



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare
Inspection of the Ann Arbor
VA Medical Center
in Michigan



MISSION

The mission of the Office of Inspector General is to serve veterans and the public by conducting meaningful independent oversight of the Department of Veterans Affairs.

In addition to general privacy laws that govern release of medical information, disclosure of certain veteran health or other private information may be prohibited by various federal statutes including, but not limited to, 38 U.S.C. §§ 5701, 5705, and 7332, absent an exemption or other specified circumstances. As mandated by law, the OIG adheres to privacy and confidentiality laws and regulations protecting veteran health or other private information in this report.

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

www.va.gov/oig/hotline

1-800-488-8244



Figure 1. Ann Arbor VA Medical Center in Michigan.
Source: <https://vaww.va.gov/directory/guide/> (accessed July 23, 2020).

Abbreviations

ADPCS	Associate Director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
COVID-19	coronavirus disease
FPPE	focused professional practice evaluation
HRS	high risk for suicide
LIP	licensed independent practitioner
LST	life-sustaining treatment
LSTD	life-sustaining treatment 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
SPC	suicide prevention coordinator
SPS	Sterile Processing Services
TJC	The Joint Commission
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Ann Arbor VA Medical Center, which includes multiple outpatient clinics in Michigan and Ohio. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

1. COVID-19 pandemic readiness and response¹
2. Quality, safety, and value
3. Medical staff privileging
4. Medication management (targeting long-term opioid therapy for pain)
5. Mental health (focusing on the suicide prevention program)
6. Care coordination (spotlighting life-sustaining treatment decisions)
7. Women's health (examining comprehensive care)
8. High-risk processes (emphasizing reusable medical equipment)

The unannounced virtual review was conducted at the Ann Arbor VA Medical Center during the week of July 20, 2020. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this medical center's performance within the identified focus areas at the time of the OIG review. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this medical center and other Veterans Health Administration (VHA) facilities

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

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

Inspection Results

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

Leadership and Organizational Risks

At the time of the OIG's virtual review, the medical center's leadership team consisted of the Director, Chief of Staff, Associate Director for Patient Care Services, Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure, with Executive Leadership Council oversight of several working groups. The leaders monitor patient safety and care through the Quality, Safety, Value and Risk Committee, 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 given that all positions were permanently assigned and only the Assistant Director had been in the role for less than a year. The Director, Chief of Staff, and Associate Director had worked together at the medical center since 2018. The Associate Director for Patient Care Services, the most tenured leader, was permanently assigned in January 2007.

The OIG reviewed employee satisfaction survey results and concluded that the leaders appeared to have created a positive workplace environment where employees felt safe bringing forth issues and concerns. For this medical center, aggregate patient survey results were generally better than VHA averages. However, gender-specific survey responses revealed opportunities to improve outpatient experiences in the patient-centered medical home and specialty care settings.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and did not identify any substantial organizational risk factors.²

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one

² 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."

way to understand the similarities and differences between the top and bottom performers within VHA.³

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

COVID-19 Pandemic Readiness and Response

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

Quality, Safety, and Value

The medical center complied with requirements for a committee responsible for quality, safety, and value oversight functions, patient safety elements, and protected peer reviews. However, the OIG expressed concerns about the Quality, Safety, Value and Risk Committee's improvement action implementation.

Medical Staff Privileging

The medical center met requirements for focused professional practice evaluations. However, the OIG noted weaknesses with ongoing professional practice evaluations and provider exit reviews.⁶

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

⁴ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017. Community living centers, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

⁵ VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

⁶ 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."

Medication Management

The OIG observed compliance with some of the elements of expected performance, including pain screening, documented justification for concurrent therapy with benzodiazepines, and use of a multidisciplinary pain management committee to oversee and monitor required quality measures. However, the OIG identified opportunities for improvement with aberrant behavior risk assessments, urine drug testing, informed consent, and patient follow-up after therapy initiation.

Mental Health

The medical center generally complied with the requirements for a suicide prevention coordinator, outreach activities, and patient follow-up. However, the OIG noted concerns with suicide safety plans and annual staff training.

Women's Health

The OIG found compliance with the provision of care and staffing requirements for women's health. However, the OIG identified deficiencies with the Women Veterans Health Committee.

High Risk Processes

The medical center met many of the requirements for the proper operations and management of reusable medical equipment. However, the OIG identified deficiencies with daily cleaning schedules, temperature and humidity monitoring, and staff training.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two nonclinical and seven clinical) and subsequently issued nine recommendations for improvement to the Medical Center Director, Chief of Staff, and Associate Director for Patient Care Services. The number of recommendations should not be used, however, as a gauge for the overall quality of care 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 Comprehensive Healthcare Inspection Program findings and recommendations and provided acceptable improvement plans (see appendixes G and H, pages 65–66, and the responses within the body of the report for the full text of the directors’ comments). The OIG will follow up on the planned actions for the open recommendations until they are completed.



JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Contents

Abbreviations.....	ii
Report Overview.....	iii
Inspection Results.....	iv
Purpose and Scope.....	1
Methodology.....	3
Results and Recommendations.....	4
Leadership and Organizational Risks.....	4
COVID-19 Pandemic Readiness and Response.....	21
Quality, Safety, and Value.....	22
Recommendation 1	25
Medical Staff Privileging.....	27
Recommendation 2	29
Recommendation 3	30
Medication Management: Long-Term Opioid Therapy for Pain.....	32
Mental Health: Suicide Prevention Program.....	35
Recommendation 4	39
Recommendation 5	40
Care Coordination: Life-Sustaining Treatment Decisions	41

Women’s Health: Comprehensive Care..... 44

 Recommendation 6 46

High-Risk Processes: Reusable Medical Equipment..... 47

 Recommendation 7 49

 Recommendation 8 50

 Recommendation 9 51

Appendix A: Comprehensive Healthcare Inspection Program Recommendations..... 52

Appendix B: Medical Center Profile..... 55

Appendix C: VA Outpatient Clinic Profiles..... 56

Appendix D: Patient Aligned Care Team Compass Metrics..... 59

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions.....61

Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and
 Learning (SAIL) Measure Definitions 63

Appendix G: VISN Director Comments 65

Appendix H: Medical Center Director Comments..... 66

OIG Contact and Staff Acknowledgments..... 67

Report Distribution..... 68



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 Ann Arbor VA 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.¹

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change.² Effective leadership has been cited as “among the most critical components that lead an organization to effective and successful outcomes.”³ Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

Because of the COVID-19 pandemic, the OIG converted this site visit to a virtual review, paused physical inspection steps—especially those involved in the environment of care-focused review topic—and initiated a COVID-19 pandemic readiness and response evaluation.⁴

As such, to examine risks to patients and the organization, the OIG focused on core processes in the following nine areas of administrative and clinical operations (see figure 2):⁵

1. Leadership and organizational risks
2. COVID-19 pandemic readiness and response
3. Quality, safety, and value (QSV)
4. Medical staff privileging

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

² Anam Parand et al., “The role of hospital managers in quality and patient safety: a systematic review,” *British Medical Journal*, 4, no. 9 (September 5, 2014): e005055.

³ Danae Sfantou et al., “Importance of Leadership Style Towards Quality of Care Measures in Healthcare Settings: A Systematic Review,” *Healthcare (Basel)* 5(4), (December 2017): 73.

⁴ “Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It,” World Health Organization, accessed August 25, 2020, [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-\(covid-2019\)-and-the-virus-that-causes-it](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it). COVID-19 (coronavirus disease) is an infectious disease caused by the “severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).”

⁵ Virtual CHIP site visits addressed these processes during fiscal year 2020 quarter 4 (July 1, 2020, through September 30, 2020); they may differ from prior years' focus areas.

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)

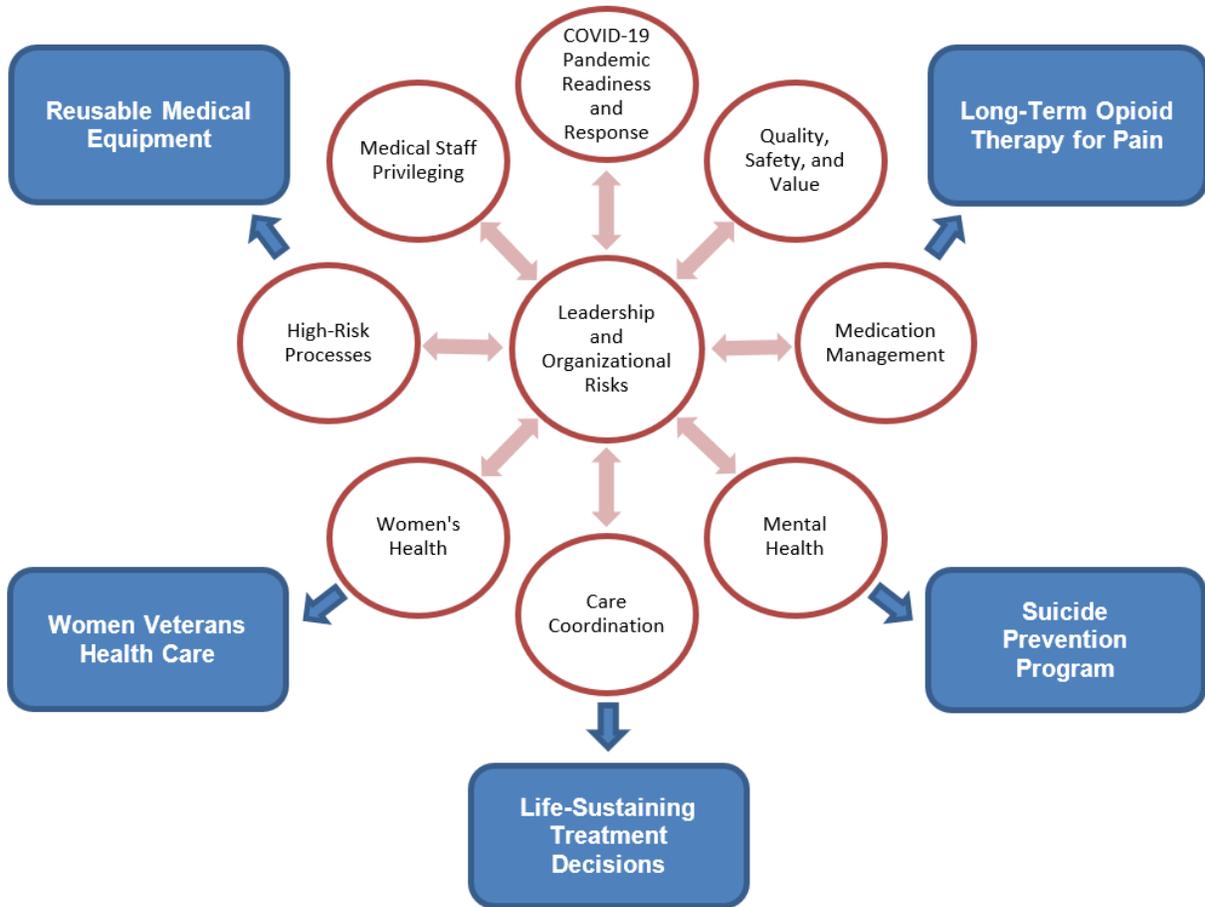


Figure 2. Fiscal year 2020 comprehensive healthcare inspection of operations and services.

Source: VA OIG.

Methodology

The Ann Arbor VA Medical Center includes multiple outpatient clinics in Michigan and Ohio. 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 and clinical functions, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.⁶ The team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

The inspection examined operations from March 31, 2018, through July 24, 2020, the last day of the unannounced multiday evaluation.⁷ During the virtual site visit, the OIG did not receive any complaints beyond the scope of the inspection.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.⁹ The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

This report's recommendations for improvement address problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the 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 medical center leaders developed based on the reasons for noncompliance.

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

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

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

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

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

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA medical center. Leadership and organizational risks can affect the medical center's ability to provide care in the clinical focus areas.¹⁰ To assess the medical center's risks, the OIG considered several indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation surveys and oversight inspections
5. Identified factors related to possible lapses in care and medical center response
6. VHA performance data (medical center)
7. VHA performance data (community living centers (CLCs))¹¹

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this 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.

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

¹¹ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017. CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

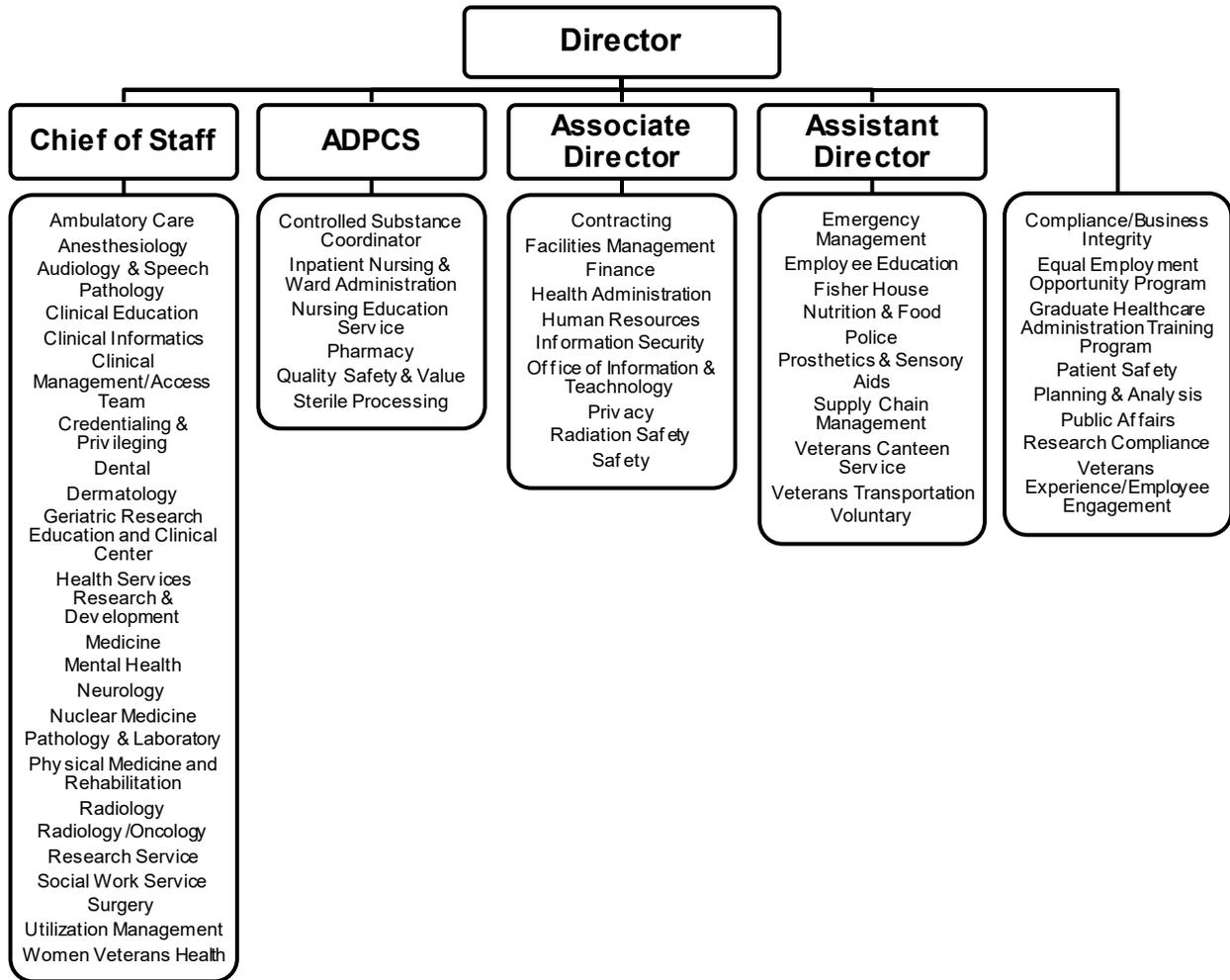


Figure 3. Medical center organizational chart.

Source: Ann Arbor VA Medical Center (received July 22, 2020).

At the time of the OIG virtual site visit, only the Assistant Director had been in the position for less than a year. The Director, Chief of Staff, and Associate Director had served in their roles since 2018. The ADPCS, the most tenured leader, had served in the role since January 2007 (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Medical Center Director	February 18, 2018
Chief of Staff	July 1, 2018
Associate Director for Patient Care Services	January 7, 2007
Associate Director	November 11, 2018
Assistant Director	October 27, 2019

Source: VISN 10 Human Resources strategic business partner (received July 23, 2020).

To help assess the medical center executive leaders’ engagement, the OIG interviewed the Director, Chief of Staff, ADPCS, Associate Director, and Assistant Director regarding their knowledge of various performance metrics and involvement and support of actions to improve or sustain performance.

The executive leaders were knowledgeable within their scope of responsibilities about VHA data and/or medical center-level factors contributing to specific poorly performing Strategic Analytics for Improvement and Learning (SAIL) measures. In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and patient experiences. These are discussed in greater detail below.

The Director serves as the chairperson of the Executive Leadership Council, which has the authority and responsibility to establish policy, maintain quality care standards, and perform organizational management and strategic planning. The Executive Leadership Council oversees various working groups such as the Clinical Executive, Administrative Executive, and Nurse Executive Committees.

These leaders monitor patient safety and care through the Quality, Safety, Value and Risk Committee. The Quality, Safety, Value and Risk Committee is responsible for tracking and trending quality of care and patient outcomes and reports to the Executive Leadership Council (see figure 4).

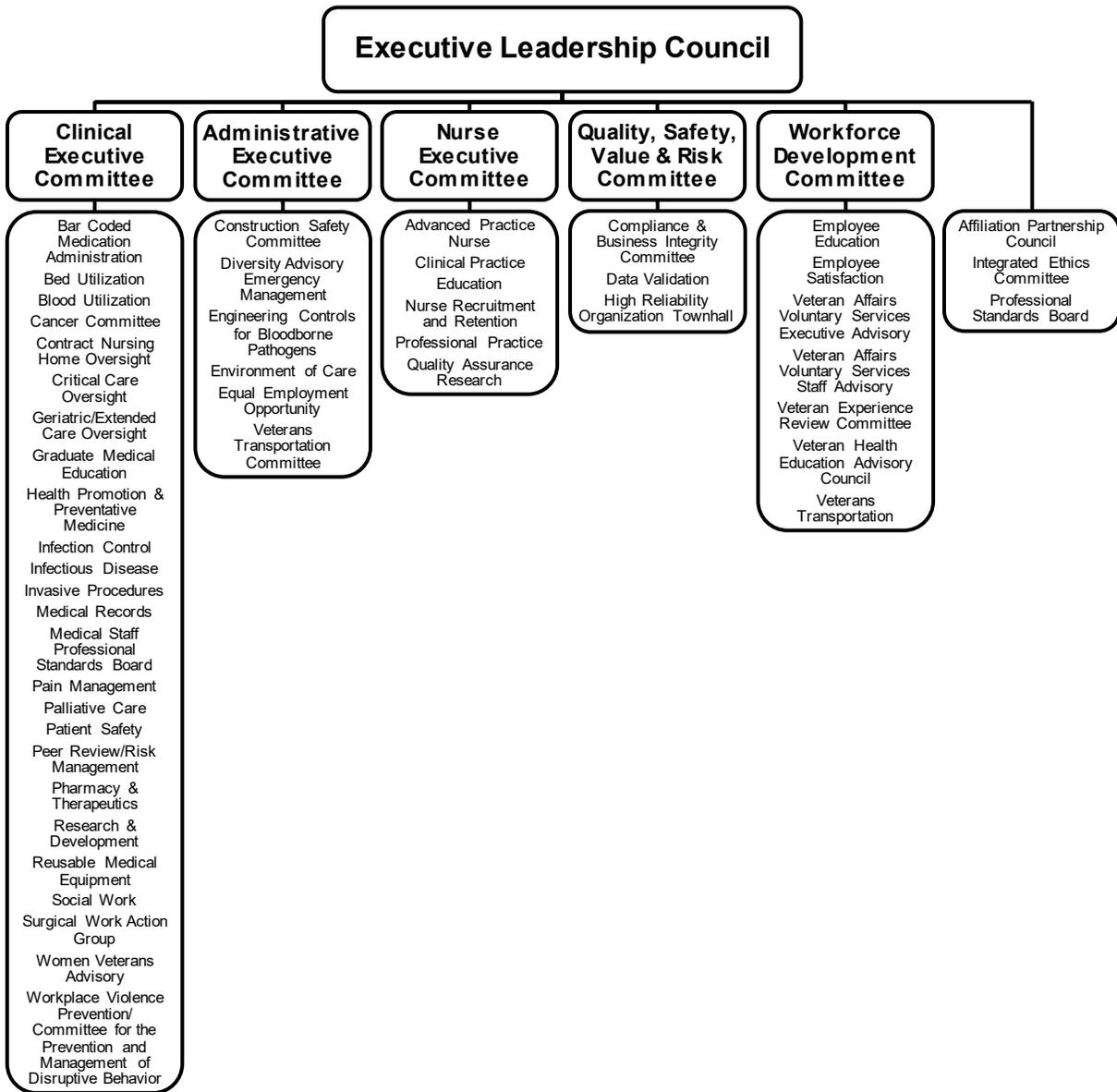


Figure 4. Medical center committee reporting structure.

Source: Ann Arbor VA Medical Center (received July 20, 2020 and September 11, 2020).

Note: Women Veterans Advisory is also known at this medical center as the Women Veterans Health Committee.

Employee Satisfaction

The All Employee Survey is an “annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential.” Since 2001, the instrument has been refined several

times in response to VA leaders’ inquiries on VA culture and organizational health.¹² Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on medical center leadership.

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA’s All Employee Survey from October 1, 2018, through September 30, 2019.¹³ Table 2 provides relevant survey results for VHA, the medical center, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA’s All Employee Survey. The OIG found the medical center averages for the selected survey leadership questions were lower than the VHA average.¹⁴ The scores for the ADPCS were similar to or lower than the VHA averages. However, survey scores for the Director, Chief of Staff, Associate Director, and Assistant Director were consistently higher than those for VHA and the medical center.¹⁵ These leaders appeared to have created a positive workplace environment and were actively engaged with employees (for example, they held regular town hall meetings and performed executive leadership walking rounds).

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: <i>Servant Leader Index Composite.*</i>	0–100 where higher scores are more favorable	72.6	71.5	84.7	88.9	72.5	88.1	90.0

¹² “VHA Workforce Surveys Portal,” VHA Support Service Center, accessed November 30, 2020, <http://aes.vssc.med.va.gov>.

¹³ 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.

¹⁴ The OIG makes no comment on the adequacy of the VHA average for each selected survey element. The VHA average is used for comparison purposes only.

¹⁵ It is important to note that the 2019 All Employee Survey results are not reflective of employee satisfaction with the current Assistant Director, who assumed the role after the survey was administered.

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>In my organization, senior leaders generate high levels of motivation and commitment in the workforce.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.4	3.2	3.8	3.9	3.4	4.1	4.2
All Employee Survey: <i>My organization's senior leaders maintain high standards of honesty and integrity.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.4	4.2	4.2	3.4	4.6	4.3
All Employee Survey: <i>I have a high level of respect for my organization's senior leaders.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.4	4.2	4.0	3.3	4.5	4.4

Source: VA All Employee Survey (accessed June 16, 2020).

**The Servant Leader Index “is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others’ contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others’ needs before their own.”*

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA’s All Employee Survey.¹⁶ The medical center averages for the selected survey questions were similar to the VHA average. Survey results for the leadership team members were generally better than the VHA average, and it appears that leaders have created a culture where employees feel safe bringing forth issues and concerns.¹⁷

¹⁶ 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.

¹⁷ It is important to note that the 2019 All Employee Survey results are not reflective of employee satisfaction with the current Assistant Director, who assumed the role after the survey was administered.

**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>I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.7	4.2	4.3	3.9	4.5	4.7
All Employee Survey: <i>Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).</i>	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.7	4.1	4.4	4.1	4.4	4.4
All Employee Survey: <i>In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?</i>	0 (Never) – 6 (Every Day)	1.4	1.4	1.1	0.8	1.3	1.5	0.9

Source: VA All Employee Survey (accessed June 16, 2020).

Patient Experience

To assess patient experiences with the medical center, which directly reflect on its leaders, the OIG team reviewed survey results that relate to the period of October 1, 2018, through September 30, 2019. VHA’s Patient Experiences Survey Reports provide results from the Survey of Healthcare Experiences of Patients program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients’ experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for VHA and the medical center.¹⁸ The OIG noted that the medical center generally provided better patient experiences than the average of all VHA facilities combined.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients’ attitudes toward their healthcare experiences (see table 4). For this medical center, patient survey results were notably higher than VHA averages—with the exception of the outpatient specialty care average, which was similar to the VHA average. Patients appeared satisfied with the care provided.

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

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): <i>Would you recommend this hospital to your friends and family?</i>	The response average is the percent of “Definitely Yes” responses.	68.3	78.5
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	84.9	90.7
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	77.3	84.4

¹⁸ Ratings are based on responses by patients who received care at this medical center.

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (outpatient specialty care): <i>I felt like a valued customer.</i>	The response average is the percent of "Agree" and "Strongly Agree" responses.	77.9	77.3

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed December 23, 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 455,875.¹⁹ 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 male and female patients were generally satisfied with their inpatient care experience. However, Patient-Centered Medical Home and Specialty Care Survey scores for female medical center patients were generally lower than female VHA averages, and male patient scores were generally similar to or lower than corresponding VHA averages. Leaders appear to have opportunities to improve male and female patient experiences in securing patient-centered medical home and specialty care appointments as soon as they are needed and to address concerns with specialty care providers.

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>During this hospital stay, how often did doctors treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	88.6	90.5

¹⁹ VA National Center for Veterans Analysis and Statistics, *The Past, Present and Future of Women Veterans*, February 2017.

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>During this hospital stay, how often did nurses treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	87.1	82.0
<i>Would you recommend this hospital to your friends and family?</i>	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	77.7	95.1

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

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

The medical center averages are based on 456–460 male and 20 female respondents, depending on the question.

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>In the last 6 months, when you contacted this provider’s office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	48.4	38.0
<i>In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	60.5	36.4

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	72.3	81.5

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

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

The medical center averages are based on 384–1,178 male and 26–67 female respondents, depending on the question.

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	38.4	15.0
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	55.0	49.1	52.1
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	67.2	57.5

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

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

The medical center averages are based on 478–1,592 male and 15 or 59 female respondents, depending on the question.

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys—including those conducted for cause—by oversight and accrediting agencies to gauge how well leaders respond to identified problems.²⁰ Table 8 summarizes the relevant medical center inspections most recently performed by the OIG and The Joint Commission (TJC).²¹ Of note, at the time of the OIG virtual review, the medical center had closed all recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in March 2018.²²

At the time of the virtual review, 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.²³ Additional results included the Long-Term Care Institute's inspection of the medical center's CLC.²⁴

²⁰ "Profile Definitions and Methodology: Joint Commission Accreditation," *American Hospital Directory*, accessed December 12, 2020, https://www.ahd.com/definitions/prof_accred.html. "The Joint Commission conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization."

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

²² VA OIG, *Comprehensive Healthcare Inspection Program Review of the VA Ann Arbor Healthcare System, Michigan*, Report No. 18-00621-245, August 14, 2018.

²³ 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. "About the College of American Pathologists," College of American Pathologists, accessed February 20, 2019, <https://www.cap.org/about-the-cap>. For 70 years, the College of American Pathologists has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016. VHA laboratories must meet the requirements of the College of American Pathologists.

²⁴ "About Us," Long Term Care Institute, accessed on March 6, 2019, <http://www.ltciorg.org/about-us/>. The Long Term Care Institute states that it has been to over 4,000 healthcare facilities conducting quality reviews and over 1,145 external regulatory surveys since 1999. The Long Term Care Institute is "focused on long-term care quality and performance improvement; compliance program development; and review in long-term care, hospice, and other residential care settings."

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (<i>Comprehensive Healthcare Inspection Program Review of the VA Ann Arbor Healthcare System, Michigan, Report No. 18-00621-245, August 14, 2018</i>)	March 2018	3	0
OIG (<i>Quality of Care Concerns Regarding a Patient Who Had Cardiac Surgery at the VA Ann Arbor Healthcare System, Michigan, Report No. 17-04875-308, September 27, 2018</i>)	October 2017	2	0
TJC Hospital Accreditation	July 2018	38	0
TJC Behavioral Health Care Accreditation		5	0
TJC Home Care Accreditation		2	0

Source: OIG and TJC (inspection/survey results verified with the Chief, Quality Management on July 20, 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’s review of the medical center’s accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. The OIG confirmed that for all sentinel events and institutional disclosures, program managers conducted required investigations, such as root cause analyses and peer review, and took corrective actions by developing standardized processes and protocols and enhancing staff education.

Table 9 lists the reported sentinel events and disclosures from March 26, 2018 (the prior OIG comprehensive healthcare inspection), through July 20, 2020.²⁵

Table 9. Summary of Selected Organizational Risk Factors (March 26, 2018, through July 20, 2020)

Factor	Number of Occurrences
Sentinel Events	11
Institutional Disclosures	3
Large-Scale Disclosures	0

Source: Ann Arbor VA Medical Center’s Chief, Quality Management (received July 20, 2020).

Veterans Health Administration Performance Data

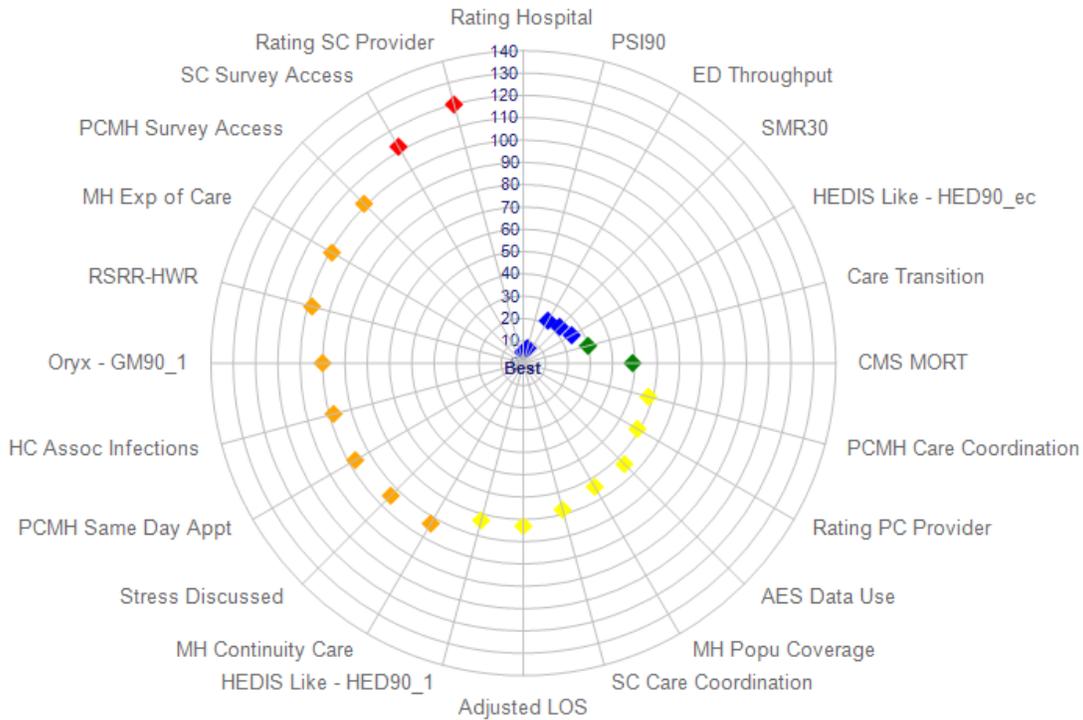
The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with “measures on healthcare quality, employee satisfaction, access to care, and efficiency.” Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.²⁶

Figure 5 illustrates the medical center’s quality of care and efficiency metric rankings and performance compared with other VA facilities as of December 31, 2019. Of note, figure 5 uses blue and green data points to indicate high performance for the Ann Arbor VA Medical Center (for example, in the areas of rating (of) hospital, emergency department (ED) throughput, and

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 Ann Arbor VA Medical Center is a high complexity (1b) affiliated system as described in appendix B.) 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.” 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 the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse.” VHA Directive 1004.08. VHA defines a large-scale disclosure of adverse events (sometimes referred to as a “notification”) as “a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue.”

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

care transition). Metrics that need improvement are denoted in orange and red (for example, health care (HC) associated (assoc) infections, specialty care (SC) survey access, and rating (of SC provider)).²⁷



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

Figure 5. Medical center quality of care and efficiency metric rankings for fiscal year 2020 quarter 1 (as of December 31, 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 &

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

Medicaid Services’ (CMS) *Nursing Home Compare* and provides a single resource to review quality measures and health inspection results.²⁸

Figure 6 illustrates the medical center’s CLC quality rankings and performance compared with other VA CLCs as of December 31, 2019. Figure 6 uses blue and green data points to indicate high performance for the Ann Arbor CLC (for example, in the areas of physical restraints–long-stay (LS), falls with major injury (LS), and moderate-severe pain (SS)). Metrics that need improvement are denoted in orange and red (for example, outpatient ED visit (SS), catheter in bladder (LS), and improvement in function (SS)).²⁹

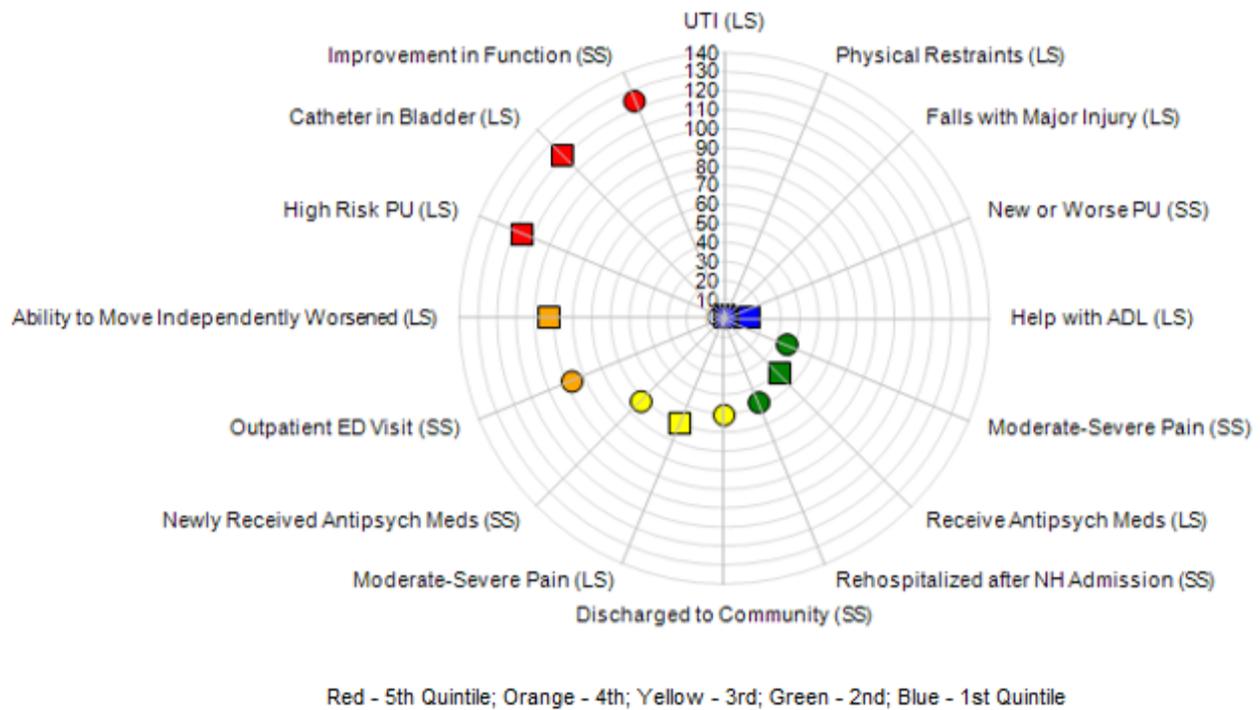


Figure 6. Ann Arbor CLC quality measure rankings for fiscal year 2020 quarter 1 (as of December 31, 2019).

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.

²⁸ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, July 23, 2020. “In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several “star” ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand an assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes.”

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

Leadership and Organizational Risks Conclusion

The medical center executive leadership team appeared stable, as all positions were permanently assigned and only the Assistant Director had been assigned for less than a year. Employee satisfaction survey data revealed that leaders had created a positive workplace environment where employees felt safe bringing forth issues and concerns. Patient experience survey data indicated satisfaction with inpatient care provided but also highlighted opportunities to improve veterans' experiences in securing patient-centered medical home and specialty care appointments as soon as they are needed and to address concerns with specialty care providers. The OIG's review of the medical center's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve employee satisfaction and patient experiences. In addition, the executive leaders were knowledgeable within their scope of responsibilities about selected VHA data used by the SAIL and CLC SAIL measures and should continue to take actions to sustain and improve performance.

COVID-19 Pandemic Readiness and Response

On March 11, 2020, due to the “alarming levels of spread and severity” of COVID-19, the World Health Organization declared a pandemic.³⁰ VHA subsequently issued its *COVID-19 Response Plan* on March 23, 2020, which presents strategic guidance on prevention of viral transmission among veterans and staff and appropriate care for sick patients.³¹ During this time, VA continued providing for veterans’ healthcare needs and engaged its fourth mission, “the provision of hospital care and medical services during certain disasters and emergencies” to persons “who would otherwise not have eligibility to receive such care and services.”³² “In effect, VHA facilities provide a safety net for the nation’s hospitals should they become overwhelmed—for veterans (whether previously eligible or not) and non-veterans.”³³

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

- Emergency preparedness
- Supplies, equipment, and infrastructure
- Staffing
- Access to care
- CLC patient care and operations

The OIG also surveyed medical center staff to solicit their feedback and potentially identify any problematic trends and/or issues that may require follow-up. The results of the OIG’s evaluation of the medical center’s COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.³⁴

³⁰ “WHO Director General’s opening remarks at the media briefing on COVID-19 – 11 March 2020,” World Health Organization, accessed March 23, 2020, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

³¹ VHA Office of Emergency Management, *COVID-19 Response Plan*, March 23, 2020.

³² VA’s missions include serving veterans through care, research, and training. A fourth mission for the provision of hospital care and medical services during certain disasters and emergencies was outlined by 38 CFR § 17.86 – “[d]uring and immediately following a disaster or emergency... VA under 38 U.S.C § 1785 may furnish hospital care and medical services (including those who otherwise do not have VA eligibility for such care and services) responding to, involved in, or otherwise affected by that disaster or emergency.”

³³ VA OIG, *OIG Inspection of Veterans Health Administration’s COVID-19 Screening Processes and Pandemic Readiness, March 19–24, 2020*, Report No. 20-02221-120, March 26, 2020.

³⁴ VA OIG, *Comprehensive Healthcare Inspection of Facilities’ COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care.³⁵ To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation.³⁶ 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.³⁷

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; 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.³⁸ 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.³⁹ The OIG team examined the completion of the following elements:

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

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

³⁶ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

³⁷ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*.

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

³⁹ VHA Directive 1190.

- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit⁴⁰
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the 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.⁴¹ 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.⁴² 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.⁴³ Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the medical center.⁴⁴ The medical center was assessed for its performance on several dimensions:

⁴⁰ VHA Directive 1190.

⁴¹ VHA Directive 1117, *Utilization Management Program*, October 8, 2020. UM reviews include evaluating the "appropriateness, medical necessity and the efficiency of health care services, according to evidence-based criteria."

⁴² VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended on April 30, 2019.

⁴³ 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."

⁴⁴ VHA Handbook 1050.01.

- Annual completion of a minimum of eight root cause analyses⁴⁵
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of an annual patient safety report to 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.⁴⁶

Quality, Safety, and Value Findings and Recommendations

The medical center complied with most of the requirements for quality, safety, and value. However, the OIG identified weaknesses in the interdisciplinary review of UM data and the quality committee's implementation of improvement actions.

At the time of the OIG inspection, VHA required that the Medical Center Director ensure an interdisciplinary group review UM data on an ongoing basis. This group must include, but not be limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [Chief Business Office Revenue-Utilization Review]."⁴⁷ The OIG found that from January 17 through November 5, 2019, the Bed Utilization Committee, the medical center's group responsible for the review of UM data, met monthly.⁴⁸ However, social work and mental health representatives attended inconsistently, and CBO R-UR had no representation. This resulted in a lack of expertise in the review and analysis of utilization management data. The Bed Utilization Committee Chair reported being unaware of the requirement to include a CBO R-UR representative as a member of the committee, and the Chief, Quality Management stated mental health and social work representatives had competing collateral duties that prevented consistent attendance. On October 8, 2020, VHA changed the

⁴⁵ VHA Handbook 1050.01, "The requirement for a total of eight RCAs [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of RCAs is driven by the events that occur and the SAC [Safety Assessment Code] score assigned to them. At least four analysis per fiscal year must be individual RCAs, with the balance being Aggregated Reviews or additional individual RCAs."

⁴⁶ For CHIP visits, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁴⁷ VHA Directive 1117(2).

⁴⁸ The Bed Utilization Committee met monthly except for July and October 2019.

representatives who review UM data to a “multidisciplinary committee, which may include representatives from” various services. Therefore, the OIG made no recommendation.⁴⁹

VHA programs, including hospitals, are “required to achieve and maintain The Joint Commission accreditation.”⁵⁰ TJC standards state that facilities establish a governing body to provide oversight and support for quality and safety processes.⁵¹ TJC standards also state facilities should measure and analyze performance using data so that improvement “effectiveness can be sustained, assessed, and measured” and to ensure that recommended actions are fully implemented and monitored for sustained improvement.⁵² The Quality, Safety, Value and Risk Committee (formerly known as the Quality Management Council) serves as the governing body that has oversight of QSV functions.⁵³ The OIG reviewed Quality, Safety, Value and Risk Committee meeting minutes from January through December 2019 and found that the minutes did not include evidence that action items for identified problems or opportunities for improvement were fully implemented. This may have resulted in missed opportunities to improve the medical center’s quality of care and patient safety processes. The Chief, Quality Management believed that medical center efforts met requirements, as workgroups were created to follow through on action item implementation. However, the Chief, Quality Management acknowledged that the medical center lacked evidence that action items were fully implemented because the assigned workgroups did not consistently report progress to the Quality, Safety, Value and Risk Committee.

Recommendation 1

1. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures action items are fully implemented when problems or opportunities for improvement are identified.

⁴⁹ VHA Directive 1117, *Utilization Management Program*, October 8, 2020.

⁵⁰ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

⁵¹ TJC. Leadership Standards rationales LD.01.01.01 and LD.01.03.01.

⁵² TJC. Leadership Standards rationales LD.03.02.01 and LD.03.05.01 and Performance Improvement Standard PI.03.01.01 Elements of Performance 2 and 4.

⁵³ The Quality Management Council was renamed the Quality, Safety, Value and Risk Committee in October 2019.

Medical center concurred.

Target date for completion: June 30, 2021

Medical center response: The Medical Center Director evaluated the Quality, Safety, Value, & Risk (QSVR) process of monitoring implemented improvement actions to identify reasons for noncompliance. The QSVR committee had appropriately identified improvement opportunities and formally chartered workgroups to identify goals, actions, and sustain improvement activity.

Quality Management will conduct audits of QSVR committee meeting minutes to ensure all action items have appropriate follow-up. Compliance will be monitored until a 90% compliance rate is sustained for six (6) consecutive months. The numerator is the number of action items completed within six months or by the identified target date. The denominator is the number of actions items in each month.

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).⁵⁴

Clinical privileges need to be specific and based on the individual practitioner’s clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the Director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo reprivileging prior to their expiration.⁵⁵

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. VA facilities must also 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.”⁵⁶ The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
 - Establishment of criteria in advance
 - Use of minimum criteria for selected specialty LIPs⁵⁷
 - Clear documentation of the results and time frames
 - Evaluation by another provider with similar training and privileges
- OPPEs
 - Application of criteria specific to the service or section
 - Use of minimum criteria for selected specialty LIPs⁵⁸
 - Evaluation by another provider with similar training and privileges

⁵⁴ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

⁵⁵ VHA Handbook 1100.19.

⁵⁶ VHA Handbook 1100.19.

⁵⁷ VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁵⁸ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*.

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

VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.⁵⁹ 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."⁶⁰ 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:

- Two solo/few practitioners who underwent initial or reprivileging during calendar year 2019⁶¹
- Six LIPs who completed an FPPE in calendar year 2019⁶²
- Ten LIPs privileged during calendar year 2019

⁵⁹ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. (This handbook was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18. The two documents contain similar language related to state licensing board requirements.)

⁶⁰ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (VHA Directive 1100.18 requires the "Credentialing and Privileging program manager to be responsible for the [state licensing board] reporting process and oversight of timely completion of exit reviews." The new directive also revises the requirement for exit review forms to be completed within seven calendar days to seven business days.)

⁶¹ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*. This memorandum refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers few practitioners as being less than three providers in the facility that are privileged in a particular specialty.

⁶² The OIG excluded LIPs hired between January 1 and March 31, 2019, to prevent data overlap. During this time frame, action items were in progress to show sustained compliance with recommendation for FPPE time frames from the previous CHIP report (August 14, 2018).

- Twenty LIPs who left the medical center in calendar year 2019

Medical Staff Privileging Findings and Recommendations

The medical center generally complied with requirements for FPPEs. However, the OIG noted weaknesses with OPPE and provider exit review processes.

VHA requires that LIPs are evaluated by practitioners with similar training and privileges.⁶³ For 2 of 12 LIPs—one general and one solo LIP—the OIG found that OPPE results were not based on evaluation by another practitioner with similar training and privileges. As a result, the LIPs continued to deliver care without thorough competency evaluations, which could have affected the quality of care and/or patient safety. For the solo LIP, the Credentialing Supervisor indicated awareness of the requirement but was unable to find an outside provider to complete the review. For the general LIP, a nonequivalent provider signed the two-year OPPE summary form and the Credentialing Supervisor expressed the belief that this process met requirements.

Recommendation 2

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

Medical center concurred.

Target date for completion: June 30, 2021

Medical center response: The Chief of Staff evaluated reasons for noncompliance and implemented improvement activity. Credentialing and Privileging staff will monitor the compliance reviews of general and solo providers to ensure reviews are completed by other providers with similar training and privileges.

Compliance will be monitored until 90% compliance rate is sustained for six (6) consecutive months. The numerator is the number of general and solo providers due for review each month completed by other providers with similar training and privileges. The denominator is the number of general and solo providers due for review each month.

At the time of the OIG inspection, VHA required provider exit review forms, which document the evaluation of LIPs' clinical practice, to "be completed within 7 calendar days of the departure of a licensed health care professional from a VA facility."⁶⁴ For the 20 LIPs who departed the

⁶³ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*.

⁶⁴ VHA Notice 2018-05.

medical center in 2019, the OIG found that 15 exit review forms were not completed within 7 calendar days.

As of January 28, 2021, VHA requires the facility director to ensure that exit forms are completed within 7 business days.⁶⁵ Based on the updated requirement, 11 exit review forms were not completed within the new time frame. Inconsistent performance of this process could have resulted in delayed reporting of substandard care to SLBs. The Credentialing Supervisor 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 3

3. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that Provider Exit Review Forms are completed within seven business days of licensed independent practitioners' departure from the medical center.

⁶⁵ VHA Directive 1100.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Medical Center Director evaluated the provider exit review process and implemented several improvements. In September 2020, Credentialing and Privileging staff began weekly monitoring of Human Resources' Gains and Losses report for term dates and immediately sent provider exit review forms to the losing service. Completion of the provider exit form was also added to the employee clearance process.

In February 2021, VA Ann Arbor HCS implemented the VISN-wide streamlined, efficient electronic clearance process. The electronic clearance process includes the Credentialing and Privileging Office which ensures timely notification of an employee loss and starts the provider exit review process.

The Chief of Staff established September 30th each year (the end of contract for Fee Basis Providers) as the standard departure date for any Fee Basis Providers. A suspense will go out to services by July 30th each year requesting information and evaluations be sent on the last duty day of the year. For contracts, the Contracting Officer Representatives (COR) will be responsible for identifying departing contract provider departure dates. The COR will notify the applicable service chief and the Credentialing and Privileging office by email when a contract provider is identified as no longer providing services.

The Credentialing and Privileging staff is responsible for monthly monitoring until a 90% compliance rate is sustained for six (6) consecutive months. The numerator is the number of provider exit reviews completed within seven business days per month. The denominator is the number of providers who departed the medical center within a given month.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁶⁶ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁶⁷ 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.⁶⁸ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁶⁹

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.⁷⁰ Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.⁷¹ 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.⁷² 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.⁷³

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

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

⁶⁶ "Information Sheet on Opioid Overdose." World Health Organization, accessed November 6, 2019, https://www.who.int/substance_abuse/information-sheet/en/.

⁶⁷ "Opioid Overdose, Understanding the Epidemic," Centers for Disease Control and Prevention, accessed November 6, 2019, <https://www.cdc.gov/drugoverdose/epidemic>.

⁶⁸ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. February 2017.

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

⁷⁰ "Benzodiazepines, Street Names: Benzos, Downers, Nerve Pills, Tranks," U.S. Drug Enforcement Administration, accessed December 1, 2019, https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. Benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety."

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

⁷² VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020.

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

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

VHA also requires facilities to establish a multidisciplinary pain management committee “to provide oversight, coordination, and monitoring of pain management activities and processes.” Monitoring measures include, but are not limited to, “adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment...patient satisfaction, physical and psychosocial functioning, and quality of life.”⁷⁴ The OIG examined indicators for program oversight and evaluation:

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

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of all 29 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 medical center addressed some of the indicators of expected performance, including pain screening, concurrent therapy with benzodiazepines, and the use of a multidisciplinary pain management committee to oversee and monitor required quality measures. 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 that includes the patient’s history of substance abuse, psychological disease, and aberrant drug-related behaviors prior to initiating long-term opioid therapy.⁷⁵ The OIG determined that providers did not assess 14 percent of the patients reviewed for psychological disease.⁷⁶ This may have resulted in providers prescribing opioids for patients at high risk for misuse. The Deputy Associate Chief of Staff attributed the noncompliance to the current Patient Aligned Care Team model in which nurses complete the initial screening and only alert the

⁷⁴ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

⁷⁵ *Pain Management, Opioid Safety, VA Educational Guide (2014)*, July 2014. Examples of aberrant drug related behaviors include “lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents.” *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

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

provider if the screening was positive. In addition, the chief cited providers' competing priorities and demands with complex patients as contributing factors.

VA/DoD clinical practice guidelines also recommend that providers conduct a "UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter."⁷⁷ The OIG determined that providers did not conduct initial urine drug testing in 17 percent of the patient records reviewed.⁷⁸ This resulted in providers' inability to identify whether patients had substance use disorder(s), were potential diversion risks, or adhered to the prescribed medication regimen. The Deputy Associate Chief of Staff stated that providers' competing priorities and demands with complex patients contributed to inconsistent urine drug testing.

VHA requires providers to obtain and document informed consent prior to the initiation of therapeutic treatments that have a "significant risk of complication or morbidity," including long-term opioid therapy.⁷⁹ VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy as well as alternative therapies.⁸⁰ The OIG determined that providers did not document informed consent prior to initiating long-term opioid therapy in 48 percent of the patients reviewed.⁸¹ Therefore, patients may have received treatment without knowledge of the risks associated with long-term opioid therapy, including opioid dependence, tolerance, addiction, and fatal overdose. The Deputy Associate Chief of Staff reported that providers lacked clarity on the expectations for completing the electronic consent form.

VA/DoD clinical practice guidelines recommend that providers follow up with patients within three months after initiating long-term opioid therapy.⁸² The OIG determined that providers did not complete patient follow-up within three months for 31 percent of the patients reviewed.⁸³ Failure to conduct follow-up and assess adherence to the plans of care and effectiveness of interventions could have resulted in missed opportunities to evaluate the risks and benefits of continued opioid therapy. The Deputy Associate Chief of Staff reported that access issues led to the inability of providers to follow up with patients in a timely manner after initiation of therapy and complete the documentation requirements.

The OIG made no recommendations due to the small sample of patients identified for these review elements.

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

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

⁷⁹ VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, revised September 20, 2017.

⁸⁰ VHA Directive 1005.

⁸¹ Confidence intervals are not included because the data represents every patient in the study population.

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

⁸³ 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.⁸⁴ The suicide rate was 1.5 times greater for veterans than for nonveteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States.⁸⁵ Veterans who recently used VHA services had higher rates of suicide than other veterans and nonveterans.⁸⁶

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.⁸⁷

VHA requires that each medical center and very large community-based outpatient clinics 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.⁸⁸ The OIG examined various requirements related to SPCs:

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

⁸⁴ "Preventing Suicide." Centers for Disease Control and Prevention, accessed March 4, 2020, <https://www.cdc.gov/violenceprevention/suicide/fastfact.html>.

⁸⁵ 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*.

⁸⁶ VA Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*. Veterans who recently used VHA services are defined as having an encounter in the calendar year of death or in the previous year.

⁸⁷ VA Office of Mental Health and Suicide Prevention, *VA Office of Mental Health and Suicide Prevention Guidebook*, June 2018.

⁸⁸ VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. "Very large CBOCs (community-based outpatient clinics) are those that serve more than 10,000 unique veterans each year." The Veterans Crisis Line connects veterans with qualified responders through a confidential toll-free hotline, online chat, and text-messaging service to receive confidential support 24 hours a day. Community outreach activities are described in VHA Handbook 1160.01.

VHA also requires that any patient determined to be at high risk for suicide be added to the facility high-risk list and have a High Risk for Suicide (HRS) Patient Record Flag (PRF) placed in his or her electronic health record “as soon as possible but no later than 1 business day after such determination by the SPC.”⁸⁹ 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.”⁹⁰ 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.⁹¹ VHA also 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.⁹²

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.”⁹³ 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.”⁹⁴ 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.”⁹⁵

⁸⁹ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

⁹⁰ VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 8, 2008.

⁹¹ *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.

⁹² VA Manual, *Safety Plan Treatment Manual to Reduce Risk: Veteran Version*, August 20, 2008. A safety plan is a “written list of coping strategies and sources of support that patients can use during or preceding suicidal crises.” Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

⁹³ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

⁹⁴ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

⁹⁵ VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

The OIG is concerned that the updated requirement may result in delayed placement of HRS PRFs for at-risk patients. Without defined time frames for SPC determination that the HRS PRF is warranted, patients identified as at-risk for suicide could have flags placed in their charts several days after referral. For example, the current requirement would allow for a patient to be identified as high risk for suicide and referred to the SPC on Monday, the SPC to assess the patient for risk and determine the need for an HRS PRF on the following Friday, and the SPC to place an HRS PRF on the subsequent Monday (a week after referral).

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRF to “occur no earlier than 10 days before and no later than 10 days after the 90-day due date.”⁹⁶

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.⁹⁷ VHA also requires that all staff receive annual refresher training.⁹⁸ In addition, SPCs are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.⁹⁹

⁹⁶ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

⁹⁷ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym “S.A.V.E” summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

⁹⁸ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

⁹⁹ VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

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

- Relevant documents;
- The electronic health records of 35 outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The medical center generally complied with SPC requirements, outreach activities, and patient follow-up. However, the OIG found deficiencies.

With VHA’s original requirement that was in place when these patients received care—that “Any patient determined to be High Risk for Suicide must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination”¹⁰⁰—the OIG estimated that 37 percent of HRS PRFs were not placed within 24 hours of referral to the SPC.¹⁰¹ Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined time frame for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was 2 days (observed range was 0–16 days).

Further, 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.¹⁰² The OIG estimated that 60 percent of patients with an HRS PRF were not reevaluated at least every 90 days.¹⁰³ However, based on the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that clinical staff reviewed 83 percent of patients within the new time frame (observed range was 69–105 days).¹⁰⁴

Additionally, the OIG noted concerns with suicide safety plans and annual suicide prevention training.

VHA requires suicide prevention safety plans to be completed within seven days before or after the current HRS PRF date and include contact information with telephone numbers and/or

¹⁰⁰ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

¹⁰¹ The OIG estimated that 95 percent of the time, the true compliance rate is between 46.4 and 78.4 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰² VHA Directive 2008-036; VHA Directive 2010-053, *Patient Record Flags*, December 3, 2010.

¹⁰³ The OIG estimated that 95 percent of the time, the true compliance rate is between 24.1 and 56.4 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰⁴ VHA Notice 2020-13, *Inactivation Process for Category 1 High Risk For Suicide Patient Record Flags*, March 27, 2020.

locations of professional agencies that can help resolve a crisis.¹⁰⁵ The OIG estimated that 32 percent of safety plans were not completed on time and 29 percent of plans did not include contact information for professional agencies.¹⁰⁶ Failure to complete safety plans in a timely manner and include professional agency contact information may limit patients' awareness of available resources in a crisis. The SPCs attributed the noncompliance to patients refusing to complete safety plans by telephone and staff not documenting patients' refusal in the medical record. Further, the SPCs acknowledged a lack of awareness to include professional agencies' contact information.

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that suicide prevention coordinators complete suicide prevention safety plans within the required time frame and include contact information for professional agencies.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Chief of Staff evaluated the process for suicide prevention safety plans and implemented improvement activity. The Chief of Mental Health will ensure completed safety plans within seven days before or after the current HRS PRF date or prior to hospital discharge. The Chief of Mental Health will ensure safety plans include contact information with telephone numbers and/or locations of professional agencies.

Suicide Prevention Coordinators will monitor monthly until 90% compliance rate is sustained for six (6) consecutive months. The numerator is the number of suicide prevention safety plans completed that include all required elements. The denominator is the number of HRS PRF in each month.

VHA also requires that all employees complete annual suicide prevention refresher training.¹⁰⁷ The OIG found that 10 of 20 selected employees did not complete the required annual training. Lack of training could have resulted in suboptimal care to veterans who were at risk for suicide. The Talent Management System Domain Manager cited medical center managers' insufficient

¹⁰⁵ VHA DUSHOM Memorandum, *Suicide Prevention Safety Plan National CPRS Templates Implementation*, June 1, 2018; *Safety Plan Treatment Manual to Reduce Suicide Risk: Veteran Version*; *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

¹⁰⁶ The OIG estimated that 95 percent of the time, the true compliance rate is between 51.4 and 82.8 percent, which is statistically significantly below the 90 percent benchmark; the OIG estimated that 95 percent of the time, the true compliance rate is between 54.3 and 85.3 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰⁷ VHA Directive 1071.

oversight of mandatory training completion and lack of staff responsiveness to Talent Management System training reminders as the reasons for noncompliance.

Recommendation 5

5. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that employees complete annual suicide prevention refresher training.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Medical Center Director evaluated staff suicide risk and intervention training. Clinical staff are assigned Skills Training for Evaluation and Management of Suicide and non-clinical staff are assigned Signs, Ask, Validate, Encourage and Expedite (S.A.V.E.) refresher training annually. Supervisors will review monthly TMS (Talent Management System) reports to ensure staff complete annual TMS suicide prevention training on or before the annual due date.

Quality Management will conduct monthly audits of all annual TMS suicide prevention training until a compliance rate of at least 90% is achieved for six (6) consecutive months. The numerator is the number of staff completing the suicide prevention training within 365 days of their annual due date. The denominator is the total number of staff that were due to complete TMS annual suicide prevention training.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decision (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTDs. 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.”¹⁰⁸

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018.¹⁰⁹ 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.¹¹⁰ 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.¹¹¹

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.

¹⁰⁸ 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.

¹⁰⁹ VHA Handbook 1004.03(1). The medical facility must fully implement handbook requirements within 18 months of publication.

¹¹⁰ 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.

¹¹¹ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017. Hospice patients are defined as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. VHA Handbook 1004.03(1). Triggering events requiring goals of care conversations include those “prior to referral or following a dmission (e.g., within 24 hours) to VA or non-VA hospice.”

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

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

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

The 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 medical center's Ethics Consultation Service.¹¹² Inspectors examined if the medical center established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from the Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the 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.

¹¹² VHA Handbook 1004.03(1).

Care Coordination Findings and Recommendations

The medical center 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, the OIG estimated that¹¹³

- 77 percent of patients' LST progress notes addressed identification of a surrogate if the patient loses decision-making capacity, and¹¹⁴
- 59 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes.¹¹⁵

However, VHA deleted requirements for the documentation of these elements in the LST progress note.¹¹⁶ The OIG remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

¹¹³ VHA Handbook 1004.03(1).

¹¹⁴ The OIG estimated that 95 percent of the time, the true compliance rate is between 62.8 and 89.5 percent, which is statistically significantly below the 90 percent benchmark.

¹¹⁵ The OIG estimated that 95 percent of the time, the true compliance rate is between 43.3 and 74.3 percent, which is statistically significantly below the 90 percent benchmark.

¹¹⁶ VHA Handbook 1004.03(1).

Women’s Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹¹⁷ 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.¹¹⁸ To help the VA better understand the needs of the growing women veterans population, efforts have been made by VHA to identify and address the urgent needs “by examining health care use, preferences, and the barriers Women Veterans face in access to VA care.”¹¹⁹ 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.”¹²⁰

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.¹²¹ 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.”¹²²

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

¹¹⁷ “VETPOP2016 LIVING VETERANS BY AGE GROUP, GENDER, 2015-2045,” Table 1L, National Center for Veterans Analysis and Statistics, accessed November 14, 2019, https://www.va.gov/vetdata/Veteran_Population.asp.

¹¹⁸ “Veteran Population,” National Center for Veterans Analysis and Statistics, accessed September 16, 2019, https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf.

¹¹⁹ Department of Veterans Affairs, *Study of Barriers for Women Veterans to VA Health Care, Final Report*, April 2015.

¹²⁰ 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.

¹²¹ VHA Directive 1330.01(4), *Health Care Services for Women Veterans*, February 15, 2017, amended January 8, 2021.

¹²² VHA Directive 1330.01(4).

- Gynecologic care coverage available 24/7
- Facility women's health primary care providers designated
- Community-based outpatient clinic women's health primary care providers designated
- Oversight of program and monitoring of performance improvement data
 - Women Veterans Health Committee established
 - Quarterly meetings held
 - Core members attend
 - Quality assurance data collected and tracked
 - Reports made to clinical executive leaders
- Assignment of required staff
 - Women Veterans Program Manager
 - Women's Health Medical Director or clinical champion
 - Maternity Care Coordinator
 - Women's health clinical liaison at each community-based outpatient clinic

Women's Health Findings and Recommendations

The medical center complied with requirements for the provision of care indicators and staffing elements reviewed. However, the OIG identified weaknesses with the Women Veterans Health Committee.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership. That membership must include a women veterans program manager; a women's health medical director; "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership."¹²³

The OIG reviewed the Women Veterans Health Committee (also known as the Women Veterans Advisory at this medical center) meeting minutes and did not find evidence that the committee met from October through December 2019. Failure to meet regularly could negatively impact the

¹²³ VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018. (This was the directive in place for the time frame of the minutes reviewed in this report. It was amended on June 29, 2020 (1330.01(3)), and again on January 8, 2021 (1330.01(4)). All three directives contain the same or similar language regarding the Women Veterans Health Committee.)

committee's development and implementation of a strategic improvement plan for providing high-quality care for women veterans. The Women Veterans Program Manager reported cancelling the regularly scheduled October meeting due to an off-site conference and the November and December meetings due to the holidays.

Further, the OIG noted a lack of representation from medical and/or surgical subspecialties, radiology, or laboratory. The OIG also did not find evidence of meeting attendance by the Emergency Department representative, based on Women Veterans Health Committee meeting minutes reviewed. This resulted in a lack of expertise and oversight in data review and analysis as the committee planned and carried out improvements for quality and equitable women veterans care. The Women Veterans Program Manager and Women's Health Medical Director attributed the noncompliance to a lack of awareness of the committee core member requirements, turnover in membership and failure to replace vacant roles, and competing priorities.

The Women's Health Medical Director and Women Veterans Program Manager stated that the Women Veterans Health Committee did not report to the Clinical Executive Committee. Failure to report activities to executive leaders potentially impedes oversight and support of the women's health program. The Women's Health Medical Director and Women Veterans Program Manager indicated a belief that annual guest attendance to the Clinical Executive Committee and monthly reporting to the Veterans Experience Review Committee met reporting requirements.

Recommendation 6

6. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain the Women Veterans Health Committee meets regularly, appoints required members who consistently attend meetings, and reports to executive leaders.

Medical center concurred.

Target date for completion: December 31, 2021

The Chief of Staff evaluated the Women Veterans Health Committee (WVHC) Committee charter. The WVHC meets quarterly, at a minimum, with assigned core committee members (or alternate delegates) in attendance. The WVHC meetings often occur monthly which exceeds the frequency set forth in the VHA Directive 1330.01 (4). The WVHC meeting minutes will be reviewed and approved quarterly by the Clinical Executive Committee.

The Women Veterans Program Manager will ensure WVHC meetings occur at least quarterly with assigned core committee members in attendance, until a 90% compliance rate is sustained for three consecutive quarters. Quality Management will monitor oversight of the WVHC by the Clinical Executive Committee quarterly until 90% compliance rate is sustained for three consecutive quarters.

High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have Sterile Processing Services (SPS) “to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment.”¹²⁴ The goal of SPS is to “provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections.”¹²⁵ To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME
- Have standard operating procedures that are based on current manufacturers’ guidelines and reviewed at least triennially
- Use CensiTrac® Instrument Tracking System for tracking reprocessed instruments¹²⁶
- 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 inspections¹²⁷

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.¹²⁸ The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.¹²⁹

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station, personal protective equipment available for immediate use, and standard operating procedures readily available to guide the reprocessing of RME.¹³⁰

¹²⁴ VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

¹²⁵ Julie Jefferson, Martha Young. *APIC Text of Infection Control and Epidemiology*. Association for Professionals in Infection Control and Epidemiology, 2019. “Chapter 108: Sterile Processing.”

¹²⁶ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.

¹²⁷ VHA Directive 1116(2).

¹²⁸ 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.

¹²⁹ VHA Directive 7704(1), *Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment*, February 16, 2016.

¹³⁰ VHA Directive 1116(2).

VHA also requires facilities to provide training for staff who reprocess RME; this training must be provided and documented prior to the reprocessing of equipment. The required training includes mandatory initial competencies, continued annual and essential staff competency assessments, and monthly continuing education. This ensures that staff have sufficient aptitude, knowledge, and skills to effectively and safely reprocess and sterilize RME.¹³¹

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

- Requirements for administrative processes
 - RME inventory file is current
 - Standard operating procedures are based on current 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
 - Required temperature and humidity maintained
- Monitoring of quality assurance
 - High-level disinfectant solution tested
 - Bioburden tested
- Completion of staff training, competency, and continuing education
 - Required training completed in a timely manner
 - Competency assessments performed
 - Monthly continuing education received

¹³¹ VHA Directive 1116(2).

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 daily cleaning schedules, temperature and humidity monitoring, and monthly staff training.

VHA requires the Chief of SPS to “develop, implement and enforce a written daily cleaning schedule for all SPS areas.”¹³² The OIG found that endoscopy clinic leaders established a daily cleaning schedule for the reprocessing area in the endoscopy clinic but could not provide evidence that the schedule was enforced or followed. Failure to follow a daily written cleaning schedule may result in an environment that could compromise infection control standards. The Environmental Management Service Chief believed that monthly random fluorescent marker testing met the requirement.¹³³

Recommendation 7

7. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures the Chief of Sterile Processing Services enforces the endoscopy clinic reprocessing area’s daily cleaning schedule.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Associate Director for Patient Care Services evaluated the established daily cleaning schedule for the reprocessing area in the endoscopy clinic. The Chief of Sterile Processing Services and the Environmental Management Service Chief established a daily cleaning schedule for endoscopy clinic reprocessing areas.

The Chiefs of Sterile Processing Services and Environmental Management Services will ensure the ongoing monitoring and documentation of scheduled daily cleaning for the endoscopy clinic reprocessing areas. Quality Management will monitor completion of the daily cleaning schedules for endoscopy clinic reprocessing areas until sustained compliance of 90% has been met for six (6) consecutive months. The numerator will be the number of days cleaning for the five (5) designated endoscopy clinic reprocessing areas were documented after utilization each month. The denominator will be the number of rooms utilized daily each month.

¹³² VHA Directive 1116(2).

¹³³ “Options for Evaluating Environmental Cleaning,” Centers for Disease Control and Prevention, accessed January 27, 2021, <https://www.cdc.gov/hai/toolkits/appendices-evaluating-enviro-cleaning.html>. Fluorescent markers can be used to assess cleaning effectiveness by indicating whether a transparent gel applied to high-touch areas prior to cleaning has been effectively removed.

VHA requires strict temperature and humidity ranges in SPS preparation areas of 66–72 degrees Fahrenheit with a relative humidity of 20–60 percent.¹³⁴ The Chief of SPS and Chief of Facilities Management Service were unable to provide real time temperature and humidity measurements for the SPS main supply room and one endoscopy reprocessing room. Failure to monitor and achieve air quality standards can lead to the spread of healthcare-associated infections. The Chief of SPS reported that the device (probe) for monitoring temperature and humidity for the main supply room was dislodged (detached resulting in loss of contact) and that warning alerts were inadvertently overlooked. The Chief of SPS attributed the failure to recognize that the system was not recording readings for nine days to a lack of familiarity with the climate monitoring system.

Recommendation 8

8. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that temperature and humidity ranges are monitored and maintained in the Sterile Processing Services main supply room and endoscopy clinic reprocessing area.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Associate Director for Patient Care Services evaluated the policy for continuous monitoring of environmental controls. In September 2020, additional training on the climate monitoring system was provided.

The Chief of Sterile Processing Services will monitor temperature and humidity levels in the Sterile Processing Services main supply room and endoscopy clinic reprocessing area. The Chief of Sterile Processing Services will ensure warning alerts are responded to timely and in accordance with the local policy.

Quality Management will monitor until 90% sustained compliance has been met for six (6) consecutive months. The numerator will be daily monitoring of temperature and humidity ranges in the sterile processing main supply room and the endoscopy clinic reprocessing area by Chief of Sterile Processing Services or designees. The denominator will be the number days in each month.

VHA requires SPS staff to receive monthly continuing education.¹³⁵ The Endoscopy Clinical Nurse Manager and the Chief of SPS acknowledged that monthly continuing education was not

¹³⁴ 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.

¹³⁵ VHA Directive 1116(2).

completed for all 10 selected staff who reprocess RME from October to December 2019. This resulted in a potential knowledge gap in reprocessing duties. The Chief of SPS and Endoscopy Clinical Nurse Manager reported being unaware that the ongoing training requirement applied to all employees who reprocess RME, including endoscopy clinic staff.

Recommendation 9

9. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that all staff who reprocess reusable medical equipment receive monthly continuing education.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Associate Director for Patient Care Services evaluated the monthly continuing education for staff who reprocess reusable medical equipment. The Chief of Sterile Processing will ensure staff who reprocess reusable medical equipment receive monthly continuing education.

Quality Management will monitor monthly continuing education for staff who reprocess reusable medical equipment until sustained compliance of 90% has been met for six (6) consecutive months. The numerator will be monthly attendance for continuing education by staff who reprocess reusable medical equipment. The denominator will be the number staff who reprocess reusable medical equipment each month.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

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.

Table A.1. Summary Table of Recommendations

Healthcare Processes	Requirements	Conclusion
Leadership and Organizational Risks	<ul style="list-style-type: none"> • Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation surveys and oversight inspections • Factors related to possible lapses in care and medical center response • VHA performance data (medical center) • VHA performance data for CLCs 	Nine OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, and ADPCS. See details below.
COVID-19 Pandemic Readiness and Response	<ul style="list-style-type: none"> • Emergency preparedness • Supplies, equipment, and infrastructure • Staffing • Access to care • CLC patient care and operations • Staff feedback 	The results of the OIG's evaluation of the medical center's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	<ul style="list-style-type: none"> • QSV Committee • Protected peer reviews • UM reviews • Patient safety 	<ul style="list-style-type: none"> • Action items are fully implemented when problems or opportunities for improvement are identified. 	<ul style="list-style-type: none"> • None
Medical Staff Privileging	<ul style="list-style-type: none"> • FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards 	<ul style="list-style-type: none"> • Practitioners with similar training and privileges complete OPPEs. 	<ul style="list-style-type: none"> • Provider Exit Review Forms are completed within seven business days of LIPs' departure from the medical center.
Medication Management: Long-Term Opioid Therapy	<ul style="list-style-type: none"> • Provision of pain management using long-term opioid therapy • Program oversight and evaluation 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None
Mental Health: Suicide Prevention Program	<ul style="list-style-type: none"> • Designated facility suicide prevention coordinator • Tracking and follow-up of high-risk veterans • Provision of suicide prevention care • Completion of suicide prevention training requirements 	<ul style="list-style-type: none"> • Suicide prevention coordinators complete suicide prevention safety plans within the required time frame and include contact information for professional agencies. 	<ul style="list-style-type: none"> • Employees complete annual suicide prevention refresher training.
Care Coordination: Life-Sustaining Treatment Decisions	<ul style="list-style-type: none"> • LSTD multidisciplinary committee • Goals of care conversation documentation • LSTD note/orders completed by an authorized provider or delegated 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None
Women's Health: Comprehensive Care	<ul style="list-style-type: none"> • Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Women Veterans Health Committee meets regularly, appoints required members who consistently attend meetings, and reports to executive leaders.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
High-Risk Processes: Reusable Medical Equipment	<ul style="list-style-type: none"> • Administrative processes • Quality assurance • Staff training 	<ul style="list-style-type: none"> • Temperature and humidity ranges are monitored and maintained in the Sterile Processing Services main supply room and endoscopy clinic reprocessing area. 	<ul style="list-style-type: none"> • The Chief of SPS enforces the endoscopy clinic reprocessing area's daily cleaning schedule. • All staff who reprocess RME receive monthly continuing education.

Appendix B: Medical Center Profile

The table below provides general background information for this high complexity (1b) affiliated medical center reporting to VISN 10.¹

**Table B.1. Profile for Ann Arbor VA Medical Center (506)
(October 1, 2016, through September 30, 2019)**

Profile Element	Medical Center Data FY 2017*	Medical Center Data FY 2018	Medical Center Data FY 2019‡
Total medical care budget	\$485,005,876	\$499,986,733	\$534,569,000
Number of:			
• Unique patients	68,108	67,786	68,667
• Outpatient visits	630,107	596,185	610,652
• Unique employees	2,204	2,119	2,224
Type and number of operating beds:			
• Community living center	46	46	46
• Medicine	61	61	61
• Mental Health	18	18	18
• Surgery	23	23	23
Average daily census:			
• Community living center	40	39	37
• Medicine	46	46	45
• Mental health	16	15	15
• Neurology	1	1	1
• Surgery	21	17	17

Source: VA Office of Academic Affiliations, VHA Support Service Center, and VA Corporate Data Warehouse.

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

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

October 1, 2017, through September 30, 2018.

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

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

Appendix C: VA Outpatient Clinic Profiles

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Ann Arbor, MI	506QA	–	260	–	–	–

¹ Includes outpatient clinics in the community that were in operation as of August 27, 2019. VHA Directive 1230(2), *Outpatient Scheduling Processes And Procedures*, July 15, 2016, amended January 22, 2020. An encounter is a “professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient’s condition.” Specialty care services refer to non -primary care and non-mental health services provided by a physician. Diagnostic services include laboratory/pathology, nuclear medicine, radiology, and vascular lab services. Ancillary services include dental, nutrition, pharmacy, prosthetics, social work, and weight management services. The OIG omitted (506QB) Green Road, MI as no workload/encounters or services were reported.

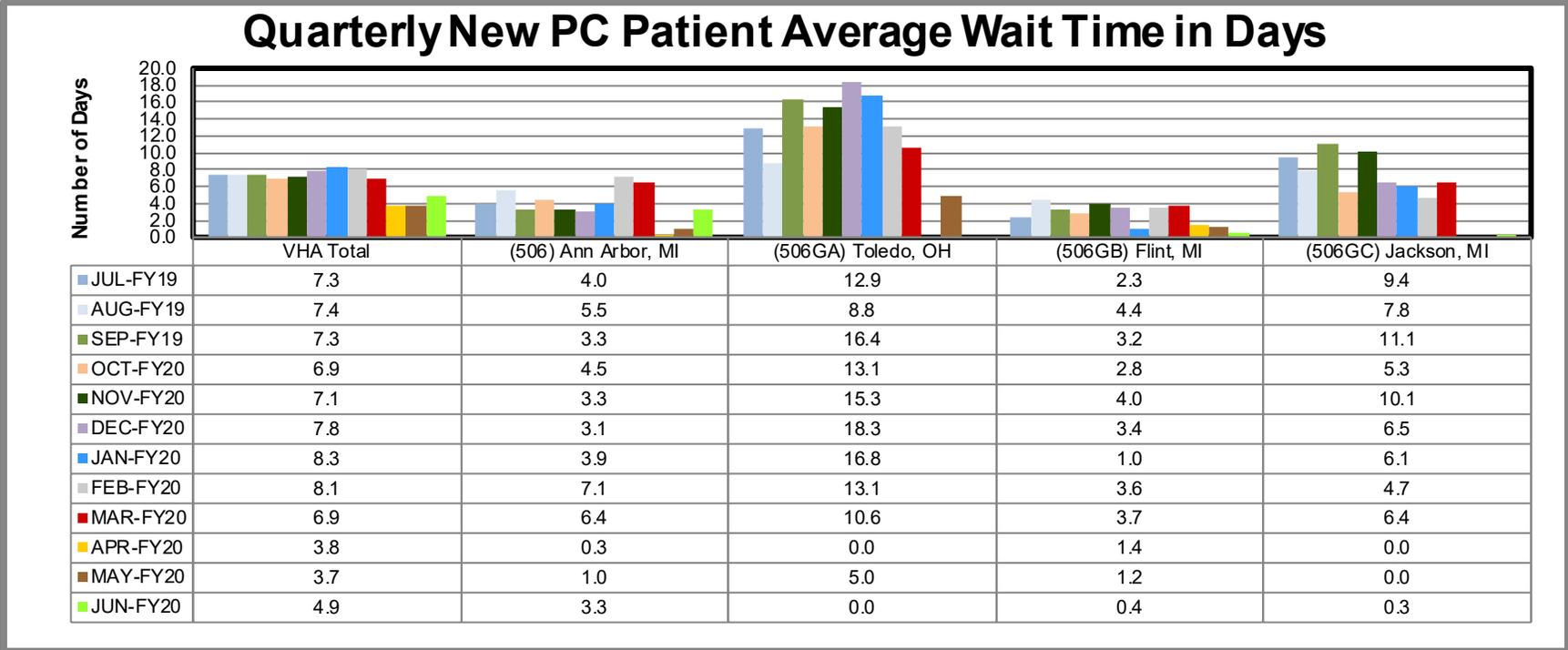
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Toledo, OH	506GA	34,708	11,507	Cardiology Dermatology Endocrinology Eye Gastroenterology General surgery Hematology/ Oncology Nephrology Neurology Neurosurgery Orthopedics Otolaryngology Plastic Poly-Trauma Pulmonary/ Respiratory disease Rehab physician Rheumatology Urology Vascular	Laboratory & Pathology Nuclear med Radiology Vascular lab	Dental Nutrition Pharmacy Prosthetics Social work Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Flint, MI	506GB	9,388	3,897	Cardiology Dermatology Gastroenterology General surgery GYN Neurosurgery Otolaryngology Plastic Poly-Trauma Rheumatology Urology Vascular	Nuclear med	Nutrition Prosthetics Weight management
Michigan Center Jackson, MI	506GC	10,379	3,119	Cardiology Dermatology Endocrinology Gastroenterology General surgery Hematology/ Oncology Otolaryngology Plastic Poly-Trauma Rheumatology Urology Vascular	Nuclear med	Nutrition Prosthetics 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.

Appendix D: Patient Aligned Care Team Compass Metrics

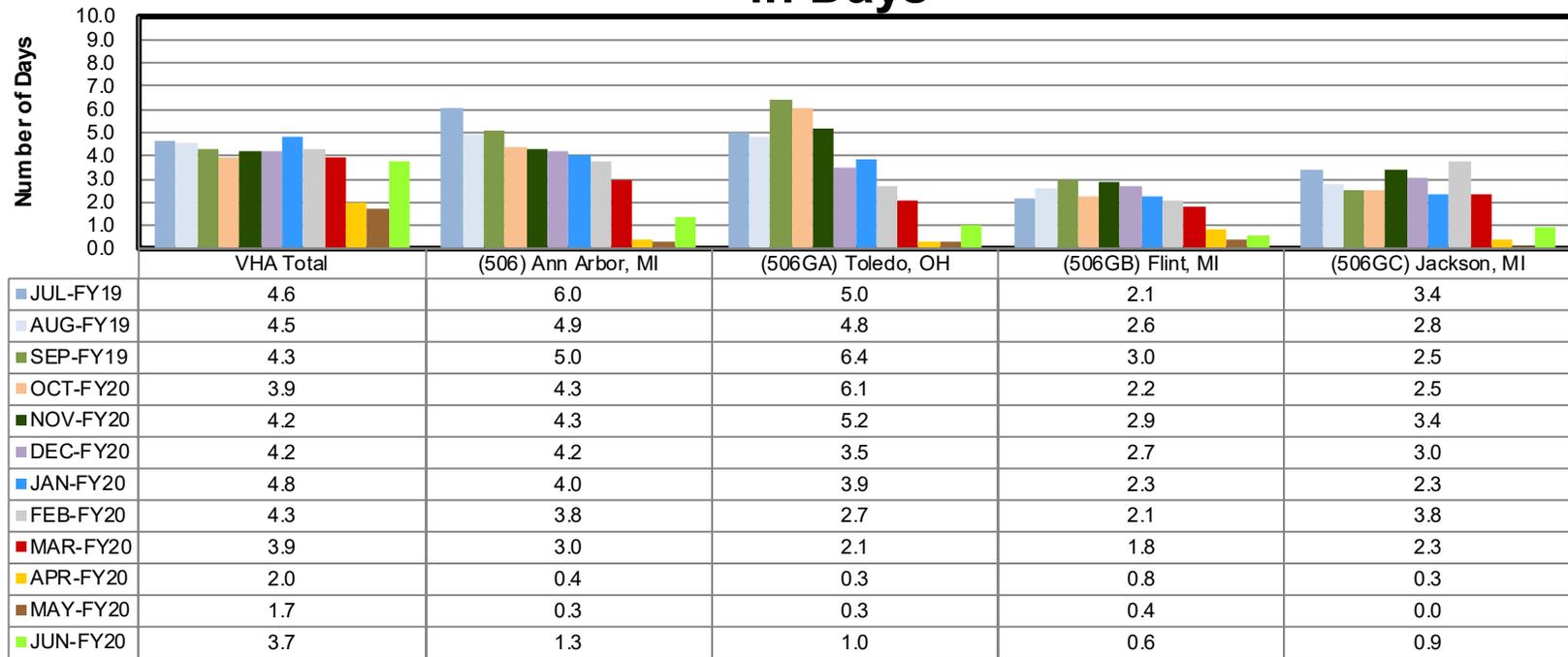


Source: VHA Support Service Center. Department of Veterans Affairs, Patient Aligned Care Teams Compass Data Definitions, <https://vssc.med.va.gov>, accessed October 21, 2019.

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted (506QA) Ann Arbor, MI, and (506QB) Green Road, MI as no data was reported.

Data Definition: “The average number of calendar days between a New Patient’s Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date.” Note that prior to FY 2015, this metric was calculated using the earliest possible create date.

Quarterly Established PC Patient Average Wait Time in Days



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

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted (506QA) Ann Arbor, MI, and (506QB) Green Road, MI as no data was reported.

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

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

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

Measure	Definition	Desired Direction
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
PSI90	Patient Safety and Adverse Events Composite (PSI90) focused on potentially avoidable complications and events	A lower value is better than a higher value
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value

Source: VHA Support Service Center.

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

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

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

Source: VHA Support Service Center.

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: March 25, 2021

From: Director, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

Subj: Comprehensive Healthcare Inspection of the Ann Arbor VA Medical Center in Michigan

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

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

1. I have reviewed and concur with the response for the draft report of our Comprehensive Healthcare Inspection Program (CHIP) review of the VA Ann Arbor Healthcare System.
2. I concur with the responses and action plans submitted by the VA Ann Arbor Healthcare System Medical Center Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson

Network Director

Appendix H: Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: March 24, 2021

From: Director, Ann Arbor VA Medical Center (506/00)

Subj: Comprehensive Healthcare Inspection of the Ann Arbor VA Medical Center in Michigan

To: Director, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

1. I have reviewed the Status Request – Comprehensive Healthcare Inspection Program Review of the VA Ann Arbor Healthcare System, Michigan.
2. I concur with the responses submitted by the VA Ann Arbor Healthcare System.

(Original signed by:)

Ginny L. Creasman, Pharm.D. FACHE
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.

Inspection Team Debra Naranjo, DNP, RN, Team Leader
Daisy Arugay-Rittenberg, MT
Cynthia Hickel, MSN, CRNA
Megan Magee, MSN, RN
Martynee Nelson, MSW/LCSW
Robert Ordonez, MPA
Simonette Reyes, BSN, RN
Joy Smith, BS, RDN
Akeberet Tesfasilase, MSN, RN

Other Contributors Shirley Carlile, BA
Alicia Castillo-Flores, MBA, MPH
Limin Clegg, PhD
Kaitlyn Delgadillo, BSPH
Ashley Fahle Gonzalez, MPH, BS
Jennifer Frisch, MSN, RN
Justin Hanlon, BS
LaFonda Henry, MSN, RN-BC
Susan Lott, MSA, RN
Scott McGrath, BS
Larry Ross, Jr., MS
Krista Stephenson, MSN, RN
Robyn Stober, JD, MBA
Caitlin Sweany-Mendez, MPH, BS
Robert Wallace, ScD, MPH

Report Distribution

VA Distribution

Office of the Secretary
Veterans Benefits Administration
Veterans Health Administration
National Cemetery Administration
Assistant Secretaries
Office of General Counsel
Office of Acquisition, Logistics, and Construction
Board of Veterans' Appeals
Director, VISN 10: VA Healthcare System Serving Ohio, Indiana and Michigan
Director, Ann Arbor VA Medical Center (506/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate:
Michigan – Gary Peters, Debbie Stabenow
Ohio – Sherrod Brown, Rob Portman
U.S. House of Representatives:
Michigan – Jack Bergman, Debbie Dingell, Bill Huizenga, Dan Kildee, Brenda Lawrence, Andy Levin, Lisa McClain, Peter Meijer, John Moolenaar, Elissa Slotkin, Haley Stevens, Rashida Tlaib, Fred Upton, Tim Walberg
Ohio – Bob Latta, Marcy Kaptur

OIG reports are available at www.va.gov/oig.