DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the VA Puget Sound Health Care System in Seattle, Washington

**Report suspected wrongdoing in VA programs and operations
to the VA OIG Hotline:**

www.va.gov/oig/hotline

1-800-488-8244

Figure 1. *VA Puget Sound Health Care System in Seattle, Washington.*

Source: https://vaww.va.gov/directory/guide/ (accessed September 9, 2020).

Abbreviations

CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
COVID-19	coronavirus disease
DDPCS	Deputy Director of Patient Care Services
FPPE	focused professional practice evaluation
FY	fiscal year
HRS	high risk for suicide
LIP	licensed independent practitioner
LST	life-sustaining treatment
LSTD	life-sustaining treatment decisions
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
RCA	root cause analysis
RME	reusable medical equipment
SAIL	Strategic Analytics for Improvement and Learning
SLB	state licensing board
SPC	suicide prevention coordinator
SPS	Sterile Processing Services
TJC	The Joint Commission
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the VA Puget Sound Health Care System, which includes two divisions—the Seattle Division and the American Lake Division (Tacoma)—and multiple outpatient clinics in Washington. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

Comprehensive healthcare 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 additional areas:

1. COVID-19 pandemic readiness and response[1]

2. Quality, safety, and value

3. Medical staff privileging

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 OIG conducted an unannounced virtual review of the VA Puget Sound Health Care System during the week of September 14, 2020. 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 the healthcare system's performance within the identified focus areas at the time of the OIG review. 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)

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[1] "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," World Health Organization, accessed August 25, 2020, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. COVID-19 (coronavirus disease) is an infectious disease caused by the "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."

facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

The OIG noted opportunities for improvement in several areas reviewed and issued 21 recommendations to the System Director, Chief of Staff, and Deputy Director of Patient Care Services. These opportunities for improvement are briefly described below.

Leadership and Organizational Risks

At the time of the OIG's virtual review, the healthcare system's leadership team consisted of the System Director, Chief of Staff, Deputy Director of Patient Care Services, Deputy Director, and Associate Director. Organizational communications and accountability were managed through a committee reporting structure, with the Executive Leadership Council overseeing several boards. The leaders monitored patient safety and care through the Executive Leadership Council, which was responsible for tracking and trending quality of care and patient outcomes.

At the time of the OIG review, the executive team had worked together for 16 months. The Director and Chief of Staff had served in their roles since 2017. The Associate Director and Deputy Director of Patient Care Services had been in their positions since 2018, and the Deputy Director had served since 2019.

The OIG reviewed employee satisfaction survey results and found the healthcare system averages for the selected survey leadership questions were similar to or slightly lower than the VHA averages. The OIG also noted opportunities for the Deputy Director to improve employee satisfaction and the Associate Director to improve employee feelings of moral distress at work.[2] For this healthcare system, patient experience survey data results generally reflected lower ratings than the VHA average. However, both male and female veteran respondents felt that inpatient doctors treated them with courtesy and respect.

The OIG's review of the system's Executive Leadership Council meeting minutes, accreditation findings, sentinel events, and disclosures identified concerns with quality, safety, and value oversight. Those concerns involved institutional disclosures, root cause analyses, incident report follow-up, and peer reviews.

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within

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[2] "2019 VA All Employee Survey (AES): Questions by Organizational Health Framework," VA Workforce Surveys Portal, VHA Support Service Center, accessed June 7, 2021, http://aes.vssc.med.va.gov/documents/05_AES_Instrument_ItemThemes.pdf. (This is an internal website not publicly accessible.) The 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."

VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite 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.[3]

The executive leaders were generally knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing SAIL and Community Living Center SAIL measures.[4] In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences.

COVID-19 Pandemic Readiness and Response

The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.[5]

Quality, Safety, and Value

The healthcare system complied with some of the requirements for quality, safety, and value. However, the OIG identified weaknesses in improvement action implementation, protected peer reviews, root cause analyses, submission of the annual patient safety report, and utilization management.[6]

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[3] "Strategic Analytics for Improvement and Learning (SAIL) Value Model," VHA Support Service Center, accessed March 6, 2020, https://vssc.med.va.gov. (This is an internal VA website not publicly accessible.)

[4] VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers,* June 1, 2017. Community living centers, 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] VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

[6] 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, identify learning opportunities for improvement, provide confidential communication of the results back to the clinician, and 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 improving the utilization of healthcare resources in VA healthcare facilities. VHA Directive 1117, *Utilization Management Program*, October 8, 2020. Utilization management involves the assessment of the "appropriateness, medical necessity and the efficiency of health care services, according to evidence-based criteria." VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluations and healthcare provider exit review processes.[7]

Medication Management

The OIG found the healthcare system was generally compliant with the use of a multidisciplinary pain management committee to oversee and monitor the required quality measures. However, the OIG identified deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, patient follow-up, and concurrent benzodiazepine therapy.

Mental Health

The healthcare system met requirements for a designated suicide prevention coordinator, high-risk veteran follow-up, outreach activities, and suicide prevention training. However, the OIG noted concerns with High Risk for Suicide Patient Record Flags.

Care Coordination

The healthcare system generally complied with requirements for the supervision of designees and a life-sustaining treatment decisions committee. However, the OIG identified concerns with the completion of life-sustaining treatment decisions notes.

High-Risk Processes

Generally, the healthcare system met requirements for the proper operations and management of reusable medical equipment and monitoring of quality assurance. However, the OIG identified deficiencies with the maintenance of required temperature and humidity, and completion of initial staff training, competency assessments, and continuing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two administrative and seven clinical) and subsequently issued 21 recommendations for improvement to the System Director, Chief of Staff, and Deputy Director of Patient Care Services. The number of recommendations should not be used, however, as a gauge for the overall quality of care provided at this system.

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[7] 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."

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 may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and System Director agreed with the comprehensive healthcare inspection findings and recommendations and provided acceptable improvement plans. (See appendixes G and H, pages 77–78, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendations 2 and 7 closed. 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 Puget Sound 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.[1]

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.[2] Effective leadership has been cited as "among the most critical components that lead an organization to effective and successful outcomes."[3] Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

Because of the COVID-19 pandemic, the OIG converted this site visit to a virtual review, paused physical inspection steps (especially those involved in the environment of care-focused review topic), and initiated a COVID-19 pandemic readiness and response evaluation.

As such, to examine risks to patients and the organization, the OIG focused on core processes in the following nine areas of administrative and clinical operations (see figure 2):[4]

1. Leadership and organizational risks

2. COVID-19 pandemic readiness and response[5]

3. Quality, safety, and value (QSV)

4. Medical staff privileging

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[1] VA administers healthcare services through a network of 18 regional offices nationwide referred to as the Veterans Integrated Service Network.

[2] Anam Parand et al., "The Role of Hospital Managers in Quality and Patient Safety: A Systematic Review," *British Medical Journal*, 4, no. 9, (September 5, 2014), https://doi.org/10.1136/bmjopen-2014-005055.

[3] Danae Sfantou et al., "Importance of Leadership Style Towards Quality of Care Measures in Healthcare Settings: A Systematic Review," *Healthcare (Basel)* 5, no. 4, (December 2017): 73, https://doi.org/10.3390/healthcare5040073.

[4] Virtual CHIP site visits address these processes during fiscal year 2020 quarter 4 (July 1 through September 30, 2020); they may differ from prior years' focus areas.

[5] "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," World Health Organization, accessed August 25, 2020, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. COVID-19 (coronavirus disease) is an infectious disease caused by the "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."

5. Medication management (targeting long-term opioid therapy for pain)

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Figure 2*. Fiscal year 2020 comprehensive healthcare inspection of operations and services. Source: VA OIG.*

Methodology

The VA Puget Sound Health Care System includes the Seattle and American Lake (Tacoma) divisions and multiple outpatient clinics in Washington state. 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 and clinical functions, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.[6] The team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

The inspection examined operations from January 13, 2018, through September 18, 2020, the last day of the unannounced multiday evaluation.[7] During the virtual review, the OIG did not receive any complaints beyond the scope of the inspection.

The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.[8]

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.[9] The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, 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 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.

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

[7] The range represents the time period from the prior CHIP site visit to the completion of the unannounced, multiday virtual CHIP visit in September 2020.

[8] VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

[9] Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3).

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 affect the healthcare system's ability to provide care in the clinical focus areas.[10] To assess the healthcare system's risks, the OIG considered several 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 (community living centers (CLCs))[11]

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 had a leadership team consisting of the System Director, Chief of Staff, Deputy Director of Patient Care Services (DDPCS), Deputy Director, and Associate Director. The Chief of Staff and DDPCS oversaw patient care, which required managing service directors and chiefs of programs and practices.

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[10] Laura Botwinick, Maureen Bisognano, and Carol Haraden, *Leadership Guide to Patient Safety*, Institute for Healthcare Improvement, Innovation Series White Paper, 2006.

[11] 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.

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Chief of Staff	Deputy Director of Patient Care Services	Deputy Director	Associate Director	
Anesthesiology	Care Coordination	Facilities Management	Canteen	Compliance
Center for Education & Development	Nursing	Financial Resources Management	Child Care	Equal Employment Opportunity
Clinical Operations and Business Intelligence	Sterile Processing	Health Administration Services	Compensation & Pension	Public Affairs
Credentialing & Privileging	Veteran Experience	Human Resources Management	Contracting	Quality Improvement
Diagnostic Imaging		Information Security	Emergency Management	Research Compliance
General Medicine		Life Safety	Environmental Management	
Geriatric Research Education & Clinical Center		Office of Information & Technology	Fisher House	
Geriatrics & Extended Care		Strategic Planner	Health Informatics & Information Management	
Hospital & Specialty Medicine		VA Police	Logistics	
Mental Health		Vet Center	Nutrition & Food Services	
Pathology & Laboratory Medicine			Prosthetics & Sensory Aids	
Pharmacy and Nutritional Care				
Rehabilitation Care				
Research & Development				
Social Work				
Spinal Cord Injury				
Surgery				
Women's Health Program				
Workplace Violence Prevention Program				

Figure 3. Healthcare system organizational chart.

Source: VA Puget Sound Health Care System (received September 15, 2020).

At the time of the OIG virtual site visit, the executive team had worked together for 16 months. The Healthcare System Director and Chief of Staff had served together in their roles since 2017, the DDPCS and Associate Director had been in their positions since 2018, and the Deputy Director had served since 2019 (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
System Director	April 30, 2017
Chief of Staff	May 28, 2017
Deputy Director of Patient Care Services	September 30, 2018
Deputy Director	May 12, 2019
Associate Director	August 5, 2018

Source: VA Puget Sound Health Care System Supervisory Human Resources Senior Strategic Business Partner (received September 14, 2020).

To help assess the healthcare system executive leaders' engagement, the OIG interviewed the Director, Chief of Staff, DDPCS, Deputy Director, 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 generally knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing Strategic Analytics for Improvement and Learning (SAIL) measures. In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences. These are discussed in greater detail below.

The Director served as the chairperson of the Executive Leadership Council, which had the authority and responsibility to establish policy, maintain quality care standards, and perform organizational management and strategic planning. The Executive Leadership Council oversaw various working groups such as the Process Improvement, Environment of Care, Clinical Executive, and Strategic Management Resources Boards. The leaders monitored patient safety and care through the Executive Leadership Council (see figure 4).
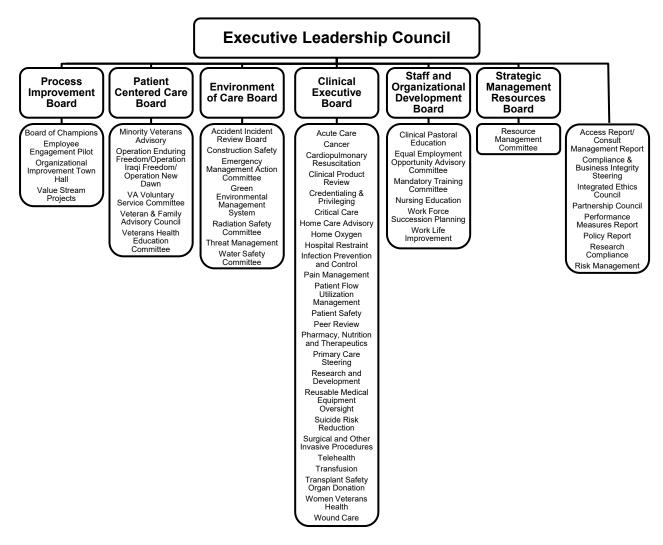
Executive Leadership Council

Process Improvement Board
- Board of Champions
- Employee Engagement Pilot
- Organizational Improvement Town Hall
- Value Stream Projects

Patient Centered Care Board
- Minority Veterans Advisory
- Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn
- VA Voluntary Service Committee
- Veteran & Family Advisory Council
- Veterans Health Education Committee

Environment of Care Board
- Accident Incident Review Board
- Construction Safety
- Emergency Management Action Committee
- Green Environmental Management System
- Radiation Safety Committee
- Threat Management
- Water Safety Committee

Clinical Executive Board
- Acute Care
- Cancer
- Cardiopulmonary Resuscitation
- Clinical Product Review
- Credentialing & Privileging
- Critical Care
- Home Care Advisory
- Home Oxygen
- Hospital Restraint
- Infection Prevention and Control
- Pain Management
- Patient Flow Utilization Management
- Patient Safety
- Peer Review
- Pharmacy, Nutrition and Therapeutics
- Primary Care Steering
- Research and Development
- Reusable Medical Equipment Oversight
- Suicide Risk Reduction
- Surgical and Other Invasive Procedures
- Telehealth
- Transfusion
- Transplant Safety Organ Donation
- Women Veterans Health
- Wound Care

Staff and Organizational Development Board
- Clinical Pastoral Education
- Equal Employment Opportunity Advisory Committee
- Mandatory Training Committee
- Nursing Education
- Work Force Succession Planning
- Work Life Improvement

Strategic Management Resources Board
- Resource Management Committee

- Access Report/ Consult Management Report
- Compliance & Business Integrity Steering
- Integrated Ethics Council
- Partnership Council
- Performance Measures Report
- Policy Report
- Research Compliance
- Risk Management

Figure 4. Healthcare system committee reporting structure.

Source: VA Puget Sound Health Care System (received September 18, 2020).

Employee Satisfaction

The All Employee Survey "is an annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential." Since 2001, the instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health.[12] 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 leaders.

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[12] "AES Survey History," VA Workforce Surveys Portal, VHA Support Service Center, accessed May 3, 2021, http://aes.vssc.med.va.gov/Documents/04_AES_History_Concepts.pdf. (This is an internal website not publicly accessible.)

To assess employee attitudes toward healthcare system leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey from October 1, 2018, through September 30, 2019.[13] 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 averages for the selected survey leadership questions were similar to or slightly lower than the VHA average.[14] The scores for the Director, Chief of Staff, and Associate Director were generally higher than those for VHA and the healthcare system. However, scores for the Deputy Director were lower than those for VHA and the healthcare system.

Executive leaders reportedly worked to sustain and improve employee engagement and satisfaction by looking for specific ways to connect people to their work, spending more time with direct reports, focusing on system rather than individual failures, and being more accessible to all staff. The Associate Director spoke of participating in the annual logistic inventory to learn about the process and how to advocate for the staff. The Director highlighted a staff member who voiced concerns that the healthcare system's pneumatic tube system upgrade would not meet the needs of the laboratory team.[15] After meeting with the staff member, the Director evaluated the concerns and made changes to the planned system upgrade. To further demonstrate a commitment to the project and staff, the Director also personally assisted in transporting samples to the lab during the upgrade.

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[13] Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, Deputy Director, and Associate Director. Data were not available for the Deputy Director of Patient Care Services due to the low number of direct report respondents.

[14] 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.

[15] The pneumatic tube system transports laboratory samples from various areas of the hospital to the laboratory for analysis.

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

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	Deputy Director Average	Assoc. Director Average
All Employee Survey: *Servant Leader Index Composite.**	0–100 where higher scores are more favorable	72.6	71.8	93.0	81.4	64.1	82.5
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	4.5	4.0	3.0	3.6
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree)– 5 (Strongly Agree)	3.6	3.5	4.7	4.1	3.3	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	4.8	4.2	3.3	3.6

Source: VA All Employee Survey (accessed August 11, 2020).

*The Servant Leader Index is a summary measure based on respondents' assessments of their supervisors' listening, respect, trust, favoritism, and response to concerns.

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.[16] The healthcare system average for the selected survey questions was similar

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[16] Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, Deputy Director, and Associate Director. Data were not available for the Deputy Director of Patient Care Services.

to the VHA average. Scores related to the Director and Chief of Staff were generally better than or similar to those for VHA and the healthcare system. However, opportunities appear to exist for the Deputy Director to improve employee attitudes toward the workplace and for the 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	Health-care System Average	Director Average	Chief of Staff Average	Deputy Director Average	Assoc. 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	4.8	4.6	3.6	4.0
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree)– 5 (Strongly Agree)	3.7	3.6	4.4	4.3	3.4	3.8

Questions/ Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	Deputy Director Average	Assoc. Director Average
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	1.6	0.4	1.6	1.8	2.4

Source: VA All Employee Survey (accessed August 11, 2020).

Patient Experience

To assess patient experiences with the healthcare system, which directly reflect on its leaders, the OIG team reviewed survey results that relate to the period of October 1, 2018, through September 30, 2019. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experiences of Patients 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 support benchmarking its performance against the private sector.

VHA also collects Survey of Healthcare Experiences of Patients 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. Table 4 provides relevant survey results for VHA and the healthcare system.[17] For this healthcare system, patient experience survey data results generally reflected lower ratings than the VHA averages.

During their interviews with the OIG, leaders spoke of physical constraints that may impact patients' experiences, including the appearance of and challenges with maintaining older buildings and the lack of private rooms and bathrooms. Examples of changes implemented by executive leaders to sustain and further improve veteran satisfaction included addressing noise complaints by purchasing soft-close trash cans and adding a nurse care coordinator to help veterans navigate the healthcare system.

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

Leaders also supported the use of cutting-edge, three-dimensional printing technology to improve and enhance patient care. For example, a three-dimensional model of a patient's heart can be printed prior to surgery so that surgeons can view the heart, evaluate the patient's unique needs, and develop plans to provide optimal surgical care. Additionally, patients, medical residents, nurses, and students can view and touch the three-dimensional models to learn and understand the treatment and healing process.

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

Questions	Scoring	VHA Average	Healthcare System Average
Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	68.3	64.4
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	81.2
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	75.4
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	78.0	74.7

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

In 2015, women were estimated to represent 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.[18] For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The healthcare system's results were generally lower for both genders when compared to the corresponding VHA averages. However, both male and female veterans indicated that inpatient doctors treated them with courtesy and respect. Leaders spoke of inadequate private rooms and bathrooms as potential causes of delays when admitting women veterans—to provide privacy for female veterans, male veterans may need to be moved from private to shared occupancy rooms.

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

Questions	Scoring	VHA*		Healthcare System†	
		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).	84.5	82.8	86.9	95.9
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).	84.8	83.1	85.4	56.2
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).	68.7	61.8	65.5	53.6

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed May 6, 2020).

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

†The healthcare system averages are based on 411–417 male and 24–25 female respondents, depending on the question.

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

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

Questions	Scoring	VHA*		Healthcare System [†]	
		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).	51.2	43.3	48.4	41.3
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).	59.9	49.7	51.7	41.0
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).	71.6	65.7	70.6	60.2

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed May 6, 2020).

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

[†]*The healthcare system averages are based on 753–1,972 male and 53–134 female respondents, depending on the question.*

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

Questions	Scoring	VHA*		Healthcare System†	
		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).	48.5	44.7	43.9	25.3
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	55.0	53.5	57.4
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	66.5	69.2

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed May 6, 2020).

*The VHA averages are based on 65,968–208,722 male and 746–2,222 female respondents, depending on the question.

†The healthcare system averages are based on 3,460–11,072 male and 38–160 female respondents, depending on the question.

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

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[19] "Profile Definitions and Methodology: Joint Commission Accreditation," *American Hospital Directory*, accessed December 12, 2020, https://www.ahd.com/definitions/prof_accred.html. "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).[20] At the time of the OIG virtual review, the system had closed all recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in January 2018.

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Comprehensive Healthcare Inspection Program Review of the VA Puget Sound Health Care System, Seattle, Washington*, Report No. 18-00334-164, May 8, 2018)	January 2018	5	0
TJC Behavioral Health: Seattle Opioid Treatment Program	June 2018	4	0
TJC Hospital Accreditation	August 2019	66	0
TJC Behavioral Health Care Accreditation		15	0
TJC Home Care Accreditation		9	0
TJC Unannounced Hospital Accreditation Follow Up	July 2020	0	–

Source: OIG and TJC (inspection/survey results verified with the Acting Director Quality and Patient Safety on September 16, 2020).

At the time of the virtual review, the OIG team noted the system's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[21] The OIG also reviewed the Paralyzed Veterans of America's inspection of the system's spinal cord injury/disease unit and related services and Long Term Care Institute's

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[20] 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."

[21] 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 collaboration with CARF [Commission on Accreditation of Rehabilitation Facilities] to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs." "About the College of American Pathologists," College of American Pathologists, accessed April 26, 2021, https://www.cap.org/about-the-cap. According to the College of American Pathologists, for 75 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." Additionally, as stated in 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.

inspection of the system's CLCs.[22] At the time of the OIG review, the Seattle CLC had three open recommendations from the Long Term Care Institute's February 2019 inspection. The American Lake CLC had 10 open recommendations from the institute's January 2020 inspection.

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 concerns regarding quality, safety, and value oversight:

- Executive Leadership Council meeting minutes documented the need to complete an institutional disclosure and root cause analysis (RCA) as a result of patient safety events; however, the OIG found no evidence that either were performed.

- The Patient Safety Manager reported a backlog of incident report follow-up since 2018, with some improvement at the time of the OIG virtual site visit.

- More than 50 percent of the peer review cases and various RCA actions assessed by the OIG were not completed on time, and RCAs did not reflect full assessments of the requisite "why" questions.

- Peer reviews were not completed on all applicable veteran deaths or suicides.

  o VHA requires peer review for all deaths "within 24 hours of admission (except in cases when death is anticipated and clearly documented, such as transfer from hospice care)."[23] The OIG found that from January 1 through December 31, 2019, one applicable death that occurred within 24 hours of admission was not evaluated to determine if peer review was warranted.

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[22] The Paralyzed Veterans of America inspection took place September 25–26, 2018. This veterans service organization review does not result in accreditation status. "About Us," Long Term Care Institute, accessed March 6, 2019, http://www.ltciorg.org/about-us/. 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."

[23] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

o VHA also requires peer review for all "[c]ompleted outpatient suicide[s] within 7 days after discharge from inpatient Mental Health treatment or residential care."[24] The OIG identified that a peer review was not conducted on one veteran suicide.

Executive leaders and the acting Director for Quality and Patient Safety stated that the VISN provided support to the Quality and Patient Safety Service to address deficiencies, which included training and assigning staff from other facilities to help complete the work.

Table 9 lists the reported sentinel events and disclosures from January 13, 2018 (the prior OIG comprehensive healthcare inspection), through September 16, 2020.[25]

Table 9. Summary of Selected Organizational Risk Factors (January 13, 2018, through September 14, 2020)

Factor	Number of Occurrences
Sentinel Events	3
Institutional Disclosures	8
Large-Scale Disclosures	0

Source: VA Puget Sound Health Care System's Patient Safety Manager, Risk Management Program Analyst, and acting Director Quality and Patient Safety (received September 14, 2020).

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with "measures on healthcare quality, employee
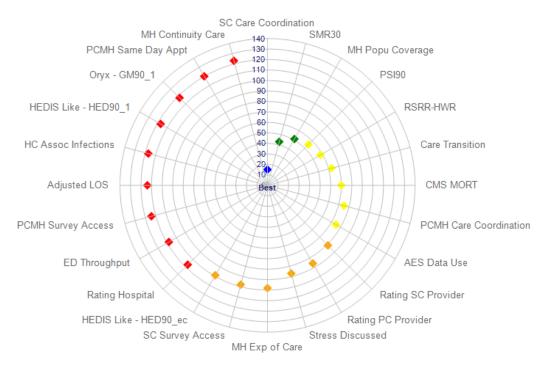
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[24] VHA Directive 1190.

[25] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (The VA Puget Sound Health Care System is a high complexity (1a) affiliated system as described in appendix B.) According to 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." Additionally, as stated in VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's 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." Lastly, in VHA Directive 1004.08, VHA defines a large-scale disclosure of adverse events (sometimes referred to as a "notification") 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."

satisfaction, access to care, and efficiency." Despite 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.[26]

Figure 5 illustrates the healthcare system's quality of care and efficiency metric rankings and performance compared with other VA facilities as of March 31, 2020. Figure 5 uses blue and green data points to indicate high performance for the VA Puget Sound Health Care System (specialty care (SC) care coordination, acute care 30 day standardized mortality ratio (SMR30), and mental health (MH) population (popu) coverage). Metrics that need improvement are denoted in orange and red (for example, rating (of) specialty care (SC) provider, rating (of) hospital, health care (HC) associated (assoc) infections, and mental health (MH) continuity (of) care).[27]

Marker color: Blue - 1st quintile; Green - 2nd; Yellow - 3rd; Orange - 4th; Red - 5th quintile.

Figure 5. System Quality of Care and Efficiency Metric Rankings, fiscal year (FY) 2020 quarter 2 (as of March 31, 2020).

Source: VHA Support Service Center.

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

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[26] "Strategic Analytics for Improvement and Learning (SAIL) Value Model," VHA Support Service Center, accessed March 6, 2020, https://vssc.med.va.gov. (This is an internal VA website not publicly accessible.)

[27] For information on the acronyms in the SAIL metrics, please see appendix E.

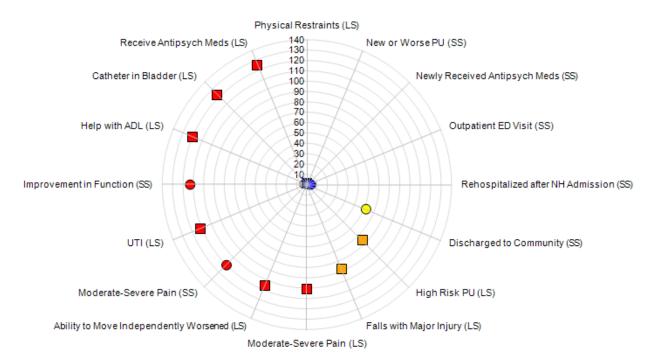## Veterans Health Administration Performance Data for Community Living Centers

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."[28]

Figures 6 and 7 illustrate the healthcare system CLCs' quality rankings and performance compared with other VA CLCs as of March 31, 2020. Figure 6 uses blue data points to indicate high performance for the American Lake CLC (for example, in the areas of physical restraints–long-stay (LS), new or worse pressure ulcer (PU)–short-stay (SS), and newly received antipsychotic (antipsych) medications (meds) (SS)). Metrics that need improvement are denoted in orange and red (for example, falls with major injury (LS), moderate-severe pain (SS), help with activities of daily living (ADL) (LS), and catheter in bladder (LS)).[29]

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[28] Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, July 23, 2020. "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."

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

Blue - 1st Quintile; Green - 2nd; Yellow - 3rd; Orange - 4th; Red - 5th Quintile.
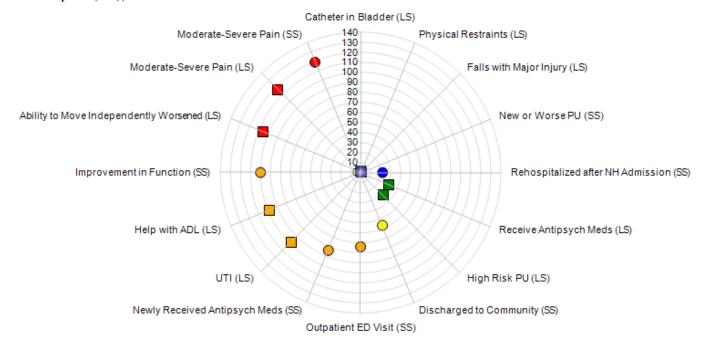
Figure 6. American Lake CLC Quality Measure Rankings, FY 2020 quarter 2 (as of March 31, 2020).

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.

Figure 7 uses blue and green data points to indicate high performance for the Seattle CLC (for example, in the areas of catheter in bladder (LS), falls with major injury (LS), and high risk pressure ulcer (LS)). Metrics that need improvement are denoted in orange and red (for example, outpatient emergency department (ED) visit (SS), improvement in function (SS), and moderate-severe pain (LS)).[30]

Blue – 1st Quintile; Green – 2nd; Yellow - 3rd; Orange – 4th; Red – 5th Quintile

Figure 7. Seattle CLC Quality Measure Rankings, FY 2020 quarter 2 (as of March 31, 2020).

LS = Long-Stay Measure   SS = Short-Stay Measure

Source: VHA Support Service Center.

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

Leadership and Organizational Risks Conclusion

At the time of the OIG virtual site visit, the executive team had worked together for 16 months. The Director and the Chief of Staff had served in their roles since 2017, the Associate Director and the DDPCS had been in their positions since 2018, and the Deputy Director had served since 2019. The OIG found that the healthcare system average for the selected survey leadership questions was similar to or lower than the VHA average, and the OIG noted opportunities for the Deputy Director to improve employee satisfaction and for the Associate Director to improve employee feelings of moral distress at work. Patient experience survey data results generally reflected lower ratings than the VHA average. Additionally, the results for healthcare system respondents were generally lower for both genders when compared to the corresponding VHA

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

averages. However, both male and female veterans felt that inpatient doctors treated them with courtesy and respect. Leaders spoke of actively engaging with patients and employees and were working to sustain and improve engagement and satisfaction. System leaders appeared to support efforts to improve and maintain patient safety, quality care, and other positive outcomes. The OIG's review of the system's Executive Leadership Council meeting minutes, accreditation findings, sentinel events, and disclosures identified concerns with quality, safety, and value oversight. The executive team was generally knowledgeable within its scope of responsibility about performance opportunities highlighted by SAIL and CLC SAIL measures and should continue to take actions to sustain and improve performance.

COVID-19 Pandemic Readiness and Response

On March 11, 2020, due to the "alarming levels of spread and severity" of COVID-19, the World Health Organization declared a pandemic.[31] VHA subsequently issued its *COVID-19 Response Plan* on March 23, 2020, which presents strategic guidance on prevention of viral transmission among veterans and staff and appropriate care for sick patients.[32]

During this time, VA continued providing for veterans' healthcare needs and engaged its fourth mission, "the provision of hospital care and medical services during certain disasters and emergencies" to persons "who otherwise do not have VA eligibility for such care and services."[33] "In effect, VHA facilities provide a safety net for the nation's hospitals should they become overwhelmed—for veterans (whether previously eligible or not) and non-veterans."[34]

Due to VHA's mission-critical work in supporting both veteran and civilian populations during the pandemic, the OIG conducted an evaluation of the pandemic's effect on the system and its leaders' subsequent response. The OIG analyzed performance in the following domains:

- Emergency preparedness

- Supplies, equipment, and infrastructure

- Staffing

- Access to care

- CLC patient care and operations

The OIG also surveyed healthcare system staff to solicit their feedback and potentially identify any problematic trends and/or issues that may require follow-up. The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.[35]

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[31] "WHO Director General's Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020," World Health Organization, accessed March 23, 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[32] VHA Office of Emergency Management, *COVID-19 Response Plan*, March 23, 2020.

[33] 38 U.S.C. § 1785. VA's missions include serving veterans through care, research, and training. 38 C.F.R. § 17.86 outlines VA's fourth mission for the provision of hospital care and medical services during certain disasters and emergencies: "During and immediately following a disaster or emergency…VA under 38 U.S.C. §1785 may furnish hospital care and medical services to individuals (including those who otherwise do not have VA eligibility for such care and services) responding to, involved in, or otherwise affected by that disaster or emergency."

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

[35] VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

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.[36] To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation.[37] 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."[38]

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.[39] 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."[40] Peer reviews are "intended to promote confidential and non-punitive" processes that consistently contribute to quality management efforts at the individual provider level.[41] The OIG team examined the completion of the following elements:

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[36] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 21, 2014.

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

[38] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*.

[39] 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, identify learning opportunities for improvement, provide confidential communication of the results back to the clinician, and 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."

[40] VHA Directive 1190.

[41] 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[42]

- Completion of final reviews within 120 calendar days

- Implementation of improvement actions recommended by the Peer Review Committee

- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the healthcare system's utilization management (UM) program, a key component of VHA's framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.[43] 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.[44] 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.[45] Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root

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[42] VHA Directive 1190.

[43] 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 was rescinded and replaced with VHA Directive 1117, *Utilization Management Program,* October 8, 2020.)

[44] VHA Directive 1117(2).

[45] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the healthcare system.[46] The healthcare system was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight patient safety analysis processes[47]

- 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 an annual patient safety report to healthcare system leaders

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents.[48]

Quality, Safety, and Value Findings and Recommendations

The healthcare system complied with some of the requirements listed above; however, the OIG identified weaknesses in improvement action implementation, protected peer reviews, root cause analyses, submission of the annual patient safety report, and UM.

VHA requires that facilities achieve and maintain TJC accreditation. According to TJC standards, facilities are to establish a governing body responsible for QSV oversight functions and practices. The governing body reviews relevant data and information and ensures that when it recommends actions, those actions are fully implemented and changes are monitored.[49] The OIG reviewed Executive Leadership Council (this healthcare system's governing body) minutes for meetings held from January through December 2019 and did not find evidence that the council's recommended improvement actions were fully implemented. Failure to implement recommended actions could prevent needed patient safety and quality of care improvements. The Director did not provide a reason for not fully implementing improvement actions but stated that

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[46] VHA Handbook 1050.01.

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

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

[49] VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs,* May 9, 2017; TJC. Leadership standards LD.01.01.01, LD.01.03.01, and LD.03.02.01.

there were opportunities to train support staff on how to consistently document, develop, and maintain meeting minutes.

Recommendation 1

1. The System Director evaluates and determines the reasons for noncompliance and ensures that improvement actions recommended by the Executive Leadership Council are fully implemented and monitored.

> Healthcare system concurred.
>
> Target date for completion: November 30, 2021
>
> Healthcare system response: The System Director evaluated the deficiency and identified no additional reason for non-compliance. Executive Leadership Council meeting minutes lacked specific actions or evidence of action items being fully implemented. As a result, the Director of QSV now monitors Executive Leadership Council meeting minutes for compliance with actions, opportunities, implementation, and closure. The Director of QSV will continue to monitor for 90% compliance for six consecutive months.

VHA requires the System Director to ensure that final peer reviews are completed within 120 calendar days from the determination that a review is needed and any requests for extensions be in writing and approved by the Director.[50] The OIG found that from January 1 through December 31, 2019, 11 of 20 peer reviews were not completed within the expected time frame and had no written extension approved by the Director. This likely prevented timely implementation of corrective actions to improve the quality of care provided at the healthcare system. The Program Analyst for Risk Management reported being aware of the requirement but stated this was an oversight.

Recommendation 2

2. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that final peer reviews are completed within 120 calendar days or have a written extension request approved by the Director.[51]

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[50] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[51] The OIG reviewed evidence sufficient to demonstrate that healthcare system staff had completed improvement actions, and therefore closed the recommendation before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The System Director reviewed completion of peer reviews, evaluated the deficiency, and identified no additional reason for non-compliance with 120-day mandated closure or with having a written extension request from the Director.

The facility implemented a VISN peer review tracking template on 11/1/2020 to track submission within 120 days. Timely completion of peer reviews is being audited by the Risk Management Analyst monthly with a target of 90% compliance for six consecutive months; to date, we have exceeded the target with 8 months of 100% compliance. Quarter 4 FY 20 and Quarter 1 FY 21 compliance is 100%, reported to Clinical Executive Board.

VHA requires the System Director to ensure that "a minimum of eight patient safety analysis processes, i.e., RCAs [root cause analyses] and Aggregated Reviews, are completed each fiscal year."[52] The OIG noted that the Patient Safety Manager or designee did not complete two of the eight root cause analyses in FY 2019. This may have hindered the timely identification and correction of system vulnerabilities that contributed to patient harm events. The Patient Safety Manager reported that only patient safety employees were trained to conduct root cause analyses at this healthcare system, and there was only one employee during the majority of FY 2019.

Recommendation 3

3. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Patient Safety Manager or designee completes at least eight patient safety analysis processes each fiscal year.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director evaluated the deficiency and identified no additional reason for non-compliance. There have been 3 RCAs [root cause analyses] completed to date from October 2020 through May 2021. The Director receives a monthly report from patient safety related to the National Center for Patient Safety requirements for RCA completion. Progress will continue to be monitored monthly for successful completion and implementation of all eight patient safety analyses. Monitoring by the Director of QSV will continue for 100% compliance by end of Fiscal Year 2021 through the Patient Safety Committee meeting minutes. The System Director will monitor compliance through the Clinical Executive Board meeting minutes.

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[52] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

VHA requires root cause analyses to include an "analysis of the underlying systems through a series of "why" questions to determine where redesigns might reduce risk," and implementation of corrective action plans. Additionally, root cause analyses must be completed and submitted to the National Center for Patient Safety within 45 days of awareness that an analysis is required.[53] Of the five root cause analyses reviewed, the OIG found that none included an analysis of the underlying systems, and four were not completed within 45 days. Further, three of the four root cause analyses with corresponding action and outcome measures were not fully implemented. Root cause analyses that are not thorough, lack action implementation, or are not completed in a timely manner allow system vulnerabilities to continue and/or worsen and could affect patient safety. The Patient Safety Manager reported a lack of training and onsite support, low patient safety staffing levels, and staff turnover in areas responsible for action implementation as reasons for noncompliance.

Recommendation 4

4. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Patient Safety Manager or designee includes an analysis of underlying systems in all root cause analyses.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director evaluated the deficiency and identified no additional reason for non-compliance. The RCAs (root cause analyses) are being audited for the inclusion of the analysis of underlying causes and completion with 45 days. Patient Safety staff were trained on RCA steps of completion. All RCAs contain Cause & Effect Diagrams and why questions. Progress will continue to be monitored monthly to ensure timely completion of RCAs and inclusion of "why" questions will be audited by the Director of QSV to determine where redesigns might reduce risk. Monitoring by the Director of QSV will continue for 90% compliance by end of FY21 through the Patient Safety Committee meeting minutes. The System Director will monitor compliance through the Clinical Executive Board meeting minutes.

Recommendation 5

5. The System Director evaluates and determines any additional reasons for noncompliance and ensures that improvement actions identified from root cause analyses are implemented.

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[53] VHA Handbook 1050.01.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director evaluated the deficiency and identified no additional reason for non-compliance. From October 2020 through May 2021, three RCAs have been completed. Improvement actions have been implemented for two RCAs. The 3rd RCA's improvement actions are in progress.

The System Director receives a monthly report from patient safety related to the National Center for Patient Safety requirements. Progress will continue to be monitored monthly by the Director of QSV for successful completion and implementation of all improvement actions that result from RCAs. Monitoring by the Director of QSV will continue for 90% compliance by end of FY21 through the Patient Safety Committee meeting minutes. The System Director will monitor compliance through the Clinical Executive Board meeting minutes.

Recommendation 6

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

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director evaluated the deficiency and identified no additional reason for non-compliance. The Director receives monthly reports from Patient Safety related to progress and compliance with National Center for Patient Safety requirements. Since October 2020, two RCAs have been submitted within 45 days as required and one additional RCA is on target to meet the National Center for Patient Safety requirements.

Progress will continue to be monitored monthly by the Director of QSV to ensure timely completion of RCAs. Monitoring will continue for 90% compliance for six consecutive months through the Patient Safety Committee meeting minutes. The System Director will monitor compliance through the Clinical Executive Board meeting minutes.

VHA requires "an end of the fiscal year Patient Safety Annual Report to facility leaders that provides an overview of Patient Safety program status."[54] Although the OIG found that an annual patient safety report was completed for FY 2019, there was no evidence it was reported to leaders. As a result, healthcare system leaders did not have an overview of patient safety issues,

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[54] VHA Handbook 1050.01.

successes, or opportunities for improvement. The Patient Safety Manager could not provide a reason why it was not reported to leaders.

Recommendation 7

7. The System Director evaluates and determines reasons for noncompliance and ensures the Patient Safety Manager or designee provides an annual patient safety report to healthcare system leaders.[55]

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The System Director evaluated the deficiency and did not identify any additional reasons for non-compliance. The annual patient safety report was presented to the Executive Leadership Council in December 2020. The annual patient safety report was documented in the December 2020 Executive Leadership Council meeting minutes.

At the time OIG conducted the virtual CHIP site visit, VHA required the Director to ensure that an interdisciplinary group review UM data. The group must have included, but was not limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [Chief Business Office Revenue-Utilization Review]."[56] The OIG found that the Patient Flow UM Committee lacked consistent representation from Mental Health and had no representation from Chief Business Office Revenue-Utilization Review for the meetings held from January through December 2019. As a result, the committee performed reviews and analyses without the perspectives of key staff. On October 8, 2020, VHA updated the requirement for the review of UM data to be performed by "a multidisciplinary committee, which may include representatives from" various services.[57] Therefore, the OIG made no recommendation.

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[55] The OIG reviewed evidence sufficient to demonstrate that healthcare system staff had completed improvement actions, and therefore closed the recommendation before publication of the report.

[56] VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. (This directive was rescinded and replaced with VHA Directive 1117, *Utilization Management Program,* October 8, 2020.)

[57] VHA Directive 1117, *Utilization Management Program*, October 8, 2020.

Medical Staff Privileging

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

Clinical privileges need to be specific 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.[59]

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."[60] The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
  - Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs[61]
  - 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[62]
  - Evaluation by another provider with similar training and privileges

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

[59] VHA Handbook 1100.19.

[60] VHA Handbook 1100.19.

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

[62] VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*.

The OIG 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.

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 subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.[63] 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."[64] The OIG reviewers assessed whether the healthcare system's staff

- Designated an individual and backup responsible for the SLB reporting process,

- Completed forms within the required time frame and with required oversight, and

- Reported results to SLBs when indicated.

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

- Ten LIPs who completed an FPPE in calendar year 2019

- Ten LIPs reprivileged during calendar year 2019

- Twenty LIPs who left the healthcare system in calendar year 2019

Medical Staff Privileging Findings and Recommendations

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

VHA requires FPPE process criteria "to be defined in advance, using objective criteria accepted by the practitioner."[65] The OIG reviewed 10 practitioner profiles and found that all lacked

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[63] VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. (This handbook was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18. The two documents contain similar language related to state licensing board requirements.)

[64] VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (VHA Directive 1100.18 requires the "Credentialing and Privileging program manager to be responsible for the [state licensing board] reporting process and oversight of timely completion of exit reviews." The new directive also revises the requirement for exit review forms to be completed within seven calendar days to seven business days.)

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

evidence that the LIPs were aware of and had accepted the evaluation criteria before service chiefs initiated the FPPE process. This could have resulted in LIPs misunderstanding FPPE expectations. The Chief of Staff reported discussing the need for revised FPPE forms with VHA during FY 2019 and indicated that modifications were made to some service line FPPE forms, while others were in draft. The Credentialing and Privileging Director stated that the healthcare system's policy was to have all providers attest to receipt of the healthcare system's bylaws with an electronic signature in a secure data program and believed this met the intent of the requirement.

Recommendation 8

8. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures service chiefs define in advance, communicate, and document focused professional practice evaluation criteria in practitioner profiles.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Chief of Staff evaluated the deficiency and identified no additional reasons for non-compliance. The Credentialing Specialist conducts audits to ensure the Service Chiefs provide focused professional practice evaluation criteria in advance and that providers document acknowledgment of receipt of criteria in advance of focused professional practice evaluation in practitioner profiles. The Chief of Staff will monitor compliance through the Credentialing and Privileging Committee meeting minutes. The last three months, March–May 2021 have shown 100% compliance. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

VHA requires that "another provider with similar training and privileges" must complete a practitioner's professional practice evaluation.[66] The OIG identified that 3 of 10 FPPEs were not completed by another provider with similar training and privileges, which may have prevented thorough reviews of professional practices. The Credentialing and Privileging Director stated that some service chiefs elected to complete the reviews themselves, despite not having similar training and privileges.

Recommendation 9

9. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that licensed independent practitioners' professional practice evaluations are completed by providers with similar training and privileges.

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

> Healthcare system concurred
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> Target date for completion: September 30, 2021
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> Healthcare system response: The Chief of Staff evaluated the deficiency and identified no additional reasons for non-compliance. The Credentialing staff audits the professional practice evaluations for completion by another provider with similar training and privileges. The Lead Credentialing Specialist and the Quality Consultant provided one on one training and group training which included information on similar training and privileges. The Chief of Staff will monitor compliance through the Credentialing and Privileging Committee meeting minutes. Monthly monitoring for the last three months March–May 2021 has been 100% compliant for completion by a provider with similar training and privileges. The Chief of Staff will continue to monitor for 90% compliance for 6 consecutive months.

VHA requires that, at the time of reprivileging, service chiefs consider relevant service- and practitioner-specific OPPE data when recommending the continuation of LIPs' privileges to the Executive Committee of the Medical Staff.[67] Such data are maintained as part of the practitioner's profile and may include "direct observation, clinical discussions, and clinical pertinence reviews."[68]

For 8 of 10 practitioners reprivileged during calendar year 2019, the OIG did not find evidence that service chiefs recommended continuation of privileges based in part on OPPE data. This resulted in providers continuing to deliver care without thorough evaluations of their practice. The Credentialing and Privileging Director stated that service chiefs believed they could not keep evidence because it was protected, but later understood that this prevents proper oversight.

Recommendation 10

10. The Chief of Staff evaluates and determines additional reasons for noncompliance and makes certain that service chiefs' reprivileging decisions are based on ongoing professional practice evaluation data.

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[67] This function is performed by the Credentialing and Privileging Committee at this healthcare system.

[68] VHA Handbook 1100.19.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Chief of Staff evaluated the deficiency and identified no additional reasons for non-compliance. The Chief of Staff will monitor compliance through the Credentialing and Privileging Committee meeting minutes. The last three months, March–May 2021, have been 100% compliant for completion by a provider re-privileging using ongoing professional practice evaluation data. The Chief of Staff will continue to monitor for 90% compliance for 6 consecutive months.

VHA requires the Executive Committee of the Medical Staff to review and evaluate LIPs' initial privileging and reprivileging requests.[69] Additionally, committee meeting minutes must include the materials reviewed and conclusion rationale. The committee's recommendation is then submitted to the Healthcare System Director for approval.[70] For 7 of the 10 practitioners who were granted initial privileges and 8 of 10 practitioners granted continuation of privileges, the OIG did not find that the Credentialing and Privileging Committee documented evaluation results or the evidence used to support privileging recommendations. Failure to properly review evaluations and data, or document recommendation decisions, may result in incomplete evidence to support the Director's approval of clinical privileges.

The Credentialing and Privileging Director reported significant challenges in receiving completed FPPEs from service chiefs, which were not forwarded for presentation to the Credentialing and Privileging Committee. Other factors reportedly added to these challenges— including the healthcare system's size (spread across two locations) and service chiefs' time constraints due to additional teaching responsibilities at local universities. The Credentialing and Privileging Director acknowledged that a tracking system was not in place to monitor completed FPPEs. The Credentialing and Privileging Director further stated that several service chiefs did not believe OPPE evidence could be retained, and therefore were not able to produce data supporting the recommendations to continue privileges.

Recommendation 11

11. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain the Credentialing and Privileging Committee meeting minutes consistently reflect the review of professional practice evaluation results and the rationale for privileging recommendations.

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[69] This function is performed by the Credentialing and Privileging Committee at this healthcare system.
[70] VHA Handbook 1100.19.

Healthcare system concurred.

Target date for completion: August 31, 2021

Healthcare system response: The Chief of Staff evaluated the deficiency and identified no additional reasons for non-compliance. The Chief of Staff reviews monthly the professional practice evaluations submitted to Credentialing & Privileging office that are non-compliant post audit. Non-compliant evaluations are defined as professional practice evaluations that do not contain all the required elements. If the elements are not in place at the time of the final cred[entialing] review, the packet will be returned for completion. These are sent back to the service line for correction and not taken to committee for evaluation. The Chief of Staff ensures accuracy of reporting the review of professional practice evaluation results and privileging recommendations in the Credentialing and Privileging Meeting Minutes. The last three months March–May 2021 were 100% compliant. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

VHA previously required that "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process."[71] The OIG identified that there was no backup individual assigned to the SLB reporting process at the time of the September 2020 inspection. Failure to designate a backup representative may have resulted in an inability to report identified professional practice concerns to the SLB in the absence of the primary designee. The Credentialing and Privileging Director indicated that a backup designee had not been named due to lack of oversight. However, on January 28, 2021, VHA amended the requirement for a designee and backup to oversee the SLB reporting process and assigned responsibility to the credentialing and privileging program manager.[72] Therefore, the OIG made no recommendation.

VHA previously required that provider exit review forms, which document the review of a provider's clinical practice, are "completed within 7 calendar days of the departure of a licensed health care professional from a VA facility."[73] As of January 28, 2021, VHA requires the facility director to ensure that provider exit review forms are completed within 7 business days.[74] For the 20 providers reviewed who departed the healthcare system in calendar year 2019, the OIG found that 1 provider exit review form was not completed, and 11 were not completed within seven calendar or business days.

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[71] VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (This handbook was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18. VHA Directive 1100.18 requires the "Credentialing and Privileging program manager to be responsible for the [state licensing board] reporting process and oversight of timely completion of exit reviews.")

[72] VHA Directive 1100.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021.

[73] VHA Notice 2018-05.

[74] VHA Directive 1100.18.

Failure to complete provider exit review forms in a timely manner may delay the reporting of healthcare professionals' substandard care to SLBs. A section chief reported that the healthcare system was a large teaching institution where providers rotate in and out of clinical assignments regularly; the affiliated university may not inform the service chiefs that a provider will not be returning, creating a time gap between the provider's exit and completion of the form. Additionally, the Credentialing and Privileging Director stated that credentialing and privileging staff were not included in the healthcare system's clearance process, which prevented awareness of provider exits.

Recommendation 12

12. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven business days of licensed healthcare professionals' departure from the healthcare system.

Healthcare system concurred.

Target date for completion: August 31, 2021

Healthcare system response: The System Director has determined no additional reasons for non-compliance. The Service Line Chiefs report departure to the Credentialing and Privileging service line and with Human Resources Department to ensure timely notification of provider departure. Timely notification of provider departure is completed by the service line chief to the Credentialing and Privileging service line chief and to human resources via email. The credentialing and privileging service line audits compliance and has been 100% compliant for the last three months, March–May 2021. The Chief of Staff will monitor compliance through the Credentialing and Privileging Committee meeting minutes. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[75] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[76] 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.[77] These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.[78]

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.[79] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[80] To achieve VHA's vision of providing patient-driven healthcare, providers are also required to obtain informed consent from patients and to provide education about the risks, benefits, and alternatives prior to initiating long-term opioid therapy.[81] 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.[82]

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

- Completion of initial screening for pain

- Assessment of aberrant behavior risk

- Avoidance of concurrent therapy with benzodiazepines

- Completion of urine drug testing with intervention, when indicated

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[75] "Information Sheet on Opioid Overdose," World Health Organization, accessed November 6, 2019, https://www.who.int/substance_abuse/information-sheet/en/.

[76] "Opioid Overdose, Understanding the Epidemic," Centers for Disease Control and Prevention, accessed November 6, 2019, https://www.cdc.gov/drugoverdose/epidemic.

[77] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. February 2017.

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

[79] "Benzodiazepines, Street Names: Benzos, Downers, Nerve Pills, Tranks," U.S. Drug Enforcement Administration, accessed December 20, 2020, https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. Benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety."

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

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

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

- Documentation of informed consent

- Timely follow-up with patients included required elements

VHA also requires facilities to establish a multidisciplinary pain management committee "to provide oversight, coordination, and monitoring of pain management activities and processes." Monitoring measures include, but are not limited to, "adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment…patient satisfaction, physical and psychosocial functioning, and quality of life."[83] The OIG examined 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 45 randomly selected outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The inspection team considered whether providers acted in accordance with guidelines for the provision of pain management and the healthcare system's oversight process for evaluating pain management outcomes and quality.

Medication Management Findings and Recommendations

The healthcare system was generally compliant with the use of a multidisciplinary pain management committee to oversee and monitor the required quality measures. However, the OIG identified deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, patient follow-up, and concurrent benzodiazepine therapy.

VA/DoD clinical practice guidelines recommend the completion of an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors prior to initiating long-term opioid therapy.[84] The OIG estimated that providers did not assess for history of substance abuse in 22 percent of patients or aberrant drug-related

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

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

behaviors in 60 percent of patients, based on the electronic health records reviewed.[85] This may have resulted in providers prescribing opioids for patients at high risk for misuse. The Anesthesia and Pain Service Line Leader indicated that providers' local training was different from the clinical practice guideline recommendation.

Recommendation 13

13. The Chief of Staff evaluates and determines the reasons for noncompliance and ensures that providers complete an aberrant behavior risk assessment that includes a history of substance abuse and aberrant drug-related behaviors for all patients prior to initiating long-term opioid therapy.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director reviewed and evaluated the deficiency and identified no additional reasons for noncompliance. Electronic Health Records lacked documentation of the provider assessing the patient for aberrant behavior risk prior to initial dispensing or during the 90-day window. VISN 20 created a new electronic health record note for providers to document ordering narcotics for a supply of greater than 5 days with required elements. This was implemented in March 2021. There is a required field for assessment of aberrant behavior risk and the record cannot be completed unless this behavior is assessed. A Primary Care Physician, who was involved with the VISN work group, has created two brief training videos for providers to review. Training has been implemented for all providers that order opioids for longer than 5 days.

[Ten] (10) (or 100% if less than 10) audits of the electronic health record per month will be completed for compliance of providers with completion of an aberrant behavior risk assessment that includes a history of substance abuse and aberrant drug-related behaviors for all patients prior to initiating long-term opioid therapy. The Chief of Staff will monitor compliance through the Clinical Executive Board meeting minutes. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

VA/DoD clinical practice guidelines also recommend that providers "obtain UDT [urine drug testing] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter."[86] The OIG found that providers did not conduct initial urine drug testing prior to

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[85] For history of substance abuse, the OIG estimated that 95 percent of the time the true compliance rate is somewhere between 65.2 and 89.1 percent. For aberrant drug related behaviors, the OIG estimated that 95 percent of the time the true compliance rate is somewhere between 26.1 and 54.5 percent. Both intervals are statistically significantly below the 90 percent benchmark.

[86] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain,* Version 3.0. February 2017.

initiating therapy for 27 percent of patients, based on the electronic health records reviewed.[87] As a result, providers may have been unable to identify whether patients had substance use disorders before starting the prescribed medication regimen. The Anesthesia and Pain Service Line Leader stated that the education provided to staff was different from the clinical practice guidelines.

Recommendation 14

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

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director reviewed and evaluated the deficiency and identified no additional reasons for noncompliance. VISN 20 created a new electronic health record note for providers to document ordering narcotics for a supply of greater than 5 days with required elements. This was implemented in March 2021. There is a required field for assessment of urine drug testing within this note. A Primary Care Physician, who was involved with the VISN work group, has created two brief training videos for providers to review. Training has been implemented for providers who order opioids for longer than 5 days.

[Ten] (10) (or 100% if less than 10) audits of the electronic health record per month will be completed for compliance of providers with conducting urine drug testing prior to initiating long term opioid therapy. The Chief of Staff will monitor compliance through the Clinical Executive Board meeting minutes. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy. VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.[88] The OIG estimated that providers failed to document informed consent prior to initiating long-term opioid therapy in 33 percent of the electronic health records reviewed.[89] This could have resulted in patients receiving treatment without knowledge of the risks associated with long-term opioid therapy, including dependence, tolerance, addiction, and unintentional fatal overdose. A primary care physician reported that the local policy allowed a single consent for a patient's lifetime, regardless of how

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[87] The OIG estimated that 95 percent of the time the true compliance rate is somewhere between 60.0 and 85.4 percent, which is statistically significantly below the 90 percent benchmark.

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

[89] The OIG estimated that 95 percent of the time the true compliance rate is somewhere between 52.3 and 80.4 percent, which is statistically significantly below the 90 percent benchmark.

many times opioids were initiated. The Anesthesia and Pain Service Line Leader stated that lack of provider education contributed to noncompliance.

Recommendation 15

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

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director reviewed and evaluated the deficiency and identified no additional reasons for noncompliance. VISN 20 created a new note for providers to document ordering narcotics for a supply of greater than 5 days with required elements. This was implemented in March 2021. There is a required field for assessment of documented informed consent and the note cannot be completed unless this behavior is assessed. A Primary Care Physician, who was involved with the VISN work group, has created two brief training videos for providers to review. Training has been implemented for providers who order opioids for longer than 5 days.

[Ten] (10) (or 100% if less than 10) audits of the electronic health record per month will be completed for compliance of providers with obtaining and documenting informed consent for patients prior to initiating long-term opioid therapy. The Chief of Staff will monitor compliance through the Clinical Executive Board meeting minutes. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

VA/DoD clinical practice guidelines recommend that providers follow up with patients at least every three months after initiating long-term opioid therapy and assess their adherence to the pain management plan of care and the effectiveness of the interventions.[90] The OIG found that providers did not assess adherence to the pain management plan of care for 32 percent of patients or the effectiveness of the interventions for 35 percent of patients, based on the electronic health records reviewed.[91] Failure to conduct comprehensive follow-up can result in missed opportunities to assess patients' adherence to therapy plans, treatment effectiveness, and risks of continued opioid therapy. A primary care physician reported access to care issues, large panel sizes, and multiple comorbidities as contributing factors for noncompliance because providers

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

[91] The OIG estimated that 95 percent of the time the true compliance rate for assessment of adherence to the pain management plan of care is somewhere between 52.5 and 82.1 percent, which is statistically significantly below the 90 percent benchmark. The OIG estimated that 95 percent of the time the true compliance rate for assessment of the effectiveness of interventions is somewhere between 48.8 and 79.8 percent, which is statistically significantly below the 90 percent benchmark.

usually have to focus on patients' major issues during clinic visits. Additionally, the primary care physician stated that patients' pain might be addressed but not documented and highlighted the lack of a formal orientation process.

Recommendation 16

16. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers' follow-up evaluations of patients receiving long-term opioid therapy include an assessment of adherence to the pain management plan of care and effectiveness of the interventions.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director reviewed and evaluated the deficiency and identified no additional reasons for noncompliance. VISN 20 created a new electronic health record note for providers to document ordering narcotics for a supply of greater than 5 days with required elements. This was implemented in March 2021. There is a required field for assessment of adherence to pain management plan and the note cannot be completed unless this behavior is assessed. A Primary Care Physician, who was involved with the VISN work group, has created two brief training videos for providers to review. Training has been implemented for providers who order opioids for longer than 5 days.

[Ten] (10) (or 100% if less than 10) audits of the electronic health record per month will be completed per month for compliance of providers' follow-up evaluations of patients receiving long-term opioid therapy includes an assessment of adherence to the pain management plan of care and effectiveness of the interventions. The Chief of Staff will monitor compliance through the Clinical Executive Board meeting minutes. The Chief of Staff will continue to monitor for 90% compliance for six consecutive months.

In addition, VA/DoD clinical practice guidelines recommend that providers avoid co-administration of drugs that could induce fatal drug-drug interactions, such as opioids and benzodiazepines.[92] The OIG found that providers did not document justification for concurrently prescribing opioids and benzodiazepines for two of three patients.[93] This may have resulted in an increased risk of harm and potential fatal drug-drug interactions. Due to the low number of patients identified, the OIG made no recommendation.

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

[93] Confidence intervals are not included because estimates were not calculated for sample sizes less than eleven.

Mental Health: Suicide Prevention Program

Suicide prevention remains a top priority for VHA. Suicide is the 10th leading cause of death, with over 47,000 lives lost across the United States in 2019.[94] The suicide rate for veterans was 1.5 times greater than for nonveteran adults and estimated to represent approximately 13.8 percent of all suicide deaths in the United States during 2018. However, suicide rates among veterans who recently used VHA services decreased by 2.4 percent between 2017 and 2018.[95] 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.[96]

VHA requires that each healthcare system and very large community-based outpatient clinic 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.[97] The OIG examined various requirements related to SPCs:

- Assignment of a full-time SPC

- Tracking and follow-up of high-risk veterans

    o Patients' completion of four appointments within the required time frame

    o Safety plan completion within the required time frame

    o 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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[94] "Preventing Suicide," Centers for Disease Control and Prevention, accessed December 9, 2020, https://www.cdc.gov/violenceprevention/suicide/fastfact.html.

[95] VA Office of Mental Health and Suicide Prevention, *2020 National Veteran Suicide Prevention Annual Report,* November 2020.

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

[97] VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. "Very large CBOCs [community-based outpatient clinics] 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."[98] 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."[99] 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.[100] 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.[101]

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."[102] However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management changed the requirement for the HRS PRF placement to be "as soon as possible but no later than 1 business day after determination by the SPC."[103] 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."[104]

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

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

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

[100] *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.

[101] VA Manual, *Safety Plan Treatment Manual to Reduce Suicide Risk: Veteran Version,* August 20, 2008. A safety plan is a "written list of coping strategies and sources of support that patients can 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*.

[102] VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*.

[103] VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*.

[104] VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

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is warranted, patients identified as at-risk for suicide could have flags placed in their charts 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."[105]

Inspectors examined the completion of several requirements:

- Review of HRS PRFs within the required time frame

- Completion of at least four mental health visits within 30 days of HRS PRF placement

- Appropriate follow-up for no-show high-risk appointments

- Completion of suicide safety plans with the required elements within the required time frame

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training.[106] VHA also requires that all staff receive annual refresher training.[107] In addition, SPCs are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[108]

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

- Relevant documents;

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

[106] 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 nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

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

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

- The electronic health records of 35 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 healthcare system complied with requirements for a designated SPC, high-risk veteran follow-up, monthly outreach activities, 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"[109]—the OIG estimated that 26 percent of HRS PRFs were not placed within 24 hours of referral to the SPC.[110] Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined time frame for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was 4 days (observed range was 0–57 days).[111]

Further, the OIG noted concerns with the review of HRS PRFs within the required time frame. Per VHA, all patients with an HRS PRF should be reevaluated at least every 90 days.[112] The OIG estimated that 57 percent of patients with an HRS PRF were not reevaluated at least every 90 days.[113] However, based on 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 clinical staff did not review 17 percent of the patients within the new time frame (observed range was 17–112 days).[114] The OIG made no recommendations but remains concerned about these updates.

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

[110] The OIG estimated that 95 percent of the time the true compliance rate is between 59.0 and 87.9 percent, which is statistically significantly below the 90 percent benchmark.

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

[112] *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*, January 5, 2018.

[113] The OIG estimated that 95 percent of the time the true compliance rate is between 26.7 and 59.5 percent, which is statistically significantly below the 90 percent benchmark.

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

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. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "eliciting, documenting, and honoring patients' values, goals, and preferences."[115]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018.[116] 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.[117] 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.[118]

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.

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

[116] VHA Handbook 1004.03(1). The medical facility must fully implement handbook requirements within 18 months of publication.

[117] 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.

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

However, on March 19, 2020, VHA amended the requirements related to documenting patients' goals of care. Although the elements of the goals of care conversation are still required, the LST progress note must include 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.[119] Inspectors examined if the healthcare system established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from the Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the healthcare system complied with the OIG-selected requirements related to LSTD for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 42 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

The healthcare system generally complied with requirements for the supervision of designees and an LSTD committee. However, the OIG identified deficiencies with the completion of LSTD

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[119] VHA Handbook 1004.03(1).

notes. With VHA's original requirements that were in place when these patients received care, the OIG estimated that

- 33 percent of patients' LST progress notes lacked identification of a surrogate if the patient loses decision-making capacity, and[120]
- 57 percent of patients' LST progress notes did not address previous advance directive(s), state-authorized portable orders, and/or LST notes.[121]

However, VHA deleted requirements for the documentation of these elements in the LST progress note.[122] The OIG remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

Additionally, VHA requires providers to complete a goals of care conversation with hospice patients and document LSTD.[123] The OIG estimated that providers did not complete LSTD progress notes for 50 percent of patients, based on the electronic health records reviewed.[124] Failure to document LSTD may prevent patients from having their care goals and preferences identified and met. The palliative care attending physician stated that providers viewed the LSTD note as a tool for documenting code status orders, not goals of care conversations, and once in the note template, providers are not able to search the electronic health record for more information without losing what had been written in the unfinished progress note. Additionally, the attending physician stated there was a perception that the note was not required in an outpatient setting, as the providers did not complete an LSTD note if a state-authorized portable order was in place. The Life-Sustaining Treatment Decisions Initiative Coordinator stated that providers were unfamiliar and/or uncomfortable with LSTD notes and depended on palliative care staff for completion.

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[120] The OIG estimated that 95 percent of the time the true compliance rate is between 45.5 and 86.7 percent, which is statistically significantly below the 90 percent benchmark.

[121] The OIG estimated that 95 percent of the time the true compliance rate is between 21.8 and 64.7 percent, which is statistically significantly below the 90 percent benchmark.

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

[123] VHA Handbook 1004.03, *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017, was amended on March 19, 2020, to 1004.03(1) and again on May 10, 2021, to 1004.03(2). VHA Handbook 1004.03 was in place for the time frame of the electronic health record review in this report. All three versions contain the same or similar language on goals of care conversations.

[124] The OIG estimated that 95 percent of the time the true compliance rate is between 35.0 and 65.8 percent, which is statistically significantly below the 90 percent benchmark.

Recommendation 17

17. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers complete goals of care conversations and life-sustaining treatment decisions progress notes.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The System Director reviewed and evaluated the deficiency and identified no additional reasons for noncompliance. As a result, the facility life-sustaining treatment decisions Coordinator implemented a reminder in the electronic health record for hospice referrals requiring a life-sustaining treatment note. Also, life-sustaining treatment champions were designated throughout the facility and implemented life-sustaining treatment decisions training to educate staff on efficient ways of doing life-sustaining treatment notes. The LST[D]I [Life-Sustaining Treatment Decisions Initiative] coordinator will monitor compliance by performing 10 (or 100% if less than 10) electronic health record audits per month to ensure that providers complete goals of care conversations and life-sustaining treatment decisions progress notes. The System Director will monitor compliance through the Executive Leadership Council meeting minutes. The System Director will continue to monitor for 90% compliance for six consecutive months.

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[125] 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.[126] To help the VA better understand the needs of the growing women veterans 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."[127] 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."[128]

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.[129] 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 veterans 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."[130]

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
  - Designated Women's Health Patient Aligned Care Team established
  - Primary Care Mental Health Integration services available

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[125] "Veteran Population," Table 1L: VetPop2016 Living Veterans by Age Group, Gender, 2015–2045, National Center for Veterans Analysis and Statistics, accessed November 14, 2019, https://www.va.gov/vetdata/Veteran_Population.asp.

[126] "Veteran Population," National Center for Veterans Analysis and Statistics, accessed September 16, 2019, https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf.

[127] Department of Veterans Affairs, *Study of Barriers for Women Veterans to VA Health Care Final Report*, April 2015.

[128] Claire Hoffmire, "Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions," Suicide Prevention, *Forum*, Spring 2018, https://www.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5.

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

[130] VHA Directive 1330.01(3).

- o Gynecologic care coverage available 24/7

- o Facility women's health primary care providers designated

- o Community-based outpatient clinic women's health primary care providers designated

- Oversight of program and monitoring of performance improvement data

  - o 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

  - o Women Veterans Program Manager

  - o Women's Health Medical Director or clinical champion

  - o Maternity Care Coordinator

  - o Women's health clinical liaison at each community-based outpatient clinic

Women's Health Findings and Recommendations

Generally, the healthcare system met the above requirements. The OIG made no recommendations.

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 Sterile Processing Services (SPS) "to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment."[131] The goal of SPS is to "provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[132] To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME

- Have standard operating procedures that are based on current manufacturers' guidelines and reviewed at least triennially

- Use CensiTrac® Instrument Tracking System for tracking reprocessed instruments[133]

- 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[134]

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.[135] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[136]

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station, personal protective equipment available for immediate use, and standard operating procedures readily available to guide the reprocessing of RME.[137]

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

[132] Julie Jefferson, Martha Young. *APIC Text of Infection Control and Epidemiology.* Association for Professionals in Infection Control and Epidemiology, 2019. "Chapter 108: Sterile Processing."

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

[134] VHA Directive 1116(2).

[135] 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.

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

[137] VHA Directive 1116(2).

VHA also requires facilities to provide training for staff who reprocess RME; this training must be provided and documented prior to the reprocessing of equipment. The required training includes mandatory initial competencies, continued annual and essential staff competency assessments, and monthly continuing education. This ensures that staff have sufficient aptitude, knowledge, and skills to effectively and safely reprocess and sterilize RME.[138]

To determine whether the healthcare system complied with OIG-selected requirements, the inspection team examined relevant documents and training records and interviewed key managers and staff on the following:

- Requirements for administrative processes
  - RME inventory file is current
  - Standard operating procedures are based on current manufacturers' 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
  - Required temperature and humidity maintained
- Monitoring of quality assurance
  - High-level disinfectant solution tested
  - Bioburden tested
- 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

Generally, the healthcare system met requirements for the proper operations and management of RME and monitoring of quality assurance. However, the OIG identified deficiencies with the

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[138] VHA Directive 1116(2).

maintenance of required temperature and humidity, and completion of initial staff training, competency assessments, and continuing education.

VHA requires a temperature range of 66–72 degrees Fahrenheit and a relative humidity range of 20–60 percent in SPS clean/sterile storage areas.[139] The OIG learned that reprocessing of reusable medical equipment occurred in both Seattle and American Lakes locations. The OIG found that humidity was not maintained within the required parameters in four of the six rooms identified as clean/sterile storage (one in American Lakes and three in Seattle). Additionally, healthcare system staff were unable to provide evidence of both temperature and humidity monitoring for one SPS clean/sterile storage area at the Seattle campus. The risk for healthcare-associated infections caused by environmental fungi and bacteria is increased when proper temperature and humidity ranges are not maintained. The Chief of Engineering stated that temperature and humidity challenges occurred in the SPS clean/sterile storage areas because the local climate was very humid in cool temperatures. The chief also stated that the Seattle campus had recently been approved for air conditioning upgrades.

The System Director reported that a project to rebuild the SPS clean/sterile storage areas at the Seattle campus was funded and a similar effort for the SPS clean/sterile storage area at the American Lakes campus is being planned. The Chief of SPS and the Gastrointestinal Nurse Manager indicated they were alerted when temperature and/or humidity readings were outside of the required range; however, the nurse manager was not able to provide a work stoppage plan. The Chief of SPS stated that the issue was generally corrected, but if the temperature and/or humidity was outside of the required range for over 24 hours, the equipment would be reprocessed.

Recommendation 18

18. The Deputy Director of Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that Sterile Processing Services maintains the required climate control parameters for areas where reusable medical equipment is reprocessed and stored.

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[139] 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.

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Deputy Director of Patient Care Services evaluated and determined no additional reasons for noncompliance. A standard operating procedure has been written, implemented, and is actively being followed in order to mitigate out of range temperature/humidity problems.

Audit of process will occur through observation of a randomly selected sampling of 10 locations per month to ensure the standard operating procedure is followed. Compliance is monitored by the Sterile Processing Services Chief and being reported monthly to the Reusable Medical Equipment Oversight Committee. The Deputy Director of Patient Care Services will monitor compliance through the Reusable Medical Equipment Oversight Committee meeting minutes. The Deputy Director of Patient Care Services will continue to monitor for 90% compliance for six consecutive months.

VHA required that system directors were responsible for ensuring that employees who reprocess RME were to be trained and have documented competency prior to performing their duties. As of March 23, 2016, VHA requires that the Chief of SPS ensure completion of training within 90 days of hire.[140] The OIG found that of the 10 selected employees reviewed, 2 of 6 hired before March 23, 2016, had not completed training, and 2 of the 4 hired after March 23, 2016, did not complete it within 90 days of hire. This could have resulted in improper cleaning and may have compromised patient safety. The Chief of SPS could not locate the training records due to a lack of attention to detail. The Gastrointestinal Nurse Manager stated the SPS Level 1 certification records were not available because employees completed the training prior to the implementation of an electronic learning system and could not locate any physical training records in employee competency folders.

Recommendation 19

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

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[140] VHA Directive 2009-004, *Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities*, February 9, 2009; VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Deputy Director of Patient Care Services evaluated the deficiency and did not identify any additional reasons for noncompliance. Effective November 2020, Sterile Processing Services managers are held accountable for ensuring that they have the current training. Managers will produce monthly reports to ensure that all employees, including new hires, will complete or be assigned the relevant training, with at least 90% compliance.

Compliance is being audited and reported monthly by the Sterile Processing Services Chief to the Reusable Medical Equipment Oversight Committee. The Deputy Director of Patient Care Services will monitor compliance through the Reusable Medical Equipment Oversight Committee meeting minutes. The Deputy Director of Patient Care Services will continue to monitor for 90% compliance for six consecutive months.

VHA requires that SPS employees complete competency assessments for RME reprocessing.[141] The OIG reviewed 10 selected employees—5 from SPS and 5 from gastrointestinal reprocessing areas—and found that 5 SPS employees completed competency assessments for two pieces of equipment. However, the assessment used for one piece of equipment was not the current version. Two of five gastrointestinal employees had not completed the competency assessment for one device, and none had completed an assessment for the second device. This could result in improper cleaning of the RME and subsequently compromise patient safety. The Gastrointestinal Nurse Manager cited lack of attention to detail and had not noticed that the competency assessments were not completed. The Chief of SPS reported being unaware that the competency assessment was not the current version.

Recommendation 20

20. The Deputy Director of Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that Sterile Processing Services employees complete competency assessments.

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

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Deputy Director of Patient Care Services evaluated the deficiency and did not identify any additional reasons for noncompliance. Effective November 2020, Sterile Processing Services managers are held accountable for ensuring that they have the current competency and standard operating procedure with the proper signature and versions in all future reassessments. The Sterile Processing Services Managers will produce monthly reports to ensure that all employees, including new hires, will complete the relevant training, with at least 90% compliance. Compliance [is] monitored by the Sterile Processing Services Chief and is being reported monthly to the Reusable Medical Equipment Oversight Committee. The Deputy Director of Patient Care Services will monitor compliance through the Reusable Medical Equipment Oversight Committee meeting minutes. The Deputy Director of Patient Care Services will continue to monitor for 90% compliance for six consecutive months.

Additionally, VHA requires SPS employees to receive monthly continuing education that focuses "on the technical aspects of SPS."[142] The OIG reviewed 10 selected employees—5 from SPS and 5 from gastrointestinal reprocessing areas—and found that SPS employees received SPS-specific continuing education in October and November 2019 and fire drill training in December 2019. The OIG also found that gastrointestinal reprocessing area employees did not receive any monthly continuing education. Lack of continuing education can create a knowledge gap that results in improperly reprocessed equipment and compromised patient safety. The Chief of SPS reported being unaware of the requirement for continuing education and the responsibility for providing oversight of education to employees outside of the SPS area. The Chief of SPS also indicated believing that the fire drill training completed by the staff in the SPS area met expectations.

Recommendation 21

21. The Deputy Director of Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that Sterile Processing Services employees receive monthly continuing education.

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[142] VHA Directive 1116(2).

Healthcare system concurred.

Target date for completion: September 30, 2021

Healthcare system response: The Deputy Director of Patient Care Services evaluated the deficiency and did not identify any additional reasons for noncompliance. Effective November 2020, Sterile Processing Services managers are held accountable for ensuring that compliance with monthly technical training requirements meets or exceeds 90% compliance. Compliance is monitored by the Sterile Processing Services Chief. The Deputy Director of Patient Care Services will monitor compliance through the Reusable Medical Equipment Oversight Committee meeting minutes. The Deputy Director of Patient Care Services will continue to monitor for 90% compliance for six consecutive months.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

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.

Table A.1. Summary Table of Recommendations

Healthcare Processes	Requirements	Conclusion
Leadership and Organizational Risks	- Executive leadership position stability and engagement - Employee satisfaction - Patient experience - Accreditation surveys and oversight inspections - Factors related to possible lapses in care and healthcare system response - VHA performance data (system) - VHA performance data for CLCs	Twenty-one OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, and DDPCS. See details below.
COVID-19 Pandemic Readiness and Response	- Emergency preparedness - Supplies, equipment, and infrastructure - Staffing - Access to care - CLC patient care and operations - Staff feedback	The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• QSV Committee • Protected peer reviews • UM reviews • Patient safety	• Improvement actions recommended by the Executive Leadership Council are fully implemented and monitored. • Improvement actions identified from root cause analyses are implemented.	• Final peer reviews are completed within 120 calendar days or there is a written extension request approved by the Director. • The Patient Safety Manager or designee completes at least eight patient safety analysis processes each fiscal year. • The Patient Safety Manager or designee includes an analysis of underlying systems in all root cause analyses. • The Patient Safety Manager or designee submits each root cause analysis to the National Center for Patient Safety within the required time frame. • The Patient Safety Manager or designee provides an annual patient safety report to healthcare system leaders.

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 define in advance, communicate, and document FPPE criteria in practitioner profiles. • Licensed independent practitioners' professional practice evaluations are completed by providers with similar training and privileges. • Service chiefs' reprivileging decisions are based on OPPE data.	• Credentialing and Privileging Committee meeting minutes consistently reflect the review of professional practice evaluation results and the rationale for privileging recommendations. • Provider exit review forms are completed within seven business days of licensed healthcare professionals' departure from the healthcare system.
Medication Management: Long-Term Opioid Therapy	• Provision of pain management using long-term opioid therapy • Program oversight and evaluation	• Providers complete an aberrant behavioral risk assessment that includes a history of substance abuse and aberrant drug-related behaviors for all patients prior to initiating long-term opioid therapy. • Providers conduct urine drug testing for patients prior to initiating long-term opioid therapy. • Providers obtain and document informed consent for patients prior to initiating long-term opioid therapy.	• Providers' follow-up evaluations of patients receiving long-term opioid therapy include an assessment of adherence to the pain management plan of care and effectiveness of the interventions.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Mental Health: Suicide Prevention Program	• Designated facility suicide prevention coordinator • Tracking and follow-up of high-risk veterans • Provision of suicide prevention care • Completion of suicide prevention training requirements	• None	• None
Care Coordination: Life-Sustaining Treatment Decisions	• LSTD multidisciplinary committee • LSTD progress note documentation • LSTD note/orders completed by an authorized provider or delegated appropriately	• Providers complete goals of care conversations and LSTD progress notes.	• None
Women's Health: Comprehensive Care	• Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements	• None	• None
High-Risk Processes: Reusable Medical Equipment	• Administrative processes • Quality assurance monitoring • Staff training	• Sterile Processing Services maintains the required climate control parameters for areas where reusable medical equipment is reprocessed and stored.	• All new Sterile Processing Services employees complete Level 1 training within 90 days of hire. • Sterile Processing Services employees complete competency assessments. • Sterile Processing Services employees receive monthly continuing education.

Appendix B: Healthcare System Profile

The table below provides general background information for this high complexity (1a) affiliated healthcare system reporting to VISN 20.[1]

Table B.1. Profile for the VA Puget Sound Health Care System (663)
(October 1, 2016, through September 30, 2019)

Profile Element	Healthcare System Data FY 2017*	Healthcare System Data FY 2018[†]	Healthcare System Data FY 2019[‡]
Total medical care budget	$836,571,278	$879,382,052	$925,325,195
Number of:			
• Unique patients	105,107	110,492	112,810
• Outpatient visits	1,025,692	1,033,673	1,028,874
• Unique employees	3,554	3,599	3,607
Type and number of operating beds:			
• Blind rehabilitation	9	9	9
• Community living center	121	121	121
• Domiciliary	64	64	64
• Medicine	82	82	82
• Mental health	25	25	25
• Rehabilitation medicine	12	12	12
• Residential rehabilitation	19	19	19
• Spinal cord injury	38	38	38
• Surgery	44	44	44
Average daily census:			
• Blind rehabilitation	6	5	5
• Community living center	78	76	60
• Domiciliary	45	46	48
• Medicine	75	68	68
• Mental health	18	18	14
• Rehabilitation medicine	6	6	6

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

Profile Element	Healthcare System Data FY 2017*	Healthcare System Data FY 2018†	Healthcare System Data FY 2019‡
• Residential rehabilitation	14	9	13
• Spinal cord injury	23	23	24
• Surgery	20	17	17

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.

*October 1, 2016, through September 30, 2017.
†October 1, 2017, through September 30, 2018.
‡October 1, 2018, through September 30, 2019.

Appendix C: VA Outpatient Clinic Profiles

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.1. provides information relative to each of the clinics.[1]

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Bellevue, WA	663GA	19,609	2,776	Anesthesia Dermatology	–	Nutrition Weight management
Bremerton, WA	663GB	9,748	2,164	Anesthesia Dermatology Poly-Trauma	–	Nutrition Pharmacy Social work Weight management

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[1] Includes outpatient clinics in the community that were in operation as of August 27, 2019. VHA Directive 1230(4), *Outpatient Scheduling Processes And Procedures*, July 15, 2016, amended June 17, 2021. An encounter is a "professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient's condition." Specialty care services refer to non-primary care and non-mental health services provided by a physician.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Mount Vernon, WA	663GC	12,354	2,766	Anesthesia Dermatology Endocrinology Eye Podiatry Poly-Trauma Rehab physician	–	Dental Pharmacy Weight management
Chehalis, WA	663GD	9,494	3,702	Anesthesia Dermatology Poly-Trauma	–	Pharmacy
Port Angeles, WA	663GE	4,588	902	Anesthesia Dermatology Endocrinology Podiatry Poly-Trauma	–	Nutrition Pharmacy Social work

Source: VHA Support Service Center and VA Corporate Data Warehouse.

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

Appendix D: Patient Aligned Care Team Compass Metrics

Quarterly New Primary Care Patient Average Wait Time in Days

	All VHA	(663) Seattle, WA	(663A4) American Lake, WA	(663GA) Bellevue, WA	(663GB) Silverdale, WA	(663GC) Mount Vernon, WA	(663GD) South Sound, WA	(663GE) North Olympic Peninsula, WA
JUL-FY19	7.3	7.3	4.0	20.0	1.1	7.1	12.8	5.8
AUG-FY19	7.4	15.0	7.3	20.3	3.1	11.2	10.2	2.2
SEP-FY19	7.3	19.8	5.7	15.9	5.9	10.5	18.9	2.3
OCT-FY20	6.9	21.4	10.3	18.6	4.5	9.7	11.4	7.7
NOV-FY20	7.1	18.4	10.1	25.0	9.9	12.8	17.8	9.0
DEC-FY20	7.8	18.9	15.4	24.7	6.4	15.5	0.0	14.7
JAN-FY20	8.3	19.0	20.1	36.8	6.6	14.6	43.8	18.4
FEB-FY20	8.1	19.6	24.3	36.5	6.6	9.0	46.1	14.7
MAR-FY20	6.9	16.6	23.0	21.9	13.3	15.3	8.7	4.4
APR-FY20	3.6	2.3	8.0	1.0	33.8	8.3	6.2	0.0
MAY-FY20	4.0	0.0	4.2	6.7	29.1	6.8	18.6	0.0
JUN-FY20	4.9	0.9	4.9	20.5	9.0	0.6	27.5	0.0

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG has on file the healthcare system's explanation for the increased wait times for the Bellevue, WA; Silverdale, WA; and South Sound, WA community-based outpatient clinics.

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." Prior to FY 2015, this metric was calculated using the earliest possible create date.

Quarterly Established Primary Care Patient Average Wait Time in Days

Number of Days

	VHA Total	(663) Seattle, WA	(663A4) American Lake, WA	(663GA) Bellevue, WA	(663GB) Silverdale, WA	(663GC) Mount Vernon, WA	(663GD) South Sound, WA	(663GE) North Olympic Peninsula, WA
JUL-FY19	4.6	7.6	5.8	10.8	15.3	5.8	4.0	7.0
AUG-FY19	4.5	6.4	4.5	12.2	6.6	5.4	3.2	6.7
SEP-FY19	4.3	7.4	5.0	10.2	8.2	7.1	4.1	9.3
OCT-FY20	3.9	6.3	6.1	9.8	11.7	5.9	4.9	8.1
NOV-FY20	4.2	7.5	7.5	11.0	12.9	7.1	5.7	8.2
DEC-FY20	4.2	7.2	6.0	13.1	14.8	10.5	3.0	12.6
JAN-FY20	4.8	8.2	6.8	16.1	16.3	9.0	11.0	23.3
FEB-FY20	4.3	8.6	7.2	15.0	16.8	7.0	14.6	8.8
MAR-FY20	3.9	7.4	6.4	14.1	14.1	5.9	12.7	5.4
APR-FY20	1.9	2.0	1.3	0.5	2.9	2.9	2.4	2.0
MAY-FY20	2.1	1.1	1.3	2.0	4.5	1.8	6.2	0.4
JUN-FY20	3.7	1.7	2.1	11.7	3.0	2.5	8.6	1.0

Source: VHA Support Service Center. Department of Veterans Affairs, Patient Aligned Care Teams Compass Data Definitions, https://vssc.med.va.gov, accessed October 21, 2019.

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

Measure	Definition	Desired Direction
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
AES Data Use	Composite measure based on three individual AES data use and sharing questions	A higher value is better than a lower value
Care transition	Care transition (inpatient)	A higher value is better than a lower value
CMS MORT	Centers for Medicare and Medicaid Services (CMS) risk standardized mortality rate	A lower value is better than a higher value
ED Throughput	Composite measure for timeliness of care in the emergency department	A lower value is better than a higher value
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like – HED90_1	Healthcare Effectiveness Data and Information Set (HEDIS) composite score related to outpatient behavioral health screening, prevention, immunization, and tobacco	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS composite score related to outpatient care for diabetes and ischemic heart disease	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx – GM90_1	ORYX inpatient composite of global measures	A higher value is better than a lower value

Measure	Definition	Desired Direction
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
PSI90	Patient Safety and Adverse Events Composite (PSI90) focused on potentially avoidable complications and events	A lower value is better than a higher 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
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
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

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.
Discharged to Community (SS)	Short-stay measure: percentage of short-stay residents who were successfully discharged to the community.
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.
Outpatient ED visit (SS)	Short-stay measure: percent of short-stay residents who have had an outpatient emergency department (ED) visit.
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.

Measure	Definition
Rehospitalized after NH Admission (SS)	Short-stay measure: percent of residents who were re-hospitalized after a nursing home admission.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

Source: VHA Support Service Center.

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: June 3, 2021

From: Director, Northwest Network (10N20)

Subj: Comprehensive Healthcare Inspection of the VA Puget Sound Health Care System in Seattle, Washington

To: Director, Office of Healthcare Inspections (54CH03)
Director, GAO/OIG Accountability Liaison (VHA 10B GOAL Action)

1. Thank you for the opportunity to provide a status report to the findings from the Comprehensive Healthcare Inspection of the VA Puget Sound Health Care System in Seattle, Washington.

2. I concur with your findings and recommendations, as well as the submitted action plans.

(Original signed by:)

Teresa D. Boyd

Appendix H: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: May 27, 2021

From: Director, VA Puget Sound HCS (663/00)

Subj: Comprehensive Healthcare Inspection of the VA Puget Sound Health Care System in Seattle, WA

To: Director, Northwest Network (10N20)

1. Thank you for the opportunity to provide a response to the findings from the Comprehensive Healthcare Inspection of the VA Puget Sound Health Care System in Seattle, Washington.

2. I concur with the findings and recommendations and will ensure that actions to correct these finding are completed as described in the responses.

(Original signed by:)

Michael C. Tadych

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