DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the VA Eastern Kansas Health Care System in Topeka

CHIP REPORT | REPORT #19-06870-175 | JUNE 18, 2020

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Figure 1. *VA Eastern Kansas Health Care System in Topeka (Source: https://vaww.va.gov/directory/guide/, accessed on November 18, 2019)*

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
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
WH-PCP	women's health primary care provider

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 Eastern Kansas Health Care System, which includes two divisions—the Colmery-O'Neil VA Medical Center (Topeka) and the Dwight D. Eisenhower VA Medical Center (Leavenworth)—and multiple outpatient clinics in Kansas 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 facility. The OIG selects and evaluates specific areas of focus each year.

The OIG team looks at leadership and organizational risks, and at the time of the inspection, focused on the following clinical areas:

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

The unannounced visit was conducted during the week of November 4, 2019, at the Colmery-O'Neil VA Medical Center, Dwight D. Eisenhower VA Medical Center, and Wyandotte 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 System Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure with the Performance Excellence Executive Council overseeing several working groups. The leaders monitored patient safety and care through the Quality Safety Value 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 two months, although several had served in their positions for more than a year. The System Director was the most tenured leader, permanently assigned in October 2012. The ADPCS was the newest member of the leadership team, assigned in September 2019. The Chief of Staff, Associate Director, and Assistant Director had served in their positions since February, September, and November 2018, respectively.

The OIG noted that selected employee satisfaction survey results indicated that the Chief of Staff and ADPCS appear to have opportunities to improve employee satisfaction, and the Chief of Staff and Associate Director appear to have opportunities to improve staff feelings of "moral distress" at work.[1] However, selected patient experience survey scores generally reflected similar or higher care ratings than the VHA average. Patients appeared satisfied 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.[2] However, the OIG had concerns regarding logistics (including supply issues), the patient safety program, and the executive leadership team's lack of shared knowledge of these two areas.

The VA Office of Operational Analytics and Reporting adapted 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.

[1] The 2019 All Employee Survey defines moral distress as being "unsure about the right thing to do or could not carry out what you believed to be the right thing."

[2] 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."

The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[3]

The executive leaders were minimally knowledgeable within their scope of responsibilities about selected VHA data used by the SAIL and CLC SAIL models.[4] In individual interviews, the executive leadership team members were not able to speak knowledgeably about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences.

The OIG noted areas for improvement in seven clinical areas reviewed and issued 39 recommendations that are directed to the System Director, Chief of Staff, ADPCS, Associate Director, and Assistant Director. These are briefly described below.

Quality, Safety, and Value

The healthcare system complied with requirements for establishment of a committee responsible for quality, safety, and value oversight functions, aggregated data review, and compliance with most patient safety elements. However, the OIG expressed concerns with the committee's lack of action plans for identified problems, as well as with the facility's protected peer reviews, utilization management, and root cause analysis processes.[5]

Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluations and healthcare provider exit review processes.[6]

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[3] 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.)

[4] 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.

[5] 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." (This directive expired July 31, 2019.)

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

Environment of Care

The healthcare system largely met the selected inpatient mental health requirements reviewed. However, the OIG identified issues with general safety, special use spaces, cleanliness and infection prevention, privacy, and availability of medical supplies.

Medication Management

The OIG observed compliance with many elements of expected performance, including pain screening, aberrant behavior risk assessment, and documented justification for concurrent therapy with benzodiazepines. The healthcare system was generally compliant with the use of a multidisciplinary pain management committee to oversee and monitor required quality measures. However, the OIG found deficiencies with urine drug testing, informed consent, and patient follow-up after therapy initiation.

Mental Health

The OIG found compliance with the requirements for suicide prevention coordinator designation, appointment and safety plan tracking, and suicide prevention training. However, areas for improvement included monthly outreach activities, no-show appointment follow-up, and suicide safety plan elements.

Women's Health

The healthcare system complied with many of the requirements for women's health, including care provision and each of the selected staffing requirements reviewed. The OIG noted concerns with community-based outpatient clinic-designated women's health primary care providers and the Women Veterans Health Committee.

High-Risk Processes

The healthcare system did not meet selected requirements for the proper operations and management of reprocessing reusable medical equipment. The OIG noted that in the past year, the healthcare system has had multiple site visits focused on Sterile Processing Services processes that identified unresolved issues because, according to the Chief of SPS, staff has not yet had time to address the findings. Additionally, the OIG identified deficiencies with administrative processes; equipment storage; and staff training, competency, and ongoing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 39 recommendations for improvement to the System Director, Chief of Staff, ADPCS, Associate Director, and Assistant 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 inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 97–98, 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 Eastern Kansas 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:[3]

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)

[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.

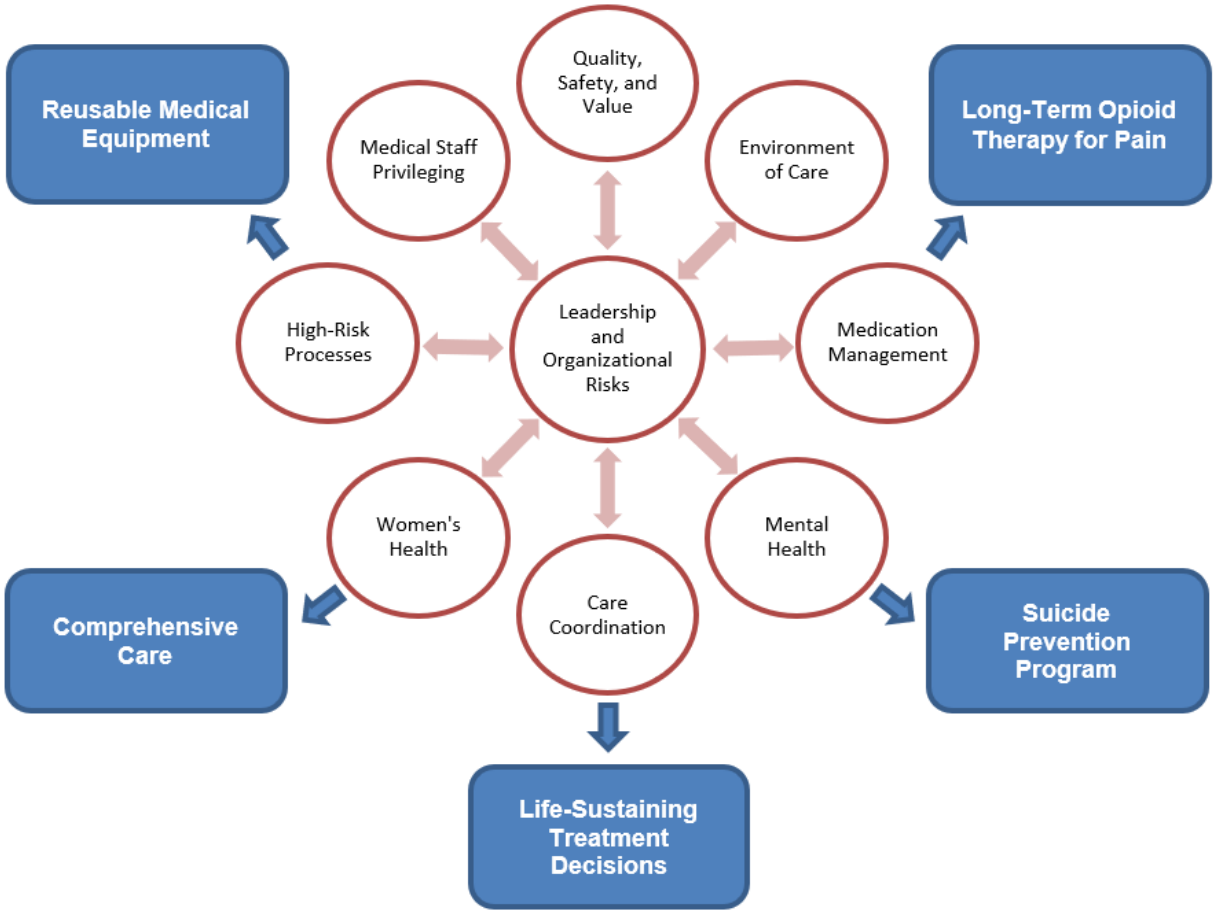

Figure 2. *Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services*
Source: VA OIG

Methodology

The VA Eastern Kansas Health Care System includes the Colmery-O'Neil VA Medical Center (Topeka VAMC), the Dwight D. Eisenhower VA Medical Center (Leavenworth VAMC), and multiple outpatient clinics in Kansas 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 selected and physically inspected the following areas of the Topeka and Leavenworth VAMCs:

- Topeka VAMC
  - Acute psychiatric units
  - Community Living Center (CLC)[5]
  - Dental clinic
  - Emergency Department
  - Intensive care unit
  - Medical/surgical inpatient unit
  - Outpatient clinics
  - Post-anesthesia care unit
  - Sterile Processing Services areas
  - Women's health clinic
- Leavenworth VAMC
  - CLC
  - Emergency Department
  - Intensive/progressive care unit

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

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

- Medical/Surgical inpatient unit
- Outpatient clinic
- Post-anesthesia care unit

The team also physically inspected the Wyandotte County VA Clinic.

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

The inspection period examined operations from May 13, 2017, through November 7, 2019, the last day of the unannounced multiday site visit.[6] While on site, the OIG 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 (CLC)

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this healthcare system's reported organizational structure. The healthcare system has a leadership team consisting of the System Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Associate Director, and Assistant 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.)

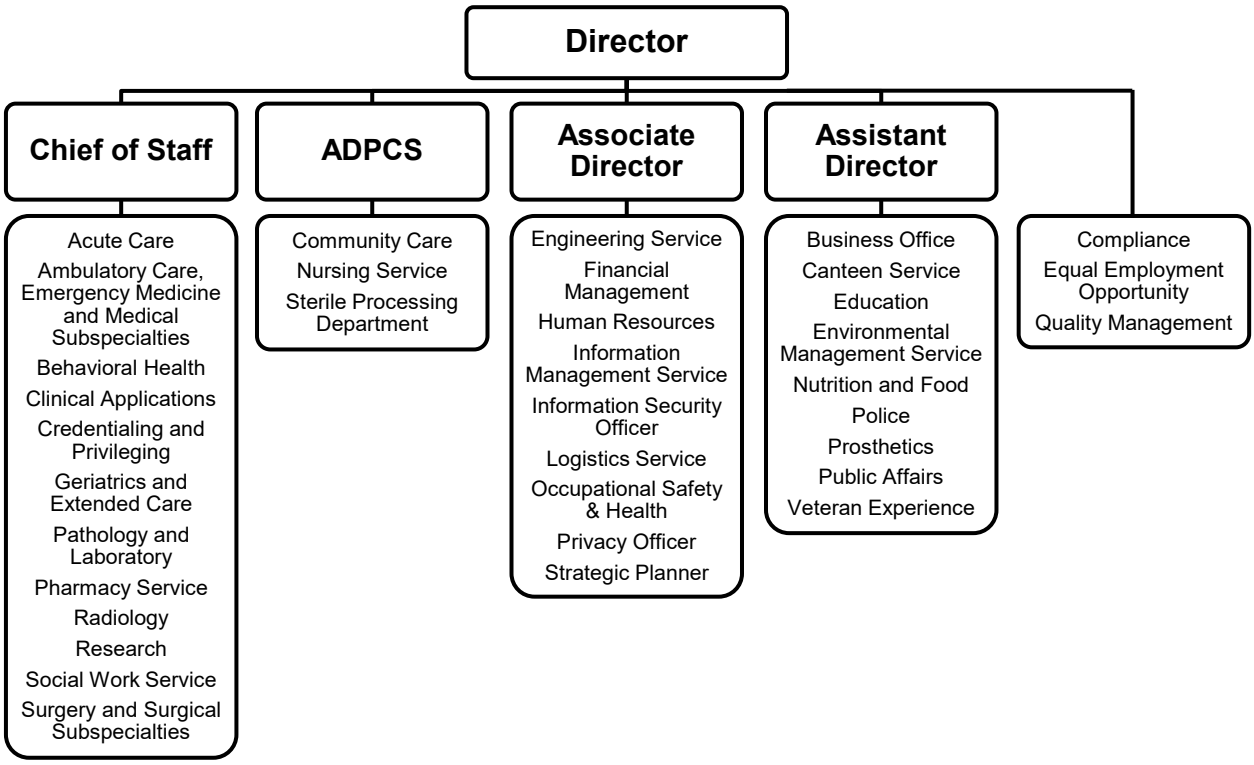

Figure 3. *Healthcare System Organizational Chart*
Source: VA Eastern Kansas Health Care System (received November 4, 2019)

At the time of the OIG site visit, the executive team had been working together as a group for two months, although the System Director had served since 2012. Several other team members had also been in their positions for more than a year (see Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
System Director	October 7, 2012
Chief of Staff	February 4, 2018
Associate Director for Patient Care Services	September 1, 2019
Associate Director	September 2, 2018
Assistant Director	November 11, 2018

Source: VA Eastern Kansas Health Care System Supervisory Human Resources Specialist (received November 6, 2019)

To help assess the healthcare system executive leaders' engagement, the OIG interviewed the System Director, Chief of Staff, ADPCS, and Associate Director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance.

The executive leaders were minimally knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing Strategic Analytics for Improvement and Learning (SAIL) measures. Leaders also lacked understanding of Community Living Center (CLC) SAIL measures, despite the healthcare system's generally positive results. In individual interviews, the executive leadership team members were not 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 System Director serves as the chairperson of the Performance Excellence Executive Council, with the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Performance Excellence Executive Council oversees various working groups such as the Environment of Care, Medical Executive, and Nursing Executive Boards.

These leaders monitor patient safety and care through the Quality Safety Value Board which is responsible for tracking, trending, and monitoring quality of care and patient outcomes and reports to the Performance Excellence Executive Council. See Figure 4.

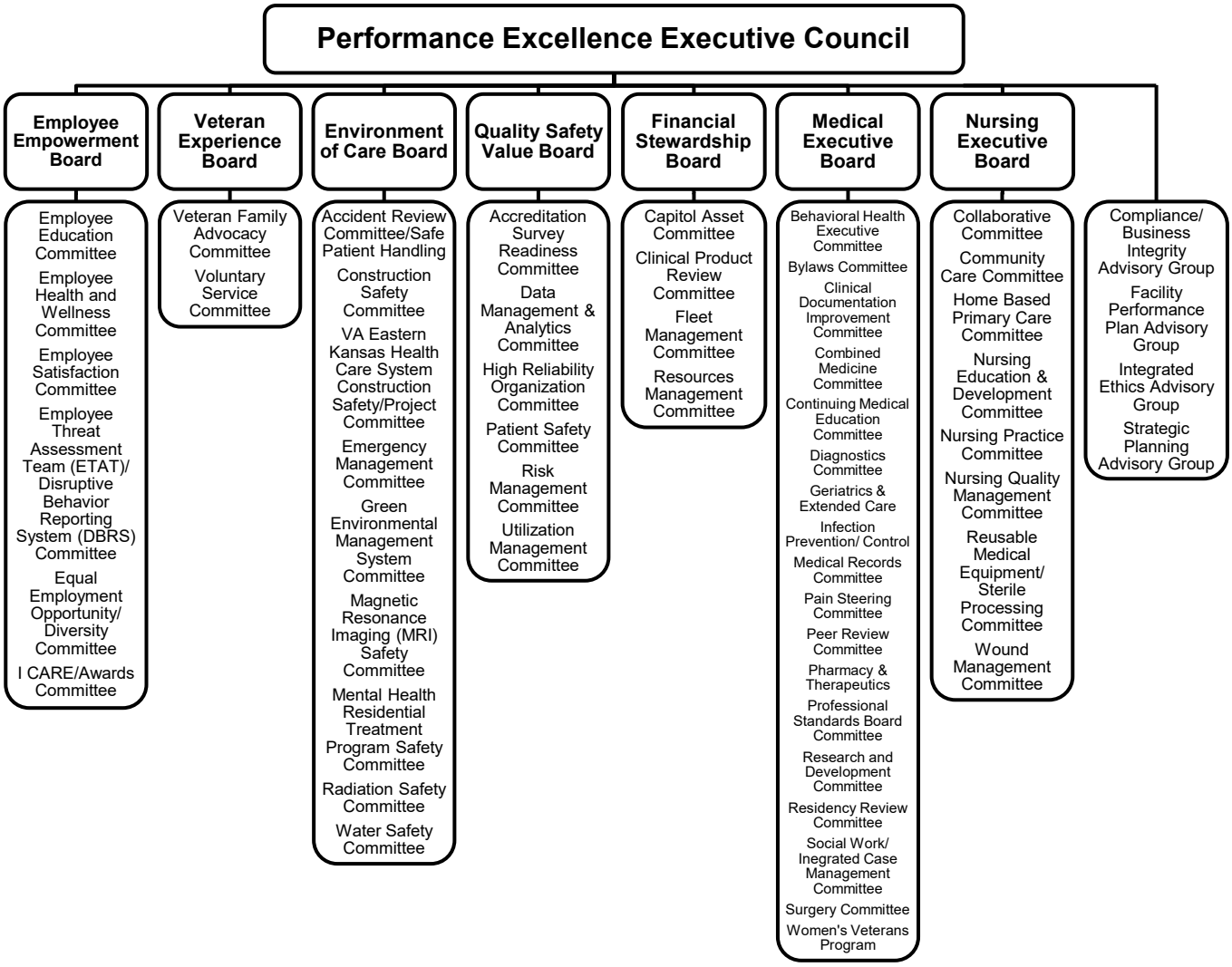

Figure 4. *Healthcare System Committee Reporting Structure*
Source: VA Eastern Kansas Health Care System (November 4, 2019)

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 selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found the healthcare system average for specific survey leadership questions was similar to or lower than the VHA average.[9] The same trend was noted for the Chief of Staff and ADPCS; however, scores for the System Director and Associate Director were consistently higher than those for VHA and the healthcare system.[10]

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

Questions/ Survey Items	Scoring	VHA Average	Healthcare System Average	System Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Servant Leader Index Composite*[11]	0–100 where higher scores are more favorable	72.6	71.4	82.0	73.5	68.5	76.4	68.5
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	3.2	3.8	3.0	3.1	4.3	3.5

[8] Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Associate Director, and Assistant 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] It is important to note that the 2019 All Employee Survey results are not reflective of employee satisfaction with the current ADPCS who assumed the role after the survey was administered.

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

Questions/ Survey Items	Scoring	VHA Average	Healthcare System Average	System Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. 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	4.3	3.4	3.3	4.1	3.9
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.4	4.1	3.2	3.3	4.0	3.8

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.[12] Note that the healthcare system average for the selected survey questions was similar to the VHA average. Scores related to the System Director and Assistant Director were consistently better than those for VHA and the healthcare system. However, opportunities appear to exist for the Chief of Staff and Associate Director to improve employee feelings of moral distress at work (uncertainty about the right thing to do or inability to carry out what you believed to be the right thing).

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

Questions/ Survey Items	Scoring	VHA Average	Healthcare System Average	System Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.8	4.6	3.5	3.7	4.6	4.2

[12] Ratings are based on responses by employees who report to or are aligned under the System Director, Chief of Staff, ADPCS, Associate Director, and Assistant Director.

Questions/ Survey Items	Scoring	VHA Average	Healthcare System Average	System Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.7	4.0	3.6	3.7	4.1	4.2
All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?*	0 (Never) – 6 (Every Day)	1.4	1.5	1.3	2.0	1.6	2.1	0.5

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's Topeka and Leavenworth medical centers.[13]

VHA also collects SHEP survey data from Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients' attitudes toward their healthcare experiences (see Table 4). For this system's

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

medical centers, the patient survey results generally reflected similar or higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

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

Questions	Scoring	VHA Average	Topeka Medical Center Average	Leavenworth Medical Center 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	63.0	71.1
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	83.8	90.3
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	80.0	81.3
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	84.3	79.6

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.[14] For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see Tables 5–7), including those for the Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG team noted that the results for

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

male respondents were generally similar to or more favorable than the corresponding VHA averages, while those for female respondents were consistently more positive when compared with female VHA patients nationally. System leaders appeared to be actively engaged with male and female patients (for example, conducting women veteran town hall meetings and using automated checkouts for veterans with a survey to learn the perception of their experience).

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

Questions	Scoring	VHA[15]		Healthcare System[16]	
		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	82.3	87.5
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	88.5	94.8
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	65.8	75.9

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

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

[16] The healthcare system averages are based on 264–270 male and 15 or 16 female respondents, depending on the question.

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

Questions	Scoring	VHA[17]		Healthcare System[18]	
		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	54.7	63.1
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	63.5	86.3
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	69.2	76.0

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

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

[18] The healthcare system averages are based on 411–1,542 male and 37–79 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[19]		Healthcare System[20]	
		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	65.9	–[21]
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	64.3	63.2
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	74.9	93.1

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.[22] Table 8 summarizes the relevant system inspections most recently performed by the OIG and The Joint

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

[20] The healthcare system averages are based on 193–682 male and 14 or 27 female respondents, depending on the question.

[21] Data are not available due to the low number of respondents.

[22] 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).[23] Of note, at the time of the OIG visit, the system had closed all but four recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in May 2017. The Acting Quality Manager reported continuing to work with system managers to address the four open recommendations resulting from a prior focused OIG report on airway management processes that was published June 20, 2019.[24]

At the time of the site visit, the OIG also noted the system's current accreditation by Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[25] Additional results included the Long Term Care Institute's inspection of the system's CLCs.[26]

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Comprehensive Healthcare Inspection Program Review of the VA Eastern Kansas Health Care System, Topeka, Kansas,* Report No. 17-01850-38, December 7, 2017)	May 2017	5	0

[23] 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."

[24] OIG. *Alleged Deficiencies in Out of Operating Room Airway Management Processes at the Colmery-O'Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas*, Report No. 18-02765-144, June 20, 2019.

[25] 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.

[26] 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.)

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Alleged Mismanagement of Inpatient Care at the Colmery-O'Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas,* Report No. 17-02484-189, June 18, 2018)	April 2017	6	0
OIG (*Delayed Radiology Test Reporting at the Dwight D. Eisenhower VA Medical Center, Leavenworth, Kansas, VA Eastern Kansas Health Care System,* Report No. 18-00980-84, March 7, 2019)	June 2018	5	0
OIG (*Alleged Deficiencies in Out of Operating Room Airway Management Processes at the Colmery-O'Neil VA Medical Center within the VA Eastern Kansas Health Care System, Topeka, Kansas,* Report No. 18-02765-144, June 20, 2019)	August 2018	7	4[27]
TJC Hospital Accreditation	July 2019	47	0
TJC Behavioral Health Care Accreditation		2	0
TJC Home Care Accreditation		6	0

Sources: OIG and TJC (Inspection/survey results verified with the Acting Quality Manager on November 4, 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 identified two concerns related to the potential for patient harm—issues with logistics (particularly supplies) and the patient safety program.

The OIG asked the System Director in an interview how facility leaders maintain adequate supplies for patient care and whether there was awareness of any related concerns such as issues with inventory control. In response, the System Director indicated that there were issues with par

[27] The four remaining recommendations for improvement were closed on April 28, 2020.

levels and reported some close calls with this issue.[28] The System Director mentioned that a root cause analysis was recently completed on incidents involving unavailability of needed supplies.[29] Further, during OIG's environment of care area inspections, Post Anesthesia Care Unit staff at the Leavenworth VAMC reported the lack of routine medical supplies typically needed for patient care. Staff reported that the problem occurs monthly. During OIG's follow-up to the reported lack of supplies in the Post Anesthesia Care Unit, the system's Chief Supply Chain Officer reported being unaware of the issue. The Supervisory Inventory Management Specialist also reported not being aware of two of the three triggering events documented in the root cause analysis, despite leading the root cause analysis.

For the system's patient safety program, the OIG found no evidence that action was taken following a root cause analysis involving a patient who underwent a wrong-site procedure by General Surgery following a referral from the Dermatology Clinic. The dermatology-specific root cause analysis actions were closed in WebSPOT (the VHA Patient Safety Information System) due to the healthcare system no longer having a dermatologist on staff. The Patient Safety Manager stated that when a new dermatologist is hired, the actions will be instituted and reported in a tracking log rather than through VHA's patient safety information system, which the Patient Safety Manager described as antiquated and cumbersome. OIG also noted that incident reports were entered by the Patient Safety Manager rather than by staff who identified the issue.

Table 9 lists the reported patient safety events from May 13, 2017 (the prior OIG comprehensive healthcare inspection), through November 5, 2019.[30]

[28] Par level is the minimally-defined quantity of an item needed in stock. Close calls are sometimes referred to as "near misses."

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

[30] 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 Eastern Kansas Health Care System is a mid-high complexity (1c) affiliated system as described in Appendix B.)

Table 9. Summary of Selected Organizational Risk Factors (May 13, 2017, through November 5, 2019)

Factor	Number of Occurrences
Sentinel Events[31]	3
Institutional Disclosures[32]	3
Large-Scale Disclosures[33]	0

Source: VA Eastern Kansas Health Care System's Quality Management Supervisor (received on November 5, 2019)

Veterans Health Administration Performance Data

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

Figures 5 and 6 illustrates the system's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, Figure 5 uses blue and green data points to indicate high performance for the Topeka VAMC (for example, in the areas of adjusted length of stay (LOS), stress discussed, rating (of) specialty care (SC) provider, registered nurse (RN) turnover, and care transition). Metrics that need improvement are denoted

[31] 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."

[32] 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."

[33] 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."

[34] 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.)

in orange and red (for example, rating (of) primary care (PC) provider, best place to work, and capacity).[35]

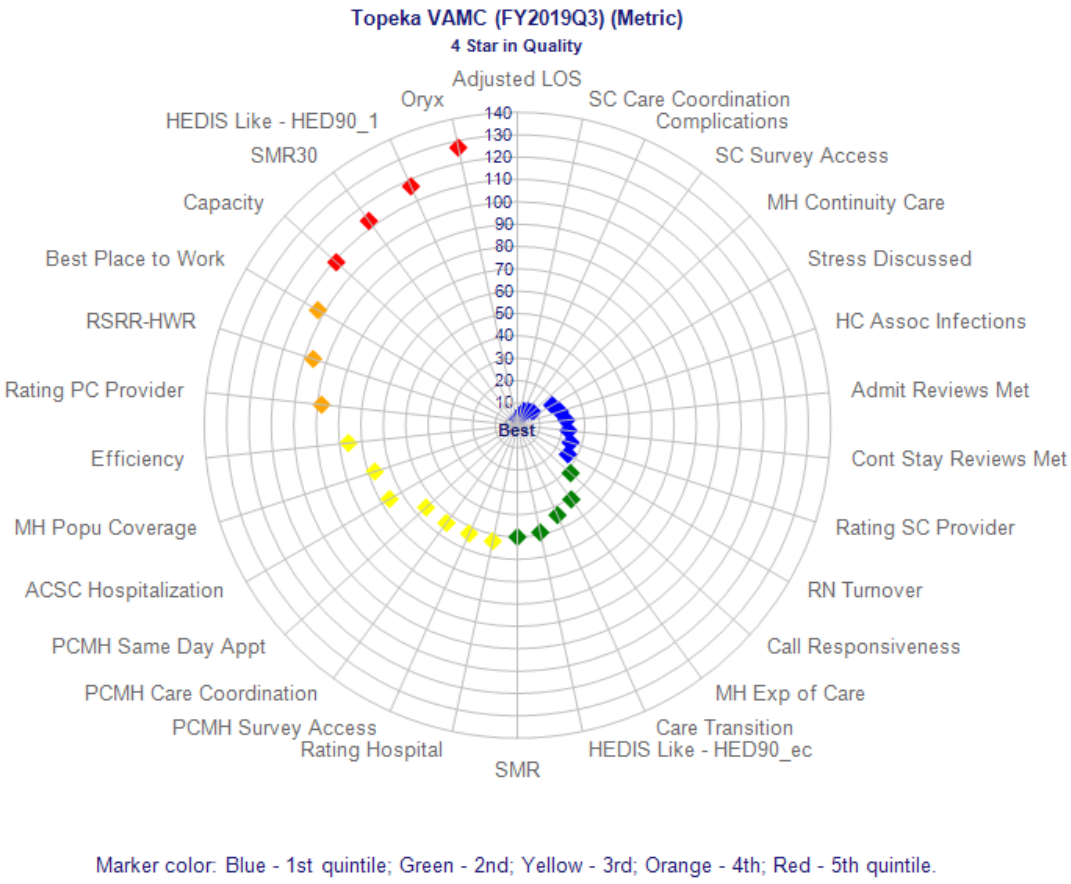

Figure 5. *Topeka VAMC Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)*
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. Data definitions are provided in Appendix E.

Figure 6 uses blue and green data points to indicate high performance for the Leavenworth VAMC (for example, in the areas of adjusted length of stay (LOS), complications, patient centered medical home (PCMH) care coordination, call responsiveness, and care transition). Metrics that need improvement are denoted in orange and red (for example, best place to work and registered nurse (RN) turnover).[36]

[35] For information on the acronyms in the SAIL metrics, please see Appendix E.

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

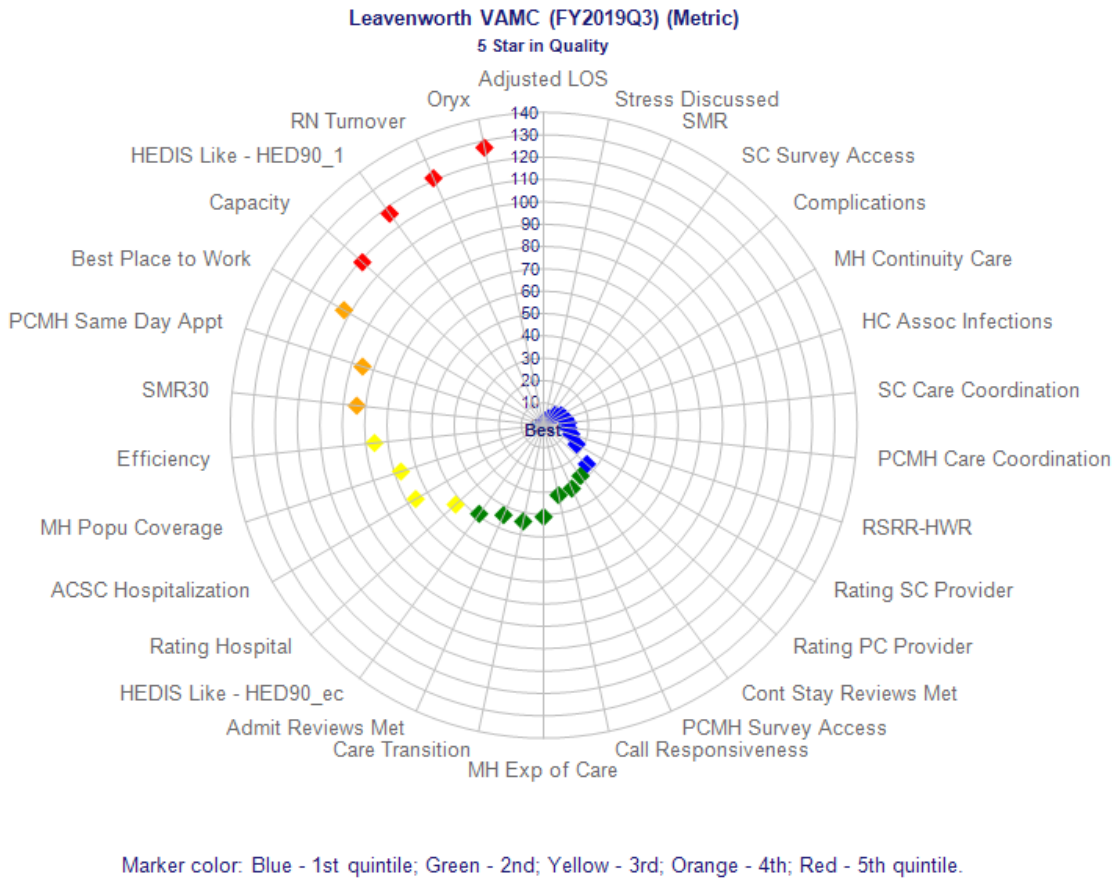

Figure 6. *Leavenworth VAMC Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)*
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. Data definitions are provided in Appendix E.

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.[37]

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

Figures 7 and 8 illustrate the system's CLC quality rankings and performance compared with other VA CLCs as of June 30, 2019. Figure 7 uses blue and green data points to indicate high performance for the Topeka VAMC CLC (for example, in the areas of urinary tract infections (UTI)–long stay (LS), new or worse pressure ulcer (PU)–short stay (SS), and high risk PU–LS). Metrics that need improvement are denoted in orange and red (for example, moderate-severe pain–SS and help with activities of daily living (ADL)–LS).[38]

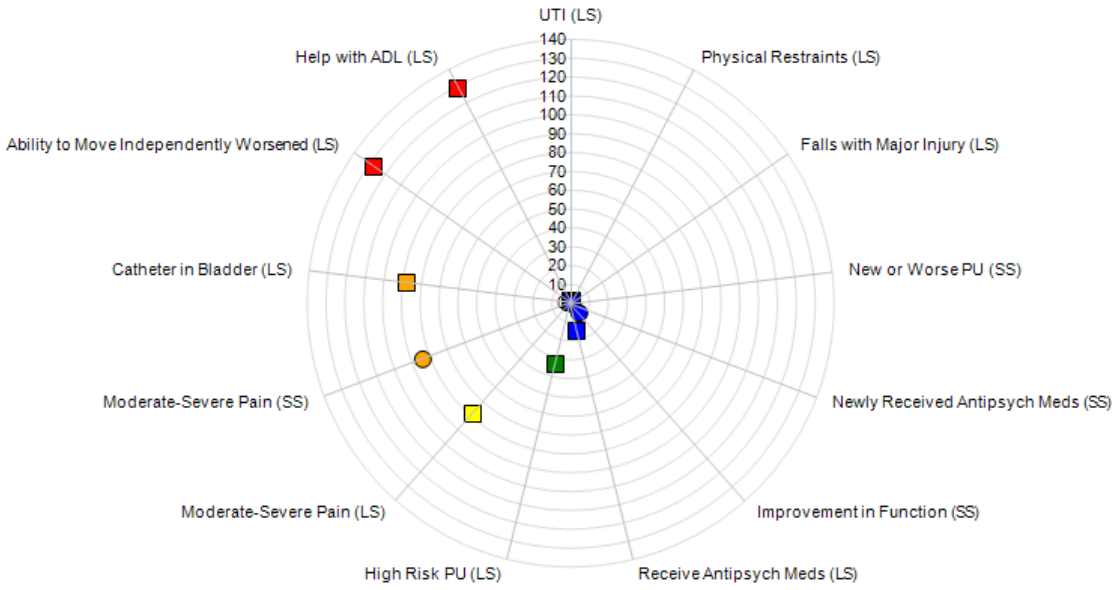

Figure 7. *Topeka VAMC CLC Quality Measure Rankings (as of June 30, 2019)*
LS = Long-Stay Measure SS = Short-Stay Measure
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix F.

Figure 8 uses blue data points to indicate high performance for the Leavenworth VAMC CLC (for example, in the areas of high risk PU–LS, help with ADL–LS, and improvement in function–SS). Metrics that need improvement are denoted in orange and red (for example, moderate-severe pain–LS, moderate-severe pain–SS, and new or worse PU–SS).[39]

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

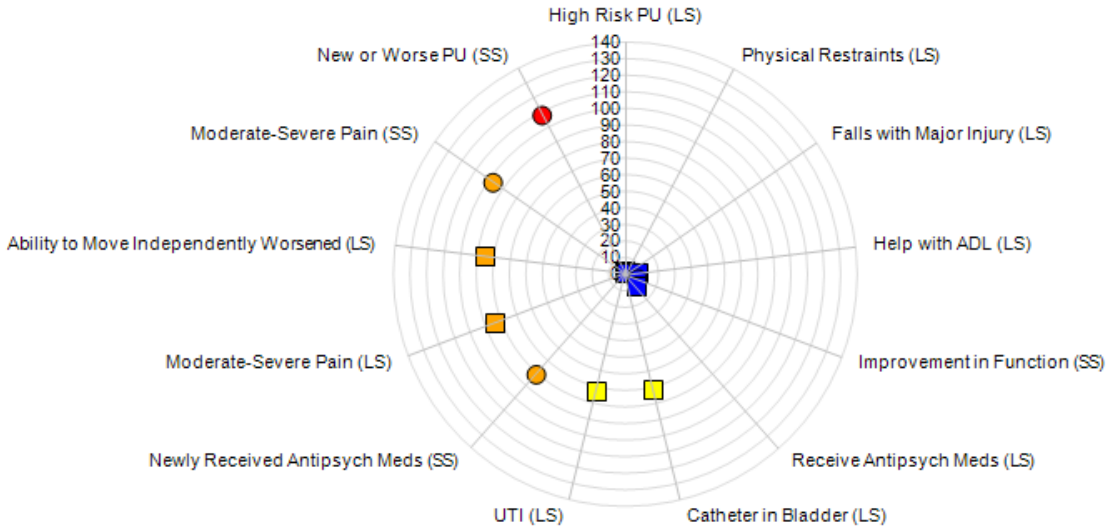

Figure 8. *Leavenworth VAMC CLC Quality Measure Rankings (as of June 30, 2019)*
LS = Long-Stay Measure SS = Short-Stay Measure
Source: VHA Support Service Center
Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix F.

Leadership and Organizational Risks Conclusion

The system's executive leadership team had vacancies in four of the five key positions since the previous May 2017 OIG CHIP inspection, and two of those positions were filled for less than one year at the time of OIG's on-site visit. Selected survey items related to employees' satisfaction with the system executive leaders revealed opportunities for the Chief of Staff and ADPCS to improve employee satisfaction and for the Chief of Staff and Associate Director to improve staff feelings of "moral distress" at work. Patient experience survey data noted that patients appeared satisfied with the care provided. Further, the OIG found that selected survey results for female respondents were consistently more favorable than those for female VHA patients nationally. The OIG's review of the system's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, the OIG identified concerns regarding logistics (including supply issues), the patient safety program, and the executive leadership team's lack of shared knowledge. In individual interviews, the executive leaders were not able to speak knowledgeably about actions taken during the previous 12 months in order to maintain or improve employee satisfaction and patient experiences. In addition, the executive leaders were minimally knowledgeable within their scope of responsibilities about selected VHA data used by the SAIL and CLC SAIL models.

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.[40] 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.[41] 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.[42]

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.[43] 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.[44] The OIG team examined the completion of the following elements:

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

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

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

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

[44] 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[45]
- 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.[46] 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.[47] 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.[48] Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for

[45] VHA Directive 1190.

[46] 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." (This directive expired July 31, 2019.)

[47] VHA Directive 1117(2).

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

Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the healthcare system.[49] The healthcare system was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses[50]
- 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 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.[51]

Quality, Safety, Value Findings and Recommendations

The healthcare system complied with requirements for establishing a committee responsible for QSV oversight functions and its review of aggregated data as well as most patient safety elements reviewed. Additionally, for the cases reviewed by OIG it was noted that the Peer Review Committee did not identify improvement actions for any of the cases determined to be a Level 2 or 3.[52]

The OIG identified significant weaknesses in various key QSV functions:

- QSV committee's recommendation and implementation of improvement actions

[49] VHA Handbook 1050.01.

[50] 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]."

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

[52] According to VHA Directive 1190, "levels of Care are to be used in assessing the clinical decisions and actions of the clinician who is the subject of a Peer Review for Quality Management. A Level of Care must be assigned by the initial reviewer(s) and in the evaluation and discussion of the initial review and the episode of care by the multi-disciplinary Peer Review Committee (PRC). (1) Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. (2) Level 2 is the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care. (3) Level 3 is the level at which most experienced and competent clinicians would have managed the case differently."

- Protected peer reviewers' 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
- Completion of final peer reviews within 120 calendar days
- Quarterly review of Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff
- Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database
- Interdisciplinary review of UM data
- Inclusion of required content in root cause analyses

Regarding QSV oversight, TJC requires that the healthcare system's governing body provide structure and resources to support quality and safety. TJC also requires facilities to measure and analyze performance using data so that performance improvement "effectiveness can be sustained, assessed, and measured."[53] The OIG reviewed Quality, Safety, and Value Board minutes from September 2018 through September 2019 and noted a lack of specific action items for identified problems or opportunities for improvement during the months of July and August. This may have prevented quality of care and patient safety process improvements at the healthcare system. The Interim Quality Manager reported there had been multiple staff and leadership changes which affected the functioning of the committee.

Recommendation 1

1. The System Director evaluates and determines any additional reasons for noncompliance and ensures specific action items are documented in Quality, Safety, and Value Board minutes when problems or opportunities for improvement are identified.

[53] TJC. Rationale for Leadership standard LD.01.03.01, Rationale for Leadership standard 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.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The System Director or designee will audit minutes for each Quality Safety Value Board meeting to ensure appropriate addition and tracking of action items until 90% compliance has been reached for two consecutive quarters. Results of the audit will be reported to the governing council for the Quality Safety Value Board: Performance Excellence Executive Council. Numerator will be Quality Safety Value Board Minutes that contain tracking of action items until closure, denominator will be total number of Quality Safety Value Minutes.

VHA requires peer reviewers to use at least one of nine aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation) to evaluate level two or three peer review findings.[54] The OIG found 7 of 14 cases lacked evidence that the reviewer used at least one of the nine aspects of care and 7 of 20 did not address the initial screener's concerns. When the reviewer does not use an aspect of care or evaluate the initial screener's concerns, it may impact the ability of the committee to determine if appropriate care was provided. The Risk Manager reported difficulty with providers agreeing to be peer reviewers.

Recommendation 2

2. The Chief of Staff determines the reason(s) for noncompliance and ensures that peer reviewers consistently use at least one of the nine aspects of care for evaluations and address the initial screener's concern.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will complete an audit of all peer review cases to evaluate the compliance rate of peer reviewers consistently using at least one of the nine aspects of care for evaluations and address the initial screener's concern until 90% compliance has been reached for two consecutive quarters. The number of peer review cases with identification of at least one of the nine aspects of care for evaluations and address the initial screener's concern will be the numerator and the total number of peer reviewed cases will be the denominator. Results will be reported to the Medical Executive Board quarterly.

[54] VHA Directive 1190. A level two peer review finding is defined as "the level at which most experienced and competent clinicians might have managed the case differently but it remains within the standard of care." A level three peer review "is the level at which most experienced and competent clinicians would have managed the case differently."

VHA also requires peer review for all deaths within 24 hours of admission, except in cases where death is anticipated and clearly documented, such as transfer from hospice care.[55] The OIG found that from October 10, 2018, through October 10, 2019, two applicable deaths had not been evaluated to determine if peer review was warranted. This may have prevented timely identification of issues in the practice of one or more healthcare providers at the system. Due to the inadequate transition of duties from the previous Risk Manager, the current manager was not aware of the types of reports available to identify cases that might trigger peer review.

Recommendation 3

3. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that all applicable deaths within 24 hours of admission are peer reviewed.

Healthcare system concurred. Target date for completion: 12/31/2020 Healthcare system response: The Chief of Staff or designee will review all auto-generated occurrence reports for any applicable deaths occurring within 24 hours of admission. An audit of all applicable deaths will show 90% compliance with peer review initiation for two consecutive quarters. Audit results will be reported to the Medical Executive Board quarterly. The number of applicable deaths within 24 hours of admission that were peer reviewed will be the numerator and the number of applicable deaths within 24 hours of admission requiring peer review will be the denominator.

In addition, VHA requires that final peer reviews are completed within 120 calendar days from the determination that a peer review is needed.[56] From April 2018 through October 2019, the OIG was unable to determine if 19 of 20 reviews were completed within the expected time frame. The OIG observed that the relevant files maintained by the previous Risk Manager were incomplete and lacked information regarding when the peer review was initiated. This likely prevented timely improvements in patient care at the system. The current Risk Manager assumed the role in June 2019 and reported to OIG that there was only a one-day transition with the departing manager. The Risk Manager acknowledged that the lack of organized files contributed to the observed noncompliance.

[55] VHA Directive 1190.

[56] VHA Directive 1190.

Recommendation 4

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

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee are conducting audits of all peer review cases completed. These peer reviews will show evidence of determination date and completion date; any peer reviews exceeding 120 days will have the required documented extension as approved by the System Director or designee. The number of final peer reviews completed within 120 calendar days from the date it is determined a peer review is required and any necessary extensions are approved in writing by the System Director will be the numerator and the total number of peer reviews will be the denominator. These audits will show a compliance rate of 90% for two consecutive quarters and are reported quarterly to Medical Executive Board.

VHA requires that summaries of the Peer Review Committee's analyses are reviewed quarterly by an executive-level medical committee.[57] The OIG found that from November 2018 through October 2019, the Peer Review Committee did not provide a summary report to the Medical Executive Board for three of four quarters. Inconsistent reviews of quarterly Peer Review Committee summary reports by the Medical Executive Board may result in the committee's failure to identify clinical practice trends, determine the need for further action, and monitor the effectiveness of quality improvement initiatives. The Risk Manager reported that some meeting minutes had not been completed by the prior Risk Manager, and the OIG noted this lack of attention to detail may have contributed to missing reports.

Recommendation 5

5. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that a summary of the Peer Review Committee's analyses is reviewed quarterly by the Medical Executive Board.

[57] VHA Directive 1190.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will ensure that Peer Review Committee analyses are submitted to and reviewed by the Medical Executive Board quarterly as evidenced by Medical Executive Board minutes, for two consecutive quarters. Results reported to Performance Excellence Executive Council.

VHA requires that physician UM advisors document, at minimum, 75 percent of their decisions in the National UM Integration database regarding appropriateness of patient admissions and continued stays.[58] The OIG found that the physician UM advisors completed 49 percent of referred reviews from April 1, 2019, through September 30, 2019. Incomplete reviews resulted in a lack of information available at the national level and for facility-level review by an interdisciplinary group to set benchmarks; identify trends, actions, and opportunities to improve efficiency; and monitor outcomes. The UM Manager stated that they only had one physician covering the UM advisor position and due to an extended leave, the system could not meet expectations. This is a repeat finding from the May 2017 OIG CHIP review.

Recommendation 6

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

Healthcare system concurred.

Target date for completion: 03/31/2021

Healthcare system response: Additional Physician Utilization Management Advisors (PUMA) were appointed on 01/06/2020 and trained for each campus by 02/29/2020. The Chief of Staff or designee will monitor documentation of Physician Utilization Management Advisors decisions in the National Utilization Management Integration database with a target goal of 75% of Physician Utilization Management Advisors reviews meeting the target for two consecutive quarters. Compliance will be reported to the Utilization Management Committee and Quality Safety Value Board Quarterly.

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]."[59] The OIG

[58] VHA Directive 1117(2).

[59] VHA Directive 1117(2).

found that from October 2018 through July2019, the UM Committee lacked representation from medicine, case management, mental health, and CBOR-UR. As a result, the UM Committee performed reviews and analyses without the perspectives of key staff. The UM Manager reported that there was confusion about the timing of UM Committee meetings due to oversight committee changes.

Recommendation 7

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

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Utilization Management Committee charter has been updated and signed by the System Director. The Chief of Staff or designee will track attendance at each Utilization Management Committee meeting will reflect the required membership and members will designate an alternate to attend in their place in the event of an absence. An audit of each member's attendance will be conducted until a compliance rate for overall committee attendance is 90% for two consecutive quarters. Audit results will be reported to the Quality Safety Value Board on a quarterly basis. Numerator will be required member's or designee's attendance and the denominator will be total number of meetings.

VHA requires root cause analyses to include several factors, such as participation by leaders, analysis of the underlying systems to determine where redesigns might reduce risk, "consideration of relevant literature, and identification of at least one root cause with a corresponding action and outcome measure." Additionally, WebSPOT (the VHA Patient Safety Information System) must be used to document the root cause analysis.[60] Of the five individual root cause analyses reviewed, the OIG found that three did not include an analysis of the underlying systems to determine where redesigns might reduce risk. This likely affected evaluation of patient safety events and limited reviewers' ability to identify vulnerabilities and implement process improvements that could help prevent patient harm events. The Patient Safety Manager reported keeping detailed notes outside of the required computer system for root cause analysis documentation.

[60] VHA Handbook 1050.01.

Recommendation 8

8. The System Director evaluates and determines any additional reasons for noncompliance and ensures that root cause analyses include all required review elements and be properly documented in the VHA Patient Safety Information System.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: A review was completed to evaluate barriers to proper Root Cause Analysis documentation within the VHA Patient Safety Information System. The review was conducted via interview with the system's Patient Safety Manager, Quality Management Officer, and the VISN Patient Safety Officer. Review noted a lack of Patient Safety/System staff, besides Patient Safety Manager, trained to complete Root Cause Analysis, as well as barriers impacting Patient Safety Manager access to electronic resources during root cause analysis team meetings. VISN Patient Safety Officer and the system Patient Safety Manager completed additional training for current and new team members during quarter two of fiscal year 2020. The system Quality Management Officer addressed the electronic barriers identified in quarter two of fiscal year 2020. The System Director or designee will review each Root Cause Analysis for inclusion of analysis of underlying systems and proper documentation in the VHA Patient Safety Information System until a target of 90% compliance rate for two consecutive quarters has been met. Numerator will be root cause analyses that include all required review elements and are properly documented in the VHA Patient Safety Information System and denominator will be total number of Root Causes Analyses conducted. Results of Root Cause Analysis audits will be reported to Quality Safety Value Board quarterly.

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).[61]

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.[62]

VHA defines the focused professional practice evaluation (FPPE) as "a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance." The FPPE process occurs when a provider is hired at the facility and granted initial privileges and before any new clinical privileges are granted. Additionally, VA facilities must continuously monitor the performance of their providers. VHA requirements state that "the on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered."[63] The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
  - Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs[64]
  - 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[65]
  - Evaluation by another provider with similar training and privileges

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

[62] VHA Handbook 1100.19.

[63] VHA Handbook 1100.19.

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

[65] 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.[66] 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."[67] 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 timeframe 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:

- Eleven solo/few practitioners who underwent initial or reprivileging during the previous 12 months[68]
- Ten LIPs hired within 18 months before the site visit
- Twenty LIPs privileged within 12 months before the visit
- Eleven LIPs who left the healthcare system in 12 months before the visit

[66] VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. (This handbook was scheduled for recertification on or before the last working day of December 2010 and has not been recertified.)

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

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

Medical Staff Privileging Findings and Recommendations

The OIG identified the following deficiencies with FPPE, OPPE, and provider exit review processes:

- FPPEs had established criteria in advance
- FPPEs included required criteria for selected specialty LIPs
- OPPEs involved criteria specific to the service or section
- OPPEs used providers with similar training and privileges
- The Executive Committee of the Medical Staff recommended continuing privileges based on FPPE and OPPE results
- Managers completed provider exit review forms within the required timeframe and with required oversight

VHA requires FPPE criteria "to be defined in advance, using objective criteria accepted by the practitioner."[69] The OIG reviewers found 4 of 13 practitioners' profiles lacked evidence that the LIPs were aware of the criteria for evaluation before service chiefs initiated the FPPE process. This could result in LIPs misunderstanding FPPE expectations. The Deputy Chief of Staff reported that with the two medical centers in the healthcare system, the person preparing the plan may not be in the same location, and the movement of documents between medical centers created challenges.

Recommendation 9

9. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures clinical managers define in advance, communicate, and document expectations for focused professional practice evaluations in the provider profiles.

[69] VHA Handbook 1100.19.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will add focused professional practice evaluation criteria to the provider orientation process to include the requirement for clinical managers to define focused professional practice evaluation criteria in advance and to document and communicate their expectations for the FPPE to the provider during orientation. The Chief of staff or designee will modify the form to include the ability to accept electronic signatures. Monitoring for compliance will be completed by designated staff until a 90% compliance rate of all required elements is met for two consecutive quarters. Audit results will be reported to Quality Safety Value Board on a quarterly basis. Numerator will be focused professional practice evaluations containing expectations documented and defined in advance and denominator will be total number of focused professional practice evaluations.

VHA requires that service chiefs include the minimum specialty-specific criteria for FPPEs of gastroenterology, nuclear medicine, pathology, and radiation oncology practitioners.[70] The OIG found that a gastroenterology and a pathology (solo/few) practitioner at the healthcare system lacked the minimum required specialty-specific criteria. This resulted in gastroenterology and pathology practitioners practicing without a thorough evaluation of their practice. The Chief of Staff reported being aware that minimum criteria were required for ongoing professional practice evaluations but unaware the minimum criteria were also required for focused professional practice evaluations.

Recommendation 10

10. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that service chiefs include the minimum required gastroenterology- and pathology-specific criteria for focused professional practice evaluations of licensed independent practitioners.

[70] VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will update the standard focused professional practice evaluation elements for Pathology and Gastroenterology providers. Designated staff will audit these providers' focused professional practice evaluation to ensure they included the required specific criteria for their specialty areas until a target goal of 90% compliance has been met for two consecutive quarters. Numerator will be number of focused professional practice evaluations with Pathology and Gastroenterology specific criteria completed and denominator will be total number of focused professional practice evaluation for Pathology and Gastroenterology providers completed. Audit results will be reported to the Quality Safety Value Board on a quarterly basis.

VHA requires that at the time of reprivileging, service chiefs consider relevant service- and practitioner-specific data when recommending the continuation of practitioners' privileges to the Executive Committee of the Medical Staff.[71] For 6 of 28 practitioners reprivileged within the last 12 months, three of which were solo/few providers, the OIG found that service chiefs could not demonstrate that the recommendation to continue privileges was based in part on service-specific OPPE data. This resulted in inadequate data to support decisions to continue clinical privileges to these LIPs. The Deputy Chief of Staff reported that new forms were implemented in 2019 to include service-specific elements; however, the OIG did not see evidence of consistent implementation.

Recommendation 11

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

[71] VHA Handbook 1100.19.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: In fiscal year 2019, all ongoing professional practice evaluation forms were updated to include service specific criteria. The Chief of Staff, or designee will perform audits of all staff undergoing review for reprivileging to ensure decisions are based upon service specific criteria. Compliance will be measured by the number of ongoing professional practice evaluations reviewed by the Medical Executive Board with the service specific criteria as the numerator and the number of total ongoing professional practice evaluations reviewed by the Medical Executive Board as the denominator. This recommendation will be considered compliant when there are two consecutive quarterly reports of data showing 90% or greater compliance with use of the service specific ongoing professional practice evaluations forms. The audit results will be reported to Quality Safety Value Board quarterly.

VHA requires that LIPs are evaluated on an ongoing basis by providers with similar training and privileges.[72] The OIG found two of eight solo/few practitioners undergoing the OPPE process were not evaluated by providers with similar training and privileges. This resulted in LIPs providing care without a thorough evaluation of their competencies, which could impact quality of care and patient safety. The Chief of Staff attributed the noncompliance to lack of attention to detail and stated the process to request assistance through the VISN was not always reliable.

Recommendation 12

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

[72] VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will ensure that licensed independent practitioners with like privileges complete professional practice evaluation chart reviews. This will be demonstrated by Service Chief pre-approval of professional practice evaluation reviewers at the beginning of each professional practice evaluation cycle. Solo providers will be sent to the VISN 15 Chief Medical Officer and/or his designee as needed to secure an appropriate professional practice evaluation reviewer. An audit to ensure similarly privileged providers performed professional practice evaluation will be conducted until a 90% compliance rate for a period of two consecutive quarters has been met. The audit results will be reported to Quality Safety Value Board on a quarterly basis. Numerator will be number of professional practice evaluations with evaluation by a provider with similar training and privileges reviewed by Medical Executive Board, the denominator will be total professional practice evaluations reviewed by Medical Executive Board.

VHA requires the Executive Committee of the Medical Staff review and evaluate LIPs' initial and reprivileging requests. 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.[73] For 35 practitioners—13 who had initial privileges granted and 22 who were reprivileged—the OIG found that the Medical Executive Board, the healthcare system's Executive Committee of the Medical Staff, did not document recommended continuation of privileges. This function was performed by the Medical Executive Board for Credentialing, which is not identified in the Medical Staff Bylaws as a committee authorized to make recommendations to the System Director.[74] Failure to appropriately document committee reviews and recommendations resulted in incomplete evidence to support the System Director's approval for continuing clinical privileges. The Chief of Staff reported that the Medical Executive Board and Medical Executive Board for Credentialing were never intended to be separate committees, but rather the same committee, and claimed that it was an administrative oversight that the attendance rosters did not match.

[73] VHA Handbook 1100.19.

[74] When a committee or subcommittee identified in the facility's medical staff bylaws perform the expected duties of the Executive Committee of the Medical Staff, the OIG considers the membership of the committees to determine if the intent of VHA requirements is met.

Recommendation 13

13. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that Medical Executive Board meeting minutes consistently reflect the review of professional practice evaluation results in the decision to recommend continuation of privileges.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee will conduct an audit of any continuation of privileges and will show a consideration of clinical practice evaluation decision by the Medical Executive Board as evidenced by Medical Executive Board minutes. Numerator will be number of professional practice evaluations with evaluation by a provider with similar training and privileges reviewed by Medical Executive Board. And the denominator will be total professional practice evaluations reviewed by Medical Executive Board with a compliance rate of 90% for two consecutive quarters. The audit results will be reported to the Quality Safety Value Board on a quarterly basis.

VHA requires "Provider Exit Review forms [be] completed within seven calendar days of departure of a licensed health care professional" to ensure timely reporting to the SLBs of practitioners who fail to meet professional practice standards for delivering patient care.[75] In addition, VHA requires that a first- or second-line supervisor sign the exit review form at the time a provider leaves the facility.[76] For the 11 providers that departed the healthcare system in the previous 12 months, the OIG found that two providers' exit forms were not completed, and seven forms were not completed within seven calendar days. The OIG also found five of nine completed exit review forms were not signed in the correct location—the signature was placed in the area of the form indicating the provider failed to meet acceptable standards despite documentation in the form that standards were met. The OIG was unable to determine, based on the review, if these providers should have been referred to the SLB or if the forms were simply completed in error. A lack of oversight of the exit review process may lead to the inability to identify providers who are not meeting professional practice standards. Additionally, improper completion of exit forms may lead to confusion, potentially delaying time-appropriate reporting of providers not meeting standards for care delivery to state licensing boards. The Deputy Chief of Staff reported that due to turnover of the designated person and supervisor, there had been a backlog in initiating the exit review, which was being addressed by the newly assigned staff member.

[75] VHA Notice 2018-05.

[76] VHA Notice 2018-05.

Recommendation 14

14. 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 and include the signature of the first- or second-line supervisor in the properly designated area.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The System Director or designee will educate Medical Staff Services on the importance of exit reviews, and completion of exit reviews will be added to the service line employee clearance processes. Designated staff have updated the exit review forms to provide clarity on the signatures needed. Designated staff will monitor and report compliance with the timely completion of exit reviews monthly to the Quality Safety Value board until a 90% compliance rate for two consecutive quarters has been met. The numerator will be number of exit review forms completed for licensed independent practitioners within seven calendar days and include signature of the first- or second-line supervisor and the denominator will be number of licensed independent practitioners that left the 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.[77]

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

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

[77] 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 18 patient care areas:

- Topeka VAMC
  - Acute psychiatric unit
  - CLC (CLC4 and CLC6 units)
  - Dental clinic
  - Emergency Department
  - Intensive care unit
  - Medical/surgical inpatient unit
  - Outpatient clinics (Red and Blue clinics)
  - Post-anesthesia care unit
  - Women's health clinic
- Leavenworth VAMC
  - CLC
  - Emergency Department
  - Intensive/progressive care unit
  - Medical/Surgical inpatient unit (floor A2)
  - Outpatient clinic (C5/PCC2 clinic)
  - Post-anesthesia care unit
- Wyandotte County VA Clinic

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

Environment of Care Findings and Recommendations

The inspection team observed general compliance with requirements for the inpatient mental health unit. The OIG also observed temporary entrances at the Leavenworth medical center due to construction in the emergency department. These entrances lacked adequate exterior signage and were not handicapped accessible; however, the healthcare system took steps to remediate the deficiencies while the OIG was on site.

The OIG also identified vulnerabilities within the healthcare system's environment:

- Topeka and Leavenworth VAMCs
  - General safety
  - Special use spaces
  - Environmental cleanliness and infection prevention
  - Logistics
- Wyandotte County VA Clinic
  - General safety
  - Environmental cleanliness and infection prevention
  - Privacy

The Occupational Safety and Health Administration requires employers to ensure safety data sheets for hazardous chemicals are available and readily accessible to employees in their work areas.[78] In the 18 areas inspected, the OIG found that employees were unable to immediately access safety data sheet information (printed or electronic) on hazardous chemicals used in the area. This resulted in staff not having information readily available in the event of exposure to hazardous chemicals. The Office of Information Technology Supervisor in Topeka indicated that after recent computer software updates, the staff's default homepage may not be the healthcare system intranet homepage, which has the safety data sheet icon/link available. In addition, the Safety Manager stated that education on how to access safety data sheets has waned, and the system's staff who perform environmental of care rounds were likely not asking staff how to access the information to validate knowledge.

Recommendation 15

15. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures employees' ability to access safety data sheet information.

[78] Occupational Safety and Health Administration (OSHA), 29 CFR 1910.1200, *Hazard Communication*.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director or designee will ensure staff have an increased awareness of the location and the use of the Safety Data Sheet system online. Ongoing monitoring will be captured during Environment of Care rounds. Audit of up to five staff will be asked to demonstrate access to the Safety Data Sheets during each month, with a target of 90% compliance sustained for two consecutive quarters. Numerator will be number of staff demonstrating ability to access safety data sheets and the denominator will be total number of staff asked to demonstrate ability to access safety data sheets. Audit results will be reported monthly to the Environment of Care Board.

Regarding special use spaces and infection prevention, VHA requires restricted access to clean/sterile storerooms.[79] The OIG found 3 of 18 patient care areas had unsecured supply room doors despite the presence of keypad locks. This constituted a failure to maintain security and increased the potential for contamination of supplies. Healthcare system staff were not able to identify reasons for the rooms being unsecured.

Recommendation 16

16. The Associate Director determines the reasons for noncompliance and ensures that clean/sterile storerooms are secured.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director or designee will ensure the locksmith has checked the existing keypad locks and replaced failed locks as necessary. Ongoing monitoring of keypad locks will be completed through Environment of Care rounds, by the Environment of Care Team, and reported monthly to Environment of Care board with a compliance rate of 90% for two consecutive quarters. Numerator will be number clean/sterile storerooms secured and the denominator will be total number of clean/sterile storerooms observed during environment of care rounds.

TJC requires hospitals to implement infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.[80] The OIG noted 13 of 18 patient care areas with damaged wheelchairs; exposed foam padding cannot be sanitized to prevent cross-contamination between patients. In addition, the OIG noted two bedside tables were in need of repair, and both were removed from service. The Associate Director admitted to

[79] VHA Directive 1761(2), *Supply Chain Inventory Management*, October 24, 2016, amended on October 26, 2018.
[80] TJC. Infection Prevention and Control standard IC.02.01.01.

the lack of a wheelchair maintenance policy. According to the Chief of Engineering, dedicated staff make rounds and take wheelchairs out of service as needed, but this process was not being followed.

Recommendation 17

17. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures damaged wheelchairs are repaired or removed from service.

Healthcare system concurred.

Target date for completion: 3/31/2021

Healthcare system response: The Associate Director or designee has purchased the replacement parts and new wheelchairs for hospital use. Ongoing wheelchair repair has been assigned by the Associate Director to the Maintenance Mechanics. Designated staff have drafted a Standard Operating Procedure regarding routine wheelchair maintenance. Ongoing monitoring to evaluate compliance with the Standard Operating Procedure will be completed with a compliance rate of 90% for two consecutive quarters. Results will be reported monthly to the Environment of Care Board. Numerator will be number of wheelchairs that are clean and not in need of repair and the denominator will be total number of wheelchairs observed during monthly environment of care rounds.

With respect to logistics, TJC requires that facility leaders provide necessary equipment, supplies, and other resources.[81] The staff in the post-anesthesia care unit at the Leavenworth facility reported to the OIG that the area is not consistently stocked with medical supplies typically needed to meet the patient care needs in the area or to fill provider orders for treatments delivered in the area. Furthermore, the facility frequently had routine medical supplies that were out of stock; this may cause patient harm by hindering the provision of appropriate medical treatment. The OIG's review of incident reports and a root cause analysis specific to supplies determined that this issue was not isolated to one area. The acting Chief of Quality Management informed OIG that the facility had identified clinical staff using the common names of items, but logistics staff were using the product names which had created barriers and breakdown in communication between clinical and logistic staff.

Recommendation 18

18. The Associate Director determines the reason(s) for noncompliance and ensures areas are consistently stocked with medical supplies typically needed to meet patient care needs.

[81] TJC. Leadership standard LD.04.01.11.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director or designee will educate the supervisor/nurse managers and end users in each area on the Pyxis Inventory Control System process; the supervisors/nurse managers will identify a super user to receive additional training and serve as a liaison for the unit. Logistics has increased the par levels and minimum levels to trigger restock in the pyxis. Logistics will audit the process compliance until 90% compliance has been met for two consecutive quarters. The numerator will be the number of compliant inventory-pull process activities by the end user and the denominator being the number of items inventoried. Audit of staff knowledge and demonstration of appropriate stock pull processes will be completed through Environment of Care Rounds. Up to five direct care staff per month will be asked to demonstrate correct Pyxis Control system processes until a target compliance rate of 90% is achieved for two consecutive quarters. Numerator will be number of direct care staff correctly demonstrating Pyxis Inventory Control System process steps, denominator will be total number of direct care staff requested to demonstrate. Results of both audits will be reported to the Environment of Care Board on a quarterly basis.

To ensure the general safety of patients and staff at all facilities, including CBOCs, VHA requires facilities to regularly test appropriate physical security precautions and equipment, including panic alarms.[82] At the Wyandotte County VA Clinic, the OIG found that staff were not aware of how to activate the alarm or testing procedures, and VA police failed to participate in alarm testing at the clinic. This leads to a lack of assurance that panic alarms are functional and may result in an unsafe environment for patients, visitors, and staff. The Associate Director stated the panic alarms were not being tested in the CBOC due to a lack of staff education on how to use and test the panic alarm system.

Recommendation 19

19. The Assistant Director evaluates and determines any additional reasons for noncompliance and makes certain that panic alarms are tested and that deficiencies identified from the testing are addressed, including staff education.

[82] VHA Directive 2012-026, *Sexual Assaults and Other Defined Public Safety Incidents in Veterans Health Administration (VHA) Facilities*, September 27, 2012. (This VHA directive expired on February 28, 2015, and has not been recertified.)

Healthcare system concurred.

Target date for completion: 3/31/2021

Healthcare system response: The Associate Director or designee will ensure Panic Alarm Education of end users will be reinforced through in-service training in the computer-based training system for all Community Based Outpatient Clinic staff. An audit to assess knowledge and demonstration of use for Panic Alarm processes will be performed during Environment of Care rounds for up to five staff per month. Audit results will be reported to the Environment of Care Board until a 90% compliance rate for two consecutive quarters has been met. Numerator will be number of staff demonstrating ability to explain and demonstrate the activation and testing of the panic alarm system process and the denominator will be total number of staff asked to demonstrate the activation and testing of the panic alarm system process. And numerator will be number of staff completing education and denominator will be total number of staff requiring the education. The Associate Director or designee will monitor compliance with panic alarm testing and ensure deficiencies are addressed. Designated staff will audit compliance of panic alarm testing and report monthly to the Environment of Care Board until a target of 90% has been met for two consecutive quarters. Numerator will be number of panic alarms that are tested, and denominator will be total number of panic alarms; numerator will be number of deficiencies identified from the testing that are addressed and denominator will be total number of deficiencies identified from the testing.

In meeting general safety criteria, VHA requires comprehensive environment of care rounds be conducted twice per fiscal year in patient care areas and that identified deficiencies and areas for improvement be tracked until resolved.[83] Additionally, to meet environmental cleanliness standards, TJC requires that facilities establish and maintain a safe, suitable environment and that areas used by patients are clean.[84] The OIG reviewed deficiencies and areas for improvement identified during environment of care rounds and entered into Performance Logic® for tracking until resolution.[85] The OIG found that the Wyandotte County VA Clinic was inspected only once in fiscal year 2019 and that deficiencies noted as resolved in Performance Logic® had not been corrected. The OIG also found dirty floors, carpeting, sinks, and countertops as well as water intrusion at windows that caused wall and wall paper damage. Additionally, disposable curtains were past maximum use date, broken laminate was noted on a cabinet, a lab chair had exposed padding, and ceiling tile in one room was observed with an approximate 3-inch hole. As a result, the healthcare system was unable to ensure a safe and functional clinical environment that supports positive patient outcomes and promotes patient safety. There was no reason provided for the lack of required EOC rounds at the Wyandotte County VA Clinic. The CBOC Manager

[83] VHA Directive 1608.

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

[85] According to VHA Directive 1608, each facility must have a comprehensive EOC Assessment and Compliance Tool (ACT) Performance Logic® is VHA's Comprehensive Environment of Care Assessment and Compliance Tool.

stated that the clinic has had ongoing issues and engaged the Contracting Officer's Technical Representative to assist with the contract expectations of the leased space.

Recommendation 20

20. The Associate Director determines the reason(s) for noncompliance and ensures that deficiencies observed during Comprehensive Environment of Care Rounds are correctly documented in the Comprehensive Environment of Care Assessment and Compliance Tool and followed until completion.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Safety and Occupational Health Specialist corrected the Performance Logic Inspection Count to ensure deficiencies are appropriately documented and followed to completion. The Associate Director or designee will conduct an audit of a random sampling of resolved deficiencies on a monthly basis until a target of 90% compliance has been reached for two consecutive quarters. Numerator will be number of resolved deficiencies that were appropriately documented as "resolved", denominator will be number of sampled resolved deficiencies. Results of this audit will be reported to Environment of Care Board on a monthly basis. Designated staff will monitor timely closure of deficiencies noted during Environment of Care Rounds a monthly basis and report to the Environment of Care Board until a compliance rate of 90% has been met for two consecutive quarters. Numerator will be number deficiencies observed during Comprehensive Environment of Care Rounds that are correctly documented in the Comprehensive Environment of Care Assessment and Compliance Tool and followed until completion and denominator will be total number of deficiencies observed during Comprehensive Environment of Care Rounds.

Recommendation 21

21. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that Wyandotte County VA Clinic managers maintain a safe and clean environment by addressing the deficiencies identified by the inspection.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The cleaning crew for the Wyandotte Community Based Outpatient Clinic conducted a thorough deep cleaning of the clinic in November of 2019. The Associate Director or designee will ensure the ongoing monitoring of cleanliness will be observed at the Community Based Outpatient Clinic and during Environment of Care rounds. Numerator will be number of deficiencies noted by staff and supervisors that have been resolved and denominator will be total number of deficiencies noted during audit period. Results will be reported to Environment of Care Board on a quarterly basis until sustained compliance of 90% has been met for two consecutive quarters.

TJC also requires the protection of patient information "against unauthorized access, use, and disclosure of health information."[86] The OIG found that specimens being transported to the parent facility were secured with commonly available, unlabeled plastic zip ties. This may result in unauthorized access to personally identifiable information. Facility managers and staff believed that facility method of securing lab specimens for transport from the CBOC met the privacy requirements.

Recommendation 22

22. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that personally identifiable information is protected when transporting information or specimens from the clinics.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: Laboratory samples will be secured using a numbered tag lock system for specimen transport to the main campus laboratories. The tag lock number will be recorded on the laboratory sheet. The Associate Director or designee will oversee monitoring for compliance with a target goal of 90% compliance for two consecutive quarters and report results to the Environment of Care Board on a monthly basis. Numerator will be number of personally identifiable information protected when transporting information or specimens from the clinics and denominator will be total number of items transported from clinics containing personally identifiable information.

[86] TJC. Information Management standard IM.02.01.03, EP 5.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[87] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[88] 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.[89] These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.[90]

VHA requires routine assessments of pain and the completion of an opioid risk assessment before initiating patients on long-term opioid therapy and recommends against the therapy for patients with untreated substance use disorders. VHA also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines.[91] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[92] To achieve VHA's vision of providing patient-driven healthcare, practitioners 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.[93] 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.[94]

The OIG reviewers assessed staff's 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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[87] 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.)

[88] 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.)

[89] *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 November 6, 2019.)

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

[91] 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.)

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

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

[94] *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.[95] 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 25 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 found the healthcare system addressed many of the indicators of expected performance, including pain screening, aberrant behavior risk assessment, and documented justification for concurrent therapy with benzodiazepines. The system was generally compliant with the use of a multidisciplinary pain management committee to oversee and monitor required quality measures. However, the OIG found deficiencies with

- Urine drug testing,
- Informed consent, and
- Patient follow-up after therapy initiation.

As mentioned earlier, VA/DoD practice guidelines recommend that providers "obtain UDT [urine drug testing] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter."[96] The OIG found that clinicians conducted initial urine drug screening in

[95] VHA Directive 2009-053, *Pain Management*, October 28, 2009. (This directive expired on October 31, 2014.)
[96] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

80 percent of the patients reviewed.[97] This resulted in providers' inability to identify whether the remaining 20 percent of patients had substance use disorders to determine the potential for diversion and to ensure patients adhered to the prescribed medication regimen. The Chief of Pharmacy reported that urine drug screening compliance had been steadily improving since 2015, and the Deputy Chief of Staff pointed out there had also been multiple providers serving in the role of pain champion prior to recent appointment of a dedicated nurse practitioner; however, the OIG determined that recommended corrective action was still warranted at the time of the inspection.

Recommendation 23

23. 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: 03/31/2021

Healthcare system response: The Urine Drug Screening process is being defined in a Standard of Work document which will include the requirements for Urine Drug Screening for patients receiving long-term opiate therapy for chronic pain. The Chief of Staff or designee will ensure monitoring of compliance with Urine Drug Screening for patients on long-term opiate therapy and report results to the Pain Steering Committee monthly with a target compliance goal of 90% for two consecutive quarters. Up to ten medical records will be reviewed monthly to ensure urine drug screen testing is completed prior to initiating or when continuing long term-opioid therapy. The number of patients newly started on long-term opioid therapy that have a urine drug screen completed prior to initiation of long-term opioid therapy will be the numerator and the number of patients newly started on long-term opioid therapy will be the denominator.

VHA requires providers to obtain and document informed consent prior to the initiation of therapeutic treatments that "have a significant risk of complication or morbidity," including long-term opioid therapy.[98] VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.[99] The OIG determined that clinicians documented informed consent prior to initiating long-term opioid therapy in 32 percent of the patients at the healthcare system, based on electronic health records reviewed.[100] The remaining patients, therefore, were receiving treatment without knowledge of the risks

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

[98] VHA Handbook 1004.01(2), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended April 4, 2019.

[99] VHA Directive 1005.

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

associated with long-term opioid therapy, including opioid dependence, tolerance, addiction, and intentional or unintentional fatal overdose. The Deputy Chief of Staff stated that providers have multiple priorities to address during 30-minute appointments and that some items can be missed due to other higher priorities.

Recommendation 24

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

Healthcare system concurred.

Target date for completion: 03/31/2021

Healthcare system response: The Informed Consent process is being defined in a Standard of Work document which will include the requirements for informed consent for patients receiving long-term opiate therapy for chronic pain. The Chief of Staff or designee will ensure monitoring of compliance with informed consent for patients initiating long-term opiate therapy and report monthly to the Pain Steering Committee with a target compliance goal of 90% for two consecutive quarters. Up to 10 medical records will be reviewed monthly to ensure healthcare providers obtain and document informed consent for patients prior to initiating long-term opioid therapy. The number of patients newly started on long-term opioid therapy that have documented informed consent will be the numerator and the number of patients newly started on long-term opioid therapy will be the denominator.

VA/DoD practice guidelines also recommend that providers evaluate the "benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months" after initiating long-term opioid therapy.[101] Follow-ups can also help providers assess adherence to plans and the effectiveness of interventions.[102] The OIG evaluated care events through the first three months after initiation of long-term opioid therapy and found that clinicians provided follow-ups for 72 percent of the patients reviewed.[103] For the remaining patients, failure to conduct follow-ups can result in missed opportunities to assess adherence to the therapy plan, effectiveness of treatment, and risks of continued opioid therapy. The Deputy Chief of Staff reported difficulty with primary care providers following up with patients in a timely manner while maintaining fully filled clinics.

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

[102] VHA Directive 2009-053.

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

Recommendation 25

25. 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.

Healthcare system concurred.

Target date for completion: 03/31/2021

Healthcare system response: The follow-up appointment process is being defined in a Standard of Work document which will include the requirement for provider follow-up within 3-months for patients receiving long-term opiate therapy for chronic pain. The Chief of Staff or designee will ensure monitoring of compliance with provider follow-up within 3-months for patients on long-term opiate therapy and report monthly to the Pain Steering Committee with a target compliance goal of 90% for two consecutive quarters. Up to 10 medical records will be reviewed monthly to ensure follow up is completed after initiating long-term opioid therapy. The number of patients newly started on long-term opioid therapy that have documented health care providers follow up with patients within the recommended three-month time frame will be the numerator and the number of patients newly started on long-term opioid therapy will be the denominator. Records will be considered compliant if the appointment is cancelled and rescheduled by the patient or the cancellation would be considered unavoidable. Records will be considered in compliance if the follow up appointment is within plus or minus 30 days of the three-month time frame.

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.[104] 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.[105] Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.[106]

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.[107]

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.[108] The OIG examined various requirements related to SPCs:

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

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

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

[105] 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*.

[106] 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.*

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

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

in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC."[109] 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."[110] 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.[111] 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.[112]

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."[113] However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management (DUSHOM) changed the requirement for the HRS PRF placement to be "as soon as possible but no later than 1 business day after determination by the SPC."[114] 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."[115]

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

[110] VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008. (This directive expired on July 31, 2013, and has not been updated.)

[111] *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.

[112] 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*.

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

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

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

The OIG is concerned that the updated requirement may result in delayed placement of the HRS PRF 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 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."[116]

Inspectors examined the completion of several requirements:

- Review of HRS PRFs within the required time frame
- Completion of at least four mental health visits completed 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.[117] VHA also requires that all staff receive annual refresher training.[118] In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[119]

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

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

[117] 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.

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

[119] 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. VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017.

- Relevant documents,
- The electronic health records of 35 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 complied with requirements associated with SPC designation, appointment and safety plan tracking, and suicide prevention training.

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"[120]—the OIG determined that 69 percent of HRS PRFs were placed within 24 hours of referral to the SPC.[121]

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.[122] The OIG estimated that 3 percent of patients with an HRS PRF were reevaluated at least every 90 days.[123] 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 33 patients' flags were reviewed within the expected time frame (observed range was 67–113 days).

Additionally, the OIG noted concerns with

- Completion of monthly outreach activities,
- Appropriate follow-up for no-show high-risk appointments, and
- Completion of suicide safety plans with the required elements within the required time frame.

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

[121] The OIG estimated that 95 percent of the time, the true compliance rate is between 52.6 and 83.8 percent, which is statistically significantly below the 90 percent benchmark. Required elements for EHR reviews are noncompliant only when the entire confidence interval falls below 90 percent.

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

[123] The OIG estimated that 95 percent of the time, the true compliance rate is between 0.0 and 9.4 percent, which is statistically significantly below the 90 percent benchmark. Required elements for EHR reviews are noncompliant only when the entire confidence interval falls below 90 percent.

SPCs are required to ensure completion of at least 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.[124] The OIG found that during the past full quarter, the SPC completed only one of five required minimum outreach activities for August 2019.[125] Failure to conduct outreach could potentially lead to missed opportunities to connect with at-risk veterans who have not received mental health services at the VA. The SPC reported being under the impression that the requirement was an average of five outreach activities per month rather than at least five outreach activities per month.

Recommendation 26

26. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that the Suicide Prevention Coordinator ensures completion of at least five outreach activities each month.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The System Director or designee will ensure at least five suicide prevention outreach activities are held monthly and provide quarterly documentation of outreach activities. The numerator will be number of outreach activities completed each month and the denominator will be at least five outreach activities each month. The compliance rate for conducting five outreach activities each month is 90% for two consecutive quarters and results will be reviewed by the Behavioral Health Executive Committee on a quarterly basis.

For patients with an HRS PRF who miss or fail to attend mental health or substance abuse appointments, VHA requires that a mental health provider contact, or attempt to contact, the patient. Further, when attempted contact is unsuccessful, "the suicide prevention coordinator will collaborate with the treatment provider(s) to determine the next appropriate step utilizing clinical judgment and the pre-developed Safety Plan."[126] Although the OIG found attempted contact documented for the eight patients who missed or failed to attend their first mental health appointment after flag placement, two patients' electronic health records lacked evidence of attempted contact by a mental health provider. Additionally, the OIG did not find evidence of mental health provider and SPC collaboration when attempted contact was unsuccessful for two

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

[125] July 1, 2019, through September 30, 2019.

[126] VHA DUSHOM Memorandum, *Guidance on Patients Failure to Attend Appointments (No Shows)*, August 6, 2013.

of five patients. Failure to follow up with a patient who is at high risk for suicide could result in missed opportunities to identify further interventions and offer follow-up. Healthcare system leaders reported lack of oversight as the reason for noncompliance.

Recommendation 27

27. The Chief of Staff evaluates and determines reasons for noncompliance and ensures that mental health providers consistently contact or attempt to contact patients flagged as high risk for suicide who miss mental health or substance abuse appointments and properly document those efforts.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee has revised the Standard of Work to include updated guidance on contacting or attempting to contact patients flagged as high risk for suicide who miss mental health or substance abuse appointments in accordance with VA Directive 1230(1). The Behavioral Health Service Line Manager will monitor compliance with documenting efforts to contact patients flagged as high risk for suicide who miss mental health or substance abuse appointments with a target of 90% compliance rate for two consecutive quarters. Results will be reported to the Behavioral Health Executive Committee on a quarterly basis. The numerator will be number of patients that mental health providers consistently contact or attempt to contact when flagged as high risk for suicide who miss mental health or substance abuse appointments and properly document those efforts, and the denominator will be total number of patients flagged as high risk for suicide who miss mental health or substance abuse appointments.

Recommendation 28

28. The Chief of Staff evaluates and reasons for noncompliance and makes certain that the mental health provider and the Suicide Prevention Coordinator collaborate to determine next steps for patients flagged as high risk for suicide when attempted contact is unsuccessful after missed mental health or substance abuse appointments.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Chief of Staff or designee has revised the Standard of Work to include updated guidance on collaboration with the mental health provider to determine next steps in care for patients flagged as high risk for suicide when attempted contact is unsuccessful after missed mental health or substance abuse appointments in accordance with VA Directive 1230(1). The Behavioral Health Service Line Manager will monitor compliance with the mental health provider and the Suicide Prevention Coordinator collaborating on patients flagged as high risk for suicide who miss mental health or substance abuse appointments a target of 90% compliance rate for two consecutive quarters. Results of the audit will be reported to the Behavioral Health Executive Committee on a quarterly basis. The numerator will be number of records documenting mental health provider and the Suicide Prevention Coordinator collaboration to determine next steps for patients flagged as high risk for suicide when attempted contact is unsuccessful after missed mental health or substance abuse appointments and the denominator will be total number of patients flagged as high risk for suicide who miss mental health or substance abuse appointments.

VHA also requires that Suicide Prevention Safety Plans include an assessment of patients' access to opioids and a discussion of safety and overdose concerns.[127] The OIG estimated that 69 percent of safety plans for patients with an HRS PRF included an assessment of patients' access to opioids.[128] Further, the OIG did not find evidence that either of the two patients with access to opioids were educated on safety and overdose risks. Failure to complete safety plans with all required elements may pose a significant danger to vulnerable patients. Staff were unable to provide a reason for noncompliance.

Recommendation 29

29. The Chief of Staff determines the reason(s) for noncompliance and ensures that Suicide Prevention Safety Plans include an assessment of patients' access to opioids and a discussion of safety and overdose risks.

[127] VHA DUSHOM Memorandum, *Suicide Prevention Safety Plan National CPRS Templates Implementation*, June 1, 2018.

[128] The OIG estimated that 95 percent of the time, the true compliance rate is between 51.6 and 85.3 percent, which is statistically significantly below the 90 percent benchmark. Required elements for EHR reviews are noncompliant only when the entire confidence interval falls below 90 percent.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The previous versions of safety plans were removed from documentation note title/templates. The Chief of Staff or designee will monitor compliance with assessing patients' access to opioids and a discussion of safety and overdose risks with a target rate of 90% compliance for two consecutive quarters. Results of the audit will be reported to the Behavioral Health Executive Committee on a quarterly basis. A minimum of 10 records containing Suicide Prevention Safety plans will be reviewed monthly to ensure that Suicide Prevention Safety Plans include an assessment of patients' access to opioids and a discussion of safety and overdose risks. In the event there are fewer than 10 records available with Suicide Prevention Safety plans to review, all available records will be reviewed for the audit. The number of patients with Suicide Prevention Safety Plans that include an assessment of patients' access to opioids and a discussion of safety and overdose risks numerator and the number of patients with Suicide Prevention Safety Plans will be the denominator.

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 their values, goals, and preferences."[129]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.[130] 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.[131] 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.[132]

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.

[129] VHA Handbook 1004.03(1), *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017.

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

[131] 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.

[132] 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 Directive 1004.03(1), triggering events requiring goals of care conversations include those "prior to referral to VA or non-VA hospice; after admission to VA hospice for patients referred from outside VA (for example within 24 hours)."

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.[133] Inspectors examined if the healthcare system established an LSTD committee 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 LSTDs for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 46 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

[133] VHA Handbook 1004.03(1).

Care Coordination Findings and Recommendations

The OIG found the healthcare system generally complied with requirements for delegated providers and LSTD committee. Additionally, with VHA's original requirements that were in place when these patients received care, the OIG estimated that

- 71 percent of patients' LST progress notes addressed identification of a surrogate if the patient loses decision-making capacity and[134]
- 67 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes.[135]

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

[134] The OIG estimated that 95 percent of the time, the true compliance rate is between 57.4 and 84.1 percent, which is statistically significantly below the 90 percent benchmark.

[135] The OIG estimated that 95 percent of the time, the true compliance rate is between 53.2 and 80.0 percent, which is statistically significantly below the 90 percent benchmark.

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[136] 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.[137] 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."[138] 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."[139]

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.[140] 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."[141]

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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[136] 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.)

[137] 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.)

[138] VHA, "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.)

[139] 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.)

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

[141] 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
  - Women's Health Medical Director or clinical champion
  - Maternity Care Coordinator
  - Women's health clinical liaison is assigned at each CBOC

Women's Health Findings and Recommendations

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

- CBOC designated women's health primary care providers and the
- Women Veterans Health Committee.

VHA requires that each CBOC have at least two designated women's health primary care providers (WH-PCPs) or that arrangements for leave coverage are in place when CBOCs have only one designated WH-PCP.[142] The OIG found that six of eight CBOCs had only one designated WH-PCP, which could limit the system's ability to provide comprehensive healthcare services to women veterans. The Women Veterans Program Manager reported that due to

[142] VHA Directive 1330.01(2).

staffing issues, turnover, and a large rural catchment area, not every CBOC had the required coverage. The Chief of Staff was unaware of the need for a second designated WH-PCP and reported that most of the CBOCs do not have the caseload for two providers.

Recommendation 30

30. The System Director evaluates and determines any additional reasons for noncompliance and ensures that each CBOC has at least two designated women's health primary care providers or arrangements for leave coverage when CBOCs have only one designated provider.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: These are small rural Community Based Outpatient Clinics with a range of 5 to 84 Women Veterans enrolled and only one provider per site; staffing two designated Women Health providers is not practical. The option of obtaining gender specific women's health care via Women's Health Consult Clinic on the main campuses or utilizing Community Care is provided. The System Director or designated staff have developed a contingency plan for staffing in the case of scheduled absences to ensure equity of access across genders. Designated staff will conduct an audit for effectiveness of the contingency plan. This will be reported to Medical Executive Board on quarterly basis until a compliance rate of 90% has been met for two consecutive quarters.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leadership, and has a core membership. That 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."[143]

The OIG team reviewed the Women Veterans Health Committee and Medical Executive Board meeting minutes from April through September 2019 and found that the Women Veterans Health Committee did not meet quarterly nor did it report to executive leadership. Failure to meet quarterly and/or report activities to executive leadership has the potential to impede oversight and support of the women's health program. The Chief of Staff reported that it was difficult to provide coverage for this committee during this time due to the Women's Health Medical Director covering primary care responsibilities and the unexpected absence of the Women Veterans Program Manager.

[143] VHA Directive 1330.01(2).

While the Women Veterans Health Committee membership included the required members, the OIG noted, after reviewing attendance from October 2018 through September 2019, that representatives from Quality Management, Pharmacy, and the Business Office did not attend any scheduled 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 for women veterans. The Chief of Staff attributed noncompliance to staff turnover and numerous programs that require staff participation. The OIG was not provided a reason for noncompliance for lack of Business Office representative.

Recommendation 31

31. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that required members consistently attend the Women Veterans Health Committee that meets at least quarterly and reports to executive leaders.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The System Director or designee has developed new charters for the Women's Veteran Program Committee for the remainder of Fiscal Year 20 to Fiscal Year 21. The new charter reflects the updated list of required membership. Designated staff will audit required member's attendance or alternate delegate attendance and audit required quarterly meeting compliance until a target of 90% compliance has been met for two consecutive quarters. Audit results will be reported to the Medical Executive Board on a quarterly basis. Numerator will be number of meetings required members (or alternate) attended, denominator will be total number of meetings held. And Numerator will be number of meeting held per quarter, denominator will be expected number of meetings to be held.

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…"[144] The goal of SPS is to "...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[145] 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[146]
- 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[147]

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.[148] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[149]

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,

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

[145] 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.)

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

[147] VHA Directive 1116(2).

[148] 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.

[149] 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.[150]

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.[151]

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

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

[150] VHA Directive 1116(2).
[151] 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 did not meet selected requirements for the proper operations and management of reprocessing RME. OIG noted that the system has had multiple site visits in the past year focused on SPS processes that identified unresolved issues. Additionally, the OIG identified deficiencies with administrative processes; equipment storage; and staff training, competency, and ongoing education.

During physical inspections of SPS areas, the OIG observed and reported to SPS leaders a staff member chewing gum in the decontamination area and an operating room staff member carrying dirty equipment without proper containment through public hallways. In addition, the OIG found several deficiencies in a fourth floor room that had been designated in May 2019 as a "temporary" room for final processing of endoscopes. The airflow for this room had not been tested prior to the room's use, nor had a commercial airflow device been installed as required. The OIG identified that the room was operating under positive air pressure, which meant air in the temporary processing area flowed into the patient care hallway. The room and hallway smelled strongly of chemicals, and Engineering staff could not provide evidence of previous airflow testing or air exchange rates. Further, there was no cleaning schedule posted, and weekly eyewash station checks were missed.

The OIG immediately notified healthcare system leaders, who had Engineering install a commercial airflow device and door sweeps. The Chief of Engineering reported replacing a fan belt and increasing air exchange rates in the room. The OIG revisited the location after the repairs and found the smell of chemicals to be minimal and the commercial airflow device showing the room under negative pressure (meaning air from the temporary room no longer flowed into the patient care hallway). System leaders reported that reprocessing equipment will be moved once construction in the gastrointestinal procedure area is completed in December 2019. However, as of March 12, 2020, the construction was not completed so the reprocessing continues in the fourth floor room.

As previously mentioned, VHA requires that "The Chief, SPS, must maintain a file (electronic or paper copy) for all reusable devices. This file must contain the manufacturer's IFU [instructions

for use] for the proper method of sterilization for each item."[152] The OIG found that the healthcare system had an electronic file for reusable medical equipment and a location to access IFUs; however, the file lacked the current manufacturer's IFUs for the equipment under OIG review. The OIG also noted that the electronic file did not accurately record the equipment's locations. This resulted in the potential for inadequate processing and/or loss of reusable equipment. The SPS Chief reported that the RME Coordinator was detailed to act as the Assistant Chief of SPS at the Leavenworth VAMC starting in August 2018 and was not able to maintain the master inventory.

Recommendation 32

32. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Service Chief maintains an accurate file for all reusable equipment that includes current manufacturers' instructions for use.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director of Patient Care Services or designee will conduct a monthly audit of the Reusable Medical Equipment Master List and 5% of Sterile Processing Service Standard Operating Procedures to ensure they include current manufacturers' instructions for use. Monthly audits will continue until a target of 90% compliance in having current manufacturers' instructions is reached for two consecutive quarters. Audit results will be reported to Reusable Medical Equipment/Sterile Processing Committee on a monthly basis. Numerator will be Standard Operating Procedures that include current manufacturers' instructions for use, denominator will be number of Standard Operation Procedures reviewed.

Additionally, VHA requires that facilities "must have standard operating procedures (SOPs) based on manufacturer's guidelines that establishes a documented and systematic approach to critical and semi-critical RME processes."[153] VHA also requires that "all SOPs are kept up-to-date, reviewed at least every 3 years, and updated when there is a change in process or a change in manufacturer's IFU [instructions for use]."[154] The OIG found that the SOP for a colonoscope did not align with the manufacturers' IFU. In addition, the OIG found paper copies of outdated SOPs in the SPS preparation room. This resulted in the potential for inadequate disinfection and reprocessing of RME. The SPS Chief stated the reason for noncompliance and a breakdown in

[152] VHA Directive 1116(2).
[153] VHA Directive 1116(2).
[154] VHA Directive 1116(2).

processes; the RME Committee was also not involved in this process, and tracking of SOPs was not the responsibility of any one person.

Recommendation 33

33. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that standard operating procedures are kept current and maintained as required, which includes alignment with manufacturers' guidelines and instructions for use, review at least every three years, and update when there is a change in process or the manufacturer's instructions for use.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director of Patient Care Services or designee will conduct a monthly audit of 10 Standard Operation Procedures in each storage location to determine if Standard Operating Procedures are current, maintained in reprocessing locations, align with manufacturer's guidelines and instructions for use, and are updated when there is a change in process and/or manufacturer's instructions or every three years (whichever is earlier) until 90% compliance is reached for two consecutive quarters. Audit results will be reported to the Reusable Medical Equipment/Sterile Processing committee on a monthly basis. Numerator 1: Number of Standard Operating Procedures that are current, align with manufacturer's guideline and instructions for use, are updated within the last three years or on change of process and/or manufacturer's instructions. Denominator 1: Total number of Standard Operating Procedures audited. Numerator 2: Number of Standard Operating Procedures reference books present in all required locations. Denominator 2: Number of Standard Operation Procedures reference books expected.

VHA requires that the SPS Chief performs an annual risk analysis and reports the results to the VISN SPS Management Board.[155] The OIG found no evidence that a risk analysis was completed for FY 2019. Failure to conduct a risk analysis can delay or prevent the identification and mitigation of problems or process failures. The SPS Chief stated the reasons for noncompliance were staffing challenges and vacancies.

[155] VHA Directive 1116(2).

Recommendation 34

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

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director of Patient Care Services or designee has completed the Sterile Processing annual risk analysis and submitted it to the local Reusable Medical Equipment/Sterile Processing Committee where it was approved in March 2020. The risk analysis was then submitted to the VISN on April 14, 2020 for out-of-cycle review by the VISN Sterile Processing Service Chief Board. Recommendation will be completed after second timely submission of annual Sterile Processing Risk Analysis to the VISN Sterile Processing Committee for review.

Despite VHA requiring strict airflow requirements in SPS, the OIG found the healthcare system staff failed to conduct the annual airflow testing during March 2019 for the Topeka VAMC's SPS area.[156] Failure to maintain proper airflow could result in exposure to airborne contaminants. The Chief of Engineering reported logistical and contracting issues as the reasons for noncompliance.

Recommendation 35

35. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that annual airflow testing is conducted in all areas where reusable medical equipment is reprocessed.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: Sterile Processing Service moved to a new location in May 2019 and the Annual Air Flow test was completed on the new space in July 2019. The Associate Director of Patient Care Services or designee will submit the next scheduled Annual Critical Space Ventilation report, testing due in July 2020, to the Reusable Medical Equipment/Sterile Processing committee for review as evidenced by committee minutes.

[156] VHA Directive 1116(2).

VHA requires that high-level disinfected endoscopes "be hung so that no part of the scope touches the bottom of the cabinet and in sufficient space for storage of multiple endoscopes without touching."[157] The OIG found that three high-level disinfected endoscopes were touching other scopes. Correct storage of endoscopes reduces the risk of contamination and damage to equipment. The operating room Nurse Manager stated that staff had not been trained on the expectation.

Recommendation 36

36. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that endoscopes are stored properly.

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: Sterile Processing Service leaders updated staff competencies to include the requirements for hanging endoscopes. The Associate Director of Patient Care Services or designee will ensure an audit will be performed to evaluate if endoscopes are hanging freely without touching. The number of endoscopes stored properly as the numerator and the total number of endoscopes stored as the denominator. Results from the audit will be reported to the Reusable Medical Equipment/Sterile Processing committee monthly until a compliance rate of 90% has been met for two consecutive quarters.

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."[158] Of the three selected SPS employees hired after March 23, 2016, the OIG found that two employees had not completed all modules of the SPS Level 1 training and one employee did not complete the training within 90 days of hire. This lack of timely and basic training for these three employees could result in improper cleaning of the RME and compromise patient safety. The SPS Chief was not able to provide a reason for noncompliance.

Recommendation 37

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

[157] VHA Directive 1116(2).
[158] VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director of Patient Care Services or designee will ensure that all current Sterile Processing Service employees complete Level 1 training. Designated staff will also perform an audit of new Sterile Processing Service employee's orientation to ensure that all Level 1 training modules have been completed within 90 days of hire and prior to starting on-the-job training in restricted areas. Numerator 1: The number of all current Sterile Processing Service staff compliant with taking Level 1 training. Denominator 1: All current Sterile Processing Service staff who have completed the orientation process and are currently working in the restricted areas. Numerator 2: All new Sterile Processing Service employees completing Level 1 training within 90 days of hire. Denominator 2: Total number of new Sterile Processing Staff expected to have completed Level 1 Training within 90 days of hire. The audit will continue until compliance with completing Level 1 training within 90 days of hire for all new staff, and current staff, have been met for two consecutive quarters. Audit results will be shared with the Reusable Medical Equipment/Sterile Processing committee on a monthly basis.

VHA requires that the Chief, SPS, ensure that competencies for RME staff are documented prior to the performance of reprocessing duties.[159] The OIG found that four of seven selected SPS staff had incomplete competency assessments for reprocessing colonoscopes. This could result in improper cleaning of the RME and compromise patient safety. The SPS Chief again was not able to provide a reason for noncompliance.

Recommendation 38

38. The Associate Director for Patient Care Services evaluates and determines reasons for noncompliance and ensures that the Chief of Sterile Processing Services documents completion of competencies for staff prior to performance of reprocessing duties.

[159] VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: 12/31/2020

Healthcare system response: The Associate Director of Patient Care Services or designees reviewed Standard Operating Procedures and staff competencies and made required updates to ensure they included the latest version and have documented completion of staff competencies. An audit of three staff per month will be conducted at each location to ensure they have completed the required competencies until a compliance rate of 90% has been met for two consecutive quarters. This will be reported to the Reusable Medical Equipment/Sterile Processing committee on a monthly basis. The number of sterile processing staff completing competencies as the numerator and the total number of sterile processing staff as the denominator.

VHA requires SPS staff participate in continuing education sessions at least once per month.[160] The OIG found no evidence of monthly continuing education for all seven selected SPS staff between February and October 2019. This resulted in a potential knowledge gap in the technical aspects of reprocessing duties. As stated earlier, the SPS Chief reported that the RME Coordinator was detailed to act as the Assistant Chief of SPS at the Leavenworth VAMC starting in August 2018, and a replacement was not provided. As a result, RME coordinator responsibilities, including monthly trainings, were not carried out.

Recommendation 39

39. 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: 12/31/2020

Healthcare system response: Sterile Processing Service leaders have re-established the monthly continuing education calendar and developed a Standard Operating Procedure which includes requirements for making up any missed training. The Associate Director of Patient Care Services or designee will conduct an audit monthly for compliance with monthly education. This will be reported to the Reusable Medical Equipment/Sterile Processing committee on a monthly basis until a compliance rate of 90% has been reached two consecutive quarters. The number of sterile processing staff completing monthly continuing education as the numerator and the total number of sterile processing staff as the denominator.

[160] VHA Directive 1116(2).

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	Performance Indicators	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 (facility or system) • VHA performance data for CLCs	Thirty-nine OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the System Director, Chief of Staff, ADPCS, Associate Director, and Assistant 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	• All applicable deaths within 24 hours of admission are peer reviewed.	• Specific action items are documented in QSV Board minutes when problems or opportunities for improvement are identified. • Peer reviewers consistently use at least one of the nine aspects of care for evaluations and address the initial screener's concern. • Final peer reviews are completed within 120 calendar days from the date it is determined a peer review is required and any necessary extensions are approved in writing by the System Director. • A summary of the Peer Review Committee's analyses is reviewed quarterly by the Medical Executive Board. • Physician UM advisors consistently document their decisions in the National UM Integration database. • All required representatives consistently participate in interdisciplinary reviews of UM data. • RCAs include all required review elements and are properly documented in the VHA Patient Safety Information System.

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 the minimum required gastroenterology- and pathology-specific criteria for FPPEs of LIPs. • Reprivileging decisions are based on service-specific OPPE data. • Providers with similar training and privileges complete OPPEs of LIPs. • Provider exit review forms are completed within seven calendar days of licensed healthcare professionals' departing the healthcare system and include the signature of the first- or second-line supervisor in the properly designated area.	• Clinical managers define in advance, communicate, and document expectations for FPPEs in the provider profiles. • Medical Executive Board meeting minutes consistently reflect the review of professional practice evaluation 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
		• Clean/sterile storerooms are secured.
		• Damaged wheelchairs are repaired or removed from service.
		• Areas are consistently stocked with medical supplies typically needed to meet patient care needs.
		• Panic alarms are tested, and deficiencies identified from the testing are addressed, including staff education.
		• Personally, identifiable information is protected when transporting information or specimens from the clinics.
			• Employees are able to access safety data sheet information.
			• Deficiencies observed during Comprehensive EOC Rounds are correctly documented in the Comprehensive EOC Assessment and Compliance Tool and followed until completion.
			• Wyandotte County VA Clinic managers maintain a safe and clean environment by addressing the deficiencies identified by the inspection.

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	• Healthcare providers consistently conduct urine drug testing as required for patients on long-term opioid therapy. • Healthcare providers obtain and document informed consent consistently for patients who are initiating long-term opioid therapy. • Healthcare providers follow up with patients within three months after initiating long-term opioid therapy.	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Mental Health: Suicide Prevention Program	• Designated facility Suicide Prevention Coordinator • Provision of suicide prevention care • Completion of suicide prevention training requirements	• Mental health providers consistently contact or attempt to contact patients flagged as high risk for suicide who miss mental health or substance abuse appointments and properly document those efforts. • Mental health provider and the Suicide Prevention Coordinator collaborate to determine next steps for patients flagged as high risk for suicide when attempted contact is unsuccessful after missed mental health or substance abuse appointments. • Suicide Prevention Safety Plans include an assessment of patients' access to opioids and a discussion of safety and overdose risks.	• The SPC ensures completion of at least five outreach activities each month.
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	• Each CBOC has at least two designated WH-PCPs or arrangements for leave coverage when CBOCs have only one designated provider. • Required members consistently attend the Women Veterans Health Committee that meets at least quarterly and reports to executive leaders.
High-Risk Processes: Reusable Medical Equipment	• Administrative processes • Data monitoring • Physical inspection • Staff training	• SOPs are kept current and maintained as required, which includes alignment with manufacturers' guidelines and instructions for use, review at least every three years, and update when there is a change in process or the manufacturer's instructions for use. • Annual airflow testing is conducted in all areas where RME is reprocessed. • Endoscopes are stored properly. • All current SPS employees complete Level 1 training and all new employees complete Level 1 training within 90 days of hire. • The SPS Chief documents completion of competencies for staff prior to performance of reprocessing duties.	• The SPS Chief maintains an accurate file for all reusable devices that includes current manufacturers' IFUs. • The SPS Chief consistently performs and documents an annual risk analysis and reports the analysis to the VISN SPS Management Board. • SPS staff receive monthly continuing education.

Appendix B: Healthcare System Profile

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

Table B. Profile for VA Eastern Kansas Health Care System (589A5) (October 1, 2015, through September 30, 2018)

Profile Element	Healthcare System Data FY 2017[3]	Healthcare System Data FY 2018[4]	Healthcare System Data FY 2019[5]
Total medical care budget in dollars	$305,595,181	$351,993,989	$346,240,378
Number of:			
• Unique patients	36,555	40,493	40,846
• Outpatient visits	440,118	459,811	455,704
• Unique employees[6]	2,042	2,326	2,636
Type and number of operating beds:			
• Community living center	138	138	138
• Domiciliary	171	171	171
• Medicine	62	36	36
• Mental health	125	125	125
• Rehabilitation medicine	2	2	2
• Residential rehabilitation	21	21	21
• Surgery	7	7	7
Average daily census:			
• Community living center	41	43	41
• Domiciliary	112	119	115
• Medicine	22	22	15
• Mental health	40	34	30
• Rehabilitation medicine	–	0	–
• Residential rehabilitation	8	8	8

[1] Associated with a medical residency program.

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

[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	0	0	0

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

Appendix C: VA Outpatient Clinic 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. 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
St. Joseph, MO	589GI	4,942	1,793	Dermatology Eye Nephrology Poly-trauma	EKG	Nutrition Pharmacy Weight management
Wyandotte County, KS	589GJ	1,886	3,345	n/a	EKG	Nutrition Social work Weight management
Chanute, KS	589GM	620	251	n/a	n/a	n/a
Garnett, KS	589GP	375	99	n/a	n/a	n/a

[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. (This directive expired on October 31, 2015, and has not been updated.) An encounter is a "professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient's condition."

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

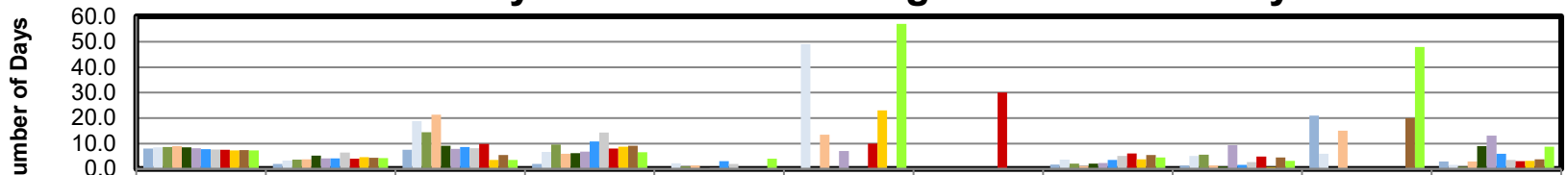
[4] Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

[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
Junction City, KS	589GR	6,755	3,120	Dermatology Infectious disease Poly-trauma Rehab physician	EKG	Nutrition Pharmacy Weight management
Lawrence, KS	589GU	2,251	1,001	n/a	EKG	Nutrition Social work Weight management
Fort Scott, KS	589GV	1,352	802	Hematology/ Oncology	EKG	Nutrition Pharmacy Social work Weight management
Platte City, KS	589JE	1,938	751	Dermatology Poly-trauma Rehab physician	n/a	Pharmacy Social work

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

Appendix D: Patient Aligned Care Team Compass Metrics[1]



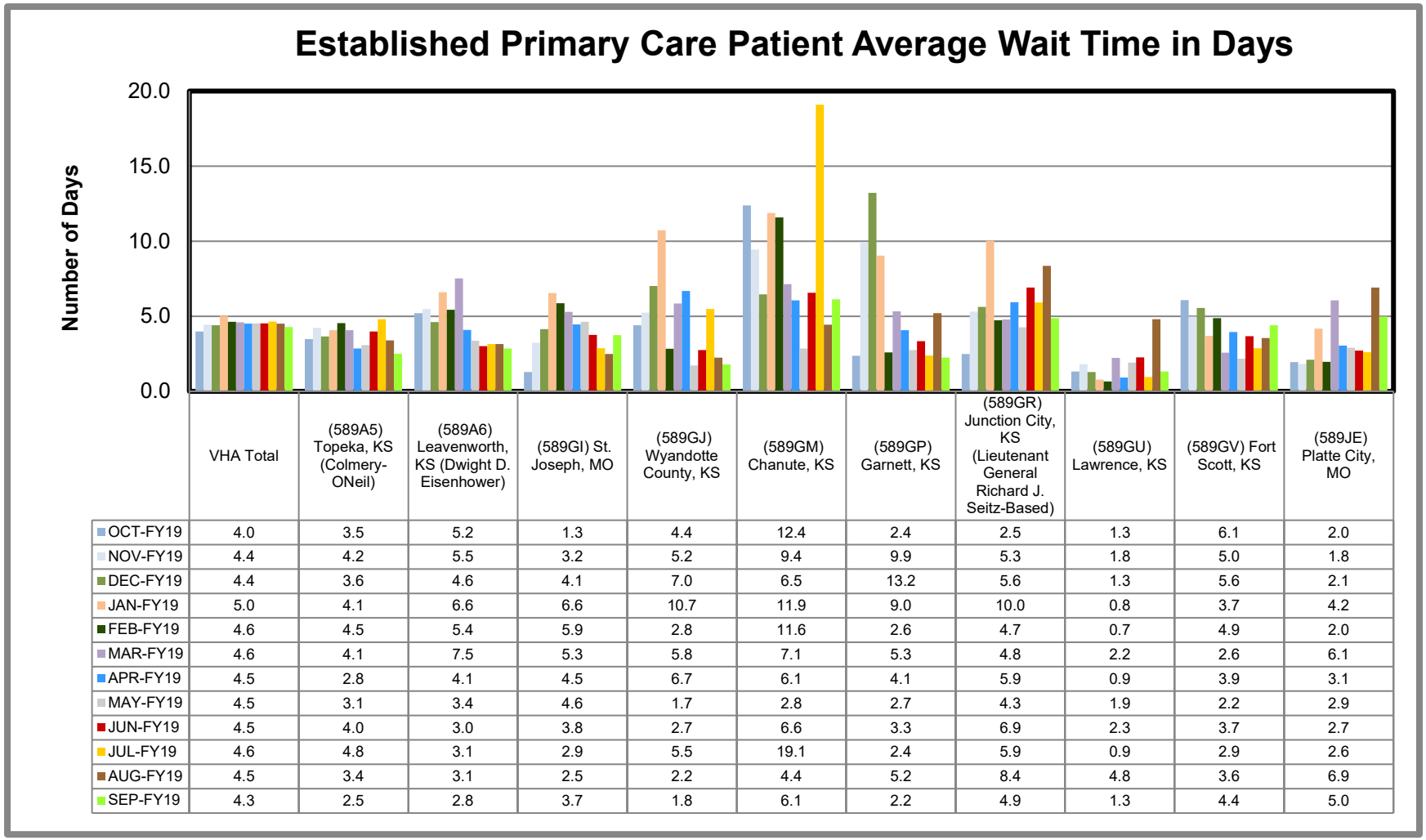
	VHA Total	(589A5) Topeka, KS (Colmery-ONeil)	(589A6) Leavenworth, KS (Dwight D. Eisenhower)	(589GI) St. Joseph, MO	(589GJ) Wyandotte County, KS	(589GM) Chanute, KS	(589GP) Garnett, KS	(589GR) Junction City, KS (Lieutenant General Richard J. Seitz-Based)	(589GU) Lawrence, KS	(589GV) Fort Scott, KS	(589JE) Platte City, MO
OCT-FY19	8.0	1.9	7.5	1.9	0.1	n/a	n/a	1.8	1.3	21.0	2.9
NOV-FY19	8.5	3.3	18.8	6.7	2.2	49.0	n/a	3.6	5.1	6.0	1.6
DEC-FY19	8.6	3.7	14.5	9.6	1.0	n/a	n/a	2.1	5.6	n/a	0.9
JAN-FY19	9.0	3.8	21.3	6.0	1.4	13.5	0.0	1.2	1.4	15.0	2.9
FEB-FY19	8.5	5.2	9.1	6.2	0.0	n/a	n/a	2.0	1.0	0.0	9.0
MAR-FY19	8.1	4.1	7.9	6.9	0.4	7.0	n/a	2.4	9.3	n/a	13.1
APR-FY19	7.8	4.2	8.7	10.8	3.1	0.0	n/a	3.5	1.6	0.0	6.0
MAY-FY19	7.6	6.5	8.2	14.3	2.0	n/a	n/a	5.1	2.7	n/a	3.6
JUN-FY19	7.6	4.1	9.9	8.1	0.0	10.0	30.0	6.1	4.8	n/a	3.1
JUL-FY19	7.3	4.7	3.5	8.7	0.0	23.0	n/a	3.8	0.7	n/a	3.1
AUG-FY19	7.4	4.3	5.5	9.1	0.0	n/a	n/a	5.5	4.5	20.0	3.8
SEP-FY19	7.3	4.3	3.5	6.5	4.0	57.0	n/a	4.5	3.2	48.0	8.7

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG has on file the healthcare system's explanation for the increased wait times for (589GM) Chanute, KS, and (589GV) Fort Scott, KS.

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

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



	VHA Total	(589A5) Topeka, KS (Colmery-ONeil)	(589A6) Leavenworth, KS (Dwight D. Eisenhower)	(589GI) St. Joseph, MO	(589GJ) Wyandotte County, KS	(589GM) Chanute, KS	(589GP) Garnett, KS	(589GR) Junction City, KS (Lieutenant General Richard J. Seitz-Based)	(589GU) Lawrence, KS	(589GV) Fort Scott, KS	(589JE) Platte City, MO
OCT-FY19	4.0	3.5	5.2	1.3	4.4	12.4	2.4	2.5	1.3	6.1	2.0
NOV-FY19	4.4	4.2	5.5	3.2	5.2	9.4	9.9	5.3	1.8	5.0	1.8
DEC-FY19	4.4	3.6	4.6	4.1	7.0	6.5	13.2	5.6	1.3	5.6	2.1
JAN-FY19	5.0	4.1	6.6	6.6	10.7	11.9	9.0	10.0	0.8	3.7	4.2
FEB-FY19	4.6	4.5	5.4	5.9	2.8	11.6	2.6	4.7	0.7	4.9	2.0
MAR-FY19	4.6	4.1	7.5	5.3	5.8	7.1	5.3	4.8	2.2	2.6	6.1
APR-FY19	4.5	2.8	4.1	4.5	6.7	6.1	4.1	5.9	0.9	3.9	3.1
MAY-FY19	4.5	3.1	3.4	4.6	1.7	2.8	2.7	4.3	1.9	2.2	2.9
JUN-FY19	4.5	4.0	3.0	3.8	2.7	6.6	3.3	6.9	2.3	3.7	2.7
JUL-FY19	4.6	4.8	3.1	2.9	5.5	19.1	2.4	5.9	0.9	2.9	2.6
AUG-FY19	4.5	3.4	3.1	2.5	2.2	4.4	5.2	8.4	4.8	3.6	6.9
SEP-FY19	4.3	2.5	2.8	3.7	1.8	6.1	2.2	4.9	1.3	4.4	5.0

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

[1] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL)* (last updated September 30, 2019). 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.)

Measure	Definition	Desired Direction
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx	ORYX	A higher value is better than a lower value
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: May 14, 2020

From: Director, VA Heartland Network (10N15)

Subj: Comprehensive Healthcare Inspection of the VA Eastern Kansas Health Care System, Topeka

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

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

Attached is the facilities response to the Comprehensive Healthcare Inspection of the VA Eastern Kansas Health Care System, Topeka draft report.

I have reviewed and concur with the facility's responses.

(Original signed by:)

William P. Patterson, MD, MSS

Appendix H: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: May 5, 2020

From: Director, VA Eastern Kansas Health Care System (589A5/00)

Subj: Comprehensive Healthcare Inspection of the VA Eastern Kansas Health Care System, Topeka

To: Director, VA Heartland Network (10N15)

Thank you for the opportunity to review the draft CHIP report for the VA Eastern Kansas Healthcare System. I appreciate the Office of Inspector General's (OIG) extensive work done in collaboration with our staff.

Since the inspection in November 2019, we began to improve our processes based on the preliminary findings. We also received confirmation from OIG that the deficiencies in the Out of OR Airway Management Program, referenced in this report, were closed after receiving evidence of sustained compliance.

The OIG report noted concerns regarding Logistics (Supply Chain Management) and our Patient Safety Program. In September 2019, a Root Cause Analysis (RCA) was initiated to address the near misses with supply issues. RCA corrective actions began in October of 2019 and were still being implemented during the CHIP survey. We are committed to ensuring that the processes put in place will enhance the reliability of our supply chain, with minimal disruption to our Veterans, and improve trust and communication within the supply chain owners. The facility recognized a need to enhance our Patient Safety Program, as part of being a High Reliable Organization (HRO). I approved a new Patient Safety RN position in October 2019 and recruitment began in November 2019. The goal of the additional staff is to increase the presence and expand the work of the Patient Safety Program by fostering proactive patient safety efforts imbedded in the daily work of front-line staff.

I have reviewed the action plans and projected completion dates. I concur with the plan and have complete confidence that the plans will be effective.

(Original signed by:)

A. Rudy Klopfer, FACHE

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