

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Chillicothe VA Medical Center in Ohio

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. Chillicothe VA Medical Center in Ohio. 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

FY fiscal year

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

SOP standard operating procedure

SPC suicide prevention coordinator

SPS Sterile Processing Services

TJC The Joint Commission

UM utilization management

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Chillicothe VA Medical Center and multiple outpatient clinics in 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 during the week of July 20, 2020, at the Chillicothe VA Medical Center. 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. 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 12 recommendations that are directed to the Medical Center 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 Medical Center Director, acting Chief of Staff, Associate Director for Patient Care Services, and Associate Director. Organizational communications and accountability are managed through a committee reporting structure, with the Leadership Council overseeing several working groups. The leaders monitor patient safety and care through the Quality Council, which is responsible for tracking and trending quality of care and patient outcomes.

When the OIG team conducted this virtual review, the medical center's leaders had worked together as a group for nearly two months, although several had served in their positions for more than a year. The Chief of Staff, the most tenured executive leader, was permanently assigned in March 2018 but then detailed to the Veterans Integrated Service Network in April 2019. Several external and internal staff had acted in the role during the detail; the medical center's Deputy Chief of Staff had served as acting Chief of Staff since June 2020. The Associate Director, assigned in August 2019, was the newest member of the leadership team. The Associate Director for Patient Care Services and Medical Center Director had served in their positions since January and February 2019, respectively.

The OIG reviewed employee satisfaction survey results and found that scores for the Medical Center Director, Associate Director for Patient Care Services, and Associate Director were generally better than those for VHA and the medical center. However, the Chief of Staff appeared to have opportunities to improve employee satisfaction and attitudes toward the workplace. Patient experience survey data indicated that patients appeared satisfied with the care provided. Further, the OIG found that selected survey results for both male and female respondents were generally more favorable than gender-specific VHA national results.

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

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."

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.³

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

COVID-19 Pandemic Readiness and Response

The results of the OIG's evaluation of the 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; review of aggregated data; and most patient safety elements. However, the OIG noted concerns with protected peer reviews, utilization management, and root cause analyses.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 VA website not publicly accessible.)

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

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

⁶ VHA Directive 1117, *Utilization Management Program*, October 8, 2020. Utilization management involves the assessment of the "appropriateness, medical necessity, and the efficiency of health care services, according to evidence-based criteria."

Medical Staff Privileging

The medical center complied with requirements for focused professional practice evaluations. However, the OIG identified deficiencies with ongoing professional practice evaluation and healthcare provider exit review processes.⁷

Medication Management

The OIG team observed compliance with many elements of expected performance, including pain screening, aberrant behavior risk assessment, and documented justification for concurrent therapy with benzodiazepines. However, the OIG identified opportunities for improvement with urine drug testing, informed consent, patient follow-up after therapy initiation, and quality measure monitoring.

Mental Health

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

Women's Health

The OIG found the medical center complied with many of the requirements for women's health, including care provision and selected staffing elements. However, the OIG noted concerns with Women Veterans Health Committee membership, attendance, and reporting requirements.

High-Risk Processes

The medical center met the requirements for quality assurance monitoring and monthly continuing education. However, the OIG identified deficiencies with standard operating procedures, an airflow directional device, and staff training and competency.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two administrative and seven clinical) and subsequently issued 12 recommendations for improvement to the Medical Center Director, Chief of Staff, and Associate Director for Patient Care Services. The number of

⁷ Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility."

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 findings and recommendations and provided acceptable improvement plans. (See appendixes G and H, pages 63–64, 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.

Solud , Vaish . 10.

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
Recommendation 2	26
Medical Staff Privileging	27
Recommendation 3	29
Recommendation 4	30
Recommendation 5	31
Medication Management: Long-Term Opioid Therapy for Pain	32
Recommendation 6	35
Mental Health: Suicide Prevention Program	36

Recommendation 7	39
Care Coordination: Life-Sustaining Treatment Decisions	40
Women's Health: Comprehensive Care	42
Recommendation 8	44
High-Risk Processes: Reusable Medical Equipment	45
Recommendation 9	47
Recommendation 10	48
Recommendation 11	48
Recommendation 12	49
Appendix A: Comprehensive Healthcare Inspection Program Recommendations	50
Appendix B: Medical Center Profile	53
Appendix C: VA Outpatient Clinic Profiles	54
Appendix D: Patient Aligned Care Team Compass Metrics	57
Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions	59
Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions	
Appendix G: VISN Director Comments	63
Appendix H: Medical Center Director Comments	64
OIG Contact and Staff Acknowledgments	65

	Insp	Inspection of the Chillicothe VA Medical Center in Ohio		
D. D. H. H.				
Report Distribution				66



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 Chillicothe 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." Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

- 1. Leadership and organizational risks
- 2. COVID-19 pandemic readiness and response⁵
- 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, no. 4, (December 2017): 73.

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

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

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

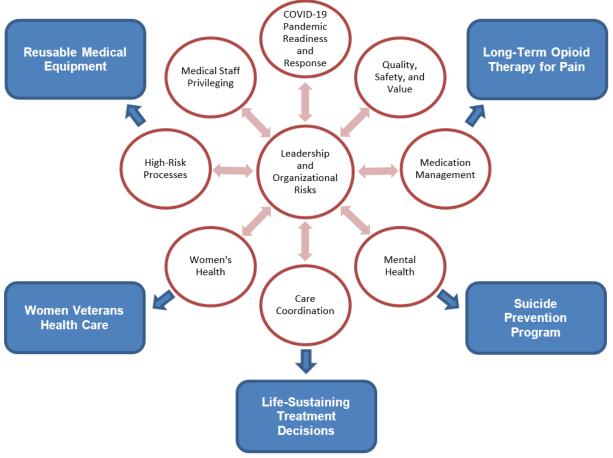


Figure 2. Fiscal year (FY) 2020 comprehensive healthcare inspection of operations and services. Source: VA OIG.

Methodology

The Chillicothe VA Medical Center also provides care through multiple outpatient clinics in 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 OIG team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

The inspection examined operations from April 21, 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. 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 (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 Medical Center Director, acting Chief of Staff, Associate Director for Patient Care Services (ADPCS), and Associate 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.

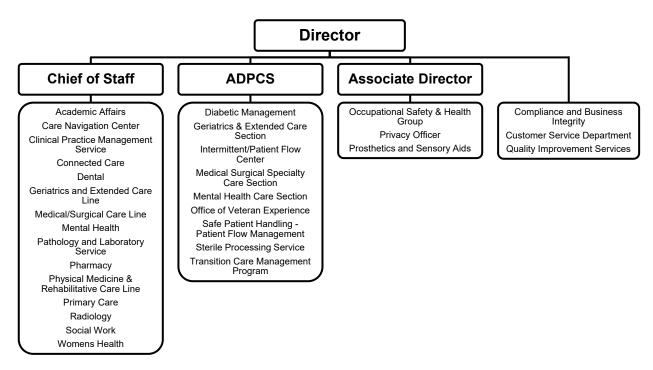


Figure 3. Medical center organizational chart.

Source: Chillicothe VA Medical Center (received July 22, 2020; updated July 30, 2020).

At the time of the OIG virtual site visit, the medical center's leaders had worked together as a group for almost two months, although several had served in their positions for more than a year. The Chief of Staff, the most tenured leader, was permanently assigned in March 2018 but had been detailed to the VISN since April 2019. Several external and internal staff had been assigned as the acting Chief of Staff; the medical center's Deputy Chief of Staff had served as the acting Chief of Staff since June 2020. The Associate Director was the newest permanent member of the leadership team, assigned in August 2019. The ADPCS and the Medical Center Director had served in their positions since January and February 2019, respectively (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Medical Center Director	February 17, 2019
Chief of Staff	March 16, 2018 (Permanent) June 1, 2020 (Acting)
Associate Director for Patient Care Services	January 6, 2019
Associate Director	August 18, 2019

Source: Assistant Chief, Human Resources VISN 10 (received July 20,2020; updated July 23, 2020).

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

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

The Medical Center Director serves as the chairperson of the Leadership Council, which has the authority and responsibility to establish policy, maintain quality care standards, and perform organizational management and strategic planning. The Leadership Council oversees the Medical Staff Executive, Administrative Executive, Organizational Health, Patient Care Executive, and Quality Councils.

The leaders monitor patient safety and care through the Quality Council. The Quality Council is responsible for tracking and trending quality of care and patient outcomes (see figure 4).

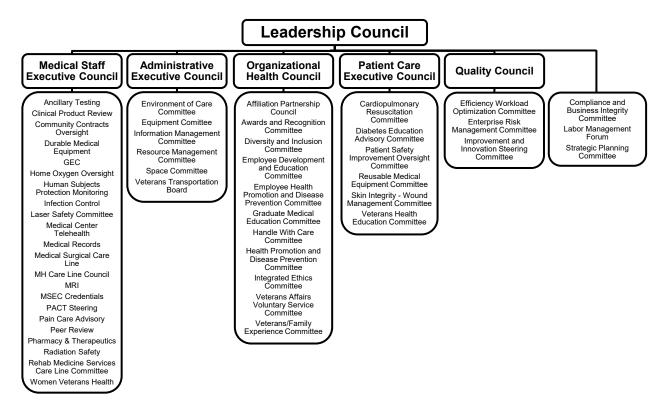


Figure 4. Medical center committee reporting structure.

Source: Chillicothe VA Medical Center (received July 21, 2020).

GEC = *Geriatrics* and *Extended Care*

MH = Mental Health

MRI = Magnetic Resonance Imaging

MSEC = Medical Staff Executive Committee

PACT = Patient Aligned Care Team

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

¹² "Survey Instruments," VA Workforce Surveys Portal, VHA Support Service Center, accessed May 3, 2021, http://aes.vssc.med.va.gov/SurveyInstruments/Pages/default.aspx. (This is an internal website not publicly accessible.)

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 average for the selected survey leadership questions was similar to or higher than the VHA average.¹⁴ The scores for the Medical Center Director, ADPCS, and Associate Director were consistently higher than those for VHA and the medical center.¹⁵ Conversely, the Chief of Staff scores were lower than VHA and the medical center. These scores indicate that the Chief of Staff has opportunities to improve employee satisfaction.

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	Medical Center Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: Servant Leader Index Composite.*	0–100 where higher scores are more favorable	72.6	74.5	77.9	66.8	87.8	92.5
All Employee Survey: In my organization, senior leaders generate high levels of motivation and commitment in the workforce.	1 (Strongly Disagree) –5 (Strongly Agree)	3.4	3.5	4.3	3.0	4.3	4.7
All Employee Survey: My organization's senior leaders maintain high standards of honesty and integrity.	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.7	4.2	3.1	4.6	4.7

¹³ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, and Associate 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 The 2019 All Employee Survey results are not reflective of employee satisfaction with the current Associate Director, who assumed the role after the survey was administered.

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Medical Center Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: I have a high level of respect for my organization's senior leaders.	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.7	4.0	3.3	4.2	4.8

Source: VA All Employee Survey (accessed June 15, 2020).

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. ¹⁶ The OIG noted that the medical center average for the selected survey questions was similar to the VHA average. Scores related to the Director, ADPCS, and Associate Director were generally better than those for VHA and the medical center. Opportunities appear to exist for the Chief of Staff to improve employee attitudes toward the workplace.

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	Medical Center Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.	1 (Strongly Disagree) –5 (Strongly Agree)	3.8	3.8	4.0	3.5	4.6	5.0

^{*}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."

¹⁶ Ratings are based on responses by employees who report to or are aligned under the Medical Center Director, Chief of Staff, ADPCS, and Associate Director.

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Medical Center Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).	1 (Strongly Disagree) –5 (Strongly Agree)	3.7	3.8	3.9	3.5	4.2	4.5
All Employee Survey: In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?	0 (Never) – 6 (Every Day)	1.4	1.4	1.6	2.3	1.0	0.8

Source: VA All Employee Survey (accessed June 15, 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.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The OIG reviewed responses to four relevant survey questions that reflect patients' attitudes toward their healthcare experiences.

Table 4 provides relevant survey results for VHA and the Chillicothe VA Medical Center. ¹⁷ For this medical center, patient survey results reflected higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

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

Questions	Scoring	VHA Average	Chillicothe Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): Would you recommend this hospital to your friends and family?	The response average is the percent of "Definitely Yes" responses.	68.3	70.2
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	88.8
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	82.7
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.	78.0	82.8

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

¹⁷ Ratings are based on responses by patients who received care at this medical center.

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

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 results for male respondents were higher than the corresponding VHA averages, and those for female respondents were also generally more positive than female VHA patients nationally. Medical center leaders appeared to be actively engaged with male and female patients (for example, conducting virtual town hall meetings and community events prior to the pandemic, involving Veterans Experience groups and patient advocates, and engaging customer service representatives to recount patients' perceptions of their experiences).

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

Questions	Questions Scoring			Medical Center		
		Male Average	Female Average	Male Average	Female Average	
During this hospital stay, how often did doctors treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	86.0	86.7	
During this hospital stay, how often did nurses treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	88.8	89.0	
Would you recommend this hospital to your friends and family?	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	69.2	89.0	

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

The medical center averages are based on 418–428 male and 19 female respondents, depending on the question.

^{*}The VHA averages are based on 48,259–48,798 male and 2,342–2,359 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 C	enter	
		Male Average	Female Average	Male Average	Female Average
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	59.1	57.3
In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	69.2	55.1
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).	71.6	65.7	77.2	60.9

 $Source: \textit{VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed \textit{May 6, 2020})}.$

The medical center averages are based on 714–1,695 male and 37–79 female respondents, depending on the question.

^{*}The VHA averages are based on 79,450–241,828 male and 5,762–13,041 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	62.3	61.3	
In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	55.0	62.0	74.0	
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	75.7	84.6	

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

The medical center averages are based on 313–926 male and 11–31 female respondents, depending on the question.

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys—including those conducted for cause—by oversight and accrediting agencies to gauge how well leaders respond to identified problems. ¹⁹ Table 8 summarizes the relevant medical center inspections most recently performed by the OIG and The

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

¹⁹ "Profile Definitions and Methodology: Joint Commission Accreditation," *American Hospital Directory*, accessed December 12, 2020, https://www.ahd.com/definitions/prof_accred.html. "The Joint Commission conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization."

Joint Commission (TJC).²⁰ 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 April 2018.

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.²¹ Additional results included the Long Term Care Institute's inspection of the medical center's four CLCs.²²

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Comprehensive Healthcare Inspection Program Review of the Chillicothe VA Medical Center, Ohio, Report No. 18-01012-228, August 9, 2018)	April 2018	2	0
OIG (Inpatient Security, Safety, and Patient Care Concerns at the Chillicothe VA Medical Center, Ohio, Report No. 17-04569-262, September 12, 2018)	September 2017	4	0

²⁰ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017. TJC provides an "internationally accepted external validation that an organization has systems and processes in place to provide safe and quality-oriented health care." TJC "has been accrediting VA medical facilities for over 35 years." Compliance with TJC standards "facilitates risk reduction and performance improvement."

²¹ VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs*, May 9, 2017. The Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term 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 April 26, 2021, https://www.cap.org/about-the-cap. According to the College of American Pathologists, for 75 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." Additionally, as stated in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
TJC Hospital Accreditation	September	12	0
TJC Behavioral Health Care Accreditation	2019	4	0
TJC Home Care Accreditation		6	0

Source: OIG and TJC (inspection/survey results verified with the Accreditation Manager 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 identified no concerns related to lapses in care or the potential for patient harm.

Table 9 lists the reported sentinel events and disclosures from April 16, 2018 (the prior OIG comprehensive healthcare inspection), through July 20, 2020.²³

_

²³ It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (The OIG noted that the Chillicothe VA Medical Center was a mid-high complexity (1c) medical center at the time of the review. Effective October 1, 2020, the designation was changed to medium complexity (2). See appendix B for more information.) According to VHA Directive 1190, Peer Review for Quality Management, November 21, 2018, a sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life." Additionally, as stated in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility 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." Lastly, in VHA Directive 1004.08, VHA defines a large-scale disclosure of adverse events (sometimes referred to as a "notification") as "a formal process by which VHA officials assist with coordinating the notification to multiple patients, (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue."

Table 9. Summary of Selected Organizational Risk Factors (April 16, 2018, through July 20, 2020)

Factor	Number of Occurrences
Sentinel Events	2
Institutional Disclosures	10
Large-Scale Disclosures	0

Source: Chillicothe VA Medical Center's Patient Safety Manager and Risk Manager (received July 20–24, 2020). Veterans Health Administration Performance Data.

Veterans Health Administration Performance Data

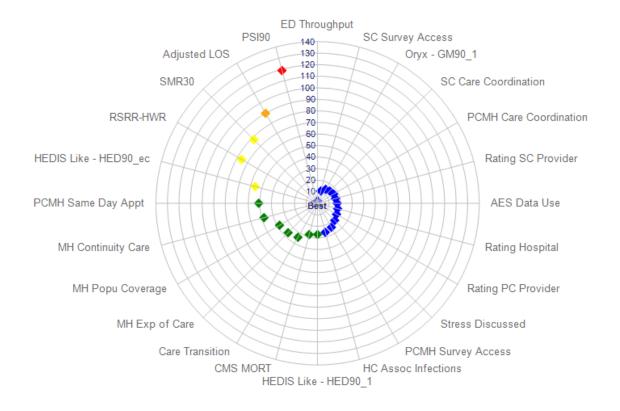
The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.²⁴

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. Figure 5 uses blue and green data points to indicate high performance for the Chillicothe VA Medical Center (for example, in the areas of emergency department (ED) throughput, specialty care (SC) care coordination, rating (of) SC provider, rating (of) hospital, and mental health continuity (of) care). Metrics that need improvement are denoted in orange and red (adjusted length of stay (LOS) and patient safety and adverse events composite (PSI90)).²⁵

-

²⁴ "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.)

²⁵ For information on the acronyms in the SAIL metrics, please see appendix E.



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 FY 2020 quarter 1 (as of December 31, 2019).

Source: VHA Support Service Center.

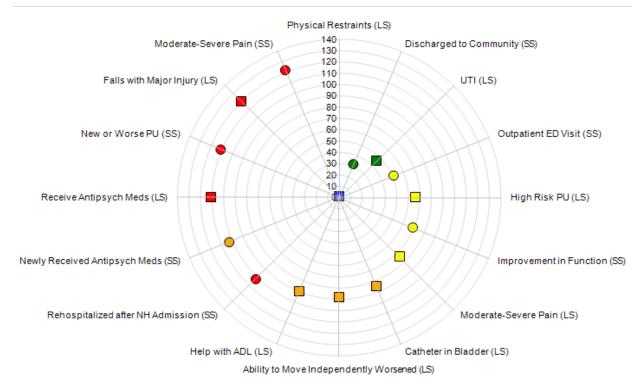
Note: The OIG did not assess VA's data for accuracy or completeness.

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

²⁶ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, July 23, 2020. "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

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 Chillicothe VA Medical Center CLC (for example, in the areas of physical restraints—long-stay (LS), discharged to community—short-stay (SS), and urinary tract infections (LS)). Metrics that need improvement are denoted in orange and red (for example, catheter in bladder (LS), ability to move independently worsened (LS), new or worse pressure ulcer (PU) (SS), and falls with major injury (LS)).²⁷



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

Figure 6. Chillicothe CLC quality measure rankings for FY 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.

Leadership and Organizational Risks Conclusion

The medical center's executive leadership team appeared stable. Selected survey items related to employees' satisfaction with the medical center executive leaders revealed opportunities for the Chief of Staff to improve employee satisfaction and attitudes toward the workplace. Patient experience survey data indicated that patients appeared satisfied with the care provided. Further,

²⁷ For data definitions of acronyms in the SAIL CLC measures, please see appendix F. Although the indicator for rehospitalization after nursing home (NH) admission–SS measure is shown in red (indicating the bottom 20 percent or fifth quintile performance), the measure is actually in the fourth quintile (60 to 80 percent performance).

the OIG found that selected survey results for both male and female respondents were generally more favorable than gender-specific VHA national results. 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, 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 models and should continue efforts to improve CLC SAIL 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. ²⁸ 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. ²⁹

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." "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." 31

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 medical center 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.³²

²⁸ "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.

²⁹ VHA Office of Emergency Management, COVID-19 Response Plan, March 23, 2020.

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

³¹ 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.

³² 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.³³ 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.³⁴ Many quality-related activities are informed and required by VHA directives, nationally recognized accreditation standards (such as The Joint Commission), and federal regulations. VHA strives to provide healthcare services that compare "favorably to the best of the private sector in measured outcomes, value, [and] efficiency."³⁵

To determine whether VHA facilities have implemented and incorporated OIG-identified key processes for quality and safety into local activities, the inspection team evaluated the medical center's committee responsible for quality, safety, and value (QSV) oversight functions; its ability to review data, information, and risk intelligence; and its ability to ensure that key QSV functions are discussed and integrated on a regular basis. Specifically, OIG inspectors examined the following requirements:

- Review of aggregated QSV data
- Recommendation and implementation of improvement actions
- Monitoring of fully implemented improvement actions

The OIG reviewers also assessed the medical center's processes for conducting protected peer reviews of clinical care.³⁶ Protected peer reviews, "when conducted systematically and credibly," reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and "long-term improvements in patient care."³⁷ Peer reviews are "intended to promote confidential and non-punitive" processes that consistently contribute to quality management efforts at the individual provider level.³⁸ The OIG team examined the completion of the following elements:

³³ Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence, September 21, 2014.

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

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

³⁶ 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."

³⁷ VHA Directive 1190.

³⁸ VHA Directive 1190.

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit³⁹
- 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.⁴⁰ 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.⁴¹ 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. ⁴² 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 medical center vulnerabilities and how to address them.

³⁹ VHA Directive 1190.

⁴⁰ VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. UM reviews include evaluating the "appropriateness, medical need and the efficiency of health care services, according to evidence-based criteria." (This directive was rescinded and replaced with VHA Directive 1117, *Utilization Management Program*, October 8, 2020.)

⁴¹ VHA Directive 1117(2).

⁴² 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."

Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the medical center.⁴³ The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses⁴⁴
- 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.⁴⁵

Quality, Safety, and Value Findings and Recommendations

The medical center complied with requirements for a committee responsible for QSV oversight functions, review of aggregated data, and most patient safety elements reviewed. However, the OIG identified weaknesses with peer review, utilization management, and root cause analysis processes.

VHA requires that summaries of the Peer Review Committee's trends and analysis are reviewed quarterly by an executive-level medical committee.⁴⁶ The OIG requested to review the Medical Staff Executive Council's meeting minutes from January 1 through December 31, 2019; however, medical center staff only provided the January, February, and December 2019 minutes despite OIG follow-up. The OIG found that the minutes provided did not include review of Peer Review Committee summary reports.⁴⁷ Inconsistent reviews of quarterly summary reports may result in the Medical Staff Executive Council's failure to identify clinical practice trends, determine the need for further action, or monitor the effectiveness of quality improvement

.

⁴³ VHA Handbook 1050.01.

⁴⁴ VHA Handbook 1050.01, "The requirement for a total of <u>eight</u> RCAs [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of RCAs is driven by the events that occur and the SAC [Safety Assessment Code] score assigned to them. At least four analysis per fiscal year must be individual RCAs, with the balance being Aggregated Reviews or additional individual RCAs."

⁴⁵ For virtual CHIP visits, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁴⁶ VHA Directive 1190.

⁴⁷ The Medical Staff Executive Council is this medical center's equivalent of the Executive Committee of the Medical Staff.

initiatives. The acting Chief of Quality Management reported that, due to inaccurate recording of the council's meeting minutes, quarterly summaries were not included.

Recommendation 1

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

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Chief of Staff evaluated and determined that there were no additional reasons for noncompliance. The Executive Assistant to the Chief of Staff will monitor the Healthcare Delivery Council (formerly the Medical Staff Executive Council) minutes to ensure the Peer Review Committee analysis is reported quarterly beginning August 2020 until 100% compliance is met for two consecutive quarters.

At the time of the OIG inspection, VHA required that the Medical Center Director ensure an interdisciplinary group review UM data. This group must have included, but was not limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [Chief Business Office Revenue Utilization Review]." The OIG found that between January 1 and December 31, 2019, the Quality Council lacked representation from CBO R-UR. As a result, the Quality Council performed reviews and analyses without the perspectives of key staff. The acting Chief of Quality Management reported that CBO R-UR representation started in February 2020 once leaders recognized that the required representative had not been in attendance. On October 8, 2020, VHA changed the representatives who review UM data to a "multidisciplinary committee, which may include representatives from" various services. Therefore, the OIG made no recommendation. 49

VHA requires root cause analyses to include several elements, such as participation by leaders, "analysis of the underlying systems...to determine where redesigns might reduce risk," and identification of "at least one root cause with a corresponding action and outcome measure." Additionally, VHA programs, including hospitals, are "required to achieve and maintain The Joint Commission accreditation." TJC standards state that corrective actions be implemented and monitored so that performance improvement "effectiveness can be sustained, assessed, and

⁵⁰ VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, March 4, 2011.

⁴⁸ VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019.

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

⁵¹ VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs, May 9, 2017.

measured."⁵² The OIG found that two of four root cause analyses lacked evidence that staff monitored implemented action items for sustained improvement. When implemented action items are not monitored, medical center leaders could miss opportunities to prevent future patient harm. The Patient Safety Manager reported the reasons for noncompliance as lack of oversight and follow-up with responsible staff.

Recommendation 2

2. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures the Patient Safety Manager monitors implemented root cause analysis action items for sustained improvement.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Medical Center Director evaluated and determined that there were no additional reasons for noncompliance. The Patient Safety Manager will submit the Root Cause Analyses action and outcome measure status report quarterly to the Quality Council beginning June 2, 2021, until two consecutive quarters of 100% compliance is demonstrated.

⁵² TJC Rationale for Leadership standard LD.03.02.01 and TJC Performance Improvement standard PI.03.01.01; TJC Leadership standard LD.03.05.01.

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).⁵³

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.⁵⁴

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

FPPEs

- o Establishment of criteria in advance
- o Use of minimum criteria for selected specialty LIPs⁵⁶
- Clear documentation of the results and time frames
- o Evaluation by another provider with similar training and privileges

OPPEs

o Application of criteria specific to the service or section

- o Use of minimum criteria for selected specialty LIPs⁵⁷
- Evaluation by another provider with similar training and privileges

55 VHA Handbook 1100.19.

⁵³ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

⁵⁴ VHA Handbook 1100.19.

⁵⁶ VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁵⁷ 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. 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." 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 reprivileging during calendar year 2019⁶⁰
- Three LIPs who completed an FPPE in calendar year 2019
- Five LIPs privileged during calendar year 2019
- Fourteen LIPs who left the medical center in calendar year 2019

⁵⁸ 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.)

⁵⁹ 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.)

⁶⁰ 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.

Medical Staff Privileging Findings and Recommendations

The medical center complied with requirements for FPPEs. However, the OIG identified deficiencies with OPPE and provider exit review processes.

VHA requires that each service chief "establish additional criteria for granting of clinical privileges within the service consistent with the needs of the service and the facility as well as within the available resources to provide these services. Clinical privileges must be based on evidence of an individual's current competence." For three of seven practitioners reprivileged in 2019, including two solo/few practitioners, the OIG found that service chiefs could not demonstrate that reprivileging decisions were based on service-specific OPPE criteria. This resulted in incomplete data to support decisions to continue clinical privileges. Furthermore, inadequate evaluation of a practitioner's competency could potentially impact the quality of care and patient safety. The acting Chief of Staff and Credentialing Coordinator reported being new in their positions and unaware of the requirement.

Recommendation 3

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

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Chief of Staff evaluated and determined that there were no additional reasons for noncompliance. The Credentialing Coordinator will monitor the OPPE process for service specific metrics monthly. Monitoring results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) monthly until a compliance rate of 90% is demonstrated for six consecutive months.

VHA also requires that OPPE and FPPE be completed on all privileged practitioners by another provider with similar training and privileges. The OIG found that in four of seven OPPE profiles of practitioners who were reprivileged in 2019—including two solo/few practitioners—the evaluations were not completed by a similarly trained and privileged provider. As a result, the practitioners continued to deliver care without a thorough evaluation of their competencies. The acting Chief of Staff reported believing that medical center efforts fulfilled the requirement.

⁶¹ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

⁶² VHA DUSHOM Memorandum, Requirements for Peer Review of Solo Practitioners.

Recommendation 4

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

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Chief of Staff evaluated and determined that there were no additional reasons for noncompliance. The Credentialing Coordinator will complete quarterly audits of ten OPPEs and ensure they are being completed by providers of the same specialty, training, and privileges. Monitoring results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) quarterly until 90% compliance is demonstrated for two consecutive quarters.

At the time of the OIG inspection, VHA required that provider exit review forms, which document the review of a provider's clinical practice, are "completed within 7 calendar days of the departure of a licensed health care professional from a VA facility."63 As of January 28, 2021, VHA requires medical center directors to ensure that a provider's first- or second-line supervisor completes the exit review form within seven business days.⁶⁴ For the 14 providers who departed the medical center in 2019, the OIG found that two exit forms were not completed within the new time frame. VHA requirements also state that practitioners who fail to meet professional practice standards for delivering patient care should be reported to SLBs. 65 The OIG found that 1 of the 14 forms was not completed correctly—signatures were placed in the area of the form indicating the provider failed to meet acceptable standards. However, an item on the form was checked, indicating the provider met the generally accepted standard of clinical practice. The OIG was unable to determine, based on the review, if this provider should have been referred to the SLB. Failure to correctly complete a provider exit form within the specified time frame could result in delayed SLB reporting of healthcare professionals who potentially provide substandard care. The acting Chief of Staff stated that one of the exit review forms was not completed on time because the responsible service line manager stepped down from the position abruptly. The Credentialing Coordinator cited miscommunication between the credentialing staff and human resources department as the reason for the delay in the completion of the second exit form.

⁶³ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18*, *Reporting and Responding to State Licensing Boards*, February 5, 2018.

⁶⁴ VHA Directive 1100.18, Reporting and Responding to State Licensing Boards, January 28, 2021.

⁶⁵ VHA Notice 2018-05. (VHA Directive 1100.18 replaced VHA Handbook 1100.18, upon which this notice was based. The directive contains the same or similar language on form completion.)

Recommendation 5

5. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that a licensed healthcare professional's first- or second-line supervisor correctly completes and signs an exit review form within seven business days of the professional's departure from the medical center.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Medical Center Director evaluated and determined that there were no additional reasons for noncompliance. The Lead Credentialing Coordinator will monitor the Exit Review forms for completion within the seven business days monthly until 90% compliance is demonstrated for six consecutive months. Monitoring results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) quarterly.

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

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

Medication Management Findings and Recommendations

The medical center addressed many of the indicators of expected performance, including pain screening, aberrant behavior risk assessment, and documented justification for concurrent therapy with benzodiazepines. The OIG found deficiencies with urine drug testing, informed consent, and patient follow-up after therapy initiation but made no recommendations due to the small sample of patients identified for these review elements. The OIG also identified a concern with quality measure monitoring.

The VA/DoD clinical practice guidelines state that providers "should obtain UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter." The OIG determined that providers conducted initial urine drug testing for 68 percent of patients, based on the electronic health record reviewed. This may have resulted in providers' inability to identify whether the remaining 32 percent of patients adhered to opioid therapy or had a substance use disorder, and determine potential drug diversion. The Chief, Pharmacy Service cited a lack of awareness of the monitoring timeframe as the reason for

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

⁷⁵ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0. February 2017.

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

noncompliance. The Clinical Pharmacist stated the medical center performs UDT twice a year on patients who are on long-term opioid therapy, and that the medical center is above 90 percent compliance based on the VISN monitoring criteria for UDT.

VHA requires providers to complete the informed consent process "prior to initiating long-term opioid therapy for pain." Additionally, "practitioners prescribing long-term opioid therapy for pain must educate patients about the risks, benefits, and alternatives to long-term opioid therapy and engage them in a discussion about a proposed long-term opioid therapy management plan." The OIG determined that providers completed informed consent prior to initiating long-term opioid therapy in 88 percent of electronic health records reviewed. The remaining 12 percent of patients may have received treatment without knowledge of the risks associated with long-term opioid therapy, including dependence, tolerance, addiction, and unintentional fatal overdose. The Chief, Pharmacy Service cited unclear guidance from the directive as the reason for noncompliance.

VA/DoD practice guidelines recommend that providers evaluate the "benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months" after initiating long-term opioid therapy. Reprive Meditionally, VHA requires "periodic evaluation of adherence, response to interventions, and achievement of time-limited therapeutic goals in the pain management plan." The OIG determined that providers followed up to assess pain management for 80 percent of patients, based on the electronic health records reviewed. Additionally, providers evaluated adherence to the pain management plan of care and effectiveness of interventions for 88 percent of patients, based on the records reviewed. Lack of follow-up could result in missed opportunities to assess patients for adherence to opioid therapy, effectiveness of treatment, or any adverse reactions. The Chief, Pharmacy Service cited a shortage of pain care providers, which limited access to care in clinics, as the reason for the lack of follow-up. The Chief, Pharmacy Services also cited passive negligence as a reason why providers did not assess adherence to pain management plans of care or document intervention effectiveness.

VHA requires facilities to have a multidisciplinary pain management committee that provides oversight and coordination of pain management activities.⁸³ The OIG found that the medical center had established an Opioid Safety Review Board to oversee pain management programs. However, based on the review of six months of meeting minutes (July to December 2019), the

⁷⁷ VHA Directive 1005.

⁷⁸ VHA Directive 1005.

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

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

⁸¹ VHA Directive 2009-053.

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

⁸³ VHA Directive 2009-053.

OIG did not find evidence that the board monitored the quality of pain assessment or the effectiveness of pain management interventions. This resulted in the Opioid Safety Review Board's inability to identify deficiencies or provide recommendations to medical center leaders. The Chief, Pharmacy Service stated that board members believed the Quality Council's oversight of some pain metrics met the requirement.

Recommendation 6

6. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that the Opioid Safety Review Board monitors the quality of pain assessment and effectiveness of pain management interventions.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Chief of Staff evaluated and determined that there were no additional reasons for noncompliance. The Clinical Pharmacist will monitor the quality of pain assessment and effectiveness of pain management interventions by reviewing Opioid Safety Review Board minutes monthly until a compliance rate of 90% is met for six consecutive months.

Mental Health: Suicide Prevention Program

Suicide prevention remains a top priority for VHA. Suicide is the 10th leading cause of death, with over 47,000 lives lost across the United States in 2019.⁸⁴ The suicide rate for veterans was 1.5 times greater than for nonveteran adults and estimated to represent approximately 13.8 percent of all suicide deaths in the United States during 2018. However, suicide rates among veterans who recently used VHA services decreased by 2.4 percent between 2017 and 2018.⁸⁵

VHA has identified suicide prevention as a top priority and implemented various evidence-based approaches to reduce the veteran suicide rate. In addition to expanded mental health services and community outreach, VHA has developed comprehensive screening and assessment processes to identify at-risk patients.⁸⁶

VHA requires that each medical center and very large 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.⁸⁷ The OIG examined various requirements related to SPCs:

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

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

⁸⁴ "Preventing Suicide," Centers for Disease Control and Prevention, accessed December 9, 2020, https://www.cdc.gov/violenceprevention/suicide/fastfact.html.

⁸⁵ VA Office of Mental Health and Suicide Prevention, 2020 National Veteran Suicide Prevention Annual Report, November 2020.

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

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

in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC." 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." 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. Additionally, VHA requires designated high-risk patients to have a completed suicide safety plan and four face-to-face visits with an acceptable provider within the first 30 days of designation.

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." 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." VHA further provided additional clarifying information:

- The "SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list."
- "The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted."
- The SPC's determination process "may be beyond 24 hours after a referral, due to case consultation and review." 94

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

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

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

⁹⁰ VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide, January 5, 2018; VHA DUSHOM Memorandum, High Risk for Suicide Patient Record Flag Changes, October 3, 2017.

⁹¹ 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*.

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

⁹³ VHA DUSHOM Memorandum, Update to High Risk for Suicide Patient Record Flag Changes.

⁹⁴ VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

is warranted, patients identified as at-risk for suicide could have flags placed in 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." ⁹⁵

Inspectors examined the completion of several requirements:

- Review of HRS PRFs within the required time frame
- Completion of at least four mental health visits within 30 days of HRS PRF placement
- Appropriate follow-up for no-show high-risk appointments
- Completion of suicide safety plans with the required elements within the required time frame

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training. ⁹⁶ VHA also requires that all staff receive annual refresher training. ⁹⁷ In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees. ⁹⁸

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

• Relevant documents;

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

⁹⁶ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym "S.A.V.E" summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for 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.

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

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

- The electronic health records of 16 outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The OIG found the medical center complied with requirements for a designated SPC, appointment tracking, suicide safety plans, and patient follow-up. However, the OIG noted concerns with the completion of suicide prevention training.

VHA requires that all employees complete suicide risk and intervention training within 90 days of entering their position and annually thereafter. ⁹⁹ The OIG found that one of five employees hired after January 1, 2018, did not complete the training within 90 days of entering the position. The OIG also found that 8 of 19 employees did not complete annual suicide prevention training as required. Lack of training could prevent employees from providing optimal treatment to veterans who are at risk for suicide. The Mental Health Care Line Manager reported that employees and supervisors did not appropriately prioritize completion of training over other required tasks.

Recommendation 7

7. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that employees complete suicide prevention training as required.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Medical Center Director evaluated and determined that there were no additional reasons for noncompliance. The Suicide Prevention Coordinator will monitor the Talent Management System reports for staff who are non-compliant with required suicide prevention training and monitor for completion of required training for six consecutive months until 90% compliance rate is met. Monitoring status will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) monthly.

⁹⁹ VHA Directive 1071.

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." 100

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018. 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. 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. In the conversation of the patient or at the time of a triggering event.

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.

¹⁰⁰ 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.

¹⁰¹ VHA Handbook 1004.03(1). The medical facility must fully implement handbook requirements within 18 months of publication.

¹⁰² 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.

¹⁰³ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017. Hospice patients are defined as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. VHA Handbook 1004.03(1). Triggering events requiring goals of care conversations include those "prior to referral or following admission (e.g., within 24 hours) to VA or non-VA hospice."

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

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

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

The medical center was assessed for its adherence to requirements for goals of care conversations:

- Completion of LSTD notes
- Timely documentation of LSTD
- Inclusion of required elements in LSTD documentation
- Completion of LSTD note/orders by an authorized provider or delegation to a designee met all requirements

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service. ¹⁰⁴ 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 47 randomly selected hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

C 11	. 1	1. 1	1 1	•	TT1 0.T.C.	1	1
(tenerally	the med	dical cente	r met the above	reguirements	The $()$	made no	recommendations
Ochician v.	, uic ilici	aicai cente.	i mei me above	reduirements.		made no	1 CCOHIHICHGanons.

¹⁰⁴ VHA Handbook 1004.03(1).

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹⁰⁵ 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.¹⁰⁶ 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."¹⁰⁷ 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."¹⁰⁸

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. ¹⁰⁹ VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veterans health committee that "develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."

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

VA OIG 20-01268-143 | Page 42 | May 27, 2021

¹⁰⁵ "Veteran Population," Table 1L: VetPop2016 Living Veterans by Age Group, Gender, 2015–2045, National Center for Veterans Analysis and Statistics, accessed November 14, 2019, https://www.va.gov/vetdata/Veteran Population.asp.

¹⁰⁶ "Veteran Population," National Center for Veterans Analysis and Statistics, accessed September 16, 2019, https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf.

¹⁰⁷ Department of Veterans Affairs, Study of Barriers for Women Veterans to VA Health Care, Final Report, April 2015.

¹⁰⁸ Claire Hoffmire, "Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions," Suicide Prevention, *Forum*, Spring 2018, https://www.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5.

¹⁰⁹ VHA Directive 1330.01(4), *Health Care Services for Women Veterans*, February 15, 2017, amended January 8, 2021.

¹¹⁰ VHA Directive 1330.01(4).

- o Gynecologic care coverage available 24/7
- o 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
 - o Women's Health Medical Director or clinical champion
 - Maternity Care Coordinator
 - o Women's health clinical liaison at each community-based outpatient clinic

Women's Health Findings and Recommendations

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

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership.¹¹¹ That membership includes a women veterans program manager; a women's health medical director; "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care, and a member from executive leadership."¹¹²

The OIG requested the Women Veterans Health Committee minutes from July through December 2019 and found that the Women's Health Medical Director and representatives from mental health, radiology, quality management and business office/Non-VA medical care did not

_

¹¹¹ VHA Directive 1330.01(2). (This directive was in place for the timeframe of the minutes reviewed in this report. It was amended on June 29, 2020, and again on January 8, 2021. All three directives contain the same or similar language regarding the Women Veterans Health Committee.)

¹¹² VHA Directive 1330.01(2).

attend the quarterly meetings. The OIG also found that the committee charter did not list radiology, laboratory, quality management or business office/Non-VA medical care representatives as core members. This could result in a lack of expertise and oversight in the review and analysis of data as the committee plans and carries out improvements for quality and equitable care for women veterans. The Women Veterans Program Manager reported being aware of the requirement but failing to update the committee charter. The program manager also stated that the women's health medical director position had been vacant until October 21, 2019.

The OIG requested to review the Medical Staff Executive Council meeting minutes for July 1 through December 31, 2019; however, the Women Veterans Program Manager only provided minutes for the December 5, 2019, meeting. There was no evidence in the meeting minutes that the Women Veterans Health Committee reported to executive leaders. Failure to report activities to leaders potentially impedes oversight and support of the women's health program. The acting Chief, Quality Management explained that noncompliance was due to inaccurate recording of the Medical Staff Executive Council's meeting minutes.

Recommendation 8

8. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that required Women Veterans Health Committee members are assigned and consistently attend meetings, and that the committee reports to the Medical Staff Executive Council.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Medical Center Director evaluated and determined that there were no additional reasons for noncompliance. The Women Veterans Program Manager will ensure that the Women Veterans Health Committee has the required members assigned, members consistently attend meetings, and the committee reports to the Healthcare Delivery Council (formerly the Medical Staff Executive Council). The Women Veterans Program Manager will monitor the members' attendance and reporting to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) monthly until 90% compliance is met for six consecutive months.

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." The goal of SPS is to "provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections." To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME
- Have standard operating procedures (SOPs) that are based on current manufacturers' guidelines and reviewed at least triennially
- Use CensiTrac[®] Instrument Tracking System for tracking reprocessed instruments¹¹⁵
- Perform annual risk analysis and report results to the VISN SPS Management Board
- Monitor data for reprocessing and storing RME
- Conduct annual airflow/ventilation system inspections 116

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

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 SOPs readily available to guide the reprocessing of RME.¹¹⁹

¹¹³ VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016.

¹¹⁴ Julie Jefferson, Martha Young. *APIC Text of Infection Control and Epidemiology*. Association for Professionals in Infection Control and Epidemiology, 2019. "Chapter 108: Sterile Processing."

¹¹⁵ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019. ¹¹⁶ VHA Directive 1116(2).

¹¹⁷ 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.

¹¹⁸ VHA Directive 7704(1), *Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment*, February 16, 2016.

¹¹⁹ 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. 120

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
 - o RME inventory file is current
 - SOPs are based on current manufacturer's guidelines and reviewed at least triennially
 - o CensiTrac® system used
 - Risk analysis performed and results reported to the VISN SPS Management Board
 - o Airflow checks made
 - o Eyewash station checked
 - Daily cleaning schedule maintained
 - o Required temperature and humidity maintained
- Monitoring of quality assurance
 - High-level disinfectant solution tested
 - o Bioburden tested
- Completion of staff training, competency, and continuing education
 - o Required training completed in a timely manner
 - Competency assessments performed
 - Monthly continuing education received

¹²⁰ VHA	Directive	1116(2)

-

High-Risk Processes Findings and Recommendations

The medical center met the requirements for quality assurance monitoring and monthly continuing education. However, the OIG identified deficiencies with administrative processes and staff training and competency.

VHA requires that facilities "must have standard operating procedures (SOPs) based on manufacturer's guidelines that establishes a documented and systematic approach to critical and semi-critical RME processes." VHA also requires that "all SOPs are kept up-to-date, reviewed at least every 3 years and updated when there is a change in process or a change in manufacturer's IFU [Instructions for Use]." The OIG found that the SOP for a colonoscope did not align with the manufacturer's IFU and was not reviewed at least every three years. This may have resulted in potential inadequate disinfection and reprocessing of RME. The Chief, SPS reported multiple role responsibilities, staffing vacancies, and COVID-19 priorities as the reasons for noncompliance. ¹²³

Recommendation 9

9. The Associate Director for Patient Care Services evaluates and determines additional reasons for noncompliance and ensures standard operating procedures are current, align with manufacturers' guidelines/instructions for use, and are reviewed at least every three years or when there is a change.

Medical Center concurred.

Target date for completion: March 1, 2022

Medical Center response: The Associate Director for Patient Care Services evaluated and determined that there were no additional reasons for noncompliance. The Chief of SPS and/or designee will monitor 15 SOPs each quarter to ensure standard operating procedures are current, align with manufacturers' guidelines/instructions for use, and are reviewed at least every three years or when there is a change until 90% compliance is demonstrated for two consecutive quarters. Results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) quarterly.

VHA requires that "Commercial airflow directional devices must be utilized to enable SPS staff to verify the airflow direction." The OIG found that the SPS sterile storage room lacked a commercial airflow directional device. Failure to monitor airflow direction could result in a

¹²¹ VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016.

¹²² VHA Directive 1116(2).

 $^{^{123}\} Staffing\ vacancies\ included\ the\ Assistant\ Chief\ of\ SPS,\ RME\ Coordinator,\ and\ two\ SPS\ staff\ on\ medical\ leave.$

¹²⁴ VHA Directive 1116(2).

potential spread of microorganisms from dirty to clean areas and increase the risk for healthcare-associated infections. ¹²⁵ The Supervisory General Engineer reported that the building design was approved by the National Program Office for Sterile Processing, and therefore was believed to be in compliance.

Recommendation 10

10. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that commercial airflow directional devices are used in areas where reusable medical equipment is reprocessed and stored.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Associate Director for Patient Care Services evaluated and determined that there were no additional reasons for noncompliance. The Supervisory General Engineer will install a commercial airflow directional device outside the SPS sterile storage room. Status of the installation will be reported monthly to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) until installation and implementation is complete.

Since March 23, 2016, VHA has required that "all new SPS employees must complete the SPS Level 1 training program within 90 days of hire." Of the two SPS employees hired after March 23, 2016, the OIG found that neither employee had completed all training modules within the required time frame. This lack of timely and basic training could have resulted in improper cleaning of RME and compromised patient safety. The Chief, SPS was unable to provide a reason why the predecessor did not ensure employees' completion of Level 1 training.

Recommendation 11

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

¹²⁵ "Guidelines for Environmental Infection Control in Health-Care Facilities," Centers for Disease Control and Prevention, accessed February 6, 2020, https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf.

¹²⁶ VHA Directive 1116(2).

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Associate Director for Patient Care Services evaluated and determined that there were no additional reasons for noncompliance. The Chief of SPS or designee will audit staff training records for SPS Level 1 training for all new SPS employees until 90% compliance is met for six consecutive months. Audit results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) monthly.

VHA requires the Chief, SPS to ensure "that all SOPs are kept up-to-date, reviewed at least every 3 years and updated when there is a change in process or a change in the manufacturer's IFU." VHA also requires that competency assessments are updated when SOPs are revised. 127 The OIG reviewed competency assessments for seven SPS employees and found that none of the colonoscope and bronchoscope competencies aligned with the medical center's SOP, therefore making the competencies invalid. This could result in improper cleaning of the RME and subsequently compromise patient safety. The Chief, SPS reported reasons for noncompliance as multiple role responsibilities, staffing vacancies, COVID-19 priorities, and interdepartmental investigations. 128

Recommendation 12

12. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that Sterile Processing Services employee competency assessments align with medical center standard operating procedures.

Medical Center concurred.

Target date for completion: February 1, 2022

Medical Center response: The Associate Director for Patient Care Services evaluated and determined that there were no additional reasons for noncompliance. The Chief of SPS will monitor 15 SPS staff competencies quarterly for alignment with the medical center's SOPs until 90% compliance is met for two consecutive quarters. Results will be reported to the Healthcare Delivery Council (formerly the Medical Staff Executive Council) quarterly.

¹²⁷ VHA Directive 1116(2).

¹²⁸ Staffing vacancies included the Assistant Chief of SPS, RME Coordinator, and two SPS staff on medical leave.

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	 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 	Twelve OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Medical Center Director, Chief of Staff, and ADPCS. See details below.
COVID-19 Readiness and Response	 Emergency preparedness Supplies, equipment, and infrastructure Staffing Access to care CLC patient care and operations Staff feedback 	The results of the OIG's evaluation of the 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	 QSV Committee Protected peer reviews UM reviews Patient safety	Root cause analysis action items are monitored for sustained improvement.	Peer Review Committee's analysis is reviewed quarterly by the Medical Staff Executive Council.
Medical Staff Privileging	 FPPEs OPPEs Provider exit reviews and reporting to state licensing boards 	 Reprivileging decisions are based on service-specific OPPE data. Providers with similar training and privileges complete OPPE of licensed independent practitioners. 	Provider exit review forms are completed and signed by first- or second-line supervisor within required timeframe.
Medication Management: Long-Term Opioid Therapy	 Provision of pain management using long-term opioid therapy Program oversight and evaluation 	• None	Opioid Safety Review Board monitors the quality of pain assessment and effectiveness of pain management interventions.
Mental Health: Suicide Prevention Program	 Designated facility suicide prevention coordinator Tracking and follow-up of high-risk veterans Provision of suicide prevention care Completion of suicide prevention training requirements 	Employees complete suicide prevention training as required.	• None
Care Coordination: Life-Sustaining Treatment Decisions	 LSTD multidisciplinary committee LSTD progress note documentation LSTD note/orders completed by an authorized provider or delegated appropriately 	• None	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Women's Health: Comprehensive Care	 Provision of care Program oversight and performance improvement data monitoring Staffing requirements 	• None	Required members are assigned, consistently attend Women Veterans Health Committee meetings, and the committee reports to the Medical Staff Executive Council.
High-Risk Processes: Reusable Medical Equipment	 Administrative processes Quality assurance Staff training 	SOPs align with manufacturer's instructions for use and are reviewed at least every three years or when there is change. Commercial airflow devices are used in areas where reusable medical equipment is reprocessed and stored.	 SPS employees complete Level 1 training within 90 days of hire. SPS employee competency assessments align with medical center SOPs.

Appendix B: Medical Center Profile

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

Table B.1. Profile for Chillicothe VA Medical Center (538) (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	\$233,010,097	\$246,893,246	\$247,786,380
Number of:			
Unique patients	22,025	22,164	22,483
 Outpatient visits 	323,562	324,134	323,416
Unique employees	1,144	1,164	1,189
Type and number of operating beds:			
 Community living center 	162	162	162
 Domiciliary 	78	78	78
Medicine	27	27	27
Mental Health	28	28	28
Average daily census:			
 Community living center 	135	154	156
Domiciliary	69	65	63
Medicine	14	16	13
Mental health	16	17	16

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

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

October 1, 2017, through September 30, 2018.

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

^{*}October 1, 2016, through September 30, 2017.

¹ Associated with a medical residency program. The VHA medical centers are classified according to a facility complexity model; a designation of "1c" indicates a facility with "medium-high volume, medium risk patients, some complex clinical programs, and medium sized research and teaching programs." As of October 1, 2020, this medical center's designation changed from "1c" to "2"—a facility with "medium volume, low risk patients, few complex clinical programs, and small or no 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
Athens, OH	538GA	4,883	3,177	Cardiology Cardio thoracic Dermatology Endocrinology Eye Neurology Podiatry	EKG Vascular lab	Pharmacy Prosthetics Weight management Nutrition

¹ Includes all outpatient clinics in the community that were in operation as of August 27, 2019. VHA Directive 1230(3), *Outpatient Scheduling Processes And Procedures*, July 15, 2016, amended January 7, 2021. An encounter is a "professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient's condition." Specialty care services refer to non-primary care and non-mental health services provided by a physician. Diagnostic services include electrocardiogram (EKG), and vascular lab services. Ancillary services include nutrition, pharmacy, prosthetic, and weight management services.

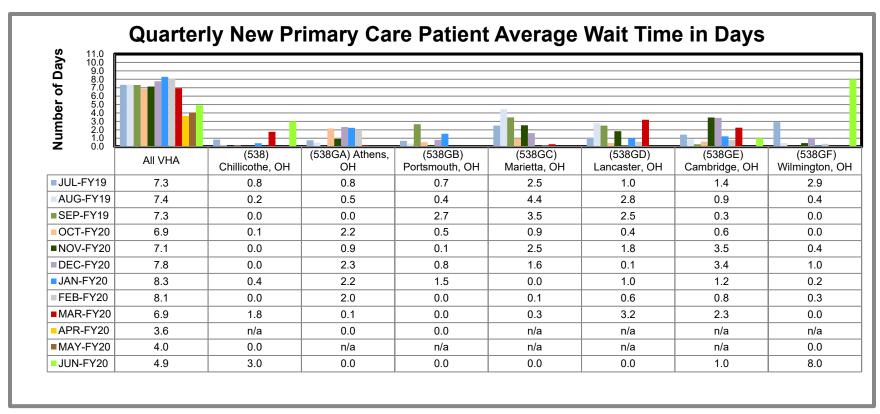
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Portsmouth, OH	538GB	7,199	3,102	Anesthesia Cardiology Cardio thoracic Dermatology Endocrinology Eye Neurology Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management
Marietta, OH	538GC	5,058	1,830	Anesthesia Cardiology Dermatology Endocrinology Eye General surgery Neurology Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management
Lancaster, OH	538GD	6,708	3,477	Cardiology Cardio thoracic Dermatology Endocrinology Eye Neurology Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Cambridge, OH	538GE	4,867	3,440	Anesthesia Cardiology Cardio thoracic Dermatology Endocrinology Eye Neurology Podiatry	EKG	Nutrition Pharmacy Prosthetics Weight management
Wilmington, OH	538GF	2,873	1,118	Dermatology Endocrinology Neurology	EKG Vascular lab	Nutrition Pharmacy 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.

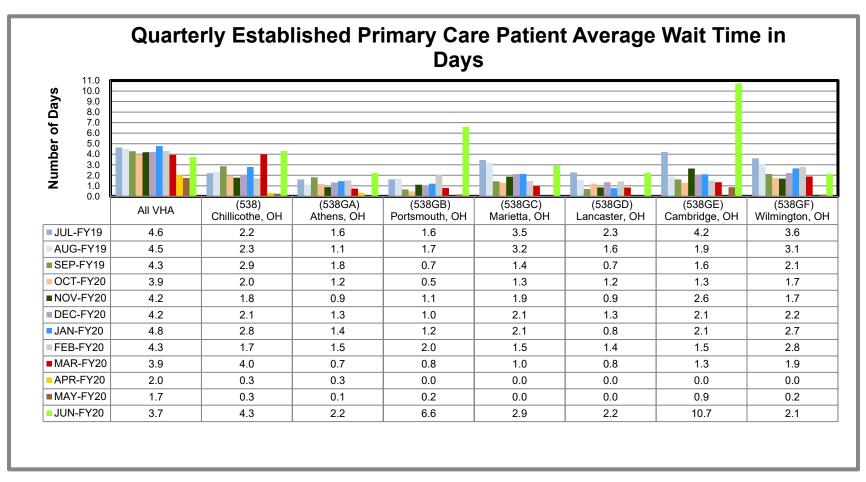
Appendix D: Patient Aligned Care Team Compass Metrics



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

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

Data Definition: "The average number of calendar days between a New Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date." Prior to FY 2015, this metric was calculated using the earliest possible create date. The absence of reported data is indicated by "n/a."



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

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

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

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

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

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

Source: VHA Support Service Center.

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

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

Measure	Definition
Receive antipsych meds (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: April 6, 2021

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

Subj: Comprehensive Healthcare Inspection of the Chillicothe VA Medical Center in Ohio

To: Director, Office of Healthcare Inspections (54CH06)

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

- I have reviewed and concur with the response for the draft report of our Comprehensive Healthcare Inspection of the Chillicothe VA Medical Center in Ohio.
- 2. I concur with the responses and action plans submitted by the Chillicothe VA 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 31, 2021

From: Director, Chillicothe VA Medical Center (538/00)

Subj: Comprehensive Healthcare Inspection of the Chillicothe VA Medical Center in

Ohio

To: Director, VISN 10 VA Healthcare System Serving Indiana, Ohio, and Michigan

(10N10)

- Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report for the Comprehensive Healthcare Inspection Program (CHIP) Review of the Chillicothe VA Medical Center.
- 2. Attached please find the facility response to the draft CHIP Review report. I have reviewed the report and concur with the findings, recommendations, and submitted action plans.

(Original signed by:)

Kathy W. Berger

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	Priscilla Agali, DNP, FNP-C, Team Leader Carol Haig, CNM, WHNP-BC Miquita Hill-McCree, MSN, RN Frank Keslof, MHA, EMT Nicole Maxey, MSN, RN
Other Contributors	Elizabeth Bullock Shirley Carlile, BA Limin Clegg, PhD Kaitlyn Delgadillo, BSPH Ashley Fahle Gonzalez, MPH, BS Jennifer Frisch, MSN, RN Justin Hanlon, BS LaFonda Henry, MSN, RN-BC 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 (10N10)

Director, Chillicothe VA Medical Center (538/00)

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: Sherrod Brown, Rob Portman

U.S. House of Representatives: Troy Balderson, Joyce Beatty, Steve Chabot, Warren Davidson, Bob Gibbs, Anthony Gonzalez, Bill Johnson, Jim Jordan, Dave Joyce, Marcy Kaptur, Bob Latta, Tim Ryan, Michael R. Turner, Brad Wenstrup

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