DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Cincinnati VA Medical Center in Ohio

CHIP REPORT | REPORT #20-01276-131 | MAY 19, 2021

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Figure 1. *Cincinnati VA Medical Center in Ohio.*
Source: https://vaww.va.gov/directory/guide/ (accessed July 27, 2020).

Abbreviations

ADPCS	Associate Director for Patient Care Services
CBOC	community-based outpatient clinic
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
SOP	standard operating procedure
SPC	suicide prevention coordinator
SPS	Sterile Processing Services
TJC	The Joint Commission
UM	utilization management
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
WH-PCP	women's health primary care provider

Report Overview

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

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

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

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

This unannounced virtual review was conducted during the week of July 27, 2020, at the Cincinnati 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 16 recommendations 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, Chief of Staff, Associate Director for Patient Care Services, and Associate Director. The medical center did not have a designated executive-level committee or board with the authority and responsibility to establish policy, maintain quality care standards, or perform organizational management and strategic planning. Organizational communications and accountability were managed through a committee reporting structure, with the Director overseeing the Administrative Executive Board, Clinical Executive Board, and Nurse Executive Committee. The Director also chaired the Management Briefings, in which various clinical services report on a rotating basis. The leaders monitored patient safety and care through the Quality, Safety and Value Committee which was responsible for tracking and trending quality of care and patient outcomes.[2]

During the OIG review, three of the four executive leadership positions were occupied by acting staff. The medical center director position became vacant on February 16, 2020, and the permanent Associate Director for Patient Care Services began serving as acting Director at that time. The resulting vacant Associate Director for Patient Care Services role has since been filled temporarily by four separate medical center staff. In addition, six different employees had served as the acting Chief of Staff since the position became vacant in May 2019. The Associate Director was permanently assigned in October 2019.

The OIG found that medical center averages for the All Employee Survey leadership questions were similar to or worse than the VHA averages. Opportunities appeared to exist for the acting Chief of Staff to improve employee attitudes toward the workplace. Patients generally appeared satisfied with the care provided; however, gender-specific results highlighted opportunities to improve experiences in the inpatient and patient-centered medical home settings.

[2] At the time of the OIG review, the committee was called the Quality, Safety and Value Committee. The medical center subsequently changed the name to the Quality and Patient Safety Council which is reflected in the action plans and updated in figure 4.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and identified organizational risk factors.[3] Specifically, the OIG noted concerns with processes related to identification of sentinel events and institutional disclosure.

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.[4]

The executive leaders were 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 and community living center measures.[5] In individual interviews, the executive leadership team members were generally able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and/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.[6]

Quality, Safety, and Value

The medical center complied with requirements for the establishment of a committee responsible for quality, safety, and value oversight functions; completion of utilization management reviews; and submission of the annual patient safety report. However, the OIG identified weaknesses in the Quality, Safety, and Value Committee's implementation of improvement actions, protected peer reviews, and root cause analysis processes.

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[3] 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."

[4] "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.)

[5] 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.

[6] 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.

Medical Staff Privileging

The OIG identified deficiencies with focused and 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, urine drug testing, and multidisciplinary pain management committee processes. However, the OIG found a deficiency with informed consent.

Mental Health

The OIG found compliance with the requirements for suicide prevention coordinator designation, suicide prevention training, and monthly outreach activities. However, the OIG identified a deficiency with timely suicide safety plan completion.

Women's Health

The medical center complied with many of the requirements for women's health. The OIG noted concerns with community-based outpatient clinic-designated women's health primary care providers and the Women Veterans Advisory Committee.[8]

High-Risk Processes

The medical center met requirements for quality assurance monitoring. However, the OIG identified deficiencies with standard operating procedures, the instrument tracking system, eyewash station testing, and staff training.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two administrative and seven clinical) and subsequently issued 16 recommendations for improvement to the Medical Center Director, Chief of Staff, and Associate Director for Patient Care Services. The number of recommendations should not be used, however, as a gauge for the overall quality of care

[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."

[8] At the time of the OIG review, the committee was called the Women Veterans Advisory Committee. The medical center subsequently changed the name to the Women Veterans Health Committee which is reflected in the action plans and updated in figure 4.

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 70–71, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendations 1, 2, 3, and 11 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Assistant Inspector General
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Contents

Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities providing healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Cincinnati VA Medical Center examines a broad range of key clinical and administrative processes associated with positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and medical center leaders so that informed decisions can be made to improve care.[1]

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

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

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

1. Leadership and organizational risks
2. COVID-19 pandemic readiness and response[5]
3. Quality, safety, and value (QSV)
4. Medical staff privileging

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

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

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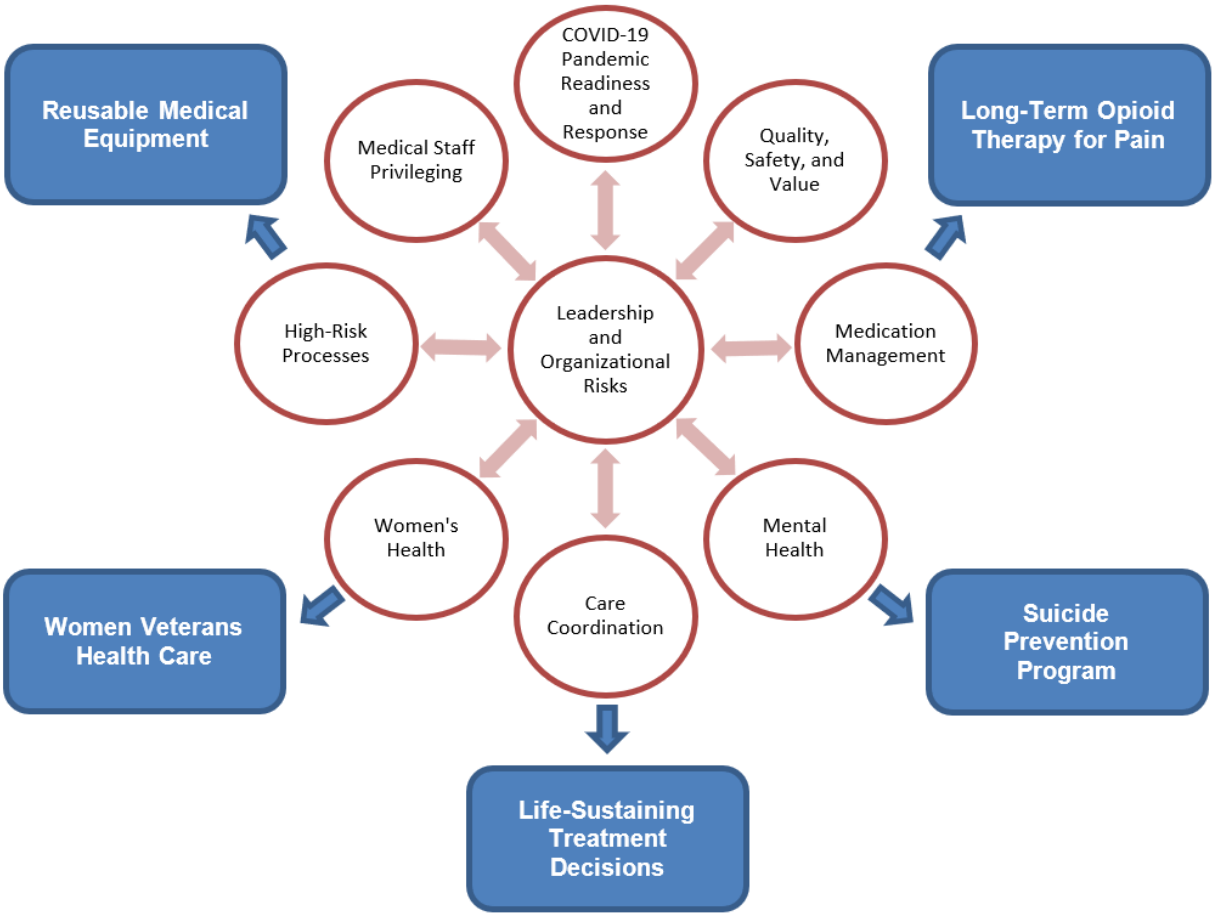

Figure 2. *Fiscal year (FY) 2020 comprehensive healthcare inspection of operations and services.*
Source: VA OIG.

Methodology

The Cincinnati VA Medical Center is a two-division campus with locations in Cincinnati, Ohio, and Fort Thomas, Kentucky, and outpatient clinics in Kentucky, Indiana, and Ohio. Additional details about the types of care provided by the medical center can be found in appendixes B and C.

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.[6]

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

The inspection examined operations from October 21, 2017, through July 31, 2020, the last day of the unannounced multiday evaluation.[7] During the virtual site visit, the OIG referred concerns beyond the scope of the review to the OIG's hotline management team for further review.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.[9] The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

[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).

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

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare system. Leadership and organizational risks can affect the healthcare system's ability to provide care in the clinical focus areas.[10] To assess the 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 (CLC)[11]

Executive Leadership Position Stability and Engagement

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

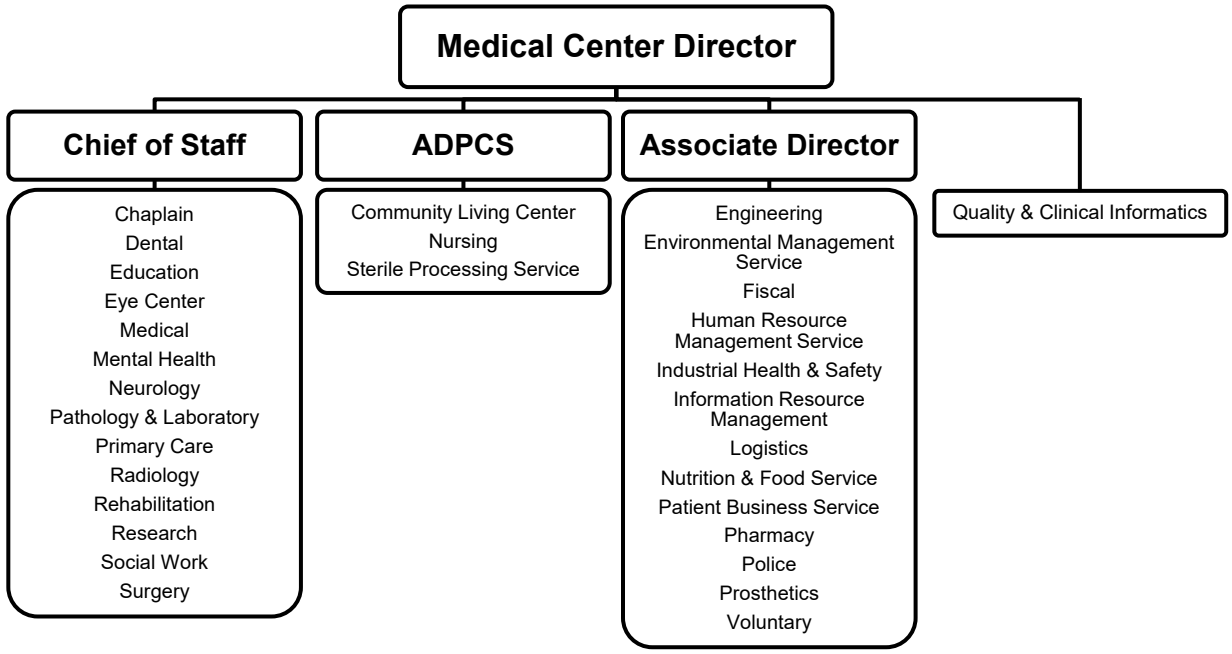

Figure 3. *Medical center organizational chart.*

Source: Cincinnati VA Medical Center (received July 27, 2020).

During the OIG virtual site visit, three of the four executive leadership positions were occupied by acting staff. The medical center director position became vacant on February 16, 2020, and the permanent ADPCS began serving as acting Director at that time. The resulting vacant ADPCS role has since been filled temporarily by four separate medical center staff. In addition, six different employees had served as the acting Chief of Staff since the position became vacant in May 2019. The Associate Director was permanently assigned in October 2019 (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Medical Center Director	February 16, 2020 (acting)
Chief of Staff	May 17, 2019 (acting)
Associate Director for Patient Care Services	January 20, 2019 (permanent) February 16, 2020 (acting)
Associate Director	October 10, 2019

Source: Cincinnati VA Medical Center Supervisory Human Resources Officer (received July 30, 2020).

To help assess the medical center executive leaders' engagement, the OIG interviewed the acting Director, acting Chief of Staff, acting 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 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) and Community Living Center (CLC) SAIL measures. In individual interviews, the executive leadership team were able to speak knowledgeably about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and/or patient experiences. These are discussed in greater detail below.

The medical center did not have a designated executive-level committee or board to establish policy, maintain quality care standards, or perform organizational management and strategic planning. The Medical Center Director oversees the Administrative Executive Board, Clinical Executive Board, and Nurse Executive Committee. The Director also chairs the Management Briefings, in which various clinical services report out on a rotating basis.

The medical center leaders monitored patient safety and care through the Quality, Safety and Value Committee. The Quality, Safety and Value Committee was responsible for tracking and trending quality of care and patient outcomes (see figure 4).[12]

[12] At the time of the OIG review, the committee was called the Quality, Safety and Value Committee. The medical center subsequently changed the name to the Quality and Patient Safety Council which is updated in figure 4.

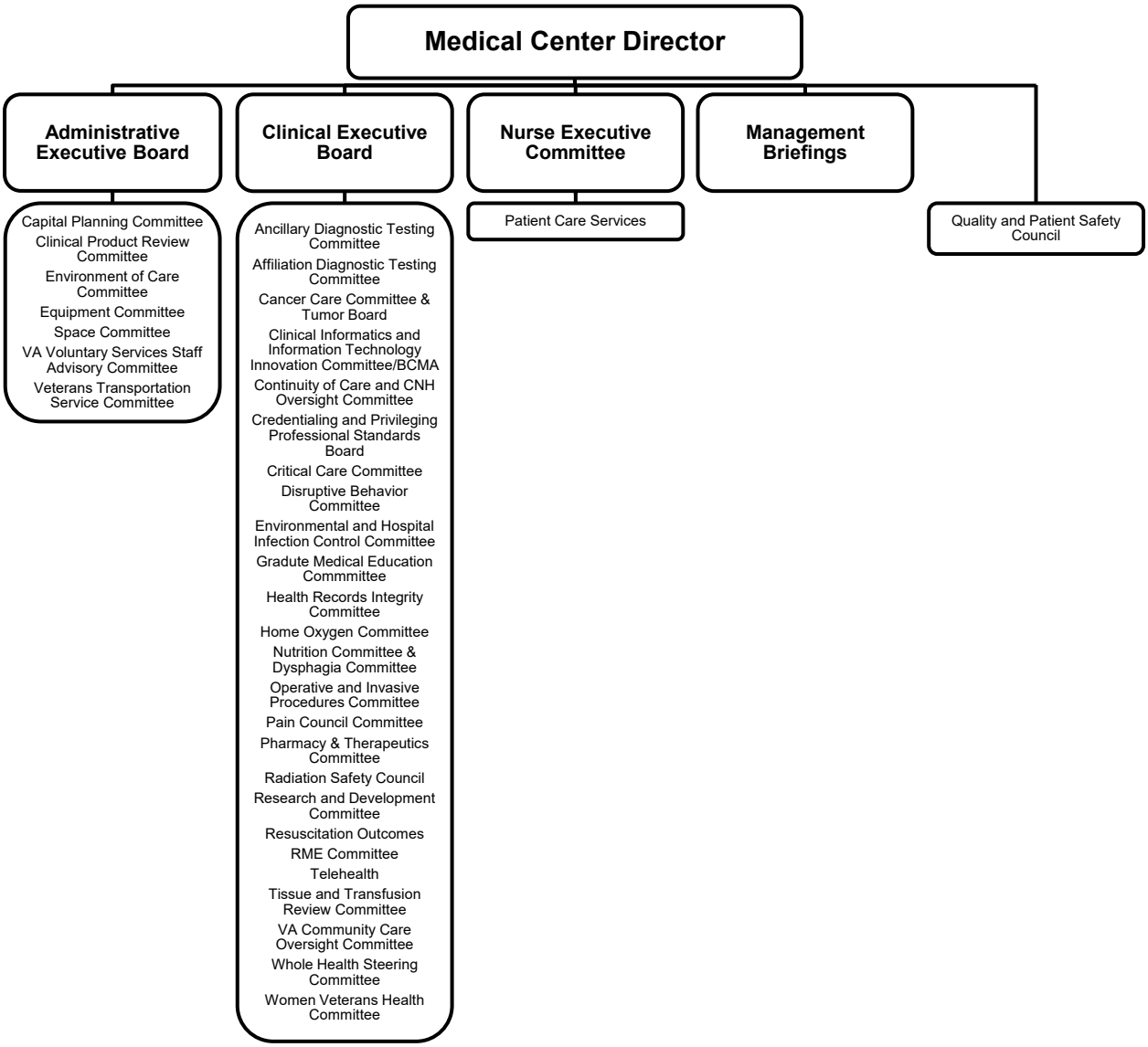

Figure 4. *VA medical center committee reporting structure.*

Source: Cincinnati VA Medical Center (received August 31, 2020, and April 13, 2021).

BCMA = Bar Code Medication Administration
CNH = Community Nursing Home
RME = Reusable Medical Equipment

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.[13] Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on medical center leadership.

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey from October 1, 2018, through September 30, 2019.[14] 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's averages for the selected survey questions were similar to or lower than the VHA averages.[15] However, executive leaders' scores were generally higher than those for VHA and the medical center. Although the survey results are not indicative of most current leaders' performance, they may still provide relevant insights into employee satisfaction improvement opportunities.[16]

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

Questions/Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: *Servant Leader Index Composite.**	0–100 where higher scores are more favorable	72.6	68.8	–	69.0	95.0	96.9

[13] "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.)

[14] Ratings are based on responses by employees who report to or are aligned under the Chief of Staff, ADPCS, and Associate Director. Scores were not available for the Medical Center Director.

[15] 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.

[16] It is important to note that the 2019 All Employee Survey results are not reflective of the staff currently serving as acting Chief of Staff, acting ADPCS, and Associate Director, as they were not in their positions at the time of the survey. The ADPCS scores are reflective of the full-time ADPCS, who has served as acting Director since February 16, 2020.

Questions/Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
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	3.3	–	3.3	4.7	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	3.4	–	3.3	4.8	4.9
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.5	–	3.8	4.9	4.9

Source: VA All Employee Survey (accessed June 23, 2020, and August 20, 2020).

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

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.[17] Medical center averages for the selected survey questions were similar to or worse than VHA averages. The Associate Director and ADPCS averages were generally better than VHA and the medical center. However, the acting Chief of Staff appears to have opportunities to improve employee attitudes toward the workplace.

[17] Ratings are based on responses by employees who report to or are aligned under the Chief of Staff, ADPCS, and Associate Director. Scores were not available for the Medical Center Director.

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

Questions/Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
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	3.6	–	3.4	4.8	4.7
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) –5 (Strongly Agree)	3.7	3.6	–	3.4	4.1	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	1.6	–	2.5	1.9	0.6

Source: VA All Employee Survey (accessed June 23, 2020, and August 20, 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 medical center.[18] Although two of the four survey results were slightly lower than the VHA average, patients generally appeared satisfied with their care experiences.

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

Questions	Scoring	VHA Average	Cincinnati 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	62.9
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	86.7
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	77.3	81.9
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	78.0	75.0

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

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

2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.[19] For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The results for male respondents were generally more favorable than the corresponding VHA national averages, except for those related to inpatient care. Likewise, female respondent scores were more positive than VHA averages, except for the patient-centered medical home setting. Medical center leaders appeared to be actively engaged with male and female patients (for example, conducting veteran town hall meetings and leadership rounds).

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
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	85.8	88.7
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	83.8	85.5
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	62.8	64.2

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

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

The medical center averages are based on 504–509 male and 20–21 female respondents, depending on the question.

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

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

Questions	Scoring	VHA*		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).	51.2	43.3	57.1	48.6
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	66.6	44.4
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	79.0	52.3

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

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

The medical center averages are based on 650–1,953 male and 27–65 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	49.7	66.5
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	57.0	88.2
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	71.0	89.5

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

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

The medical center averages are based on 539–1,653 male and 17– 65 female respondents, depending on the question.

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys—including those conducted for cause—by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[20] Table 8 summarizes the relevant medical center inspections most recently performed by the OIG and The

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

Joint Commission (TJC).[21] Of note, at the time of the OIG virtual review, the medical center had closed all recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in October 2017.

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.[22] Additional results included the Long Term Care Institute's inspection of the medical center's CLCs.[23]

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 Cincinnati VA Medical Center, Cincinnati, Ohio*, Report No. 17-05398-172, May 23, 2018)	October 2017	7	0
OIG (*Follow-up to Clinical and Administrative Concerns at the Cincinnati VA Medical Center, Ohio*, Report No. 17-05398-177, May 23, 2018)	October 2017	0	n/a*
TJC Hospital Accreditation	July 2019	46	0
TJC Behavioral Health Care Accreditation		3	0
TJC Home Care Accreditation		11	0

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

[22] VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs*, May 9, 2017. The Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term collaboration with 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.

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
TJC Opiate Substitution Services (Behavioral Health)	June 2018	9	0

Source: OIG and TJC (inspection/survey results verified with the Chief of Quality Management on July 29, 2020).
**n/a = not applicable*

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 weaknesses related to the patient safety program and completion of timely disclosures.

The OIG requested a list of sentinel events from October 16, 2017, to July 27, 2020; the Patient Safety Manager and Chief of Quality Management stated that the facility did not identify any sentinel events during that period.[24] However, during the review of root cause analyses listed in the facility's fiscal year 2019 *Patient Safety Annual Report*, the OIG identified four cases that may have met the criteria for sentinel events. Three of the four cases resulted in the patient's death: the first was related to timely treatment for a critical lab value, the second was associated with a delayed transfer to a community hospital, and the third involved an invasive procedure. The fourth event concerned an attempted act of self-harm by an unattended patient with suicidal thoughts.

Additionally, VHA requires medical centers to conduct timely disclosure of events that meet criteria.[25] Of the four root cause analyses noted above, none had evidence of institutional disclosure. Further, the OIG requested a list of institutional disclosures from October 16, 2017,

[24] 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."

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

through July 27, 2020, and noted that none were completed in a timely manner and that the associated documentation in the patients' electronic health record lacked the required reasons for the delays. There appear to be opportunities for medical center leaders to evaluate and improve the processes used to identify adverse patient events that warrant timely disclosure to patients.

Table 9 lists the reported sentinel events and disclosures from October 16, 2017 (the prior OIG comprehensive healthcare inspection), through July 27, 2020.[26]

Table 9. Summary of Selected Organizational Risk Factors (October 16, 2017, through July 27, 2020)

Factor	Number of Occurrences
Sentinel Events	0
Institutional Disclosures	4
Large-Scale Disclosures	0

Source: Cincinnati VA Medical Center, Chief Quality of Quality Management (received July 27 and July 28, 2020).

Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.[27]

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA facilities as of December 31, 2019. Of note, figure 5 uses blue and green data points to indicate high performance for the Cincinnati VA Medical Center (for example, in the areas of rating (of) specialty care (SC) provider, mental health (MH) experience (exp) of care, and rating (of) primary care (PC) provider). Metrics that need improvement are denoted in orange and red (for example, care transition, health care (HC)

[26] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the Cincinnati VA Medical Center is a -high complexity (1b) affiliated system as described in appendix B.)

[27] "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.)

associated (assoc) infections, rating (of) hospital, and healthcare effectiveness data and information set outpatient performance measures (HEDIS like – HED90_ec)).[28]

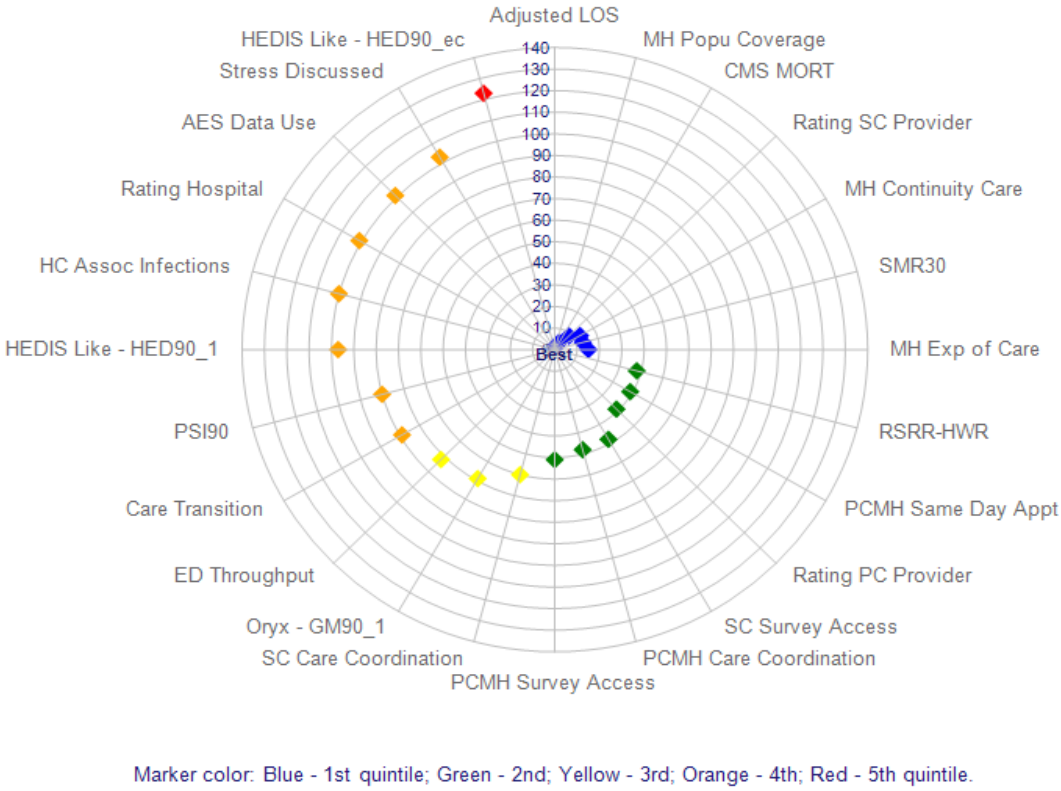

Figure 5. *System quality of care and efficiency metric rankings for FY 2020 quarter 1(as of December 31, 2019).*

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 &

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

Medicaid Services' (CMS) *Nursing Home Compare* and provides a single resource "to review quality measures and health inspection results."[29]

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 Cincinnati CLC (for example, in the areas of physical restraints–long-stay (LS), outpatient emergency department (ED) visit–short-stay (SS), and high-risk pressure ulcer (PU) (LS)). Metrics that need improvement are denoted in orange and red (for example, rehospitalized after nursing home (NH) admission (SS), urinary tract infection (UTI) (LS), and moderate-severe pain (LS)).[30]

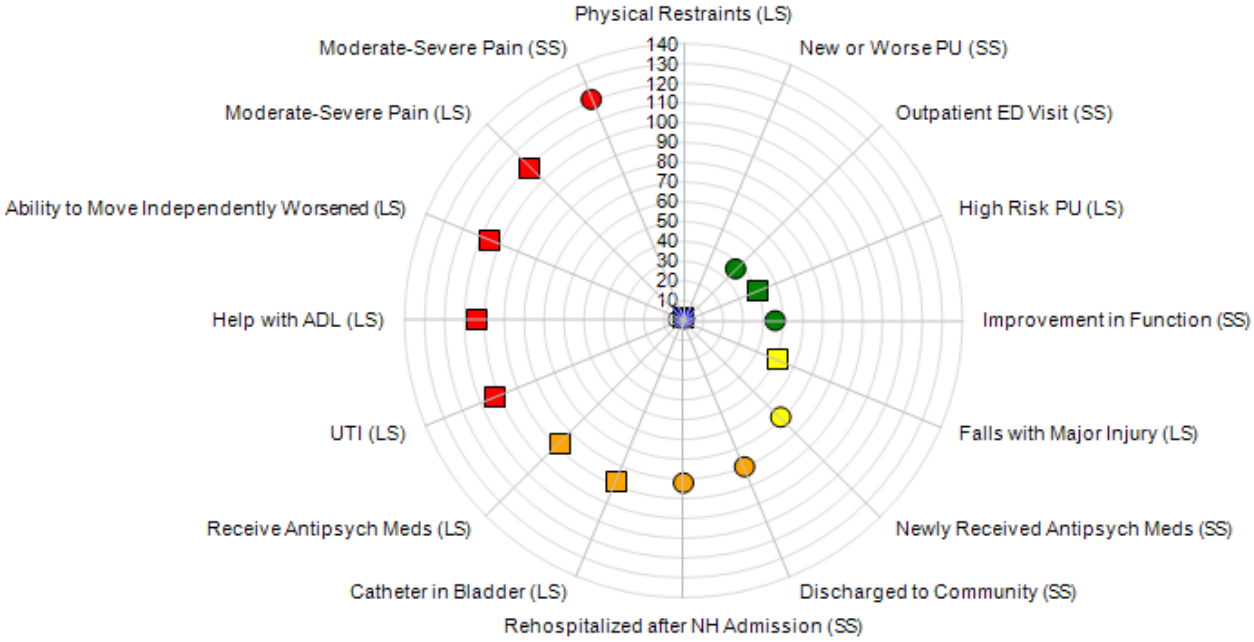

Figure 6. *Cincinnati CLC Quality Measure Rankings for FY 2020 quarter 1 (as of December 31, 2019).*

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.

[29] 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."

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

Leadership and Organizational Risks Conclusion

The OIG noted that three of the four executive leadership positions were occupied by acting staff at the time of the virtual inspection. The permanent ADPCS, who was serving as the acting Medical Center Director, was the most tenured member of the leadership team, having served as ADPCS since January 2019. Survey results revealed opportunities for the acting Chief of Staff to improve employees' attitudes toward the workplace. While patient experience survey data indicated overall satisfaction with care, gender-specific results highlighted opportunities to improve experiences in the inpatient and patient-centered medical home settings. However, medical center leaders appeared to be actively engaged with patients by conducting veteran town hall meetings and leadership rounds. The OIG's review of selected organizational risk factors identified concerns with processes related to identification of sentinel events and institutional disclosure. In individual interviews, executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and/or patient experiences. Additionally, 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 CLC SAIL measures.

COVID-19 Pandemic Readiness and Response

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

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

Due to VHA's mission-critical work in supporting both veteran and civilian populations during the pandemic, the OIG conducted an evaluation of the pandemic's 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.[35]

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

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

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

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

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

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care.[36] To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation.[37] Many quality-related activities are informed and required by VHA directives, nationally recognized accreditation standards (such as The Joint Commission), and federal regulations. VHA strives to provide healthcare services that compare "favorably to the best of the private sector in measured outcomes, value, [and] efficiency."[38]

To determine whether VHA facilities have implemented and incorporated OIG-identified key processes for quality and safety into local activities, the inspection team evaluated the 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.[39] Protected peer reviews, "when conducted systematically and credibly," reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and "long-term improvements in patient care."[40] Peer reviews are "intended to promote confidential and non-punitive processes" that consistently contribute to quality management efforts at the individual provider level.[41] The OIG team examined the completion of the following elements:

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

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

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

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

[40] VHA Directive 1190.

[41] VHA Directive 1190.

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[42]
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the 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.[43] It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[44] Inspectors reviewed several aspects of the UM program:

- Completion of at least 80 percent of all required inpatient reviews
- Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database
- Interdisciplinary review of UM data
- Implementation and monitoring of improvement actions recommended by the interdisciplinary UM group

Finally, the OIG reviewers assessed the medical center's reports of patient safety incidents with related root cause analyses.[45] Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root

[42] VHA Directive 1190.

[43] VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. UM reviews include evaluating the "appropriateness, medical need, and 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.)

[44] VHA Directive 1117(2).

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

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

- Annual completion of a minimum of eight root cause analyses[47]
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of an annual patient safety report to medical center leaders

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

Quality, Safety, and Value Findings and Recommendations

The medical center complied with requirements for the establishment of a committee responsible for QSV oversight functions, completion of UM reviews, and submission of the annual patient safety report. However, the OIG identified weaknesses in the QSV Committee's implementation of improvement actions, protected peer reviews, and root cause analysis processes.[49]

VHA requires that facilities achieve and maintain TJC accreditation. TJC standards specify that facilities establish a governing body responsible for QSV oversight functions and practices. The governing body reviews relevant data and information and ensures that when actions are recommended by the committee, they are fully implemented and changes are monitored.[50] The OIG reviewed meeting minutes from January through December 2019 and found the QSV Committee, which was responsible for tracking and trending quality of care and patient outcomes, did not consistently implement action items. This could have resulted in insufficient

[46] VHA Handbook 1050.01.

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

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

[49] At the time of the OIG review, the committee was called the QSV Committee. The medical center subsequently changed the name to the Quality and Patient Safety Council which is reflected in the action plans and updated in figure 4.

[50] VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs,* May 9, 2017; TJC. Leadership standards LD.01.01.01, LD.02.01.01, and LD.03.01.01.

oversight of needed patient safety and quality of care improvements. The Chief of Quality Management stated that a separate spreadsheet was kept to track actions but it was not included in the QSV Committee minutes or agenda.

Recommendation 1

1. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures the Quality, Safety, and Value Committee fully implements and monitors improvement actions.[51]

Medical Center concurred.

Target date for completion: Completed

Medical Center response: The Quality and Patient Safety (QPS) Council Action Grid was made as a standing agenda item on the QPS council agenda beginning September 2020. The agenda items are reviewed by the committee at the beginning of the meeting and action grid noted in the minutes. Talking points for the open items have also been added to the agenda of related open action items for visibility and as a discussion reminder beginning with the October 2020 QPS meeting. The Action Grid is used to document progress and closure of action items when they are due to be addressed by the subject matter experts. Tracking of action items from the September 2020 meeting through March 2021 demonstrated 6 closed actions and 11 actions still being implemented towards closure.

VHA requires peer review for all deaths "within 24 hours of admission (except in cases when death is anticipated and clearly documented, such as transfer from hospice care)" and completed suicides occurring within seven days after discharge from an inpatient mental health or residential care facility.[52] The OIG found that between January 1 and December 31, 2019, two applicable deaths were not evaluated to determine if peer review was warranted.[53] This may have prevented timely identification of inconsistencies in healthcare providers' practices or the opportunity to identify systemic issues. The Chief of Quality Management could not provide a reason for the lack of evaluation.

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

[52] VHA Directive 1190.

[53] Two deaths occurred within 24 hours of admission.

Recommendation 2

2. The Chief of Staff determines the reasons for noncompliance and makes certain that all applicable deaths are peer reviewed.[54]

Medical center concurred.

Target date for completion: Completed

Medical center response: A tracking system of mortality reviews had not been maintained on the Quality-shared drive. The Risk Manager is responsible to complete and track mortality reviews. A report is pulled at least monthly to determine deaths within 24 hours of admission. These are reviewed for peer review appropriateness. These mortalities reviews are documented on a spreadsheet and stored on the Quality share drive for availability. The number of deaths within 24 hours of admissions and the number reviewed for peer review appropriateness are documented on a spreadsheet and uploaded to the VISN quarterly. There has been one mortality within 24 hours from October 2020-March 2021 and it has been reviewed for peer review appropriateness. 1/1 (100%) compliance.

Any suicides which occur within seven days after discharge from an inpatient mental health or residential care are monitored through issues briefs from the suicide prevention coordinator and noted on the mortality spreadsheet. Currently since June 2020-March 2021, no suicides fell into this category.

Completed mortality and suicide reviews are included in the quarterly peer review trends report presented to CEB [Clinical Executive Board] each quarter.

VHA required the Medical Center Director to ensure that an interdisciplinary group to review UM data was established. 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]."[55] The OIG found that between February and December 2019, there was no interdisciplinary team reviewing UM data. On October 8, 2020, VHA updated the requirement for the review of UM data to be performed by "a multidisciplinary committee, which may include representatives from" various services.[56] Therefore, the OIG made no recommendation.

For thoroughness and credibility, VHA requires root cause analyses to include several factors. These include participation by leaders, "analysis of the underlying systems…to determine where redesigns might reduce risk," "determination of potential improvement in processes or systems

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

[55] VHA Directive 1117(2).

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

that would tend to decrease the likelihood" of future events, identification of "at least one root cause with a corresponding action and outcome measure," and feedback on action(s) taken (resulting from the root cause analysis) provided to the reporter of the adverse event or close call. Once corrective actions are implemented, monitoring must be conducted to assess for effectiveness.[57]

Of the five root cause analyses reviewed, the OIG found that none included an analysis of the underlying systems, and three did not address the determination of potential improvement processes that would decrease the likelihood of future events. Three of the five root cause analyses lacked evidence that action items were fully implemented.

When root cause analyses are not thorough and credible, the process to identify vulnerabilities and implement improvements to prevent future patient harm may be impacted. The Patient Safety Manager could not provide a reason for noncompliance. The Patient Safety Manager reported that the determination of potential improvement processes was implicit in the root cause statement, and lack of monitoring outcome measures for one root cause analysis was due to a documentation flaw. The Patient Safety Manager also reported not fully understanding that the series of "why" questions were to be documented in WebSPOT when these reviews were completed.

Recommendation 3

3. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures that root cause analyses include all required review elements.[58]

Medical Center concurred.

Target date for completion: Completed

Medical Center response: The root cause analyses (RCA) were completed and shared during RCA report out to leadership, however, not all required items were documented into WebSPOT. All required items for RCAs and documentation into WebSPOT has been completed as required based upon Patient Safety Managers' peer to peer audits of each RCA. This audit process began with new RCAs after May 2020 to ensure documentation completeness in WebSPOT. Audit demonstrates 7/7 (100%) compliance for RCAs having all required elements from June 2020-March 2021. The results of this audit period have been shared with the Interim Medical Center Director and at the April 13, 2021 Quality and Patient Safety Council.

[57] VHA Handbook 1050.01.

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

Medical 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).[59]

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.[60]

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

- FPPEs
  - Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs[62]
  - Clear documentation of the results and time frames
  - Evaluation by another provider with similar training and privileges
- OPPEs
  - Application of criteria specific to the service or section
  - Use of minimum criteria for selected specialty LIPs[63]
  - Evaluation by another provider with similar training and privileges

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

[60] VHA Handbook 1100.19.

[61] VHA Handbook 1100.19.

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

[63] 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 and subsequently respond to inquiries from state licensing boards concerning the licensed practitioner's clinical practice.[64] Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB [state licensing board] 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."[65] The OIG reviewers assessed whether the medical center's staff

- Designated an individual and backup responsible for the state licensing board reporting process,
- Completed forms within the required time frame and with required oversight, and
- Reported results to state licensing boards 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:

- Five solo/few practitioners who underwent initial or reprivileging during calendar year 2019[66]
- Ten LIPs who completed an FPPE in calendar year 2019
- Ten LIPs privileged during calendar year 2019
- Twenty LIPs who left the medical center in calendar year 2019

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

[65] 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.)

[66] 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 OIG identified deficiencies with FPPE, OPPE, and provider exit review processes. During the review of FPPEs, the OIG also noted that one practitioner received an expedited appointment to the medical staff. VHA acknowledges that "there may be instances where expediting a medical staff appointment for LIPs is in the best interest of quality patient care."[67] The Medical Staff Coordinator explained that this type of appointment allows the practitioner to see patients before the credentialing request is approved by the Clinical Executive Board. However, the OIG did not find an urgent need for the practitioner to be appointed in this manner and circumvent the standard credentialing process. The acting Chief of Staff confirmed that expedited credentialing was completed only because the provider transferred from another VA.

VHA requires the criteria for the FPPE process "to be defined in advance, using objective criteria accepted by the practitioner." VHA also requires that FPPE results be documented in the provider's profile.[68] The OIG reviewed six LIP profiles and found that all lacked evidence that the practitioners were aware of the evaluation criteria before clinical managers initiated the FPPE process. This could have caused LIPs to misunderstand FPPE expectations. The acting Chief of Medicine acknowledged that due to lack of oversight, none of the prior FPPEs included documentation of the practitioner accepting the criteria in advance of the process.

Recommendation 4

4. The Chief of Staff determines the reasons for noncompliance and ensures clinical managers define in advance, communicate, and document criteria for focused professional practice evaluations in practitioner profiles.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The FPPE form will include the evaluation criteria and an acknowledgment of the discussion of the evaluation criteria for the initial FPPE between the provider and supervisor. An audit of all (100%) new provider FPPEs will be audited for 6 consecutive months. Evidence of evaluation criteria for FPPE and practitioner's awareness prior to the FPPE process will be achieved with a target of 90% compliance rate. Compliance will be reported at CEB.

VHA uses the FPPE process as an oversight tool and requires FPPEs to be completed "when a practitioner does not have the documented evidence of competent performance of the privileges requested." The FPPE must be time-limited and may include "periodic chart review, direct

[67] VHA Handbook 1100.19.

[68] VHA Handbook 1100.19.

observation, monitoring of diagnostic and treatment techniques, or discussion with other individuals involved in the care of patients." Additionally, results of the review "must be documented in the practitioner's provider profile and reported to the Executive Committee of the Medical Staff."[69]

In three of six LIP profiles, the OIG did not find evidence of FPPE results. During the course of the review, the OIG also noted that four low-volume practitioners, who had been on staff at the medical center between five and eight months, had no FPPEs completed at the time of the inspection. When FPPEs are not conducted—or not documented—it may result in practitioners providing patient care without a thorough review of their clinical competencies, which could impact quality care and patient safety. The acting Chief of Medicine was not able to provide a reason for the lack of FPPE results but reported that the four noted LIPs were hired to support staffing when needed, had not begun providing patient care, and were never started on the evaluation process. This is a repeat finding from the previous inspection.[70]

Recommendation 5

5. The Chief of Staff evaluates and determines additional reasons for noncompliance and ensures that service chiefs document the results of focused professional practice evaluations in practitioner profiles.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: FPPE forms will have the documented results of the FPPE evaluation along with the provider and supervisor acknowledgment of the review. An audit of all (100%) new provider FPPEs will be audited for 6 consecutive months with a 90% target of documented results and acknowledgment of review on the FPPE form. Compliance will be reported at CEB.

VHA requires that, at the time of reprivileging, service chiefs consider relevant, service- and practitioner-specific data using defined criteria when recommending the continuation of LIP privileges to the Executive Committee of the Medical Staff (known as the Clinical Executive Board at this medical center).[71] Such data are maintained as part of the practitioner's profile and may include "direct observation, clinical discussions, and clinical pertinence reviews."[72]

[69] VHA Handbook 1100.19.

[70] VA OIG, *Comprehensive Healthcare Inspection Program Review of the Cincinnati VA Medical Center, Cincinnati, Ohio*, Report No. 17-05398-172, May 23, 2018. The previous recommendation was closed when medical center leaders submitted evidence of sustained improvement, but the OIG team found continued issues that warranted a repeat recommendation for improvement.

[71] VHA Handbook 1100.19.

[72] VHA Handbook 1100.19.

The OIG found that two provider profiles did not contain evidence of either service-specific OPPE data or the service chief's recommendation to continue privileges based in part on OPPE activities. One additional provider's profile lacked evidence of service-specific OPPE data while one other provider's profile lacked evidence that the service chief recommended privileges based in part on the OPPE activities. This resulted in incomplete data to support decisions to continue clinical privileges. The Medical Staff Coordinator stated that although service chiefs were educated on the need to include service-specific elements in OPPEs, not all followed the requirements. The acting Chief of Staff was unable to provide a clear reason for the challenges with the OPPE process. Service-specific OPPE data is a repeat finding from the previous inspection.[73]

Recommendation 6

6. The Chief of Staff evaluates and determines additional reasons for noncompliance and ensures that service chiefs collect service-specific ongoing professional practice evaluation data.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: Service specific data for OPPEs and service chief recommendation to continue privileges based upon the OPPE activities will be documented on the OPPE forms prior to review and consideration by the CEB. An audit of 30 random OPPEs will be performed monthly for 6 consecutive months. A compliance rate for service chiefs' service-specific OPPE evaluation data documented on the OPPE will be 90%. Compliance will be reported at CEB.

Recommendation 7

7. The Chief of Staff determines the reasons for noncompliance and ensures service chiefs recommend continuation of privileges based on ongoing professional practice evaluation data.

[73] VA OIG, *Comprehensive Healthcare Inspection Program Review of the Cincinnati VA Medical Center*, *Cincinnati, Ohio*, May 23, 2018. The previous recommendation was closed when medical center leaders submitted evidence of sustained improvement, but the OIG team found continued issues that warranted a repeat recommendation for improvement.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: Service chief recommendation to continue privileges based upon the OPPE activities will be documented on the OPPE forms prior to review and consideration by the CEB. An audit of 30 random OPPEs will be performed monthly for 6 consecutive months. A compliance rate of service chiefs recommendation for continuation of privileges based upon OPPE evaluation data will be 90%. Compliance will be reported at CEB.

VHA requires that FPPE and OPPE results be reported to the Executive Committee of the Medical Staff for review and evaluation of LIPs' initial and reprivileging requests. Committee minutes must indicate the materials reviewed and the rationale for the privileging determinations. The committee's recommendation is then submitted to the Medical Center Director for approval.[74]

For three of the six practitioners who were granted initial privileges, the OIG did not find evidence that the Clinical Executive Board documented its decision to recommend continuing privileges based upon FPPE activities. Additionally, three had incomplete documentation to support the Clinical Executive Board's decision to recommend privileges based on OPPE results. Failure to use FPPE and OPPE data and document the rationale for recommendations may result in incomplete evidence to support the Director's approval of clinical privileges. The acting Chief of Medicine reported that each service provides OPPE results to the Clinical Executive Board twice per year and conceded it was possible that a practitioner was not listed on the agenda, or the results were not captured in the minutes, due to the high volume of practitioners discussed.

Recommendation 8

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

[74] VHA Handbook 1100.19.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The CEB meeting minutes will consistently reflect the review of professional practice evaluation results in the decision to recommend initiation and continuation of privileges during time of appointment and reappointment of providers based upon FPPE/OPPE documented activities/data. An audit of 30 random FPPE/OPPEs for initial appointment or reappointment for privileges will be performed monthly for 6 consecutive months with a 90% target. The review will include accurate documentation in the meeting minutes reflecting CEB review and decision based upon FPPE/OPPE activities/data. Compliance will be reported at CEB.

VHA required the "Director, or head," to ensure that exit review forms, which document the review of practitioners' clinical practice, are "completed within 7 calendar days of departure of any licensed health care professional."[75] VHA changed the requirement to seven business days in January 2021.[76] Of the 20 practitioners who departed the medical center in calendar year 2019, the OIG found that 18 had a completed exit form; however, nine of those were not completed within seven business days. Failure to complete exit review forms in a timely manner may delay reporting of practitioners' potential substandard care to state licensing boards. The Medical Staff Coordinator reported that medical center leaders had become aware of the problematic exit review processes, noting the exit forms were not completed due to lack of oversight. The Medical Staff Coordinator stated that each service line now maintains the Provider Exit Form, receives reminders from credentialing staff, and completes the forms electronically with digital signatures/time stamps.

Recommendation 9

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

[75] VHA Notice 2018-05; VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. VHA Handbook 1100.18 was replaced with VHA Directive 1100.18 on January 28, 2021. The new directive changed the requirement from seven calendar days to seven business days.

[76] VHA Directive 1108.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Credentialing and Privileging Office has been added to the facility clearance checklist for all licensed professionals. A line item has also been added to the clearance form for the supervisor to initiate and check off that the provider exit review has been initiated. The policy for employee clearance was updated March 2021 which includes the 7-day requirement. An audit of exit reviews completed within 7 business days will be completed for 6 consecutive months for a 90% compliance rate. Compliance will be reported at CEB.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[77] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[78] 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.[79] These disorders, coupled with high-dose opioid use, can potentially lead to an increased risk of overdose compared to the general population.[80]

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.[81] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[82] 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.[83] 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.[84]

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

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

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

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

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

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

[81] "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."

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

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

[84] *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."[85] 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 nine selected outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The 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 was generally compliant with indicators of expected performance for pain screening, aberrant behavior risk assessment, urine drug testing, and multidisciplinary pain management committee processes. However, the OIG found a deficiency with informed consent.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy. VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.[86] The OIG did not find evidence that clinicians documented informed consent prior to initiating long-term opioid therapy in three of nine patient electronic health records reviewed. These patients may have received treatment without knowledge of the risks associated with long-term opioid therapy, including opioid dependence, tolerance, addiction, and intentional or unintentional fatal overdose. The acting Chief of Rehabilitation Care Line reported that compliance for consent was reviewed about five years ago with some noted improvement. However, the acting chief acknowledged that primary care and community-based outpatient clinic provider turnover had negatively impacted compliance; while a recent quarterly report had shown improvement in completion of informed

[85] VHA Directive 2009-053, *Pain Management*, October 28, 2009.
[86] VHA Directive 1005.

consent, the acting chief also acknowledged that the consent process needed refining. Due to the small sample size of patient records available for review, the OIG made no recommendation.

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.[87] 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.[88]

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.[89]

VHA requires that each medical center and very large community-based outpatient clinic (CBOC) have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.[90] The OIG examined various requirements related to SPCs:

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

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

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

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

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

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

in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC."[91] 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."[92] 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.[93] 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.[94]

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."[95] 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."[96] 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."[97]

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

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

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

[93] *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.

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

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

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

[97] 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."[98]

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.[99] VHA also requires that all staff receive annual refresher training.[100] In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[101]

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

- Relevant documents;

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

[99] 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.

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

[101] 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 36 outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The medical center generally complied with requirements associated with a designated SPC, suicide prevention training, and monthly outreach activities. However, the OIG found deficiencies.

With VHA's original requirement that was in place when these patients received care—that "Any patient determined to be High Risk for Suicide must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination."[102]—the OIG estimated that 47 percent of HRS PRFs were placed within 24 hours of referral to the SPC.[103] Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined time frame for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was 5 days (observed range was 0–38 days).

The OIG also noted concerns with the review of HRS PRFs within the required time frame. VA guidance states that all patients with an HRS PRF should be reevaluated at least every 90 days.[104] The OIG estimated that 56 percent of patients with an HRS PRF were reevaluated at least every 90 days.[105] Based on the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that clinical staff reviewed 26 of 36 patients within the new time frame (observed range was 14–104 days).[106]

Additionally, the OIG noted deficiencies with safety plan completion. Per VHA, patients with a high-risk designation should have a completed suicide safety plan within seven days before or after the current HRS PRF date.[107] The OIG found that safety plans were completed within seven days for 65 percent of the electronic health records reviewed.[108] Completion of safety plans ensures the patient has a "prioritized written list of coping strategies…to help them lower their

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

[103] The OIG estimated that 95 percent of the time, the true compliance rate is between 31.2 and 63.3 percent, which is statistically significantly below the 90 percent benchmark.

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

[105] The OIG estimated that 95 percent of the time, the true compliance rate is between 39.4 and 71.4 percent, which is statistically significantly below the 90 percent benchmark.

[106] VHA Notice 2020-13.

[107] VHA suicide subject matter expert response to timing of safety plan completion, July 8, 2019.

[108] The OIG estimated that 95 percent of the time, the true compliance rate is between 46.9 and 80.8 percent, which is statistically significantly below the 90 percent benchmark.

imminent risk of suicidal behavior."[109] A staff psychiatrist stated that the lack of attention to detail by providers was a reason for noncompliance, noting instances in which providers missed opportunities to complete the safety plans during appointments.

Recommendation 10

10. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures clinicians complete suicide prevention safety plans in the expected time frame for patients with High Risk for Suicide Patient Record Flags.

Medical center concurred.

Target date for completion: October 31, 2021

Medical center response: Clinicians have been educated on the elements and timeframes to complete a Suicide Safety Plan for Veterans with a High Risk for Suicide Patient Record Flag (HRS PRF). Compliance with completion of the Suicide Safety Plan will be monitored through 30 retrospective chart reviews for Veterans with an HRS PRF each month. At least 90% of records reviewed will have a completed Suicide Safety Plan with all required elements for 6 consecutive months. Compliance will be reported at QPS Council.

[109] VHA Manual, *Safety Plan Treatment Manual to Reduce Suicide Risk: Veteran Version*.

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."[110]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018.[111] 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.[112] 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.[113]

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.

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

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

[112] 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.

[113] 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 document at a minimum

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

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

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

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

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service.[114] 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 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

Generally, the medical center met the above requirements. With VHA's original requirements that were in place when these patients received care, the OIG estimated that 56 percent of

[114] VHA Handbook 1004.03(1).

patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes.[115] However, VHA deleted requirements for the documentation of these elements in the LST progress note.[116] The OIG made no recommendations but remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

[115] The OIG estimated that 95 percent of the time, the true compliance rate is between 40.9 and 69.8 percent, which is statistically significantly below the 90 percent benchmark.

[116] VHA Handbook 1004.03(1).

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[117] According to data released by the National Center for Veterans Analysis and Statistics in May 2019, the total veteran population and proportion of male veterans are projected to decrease while the proportion of female veterans are anticipated to increase.[118] To help the VA better understand the needs of the growing women veterans population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."[119] Additionally, a VA report in 2016 on suicide among veterans pointed out concerning trends in suicide among women veterans and discussed "the importance of understanding suicide risk among women veterans and developing gender-tailored suicide prevention strategies."[120]

VHA requires that all eligible and enrolled women veterans have access to timely, high-quality, and comprehensive healthcare services in a sensitive and safe environment. Facilities must, therefore, ensure availability of appropriate resources, services, and staffing ratios.[121] VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veteran health committee "that develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."[122]

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

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

[117] "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.

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

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

[120] 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.

[121] VHA Directive 1330.01(3), *Health Care Services for Women Veterans,* February 15, 2017, amended June 29, 2020. (This directive was amended again on January 8, 2021.)

[122] VHA Directive 1330.01(3).

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

Women's Health Findings and Recommendations

The medical center complied with requirements for most of the provision of care indicators reviewed. However, the OIG identified weaknesses with designated CBOC women's health primary care providers and the Women Veterans Advisory Committee.[123]

VHA requires that each CBOC have at least two designated women's health primary care providers (WH-PCPs) or that appropriate arrangements are in place for leave coverage in CBOCs with only one designated WH-PCP.[124] The OIG found that three CBOCs did not have at least two designated WH-PCPs. One CBOC (Georgetown) did not have any designated WH-PCPs, and two CBOCs (Clermont and Dearborn) had only one designated WH-PCP. When CBOCs do not have the required number of WH-PCPs or arrangements for leave coverage when there is only one designated WH-PCP, the medical center's ability to provide comprehensive healthcare services to women veterans may be limited. The OIG reviewed the Women Veterans Advisory Committee minutes for September 2019 and identified that committee members were

[123] At the time of the OIG review, the committee was called the Women Veterans Advisory Committee. The medical center subsequently changed the name to the Women Veterans Health Committee which is reflected in the action plans and updated in figure 4.

[124] VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018. (This directive was amended on June 29, 2020, and again on January 8, 2021.)

aware that the medical center did not have the required two WH-PCPs at each CBOC. The Chief of Primary Care and Chief Nurse Primary Care stated that women's health training for primary care providers was scheduled for May 2020; however, it was rescheduled for September 2020, due to issues caused by the COVID-19 pandemic. The Chief Nurse Primary Care also reported that primary care providers had left the medical center in 2020 and that there is a provider who travels to the Georgetown CBOC to conduct gender-specific exams when needed.

Recommendation 11

11. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that each community-based outpatient clinic has at least two designated women's health primary care providers or plans for leave coverage if there is only one designated provider.[125]

Medical center concurred.

Target date for completion: Completed

Medical center response: Two Women's Health providers have been put in place at each of the CBOCs except Georgetown. A second provider is being onboarded for Georgetown and likely to begin approximately June/July 2021. There is one Women's Health provider currently at the Georgetown CBOC and there is coverage for that provider during periods of leave. Additionally, the CBOC Physician Section Chief, who is a Women's Health provider, is available for coverage.

VHA requires women veterans health committees to have an active charter, meet quarterly, report to executive leaders, and have a core membership. That membership must include a women veterans program manager; a women's health medical director; "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership."[126] The OIG reviewed the Women Veterans Advisory Committee (this medical center's women veterans health committee equivalent) charter and meeting minutes for the four meetings held between August 1 and December 31, 2019, and found the committee lacked members from gynecology, social work, and business office/non-VA medical care.

The OIG team also noted that the following members had not attended any meetings: representatives from medical and/or surgical subspecialties, pharmacy, radiology, and quality

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

[126] VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018. (This directive was amended on June 29, 2020, and again on January 8, 2021.)

management. Lack of expertise and oversight in the review and analysis of data could impact improvements for quality and equitable women's health care. Medical center program staff, including the acting Women's Health Program Manager, Chief Nurse Primary Care, and acting Women's Health Medical Director were unable to provide a reason for noncompliance.

Recommendation 12

12. The Chief of Staff determines the reasons for noncompliance and makes certain that required members are assigned and consistently attend Women Veterans Advisory Committee meetings.

Medical center concurred.

Target date for completion: July 31, 2021

Medical center response: The required members have been educated on the importance of attending or having a representative attend all meetings of the Women Veterans Health Committee. The Women Veterans Health Committee will demonstrate attendance compliance of at least 90% for six months. Compliance will be reported at CEB.

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."[127] The goal of SPS is to "provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[128] 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 instruments[129]
- 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[130]

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.[131] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[132]

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.[133]

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

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

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

[130] VHA Directive 1116(2).

[131] 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.

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

[133] 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.[134]

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

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

High-Risk Processes Findings and Recommendations

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

[134] VHA Directive 1116(2).

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]."[135] The OIG found that the colonoscope SOP did not contain all the required steps when compared to the IFU. This may have resulted in inadequate disinfection of RME. The Chief of SPS and the RME Coordinator cited lack of attention to detail as the reason for the discrepancies.

Recommendation 13

13. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that standard operating procedures align with manufacturer's instructions for use.

Medical center concurred.

Target date for completion: October 31, 2021

Medical center response: The standard operating procedure (SOP) for the colonoscope has been updated to be consistent with all steps of the manufacturer's instructions for use as required to adequately disinfect the colonoscope. In addition, the facility has a process in place to review all SOPs on an ongoing basis to ensure alignment with the manufacturer's instructions for use. The SOPs reviewed are documented in the monthly RME committee which reports quarterly to CEB. For SOPs reviewed they will be in alignment with IFU for 100% compliance over two quarters.

VHA also requires that facilities deploy CensiTrac®, a system for instrument-level tracking.[136] The OIG found evidence that while CensiTrac® was operational, the Chief of SPS reported that it was not yet implemented in one location. The endoscopes stored in the gastrointestinal suite were tracked through a different program. The use of multiple tracking systems could result in confusion and potential loss of equipment. The Chief of SPS reported that the VISN purchased the computers, which are required to fully implement the CensiTrac® system, for installation by May 31, 2020. However, the goal was not met due to delayed delivery.

Recommendation 14

14. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that CensiTrac® is fully operational.

[135] VHA Directive 1116(2).

[136] VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*.

Medical center concurred.

Target date for completion: May 31, 2021

Medical center response: CensiTrac will be operational in the GI [GastroIntestinal] Lab. Appropriate technology has been received. Upon completion of set up procedures by OIT [Office of Information and Technology] and biomedical engineering, staff will be educated on use in the GI Lab.

According to VHA, facilities must maintain written records of weekly eyewash station function testing.[137] The OIG found that the eyewash stations in the SPS preparation and decontamination areas were not being tested weekly. This could potentially result in staff injury if the eyewash station is unavailable in an emergency or not operating properly. The Chief of SPS stated lack of oversight and attention to detail as reasons for noncompliance.

Recommendation 15

15. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that the Chief of Sterile Processing Services maintains written records of weekly eyewash station function testing.

Medical center concurred.

Target date for completion: October 31, 2021

Medical center response: SPS staff will complete required weekly eyewash station testing. Results will be documented and reported to the Reusable Medical Equipment (RME) Committee quarterly until there is at least 90% compliance for two consecutive quarters. This will be reported to CEB quarterly.

Additionally, VHA requires that SPS staff receive monthly continuing education, noting the Chief of SPS is responsible for "ensuring that all individuals charged with reprocessing duties are appropriately trained and competency is documented prior to the performance of the assigned tasks."[138] The Chief of SPS reported that reprocessing occurs in both SPS and the gastrointestinal suite. The OIG did not find evidence of completed monthly continuing education for 8 of the 10 selected staff during October through December 2019. Of these staff, two assigned to SPS had some monthly training and the six assigned to the gastrointestinal suite had no monthly training. Lack of training can create a knowledge gap among staff that results in improperly reprocessed equipment and compromised patient safety. The Chief of SPS and the RME Coordinator cited

[137] VHA Directive 7704(1).
[138] VHA Directive 1116(2).

lack of oversight and unawareness that the Chief of SPS had to oversee the monthly education of all staff who reprocess equipment, regardless of location or supervision.

Recommendation 16

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

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: A monthly education schedule has been developed for the fiscal year for required continuing education. Employee attendance at education sessions will be tracked, and completion rates reported to the RME committee monthly until 90% completion rate is met for 6 consecutive months.

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	Sixteen OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, 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	• The QSV Committee fully implements and monitors improvement actions. • All applicable deaths are peer reviewed. • Root cause analyses include all required elements.	• None
Medical Staff Privileging	• FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards	• Clinical managers define in advance, communicate, and document criteria for FPPE in practitioner profiles. • Service chiefs document the results of FPPEs in practitioner profiles. • Service chiefs collect service-specific OPPE data. • Service chiefs recommend continuation of privileges based upon OPPE data.	• Clinical Executive Board meeting minutes consistently reflect the review of professional practice evaluation results in the decision to recommend initiation and continuation of privileges. • Provider exit review forms are completed within seven business days of licensed healthcare professionals' departure from the medical center.
Medication Management: Long-Term Opioid Therapy	• Provision of pain management using long-term opioid therapy • Program oversight and evaluation	• None	• None
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	• Clinicians complete suicide prevention safety plans within the expected time frame for patients with High Risk for Suicide Patient Record Flags.	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Care Coordination: Life-Sustaining Treatment Decisions	• LSTD multidisciplinary committee • Goals of care conversation documentation • LSTD note/orders completed by an authorized provider or delegated appropriately	• None	• None
Women's Health: Comprehensive Care	• Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements	• Each CBOC has at least two designated women's health primary care providers or plans for leave coverage plans if there is only one designated provider.	• Required members are assigned and consistently attend Women Veterans Advisory Committee meetings.
High-Risk Processes: Reusable Medical Equipment	• Administrative processes • Quality assurance • Staff training	• Standard operating procedures align with manufacturer's instructions for use.	• CensiTrac® is fully operational. • Chief of SPS maintains written records of weekly eyewash station function testing. • Staff who reprocess RME receive monthly continuing education.

Appendix B: Medical Center Profile

The table below provides general background information for this high complexity (1b) affiliated medical center reporting to VISN 10.[1]

Table B.1. Profile for Cincinnati VA Medical Center (539)
(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	$435,616,990	$453,284,014	$477,527,792
Number of:			
• Unique patients	42,100	42,306	42,377
• Outpatient visits	583,495	600,491	605,704
• Unique employees	2,045	2,035	2,092
Type and number of operating beds:			
• Community living center	64	64	64
• Domiciliary	107	107	107
• Medicine	62	62	62
• Mental health	24	23	23
• Neurology	2	2	2
• Surgery	29	29	29
Average daily census:			
• Community living center	44	46	46
• Domiciliary	86	88	85
• Medicine	43	42	43
• Mental health	15	15	15
• Neurology	2	1	1

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

Profile Element	Medical Center Data FY 2017*	Medical Center Data FY 2018	Medical Center Data FY 2019‡
• Surgery	9	7	7

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

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

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

October 1, 2017, through September 30, 2018.

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

Appendix C: VA Outpatient Clinic Profiles

The VA outpatient clinics in communities within the catchment area of the 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
Bellevue, KY	539GA	5,906	3,339	Anesthesia Dermatology	EKG	Nutrition Pharmacy Social work Weight management
Cincinnati, OH	539GB	10,931	6,844	Anesthesia Dermatology Eye Infectious disease Podiatry Rehab physician	EKG	Nutrition Pharmacy Social work Weight management

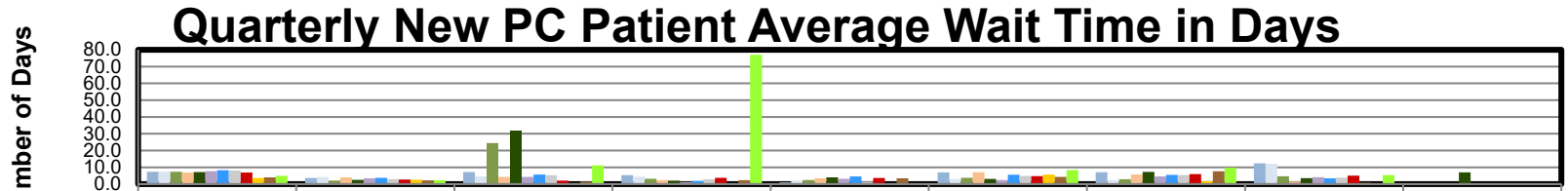
[1] VHA Directive 1230(3), *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended January 7, 2021. An encounter is a "professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient's condition." Specialty care services refer to non-primary care and non-mental health services provided by a physician. Diagnostic services include electrocardiogram (EKG). Ancillary services include nutrition, pharmacy, social work, and weight management.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Greendale (Dearborn), IN	539GC	6,420	3,255	Anesthesia Dermatology Eye Podiatry	EKG	Nutrition Pharmacy Social work Weight management
Florence, KY	539GD	8,532	3,349	Dermatology Eye Podiatry	EKG	Nutrition Pharmacy Social work Weight management
Hamilton, OH	539GE	7,473	4,380	Anesthesia Dermatology Eye Podiatry Pulmonary/ Respiratory disease	EKG	Pharmacy Nutrition Social work Weight management
Georgetown, OH	539GF	3,639	825	Anesthesia Dermatology Eye Podiatry	EKG	Nutrition Pharmacy
Cincinnati, OH	539QC	1	–	–	–	–
Cincinnati, OH	539QD	–	711	Endocrinology Poly-Trauma	–	Nutrition 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

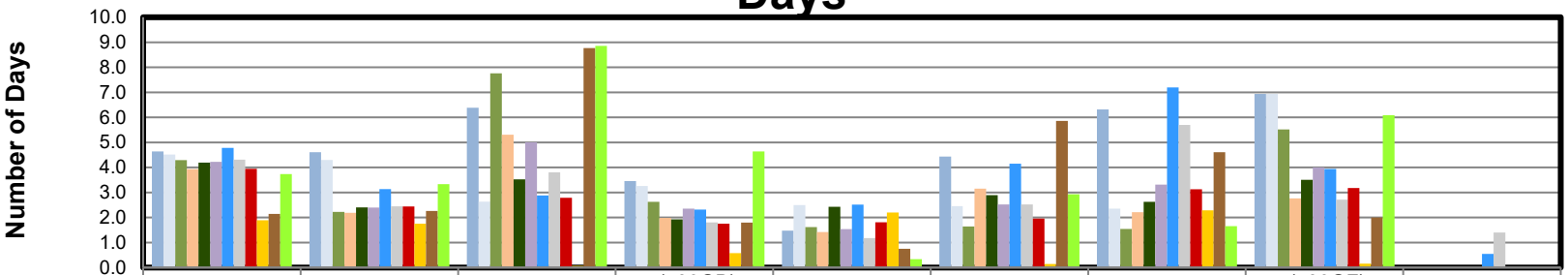


	VHA Total	(539) Cincinnati, OH	(539GA) Bellevue, KY	(539GB) Clermont County, OH	(539GC) Dearborn, IN	(539GD) Florence, KY	(539GE) Hamilton, OH	(539GF) Georgetown, OH	(539QC) Vine Street, OH
JUL-FY19	7.3	3.6	7.2	5.3	1.0	7.0	7.1	12.4	n/a
AUG-FY19	7.4	4.2	4.5	4.4	1.8	3.1	2.4	12.1	n/a
SEP-FY19	7.3	2.1	24.5	3.2	2.4	3.7	2.9	4.6	n/a
OCT-FY20	6.9	4.0	4.3	2.4	3.5	7.0	5.8	1.6	0.0
NOV-FY20	7.1	2.5	31.8	2.1	4.0	3.1	7.3	3.5	7.0
DEC-FY20	7.8	3.4	4.3	1.3	3.2	2.5	4.5	4.1	0.0
JAN-FY20	8.3	3.7	5.7	1.9	4.6	5.6	5.5	3.5	0.0
FEB-FY20	8.1	3.0	5.3	2.9	1.5	4.8	5.4	3.8	0.0
MAR-FY20	6.9	2.7	2.1	3.7	3.6	4.8	6.0	5.0	0.0
APR-FY20	3.6	2.6	0.6	0.0	n/a	5.7	1.8	0.7	n/a
MAY-FY20	4.0	2.2	1.5	2.3	3.5	4.3	7.6	0.3	0.0
JUN-FY20	4.9	2.4	11.2	77.0	0.0	8.4	9.7	5.4	0.0

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

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (539A4) Fort Thomas, KY and (539QB) Cincinnati, OH as no data were reported. The OIG has on file the medical center's explanation for the increased wait times for the Clermont County, OH CBOC.

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."



	VHA Total	(539) Cincinnati, OH	(539GA) Bellevue, KY	(539GB) Clermont County, OH	(539GC) Dearborn, IN	(539GD) Florence, KY	(539GE) Hamilton, OH	(539GF) Georgetown, OH	(539QC) Vine Street, OH
JUL-FY19	4.6	4.6	6.4	3.5	1.5	4.4	6.3	6.9	n/a
AUG-FY19	4.5	4.3	2.6	3.3	2.5	2.5	2.4	6.9	n/a
SEP-FY19	4.3	2.2	7.8	2.6	1.6	1.6	1.5	5.5	n/a
OCT-FY20	3.9	2.2	5.3	2.0	1.4	3.2	2.2	2.8	0.0
NOV-FY20	4.2	2.4	3.5	1.9	2.4	2.9	2.6	3.5	0.0
DEC-FY20	4.2	2.4	5.0	2.4	1.5	2.5	3.3	4.0	0.0
JAN-FY20	4.8	3.1	2.9	2.3	2.5	4.1	7.2	3.9	0.5
FEB-FY20	4.3	2.4	3.8	1.8	1.2	2.5	5.7	2.7	1.4
MAR-FY20	3.9	2.4	2.8	1.8	1.8	2.0	3.1	3.2	0.0
APR-FY20	1.9	1.8	0.1	0.6	2.2	0.1	2.3	0.2	n/a
MAY-FY20	2.1	2.3	8.8	1.8	0.7	5.9	4.6	2.0	n/a
JUN-FY20	3.7	3.3	8.9	4.6	0.3	2.9	1.7	6.1	n/a

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

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (539A4) Fort Thomas, KY and (539QB) Cincinnati, OH) as no data were reported.

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

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

Measure	Definition	Desired Direction
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
AES Data Use	Composite measure based on three individual All Employee Survey 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, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

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

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

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

1. I have reviewed and concur with the response for the draft report of our Comprehensive Healthcare Inspection of the Cincinnati VA Medical Center in Ohio.

2. I concur with the responses and action plans submitted by the Cincinnati VA Medical Center Interim Director.

3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson

Appendix H: Interim Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: April 5, 2021

From: Interim Director, Cincinnati VA Medical Center (539/00)

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

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

Thank you for your thorough review. Please find the Medical Center's attached response to the draft Comprehensive Healthcare Inspection of the Cincinnati VA Medical Center in Ohio. I concur with the finding, recommendations and action plans.

(Original signed by:)

Thelma J. Johnson

OIG Contact and Staff Acknowledgments

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