS Management Board.¹⁵⁰ The OIG found no evidence that the FY 2019 risk analysis, which was completed in March 2019, was reported to the VISN SPS Management Board. Failure to report the risk analysis could result in a lack of identification of potential problems or process failures.¹⁵¹ The RME Coordinator stated the reason for noncompliance was a lack of oversight by the SPS Chief and the VISN SPS Lead.

Recommendation 25

25. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Services Chief reports the annual risk analysis to the Veteran Integrated Service Network Sterile Processing Services Management Board.

¹⁵⁰ VHA Directive 1116(2).

¹⁵¹ VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: January 31, 2021

Healthcare system response: The Associate Director for Patient Care Services attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Sterile Processing Service Chief will report the annual risk analysis to the Veteran Integrated Service Network (VISN) Sterile Processing Services Management Board annually. The Associate Director for Patient Care Services will ensure the Sterile Processing Service Chief reports submission to VISN 7 no later than one month after completion of the annual risk assessment. Initial compliance will be reported by the Reusable Medical Equipment Committee into the Healthcare Excellence Council, which the Associate Director for Patient Care Services chairs and then annually.

VHA requires that airflow checks be performed annually and “after the repair of the heating, ventilation and air-conditioning (HVAC) system, extended shut-down or equipment replacement.”¹⁵² The OIG found the SPS core room did not have an annual airflow check completed.¹⁵³ Failure to evaluate the heating, ventilation, and air-conditioning system may result in an increased opportunity for healthcare-associated infections.¹⁵⁴ The RME Coordinator reported being aware of the requirement but was unaware the room was not included in the annual airflow report. The annual airflow inspection for the SPS core room was completed while the OIG was on site.

Recommendation 26

26. The Deputy Director evaluates and determines any additional reasons for noncompliance and ensures that the Chief, Engineering Services conducts annual airflow testing in all areas where reusable medical equipment is reprocessed or stored.

¹⁵² VHA Directive 1116(2).

¹⁵³ The SPS core room houses sterile storage and is centrally located to the operating room, endoscopy work room, scope storage room, and sterile storage area.

¹⁵⁴ Centers for Disease Control and Prevention, *Guidelines for Environmental Infection Control in Health-Care Facilities, July 2019*. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>. (The website was accessed on August 15, 2019.)

Healthcare system concurred.

Target date for completion: July 30, 2020

Healthcare system response: The Deputy Director attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. Engineering Services will have vendors conduct annual airflow testing in all areas where reusable medical equipment is reprocessed or stored. The Deputy Director will ensure the Chief, Engineering Service provides an annual report for review as evidenced in the Environment of Care Committee minutes.

VHA requires that “commercial airflow directional devices must be utilized to enable SPS staff to verify the airflow direction.”¹⁵⁵ The OIG found the SPS core room lacked a commercial airflow directional device. Failure to monitor airflow direction could result in a potential spread of microorganisms from dirty to clean areas and increase the risk for healthcare-associated infections.¹⁵⁶ The RME Coordinator was reportedly unaware that an airflow directional device must be used in the SPS core room.

Recommendation 27

27. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that commercial airflow directional devices are used in areas where reusable medical equipment is reprocessed and stored.

Healthcare system concurred.

Target date for completion: February 28, 2021

Healthcare system response: The Associate Director for Patient Care Services attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Reusable Medical Equipment Coordinator will ensure commercial airflow directional devices are utilized to enable sterile processing service staff to verify the airflow direction in all areas where reusable medical equipment is reprocessed and stored. The Associate Director for Patient Care Services will ensure the Reusable Medical Equipment Coordinator provides an annual report for review as evidenced in the Environment of Care Committee minutes.

¹⁵⁵ VHA Directive 1116(2).

¹⁵⁶ Centers for Disease Control and Prevention, *Guidelines for Environmental Infection Control in Health-Care Facilities, July 2019*. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>. (The website was accessed on August 15, 2019.)

Since March 23, 2016, VHA has required that “all new SPS employees must complete the SPS Level 1 training program within 90 days of hire.”¹⁵⁷ The OIG found that the two SPS staff hired after March 23, 2016, had completed the SPS Level 1 training modules but not within 90 days of hire. A lack of timely training could result in improperly cleaned RME and place patients and employees at risk of microbial contamination and exposure to chemical and material hazards. The RME Coordinator reported a time-consuming SPS orientation and lack of a staff training tracking process as contributing factors to noncompliance.

Recommendation 28

28. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that all new Sterile Processing Services employees complete Level 1 training within 90 days of hire.

Healthcare system concurred.

Target date for completion: September 30, 2020

Healthcare system response: The Associate Director for Patient Care Services attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. Sterile Processing Service Level 1 education will be distributed through the Talent Management System module to ensure new Sterile Processing Service staff complete Level 1 training within 90 days of hire. Talent Management System reports will be provided monthly to the Sterile Processing Service Supervisor. The Associate Director for Patient Care Services will ensure the Reusable Medical Equipment Committee tracks and reports the education for all Sterile Processing Service staff into the Health Care Excellence Council as evidenced by the Council minutes, which the Associate Director for Patient Care Services chairs for six months until compliance is achieved.

VHA requires that SPS staff complete competency assessments for reprocessing RME that include two methods of verification to validate and measure an individual’s proficiency for a specific task.¹⁵⁸ The OIG found that three of eight SPS staff had incomplete competency assessments. Failure to properly complete the required competency assessments could result in improper reprocessing of RME and place patients and employees at risk of microbial contamination and exposure to chemical and material hazards.¹⁵⁹ The RME Coordinator reported

¹⁵⁷ VHA Directive 1116(2).

¹⁵⁸ VHA DUSHOM Memorandum, *Competency Assessment for Employees Reprocessing Critical and Semi-critical Reusable Medical Equipment*, April 11, 2017.

¹⁵⁹ Centers for Disease Control and Prevention, *Guidelines for Environmental Infection Control in Health-Care Facilities, July 2019*. <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>. (The website was accessed on August 15, 2019.)

that dual roles coordinating RME processes and educating SPS staff, along with attending either weekly or bi-weekly CBOC inspections resulted in insufficient time to complete the assessments.

Recommendation 29

29. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that the Reusable Medical Equipment Coordinator completes competency assessments for all staff reprocessing reusable medical equipment.

Healthcare system concurred.

Target date for completion: September 30, 2020

Healthcare system response: The Associate Director for Patient Care Services attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Sterile Processing Service Educator will perform audits every two months on all competency assessments for staff reprocessing medical equipment for completeness. The audits performed every two months will be reported by the Reusable Medical Equipment Committee into the Healthcare Excellence Council as evidenced by the Council minutes, which is chaired by the Associate Director for Patient Care Services until compliance is achieved for six months.

In addition, VHA requires that SPS staff receive monthly “in-service education sessions focusing on the technical aspects of SPS...including an attendance roster, clear objectives of the training and a brief description of the content to be covered.”¹⁶⁰ The OIG found no evidence of monthly education for three of eight SPS staff from November 2019 through January 2020. This resulted in a potential knowledge gap in the technical aspects of sterile processing duties. The RME Coordinator reported competing priorities and collateral duties as reasons for noncompliance.

Recommendation 30

30. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that Sterile Processing Services staff receive monthly continuing education.

¹⁶⁰ VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: September 30, 2020

Healthcare system response: The Associate Director for Patient Care Services attests that additional reasons for noncompliance were considered when developing the action plan and there were no additional reasons found. The Reusable Medical Equipment Committee will track staff compliance for monthly continuing education by utilization of a tracking tool. The compliance will be reported by the Reusable Medical Equipment Committee quarterly into the Healthcare Excellence Council, which the Associate Director for Patient Care Services chairs for six months until 90 percent compliance is achieved.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

The intent is for system 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	Requirements	Conclusion
Leadership and Organizational Risks	<ul style="list-style-type: none"> • Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation surveys and oversight inspections • Factors related to possible lapses in care and healthcare system response • VHA performance data (facility or system) • VHA performance data for CLCs 	<p>Thirty 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, Chief of Staff, ADPCS, Deputy Director, and Associate Director. See details below.</p>

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	<ul style="list-style-type: none"> • QSV Committee • Protected peer reviews • UM reviews • Patient safety 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Final peer reviews are completed within 120 calendar days from the date a peer review is required and any necessary extensions are approved in writing by the System Director. • A summary of the Peer Review Committee's analyses is reviewed quarterly by the Medical Executive Council. • Physician utilization management advisors consistently document their decisions in the National UM Integration database. • All required representatives consistently participate in interdisciplinary reviews of UM data. • Patient Safety Manager ensures that root cause analyses include all required review elements and are properly documented in the VHA Patient Safety Information System. • The Patient Safety Manager submits each root cause analysis to the National Center for Patient Safety timely. • The Patient Safety Manager or designee provides feedback to staff who submit adverse event reports that result in root cause analysis actions.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	<ul style="list-style-type: none"> • FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards 	<ul style="list-style-type: none"> • Providers with similar training and privileges complete focused and ongoing professional practice evaluations of licensed independent practitioners. • Reprivileging decisions are based on service- or section-specific ongoing professional practice evaluation data. 	<ul style="list-style-type: none"> • The licensed healthcare professional's first- or second-line supervisor completes and signs the exit review form within seven calendar days of departure from the healthcare system.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Environment of Care	<ul style="list-style-type: none"> • Medical centers <ul style="list-style-type: none"> ○ General safety ○ Special use spaces ○ Environmental cleanliness and infection prevention ○ Privacy ○ Accommodation and privacy for women veterans ○ Logistics • Inpatient mental health unit <ul style="list-style-type: none"> ○ General safety ○ Special use spaces ○ Environmental cleanliness and infection prevention ○ Privacy ○ Accommodation for women veterans ○ Logistics • Community-based outpatient clinic <ul style="list-style-type: none"> ○ General safety ○ Special use spaces ○ Environmental cleanliness and infection prevention ○ Privacy ○ Privacy for women veterans ○ Logistics 	<ul style="list-style-type: none"> • Healthcare system managers maintain a safe and clean environment by identifying and resolving environmental deficiencies found during environment of care rounds. 	<ul style="list-style-type: none"> • None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
<p>Medication Management: Long-Term Opioid Therapy</p>	<ul style="list-style-type: none"> • Provision of pain management using long-term opioid therapy • Program oversight and evaluation 	<ul style="list-style-type: none"> • Providers complete an aberrant behavior risk assessment on all patients prior to initiating long-term opioid therapy. • Providers document justification for prescribing opioids and benzodiazepines concurrently. • Providers consistently conduct urine drug testing for patients on long-term opioid therapy. • Providers consistently obtain and document informed consent for patients prior to initiating long-term opioid therapy. • Providers follow up with patients within the required time frame after initiating long-term opioid therapy. • Providers' follow-up of patients receiving long-term opioid therapy includes an assessment of adherence to the pain management plan of care. • Providers' follow-up with patients receiving long-term opioid therapy includes an assessment of intervention effectiveness. 	<ul style="list-style-type: none"> • The Pain Management Committee monitors the quality of pain assessment and the effectiveness of pain management interventions.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Mental Health: Suicide Prevention Program	<ul style="list-style-type: none"> • Designated facility suicide prevention coordinator • Provision of suicide prevention care • Completion of suicide prevention training requirements 	<ul style="list-style-type: none"> • Providers conduct four follow-up appointments within the required time frame for patients flagged as high risk for suicide. 	<ul style="list-style-type: none"> • Clinical and nonclinical staff receive annual suicide prevention refresher training.
Care Coordination: Life-Sustaining Treatment Decisions	<ul style="list-style-type: none"> • LSTD multidisciplinary committee • Goals of care conversation documentation • LSTD note/orders completed by an authorized provider or delegated 	<ul style="list-style-type: none"> • Providers complete and document goals of care conversations prior to hospice referrals. 	<ul style="list-style-type: none"> • None
Women's Health: Comprehensive Care	<ul style="list-style-type: none"> • Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Required members consistently attend Women Veterans Health Committee meetings and the committee reports to executive leaders. • Healthcare system staff collect and track the required quality assurance data.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
<p>High-Risk Processes: Reusable Medical Equipment</p>	<ul style="list-style-type: none"> • Administrative processes • Data monitoring • Physical inspection • Staff training 	<ul style="list-style-type: none"> • The Chief, Engineering Services conducts annual airflow testing in all areas where reusable medical equipment is reprocessed and stored. • Commercial airflow directional devices are used in areas where reusable medical equipment is reprocessed and stored. 	<ul style="list-style-type: none"> • The Sterile Processing Services Chief reports the annual risk analysis to the Veteran Integrated Service Network Sterile Processing Services Management Board. • Sterile Processing Services employees complete Level 1 training within 90 days of hire. • Reusable Medical Equipment Coordinator completes competency assessments for all staff reprocessing reusable medical equipment. • Sterile Processing Services staff receive monthly continuing education.

Appendix B: Healthcare System Profile

The table below provides general background information for this high complexity (1c) healthcare system reporting to VISN 7.¹

**Table B.1. Profile for Central Alabama Veterans Health Care System (619)
(October 1, 2016, through September 30, 2019)**

Profile Element	Healthcare System Data FY 2017 ²	Healthcare System Data FY 2018 ³	Healthcare System Data FY 2019 ⁴
Total medical care budget in dollars	\$315,918,319	\$323,722,618	\$322,138,369
Number of:			
• Unique patients	49,087	49,705	49,831
• Outpatient visits	550,446	542,625	498,582
• Unique employees ⁵	1,409	1,385	1,367
Type and number of operating beds:			
• Community living center	160	160	160
• Domiciliary	73	73	73
• Medicine	27	27	27
• Mental health	30	30	30
• Rehabilitation medicine	10	10	10
• Residential rehabilitation	12	12	12
• Surgery	4	4	4
Average daily census:			
• Community living center	55	63	49
• Domiciliary	60	56	51
• Medicine	13	10	5
• Mental health	25	16	16
• Rehabilitation medicine	0	–	–
• Residential rehabilitation	4	4	4

¹ The VHA medical centers are classified according to a facility complexity model; a designation of “1c” indicates a facility with “medium-high volume, medium risk patients, some complex clinical programs, and medium sized research and teaching programs.”

² October 1, 2016, through September 30, 2017.

³ October 1, 2017, through September 30, 2018.

⁴ October 1, 2018, through September 30, 2019.

⁵ Unique employees involved in direct medical care (cost center 8200).

Profile Element	Healthcare System Data FY 2017 ²	Healthcare System Data FY 2018 ³	Healthcare System Data FY 2019 ⁴
• Surgery	0	0	0

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.

Appendix C: VA Outpatient Clinic Profiles¹

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

Table C.1. VA Outpatient Clinic Workload/Encounters and Specialty Care, Diagnostic, and Ancillary Services Provided (October 1, 2018, through September 30, 2019)²

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Columbus, GA	619GA	9,491	11,473	Endocrinology Eye Neurology	n/a	Nutrition Pharmacy Social work Weight management
Dothan, AL	619GB	1,341	23	n/a	n/a	Nutrition Social work

¹ Includes all outpatient clinics in the community that were in operation as of August 27, 2019.

² 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. An encounter is a “professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient’s condition.”

³ Specialty care services refer to non-primary care and non-mental health services provided by a physician.

⁴ Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

⁵ Ancillary services include chiropractic, dental, nutrition, pharmacy, prosthetic, social work, and weight management services.

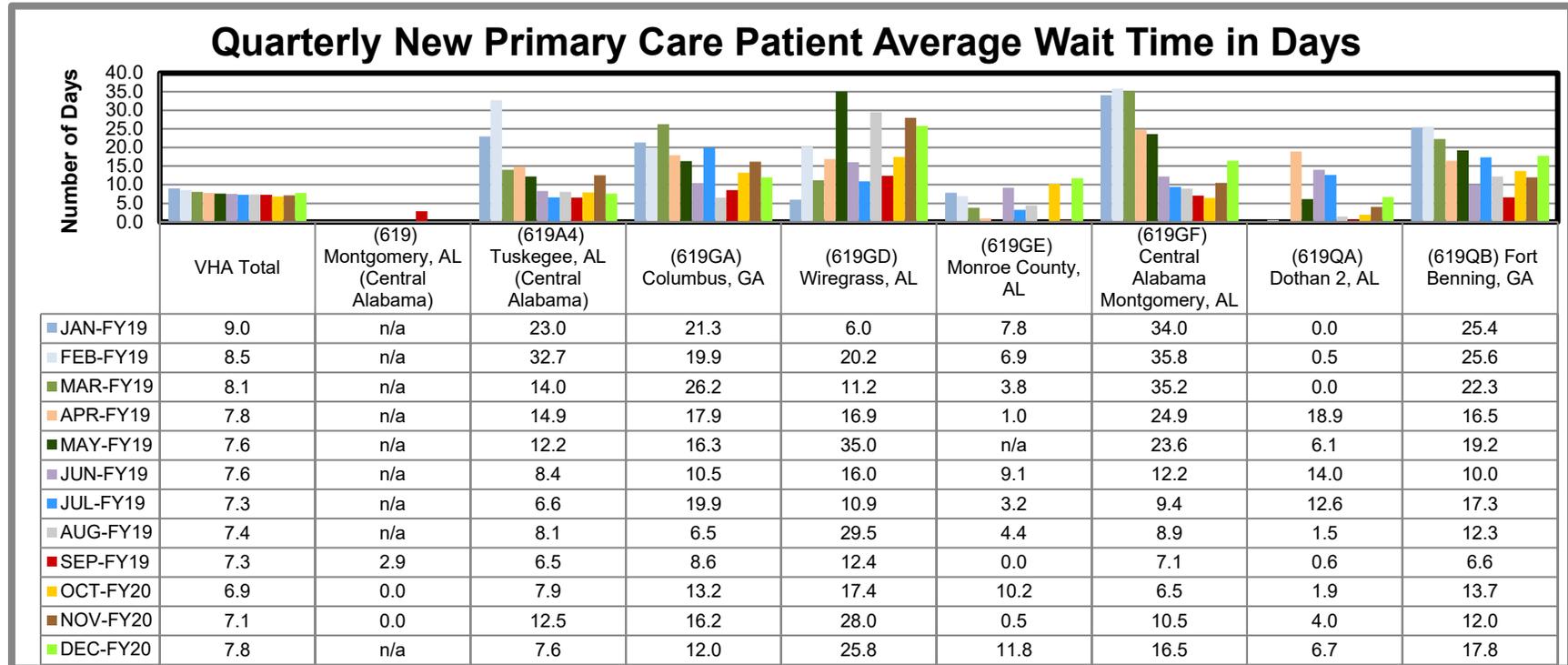
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Fort Rucker, AL	619GD	11,388	4,389	Dermatology Endocrinology Eye	n/a	Dental Nutrition Pharmacy Social work Weight management
Monroeville, AL	619GE	3,626	1,771	n/a	n/a	Pharmacy Social work Weight management
Montgomery, AL	619GF	39,470	2,224	Eye Spinal cord injury	n/a	Dental Nutrition Pharmacy Prosthetics Social work Weight management
Dothan, AL	619QA	5,168	6,674	n/a	n/a	n/a
Fort Benning, GA	619QB	19,160	1,351	Eye	n/a	Nutrition Pharmacy Social work

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 D: Patient Aligned Care Team Compass Metrics¹



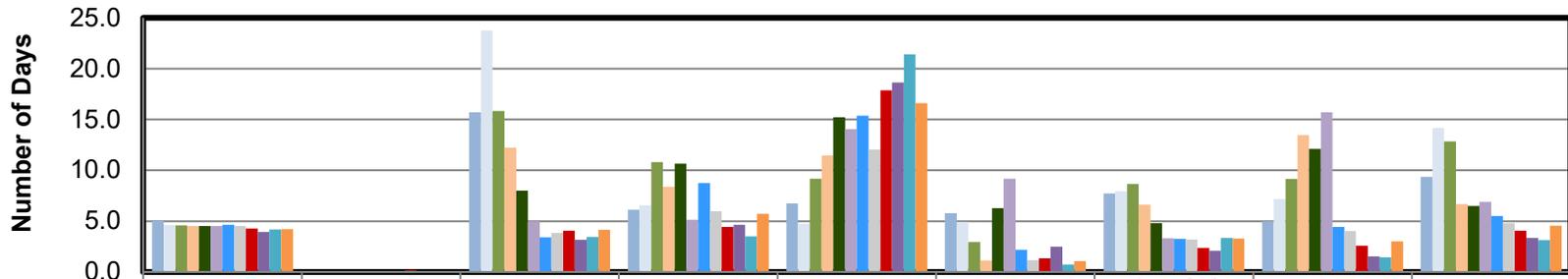
Source: VHA Support Service Center

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG has on file the healthcare system’s explanation for the increased wait times for the (619GD) Wiregrass, AL; and ((619GF) Central Alabama Montgomery, AL, CBOCs. The OIG omitted (619GB) Dothan 1, AL, 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. The absence of reported data is indicated by “n/a.”

¹ Department of Veterans Affairs, *Patient Aligned Care Teams Compass Data Definitions*, accessed on October 21, 2019.

Quarterly Established Primary Care Patient Average Wait Time in Days



	VHA Total	(619) Montgomery, AL (Central Alabama)	(619A4) Tuskegee, AL (Central Alabama)	(619GA) Columbus, GA	(619GD) Wiregrass, AL	(619GE) Monroe County, AL	(619GF) Central Alabama Montgomery, AL	(619QA) Dothan 2, AL	(619QB) Fort Benning, GA
JAN-FY19	5.0	n/a	15.7	6.1	6.7	5.8	7.7	5.0	9.4
FEB-FY19	4.6	n/a	23.7	6.6	4.7	4.9	8.0	7.2	14.2
MAR-FY19	4.6	n/a	15.8	10.8	9.2	3.0	8.7	9.1	12.8
APR-FY19	4.5	n/a	12.2	8.4	11.5	1.1	6.6	13.5	6.7
MAY-FY19	4.5	n/a	8.0	10.7	15.2	6.3	4.8	12.1	6.5
JUN-FY19	4.5	n/a	5.0	5.1	14.0	9.2	3.3	15.7	6.9
JUL-FY19	4.6	n/a	3.4	8.7	15.4	2.2	3.3	4.4	5.5
AUG-FY19	4.5	n/a	3.8	6.0	12.0	1.2	3.2	4.0	4.8
SEP-FY19	4.3	0.2	4.1	4.4	17.9	1.4	2.4	2.6	4.1
OCT-FY20	3.9	0.0	3.2	4.7	18.6	2.5	2.1	1.5	3.3
NOV-FY20	4.2	0.0	3.5	3.5	21.4	0.7	3.3	1.4	3.1
DEC-FY20	4.2	0.0	4.2	5.7	16.6	1.1	3.3	3.0	4.6

Source: VHA Support Service Center

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted (619GB) Dothan 1, AL, as no data were 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 E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions¹

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
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
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
HC assoc infections	Health care associated infections	A lower value is better than a higher 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 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

¹ VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL)* (last updated September 30, 2019). <https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428>. (The website was accessed on March 6, 2020, but is not accessible by the public.)

Measure	Definition	Desired Direction
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
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
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
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
SC care coordination	SC (specialty care) care coordination	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
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
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value

Source: VHA Support Service Center

Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions¹

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.

¹ *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated December 12, 2019). <http://vawww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410>. (The website was accessed on January 13, 2020, but is not accessible by the public.)

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: July 6, 2020

From: Interim Director, VA Southeast Network (VISN 7) (10N7)

Subj: Draft Report: Comprehensive Healthcare Inspection of the Central Alabama Veterans Health Care System, Montgomery, AL

To: Director, Office of Healthcare Inspections (54CH06)

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

1. I have had the opportunity to review the Draft Report: Comprehensive Healthcare Inspection of the Central Alabama Veterans Health Care System, Montgomery, AL.
2. VISN 7 submits concurrence to the findings, recommendations and concurrence to recommendations 1-30. VISN 7 concurs with the attached Tuscaloosa VA Medical Center action plan.
3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.
4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

(Original signed by:)

Joe D. Battle

Appendix H: Central Alabama Veterans Health Care System Director Comments

Department of Veterans Affairs Memorandum

Date: June 16, 2020

From: Director, Central Alabama Veterans Health Care System (619/00)

Subj: Comprehensive Healthcare Inspection of the Central Alabama Veterans Health Care System, Montgomery

To: Director, VA Southeast Network (10N7)

1. The System Director has reviewed the draft Comprehensive Healthcare Inspection report for Central Alabama Veterans Health Care System. I concur with the thirty (30) recommendations made to include actions developed by CAVHCS to support the facility with sustained compliance.
2. Please express my thanks to the Team for their professionalism and assistance to CAVHCS as we continue to provide quality, patient centered care to all the Veterans we serve.

(Original signed by:)

Amir Farooqi, FACHE
Interim System Director

OIG Contact and Staff Acknowledgments

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