DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the VA St. Louis Health Care System in Missouri

CHIP REPORT | REPORT #19-06873-210 | AUGUST 12, 2020

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Figure 1. *VA St. Louis Health Care System in Missouri (Source: https://vaww.va.gov/directory/guide/, accessed on January 29, 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 VA St. Louis Health Care System, which includes two divisions—John Cochran and Jefferson Barracks—and multiple outpatient clinics in Illinois and Missouri. 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 healthcare system. 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 November 4, 2019, at the John Cochran and Jefferson Barracks divisions of the VA St. Louis Health Care System and the St. Clair County 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 Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Deputy Director, and Associate Director. Organizational communications and accountability were managed through a committee reporting structure with the Executive Board overseeing several working groups. The leaders monitored patient safety and care through the Quality Executive Board which was responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this inspection, the healthcare system's leaders had been working together as a group for over two years. The Director was permanently assigned in October 2016. The ADPCS and Associate Director, the most tenured members, were assigned in April 2015 and June 2015, respectively. The Chief of Staff and Deputy Director had served in their positions since June 2017 and October 2017, respectively.

The OIG reviewed employee satisfaction survey results and concluded that employees were generally satisfied and that leaders appeared to be maintaining an environment where employees feel safe bringing forth issues and concerns. Of the selected Inpatient, Patient-Centered Medical Home, and Specialty Care patient experience survey questions reviewed, the OIG noted that the results were often lower than the corresponding VHA averages, indicating opportunities for system leaders to improve patient satisfaction with the care provided.

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] However, the OIG noted a concern with the healthcare system's lack of a permanent pain director since April 2018.

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 quality and

[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*, http://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.)

efficiency measures. In individual interviews, the executive leadership team members 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.

The OIG noted opportunities for improvement in seven clinical areas reviewed and issued 20 recommendations to the Director, Chief of Staff, ADPCS, and Associate Director. These are briefly described below.

Quality, Safety, and Value

The healthcare system complied with requirements for establishing a committee responsible for Quality, Safety, and Value oversight functions and conducting protected peer reviews. However, the OIG noted concerns with the Quality Executive Board's implementation and monitoring of improvement actions, interdisciplinary review of utilization management data, and implementation of root cause analysis actions.[3]

Medical Staff Privileging

The healthcare system complied with requirements for focused professional practice evaluations. However, the OIG identified deficiencies with ongoing professional practice evaluation and provider exit review processes.[4]

Environment of Care

The OIG observed general compliance with requirements for environmental cleanliness and infection prevention and privacy in areas across the healthcare system and at the St. Clair County VA Clinic. The OIG did not identify issues with equipment and supplies. However, the OIG noted a safety concern in the geriatric mental health unit.

Medication Management

The OIG noted compliance with some elements of expected performance, including pain screening and documenting justification for concurrent opioid and benzodiazepine therapy. However, the OIG found deficiencies with aberrant behavior risk assessments, urine drug testing,

[3] 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."

[4] 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 healthcare system."

informed consent, and patient follow-up. Additionally, the OIG determined that the system did not have an active pain committee.

Mental Health

The OIG found compliance with the requirements for suicide prevention coordinator designation, patient outreach for missed appointments, and timely safety plan completion. Areas of noncompliance included monthly outreach activities, follow-up visits, and annual suicide prevention refresher training.

Women's Health

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

High-Risk Processes

The healthcare system met many of the requirements for the proper operations and management of reprocessing and storage area reusable medical equipment. The OIG identified deficiencies with bioburden testing and staff training and ongoing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 20 recommendations for improvement to the System Director, Chief of Staff, ADPCS, 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 System Director agreed with the CHIP review findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 87–88, 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

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 VA St. Louis 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.

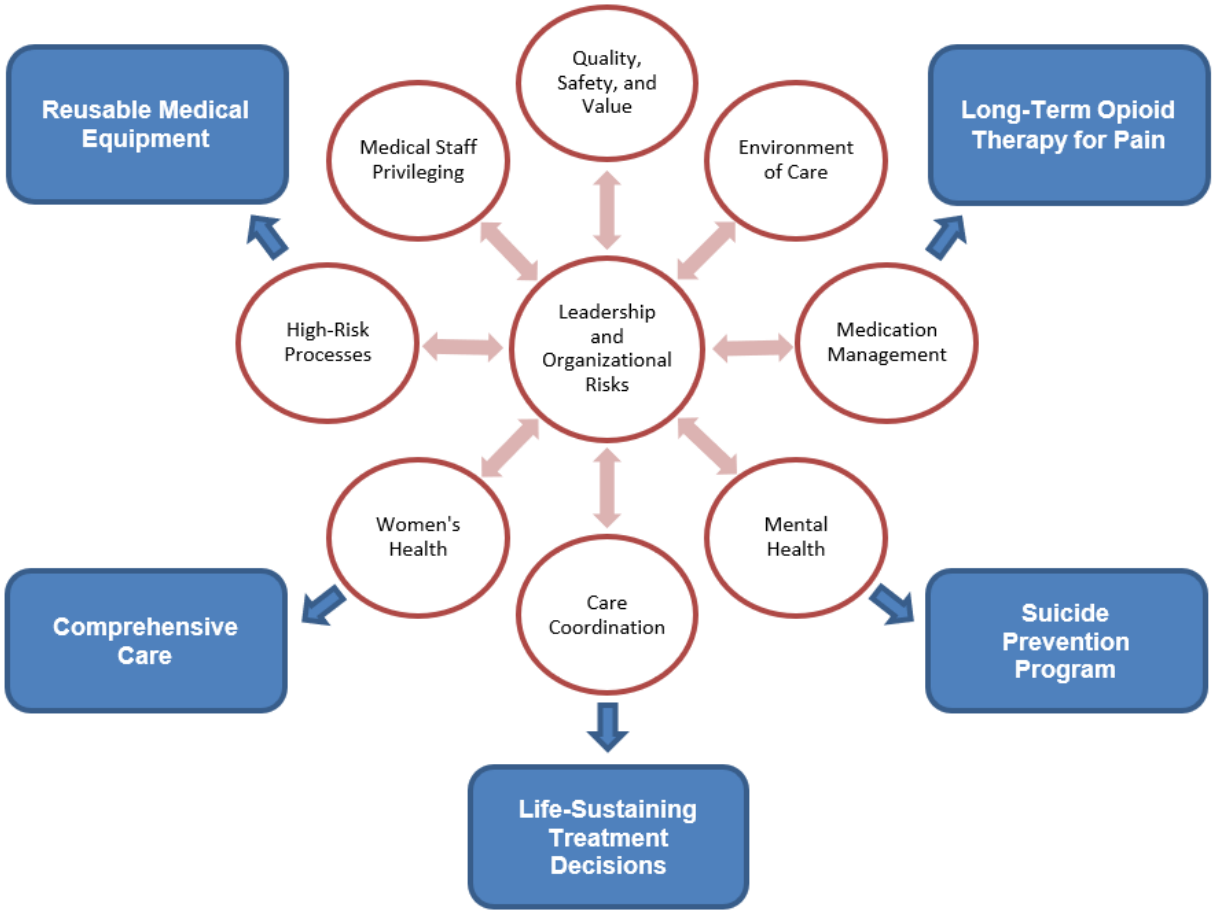

Figure 2. *Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services*
Source: VA OIG

Methodology

The VA St. Louis Health Care System includes the John Cochran Division, Jefferson Barracks Division, and multiple outpatient clinics in Illinois and Missouri. 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 St. Clair County VA Clinic and the following areas of the John Cochran and Jefferson Barracks Divisions:

- John Cochran Division
  - Dental clinic
  - Emergency Department
  - Intensive care units (medical and surgical)
  - Medical/surgical inpatient units
  - Primary care clinic
  - Post-anesthesia care unit
  - Sterile processing services areas
  - Women's health clinic
- Jefferson Barracks Division
  - Community living center[5]
  - Inpatient mental health units
  - Primary care clinic
  - Spinal cord injury unit

The OIG inspection team 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 healthcare system 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 period examined operations from February 12, 2018, through November 8, 2019, the last day of the unannounced multiday site visit.[6] Two weeks after the on-site visit, the OIG received and referred concerns beyond the scope of the CHIP inspection to the OIG's hotline management team for further review.

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 November 2019.

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 healthcare system 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 Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Deputy Director, and Associate Director. The Chief of Staff and 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.)

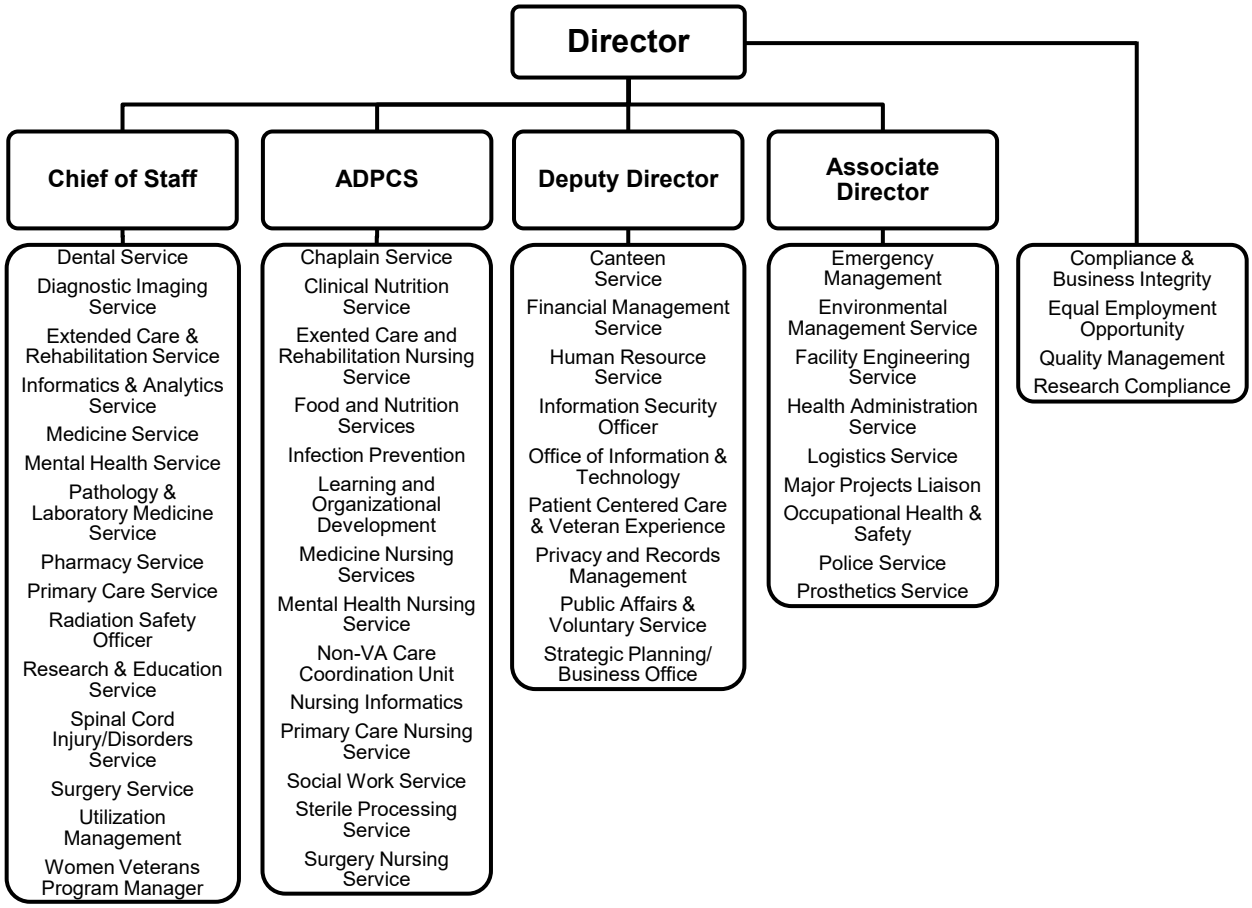

Figure 3. *Healthcare System Organizational Chart*
Source: VA St. Louis Health Care System (updated organization chart received February 6, 2020)

At the time of the OIG site visit, the executive team had been working together as a group for over two years (see Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Director	October 2, 2016
Chief of Staff	June 11, 2017
Associate Director for Patient Care Services	April 15, 2015
Deputy Director	October 2, 2017
Associate Director	June 28, 2015

Source: VA St. Louis Health Care System Human Resources Officer (received November 4, 2019)

To help assess the healthcare system executive leaders' engagement, the OIG interviewed the Associate Director (who was the Acting Director at the time of the inspection), Chief of Staff,

ADPCS, and Deputy Director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance. The Director was on leave at the time of the OIG visit.

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) and Community Living Center (CLC) SAIL quality and efficiency measures. In individual interviews, the executive leadership team members were able to speak knowledgeably 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 Executive Board, which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Executive Board oversees various working groups such as the Medical, Nursing, Resource, Quality, and Administrative Executive Boards.

These leaders monitor patient safety and care through the Quality Executive Board. The Quality Executive Board is responsible for tracking and trending quality of care and patient outcomes and reports to the Executive Board. See Figure 4.

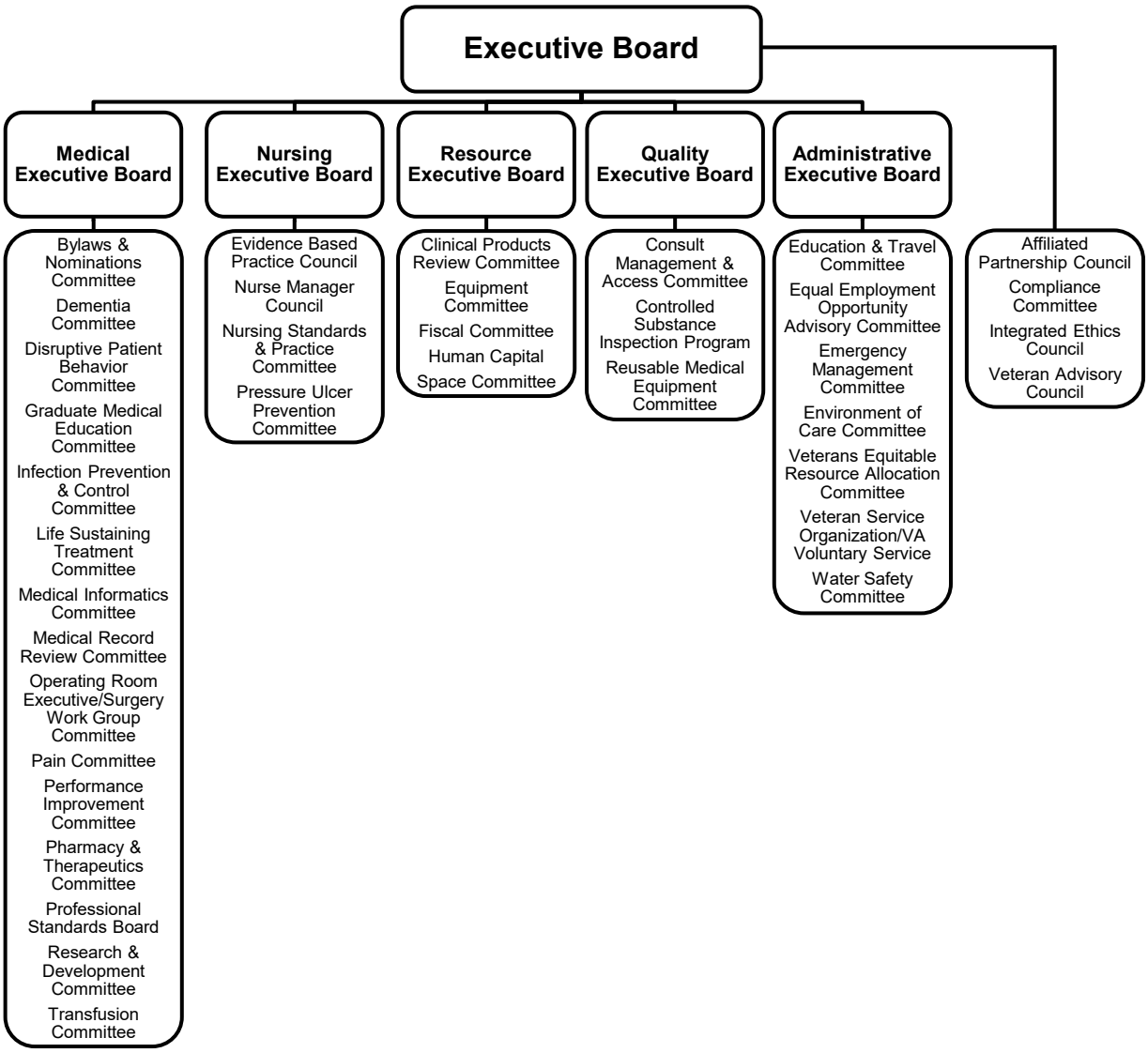

Figure 4. *Healthcare System Committee Reporting Structure*
Source: VA St. Louis Health Care System (November 4, 2019)

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential." Since 2001, the instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health. Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point 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.[8] Table 2 provides relevant survey results for VHA, the healthcare system, and executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found that executive leader averages on the survey leadership questions were higher than the healthcare system and VHA averages. However, the OIG noted the overall system average was similar to or lower than the VHA average.[9]

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	Assoc. Director Average	Deputy Director Average
All Employee Survey: *Servant Leader Index Composite*[10]	0–100 where higher scores are more favorable	72.6	69.9	83.3	83.7	89.0	82.8	88.0
All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.4	3.3	4.3	4.1	4.7	4.4	4.0

[8] 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.

[9] 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.

[10] According to the 2019 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." http://aes.vssc.med.va.gov/Documents/SL_Index_FieldGuide.pdf. (The website was accessed on March 18, 2020, but is not accessible by the public)

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.4	4.4	4.3	4.5	4.6	4.0
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.5	4.4	4.3	4.8	4.6	4.2

Source: VA All Employee Survey (accessed October 8, 2019)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.[11] Note that the healthcare system averages for the survey questions were similar to VHA averages. The OIG noted that the executive leaders' results were better than the healthcare system and VHA results. System leaders appear to be generally maintaining an environment where employees feel safe bringing forth issues and concerns.

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	Assoc. Director Average	Deputy Director Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.6	4.4	4.3	4.8	4.6	4.2

[11] 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.

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Deputy Director Average
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.6	4.1	4.0	4.5	4.3	4.3
All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?*	0 (Never) – 6 (Every Day)	1.4	1.5	1.1	1.0	0.7	1.3	1.2

Source: VA All Employee Survey (accessed October 8, 2019)

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.[12]

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

[12] Ratings are based on responses by patients who received care at this healthcare system.

reflect patients' attitudes toward their healthcare experiences (see Table 4). For this system, patient survey results were generally lower than the VHA average. Patients appeared dissatisfied with specific aspects of their experiences at the healthcare system. Executive leaders acknowledged a history of negative press coverage, problems with noise, lack of private rooms, and slow responses from staff when responding to patient call lights. System leaders reported that they are conducting townhall meetings with veterans and the community to address issues, implementing quiet hours, developing a construction plan to build a bed tower with more private rooms, and implementing a system for staff members to carry cell phones to respond to patient call lights in a timely fashion.

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): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	68.1	55.1
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	81.1
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	77.3	77.2
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	78.0	74.4

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed October 9, 2019)

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.[13] 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 (PCMH), and Specialty Care Surveys. During the leadership interviews, executive members, except for the Associate Director, did not appear to be aware of the patient experience scores by gender. Executive leaders acknowledged not focusing on gender-specific resources.

The OIG noted that the results for male and female inpatient respondents were generally lower than the corresponding VHA averages. The overall Inpatient Survey results represent opportunities for executive leaders to determine the root cause(s) of the dissatisfaction and take actions to improve inpatient experiences.

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

Questions	Scoring	VHA[14]		Healthcare System[15]	
		Male Average	Female Average	Male Average	Female Average
During this hospital stay, how often did doctors treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.3	83.6	82.8	78.2
During this hospital stay, how often did nurses treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.7	83.0	79.7	75.1
Would you recommend this hospital to your friends and family?	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.5	62.0	55.0	57.2

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed October 9, 2019)

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

[14] The VHA averages are based on 34,077–34,469 male and 1,647–1,665 female respondents, depending on the question.

[15] The healthcare system averages are based on 351-352 male and 22 female respondents, depending on the question.

Female patient experiences scores for obtaining an outpatient PCMH appointment as soon as needed and rating PCMH providers were less favorable than male respondents at the system and VHA national averages (Table 6). The differences provide opportunities for system leaders to determine the factors contributing to these results and to take actions to improve overall female veteran experiences.

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

Questions	Scoring	VHA[16]		Healthcare System[17]	
		Male Average	Female Average	Male Average	Female Average
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?	The measure is calculated as the percentage of responses that fall in the top category (Always).	50.8	43.2	51.4	36.2
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?	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.8	49.5	58.4	52.4
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?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.0	64.8	72.8	60.1

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed October 9, 2019)

The OIG noted male respondent scores for the selected survey questions were similar or higher than VHA averages. Outpatient specialty care experience scores for obtaining routine appointments and rating specialty providers were generally lower than VHA averages for female respondents, reflecting opportunities for executive leaders to improve female patient experience in outpatient specialty care (Table 7).

[16] The VHA averages are based on 60,437–183,790 male and 4,400–9,816 female respondents, depending on the question.

[17] The healthcare system averages are based on 500–1,487 male and 70–137 female respondents, depending on the question.

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

Questions	Scoring	VHA[18]		Healthcare System[19]	
		Male Average	Female Average	Male Average	Female Average
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?	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.3	44.4	58.6	45.4
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?	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	53.9	57.8	44.8
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?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	69.9	69.4	75.2	54.0

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed October 9, 2019)

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys—including those conducted for cause—by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[20] Table 8 summarizes the relevant system inspections most recently performed by the OIG and The Joint

[18] The VHA averages are based on 50,373–158,294 male and 2,617–8,357 female respondents, depending on the question.

[19] The healthcare system averages are based on 411–61,323 male and 29–99 female respondents, depending on the question.

[20] 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.

Commission (TJC).[21] Of note, at the time of the OIG visit, the system had closed all recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in February 2018.

At the time of the site visit, the OIG also noted the system's current accreditations by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[22] Additional results included the Long Term Care Institute's inspection of the system's CLC[23] and the Paralyzed Veterans of America's inspection of the system's spinal cord injury/disease unit and related services.[24]

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

[22] 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.

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

[24] The Paralyzed Veterans of America inspection took place October 15–17, 2019. This veterans service organization review does not result in accreditation status.

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 (*Comprehensive Healthcare Inspection Program Review of the VA St. Louis Health Care System, Missouri*, Report No. 18-00612-260, August 23, 2018)	February 2018	7	0
TJC For Cause	April 2019	0	0
TJC Hospital Accreditation	July 2019	48	0
TJC Behavioral Health Care Accreditation		1	0
TJC Home Care Accreditation		5	0

Source: OIG and TJC (inspection/survey results verified with the Chief of Quality Management on November 5, 2019)

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 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's review of the system's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, the OIG noted a concern with the lack oversight of pain management quality measures, including those for long-term opioid therapy, reportedly due to not having a permanent pain director since April 2018. Additional detail is contained in the medication management section of this report.

Table 9 lists the reported patient safety events from February 12, 2018 (the prior OIG comprehensive healthcare inspection), through November 6, 2019.[25]

[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 VA St. Louis Health Care System is a highest complexity (1a) affiliated healthcare system as described in Appendix B.)

Table 9. Summary of Selected Organizational Risk Factors (February 12, 2018, through November 6, 2019)

Factor	Number of Occurrences
Sentinel Events[26]	0
Institutional Disclosures[27]	2
Large-Scale Disclosures[28]	0

Source: VA St. Louis Health Care System's Chief of Quality Management (received November 6, 2019)

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 "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 example, in the areas of adjusted length of stay (LOS), complications, healthcare (HC) associated (assoc) infections, and registered nurse (RN) turnover). Metrics that need improvement are denoted in orange and red (for example, best place to work, care transition, call responsiveness, and rating hospital).[30]

[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."

[29] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://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.

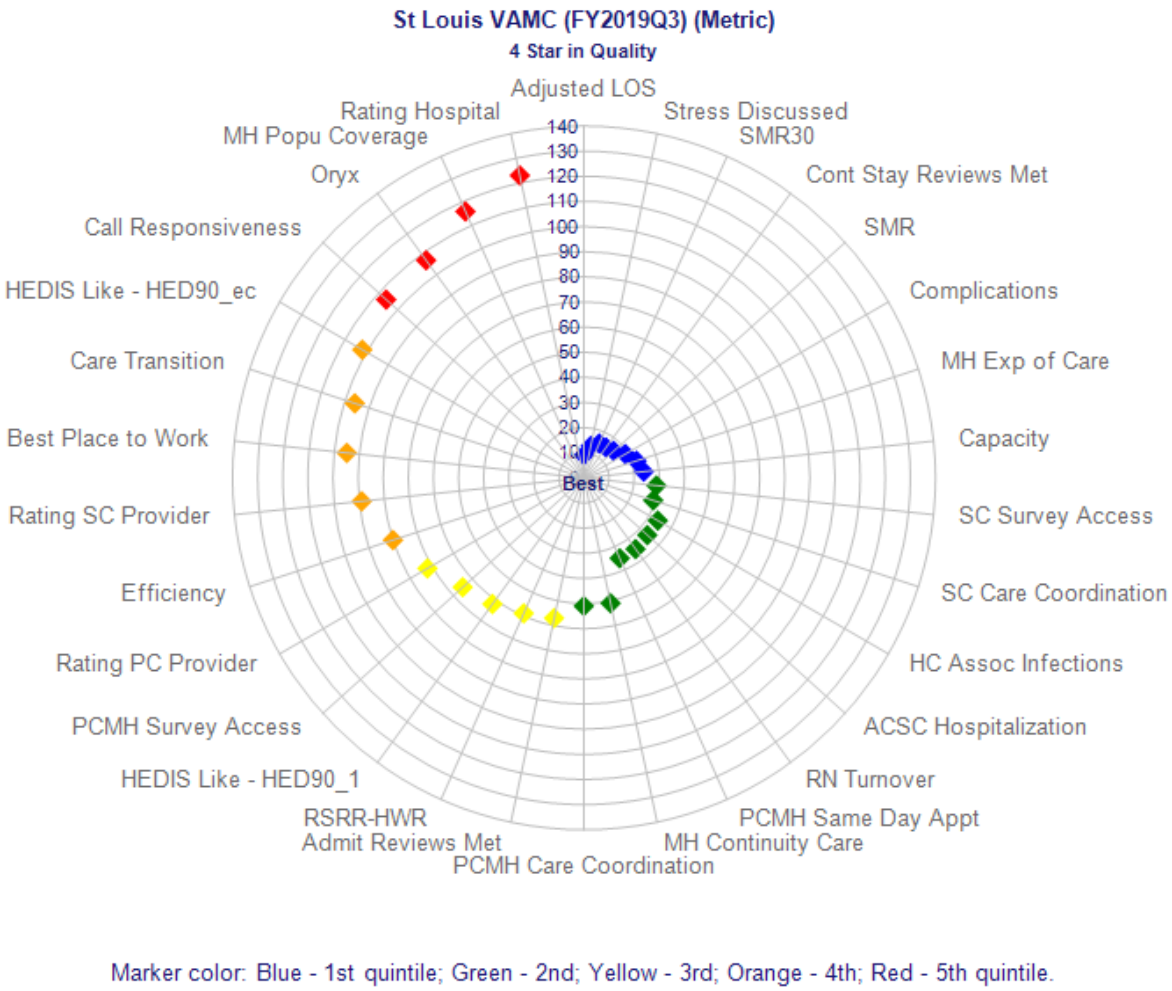

Figure 5. *System Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)*
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.

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]

Figure 6 illustrates the system's CLC quality rankings and performance compared with other VA CLCs as of June 30, 2019. Figure 6 uses blue data points to indicate high performance (for example, in the areas of moderate-severe pain–long-stay (LS), urinary tract infections (UTI)–LS, and improvement in function–short-stay (SS)). Metrics that need improvement are denoted in orange (for example, newly received antipsychotic (antipsych) medications (meds)–SS), new or worse pressure ulcer (PU)–SS, and moderate-severe pain–SS).[32] There were no metrics in red.

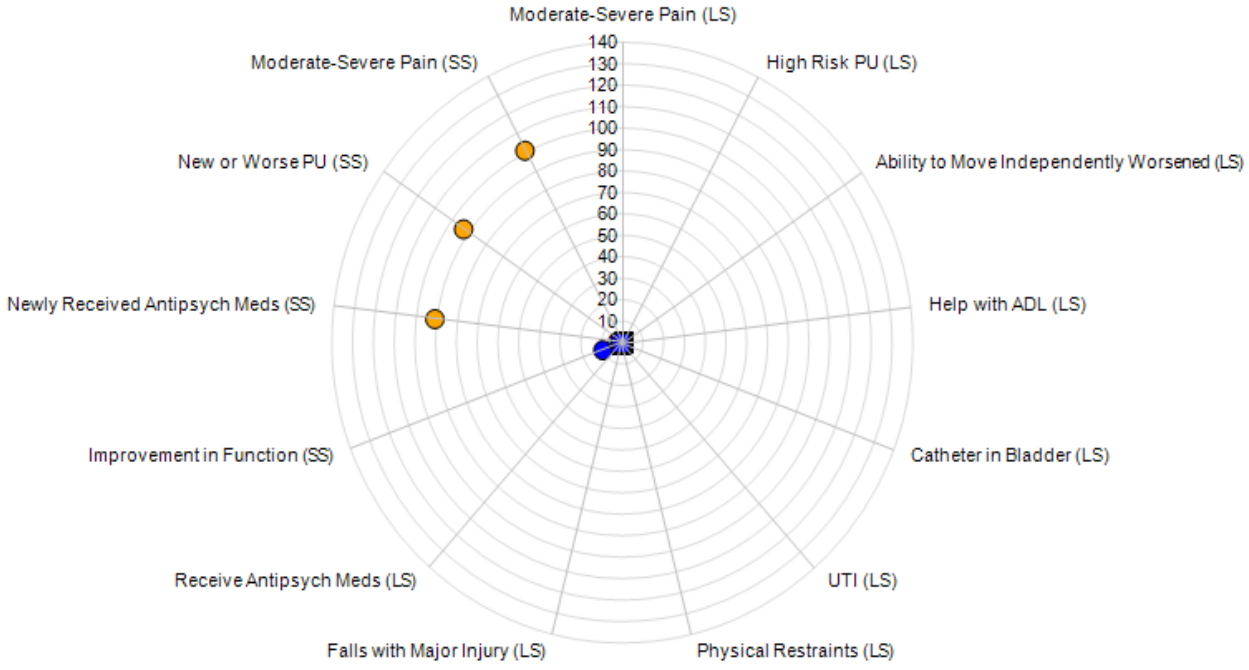

Figure 6. *System CLC Quality Measure Rankings (as of June 30, 2019)*
LS = Long Stay Measure SS = Short Stay Measure
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.

[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."

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

Leadership and Organizational Risks Conclusion

The system's executive leadership team had been working together as team for over two years at the time of the OIG's on-site inspection. Specific survey results indicated that employees were generally satisfied and that leaders appeared to be maintaining an environment where employees feel safe bringing forth issues and concerns. Of the selected Inpatient, Patient-Centered Medical Home, and Specialty Care Survey questions reviewed, the OIG noted that the survey results were often lower than the corresponding VHA averages. Patient experience survey data indicated multiple opportunities for system leaders to improve patient satisfaction. The OIG's review of the system's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, the OIG identified the lack of a permanent pain director as an area of vulnerability for the healthcare system. Executive leaders interviewed were able to speak knowledgeably about actions taken during the previous 12 months to maintain or improve performance, as well as employee satisfaction and patient experiences.

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:

[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.

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[38]
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of 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

[38] VHA Directive 1190.

[39] According to VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019, UM 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."

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:

- Annual completion of a minimum of eight root cause analyses[43]
- 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 and conducting protected peer reviews. However, the OIG identified concerns with

- The QSV committee's implementation and monitoring of improvement actions,
- Interdisciplinary review of UM data, and
- Implementation of root cause analysis action items.

TJC requires the committee responsible for QSV oversight reviews relevant data and information and ensures that when actions are recommended by the committee they are fully implemented, and changes are monitored.[45] The ADPCS reported that the Quality Executive Board (QEB) was responsible for key QSV oversight and practices. Although QEB minutes from August 2018 through July 2019 included reviews of aggregate QSV data and information with corresponding action items, the OIG was unable to find evidence that actions were fully implemented or changes were monitored to determine if actions resulted in the desired effects. This likely

[42] VHA Handbook 1050.01.

[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] TJC. Rationale for Leadership standard LD.01.03.01, Rationale for Leadership standard 03.02.01, Rationale for Leadership standard LD.03.05.01, Leadership Introduction to Operations standards LD.03.07.01 through LD.04.03.11, and Performance Improvement standard PI.03.01.01.

resulted in missed opportunities to improve the quality and safety of patient care processes. The ADPCS believed facility efforts met requirements as action items were fully implemented and monitored but acknowledged that QEB documentation did not support this.

Recommendation 1

1. The System Director evaluates and determines any additional reasons for noncompliance and ensures improvement actions recommended by the Quality Executive Board are fully implemented and improvement changes are monitored.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The System Director, the former acting Quality Management Officer, the current Quality Management Officer evaluated additional reasons for noncompliance. Previously, the Quality Executive Board properly created action items for each improvement item identified, and the former acting Quality Management Officer could speak to each identified improvement action, implementation, and monitoring, but there was not specific documentation located within the Quality Executive Board minutes detailing all of the action items implementation, changes, and monitoring of effectiveness.

The System Director and the Quality Management Officer as co-chairs of the Quality Executive Board revised the minutes to format a section that captures recommended improvement actions, the implementation status, the improvement changes, and the monitoring of the effectiveness of the change. This was adopted in June 2020.

The Quality Management Officer or designee will audit minutes from each Quality Executive Board meeting to ensure requisite documentation of recommended improvement actions, the implementation status, the improvement changes, and the monitoring of the effectiveness of the change is annotated.

Audits will continue until a 90 percent or greater compliance has been reached for two consecutive quarters. The results of the audits will be reported to the Quality Executive Board. The numerator will be the total number of Quality Executive Board Minutes reviewed that contain recommended improvement actions, the implementation status, the improvement changes, and the monitoring of the effectiveness of the change documented. The denominator will be the total number of Quality Executive Board Minutes reviewed.

VHA requires that an interdisciplinary group review UM data. 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]."[46] The OIG found that from August 2018 through July 2019, the QEB reviewed UM data for two of four

[46] VHA Directive 1117(2).

quarters; however, the board lacked representation from social work, case management, and CBO R-UR. As a result, the QEB was unable to review UM data on an ongoing basis and performed reviews and analyses without key interdisciplinary team members. The UM Coordinator reported that the QEB shifted its focus to SAIL metrics and removed UM as an agenda item. The shift in the board's focus resulted in changes to the interdisciplinary membership, and some UM representatives no longer attended.

Recommendation 2

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

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Quality Management Officer, and the Utilization Management Coordinator met to determine additional reasons for non-compliance of the lack of requisite stakeholders for the interdisciplinary review of utilization management data reviews. It was determined that the utilization management data was being reviewed, but it did not capture all required VHA stakeholders on a consistent basis. It was noted that the St. Louis system utilizes medical social workers in the same capacity as VHA case management. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff instituted an interdisciplinary utilization management work group led by the facility Utilization Management Coordinator, the Chief Business Office-Utilization Review (CBO R-UR) nurse, and the system Medical Social Worker (Case Management) to review, analyze, and report utilization management data to the Quality Executive Board who includes representatives from medicine, nursing, social work, and the mental health service where the utilization management trends, deficiencies, benchmarks, and improvement actions are reported.

The Chief of Staff will ensure ongoing compliance. The Quality Executive Board minutes will be audited by the Quality Management Officer or designee for consistent attendance of all required representatives for the interdisciplinary utilization management data reviews. The audits will continue until a 90 percent or greater compliance rate has been reached for two consecutive quarters. The audit results will be reported to the Quality Executive Board. The numerator will be the total number of required members for interdisciplinary utilization management data reviews that attended the Quality Executive Board. The denominator will be the total number of required members for interdisciplinary utilization management data reviews.

VHA requires corrective actions identified through root cause analysis processes are implemented "to prevent future occurrences of similar events."[47] For all five root cause analyses reviewed, the OIG did not find evidence of fully implemented improvement actions. This resulted in missed opportunities to identify potential and actual causes of harm to patients, systems vulnerabilities, as well as patient safety improvement processes. The acting Quality Management Officer stated that the Patient Safety Manager resigned in October 2019, and prior to departing the healthcare system, had not completed the required spreadsheet to track root cause analysis actions or outcome measures.

Recommendation 3

3. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Patient Safety Manager or designee consistently implements improvement actions arising from root cause analysis activities.

[47] VHA Handbook 1050.01.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The System Director, Quality Management Officer and the VISN 15 Patient Safety Officer evaluated additional reasons for noncompliance of consistently implementing improvement actions arising from root cause analysis activities. It was determined that there was a gap in follow through for root cause analysis corrective action implementation and the monitoring documentation during the transition and turnover of the full-time Patient Safety Manager position. These findings were considered and incorporated in the development of this action plan.

The Quality Management Officer instituted a patient safety root cause analysis tool that was developed by the National Center for Patient Safety (NCPS) that facilitates effective root cause analysis action item identification, implementation, tracking, and monitoring of effectiveness. This tool will be used by all Patient Safety staff to eliminate any gaps in coverage and on-going compliance of root cause analysis corrective action implementation. Implementation data of this root cause analysis tool will be presented in the quarterly patient safety report at the Quality Executive Board. This was adopted in June 2020.

The System Director will ensure ongoing compliance. The Quality Management Officer or designee will audit consistent implementation of improvement actions arising from root cause analysis activities on a monthly basis. Audits will continue until a 90 percent compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the number of fully implemented actions arising from root cause analyses activities. The denominator will be the total number of actions arising from root cause analyses activities.

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).[48]

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.[49]

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 healthcare system 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."[50] The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
  - Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs[51]
  - 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 LIPs[52]
  - Evaluation by another provider with similar training and privileges

[48] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

[49] VHA Handbook 1100.19.

[50] VHA Handbook 1100.19.

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

[52] VHA Acting 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.[53] 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."[54] 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:

- All three solo/few practitioners who underwent initial or reprivileging during the previous nine months (on or after January 1, 2019)[55]
- Eight LIPs hired within 18 months before the site visit and initially privileged on or after January 1, 2019
- Fourteen LIPs privileged within nine months before the visit (on or after January 1, 2019)
- Twenty LIPs who left the healthcare system in 12 months before the visit

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

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

[55] VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the healthcare system that is privileged in a particular specialty. The OIG considers few practitioners as being less than three providers in the healthcare system that are privileged in a particular specialty. The 12-month review period was from November 4, 2018, through November 4, 2019.

Medical Staff Privileging Findings and Recommendations

The OIG found general compliance with the above FPPE requirements. The OIG identified deficiencies with OPPE service- or section-specific criteria, Service Chief and Executive Committee of the Medical Staff recommendations based in part on OPPE results, and provider exit review forms.

VHA requires that reprivileging decisions are based on OPPE criteria that is specific to the service or section.[56] For one (a gynecologist) of three solo or few practitioners reprivileged within the last nine months, the service chief could not provide evidence that the reprivileging decision was based upon service-specific OPPE criteria. This resulted in the LIP practicing without a thorough competency evaluation. The Chair of the Professional Standards Board and credentialing and privileging program staff reported being unaware that a service-specific OPPE summary form for gynecology providers had not been developed.

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that service chiefs include service-specific criteria for ongoing professional practice evaluations of licensed independent practitioners.

[56] VHA Handbook 1100.19.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, Credentialing and Privileging Supervisor, Professional Standards Board, and the Quality Management Officer met to determine additional reasons for non-compliance to include interviews with several service and section chiefs related to the ongoing professional practice evaluation's barriers to include service-specific criteria for solo providers. The one solo provider (Gynecologist) did not have a summary of ongoing professional practice evaluation activities and the service chief decision completed at the time of re-privileging.

The service-specific criteria for ongoing professional practice evaluation for Gynecologist was completed in February 2020. The Professional Standard Board will review service-specific criteria used in ongoing professional practice evaluation activities at least annually when periodic review of service level privileges forms is completed. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will ensure on-going compliance by providing oversight to ongoing professional practice evaluation processes with the Professional Standards Board review of service-specific criteria for ongoing professional practice activity.

The Quality Management Officer and the Credentialing and Privileging Supervisor will conduct quality assurance audits of each service for service-specific criteria for ongoing professional practice activities. Audits will continue until a compliance rate of 90 percent or greater is reached for two consecutive quarters. The audit results will be reported to the Quality Executive Board. The numerator will be the total number of services reviewed that accurately include service-specific criteria for ongoing professional practice evaluations activities. The denominator will be the total number of services reviewed.

VHA requires that service chief determination to continue current privileges be based, in part, on OPPE activities such as direct observation, clinical pertinence reviews, and clinical discussions. VHA also requires the Executive Committee of the Medical Staff (locally known as the Medical Executive Board) recommend continuing privileges based on OPPE results. Committee minutes must indicate the materials reviewed and the rationale for the conclusion. The committee's recommendation is then submitted to the System Director for approval.[57]

The OIG found that for 11 of 17 LIPs reprivileged within the prior nine months, including two solo/few LIPs, service chiefs could not demonstrate that determination to continue privileges was based in part on OPPE activities. Consequently, the Medical Executive Board's decision, through the Professional Standards Board, to recommend continuation of privileges was not based on OPPE data. This resulted in providers continuing to deliver care without thorough

[57] VHA Handbook 1100.19.

evaluations of their practice. Credentialing and privileging program staff attributed the noncompliance to quality management staff not maintaining necessary data. In addition, due to staffing shortages, service chiefs did not have enough time for administrative duties, resulting in late completion and submission of OPPEs to the Professional Standards and Medical Executive Boards. This is a repeat finding from the previous CHIP inspection.

Recommendation 5

5. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that service chiefs' reprivileging recommendations are based on ongoing professional practice evaluation activities.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Credentialing and Privileging Supervisor, the Professional Standards Board, and the Quality Management Officer met to determine additional reasons for non-compliance. A review of ongoing professional practice evaluation processes was completed that included discussion with Quality Management and executive leadership. Inconsistencies were identified with data maintenance used to evaluate re-privileging activities and insufficient time for administrative duties in some services. The Quality Management Officer accepted shared responsibility with the Credentialing and Privileging Supervisor for all data management for ongoing professional practice evaluation to reduce the administrative burden on the services. The Professional Standards Board received and reviewed a summary of ongoing professional practice activities used by the service chief to make re-privileging recommendation. The Professional Standards Board will not act on service recommendation without a summary of ongoing professional practice activities. Professional Standards Board minutes will reflect material reviewed and rationale for the conclusion. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will ensure on-going compliance by providing oversight to ongoing professional practice evaluation processes. The Quality Management Officer in collaboration with the Credentialing and Privileging Supervisor will maintain ongoing professional practice evaluation data that will be used to support renewal of privileges by the Professional Standards Board and the Medical Executive Board.

Audits will be completed on all re-privileging requests for evidence that the service chief's recommendations were based on ongoing professional practice activities and that it was presented to the Professional Standard Board. Audits will continue and be reported at the Quality Executive Board until a compliance rate of 90 percent or greater is reached for two consecutive quarters. The numerator will be the total number of providers that were recommended by service chiefs for reprivileging based on ongoing professional practice evaluation activities (including ongoing professional practice evaluation data). The denominator will be the total number of providers recommended by service chiefs for reprivileging.

Recommendation 6

6. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that the Medical Executive Board's decision to recommend continuation of privileges is based on ongoing professional practice evaluation results.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Credentialing and Privileging Supervisor, the Professional Standards Board, and the Quality Management Officer met to determine additional reasons for non-compliance. It was determined that the Professional Standards Board and the Medical Executive Committee meeting minutes did not include materials reviewed and rationale for conclusion. These findings were considered and incorporated in the development of this action plan.

As a result, the Chief of Staff will ensure that the decision to recommend continuation of privileges is based on ongoing professional practice evaluations activity criteria and that it is documented in the Professional Standards Board meeting minutes. The Medical Executive Board minutes will include Professional Standards Board meeting minutes and the Medical Executive Board conclusions.

The Chief of Staff or designee will monitor ongoing compliance by ensuring that the Medical Executive Board meeting minutes include, and document relevant ongoing professional practice evaluation criteria activity was reviewed and decided upon for the determination of continuing privileges. Audits adopted June 2020 and will continue monthly until a compliance rate of 90 percent or greater is reached for two-consecutive quarters. Audit results will be reported at the Quality Executive Board. The numerator will be the total number of providers that were recommended by the Medical Executive Board to continue privileges based on ongoing professional practice evaluation activities (including ongoing professional practice evaluation data). The denominator will be the total number of providers recommended by the Medical Executive Board to continue privileges.

VHA requires Provider Exit Review forms, which documents the review of a provider's clinical practice, to "be completed within 7 calendar days of the departure of a licensed health care professional from a VA facility"[58] For 14 of 20 providers that departed the healthcare system in the previous 12 months, the OIG found that exit forms were incomplete or not completed within the required seven calendar days. This could have resulted in delayed reporting of healthcare professionals' potential substandard care to state licensing boards. The Credentialing and Privileging Supervisor reported that when the Credentialing and Privileging Service was realigned from the Human Resources Department to the Chief of Staff's office, credentialing staff were unable to access LIP exit data, resulting in late completion of provider exit forms.

[58] VHA Notice 2018-05.

Recommendation 7

7. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven calendar days of licensed healthcare professionals departing the healthcare system.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The System Director, the Chief of Staff, the Credentialing and Privileging Supervisor, and the Quality Management Officer evaluated the additional reasons for non-compliance. It was discovered that there was a gap of information flow from Human Resources to Credentialing and Privileging as to an identified process to ensure a provider exiting the health care system has a Provider Exit Review form completed. Additionally, it was determined that there were inconsistencies in understanding the timeframe in which a Provider Exit Review form was submitted accordingly. These findings were considered and incorporated in the development of this action plan.

The System Director will ensure ongoing compliance. Human Resources will provide information on clinical employee departures from the health care system to the Credentialing and Privileging Supervisor, and the Provider Exit Review form will be added to the organizational Employee Clearance Checklist exiting process. The Credentialing and Privileging Supervisor in collaboration with the Quality Management Officer will provide oversight to the services on timeliness and completion of the Provider Exit Review form and report outcomes to the Quality Executive Board.

Monthly audits will continue until a 90 percent or greater compliance rate is reached for two consecutive quarters. The numerator will be the total number of licensed healthcare professionals departing the health care system that complete the Providers Exit Review form within seven days of departure. The denominator will be the total number of licensed healthcare professionals departing the health care system.

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.[59]

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:

- Healthcare system divisions (John Cochran and Jefferson Barracks)
  - 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

[59] 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 17 patient care areas:

- John Cochran Division
  - Dental clinic
  - Emergency Department
  - Intensive care units (medical and surgical)
  - Medical/surgical inpatient units (7 South and 7 North)
  - Post-anesthesia care unit
  - Primary care clinic
  - Women's health clinic
- Jefferson Barracks Division
  - CLC (North and South units)
  - Inpatient mental health units (51N, 51N 2, and 51W)
  - Primary care clinic
  - Spinal cord injury unit
- St. Clair County VA Clinic

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

Environment of Care Findings and Recommendations

The OIG observed general compliance with requirements for environmental cleanliness, infection prevention, and privacy in areas across the healthcare system and at the St. Clair County VA Clinic and did not identify issues with equipment and supplies. However, the OIG noted a safety concern in the geriatric inpatient mental health unit.

VHA requires that mental health units treating suicidal patients must be optimally designed to eliminate blind spots.[60] Despite the presence of cameras, the OIG noted a blind spot in the geriatric inpatient mental health unit (51W) day room. The inadequate visual coverage could

[60] VHA Directive 1167, *Mental Health Environment of Care Checklist for Mental Health Units Treating Suicidal Patients,* May 12, 2017.

pose a serious risk to patient and staff safety. The nurse manager did not consider the blind spot in the day room as a safety issue nor provide a reason for noncompliance.

Recommendation 8

8. The Associate Director determines the reasons for noncompliance and ensures mental health unit cameras are reconfigured to eliminate blind spots.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Associate Director along with the Associate Chief of Staff Mental Health Service, Veteran Affairs Police, and the Quality Management Officer met to evaluate additional reasons for non-compliance. It was determined that despite the presence of optimally placed security cameras there was a blind spot identified for the first time even after two other national accrediting bodies recently completed their triennial surveys of the same mental health unit was found. These findings were considered and incorporated in the development of this action plan.

The Associate Director will ensure ongoing compliance. Specifically, the Associate Chief of Staff Mental Health Service will review the geriatric psychiatry day room with the Suicide Prevention Coordinator, Patient Safety representative, unit nurse manager, and the Mental Health Associate Chief Nurse to identify any remaining blind spots. Veteran Affairs Police will make camera angle adjustments as indicated to reconfigure and eliminate blind spots. Planned walk-thru and camera adjustments scheduled for July 2020.

Monthly *completed versus not-completed* monitoring by the Associate Chief of Staff Mental Health Service in collaboration with the Veterans Affairs Police will continue until a compliance rate of *completed* is reached within two consecutive quarters. Monitoring results will be reported to the Quality Executive Board. The numerator will be the total number of eliminated blind spots in the mental health unit by reconfigured cameras. The denominator will be the total number of blind spots in the mental health unit.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[61] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[62] 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.[63] These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.[64]

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 and also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines.[65] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[66] 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.[67] 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.[68]

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

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

[62] 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.)

[63] *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.)

[64] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

[65] 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 December 1, 2019.)

[66] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

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

[68] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

- Completion of urine drug testing with intervention, when indicated
- 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.[69] 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 26 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 OIG determined that the healthcare system met some of the indicators of expected performance. However, OIG noted a concern with the system's lack of oversight of pain management quality measures, including those for long-term opioid therapy, reportedly due to the lack of a permanent pain director since April 2018. Additionally, the OIG found deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, and patient follow-up.

The OIG also determined that the system did not have a functioning pain management committee to evaluate pain management outcomes and quality.

VA/DoD clinical practice guidelines recommend that providers complete a behavior risk assessment that includes the patient's history of substance abuse, psychological disease, and

[69] VHA Directive 2009-053, *Pain Management*, October 28, 2009.

aberrant drug-related behaviors[70] prior to initiating long-term opioid therapy.[71] The OIG determined that providers documented patients' history of substance abuse and aberrant drug-related behaviors in 85 percent and 77 percent of the patients reviewed, respectively.[72] This may have resulted in providers prescribing opioids for patients at high risk for misuse. The acting Associate Chief of Staff of Primary Care attributed the noncompliance to a lack of program oversight because the pain director position had been vacant since April 2018.

Recommendation 9

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

[70] Examples of aberrant drug related behaviors include "lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, frequent accidents". *Pain Management, Opioid Safety, VA Educational Guide* (2014), July 2014.

[71] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

[72] Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief of Staff Primary Care Service, and the current Pain Service Director met to evaluate additional reasons for non-compliance. It was determined that there was an existing gap in service between the current full-time Pain Service Director and the past Pain Service Director. Additionally, it was discovered that the process for documenting the assessment was fragmented secondary to inconsistent and varying methods of documentation by clinicians, and a deficit for a method to address specific concerns, patient outcomes or behaviors. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will provide ongoing compliance with oversight on the development, implementation, and appropriate use of a Behavior Risk Assessment template to ensure ongoing compliance with this recommendation. Specifically, the Pain Service Director will implement the use of that standardized Behavior Risk Assessment for provider use when the decision has been made to initiate long-term opioid therapy. The standardized template will consist of a behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors. Initial education of the standardized template will be provided by the Pain Service Director and the Pain Committee.

The Pain Committee will conduct monthly audits of electronic health records of newly initiated long-term opioid therapy patients for accurate behavioral risk assessment and the results of the audit will be reported to the Quality Executive Board. Audits will continue until a compliance rate of 90 percent or greater is reached for two consecutive quarters. The numerator will be the total number of patients newly initiated on long-term opioid therapy with documented complete behavioral risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors. The denominator will be the total number of patients newly initiated on long-term opioid therapy.

VA/DoD clinical practice guidelines recommend that providers perform urine drug testing "prior to initiating or continuing long-term opioid therapy and periodically thereafter."[73] The OIG determined that providers conducted initial urine drug testing in 69 percent of the patients reviewed.[74] This resulted in providers' inability to identify whether the remaining 31 percent of patients had substance use disorders, determine potential diversion, and ensure patients adhered to the prescribed medication regimen. As stated previously, the acting Associate Chief of Staff of Primary Care attributed the noncompliance to a lack of oversight due to the vacant pain director position.

[73] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

[74] Confidence intervals are not included because the data represents every patient in the study population.

Recommendation 10

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

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief of Staff Primary Care Service, and the current Pain Service Director met to evaluate additional reasons for non-compliance. It was determined that there was an existing gap in service between the current full-time Pain Service Director and the past Pain Service Director. Additionally, it was determined that there was not a defined timeline for urine drug screens. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will provide oversight on the development, implementation, and appropriate use of this Behavior Risk Assessment template to ensure ongoing compliance with this recommendation. Specifically, the Pain Service Director will implement the use of a standardized Behavior Risk Assessment template for provider use when the decision has been made to initiate and/or continue chronic long-term opioid therapy. The standardized template will include alerts for obtaining urine drug screen monitoring prior to initiating and during long term opioid therapy. Also, the template will have instructions that ensures the urine drug screen is completed within 30 days before or after opioids are started. Providers will determine if a new urine drug screen is needed and will order/obtain as appropriately needed. Initial education of the template will be provided by the Pain Service Director and the Pain Committee.

The Pain Committee will conduct monthly audits of electronic health records of patients on long-term opioid therapy for consistent conduct of urine drug testing as required and will have audit results reported to the Quality Executive Board. Audits will continue until a 90 percent or greater compliance rate is reached for two consecutive quarters. The numerator will be the total number of patients on long-term opioid therapy with documented consistent conduct of urine drug testing as required. The denominator will be the total number of patients on long-term opioid therapy.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy. VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.[75] The OIG determined that providers documented informed consent prior to initiating long-term opioid therapy in 58 percent of patients reviewed.[76] The remaining patients, therefore, may have received treatment without knowledge of the risks associated with long-term opioid therapy, including opioid dependence,

[75] VHA Directive 1005.

[76] Confidence intervals are not included because the data represents every patient in the study population.

tolerance, addiction, and intentional or unintentional fatal overdose. Again, the acting Associate Chief of Staff of Primary Care cited the vacant pain director position and lack of oversight as the reasons for noncompliance.

Recommendation 11

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

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief Primary Care Service, the current Pain Service Director, and the Quality Management Officer met to evaluate additional reasons for non-compliance. Guidelines for obtaining and documenting informed consent prior to the initiation of therapeutic treatments such as long-term opioid therapy were reviewed. It was determined that there was an existing gap in service between the current full-time Pain Service Director and the past Pain Service Director. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will provide oversight on the development, implementation, and appropriate use of this Behavior Risk Assessment template to ensure ongoing compliance with this recommendation. The Pain Service Director will implement the use of a standardized Behavior Risk Assessment template for provider use when the decision has been made to initiate and/or continue chronic long-term opioid therapy. The standardized template will include alerts for obtaining informed consent prior to initiating long term opioid therapy. Furthermore, the Pain Service Director will establish a consistent and reliable educational handout process for patients to receive the VHA publication "Safe and Responsible Use of Opioids for Chronic Pain" to coincide with obtaining informed consent prior to starting opioid therapy. The initial education of the template and handout use will be provided by the Pain Service Director and the Pain Committee. The Acute Pain Report will be utilized as a trigger to capture those patients needing an informed consent who were started on opioids within the past 90 days, and who did not receive an informed consent prior to initiating long term opioids as a resilient backup.

The Pain Committee will conduct monthly audits of electronic health records of newly initiated long-term opioid therapy patients for providers obtaining and documenting informed consent. Audits will continue until a compliance rate of 90 percent or higher is reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of patients newly initiated on long-term opioid therapy with obtained and documented informed consent. The denominator will be the total number of patients newly initiated on long-term opioid therapy.

VA/DoD clinical practice guidelines recommend providers follow up with patients within three months after initiating long-term opioid therapy.[77] The OIG determined that providers completed patient follow-ups within three months after initiating long-term opioid therapy and documented effectiveness of interventions at the follow-up visit in 77 and 85 percent of the patients reviewed, respectively.[78] For the remaining patients, failure to conduct follow-ups can result in missed opportunities to assess effectiveness of treatment and monitor risks of continued therapy. Again, the acting Associate Chief of Staff of Primary Care attributed the noncompliance to a lack of program oversight because the pain director position had been vacant since April 2018.

Recommendation 12

12. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures healthcare providers follow up with patients within three months after initiating long-term opioid therapy and assess intervention effectiveness.

[77] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

[78] Confidence intervals are not included because the data represents every patient in the study population.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff along with the Associate Chief of Staff Primary Care Service, and the current Pain Director met to evaluate additional reasons for non-compliance. It was determined that there was an existing gap in service between the current full-time Pain Service Director and the past Pain Service Director. Additionally, it was discovered that the process for documenting the assessment was fragmented secondary to inconsistent and varying methods of documentation by clinicians. Furthermore, there was a deficit for a method to address specific concerns, patient outcomes or behaviors. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will ensure ongoing compliance by providing oversight on the development, implementation, and appropriate use of a Behavior Risk Assessment template. Specifically, the Pain Service Director will implement the use of a standardized Behavior Risk Assessment template for provider use when the decision has been made to initiate, continue or follow-up long-term opioid therapy. The standardized template will consist of a behavior risk assessment that includes a history of substance abuse, psychological disease, aberrant drug-related behaviors, and intervention effectiveness as appropriate. Initial education of the template will be provided by the Pain Service Director and the Pain Committee. Additionally, a standard of work has been developed for Medical Support Assistants making long-term opioid therapy appointment follow-up, cancellation, and scripted responses to questions.

The Pain Committee will conduct monthly audits of electronic health records for confirmation of provider follow up within three months which includes assessing intervention effectiveness for individuals initiated on long-term opioid therapy. Audits will continue until a 90 percent or greater compliance rate is reached for two consecutive quarters. The audit results will be reported to the Quality Executive Board. The numerator will be the total number of patients newly initiated on long-term opioid therapy that have a follow up within three months that includes assessing intervention effectiveness. The denominator will be the total number of patients newly initiated on long-term opioid therapy.

VHA requires the healthcare system to have a multidisciplinary pain management committee to provide oversight, coordination, and at least yearly monitoring of pain management activities and processes.[79] The OIG found the healthcare system did not have a functioning multidisciplinary pain management committee. This resulted in lack of oversight, coordination, and monitoring of pain management strategies to ensure compliance with evidence-based standards of care. The acting Associate Chief of Staff of Primary Care stated that the previous Associate Chief of Staff of Primary Care—who acted as the Pain Director—left the healthcare system in April 2018. A primary care pain physician stepped into the role in an acting capacity more than a year later;

[79] VHA Directive 2009-053.

however, the Pain Committee was not chartered until August 2019. The committee held one meeting prior to the OIG site visit; however, this was a charter meeting and did not include a review of aggregated data such as quality of pain assessment or effectiveness of pain management measures.

Recommendation 13

13. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that the Pain Committee monitors the quality of pain assessment, effectiveness of pain management interventions, and opportunities for improvements.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief of Staff Primary Care Service, and the current Pain Service Director met to evaluate additional reasons for non-compliance. It was determined that there was an existing gap in service between the current full-time Pain Service Director and the past Pain Service Director. Additionally, it was discovered that the process for documenting the assessment was fragmented secondary to inconsistent and varying methods of documentation by clinicians. Furthermore, there was a deficit for a method to address specific concerns, patient outcomes or behaviors. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff has established a permanent full-time Pain Service Director who has restored the Pain Committee to full functionality. The Pain Committee will provide oversight, coordination, and monitoring of pain management strategies to ensure compliance with evidence-based standards of care. The Pain Management Committee has created a sub-committee to assist in the coordination and monitoring of pain management activities and processes at least yearly.

Additionally, the Pain Management Committee Charter has been updated to reflect: *"Quarterly Chart Reviews: Will review random charts quarterly to assess for adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment including behavioral health and pain medicine consultation and treatment and/or clinical outcomes such as quality of pain assessment, effectiveness of pain management interventions, improvements in pain control, opportunities for improvements, patient satisfaction, physical and psychosocial functioning, and quality of life."*

The Associate Chief of Staff Primary Care or designee will audit quarterly Pain Committee minutes for confirmation of accurate monitoring of providers quality of pain assessment, effectiveness of pain management interventions, and opportunities for improvements for individuals on long-term opioid therapy and report results to the Quality Executive Board. These audits will continue until a 90 percent or greater compliance rate is reached for two consecutive quarters. The numerator will be the total number of Pain Committee minutes reviewed that include confirmation of accurate monitoring of providers quality of pain assessment, effectiveness of pain management interventions, and opportunities for improvements for individuals on long-term opioid therapy. The denominator will be the total number of Pain Committee minutes reviewed.

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.[80] 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.[81] Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.[82]

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.[83]

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.[84] 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 healthcare system high-risk list and have a High Risk for Suicide (HRS) Patient Record Flag

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[80] Centers for Disease Control and Prevention. *Preventing Suicide*. https://www.cdc.gov/violenceprevention/suicide/fastfact.html. (The website was accessed on March 4, 2020.)

[81] 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*.

[82] 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.*

[83] *VA Office of Mental Health and Suicide Prevention Guidebook*, June 2018.

[84] 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.

(PRF) placed in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC."[85] 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."[86]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.[87] 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.[88]

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."[89] However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management 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."[90] 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."[91]

The OIG is concerned that the updated requirement may result in delayed placement of HRS PRFs for at-risk patients. Without defined time frames for SPC determination that the HRS PRF is warranted, patients identified as at-risk for suicide could have flags placed in his or her chart

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

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

[87] *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.

[88] 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*.

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

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

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

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 PRF to "occur no earlier than 10 days before and no later than 10 days after the 90-day due date."[92]

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.[93] VHA also requires that all staff receive annual refresher training.[94] In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[95]

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

- Relevant documents;

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

[93] 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.

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

[95] 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 36 randomly selected 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 met the requirements associated with SPC designation, patient outreach for missed appointments, and timely safety plan completion.

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[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination,"[96]—the OIG estimated that 64 percent of HRS PRFs were placed within 24 hours of referral to the SPC.[97] Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined time frame for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was two days (observed range was 0–15 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.[98] The OIG estimated that 50 percent of patients with an HRS PRF were reevaluated at least every 90 days.[99] However, based upon the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that 34 of 36 patients (94 percent) were reviewed within the expected time frame (observed range was 29–98 days).[100]

Additionally, the OIG noted concerns with monthly outreach activities, follow-up visits after HRS PRF placement, and suicide prevention annual refresher training.

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

[97] The OIG estimated that 95 percent of the time, the true compliance rate is between 47.5 and 79.4 percent, which is statistically significantly below the 90 percent benchmark.

[98] VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide,* July 18, 2008; *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

[99] The OIG estimated that 95 percent of the time, the true compliance rate is between 33.3 and 65.8 percent, which is statistically significantly below the 90 percent benchmark.

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

VHA requires SPCs to complete five outreach activities each month for community organizations, mental health groups, and/or other community advocacy groups. Suggested outreach activities include participating in homeless stand down events, attending military "welcome home" events, collaborating with state and local suicide prevention groups and organizations, and connecting with veterans' service organizations and local veteran groups.[101] The OIG found that the SPC did not complete the five required outreach activities for two of three months in the fourth quarter of FY 2019. Failure to conduct outreach could negatively impact at-risk veterans who could benefit from mental health services at the VA. The SPC misunderstood the requirement and believed Operation S.A.V.E. training conducted during new employee orientation sessions were considered as outreach activities.

Recommendation 14

14. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that the Suicide Prevention Coordinator delivers at least five outreach activities each month.

[101] *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief of Staff Mental Health Service, the Suicide Prevention Team, and the Suicide Prevention Coordinator met to evaluate additional reasons for non-compliance. It was determined that the facility Operation S.A.V.E. trainings conducted during new employee orientation did not meet the outreach requirement, and that other community outreach activities will be necessary in light of the requirement. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will ensure ongoing compliance by providing oversight to the Suicide Prevention Coordinator's delivery of at least five outreach activities monthly. Specifically, the Chief of Staff Mental Health Service will reinforce the Suicide Prevention Coordinator and the Suicide Prevention Team's accountability and participation in at least five required number of community outreach activities by monitoring results of monthly outreach activities for community organizations, mental health groups, and/or other community advocacy groups. A few of the suggested outreach activities identified are homeless stand down events, attending military "welcome home" events, collaborating with state and local suicide prevention groups and organizations and local Veteran groups.

The Associate Chief of Staff Mental Health Service or designee will audit monthly outreach activities delivered by the Suicide Prevention Coordinator until a 90 percent or greater compliance rate is reached for two consecutive quarters, and the results will be reported to the Quality Executive Board. The numerator will be the total number of required (at least five) monthly outreach activities completed that are authorized as outreach activities delivered by the Suicide Prevention Coordinator. The denominator will be the minimum number of required (at least five) monthly outreach activities.

To note: *Pandemic precautions have prohibited many physical community outreach events. Many community partners who have historically accepted training and education have paused outreach activities during this time. The Suicide Prevention Coordinator and Suicide Prevention Team are seeking out alternate outreach opportunities to provide virtual and proper social distancing community outreach activities as public health and VHA will allow.*

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 telephone call.[102] The OIG estimated that providers conducted four mental health visits for 64

[102] *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*.

percent of patients reviewed.[103] This resulted in insufficient follow-up of high-risk patients. Program managers reported being unaware of the requirement for face-to-face visits or to document patients' preference for telephone calls.

Recommendation 15

15. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers conduct four follow-up visits, either face-to-face or telephonic with documented consent, within the required time frame.

[103] The OIG estimated that 95 percent of the time, the true compliance rate is between 48.3 and 79.1 percent, which is statistically significantly below the 90 percent benchmark.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Chief of Staff, the Associate Chief of Staff Mental Health Service, the Suicide Prevention Team, and the Suicide Prevention Coordinator met to evaluate the additional reasons for non-compliance. It was determined that non-compliance was related to a combination of human factors to include the specificity of Veteran consent for telephonic preference having had a requirement to document in the electronic health record obtaining consent, the provider awareness of the requirement for obtaining consent, and then in turn documenting the consent for telephonic preference for follow-up visits, and a standardized tool for providers to use to make certain that follow-up high risk for suicide, patient record flagged visits encompassing all Veterans Health Administration criteria and requirements as directed. These findings were considered and incorporated in the development of this action plan.

The Chief of Staff will ensure ongoing compliance by providing oversight to providers ability to conduct four follow-up visits, either face-to-face or telephonic with documented consent, within the required time frame. Additionally, providers will have an electronic health record standardized tool for use named the "Suicide Risk Management Follow Up" that Veterans Health Administration developed for field use.

The Associate Chief of Staff Mental Health Service in collaboration with the Quality Management Officer will reinforce compliance on follow up visit scheduling process whereby clear delineation on attempts made count towards required visits with identified exclusions in accordance with VHA Directive 1230(2) Outpatient Scheduling Processes and Procedures amended January 22, 2020. Furthermore, provider accountability in obtaining and documenting consent as required for non-face-to-face Veteran follow-up appointment preference will be enforced with the use of the standardized tool "Suicide Risk Management Follow Up." The Suicide Prevention Coordinator will work with service section chiefs through communication of a deficiency report to enhance accurate documentation of Veteran preference for telephonic follow-up appointment preference and provide necessary training as indicated.

The Suicide Prevention Coordinator will audit the providers conduct of four follow up visits through electronic health record reviews, either face-to-face or telephonic with documented consent, within the required time frame until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of patients with four completed follow-up visits (either face-to-face or telephonic with documented consent) within 30 days of High Risk for Suicide (HRS) Patient Record Flag (PRF) placement. The denominator will be the total number of patients with High Risk for Suicide (HRS) Patient Record Flag (PRF) placement requiring follow-up visits.

VHA requires that all employees complete suicide risk and intervention training within 90 days of entering their position. VHA mandates that all staff, clinical and nonclinical, receive annual

refresher training thereafter.[104] The OIG found that 3 of 10 clinical staff did not receive annual refresher training at or within one year of initial training. Lack of training may prevent providers from delivering optimal treatment to patients at risk for suicide. Program managers were aware of the requirement and attributed the noncompliance to the system's sole reliance on VHA national alerts to prompt staff to complete the required training.

Recommendation 16

16. The System Director evaluates and determines any additional reasons for noncompliance and ensures staff receive annual suicide prevention refresher training.

[104] VHA Directive 1071.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The System Director, the Chief of Staff, the Associate Chief of Staff Mental Health Service, the Suicide Prevention Team, and the Suicide Prevention Coordinator met to evaluate the additional reasons for non-compliance. It was determined that non-compliance was related to variable oversight and singular reliance on VHA National Talent Management System training alerts to prompt staff to complete the required training. These findings were considered and incorporated in the development of this action plan.

The System Director will ensure ongoing compliance for staff to complete suicide prevention refresher training. Specifically, the Chief of Staff along with the Associate Chief of Staff Mental Health Service will provide direction for staff to receive annual suicide prevention training utilizing the Talent Management System according to clinical and non-clinical roles of the employee.

The Suicide Prevention Coordinator will work with the local Learning and Organizational Development Service on accurately and enhancing auto-generated email notification reminders to staff and supervisors. The Talent Management System will provide a compliance deficiency report monthly to the Suicide Prevention Coordinator on required annual suicide prevention refresher training. In turn, the Suicide Prevention Coordinator will work with facility supervisors through communication of the deficiency reports to enhance compliance of course completion.

Monthly audits by the Suicide Prevention Coordinator for staff compliance with annual suicide refresher training completion within the required time (one year) will continue until a 90 percent or greater compliance rate is reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of employees that completed annual suicide prevention refresher training within the required time frame (one year). The denominator will be the total number of employees required to complete annual suicide prevention refresher training.

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."[105]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.[106] 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.[107] 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.[108]

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.

[105] 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.

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

[107] 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.

[108] 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.[109] 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 47 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

The OIG found the healthcare system had generally complied with requirements for the LSTD committee and supervision of designees. Additionally, with VHA's original requirements that

[109] VHA Handbook 1004.03(1).

were in place when these patients received care[110], the OIG estimated that 78 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes.[111]

However, VHA no longer requires these elements to be documented in the LST progress note.[112] The OIG made no recommendations but remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

[110] VHA Handbook 1004.03(1).

[111] The OIG estimated that 95 percent of the time, the true compliance rate is between 65.2 and 89.1 percent, which is statistically significantly below the 90 percent benchmark.

[112] VHA Handbook 1004.03(1).

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[113] 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.[114] 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."[115] 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."[116]

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.[117] 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."[118]

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

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[113] 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.)

[114] 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.)

[115] 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.)

[116] 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.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5. (The website was accessed on September 16, 2019.)

[117] VHA Directive 1330.01(2), *Health Care Services for Women Veterans,* February 15, 2017, amended July 24, 2018.

[118] VHA Directive 1330.01(2).

  - Designated Women's Health Patient Aligned Care Team established
  - Primary Care Mental Health Integration 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 position filled
  - Women's Health Medical Director or clinical champion on staff
  - Maternity Care Coordinator position filled
  - Women's health clinical liaison is assigned at each CBOC

Women's Health Findings and Recommendations

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

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leadership, and has core members. That required membership includes a Women Veterans Program Manager; a Women's Health Medical Director; "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."[119]

[119] VHA Directive 1330.01(2).

The OIG reviewed the Women Veterans Health Committee meeting minutes from April 2019 through September 2019 and noted a lack of representation from medical and/or surgical subspecialties, laboratory, and business office/non-VA medical care. Additionally, other designated committee members did not consistently attend meetings. This resulted in a lack of expertise and oversight in the review and analysis of data as the committee planned and carried out improvements for quality and equitable care. The Women Veterans Program Manager and Women's Health Medical Director cited a lack of authority to require members to represent their services or consistently attend meetings as the reasons for noncompliance.

The OIG also reviewed the Quality Executive Board meeting minutes from April through September 2019 and determined that the Women Veterans Health Committee did not report to this executive leadership board on a quarterly basis. Failure to report activities to executive leaders potentially impedes oversight and support of the women's health program. The Women Veterans Program Manager and Women's Health Medical Director reported that competing priorities, including covering administrative support duties, contributed to the noncompliance.

Recommendation 17

17. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that required members are assigned and consistently attend Women Veterans Health Committee meetings and that the committee reports to an executive leadership board.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The System Director, Chief of Staff, Associate Chief of Staff Primary Care Service, the Women's Health Program Manager, and the Women's Health Medical Director met to evaluate additional reasons for non-compliance. It was discovered that there was a gap in service during the absence of a full-time permanent Women's Health Program Manager, and it was also determined that the Women Health Committee did not systematically report to an executive leadership board. These findings were considered and incorporated in the development of this action plan.

The System Director along with the Chief of Staff will ensure ongoing compliance of required members are assigned and consistently attend the Women Veterans Health Committee meetings and that the committee will report to the Medical Executive Board. The executive leadership board reporting structure for the committee was adopted June 2020. Specifically, the Women's Health Program Manager will develop a revised Women's Veteran Program Committee charter that reflects the committee's purpose, membership, reporting structure to an executive leadership board, responsibilities, meeting times, attendance requirements, and voting requirements. The revised charter was completed and presented to the Medical Executive Board June 2020.

The Women's Health Program Manager will audit the Women Veterans Health Committee membership attendance at all committee meetings until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of required Women Veterans Health Committee members in attendance. The denominator will be the total number of required Women Veterans Health Committee members.

The Women's Health Program Manager will audit the Women Veterans Health Committee reporting to the Medical Executive Board until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audits will be reported to the Quality Executive Board. The numerator will be the number of Medical Executive Board meeting minutes demonstrating that the Women Veterans Health Committee reported to the Medical Executive Board. The denominator will be the total number of Medical Executive Board meeting minutes audited.

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…"[120] The goal of SPS is to "...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[121] 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 instruments[122]
- 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 inspections[123]

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.[124] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[125]

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,

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

[121] 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.)

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

[123] VHA Directive 1116(2).

[124] 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.

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

personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME.[126]

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 the sufficient aptitude, knowledge, and skills to effectively and safely reprocess and sterilize RME.[127]

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 clinic clean 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

[126] VHA Directive 1116(2).
[127] VHA Directive 1116(2).

  - Eating or drinking in the area prohibited
  - Equipment properly stored
  - Required temperature and humidity maintained
- 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 many of the requirements for the proper operations and management of reprocessing RME. However, the OIG noted concerns with bioburden testing and staff training and continuing education.

According to VHA, SPS must have a quality assurance program that tests at least 10 percent of endoscopes for bioburden, and the testing must include each endoscope model.[128] The OIG was unable to determine whether at least 10 percent of reprocessed endoscopes were tested for bioburden because gastroenterology staff did not clearly identify which endoscopes were tested. This resulted in a lack of assurance that appropriate and safe reprocessing had been performed. The Gastroenterology Nurse Manager believed that the current documentation process for bioburden testing had met quality assurance requirements.

Recommendation 18

18. The Associate Director for Patient Care Services determines the reasons for noncompliance and ensures that gastroenterology staff test at least 10 percent of reprocessed endoscopes for bioburden and testing to include each endoscope model.

[128] VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Associate Director for Patient Care Services, the Nurse Manager of Gastroenterology, and the Chief of Sterile Processing Services met to evaluate additional reasons for noncompliance to determine appropriate measures to strengthen internal processes. It was determined that the reprocessing process tracking log was insufficient to meet the requisite standards. These findings were considered and incorporated in the development of this action plan.

The Associate Director of Patient Care Services will ensure ongoing compliance by providing oversight to the development, implementation, and monitoring of the required processes and tracking management for the Gastroenterology Service and Sterile Processing Service. The Nurse Manager of the Gastroenterology will ensure that gastroenterology staff test at a minimum 10 percent of reprocessed endoscopes for bioburden to include each endoscopes model number. The current gastroenterology scope log was modified to be the same as the Sterile Processing Service compliant scope log on November 2019. Each staff member was trained on the new log by the Reusable Medical Equipment Coordinator on November 2019.

Monthly audits by the Chief of Sterile Processing or designee on the revised scope log confirming accurate completion of at least 10 percent of reprocessed scopes are tested for bioburden and the testing includes the endoscope model number. Audits will continue until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of reprocessed scopes where at least 10 percent of reprocessed scopes are tested for bioburden and the testing includes the scope model number. The denominator will be the total number of reprocessed scopes.

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."[129] Of the four selected SPS employees hired after March 2016, the OIG found that none completed the training within 90 days of hire. This could result in improperly cleaned equipment. Additionally, VHA requires that SPS staff receive continuing education monthly.[130] Between August and October 2019, the OIG found no evidence of monthly continuing education for 3 of 10 selected SPS staff. This resulted in a potential knowledge gap in reprocessing duties. The SPS Assistant Chief cited staffing issues, competing priorities, and the newly hired RME Coordinator's training as reasons for noncompliance.

[129] VHA Directive 1116(2).
[130] VHA Directive 1116(2).

Recommendation 19

19. 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: December 31, 2020

Healthcare system response: The Associate Director for Patient Care Services along with the Chief of Sterile Processing Services, the Assistant Chief of Sterile Processing, and the Reusable Medical Equipment Coordinator met to evaluate additional reasons for noncompliance to determine appropriate measures to strengthen internal processes. It was determined that there were a few human factor issues of competing priorities and staffing shortages identified as barriers for meeting the education and training requirements. These findings were considered and incorporated in the development of this action plan.

The Associate Director of Patient Care Services will ensure ongoing compliance by providing oversight to the development, implementation, and monitoring of the required processes that Sterile Processing Services employees complete Level 1 training within 90 days of hire. Specifically, the Chief of Sterile Processing Service will ensure that all new staff in Sterile Processing Service and the gastroenterology technicians will automatically be enrolled in Level 1 Talent Management System training upon onboarding to duty.

The Chief of Sterile Processing Service or designee will ensure that all new Sterile Processing Services employees and gastroenterology technicians complete Level 1 training within 90 days of hire. Adequate time during orientation has been identified as a reliable time to complete this requirement. Monthly audits by the Chief of Sterile Processing or designee will continue until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of new Sterile Processing Services employees and gastroenterology technicians that complete Level 1 training within 90 days of hire. The denominator will be the total number of new Sterile Processing Services employees and gastroenterology technicians.

Recommendation 20

20. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures Sterile Processing Services staff receive monthly continuing education.

Healthcare system concurred.

Target date for completion: December 31, 2020

Healthcare system response: The Associate Director for Patient Care Services along with the Chief of Sterile Processing Services, the Assistant Chief of Sterile Processing, and the Reusable Medical Equipment Coordinator met to evaluate additional reasons for noncompliance to determine appropriate measures to strengthen internal processes. It was determined that there were a few human factor issues of competing priorities and staffing shortages identified as barriers for meeting the continuing education requirements. These findings were considered and incorporated in the development of this action plan.

The Associate Director of Patient Care Services will ensure ongoing compliance by providing oversight to the development, implementation, and monitoring of the required processes that all Sterile Processing Services staff and the gastroenterology technician receive monthly continuing education. Specifically, the Chief of Sterile Processing Service will ensure that Education and training files will be maintained for all staff to document monthly continuing education and training. Additionally, the Chief of Sterile Processing Service or designee will establish a continuing education plan for each fiscal year.

The Chief of Sterile Processing Service will ensure that all new Sterile Processing Services employees and gastroenterology technicians receive monthly continuing education. Monthly audits by the Chief of Sterile Processing or designee will continue until a 90 percent or greater compliance rate has been reached for two consecutive quarters. Audit results will be reported to the Quality Executive Board. The numerator will be the total number of Sterile Processing Services employees and gastroenterology technicians that receive monthly continuing education. The denominator will be the total number of Sterile Processing Services employees and gastroenterology technicians.

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	• 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 (system) • VHA performance data for CLCs	Twenty 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, and Associate Director. See details below.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• QSV Committee • Protected peer reviews • UM reviews • Patient safety	• The Patient Safety Manager consistently implements improvement actions from root cause analyses.	• Specific improvement actions recommended by the Quality Executive Board are documented, implemented, and monitored. • All required representatives consistently participate in quarterly interdisciplinary reviews of UM data.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	• FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards	• Service chiefs include service- and practitioner-specific OPPE criteria. • Service Chief reprivileging decision is based on service- and practitioner-specific OPPE data. • Provider exit review forms are completed within seven calendar days of licensed healthcare professionals departing the system.	• Medical Executive Board meeting minutes consistently reflect the review of OPPE results in the decision to recommend continuation of privileges.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement

Environment of Care	• 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
	  ○ General safety
	  ○ Special use spaces
	  ○ Environmental cleanliness and infection prevention
	  ○ Privacy
	  ○ Privacy for women veterans
	  ○ Logistics
		• Ensure mental health unit camera placement is reconfigured to mitigate the risk caused by blind spots.	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	• Provision of pain management using long-term opioid therapy • Program oversight and evaluation	• Providers complete and document a behavioral risk assessment to include history of substance abuse and aberrant behavior risk. • Providers consistently conduct urine drug testing for patients on long-term opioid therapy. • Providers obtain and document informed consent for patients prior to initiating long-term opioid therapy. • Providers follow up with patients within the required time frame, to include a review of intervention effectiveness after initiating long-term opioid therapy.	• The Pain Committee monitors the quality of pain assessment, effectiveness of pain management interventions, and opportunities for improvements.
Mental Health: Suicide Prevention Program	• Designated facility suicide prevention coordinator • Provision of suicide prevention care • Completion of suicide prevention training requirements	• Providers conduct four follow-up visits, either face-to-face or telephonic, with documented consent within the required time frame.	• The SPC delivers at least five outreach activities each month. • Staff receive annual suicide prevention refresher training.
Care Coordination: Life-Sustaining Treatment Decisions	• LSTD multidisciplinary committee • Goals of care conversation documentation • LSTD note/orders completed by an authorized provider or delegated	• None	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Women's Health: Comprehensive Care	• Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements	• None	• Required members consistently attend Women Veterans Health Committee quarterly meetings, and the committee reports to executive leaders.
High-Risk Processes: Reusable Medical Equipment	• Administrative processes • Data monitoring • Physical inspection • Staff training	• At least 10 percent of endoscopes reprocessed are tested for bioburden and testing include each endoscope model. • All new SPS employees complete Level 1 training within 90 days of hire.	• SPS staff receive monthly continuing education.

Appendix B: Healthcare System Profile

The table below provides general background information for this highest complexity (1a) affiliated[1] healthcare system reporting to VISN 15.[2]

Table B.1. Profile for VA St. Louis Health Care System (657)
(October 1, 2016, through September 30, 2019)

Profile Element	Healthcare System Data FY 2017[3]	Healthcare System Data FY 2018[4]	Healthcare System Data FY 2019[5]
Total medical care budget	$497,940,735	$550,638,254	$587,314,000
Number of:			
• Unique patients	62,038	58,378	58,702
• Outpatient visits	697,879	718,464	743,719
• Unique employees[6]	2,042	2,326	2,636
Type and number of operating beds:			
• Community living center	71	71	71
• Domiciliary	75	66	66
• Medicine	66	66	66
• Mental health	46	46	46
• Spinal cord injury	38	38	38
• Surgery	50	50	50
Average daily census:			
• Community living center	53	53	54
• Domiciliary	51	51	49
• Medicine	54	49	46
• Mental health	26	26	23
• Neurology	3	2	2
• Spinal cord injury	25	23	26

[1] Associated with a medical residency program.

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

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

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

[5] October 1, 2018, through September 30, 2019.

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

Profile Element	Healthcare System Data FY 2017[3]	Healthcare System Data FY 2018[4]	Healthcare System Data FY 2019[5]
• Surgery	19	19	20

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 Profiles[1]

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
Shiloh, IL	657GA	10,415	1,453	n/a	n/a	Nutrition Pharmacy Weight management
Florissant, MO	657GB	10,179	1,358	n/a	n/a	Nutrition Pharmacy
O'Fallon, MO	657GD	9,863	398	n/a	n/a	Nutrition Pharmacy Weight management

[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.

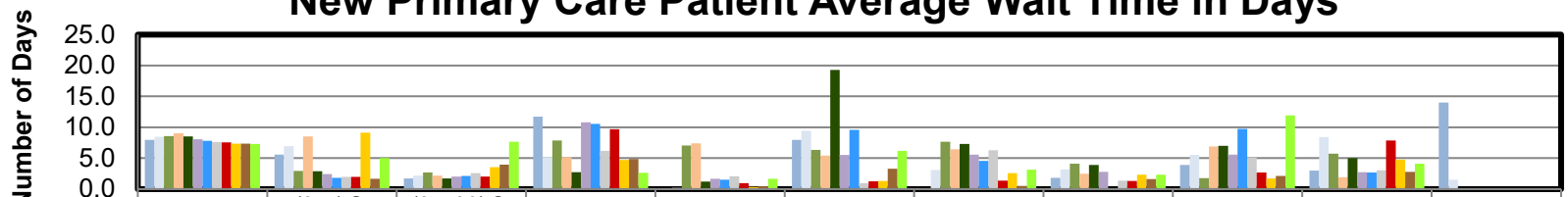
[4] Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

[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
Washington, MO	657GS	4,306	629	n/a	n/a	Nutrition Pharmacy
St. Louis, MO	657GX	10,124	1,009	Anesthesia	n/a	Nutrition Pharmacy
St. Louis, MO	657GY	10,297	205	n/a	n/a	Nutrition Pharmacy
St. Louis, MO	657QA	4,604	594	Dermatology Gynecology	n/a	Nutrition
St. Louis, MO	657QB	351	n/a	n/a	n/a	n/a
Scott Air Force Base, IL	657QE	n/a	440	n/a	n/a	n/a

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 Metrics[1]

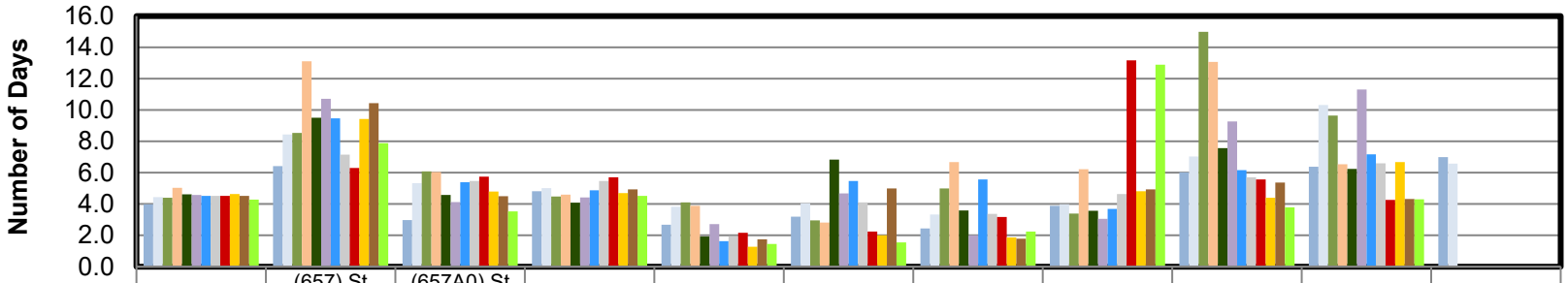


	VHA Total	(657) St. Louis John Cochran, MO (John Cochran)	(657A0) St. Louis Jefferson Barracks, MO	(657GA) St. Clair County, IL	(657GB) St. Louis County, MO	(657GD) St. Charles County, MO	(657GS) Franklin County, MO	(657GX) Washington Avenue, MO	(657GY) Manchester Avenue, MO	(657QA) Olive Street, MO	(657QB) Washington Boulevard, MO
OCT-FY19	8.0	5.6	1.7	11.7	0.0	8.0	0.1	1.8	3.9	3.0	14.0
NOV-FY19	8.5	6.9	2.2	5.2	0.2	9.4	3.1	3.2	5.5	8.4	1.5
DEC-FY19	8.6	2.9	2.7	7.9	7.1	6.4	7.7	4.1	1.8	5.7	n/a
JAN-FY19	9.0	8.5	2.2	5.2	7.4	5.4	6.5	2.5	6.9	1.9	n/a
FEB-FY19	8.5	2.9	1.7	2.7	1.2	19.3	7.3	3.9	7.0	5.0	n/a
MAR-FY19	8.1	2.5	2.0	10.8	1.7	5.5	5.6	2.8	5.6	2.8	n/a
APR-FY19	7.8	1.8	2.1	10.6	1.5	9.6	4.6	0.2	9.8	2.7	n/a
MAY-FY19	7.6	2.0	2.6	6.2	2.1	1.0	6.3	1.3	5.1	3.0	n/a
JUN-FY19	7.6	2.0	2.0	9.7	0.9	1.3	1.4	1.3	2.7	7.9	n/a
JUL-FY19	7.3	9.1	3.5	4.7	0.3	1.3	2.6	2.3	1.7	4.8	n/a
AUG-FY19	7.4	1.7	4.0	4.9	0.5	3.3	0.5	1.6	2.1	2.8	n/a
SEP-FY19	7.3	5.0	7.7	2.7	1.7	6.2	3.2	2.4	11.9	4.1	n/a

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness.
The OIG omitted (657QE) Scott Air Force Base, IL as no data was 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 FY 2015, 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 October 21, 2019.

Established Primary Care Patient Average Wait Time in Days



	VHA Total	(657) St. Louis John Cochran, MO (John Cochran)	(657A0) St. Louis Jefferson Barracks, MO	(657GA) St. Clair County, IL	(657GB) St. Louis County, MO	(657GD) St. Charles County, MO	(657GS) Franklin County, MO	(657GX) Washington Avenue, MO	(657GY) Manchester Avenue, MO	(657QA) Olive Street, MO	(657QB) Washington Boulevard, MO
OCT-FY19	4.0	6.4	3.0	4.8	2.7	3.2	2.4	3.9	6.0	6.4	7.0
NOV-FY19	4.4	8.4	5.3	5.0	3.8	4.0	3.3	4.0	7.0	10.3	6.6
DEC-FY19	4.4	8.5	6.1	4.5	4.1	3.0	5.0	3.4	15.0	9.7	n/a
JAN-FY19	5.0	13.1	6.0	4.6	3.9	2.8	6.7	6.2	13.1	6.5	n/a
FEB-FY19	4.6	9.5	4.6	4.1	1.9	6.8	3.6	3.6	7.6	6.3	n/a
MAR-FY19	4.6	10.7	4.1	4.4	2.7	4.7	2.0	3.0	9.3	11.3	n/a
APR-FY19	4.5	9.5	5.4	4.9	1.6	5.5	5.6	3.7	6.2	7.2	n/a
MAY-FY19	4.5	7.2	5.5	5.5	2.0	4.1	3.4	4.6	5.7	6.6	n/a
JUN-FY19	4.5	6.3	5.8	5.7	2.2	2.2	3.2	13.2	5.6	4.3	n/a
JUL-FY19	4.6	9.4	4.8	4.7	1.3	2.0	1.9	4.8	4.4	6.7	n/a
AUG-FY19	4.5	10.4	4.5	4.9	1.7	5.0	1.8	4.9	5.4	4.3	n/a
SEP-FY19	4.3	7.9	3.5	4.5	1.5	1.6	2.2	12.9	3.8	4.3	n/a

Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (657QE) Scott Air Force Base, IL as no data was reported.
Data Definition: "The average number of calendar days between an Established Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date."

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions[1]

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 Definitions[1]

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://vaww.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 7, 2020

From: Director, VA Heartland Network (10N15)

Subj: Comprehensive Healthcare Inspection of the VA St. Louis Health Care System in Missouri

To: Director, Office of Healthcare Inspections (54CH01)

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

Attached is the facilities response to the Comprehensive Healthcare Inspection of the VA St. Louis Health Care System in Missouri draft report.

I have reviewed and concur with the facility's response to the findings, recommendations, and submitted action plans.

(Original signed by:)

William P. Patterson, M.D., MSS
Network Director
VA Heartland Network (VISN 15)

Appendix H: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: July 1, 2020

From: Director, VA St. Louis Health Care System (657/00)

Subj: Comprehensive Healthcare Inspection of the VA St. Louis Health Care System in Missouri

To: Director, VA Heartland Network (10N15)

1. In response to the findings of the OIG CHIP Review of the VA St. Louis Health Care System conducted November 4 to November 8, 2019, the facility has taken actions to address the twenty (20) recommendations.
2. I have reviewed and concur with the findings, recommendations and actions as submitted. The action plans will be followed through to completion and sustainment.

(Original signed by:)

Keith D. Repko
Medical Center Director
VA St. Louis Health Care System

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