DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin

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Figure 1. *William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin*
(Source: https://vaww.va.gov/directory/guide/, accessed on January 29, 2020)

Abbreviations

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

Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the William S. Middleton Memorial Veterans Hospital ("medical center") and multiple outpatient clinics in Illinois and Wisconsin. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

1. Quality, safety, and value

2. Medical staff privileging

3. Environment of care

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

5. Mental health (focusing on the suicide prevention program)

6. Care coordination (spotlighting life-sustaining treatment decisions)

7. Women's health (examining comprehensive care)

8. High-risk processes (emphasizing reusable medical equipment)

The unannounced visit was conducted during the week of January 13, 2020, at the William S. Middleton Memorial Veterans Hospital and the Baraboo VA Clinic. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this medical center's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this medical center and other Veterans Health Administration (VHA) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

Leadership and Organizational Risks

At the time of the OIG's visit, the medical center's leadership team consisted of the Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure with the Executive Leadership and Planning Board overseeing several working groups. The leaders monitored patient safety and care through the Quality Council which was responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this inspection, the medical center's executive team appeared stable. The Director and ADPCS had worked together at the medical center since 2016. The Chief of Staff, the most tenured leader, was permanently assigned in September 2005. The Associate Director was temporarily appointed in January 2020 but served as Assistant Director for over three years. The Assistant Director was a service chief at the medical center for over seven years before being temporarily assigned to the current position in January 2020.

The OIG reviewed selected survey results and concluded that employees were generally satisfied with the work environment and felt safe bringing forth issues and concerns to leadership. The survey results seemed consistent with the medical center's high-performing "best place to work" measure.

For this medical center, patient survey results were better than VHA averages. However, survey responses by gender revealed opportunities to improve female patient experiences.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and did not identify any substantial organizational risk factors.[1] However, the OIG identified the concerns with poor communication among program leaders as an area of vulnerability for the medical center.

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[2]

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

[2] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

The executive leaders were generally knowledgeable within their scopes of responsibilities about VHA data and/or SAIL measures.

The OIG noted opportunities for improvement in six of the eight clinical areas reviewed and issued 16 recommendations to the Director, Chief of Staff, ADPCS, and Associate Director. These are briefly described below.

Quality, Safety, and Value

The medical center complied with requirements for a committee responsible for quality, safety, and value oversight functions; protected peer reviews; and most utilization management and patient safety elements reviewed. However, the OIG noted concerns with the Quality Council's implementation of improvement actions and the interdisciplinary review of utilization management data.[3]

Medical Staff Privileging

The medical center met most of the requirements for medical staff privileging. However, the OIG identified weaknesses with professional practice evaluation of specialty providers and licensed healthcare provider exit review processes.[4]

Environment of Care

The OIG determined that the medical center and the Baraboo VA Clinic largely met requirements for environmental cleanliness, infection prevention, and accommodation and privacy for women veterans. The medical center also complied with requirements for the inpatient mental health unit. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified concerns with safety inspections of medical equipment and management of expired medications.

Medication Management

The OIG observed compliance with some elements of expected performance, including pain screening and justification for concurrent therapy with benzodiazepines. The medical center also complied with the use of a multidisciplinary pain management committee to monitor quality

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

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

measures. However, the OIG found deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, and patient follow-up after therapy initiation.

Mental Health

The medical center complied with requirements associated with a designated suicide prevention coordinator, suicide safety plans, and patient follow-up for missed appointments. However, the OIG noted concerns with suicide prevention training.

High-Risk Processes

The medical center met many of the requirements for the proper operations and management of reprocessing reusable medical equipment. However, the OIG identified deficiencies with risk analysis reporting; traffic flow, temperature, and humidity in reprocessing areas; and staff competency and continuing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 16 recommendations for improvement to the Medical Center Director, Chief of Staff, ADPCS, and Associate Director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this medical center. The intent is for medical center leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 71–72, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendations 12 and 13 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Assistant Inspector General
for Healthcare Inspections

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 William S. Middleton Memorial Veterans Hospital ("medical center") 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 medical center leaders so that informed decisions can be made to improve care.

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change.[1] Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes.[2] Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

To examine risks to patients and the organization, the OIG focused on core processes in the following nine areas of administrative and clinical operations:

1. Leadership and organizational risks

2. Quality, safety, and value (QSV)

3. Medical staff privileging

4. Environment of care

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

6. Mental health (focusing on the suicide prevention program)

7. Care coordination (spotlighting life-sustaining treatment decisions)

8. Women's health (examining comprehensive care)

9. High-risk processes (emphasizing reusable medical equipment)[3]

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[1] Anam Parand, Sue Dopson, Anna Renz, and Charles Vincent, "The role of hospital managers in quality and patient safety: a systematic review," *British Medical Journal*, 4, no. 9 (September 5, 2014): e005055. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4158193/. (The website was accessed on September 25, 2019.)

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

[3] See Figure 2. CHIP inspections address these processes during FY 2020 (October 1, 2019, through September 30, 2020); they may differ from prior years' focus areas.
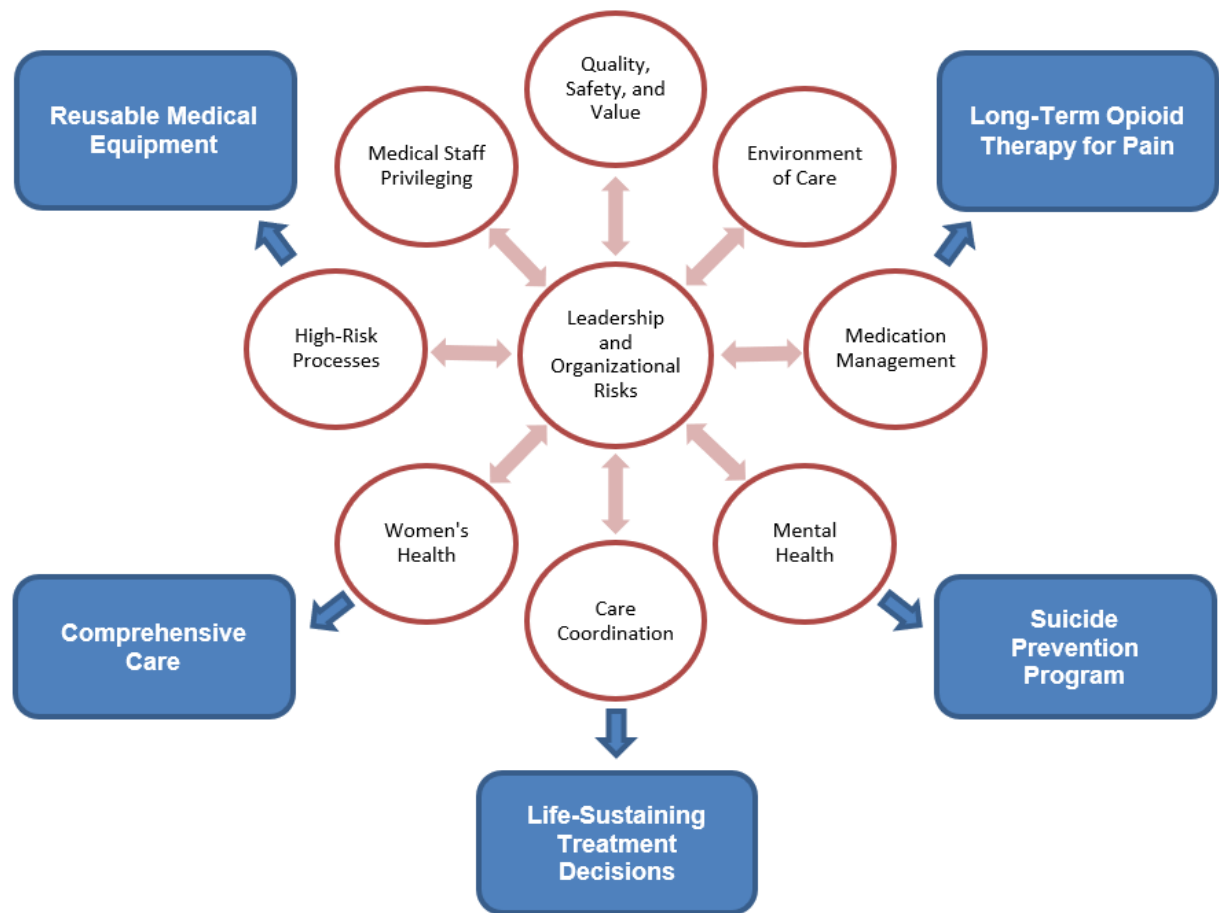
Figure 2. Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services
Source: VA OIG

Methodology

The William S. Middleton Memorial Veterans Hospital includes multiple outpatient clinics in Illinois and Wisconsin. Additional details about the types of care provided by the medical center can be found in Appendixes B and C.

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.[4]

The OIG team also selected and physically inspected the Baraboo VA Clinic and the following areas of the William S. Middleton Memorial Veterans Hospital:

- Community living center (CLC)[5]

- Emergency department

- Inpatient mental health unit

- Intensive care unit

- Medical/surgical inpatient unit

- Outpatient clinic

- Post-anesthesia care unit

- Sterile processing services areas

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

The inspection period examined operations from September 1, 2018, through January 17, 2020, the last day of the unannounced multiday site visit.[6] While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and

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

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

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

methodology and makes recommendations to VA leadership, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

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

Results and Recommendations

Leadership and Organizational Risks

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

1. Executive leadership position stability and engagement

2. Employee satisfaction

3. Patient experience

4. Accreditation surveys and oversight inspections

5. Identified factors related to possible lapses in care and medical center response

6. VHA performance data (medical center)

7. VHA performance data (CLC)

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this medical center's reported organizational structure. The medical center has a leadership team consisting of the Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Associate Director, and Assistant Director. The Chief of Staff and ADPCS oversee patient care which requires managing service directors and chiefs of programs and practices.

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[7] L. Botwinick, M. Bisognano, and C. Haraden, Leadership Guide to Patient Safety, Institute for Healthcare Improvement, Innovation Series White Paper. 2006. www.IHI.org. (The website was accessed on November 6, 2019.)

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Chief of Staff	ADPCS	Associate Director	Assistant Director	Equal Employment
Ambulatory Care	Education	Business Planning Office	Emergency Management	Equal Employment
Anesthesiology	Emergent & Transitional Nursing	Canteen	Environmental Health & Safety	Organizational Improvement
Coordinated Community Care	Evidence-Based Practice, Innovation, Research and Magnet	Consolidated Patient Account Center	Health Physicist	
Dental	Inpatient Nursing	Decision Support System	Industrial Hygiene	
Deputy Chief of Staff	Perioperative Nursing	Engineering	Information Security Officer	
Geriatric Research, Education and Clinical Center	Specialty Care Nursing	Environmental Management Service	Patient Administration	
Group Practice Manager	Sterile Processing Service	Finance	Police	
Medical Imaging	Telephone Triage	Human Resources	Privacy Officer	
Medicine		Nutrition & Food Services	Supply Chain Management	
Neurology		Office of Information & Technology	VISN 12 Call Center	
Pathology and Laboratory Medicine			Voluntary Service	
Pharmacy				
Physical Therapy				
Psychiatry				
Research				
Social Work				
Surgery				
Telehealth				
Women's Veteran Program Manager				

Figure 3. *Medical Center Organizational Chart*
Source: William S. Middleton Memorial Veterans Hospital (received January 15, 2020)

At the time of the OIG site visit, two of the five executive leaders were new to their positions. However, all executive team members, except for the Assistant Director, had worked together for several years (see Table 1). The Director and ADPCS had worked together at the medical center since 2016. The Chief of Staff, the most tenured leader, was permanently assigned in September 2005. The Associate Director was temporarily appointed on January 9, 2020, but served as Assistant Director for over three years. The Assistant Director was a service chief at the medical center for over seven years before being temporarily assigned to the current position on January 20, 2020.

Table 1. Executive Leader Assignments

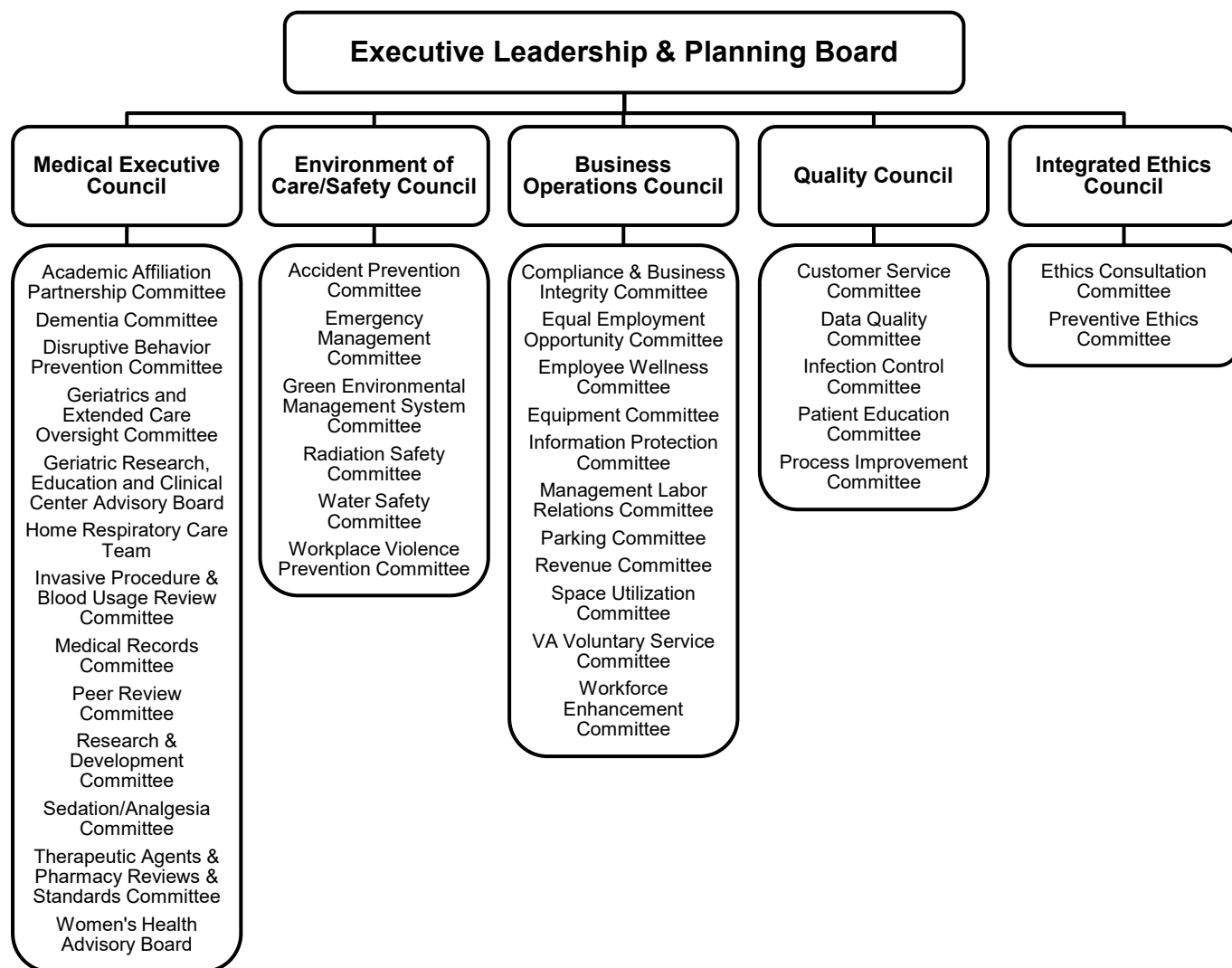| Leadership Position	Assignment Date
Director	January 10, 2016
Chief of Staff	September 4, 2005
Associate Director for Patient Care Services	March 20, 2016
Associate Director	January 9, 2020 (previous Assistant Director)
Assistant Director	January 20, 2020 (previous Chief of Nutrition and Food Services)

Source: William S. Middleton Memorial Veterans Hospital acting Human Resources Officer (received January 17, 2020)

To help assess the medical center executive leaders' engagement, the OIG interviewed the Director, Chief of Staff, ADPCS, and Assistant Director (acting Associate Director) regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance. The Associate Director was on a temporary assignment for three months at another medical center at the time of the OIG site visit.

The executive leaders were generally knowledgeable within their scopes 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, executive 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 serves as the chairperson of the Executive Leadership and Planning Board, which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Executive Leadership and Planning Board oversees various working groups such as the Medical Executive, Business Operations, and Integrated Ethics Councils.

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

Executive Leadership & Planning Board

Medical Executive Council

Academic Affiliation Partnership Committee

Dementia Committee

Disruptive Behavior Prevention Committee

Geriatrics and Extended Care Oversight Committee

Geriatric Research, Education and Clinical Center Advisory Board

Home Respiratory Care Team

Invasive Procedure & Blood Usage Review Committee

Medical Records Committee

Peer Review Committee

Research & Development Committee

Sedation/Analgesia Committee

Therapeutic Agents & Pharmacy Reviews & Standards Committee

Women's Health Advisory Board

Environment of Care/Safety Council

Accident Prevention Committee

Emergency Management Committee

Green Environmental Management System Committee

Radiation Safety Committee

Water Safety Committee

Workplace Violence Prevention Committee

Business Operations Council

Compliance & Business Integrity Committee

Equal Employment Opportunity Committee

Employee Wellness Committee

Equipment Committee

Information Protection Committee

Management Labor Relations Committee

Parking Committee

Revenue Committee

Space Utilization Committee

VA Voluntary Service Committee

Workforce Enhancement Committee

Quality Council

Customer Service Committee

Data Quality Committee

Infection Control Committee

Patient Education Committee

Process Improvement Committee

Integrated Ethics Council

Ethics Consultation Committee

Preventive Ethics Committee

Figure 4. Medical Center Committee Reporting Structure
Source: William S. Middleton Memorial Veterans Hospital (received January 16, 2020)

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential." Since 2001, the instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health. Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on medical center leadership.

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of

October 1, 2018, through September 30, 2019.[8] Table 2 provides relevant survey results for VHA, the medical center, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG team noted that survey results for the medical center were better than VHA averages. The results for the executive leaders were markedly higher than VHA averages.[9] These results appeared congruent with the high-performing Best Place to Work SAIL metric (see Figure 5). Medical center leaders appeared to have created a positive workplace environment.

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Servant Leader Index Composite[10]*	0–100 where higher scores are more favorable	72.6	76.4	89.2	81.8	85.0	93.0	93.0
All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.4	3.7	4.8	4.5	4.5	4.8	4.8

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

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

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.9	4.8	4.6	4.4	4.8	4.8
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.9	4.8	4.7	4.5	4.9	4.8

Source: VA All Employee Survey (accessed November 18, 2019)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.[11] Survey results for the leadership team members were consistently better than the VHA average, and it appears that leaders have created a culture where employees feel safe bringing forth concerns and doing 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	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.9	4.7	4.2	4.6	4.8	4.9

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.8	4.7	4.1	4.5	4.6	4.6
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	1.4	1.0	0.8	1.0	0.6	0.7

Source: VA All Employee Survey (accessed November 18, 2019)

Patient Experience

To assess patient experiences with the medical center, which directly reflect on its leaders, the OIG team reviewed patient experience survey results that relate to the period of October 1, 2018, through July 31, 2019. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experience of Patients (SHEP) program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for VHA and the medical center.[12]

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

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

center, the patient survey results were notably higher than VHA averages. Patients appeared satisfied with the care provided.

Table 4. Survey Results on Patient Experience
(October 1, 2018, through July 31, 2019)

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	68.1	84.4
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	94.4
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	83.6
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	86.2

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed November 18, 2019)

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from 2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.[13] For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see Tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that female patients were generally less satisfied with their care experiences than female patients nationally, and male patient scores

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

were generally similar to or higher than corresponding VHA national averages. Leaders have opportunities to improve female patient experiences.

**Table 5. Inpatient Survey Results on Experiences by Gender
(October 1, 2018, through July 31, 2019)**

Questions	Scoring	VHA[14]		Medical Center[15]	
		Male Average	Female Average	Male Average	Female Average
During this hospital stay, how often did doctors treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.3	83.8	90.2	78.6
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).	84.6	83.4	92.6	100
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).	68.4	62.2	85.7	41.6

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed November 18, 2019)

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[14] The VHA averages are based on 38,790–39,236 male and 1,858–1,875 female respondents, depending on the question.

[15] The medical center averages are based on 365–368 male and 10 female respondents, depending on the question.

Table 6. Patient-Centered Medical Home Survey Results on Patient Experiences by Gender (October 1, 2018, through July 31, 2019)

Questions	Scoring	VHA[16]		Medical Center[17]	
		Male Average	**Female Average**	**Male Average**	**Female Average**
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	50.6	43.1	50.5	29.9
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).	59.7	49.7	64.1	37.4
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.5	65.8	68.0	70.9

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed March 16, 2020)

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[16] The VHA averages are based on 66,977–203,592 male and 4,905–10,953 female respondents, depending on the question.

[17] The medical center averages are based on 561–1,597 male and 35–92 female respondents, depending on the question.

**Table 7. Specialty Care Survey Results on Patient Experiences by Gender
(October 1, 2018, through July 31, 2019)**

Questions	Scoring	VHA[18]		Medical Center[19]	
		Male Average	Female Average	Male Average	Female Average
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.0	46.0	57.2	0.0
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	55.4	60.1	3.6
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	70.8	66.8	46.3

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed March 16, 2020)

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from a previous inspection to gauge how well leaders respond to identified problems. Table 8 summarizes the relevant medical center inspection most recently performed by the OIG. Of note, at the time of the OIG visit, the medical center had closed all but one recommendation for improvement issued since the previous CHIP in August 2018. The Chief of Organizational Improvement reported continuing to work with program staff to close the last open recommendation by ensuring completion of professional practice evaluations by providers with similar training and privileges.[20]

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[18] The VHA averages are based on 55,910–175,665 male and 2,905–9,304 female respondents, depending on the question.

[19] The medical center averages are based on 371–1,325 male and 13–57 female respondents, depending on the question.

[20] VA Office of Inspector General, *Comprehensive Healthcare Inspection Program Review of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin*, Report No.18-01147-47, December 20, 2018.

The OIG team also noted the medical center's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[21] Additional results included the Long Term Care Institute's inspection of the system's CLCs.[22]

Table 8. Office of Inspector General Inspection

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Comprehensive Healthcare Inspection Program Review of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin*, Report No.18-01147-47, December 20, 2018)	August 2018	4	1[23]

Source: OIG (inspection/survey results verified with the Chief of Organizational Improvement on January 14, 2020)

Identified Factors Related to Possible Lapses in Care and Medical Center 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 a concern related to a potential safety issue in the gastroenterology reusable medical equipment clean storage area.

During physical inspection of the gastroenterology clean storage area, the SPS Chief and Gastroenterology Nurse Manager were unable to provide real time evidence of temperature and

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[21] According to VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs,* May 9, 2017, the Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term joint collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs; According to the College of American Pathologists, for 70 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." College of American Pathologists. https://www.cap.org/about-the-cap. (The website was accessed on February 20, 2019.) In accordance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

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

[23] The OIG closed the open recommendation on March 30, 2020.

humidity measurements. Out-of-range temperature and humidity could potentially compromise clean and sterile supplies. Unbeknown to the SPS managers, a Logistics staff[24] was assigned to monitor temperature and humidity daily but did not document measurements. In response to the OIG's concern, the medical center has implemented a contingency plan to include manually documenting environmental conditions in the gastroenterology clean storage area until the TempTrak system can be made fully functional. The OIG noted the appearance of poor communication among program leaders as a vulnerability for the medical center. This issue is discussed in detail in the High Risk Processes: Reusable Medical Equipment section of the report.

Table 9 lists the reported patient safety events from September 1, 2018 (the prior OIG comprehensive healthcare inspection), through January 13, 2020.[25]

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[24] Logistics falls under Engineering Service at this medical center.

[25] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the William S. Middleton Memorial Veterans Hospital is a mid-high complexity (1b) affiliated medical center as described in Appendix B.)

Table 9. Summary of Selected Organizational Risk Factors (September 1, 2018, through January 13, 2020)

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

Source: William S. Middleton Memorial Veterans Hospital, Chief, Organizational Improvement (received January 13, 2020)

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[29]

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, Figure 5 uses blue and green data points to indicate high performance (for example, in the areas of best place to work, rating (of) hospital, and specialty care (SC) survey access). Metrics that need improvement are denoted in orange and red (for example, complications, call responsiveness, continued (Cont) stay reviews met, and registered nurse (RN) turnover).[30]

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

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

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

[29] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

[30] For information on the acronyms in the SAIL metrics, please see Appendix E.
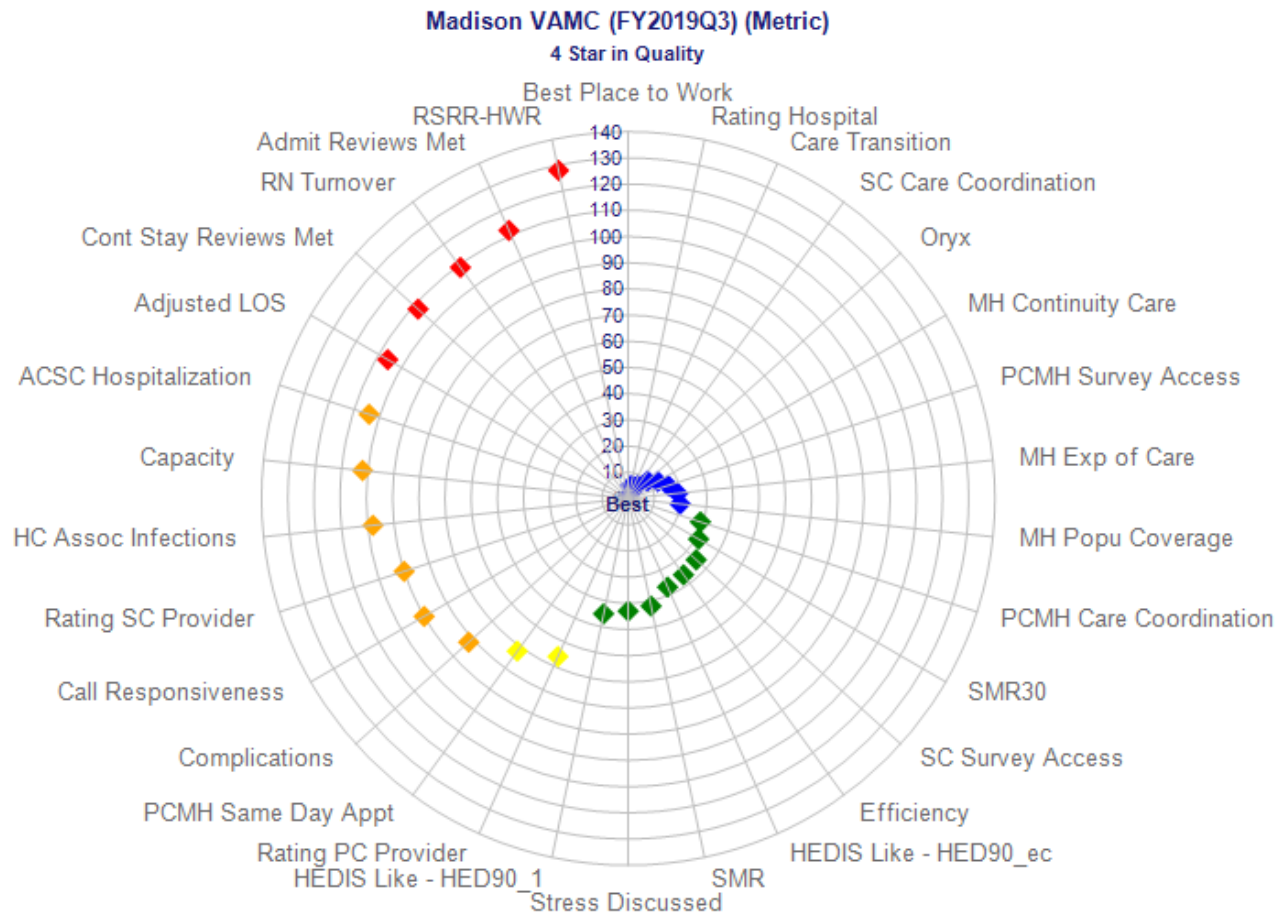
Figure 5. *Medical Center Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)*
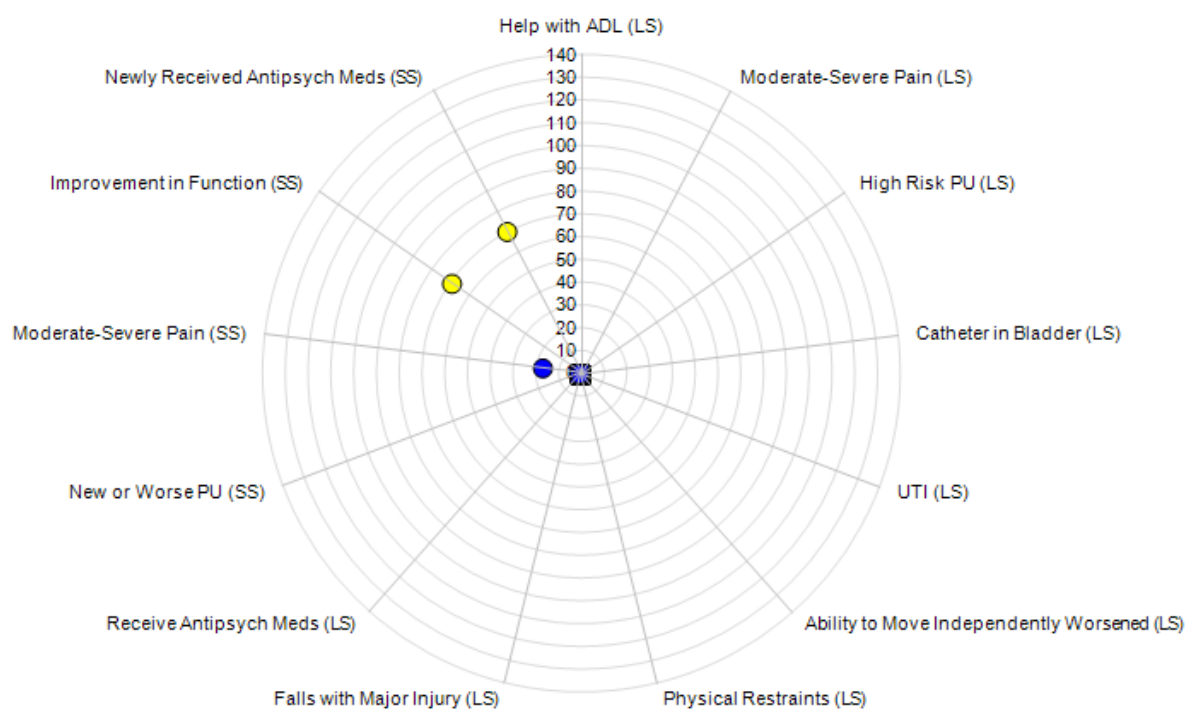*Source: VHA Support Service Center*
Note: The OIG did not assess VA's data for accuracy or completeness.

Veterans Health Administration Performance Data for Community Living Centers

The "CLC SAIL" Value Model is a tool to summarize and compare the performance of CLCs in the VA. The model leverages much of the same data used in the Centers for Medicare &

Medicaid Services' (CMS) *Nursing Home Compare* and provides a single resource to review quality measures and health inspection results.[31]

Figure 6 illustrates the medical center's CLC quality rankings and performance compared with other VA CLCs as of June 30, 2019. Figure 6 uses blue data points to indicate high performance for the CLC (for example, in the areas of moderate-severe pain–long-stay (LS), physical restraints–LS, and moderate-severe pain–short-stay (SS)). Metrics that shows average performance are denoted in yellow (improvement in function–SS and newly received antipsychotic (antipsych) medications (meds)–SS.[32] The medical center's CLC has no metrics in orange or red that indicate the need for improvement.

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

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

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

Leadership and Organizational Risks Conclusion

The medical center executive leadership team appeared stable, with all positions assigned at the time of the OIG's on-site visit. Survey results indicated that employees were generally satisfied with the work environment and felt safe bringing forth issues and concerns to leadership and seemed consistent with the medical center's high-performing Best Place To Work SAIL measure. Inpatient, Patient-Centered Medical Home, and Specialty Care patient survey results generally reflected higher care ratings than the VHA average. However, patient survey responses by gender revealed that female patients appeared less satisfied with their care experiences than female VHA patients nationally. The OIG's review of the medical center's sentinel event did not identify any substantial organizational risk factors. However, the OIG identified concerns with poor communication among program leaders as an area of vulnerability for the medical center.

In individual interviews, executive leaders were able to speak in depth about actions taken during the previous 12 months in order to maintain or improve performance, as well as employee and patient survey results. In addition, the executive leaders were knowledgeable within their scopes of responsibilities about SAIL and CLC data and should continue to take actions to improve and sustain performance.

Quality, Safety, and Value

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

To determine whether VHA facilities have implemented and incorporated OIG-identified key processes for quality and safety into local activities, the inspection team evaluated the medical center's committee responsible for quality, safety, and value (QSV) oversight functions (Quality Council at this medical center); 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 medical center's processes for conducting protected peer reviews of clinical care.[36] Protected peer reviews, when conducted systematically and credibly, reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[37] The OIG team examined the completion of the following elements:

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

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

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

[36] The definition of a peer review can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a critical review of care, performed by a peer, to evaluate care provided by a clinician for a specific episode of care, to identify learning opportunities for improvement, to provide confidential communication of the results back to the clinician, and to identify potential system or process improvements. In the context of protected peer reviews, "protected" refers to the designation of review as a confidential quality management activity under 38 U.S.C. 5705 as "a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or the utilization of health-care resources in VA facilities."

[37] VHA Directive 1190.

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

- Peer review of all applicable deaths within 24 hours of admission to the hospital

- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[38]

- Completion of final reviews within 120 calendar days

- Implementation of improvement actions recommended by the Peer Review Committee

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

Next, the inspection team assessed the medical center's utilization management (UM) program, a key component of VHA's framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.[39] It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[40] Inspectors reviewed several aspects of the UM program:

- Completion of at least 80 percent of all required inpatient reviews

- Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database

- Interdisciplinary review of UM data

- Implementation and monitoring of improvement actions recommended by the interdisciplinary UM group

Finally, the OIG reviewers assessed the medical center's reports of patient safety incidents with related root cause analyses.[41] Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual

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[38] VHA Directive 1190.

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

[40] VHA Directive 1117(2).

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

causes of harm to patients throughout the medical center.[42] The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses[43]

- Inclusion of required content in root cause analyses

- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days

- Provision of feedback about root cause analysis actions to reporting employees

- Submission of annual patient safety report to medical center leaders

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents.[44]

Quality, Safety, and Value Findings and Recommendations

The OIG determined that the medical center addressed most of the indicators of expected performance, including requirements for a committee responsible for QSV oversight functions, protected peer reviews, and most utilization management and patient safety elements reviewed. However, the OIG found deficiencies with the Quality Council's implementation of improvement actions and the interdisciplinary review of UM data.

TJC requires that the medical center's governing body provide structure and resources to support quality and safety, and that facilities measure and analyze performance data so that improvement "effectiveness can be sustained, assessed, and measured."[45] The OIG reviewed Quality Council—the committee with QSV oversight responsibility—minutes from January through November 2019 and noted a lack of evidence of action plan implementation for identified problems or opportunities for improvement. This may have prevented quality of care and patient safety process improvements at the medical center. The Chief of Organizational Improvement identified that documentation issues occurred when a nonclinical staff member was assigned as the Quality Council scribe and did not record all data and information in the minutes.

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[42] VHA Handbook 1050.01.

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

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

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

Recommendation 1

1. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures implementation of specific action items are documented in Quality Council minutes when problems or opportunities for improvement are identified.

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that reasons for noncompliance were considered when developing this action plan. "Open Actions" has been added as a standing agenda item which includes an Action Item Log. The Open Action Item Log will be reviewed monthly to review the status of each open action. This action will be considered compliant when there are six consecutive months of Quality Council minutes that include review of the Open Action Log. The Medical Center Director is the Chair of the Quality Council.

VHA requires that an interdisciplinary group review UM data. This group must include, but should not be limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [Chief Business Office Revenue-Utilization Review]."[46] The OIG found that from January through December 2019, the Patient Flow Committee, which is responsible for reviewing UM data, lacked representation from Chief Business Office Revenue-Utilization Review, and attendance by UM, medicine, and mental health representatives was inconsistent. As a result, the UM Committee performed reviews and analyses without the perspectives of key staff. The Associate Chief of Nursing—the Patient Flow Committee chairperson—acknowledged lack of awareness of the interdisciplinary group review requirement.

Recommendation 2

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

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[46] VHA Directive 1117(2).

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that reasons for noncompliance were considered when developing this action plan. Patient Flow Committee charter has been created and includes all of the required members. If a required member is not able to attend the committee meeting, a designee will attend in his or her place. Compliance will be achieved when ninety percent or greater of required attendees or their designee(s) have attended Patient Flow Committee meetings for six consecutive months. Compliance rates will be reported on a monthly basis by the Patient Flow Committee (co)Chair to the Quality Council in which the Chief of Staff is a member.

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).[47]

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 repriviliging prior to their expiration.[48]

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

- FPPEs

    o Establishment of criteria in advance

    o Use of minimum criteria for selected specialty LIPs[50]

    o Clear documentation of the results and time frames

    o Evaluation by another provider with similar training and privileges

- OPPEs

    o Application of criteria specific to the service or section

    o Use of minimum criteria for selected specialty LIPs[51]

    o Evaluation by another provider with similar training and privileges

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

[48] VHA Handbook 1100.19.

[49] VHA Handbook 1100.19.

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

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

The OIG also determined whether service chiefs recommended continuing the LIPs' current privileges based in part on the results of OPPE activities and if the medical center's Executive Committee of the Medical Staff (Medical Executive Council at this medical center) decided to recommend continuing privileges based on FPPE and OPPE results.

Further, VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and to subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.[52] 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."[53] The OIG reviewers assessed whether the medical center'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 medical center complied with requirements, the OIG interviewed key managers and selected and reviewed the privileging folders of several medical staff members:

- One solo/few practitioner who underwent initial or reprivileging during the previous 12 months[54]

- Ten LIPs hired within 18 months before the site visit

- Twenty LIPs privileged within 12 months before the visit

- Twenty LIPs who left the medical center in 12 months before the visit

Medical Staff Privileging Findings and Recommendations

The OIG noted noncompliance with FPPE and OPPE of specialty providers and provider exit review processes.

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

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

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

For FPPEs and OPPEs of specialty providers, VHA requires that service chiefs include the minimum required specialty-specific criteria for professional practice evaluation for gastroenterology, nuclear medicine, pathology, and radiation oncology practitioners.[55] The OIG found that for two gastroenterology providers, professional practice evaluations (one FPPE and one OPPE) lacked the minimum required specialty-specific criteria. This resulted in gastroenterology practitioners providing care without thorough evaluations of their practice. The Chief of Staff believed that the medical center's practice of completing and documenting chart reviews on the FPPE and OPPE forms met the required specialty-specific criteria.

Recommendation 3

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

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The facility attests that reasons for noncompliance were considered when developing this action plan. Gastroenterology-specific criteria were added to the focused and ongoing professional practice evaluation forms for licensed Gastroenterology independent practitioners. Both forms were reviewed and approved by the Medical Executive Committee on March 17, 2020 and put into process on March 18, 2020. With the addition of the Gastroenterology-specific criteria on the forms, the Chief of Staff can now ensure that they are used by the service chiefs for focused and ongoing professional practice evaluations of licensed Gastroenterology independent practitioners. The Health Systems Specialist in the Chief of Staff Office will monitor compliance that the focused and ongoing professional practice evaluation forms containing Gastroenterology-specific criteria (numerator) are utilized for the total of all appropriate focused and ongoing professional practice evaluations of licensed independent practitioners (denominator). This item will be reported to the Medical Executive Committee. This action will be considered compliant when compliance is reported for six consecutive months at ninety percent or above to the Medical Executive Committee, of which the Chief of Staff is Chair.

VHA requires that provider exit review forms, which documents the review of a provider's clinical practice, are "completed within 7 calendar days of departure of a licensed health care

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

professional from a VA facility."[56] For 6 of 20 providers that departed the medical center in the previous 12 months, the OIG found that providers' exit forms were not completed within seven calendar days. This could have resulted in delayed reporting of healthcare professionals' potential substandard care to SLBs. Credentialing and privileging staff cited lack of timely communication with an affiliate facility, resulting in delayed notification to the service chiefs that providers had exited the medical center as the reason for noncompliance.

Recommendation 4

4. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven calendar days of licensed healthcare professionals' departure from the medical center.

Medical center concurred.

Target date for completion: August 31, 2020

Medical center response: The facility attests that reasons for noncompliance were considered when developing this action plan. As of February 2020, the Madison VA Medical Staff Office started to receive termination/expiration dates directly from our affiliate to better track shared providers who depart from service. The Chief of Staff office conducted an audit of one hundred percent of the exit review forms kept in the medical staff office for part-time, full-time and fee-based providers who departed from the facility between January 31, 2020 and June 9, 2020. Eighteen provider files (numerator) contained a completed and signed exit review form within seven days of departure (denominator) for twenty providers who departed the facility during that time period. This audit will be reported to the Medical Executive Committee which is chaired by the Chief of Staff.

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

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct Comprehensive Environment of Care Inspection Rounds and to resolve issues in a timely manner. The goal of the Comprehensive Environment of Care Program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.[57]

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

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

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

- o Environmental cleanliness and infection prevention

- o Privacy

- o Privacy for women veterans

- o Logistics

During its review of the environment of care, the OIG team inspected the Baraboo VA Clinic and the following seven patient care areas of the medical center:

- CLC

- Emergency department

- Inpatient mental health unit

- Intensive care unit

- Medical/surgical inpatient unit

- Outpatient clinic (West clinic)

- Post-anesthesia care unit

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

Environment of Care Findings and Recommendations

The OIG determined that the medical center and the Baraboo VA Clinic largely met requirements for environmental cleanliness, infection prevention, and accommodation and privacy for women veterans. The medical center's inpatient mental health unit also met requirements. The inspection team did not note any issues with the availability of medical equipment and supplies. However, the OIG noted concerns with general safety and special use spaces at the medical center and general safety at the Baraboo VA Clinic.

VHA Center for Engineering and Occupational Safety and Health requires facilities to have a mechanism or method in place for equipment users to be confident that equipment is safe and functional.[58] The medical center uses stickers with dates of inspection or "no preventative maintenance required" as a visual method for users to identify if the equipment has been inspected prior to being put into use. The OIG found 13 pieces of equipment with expired inspection stickers: nine vital sign machines at the medical center; and one centrifuge,[59] two

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[58] Environment of Care Guidebook, *VHA Center for Engineering & Occupational Safety and Health (CEOSH)*, June 2017.

[59] A vital sign machine is used to take a patient's body temperature, respiratory rate, pulse rate, and blood pressure. A centrifuge is a machine used to separate substances that have different densities (weights).

Hoyer lifts,[60] and an otoscope[61] at the Baraboo VA Clinic. This meant that equipment lacked visual evidence that it was safe to use. The Chief of Engineering cited staffing shortages as the reason for noncompliance.

Recommendation 5

5. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures all medical equipment is identified as safe for patient use.

Medical center concurred.

Target date for completion: April 30, 2021

Medical center response: The facility attests that reasons for noncompliance were considered when developing this action plan. Engineering will track monthly the number of pieces of equipment requiring preventive maintenance completed (numerator) with the number of pieces of equipment due for preventive maintenance (denominator). This action will be considered compliant when rates are ninety percent or greater for six consecutive months. The Chief of Biomedical Engineering will report the compliance rate monthly to the Environment of Care Committee of which the Assistant Director is Chair.

TJC requires that "the hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration."[62] In two clinical areas inspected,[63] the OIG found expired nitroglycerin (drugs used to prevent and treat chest pain), acetaminophen (Tylenol®), ceftriaxone (an antibiotic used to fight infection), and Xylocaine (numbing medication to help reduce pain) in the primary care clinic and expired potassium chloride (used to treat low potassium levels) in the post-anesthesia care unit. This raised concerns about safe medication administration. The Primary Care Assistant Nurse Manager, a clinical pharmacist, and the Outpatient Pharmacy Supervisor stated staff were aware of the requirements but had multiple competing demands, resulting in a lack of attention to detail.

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[60] A Hoyer lift is a mobility device to help move (by lifting or transferring) individuals with limited to no mobility from one area to another.

[61] An otoscope is a medical device with lighting and magnifying systems used for visual examination of the tympanic membrane (eardrum) and ear the canal

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

[63] Primary care clinic (West clinic) and post-anesthesia care unit.

Recommendation 6

6. The Associate Director evaluates and determines any additional reasons for noncompliance and makes certain that staff remove expired medications from patient care areas.

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Audits of two automated dispensing cabinets by the Chief of Pharmacy each month will show (numerator) number of unexpired medications (denominator) out of the number of medications total in the cabinet. Compliance will be achieved when there are no expired medications in ninety percent or greater of these audits for six consecutive months. Compliance rates will be reported monthly to the Quality Council of which the Associate Director is a member.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[64] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[65] 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.[66] These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.[67]

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.[68] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[69] 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.[70] 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.[71]

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

- Completion of initial screening for pain

- Assessment of aberrant behavior risk

- Avoidance of concurrent therapy with benzodiazepines

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

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

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

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

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

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

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

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

- Completion of urine drug testing with intervention, when indicated

- Documentation of informed consent

- Timely follow-up with patients included required elements

VHA also requires facilities to establish a multidisciplinary pain management committee "to provide oversight, coordination, and monitoring of pain management activities and processes." Monitoring measures include, but are not limited to, adherence to published clinical practice guidelines, timeliness of treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment, patient satisfaction, and quality of life.[72] The OIG examined the following indicators for program oversight and evaluation:

- Performance of pain management committee activities

- Monitoring of quality measures

- Following the quality improvement process

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 20 outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The team considered whether providers acted in accordance with guidelines for the provision of pain management and the medical center's oversight process for evaluating pain management outcomes and quality.

Medication Management Findings and Recommendations

The OIG determined that the medical center met some of the indicators of expected performance, including pain screenings, and justifications for concurrent therapy with benzodiazepines, and quality measure monitoring by a multidisciplinary pain management committee. However, the OIG found deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, and patient follow-up after therapy initiation.

VA/DoD clinical practice guidelines recommend that providers complete an aberrant behavior risk assessment, including history of substance abuse, psychological disease, and aberrant drug-related behaviors,[73] prior to initiating long-term opioid therapy.[74] The OIG determined that providers documented history of substance abuse and psychological disease in 75 percent of the electronic health records reviewed.[75] This may have resulted in providers prescribing opioids for

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

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

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

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

patients at high risk for misuse. The Pain Care Resource Nurse and Pharmacy Service Chief stated they were unaware of the requirement to follow pain management clinical practice guidelines.

Recommendation 7

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

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Monthly audits will be completed by the Pain Care Resource Specialist monthly for compliance. Compliance will be achieved when a behavioral risk assessment is documented (numerator) for patients started on long-term opioid therapy (denominator)--ninety percent or greater for six consecutive months. Compliance rates will be reported monthly to Quality Council of which the Chief of Staff is a member.

VA/DoD clinical practice guidelines also recommend that providers conduct "UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter."[76] The OIG found that providers conducted initial urine drug testing in 45 percent of patients, based on electronic health records reviewed.[77] This limited providers' ability to identify whether the remaining patients had substance use disorders, determine potential diversion, or ensure that patients adhered to the prescribed medication regimen. The Pain Care Resource Nurse and Pharmacy Service Chief stated they were unaware of the requirement to follow VA/DoD pain management clinical practice guidelines.

Recommendation 8

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

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

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

Medical center concurred.

Target date for completion: February 28, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Monthly audits will be completed by the Pain Care Resource Specialist to monitor compliance. Compliance will be achieved when (numerator) urine drug testing is documented for patients on long-term opioid therapy (denominator) ninety percent or greater for six consecutive months. Compliance rates will be reported monthly to Quality Council of which the Chief of Staff is a member.

VHA requires that providers 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.[78] The OIG determined that providers documented informed consent prior to initiating long-term opioid therapy for 50 percent of the patients at the medical center, according to electronic health records reviewed.[79] The remaining patients may have received treatment without knowledge of the risks associated with long-term opioid therapy, including opioid dependence, tolerance, addiction, and intentional or unintentional fatal overdose. The Chief of Primary Care stated that providers were aware of the requirements but had multiple competing demands, resulting in a lack of attention to detail.

Recommendation 9

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

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Monthly audits will be completed by the Pain Care Resource Specialist to monitor compliance. Compliance will be achieved when informed consent is obtained and documented (numerator) prior to initiation of long-term opioid therapy (denominator) ninety percent or greater for six consecutive months. Compliance rates will be reported monthly to Quality Council of which the Chief of Staff is a member.

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[78] VHA Directive 1005.

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

VA/DoD clinical practice guidelines recommend providers follow up with patients within three months after initiating long-term opioid therapy[80] to assess adherence to the therapy plan and the effectiveness of treatment.[81] The OIG determined that providers completed patient follow-ups within three months after initiating long-term opioid therapy in 55 percent of patients, according to electronic health records reviewed.[82] For the remaining patients, failure to conduct follow-ups can result in missed opportunities to assess adherence to the therapy plan, effectiveness of treatment, and risks of continued opioid therapy. The Pain Care Resource Nurse and Pharmacy Service Chief stated they were unaware of the requirement to follow VA/DoD pain management clinical practice guidelines.

Recommendation 10

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

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Monthly audits will be completed by the Pain Care Resource Specialist to monitor compliance. Compliance will be achieved when there is a documented follow-up visit (numerator) to assess adherence to the therapy plan and effectiveness of treatment within three months for patients started on long-term opioid therapy (denominator), ninety percent or greater of the time for six consecutive months. Compliance rates will be reported monthly to Quality Council of which the Chief of Staff is a member.

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

[81] VHA Directive 2009-053.

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

Mental Health: Suicide Prevention Program

In 2017, suicide was the 10th leading cause of death, with approximately 47,000 lives lost across the United States.[83] The suicide rate was 1.5 times greater for veterans than for non-veteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States.[84] Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.[85]

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.[86]

VHA requires that each medical center and very large CBOC have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.[87] 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 medical center's high-risk list and have a High Risk for Suicide (HRS) Patient Record Flag

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

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

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

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

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

(PRF) placed in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC.[88] 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."[89] 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.[90] 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.[91]

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."[92] 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."[93] 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."[94]

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

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

[90] *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.

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

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

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

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

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

On March 27, 2020, VHA also updated existing policy requirements to allow the review of HRS PRFs to "occur no earlier than 10 days before and no later than 10 days after the 90-day due date."[95]

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.[96] VHA also requires that all staff receive annual refresher training.[97] In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[98]

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

- Relevant documents;

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

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

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

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

- The electronic health records of 47 randomly selected outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and

- Staff training records.

Mental Health Findings and Recommendations

The OIG found the medical center had complied with requirements for a designated SPC, suicide safety plans, and patient follow-up for missed appointments. However, the OIG noted concerns with the review of HRS PRFs within the required time frame. VHA required that all patients with an HRS PRF be reevaluated at least every 90 days and there is documented justification for continuing or discontinuing the flag.[99] The OIG estimated that 34 percent of patients with an HRS PRF were reevaluated at least every 90 days.[100] However, based upon VHA's updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that 46 of 47 patients were reviewed within the expected time frame (observed range was 45–98 days).

The OIG also identified issues with required employee training. VHA requires that all employees complete suicide risk and intervention training within 90 days of entering their position. VHA mandates that all staff, clinical and nonclinical, receive annual refresher training thereafter.[101] The OIG determined that two of six staff did not complete initial training within 90 days of hire. The OIG also found that 9 of 20 staff did not complete annual refresher training as required. Lack of training could prevent staff from providing optimal care to veterans who are at risk for suicide. The Chief of Education Service attributed the noncompliance to the medical center's reliance on VHA's national alerts to staff to complete the required training and service line managers' failure to monitor completion of staff training.

Recommendation 11

11. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures that employees receive initial suicide prevention training within 90 days of hire and annual refresher training thereafter.

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[99] VHA Directive 2008-036; VHA Directive 2010-053, *Patient Record Flags*, December 3, 2010.

[100] The OIG estimated that 95 percent of the time, the true compliance rate is between 20.8 and 48.9 percent, which is statistically significantly below the 90 percent benchmark.

[101] VHA Directive 1071.

Medical center concurred.

Target date for completion: December 31, 2020

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Suicide prevention training for new employees from Jan. 1, 2020 thru June 11, 2020 had a 97.1% completion rate within 90 days of hire. The overall suicide prevention training compliance rate for annual refresher training during this same time period was 96.2%. When (numerator) the number of new employees OR number of established employees have completed training within 90 days of hire OR within 12-months of their previous training (denominator) ninety percent or greater of the time for six months, compliance will be achieved. Compliance rates will be reported monthly to the Quality Council where the Medical Center Director is chair.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. Life-sustaining treatments may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the Life-Sustaining Treatment Decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "…eliciting, documenting, and honoring patients' values, goals, and preferences."[102]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.[103] 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.[104] 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.[105]

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

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

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

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

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

- Decision-making capacity,

- Goal(s) of care,

- Plan of care for the use of LST, and

- Informed consent for the LST plan.

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

The medical center 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.[106] Inspectors examined if the medical center established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the medical center 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.

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[106] VHA Handbook 1004.03(1).

Care Coordination Findings and Recommendations

The OIG found the medical center had generally complied with requirements for the LSTD committee and supervision of designees. Additionally, with VHA's original requirements that were in place when these patients received care,[107] the OIG estimated that

- 58 percent of patients' LST progress notes addressed identification of a surrogate if the patient loses decision-making capacity,[108]
- 53 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes, and[109]
- 63 percent of patients' LST progress notes addressed the patient's or surrogate's understanding of the patient's condition.[110]

However, VHA no longer requires these elements to be documented in the LST progress note.[111] The OIG made no recommendations but remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

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[107] VHA Handbook 1004.03(1).

[108] The OIG estimated that 95 percent of the time, the true compliance rate is between 41.9 and 73.7 percent, which is statistically significantly below the 90 percent benchmark.

[109] The OIG estimated that 95 percent of the time, the true compliance rate is between 36.7 and 68.4 percent, which is statistically significantly below the 90 percent benchmark.

[110] The OIG estimated that 95 percent of the time, the true compliance rate is between 47.4 and 78.0 percent, which is statistically significantly below the 90 percent benchmark.

[111] VHA Handbook 1004.03(1).

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[112] 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.[113] To help the VA better understand the needs of the growing women's veteran population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."[114] 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."[115]

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.[116] VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veteran health committee "that develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."[117]

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

- Provision of care requirements

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

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

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

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

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

[117] VHA Directive 1330.01(2).

- o Designated Women's Health Patient Aligned Care Team established
- o Primary Care Mental Health Integration services available
- o Gynecologic care coverage available 24/7
- o Gynecology care accessible
- o Facility women health primary care providers designated
- o CBOC women's health primary care providers designated
- o Emergency contraception accessible
- 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 CBOC

Women's Health Findings and Recommendations

Generally, the medical center achieved the requirements listed above. 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 a sterile processing services (SPS) "to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment…"[118] The goal of SPS is to "...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[119] To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME

- Have standard operating procedures (SOPs) that are based on current manufacturer's guidelines and reviewed at least triennially

- Use CensiTrac® Instrument Tracking System for tracking reprocessed instruments[120]

- 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[121]

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.[122] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[123]

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,

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

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

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

[121] VHA Directive 1116(2).

[122] 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.

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

personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME.[124]

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.[125]

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

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

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[124] VHA Directive 1116(2).
[125] VHA Directive 1116(2).

- o Eating or drinking in the area prohibited

- o Equipment properly stored

- o Required temperature and humidity maintained

- Completion of staff training, competency, and continuing education

- o Required training completed in a timely manner

- o Competency assessments performed

- o Monthly continuing education received

High-Risk Processes Findings and Recommendations

The medical center met many of the requirements for the proper operations and management of reprocessing RME. However, the OIG identified deficiencies with risk analysis reporting; traffic flow, temperature, and humidity in reprocessing areas; and staff competency and education.

VHA requires that the SPS Chief performs an annual risk analysis and reports the results to the VISN SPS Management Board.[126] The OIG found that the annual risk analysis for FY2019 was completed, but results were not reported to the board. Failures to report risk analysis results can delay or prevent the identification of problems or process failures and cause missed opportunities for mitigation across the VISN. The SPS Chief and Chief of Perioperative Nursing Services were reportedly aware of the requirement and believed that the RME Committee had reported analysis results to the VISN SPS Management Board.

Recommendation 12

12. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Services Chief reports the annual risk analysis to the Veterans Integrated Service Network Sterile Processing Services Management Board.[127]

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[126] VHA Directive 1116(2).

[127] The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

Medical center concurred.

Target date for completion: Completed

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. The Associate Director of Patient Care Services and the Chief of Sterile Processing Services sent the annual risk analysis to VISN 12 on March 10, 2020 to be reported to the VISN Sterile Processing Services Management Board. Compliance was achieved when the Chief of SPS sent this to the VISN and it was reported at the March 2020 VISN Sterile Processing Services Management Board of which the Associate Director for Patient Care Services is a member. We request closure of this recommendation based on the evidence provided.

Despite VHA requiring strict traffic flow of people in SPS, the OIG did not find a keyed entry or other mechanism to restrict access to the Gastroenterology clean storage areas.[128] This could have compromised the integrity of the environment by increasing the potential spread of microorganisms. The SPS Chief, Chief of Perioperative Nursing Services, and Gastroenterology Nurse Manager were reportedly aware of the requirement but considered the area to be semi-restricted because individuals must pass through the front desk to gain access.

Recommendation 13

13. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that traffic flow in the Gastroenterology clean storage areas is restricted.[129]

Medical center concurred.

Target date for completion: Completed

Medical center response: The facility attests that reasons for noncompliance were considered when developing the action plan. Compliance was achieved when a keypad to the door of the Gastroenterology clean storage areas was installed and traffic flow was restricted. The Chief of Engineering reported completion of this action to the Reusable Medical Equipment (RME) Committee, which is Chaired by the Associate Director for Patient Care Services. We request closure of this recommendation based on the evidence provided.

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[128] VHA Directive 1116(2).

[129] The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

VHA requires a strict temperature range in clean storage areas of 66–72 degrees Fahrenheit.[130] The SPS Chief and Gastroenterology Nurse Manager were unable to provide documented evidence of temperature and humidity measurements for the Gastroenterology clean storage areas. Failure to achieve air quality standards can lead to the spread of healthcare-associated infections. The SPS Chief and Gastroenterology Nurse Manager were reportedly unaware that the TempTrak system was not fully functional in the gastroenterology area and that the system did not electronically maintain temperature and humidity measurements.[131] Unbeknown to the SPS Chief and Gastroenterology Nurse Manager, a Logistics staff was assigned to monitor the TempTrak system daily but did not document the temperature and humidity measurements. In response to the OIG's request for additional information to assess the impact of this issue, the Chief of Organizational Improvement reported that no work orders were submitted to correct any problem related to temperature or humidity in the area, and there were no gastroenterology-related patient safety incidents reported during the time period in question. Further, the medical center reported that the Chief of Medicine, who is Board Certified in Infectious Disease, reviewed the situation for clinical risk and determined that there was no evidence of patient safety risk associated with the lack of documented humidity and temperature monitoring in the gastroenterology clean area. Managers attributed the noncompliance to a lack of communication between the SPS Chief, Gastroenterology Nurse Manager, and Logistics staff.

Recommendation 14

14. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that temperature and humidity requirements are maintained and documented for the Gastroenterology clean storage areas.

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[130] 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.

[131] A commercial central temperature and humidity monitoring system.

Medical center concurred.

Target date for completion: March 11, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. On 2/24/2020, Engineering Services re-established complete functionality for continuous temperature and humidity monitoring in the Gastroenterology clean storage areas by the TempTrak system by replacing the system's server. Under the direction of the Associate Director for Patient Care Services, compliance is considered achieved when temperature and humidity readings for the Gastroenterology clean storage areas have been maintained and documented ninety percent or greater for six consecutive months. If out of range, it will not be considered non-compliant if documentation of appropriate follow-up is completed. Compliance rates will be reported monthly to the Quality Council, of which the Associate Director for Patient Care Services is a member, by the Chief of Engineering.

VHA also requires that SPS staff complete competency assessments for the reprocessing of RME.[132] The OIG found that all 10 SPS staff selected for review had expired or missing competency assessments for the applicable RME. Also, the SPS Chief could not confirm whether staff with expired competencies were reprocessing the corresponding RME. This could have resulted in improper cleaning of RME and subsequently compromised patient safety. The SPS Chief attributed the noncompliance to staffing issues and competing priorities.

Recommendation 15

15. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that Sterile Processing Services staff receive competency assessments prior to reprocessing reusable medical equipment.

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[132] VHA Directive 1116(2).

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. When (numerator) the number of staff who have completed competency training each month out of the total number of Sterile Processing Services staff (denominator) has a rate of ninety percent or greater for six consecutive months, compliance will be achieved. The action will not be considered non-compliant if a Sterile Processing Services staff member is on extended leave and continuing education is completed within 30 days of their return. Compliance will be reported monthly to the Reusable Medical Equipment Committee, where the Associate Director for Patient Care Services is the co-Chair.

VHA requires SPS staff to receive monthly continuing education.[133] The OIG found no evidence of monthly continuing education for 2 of 10 selected SPS staff between October and December 2019. This resulted in a potential knowledge gap in reprocessing duties. The SPS Chief and RME Nurse Educator attributed the noncompliance to staffing issues and competing priorities.

Recommendation 16

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

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The facility attests that additional reasons for noncompliance were considered when developing this action plan. Compliance will be achieved when (numerator) continuing education was completed (denominator) for all SPS staff of for six consecutive months. The action will not be considered non-compliant if an SPS staff member is on extended leave and continuing education is completed within 30 days of their return. Compliance will be reported monthly to the Reusable Medical Equipment Committee, which the Associate Director for Patient Care is chair.

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[133] VHA Directive 1116(2).

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

Healthcare Processes	Requirements	Conclusion
Leadership and Organizational Risks	• Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation surveys and oversight inspections • Factors related to possible lapses in care and medical center response • VHA performance data (facility or system) • VHA performance data for CLCs	Sixteen OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, ADPCS, and Associate Director. See details below.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• QSV Committee • Protected peer reviews • UM reviews • Patient safety	• None	• Implementation of specific action items are documented in Quality Council minutes when problems or opportunities for improvement are identified. • All required representatives are assigned and consistently participate in interdisciplinary reviews of UM data.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	- FPPEs - OPPEs - Provider exit reviews and reporting to state licensing boards	Service chiefs include the minimum required gastroenterology-specific criteria for FPPEs and OPPEs of LIPs.	Exit review forms are completed within seven calendar days of licensed healthcare professionals departing the medical center.
Environment of Care	- Medical center - General safety - Special use spaces - Environmental cleanliness and infection prevention - Privacy - Accommodation and privacy for women veterans - Logistics - Inpatient mental health unit - General safety - Special use spaces - Environmental cleanliness and infection prevention - Privacy - Accommodation for women veterans - Logistics - Community-based outpatient clinic - General safety - Special use spaces - Environmental cleanliness and infection prevention - Privacy - Privacy for women veterans - Logistics	Staff remove expired medications from patient care areas.	Medical equipment is identified as safe for patient use.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	• Provision of pain management using long-term opioid therapy • Program oversight and evaluation	• Providers complete an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors on all patients prior to initiating long-term opioid therapy. • Providers consistently conduct urine drug testing for patients on long-term opioid therapy. • Providers consistently obtain and document informed consent for patients prior to initiating long-term opioid therapy. • Providers follow up with patients within three months after initiating long-term opioid therapy to assess adherence to therapy plan and effectiveness of treatment.	• None
Mental Health: Suicide Prevention Program	• Designated facility suicide prevention coordinator • Provision of suicide prevention care • Completion of suicide prevention training requirements	• Employees receive initial suicide prevention training within 90 days of hire and annual refresher training thereafter.	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Care Coordination: Life-Sustaining Treatment Decisions	• LSTD multidisciplinary committee • Goals of care conversation documentation • LSTD note/orders completed by an authorized provider or delegated	• None	• None
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 • Data monitoring • Physical inspection • Staff training	• Traffic flow in the Gastroenterology clean storage areas is restricted. • Temperature and humidity requirements are maintained and documented for the Gastroenterology clean storage areas. • SPS staff receive proper competency assessments prior to reprocessing RME. • SPS staff receive monthly continuing education.	• The SPS Chief reports annual risk analysis to the VISN SPS Management Board.

Appendix B: Medical Center Profile

The table below provides general background information for this medium-high complexity (1b) affiliated[1] medical center reporting to VISN 12.[2]

Table B.1. Profile for William S. Middleton Memorial Veterans Hospital (607) (October 1, 2016, through September 30, 2019)

Profile Element	Medical Center Data FY 2017[3]	Medical Center Data FY 2018[4]	Medical Center Data FY 2019[5]
Total medical care budget	$385,637,854	$393,496,064	$415,477,268
Number of:			
• Unique patients	42,929	42,202	41,518
• Outpatient visits	478,839	492,546	487,273
• Unique employees[6]	2,063	2,134	2,228
Type and number of operating beds:			
• Community living center	26	26	26
• Domiciliary	12	12	12
• Medicine	50	51	51
• Mental health	14	14	14
• Residential rehabilitation	6	6	6
• Surgery	21	22	22
Average daily census:			
• Community living center	21	21	21
• Domiciliary	11	11	10
• Medicine	45	43	46
• Mental health	10	10	9
• Neurology	1	2	1
• Residential rehabilitation	5	4	5

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[1] Associated with a medical residency program.

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

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

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

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

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

Profile Element	Medical Center Data FY 2017[3]	Medical Center Data FY 2018[4]	Medical Center Data FY 2019[5]
• Surgery	13	13	13

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

Appendix C: VA Outpatient Clinic Profiles[1]

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[3] Provided	Diagnostic Services[4] Provided	Ancillary Services[5] Provided
Janesville, WI	607GC	6,592	1,485	Cardiology Dermatology Gastroenterology Hematology/ Oncology Nephrology Rheumatology	n/a	Nutrition Pharmacy Social work Weight management

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

[2] The definition of an "encounter" can be found in VHA Directive 2010-049, *Encounter and Workload Capture for Therapeutic and Supported Employment Services Vocational Programs*, October 14, 2010. An encounter is a "professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient's condition."

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

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[3] Provided	Diagnostic Services[4] Provided	Ancillary Services[5] Provided
Baraboo, WI	607GD	4,954	732	Cardiology Dermatology Gastroenterology Hematology/ Oncology Nephrology Rheumatology	n/a	Nutrition Pharmacy Social work Weight management
Beaver Dam, WI	607GE	5,726	1,308	Cardiology Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Nephrology	n/a	Nutrition Pharmacy Social work Weight management
Freeport, IL	607GF	3,442	616	Cardiology Dermatology Gastroenterology Hematology/ Oncology Infectious disease Nephrology Rheumatology	n/a	Nutrition Pharmacy Social work Weight management
Madison, WI	607GG	17,487	3,310	n/a	n/a	Nutrition Pharmacy Social work Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services[3] Provided	Diagnostic Services[4] Provided	Ancillary Services[5] Provided
Rockford, IL	607HA	15,881	11,068	Cardiology Cardio thoracic Dermatology Endocrinology Gastroenterology Hematology/ Oncology Infectious disease Nephrology Neurology Podiatry Poly-Trauma Rheumatology	Radiology	Nutrition Pharmacy Social work Weight management

Source: VHA Support Service Center and VA Corporate Data Warehouse

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

n/a = not applicable

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

New Primary Care Patient Average Wait Time in Days

	VHA Total	(607) Madison, WI (William S. Middleton)	(607GC) Janesville, WI	(607GD) Baraboo, WI	(607GE) Beaver Dam, WI	(607GF) Freeport, IL	(607GG) Madison West, WI	(607HA) Rockford, IL
JAN-FY19	9.0	49.7	16.0	19.1	17.4	8.6	12.3	14.0
FEB-FY19	8.5	25.6	16.1	16.0	13.5	7.0	10.2	11.3
MAR-FY19	8.1	8.0	15.9	13.9	11.8	15.8	12.0	13.3
APR-FY19	7.8	28.0	14.7	22.6	16.8	10.5	14.1	11.8
MAY-FY19	7.6	18.7	15.2	15.2	19.1	5.5	14.1	8.7
JUN-FY19	7.6	11.2	7.3	8.6	9.6	5.8	8.8	7.4
JUL-FY19	7.3	11.3	10.1	7.0	7.8	7.5	8.6	10.5
AUG-FY19	7.4	18.1	9.2	9.2	9.7	7.8	8.0	9.6
SEP-FY19	7.3	9.0	12.7	5.2	7.1	6.2	10.9	8.3
OCT-FY20	6.9	10.0	11.7	4.1	7.9	6.8	8.7	7.5
NOV-FY20	7.1	8.3	11.6	4.2	5.6	4.8	8.3	7.3
DEC-FY20	7.8	11.4	8.1	6.1	7.4	5.4	6.5	4.9

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG has on file the medical center's explanation for the increased wait times in January 2019 for the Madison, WI (607) clinic.

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

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

Established Primary Care Patient Average Wait Time in Days

	VHA Total	(607) Madison, WI (William S. Middleton)	(607GC) Janesville, WI	(607GD) Baraboo, WI	(607GE) Beaver Dam, WI	(607GF) Freeport, IL	(607GG) Madison West, WI	(607HA) Rockford, IL
JAN-FY19	5.0	10.2	5.9	6.0	3.3	3.2	6.2	3.4
FEB-FY19	4.6	8.8	5.5	6.5	2.5	2.5	6.3	2.6
MAR-FY19	4.6	8.5	6.6	5.3	2.6	2.4	6.2	3.0
APR-FY19	4.5	8.4	5.4	4.2	2.4	2.3	6.7	3.2
MAY-FY19	4.5	7.8	5.5	7.6	3.5	2.8	9.0	3.0
JUN-FY19	4.5	9.1	6.3	7.0	2.7	2.9	5.9	4.6
JUL-FY19	4.6	10.1	8.7	4.1	1.4	2.2	7.9	5.5
AUG-FY19	4.5	9.6	6.3	4.8	1.6	2.4	7.4	4.3
SEP-FY19	4.3	10.8	6.1	7.5	1.2	2.1	5.1	4.7
OCT-FY20	3.9	10.1	6.7	3.1	1.1	2.7	5.8	4.1
NOV-FY20	4.2	9.8	6.5	3.6	1.6	3.0	4.6	3.3
DEC-FY20	4.2	6.2	5.6	4.0	1.4	2.6	4.8	2.5

Source: VHA Support Service Center

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

Data Definition: "The average number of calendar days between an Established Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date."

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

Measure	Definition	Desired Direction
ACSC hospitalization	Ambulatory care sensitive conditions hospitalizations	A lower value is better than a higher value
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
Admit reviews met	Percent acute admission reviews that meet interqual criteria	A higher value is better than a lower value
Best place to work	All employee survey best places to work score	A higher value is better than a lower value
Call responsiveness	Call center speed in picking up calls and telephone abandonment rate	A lower value is better than a higher value
Care transition	Care transition (inpatient)	A higher value is better than a lower value
Complications	Acute care risk adjusted complication ratio (observed to expected ratio)	A lower value is better than a higher value
Cont stay reviews met	Percent acute continued stay reviews that meet interqual criteria	A higher value is better than a lower value
Efficiency	Overall efficiency measured as 1 divided by SFA (Stochastic Frontier Analysis)	A higher value is better than a lower value
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like – HED90_1	HEDIS-EPRP based PRV TOB BHS	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS-eOM based DM IHD	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value

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

Measure	Definition	Desired Direction
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx	ORYX	A higher value is better than a lower value
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RN turnover	Registered nurse turnover rate	A lower value is better than a higher value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SMR	Acute care in-hospital standardized mortality ratio	A lower value is better than a higher value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value

Source: VHA Support Service Center

Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions[1]

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

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

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: June 29, 2020

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Comprehensive Healthcare Inspection of the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin

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

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

1. I have reviewed the Comprehensive Healthcare Inspection of the William S. Middleton Memorial Veterans Hospital draft report.

2. I concur with the findings and recommendations proposed.

3. I concur with the submitted action plans from the facility.

4. I would like to thank the OIG Inspection team for a thorough review of the of the William S. Middleton Memorial Veterans Hospital, Madison, WI.

(Original signed by:)

Victoria P. Brahm, MSN, RN, VHA-CM
Director, VA Great Lakes Health Care System (10N12)

Appendix H: Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: June 29, 2020

From: Director, William S. Middleton Memorial Veterans Hospital (607/00)

Subj: Comprehensive Healthcare Inspection of the William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the draft of the Inspector General report from the Comprehensive Healthcare Inspection of the William S. Middleton Memorial Veterans Hospital CHIP Review.

2. I have reviewed each recommendation and concur with the findings, recommendations and submitted action plans. The plans have been carefully analyzed and will be implemented and monitored through satisfactory completion.

(Original signed by:)

John J. Rohrer, MHA
Medical Center Director

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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