

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

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



Figure 1. Birmingham VA Medical Center in Alabama (Source: https://vaww.va.gov/directory/guide/, accessed on March 24, 2020)

Abbreviations

ADPNS Associate Director for Patient/Nursing Services

CBOC community-based outpatient clinic

CHIP Comprehensive Healthcare Inspection Program

FPPE focused professional practice evaluation

FY fiscal year

HRS high risk for suicide

LIP licensed independent practitioner

LST life-sustaining treatments

LSTD life-sustaining treatments decision

OIG Office of Inspector General

OPPE ongoing professional practice evaluation

QSV quality, safety, and value

RME reusable medical equipment

SAIL Strategic Analytics for Improvement and Learning

SLB state licensing board

SOP standard operating procedure

SPC suicide prevention coordinator

SPS Sterile Processing Services

TJC The Joint Commission

UM utilization management

VHA Veterans Health Administration

VISN Veterans Integrated Service Network

WH-PCP women's health primary care provider



Report Overview

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

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

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

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

The unannounced visit was conducted during the week of March 2, 2020, at the Birmingham VA Medical Center and Birmingham VA Clinic. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical centers limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this medical center's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this medical center and other Veterans Health Administration (VHA) medical centers identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

Leadership and Organizational Risks

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

When the team conducted this inspection, the medical center's leaders had been working together for four days. The Chief of Staff was detailed to Veterans Integrated Service Network (VISN) 7 since October 2019, during which time the Medical Center Chief of Medicine and Deputy Chief of Staff served in acting capacities to fill the vacant role. The Director and Assistant Director were assigned on April 28, 2019, and September 30, 2018, respectively. The ADPNS and Associate Director had been working together on the executive leadership team for almost four years.

The OIG noted that specific medical center survey scores related to employee satisfaction were generally similar to or better than the corresponding VHA and medical center averages. Selected patient experience scores generally reflected similar or lower care ratings than the VHA average.

The inspection team also reviewed accreditation agency findings and sentinel events and did not identify any substantial organizational risk factors.² However, the OIG identified a repeat finding considered closed in March 2018, from the February 2017 Clinical Assessment Program inspection, related to dirty floors in patient care areas.³

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk.

¹ The Chief of Staff was detailed as the Chief Medical Officer for VISN 7 on October 27, 2019, through the OIG visit. There were two acting chiefs of staff during that time frame; one (Medical Center Chief of Medicine) from October 27, 2019, through February 27, 2020, and the other (Deputy Chief of Staff) from February 28, 2020, through the OIG site visit.

² The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

³ VA Office of Inspector General, *Clinical Assessment Program Review of the Birmingham VA Medical Center, Alabama*, Report No. 16-00581-239, June 1, 2017.

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

The OIG noted opportunities for improvement in seven of eight clinical areas reviewed and issued 18 recommendations that are directed to the Medical Center Director, Chief of Staff, ADPNS, and Associate Director. These are briefly described below.

Quality, Safety, and Value

The medical center complied with requirements for a quality, safety, and value oversight committee, protected peer reviews, and utilization management processes.⁵ However, the OIG identified a deficiency with root cause analyses.

Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluation and provider exit review processes.⁶

Environment of Care

The medical center and Birmingham VA Clinic met many of the requirements reviewed in the areas of general safety, special use spaces, and accommodation and privacy for women veterans. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified deficiencies with the cleanliness and infection prevention at the medical center and security of protected health information at the Birmingham VA Clinic.

⁴ VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

⁵ The definition of utilization management can be found within VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria."

⁶ The definitions of focused professional practice evaluation (FPPE) and ongoing professional practice evaluation (OPPE) can be found within Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility."

Additionally, the OIG issued a repeat finding related to dirty floors in patient care areas which was also identified during the February 2017 Clinical Assessment Program inspection.

Medication Management

The OIG observed the medical center's compliance with some elements of expected performance, including initial pain screening, patient follow-up, and quality measure oversight. However, the OIG noted significant deficiencies with aberrant behavior risk assessments, concurrent therapy with benzodiazepines, urine drug testing, and informed consent.

Mental Health

Generally, the medical center met the requirements for a designated suicide prevention coordinator and patient appointment tracking. However, areas for improvement included suicide safety plans and staff training.

Women's Health

The medical center complied with most of the requirements for women's health, including program oversight and performance improvement data monitoring. The OIG noted staffing concerns with designated women's health primary care providers at community-based outpatient clinics.

High-Risk Processes

The medical center met the requirements for quality assurance monitoring; reprocessing and storage area physical inspections; and staff training, competency, and continuing education. However, the OIG identified a deficiency with the annual risk analysis.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 18 recommendations for improvement to the Medical Center Director, Chief of Staff, ADPNS, and Associate Director. The number of recommendations should not be used, however, as a gauge for the overall quality of care provided at this medical center. The intent is for medical center leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes F and G, pages 72–73, and the responses within the body of the report for the

full text of the directors' comments.) The OIG will follow up on the planned actions for the open recommendations until they are completed.

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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 centers providing healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Birmingham 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.

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. Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes. Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

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

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

³ See Figure 2. CHIP inspections address these processes during FY 2020 (October 1, 2019, through September 30, 2020); they may differ from prior years' focus areas.

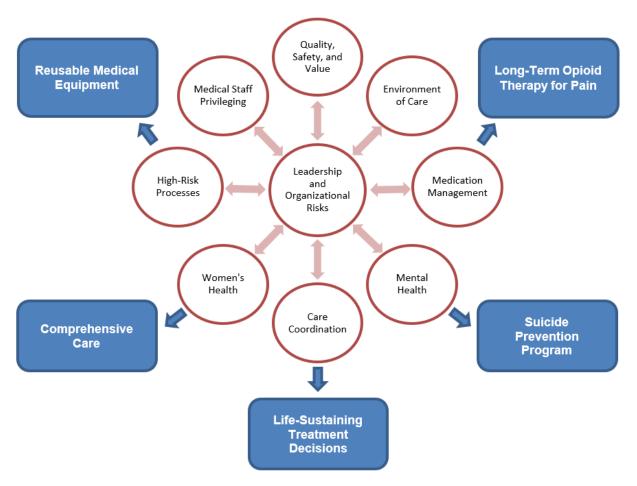


Figure 2. Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services Source: VA OIG

Methodology

The Birmingham VA Medical Center includes the medical center and multiple outpatient clinics in Alabama. Additional details about the types of care provided by the medical center can be found in Appendixes B and C.

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

The OIG team also selected and physically inspected the Birmingham VA Clinic and the following areas of the medical center:

- Emergency Department
- Medical inpatient units
- Medical intensive care unit
- Outpatient clinic
- Post-anesthesia care unit
- Sterile processing services areas
- Surgical inpatient unit
- Surgical intensive care unit

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

The inspection examined operations from March 4, 2017, through March 6, 2020, the last day of the unannounced multiday site visit.⁵ While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leadership, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

⁵ The range represents the time period from the prior Clinical Assessment Program inspection to the completion of the unannounced, multiday CHIP site visit in March 2020.

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 response 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.

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

Results and Recommendations

Leadership and Organizational Risks

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

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

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 had a leadership team consisting of the Medical Center Director, acting Chief of Staff, Associate Director for Patient/Nursing Services (ADPNS), Associate Director, and Assistant Director. The acting Chief of Staff and ADPNS oversaw patient care which required managing service directors and chiefs of programs and practices.

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

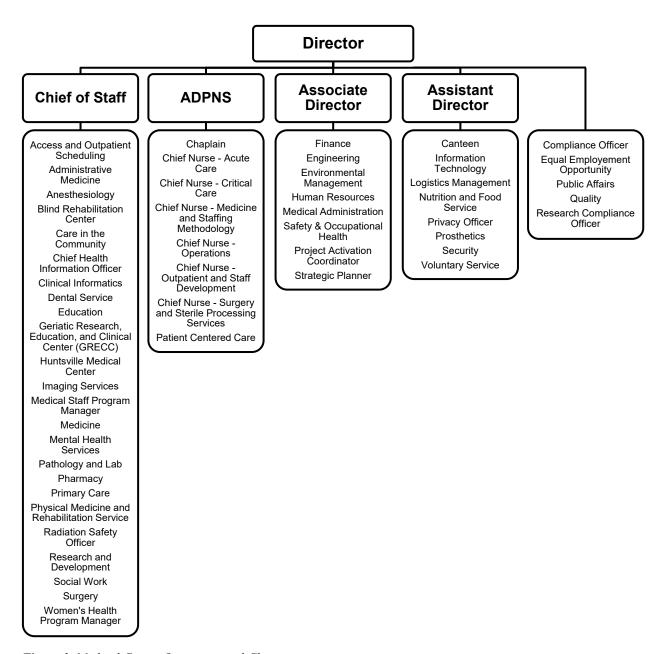


Figure 3. Medical Center Organizational Chart Source: Birmingham VA Medical Center (received on March 2, 2020)

The executive team had been working together for four days at the time of the OIG site visit. The permanent Chief of Staff, assigned May 28, 2017, was detailed as the VISN 7 Chief Medical Officer from October 27, 2019, through the OIG visit. During this time, the chief of staff role was assumed by the Chief of Medicine (October 27, 2019, through February 27, 2020) and Deputy Chief of Staff (February 28, 2020, through the OIG visit). The Director, ADPNS, Associate Director, and Assistant Director had worked together for approximately 10 months (See Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Medical Center Director	April 28, 2019
Chief of Staff	May 28, 2017 (permanent) February 28, 2020 (current acting)
Associate Director for Patient/Nursing Services	June 2, 2013
Associate Director	May 29, 2016
Assistant Director	September 30, 2018

Source: Birmingham VA Medical Center Human Resources Officer (received on March 2 and 4, 2020)

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

The Director serves as the chairperson of the Facility Leadership Board, which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Facility Leadership Board oversees various working groups such as the Medical Staff, Nursing, and Administrative Executive Councils.

Executive leaders monitored patient safety and care through the Quality Value Council, which was responsible for tracking and trending quality of care and patient outcomes and reports to the Facility Leadership Board. See Figure 4.

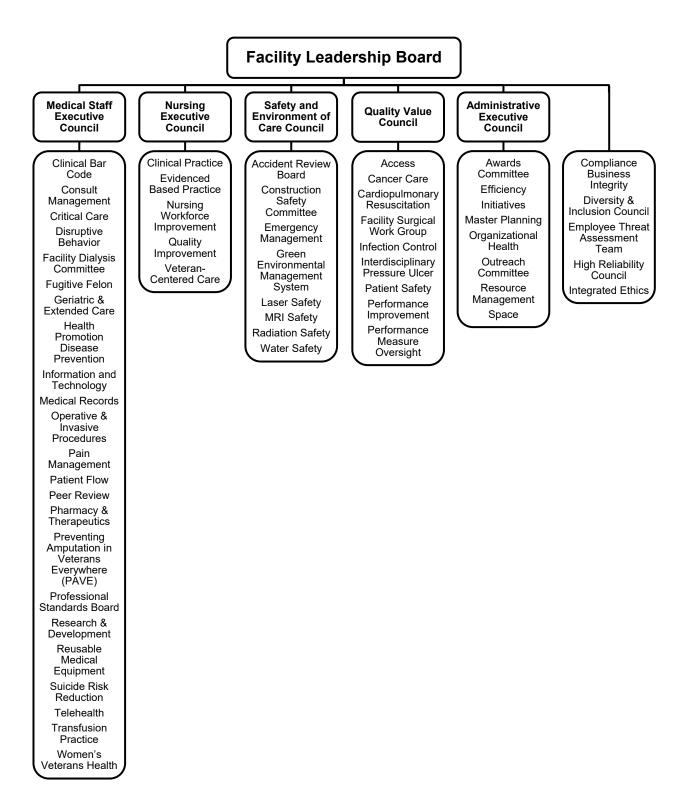


Figure 4. Medical Center Committee Reporting Structure Source: Birmingham VA Medical Center (received on March 2, 2020)

Employee Satisfaction

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

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of October 1, 2018, through September 30, 2019.⁷ Table 2 provides relevant survey results for VHA, the medical center, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found the medical center averages were generally similar to those for VHA, while the leaders' results were generally similar to or better than the corresponding VHA and the medical center averages.⁸

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Medical Center Director Average	Chief of Staff Average	ADPNS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: Servant Leader Index Composite ⁹	0–100 where higher scores are more favorable	72.6	70.9	76.7	83.3	70.0	88.1	92.0

⁷ Ratings are based on responses by employees who report to or are aligned under the Medical Center Director, Chief of Staff, ADPNS, Associate Director, and Assistant Director.

⁸ 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.

⁹ According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, the Servant Leader Index "is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others' contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others' needs before their own."

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Medical Center Director Average	Chief of Staff Average	ADPNS Average	Assoc. Director Average	Asst. 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	3.5	4.0	3.9	3.5	4.0	4.0
All Employee Survey: My organization's senior leaders maintain high standards of honesty and integrity.	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.6	4.2	3.9	3.5	4.4	4.0
All Employee Survey: I have a high level of respect for my organization's senior leaders.	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.7	4.3	4.0	3.7	4.5	4.2

Source: VA All Employee Survey (accessed on February 3, 2020)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. ¹⁰ Note that the medical center averages for the specific survey questions were similar to the VHA average. Scores related to the individual leaders were generally similar to or better than those for VHA and the medical center.

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¹⁰ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPNS, Associate Director, and Assistant 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	ADPNS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.8	4.3	4.4	3.7	4.4	4.6
All Employee Survey: Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.6	4.1	3.9	3.5	4.4	11
All Employee Survey: In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?	0 (Never) – 6 (Every Day)	1.4	1.4	1.0	1.3	1.5	2.0	0.4

Source: VA All Employee Survey (accessed on February 3, 2020)

Patient Experience

To assess patient experiences with the medical center, which directly reflect on its leaders, the OIG team reviewed patient experience survey results that relate to the period of October 1, 2018,

¹¹ Data was not available due to a low number of responses.

through September 30, 2019. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experience of Patients (SHEP) program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for VHA and the medical center.¹²

VHA also collects SHEP survey data from Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients' attitudes toward their healthcare experiences (see Table 4). For this medical center, the patient survey results were generally similar to or lower than VHA averages. The medical center leaders appear to have opportunities to improve veterans' experiences.

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

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): Would you recommend this hospital to your friends and family?	The response average is the percent of "Definitely Yes" responses.	68.3	58.9
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	80.2
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): I felt like a valued customer.	The response average is the percent of "Agree" and "Strongly Agree" responses.	77.3	77.3
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	76.9

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on February 3, 2020)

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

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

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see Tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that the inpatient results for male and female respondents were generally less favorable than the corresponding VHA national averages. However, it is noteworthy that most Patient-Centered Medical Home and Specialty Care Survey results for women veterans were better than those for VHA nationally. Medical center leaders appeared to be actively engaged with female patients (for example, conducting baby showers).

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

Questions	Questions Scoring			Medical Center ¹⁵		
		Male Average	Female Average	Male Average	Female Average	
During this hospital stay, how often did doctors treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	87.0	76.3	
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	78.6	84.0	
Would you recommend this hospital to your friends and family?	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	60.1	39.0	

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on February 3, 2020)

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

¹⁴ The VHA averages are based on 48,259–48,798 male and 2,342–2,359 female respondents, depending on the question.

¹⁵ The facility averages are based on 365–367 male and 17 or 18 female respondents, depending on the question.

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

Questions	Scoring	VHA ¹⁶	VHA ¹⁶		enter ¹⁷
		Male Average	Female Average	Male Average	Female Average
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	51.7	49.5
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).	59.9	49.7	58.5	69.4
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	70.0	87.3

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on February 3, 2020)

 $^{^{16}}$ The VHA averages are based on 79,450–241,828 male and 5,762–13,041 female respondents, depending on the question.

 $^{^{17}}$ The medical center averages are based on 595–2,046 male and 54–119 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 ¹⁸		Medical C	enter ¹⁹
		Male Average	Female Average	Male Average	Female Average
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	49.3	54.1
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	57.6	70.0
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	71.7	67.3

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on February 3, 2020)

Accreditation Surveys and Oversight Inspections

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

¹⁸ The VHA averages are based on 65,968–208,722 male and 3,460–11,072 female respondents, depending on the question.

¹⁹ The medical center averages are based on 385–1,312 male and 29–86 female respondents, depending on the question.

²⁰ The Joint Commission conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization.

²¹ According to 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."

closed all recommendations for improvement issued since the previous clinical assessment program inspection conducted in February 2017. However, the OIG identified a repeat finding from the previous inspection related to dirty floors in patient care areas, which is discussed in greater detail in the Environment of Care section of this report.²²

At the time of the site visit, the OIG team also noted the medical center's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²³

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Clinical Assessment Program Review of the Birmingham VA Medical Center, Alabama, Report No. 16-00581-239, June 1, 2017)	February 2017	12	0
TJC Hospital Accreditation	August 2019	30	0
TJC Behavioral Health Care Accreditation		1	0
TJC Home Care Accreditation		3	0

Source: OIG and TJC (inspection/survey results verified with the Accreditation Manager and Assistant Quality Manager on March 3, 2020)

²² VA Office of Inspector General, *Clinical Assessment Program Review of the Birmingham VA Medical Center, Alabama*, Report No. 16-00581-239, June 1, 2017.

²³ According to VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs*, May 9, 2017, the Commission on Accreditation of Rehabilitation Facilities "provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies." VHA's commitment is supported through a system-wide, long-term joint collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs; According to the College of American Pathologists, for 70 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." College of American Pathologists. https://www.cap.org/about-the-cap. (The website was accessed on February 20, 2019.) In accordance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

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.

Table 9 lists the reported patient safety events from March 4, 2017, (the prior OIG Clinical Assessment Program review), through March 3, 2020.²⁴ The OIG found no significant organizational risks related to lapses in care.

Table 9. Summary of Selected Organizational Risk Factors (March 4, 2017, through March 3, 2020)

Factor	Number of Occurrences
Sentinel Events ²⁵	0
Institutional Disclosures ²⁶	4
Large-Scale Disclosures ²⁷	0

Source: Birmingham VA Medical Center Risk Manager and Patient Safety Manager (received on March 2 and 3, 2020)

²⁴ 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 Birmingham VA Medical Center is a high complexity (1a) affiliated system as described in Appendix B.)

²⁵ The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

²⁶ According to VHA Directive 1004.08, *Disclosure of Adverse Events To Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility leaders together with clinicians and others, as appropriate, inform the patient or [his or her] personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."

²⁷ According to VHA Directive 1004.08, VHA defines large-scale disclosures of adverse events (sometimes referred to as "notifications") as "a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue."

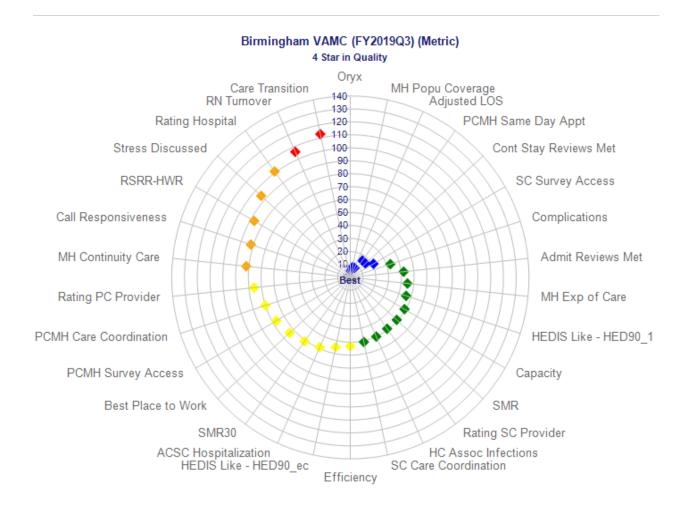
Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.²⁸

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA medical centers as of June 30, 2019. Of note, Figure 5 uses blue and green data points to indicate high performance for the Birmingham VA Medical Center (for example, in the areas of mental health (MH) population (popu) coverage, complications, capacity, and specialty care (SC) care coordination). Metrics that need improvement are denoted in orange and red (for example, MH continuity (of) care, rating (of) hospital, and registered nurse (RN) turnover).²⁹

²⁸ VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

²⁹ For information on the acronyms in the SAIL metrics, please see Appendix E.



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

Figure 5. Medical Center Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)

Source: VHA Support Service Center

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

Leadership and Organizational Risks Conclusion

The medical center's leadership team consisted of the Medical Center Director, acting Chief of Staff, ADPNS, Associate Director, and Assistant Director, and these leaders had worked together for four days at the time of the OIG visit. Specific survey results related to employees' satisfaction were generally similar to or better than the VHA averages. Patient survey results were generally similar to or lower than VHA averages. Although the medical center leaders appeared to have opportunities to improve veterans' experiences, the OIG found it noteworthy that most Patient-Centered Medical Home and Specialty Care Survey results for women veterans were better than those for female patients nationally. Further, in individual interviews, the executive leadership team members were able to speak in depth about actions taken during the

previous 12 months to maintain or improve employee satisfaction and patient experiences. The medical center's accreditation findings and sentinel events did not identify any substantial organizational risk factors. However, the OIG's inspection of patient care areas noted a repeat finding from the previous clinical assessment program review related to dirty floors. The executive leaders were extremely knowledgeable within their scopes of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing SAIL measures and should continue to take actions to sustain and improve performance.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care. ³⁰ To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and to maintain Joint Commission accreditation. ³¹ 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. ³²

To determine whether VHA medical centers 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.³³ Protected peer reviews, when conducted systematically and credibly, reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.³⁴ The OIG team examined the completion of the following elements:

³⁰ Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence, September 2014.

³¹ VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs, May 9, 2017.

³² Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence, September 2014.

³³ The definition of a peer review can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a critical review of care, performed by a peer, to evaluate care provided by a clinician for a specific episode of care, to identify learning opportunities for improvement, to provide confidential communication of the results back to the clinician, and to identify potential system or process improvements. In the context of protected peer reviews, "protected" refers to the designation of review as a confidential quality management activity under 38 U.S.C. 5705 as "a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or the utilization of health-care resources in VA facilities."

³⁴ 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 unit³⁵
- 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 Medical Staff Executive Council

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.³⁶ 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.³⁷ 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. ³⁸ Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual

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³⁵ VHA Directive 1190.

³⁶ According to VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019, UM reviews include evaluating the "appropriateness, medical need, and efficiency of health care services according to evidence-based criteria."

³⁷ VHA Directive 1117(2).

³⁸ The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

causes of harm to patients throughout the medical center.³⁹ The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses⁴⁰
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of annual patient safety report to medical center leaders

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents.⁴¹

Quality, Safety, and Value Findings and Recommendations

The medical center complied with requirements for a QSV oversight committee, protected peer reviews, and utilization management processes. However, the OIG identified a deficiency with root cause analyses.

To ensure credibility, VHA requires root cause analyses to include the consideration of relevant literature, which must be documented in the VHA Patient Safety Information System. ⁴² The OIG found that two of five individual root cause analyses included relevant literature reviews. This resulted in insufficient evaluations of patient safety events and limited analyses of system vulnerabilities for the remaining three root cause analyses. Although aware of the literature review requirement, the Chief Nurse, Patient Care Services (previous Patient Safety Manager) reported the three patient events that required root cause analyses were specific to medical center processes and, therefore, did not require relevant literature reviews.

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³⁹ VHA Handbook 1050.01.

⁴⁰ According to VHA Handbook 1050.01, "the requirement for a total of <u>eight</u> [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of [root cause analyses] is driven by the events that occur and the [Safety Assessment Code] SAC score assigned to them. At least four analyses per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses]."

⁴¹ For CHIP inspections, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁴² VHA Handbook 1050.01.

Recommendation 1

1. The Medical Center Director determines the reasons for noncompliance and ensures that root cause analyses include all required review elements and are properly documented in the VHA Patient Safety Information System.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Medical Center Director determined the reason for noncompliance and considered this when developing the action plan. The VISN 7 Patient Safety Officer provided education to the Patient Safety Manager of the required review elements and proper documentation in the VHA Patient Safety Information System on November 21, 2019, during the VISN 7 Quality, Safety, and Value Face-to-Face Conference.

The patient safety dashboard will be utilized to track 90 percent or greater compliance of root cause analyses inclusion of required review elements and proper documentation in the VHA Patient Safety Information System monthly until six consecutive months of 90 percent or greater compliance is achieved. The Patient Safety Manager reports dashboard compliance quarterly to Quality Value Council of which the Medical Center Director chairs.

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).⁴³

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.

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."⁴⁴ The OIG examined various requirements for FPPEs and OPPEs:

FPPEs

- o Establishment of criteria in advance
- o Use of minimum criteria for selected specialty LIPs⁴⁵
- Clear documentation of the results and time frames
- o Evaluation by another provider with similar training and privileges

OPPEs

o Application of criteria specific to the service or section

- o Use of minimum criteria for selected specialty LIPs⁴⁶
- o Evaluation by another provider with similar training and privileges

The OIG also determined whether service chiefs recommended continuing the LIPs' current privileges based in part on the results of OPPE activities and if the medical center's Executive

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⁴³ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

⁴⁴ VHA Handbook 1100.19.

⁴⁵ VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁴⁶VHA Acting DUSHOM Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

Committee of the Medical Staff (locally referred to as the Medical Staff Executive Council) decided to recommend continuing privileges based on FPPE and OPPE results.

Further, VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and to subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.⁴⁷ Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process. This individual will be the subject matter expert (SME) for the facility...and ensure oversight of the exit review process, including receipt, review, and maintenance of the Provider Exit Review Forms."⁴⁸ The OIG reviewers assessed whether the medical center's staff

- Designated an individual and backup responsible for the SLB reporting process,
- Completed forms within the required time frame and with required oversight, and
- Reported results to SLBs when indicated.

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

- Seven solo/few practitioners who underwent initial or reprivileging during the previous 12 months⁴⁹
- Ten LIPs hired within 18 months before the site visit
- Twenty LIPs privileged within 12 months before the visit
- Twenty LIPs who left the medical center in 12 months before the visit

Medical Staff Privileging Findings and Recommendations

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

Despite VHA defining the minimum-required specialty-specific criteria to be used for gastroenterology, pathology, nuclear medicine, and radiation oncology specialties, the OIG found the service chief did not include required criteria for a solo pathologist's FPPE.⁵⁰ This may

⁴⁷ VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards, December 22, 2005.

⁴⁸ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18*, *Reporting and Responding to State Licensing Boards*, February 5, 2018.

⁴⁹ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, 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. The 12-month review period was from March 2, 2019, through March 1, 2020.

⁵⁰ VHA Acting DUSHOM Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

have resulted in the pathologist participating in care without a thorough evaluation of the provider's practice. The acting Chief of Staff and the Associate Chief of Staff–Primary Care stated that due to human error, the Chief of Pathology and Lab did not use the correct form to complete the FPPE.

Recommendation 2

2. The Chief of Staff determines the reasons for noncompliance and makes certain that the service chief includes the minimum pathology-specific criteria for focused professional practice evaluations.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. The pathology focused professional practice evaluation is under revision. The Professional Standards Board will review and approve the revised focused professional practice evaluation forms in August 2020. The Medical Staff Office Supervisor will review all focused professional practice evaluations monthly to ensure inclusion of the minimum specific criteria.

Audit results will be reported to the Professional Standards Board monthly by the Medical Staff Office Supervisor until six consecutive months of 90 percent or greater compliance is achieved. The Professional Standards Board minutes are reviewed bi-annually during Medical Staff Executive Council meetings which are chaired by the Chief of Staff.

VHA requires that service chiefs "establish additional criteria for granting of clinical privileges within the service consistent with the needs of the service and the facility as well as within the available resources to provide these services. Clinical privileges must be based on evidence of an individual's current competence."⁵¹ The OIG did not find service-specific criteria for 5 of 26 practitioners reprivileged within the last 12 months. This resulted in inadequate data in the remaining practitioners' OPPEs —including three who were solo/few providers—to support decisions to continue clinical privileges. The acting Chief of Staff and the Associate Chief of Staff—Primary Care stated they did not ensure that new service chiefs received training on the requirement to document specialty-specific criteria in the OPPE.

⁵¹ VHA Handbook 1100.19.

Recommendation 3

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

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. All twenty of the medical staff service chiefs received education on the requirements for ongoing professional practice evaluations on May 5, 2020. The Medical Staff Office Supervisor will review service chief's documentation monthly to ensure relevant service-specific data for ongoing professional practice evaluations have been used to determine continuation of current practitioners' privileges.

Audit results will be reported to the Professional Standards Board monthly by the Medical Staff Office Supervisor until six consecutive months of 90 percent or greater compliance is achieved. The Professional Standards Board minutes are reviewed during bi-annual Medical Staff Executive Council meetings which are chaired by the Chief of Staff.

VHA requires that LIPs are evaluated on an ongoing basis by providers with similar training and privileges.⁵² The OIG found that 2 of 26 OPPEs were not completed by another similarly-trained and privileged provider. This may have resulted in the remaining LIPs (a gynecologist and a podiatrist) providing care without a thorough competency evaluation. The acting Chief of Staff and the Associate Chief of Staff–Primary Care stated that due to lack of training in administrative functions, the Chief of Surgery did not understand the requirements and believed that a service chief with dissimilar training could complete the OPPEs.

Recommendation 4

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

⁵² VHA Acting DUSHOM Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. All twenty of the medical staff service chiefs received education on the requirements and reviewer specifics for ongoing professional practice evaluations on May 5, 2020. The Medical Staff Office Supervisor will review service chief's documentation monthly to ensure relevant service-specific data for ongoing professional practice evaluations from similarly trained licensed independent providers have been used to determine continuation of current practitioners' privileges. Audit results will be reported to the Professional Standards Board monthly by the Medical Staff Office Supervisor until six consecutive months of 90 percent or greater compliance is achieved. The Professional Standards Board minutes are reviewed bi-annually during Medical Staff Executive Council meetings which are chaired by the Chief of Staff.

VHA states that provider exit review forms, which document the review of a provider's clinical practice, must be "completed within 7-calendar days of the departure of a licensed health care professional from a VA facility." For the 20 LIPs that departed the medical center in the previous 12 months, the OIG found that 18 provider exit review forms included the date of signing by a higher level official, and 11 were completed within seven calendar days. This could have resulted in delayed reporting of potential substandard practice to SLBs. The acting Chief of Staff and the Associate Chief of Staff—Primary Care stated that for the two undated forms, there was a lack of oversight by the Associate Chief of Staff—Primary Care. For the seven forms that were not completed in a timely manner, the Medical Staff Office and Human Resources did not coordinate the LIPs' out-processing, and this caused delays. Furthermore, the acting Chief of Staff and the Associate Chief of Staff—Primary Care also stated that LIPs with multiple types of appointments—such as without-compensation and fee-for-service—were not formally in the VHA payroll system which created challenges in following the customary out-processing steps.

Recommendation 5

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

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⁵³ VHA Notice 2018-05.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Medical Center Director determined the reason for non-compliance and considered this when developing the action plan. On March 30, 2020, the Human Resource Officer and the Medical Staff Office Supervisor met to discuss incorporation of the exit review forms into the current Employee Clearance Medical Center Policy 05-07. The provider exit form was added to the policy as attachment E on April 13, 2020. The revised policy requires providers to clear with the Medical Staff Office. The Medical Staff Office Supervisor will continue to send monthly reminders to clinical service chiefs to attest or update the Medical Staff Office of providers who have exited their service. The Medical Staff Office Supervisor will provide an attestation memo monthly to the Professional Standards Board of the completed exit review forms.

The Medical Staff Office Supervisor will monitor completion of the exit review forms until 90 percent or greater compliance is met for six consecutive months and report compliance monthly to the Medical Staff Executive Council. The Medical Staff Executive Council reports monthly to the Facility Leadership Board which is chaired by the Medical Center Director.

Environment of Care

Any medical center, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct Comprehensive Environment of Care Inspection Rounds and to resolve issues in a timely manner. The goal of the Comprehensive Environment of Care Program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.⁵⁴

The purpose of this facet of the OIG inspection was to determine whether the medical center maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the medical center met requirements in selected areas that are often associated with higher risks of harm to patients.⁵⁵ Inspectors reviewed several aspects of the medical center's environment:

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

⁵⁴ VHA Directive 1608, Comprehensive Environment of Care (CEOC) Program, February 1, 2016.

⁵⁵ The medical center did not have an inpatient mental health unit.

During its review of the environment of care, the OIG inspected the Birmingham VA Clinic (Blue and Gold primary care clinics) and the following eight patient care areas of the medical center:

- Emergency Department
- Medical inpatient units (6A Safe Harbor, 6B)
- Medical intensive care unit.
- Outpatient clinic (Red)
- Post-anesthesia care unit
- Surgical inpatient unit (4A)
- Surgical intensive care unit

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

Environment of Care Findings and Recommendations

Generally, the OIG found compliance with many of the performance indicators at both the medical center and VA Clinic. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified deficiencies in environmental cleanliness and infection prevention (includes a repeat finding from the February 2017 Clinical Assessment Program review) and privacy.⁵⁶

TJC requires hospitals to minimize the possibility of transmitting infections by ensuring that "furnishings and equipment safe and in good repair."⁵⁷ For eight patient care areas, the OIG found five areas with furnishings or equipment that were dirty or worn, had exposed foam, ⁵⁸ or had medical tape repair. ⁵⁹ This may have prevented effective cleaning and disinfection. The Associate Director stated there was a lack of employee attention to detail and insufficient supervisory oversight within Acute Care Services.

Recommendation 6

 The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that medical center managers keep furnishings and equipment safe and in good repair.

⁵⁶ VA OIG, *Clinical Assessment Program Review of the Birmingham VA Medical Center, Alabama*, Report No. 16-00581-239, June 1, 2017. The review was conducted in February 2017.

⁵⁷ TJC. Environment of Care Standard EC.02.06.01.

⁵⁸ Units 4A-surgical inpatient unit, 6A and 6B-medical inpatient units.

⁵⁹ Units 6B-medical inpatient unit, medical intensive care unit, and Blue clinic.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Associate Director determined the reason for noncompliance and considered this when developing the action plan. On March 16, 2020, housekeeping aid supervisors began completing daily environment of care (EOC) checklists which include the status of furnishings and equipment. The housekeeping aide supervisors, who report to the Hospital Housekeeping Officer, will correct any deficiencies.

The Supervisory General Engineer has developed an audit tool to track compliance from the weekly checklist. The compliance data will be reported monthly in the Safety and Environment of Care Council until 90 percent or greater compliance is maintained for six consecutive months. The Associate Director chairs the Safety and Environment of Care Council.

TJC requires that a medical center "implements infection prevention and control activities when...[s]toring medical equipment, devices, and supplies" so that clean and dirty items are not comingled. The OIG found one unit had three rooms with clean and dirty equipment and supplies stored together. Failure to follow proper storage practices may result in potential exposure of patients, staff, and visitors to infectious material. The acting Chief of Environmental Management Services stated that Environmental Management Services staff were inattentive to detail when storing cleaning tools, and the Associate Director stated that Environmental Management Services supervisors lacked sufficient oversight of the separation of clean and dirty equipment.

Recommendation 7

7. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that Environmental Management Services staff separate clean and dirty equipment, devices, and supplies.

⁶⁰ TJC. Infection Prevention and Control Standard 02.02.01.

⁶¹ Unit 4A-surgical inpatient unit.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Associate Director determined the reason for noncompliance and considered this when developing the action plan. The Hospital Housekeeping Officer will ensure the housekeeping aide supervisors complete daily checks of discharge rooms/areas that have been cleaned by the housekeepers and the housekeepers will make corrections as needed. Hospital housekeeping aide supervisors began weekly checks March 15th, 2020.

Hospital housekeeping supervisors will perform 100 percent compliance checks of rooms with a discharge using the approved environment of care checklist which contains assessment of separation of clean and dirty supplies. The Hospital Housekeeping Officer will review the data weekly and report monthly to the Safety and Environmental Care Council, which the Associate Director chairs, until 90 percent or greater compliance is maintained for six consecutive months.

TJC requires that a medical center "establishes and maintains a safe, functional environment" that is clean and suitable for patient care. A repeat finding from the 2017 Clinical Assessment Program inspection, 62 the OIG found that two of eight patient care areas inspected were not dirty or dusty. 63 Additionally, three of eight patient care areas did not have damaged floors or poorly maintained heating, ventilation, and air conditioning (HVAC) grills. 64 Lack of cleanliness may increase the potential for spreading infection. The acting Chief of Environmental Management Services reported that a consistently high patient census did not allow medical center staff to perform deep cleaning. The Associate Director stated the dirty, dusty floors were due to high employee turnover, lack of staff attention to detail, and lack of supervisory oversight within Environmental Management Services. The acting Chief of Engineering stated the floors remained damaged due to a lack of employee accountability and supervisory oversight within the Department of Engineering.

Recommendation 8

8. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that medical center managers maintain safe, functional, and clean patient care areas.

Medical center concurred.

Target date for completion: October 1, 2020

⁶² VA OIG, Clinical Assessment Program Review of the Birmingham VA Medical Center, Alabama, Report No. 16-00581-239, June 1, 2017.

⁶³ Emergency department and medical intensive care unit.

⁶⁴ Emergency department, medical intensive care unit, and post anesthesia care unit.

Medical center response: The Associate Director determined the reason for noncompliance and considered this when developing the action plan. On March 16, 2020, the hospital housekeeping aides and the maintenance mechanics, who report to the Hospital Housekeeping Officer and Supervisory General Engineer, began completing a daily environment of care checklist that includes inspections of dirty and dusty rooms, damaged floors and walls, and worn or damaged heating ventilation and air conditioning grills.

The hospital housekeeping supervisors, reporting to the Hospital Housekeeping Officer, and the maintenance work leaders, reporting to the Supervisor General Engineer, will monitor compliance of the weekly checklist and correct deficiencies. The Hospital Housekeeping Officer and Supervisor General Engineer will report data to the Safety and Environmental Care Council, chaired by the Associate Director, until 90 percent or greater compliance is maintained for six consecutive months.

The Health Insurance Portability and Accountability Act requires health care organizations to "maintain reasonable and appropriate...safeguards to prevent unintentional use or disclosure of protected health information."65 The OIG found that patient-identifiable information was not adequately protected on laboratory specimens awaiting courier transport from the Birmingham VA Clinic to the medical center. The transport container could be easily opened, and unauthorized individuals could access patient information. A medical center Privacy Officer stated that the transport cooler was always under observation and that the transport vessel did not require a lock.⁶⁶

Recommendation 9

9. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that staff secure protected health information within laboratory transport containers.

Medical center concurred.

Target date for completion: February 01, 2021

Medical center response: The Associate Director determined the reason for noncompliance and considered this when developing the action plan. The Associate Chief of Staff for Primary Care

⁶⁵ The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to develop regulations protecting the privacy and security of certain health information. To fulfill this requirement, HHS published the HIPAA Privacy Rule, or Standards for Privacy of Individually Identifiable Health Information. https://www.hhs.gov/hipaa/for-professionals/security/lawsregulations/index.html.

⁶⁶ VHA Information Access and Privacy Office, Privacy Fact Sheet: Exhibiting and Transporting Patient Information Within and Outside of VA Health Care Facilities, Vol. 03, No. 1, July 2003, revised June 2013.

authorized purchase of combination locks for the lab coolers for the Community Based Outpatient Clinics (CBOC) which include the VA Birmingham clinic. The CBOC nurse managers will educate the CBOC lab personnel to ensure the lab coolers are secured.

The Chief Medical Technologist will educate facility health and medical technicians on how to validate secured coolers so they can monitor 100 percent of lab coolers received from the CBOCs each business day. The Chief Medical Technologist will notify the Associate Chief of Staff for Primary Care of unsecured coolers so that action may be taken by the Associate Chief of Staff for Primary Care. Compliance will be reported by the Chief of Pathology and Lab to the Safety and Environment of Care Council, which is chaired by the Associate Director, monthly until 90 percent or greater compliance is met for six consecutive months.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁶⁷ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁶⁸ 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.⁶⁹ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁷⁰

VHA requires routine assessments of pain and the completion of an opioid risk assessment before initiating patients on long-term opioid therapy and recommends against the therapy for patients with untreated substance use disorders. VHA also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines. Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy. To achieve VHA's vision of providing patient-driven healthcare, providers are also required to obtain informed consent from patients and to provide education about the risks, benefits, and alternatives prior to initiating long-term opioid therapy. VHA recommends evaluating patients receiving continued opioid therapy for improvement of pain and opioid-related adverse events at least every three months and more frequently as doses increase.

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

- Completion of initial screening for pain
- Assessment of aberrant behavior risk
- Avoidance of concurrent therapy with benzodiazepines

⁶⁷ World Health Organization. "Information sheet on opioid overdose," August 2018. https://www.who.int/substance_abuse/information-sheet/en/. (This website was accessed on November 6, 2019.)

⁶⁸ Centers for Disease Control and Prevention. "Opioid Overdose, Understanding the Epidemic," December 19, 2018. https://www.cdc.gov/drugoverdose/epidemic. (The website was accessed on November 6, 2019.)

⁶⁹ VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain, Version 3.0. February 2017. https://www.healthquality.va.gov/guidelines/Pain/cot/. (The website was accessed on November 6, 2019.)

⁷⁰ VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain.

⁷¹ According to the U.S. Department of Justice's Drug Enforcement Administration, benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety." https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. (The website was accessed on December 1, 2019.)

⁷² VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain.

⁷³ VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, May 13, 2020.

⁷⁴ VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain.

- Completion of urine drug testing with intervention, when indicated
- Documentation of informed consent
- Timely follow-up with patients included required elements

VHA also requires medical centers to establish a multidisciplinary pain management committee "to provide oversight, coordination, and monitoring of pain management activities and processes." Monitoring measures include, but are not limited to, adherence to published clinical practice guidelines, timeliness of treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment, patient satisfaction, and quality of life.⁷⁵ The OIG examined the following indicators for program oversight and evaluation:

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

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 39 randomly selected outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The team considered whether providers acted in accordance with guidelines for the provision of pain management and the medical center's oversight process for evaluating pain management outcomes and quality.

Medication Management Findings and Recommendations

The medical center addressed some of the indicators of expected performance, including initial pain screening, patient follow-up, and quality measure oversight. However, the OIG found deficiencies with aberrant behavior risk assessments, concurrent benzodiazepine therapy, urine drug testing, and informed consent.

VA/DoD clinical practice guidelines recommend completion of an aberrant behavior risk assessment that includes a history of untreated substance abuse, unstable psychological disease, and aberrant drug-related behaviors, prior to initiating opioid therapy. The OIG estimated that providers assessed 74 percent of patients for aberrant drug-related behaviors, based on electronic

⁷⁵ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

⁷⁶ VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain. Examples of aberrant drug related behaviors include "lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents." Pain Management, Opioid Safety, VA Educational Guide (2014), July 2014. https://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Tookit_Provider_AD_Educational_Guide_7_17.pdf. (The website was accessed on September 17, 2019.)

health records reviewed.⁷⁷ Failure to assess behavior risk among the remaining patients may increase the possibility of overdose and death. The Chief of Physical Medicine and Rehabilitation Services—who was also the Chair of the Pain Committee—the acting Chief of Staff, and the Associate Chief of Staff–Primary Care reported that providers believed they were following the VHA directive. They also stated there was variability in the interpretation of the directive and VA/DoD guidelines on pain management, and their understanding of the documentation requirements for assessment of drug-related behavior was unclear.

Recommendation 10

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

Medical center concurred.

Target date for completion: February 1, 2021

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. A Controlled Substance One Note was implemented in January 2020. This note must be completed when initiating long-term opioid therapy. The Controlled Substance One Note contains an aberrant behavior risk assessment that includes a history of untreated substance abuse, unstable psychological disease, and aberrant drug-related behaviors. One Note training was completed from October 2019 through March 2020 with providers who prescribe controlled substances throughout the facility and Community Based Outpatient Clinics. One week prior to implementation an email was shared with providers containing screen shot guidance of the Controlled Substance One Note.

The Chief of Physical Medicine and Rehabilitation Service will review 100 percent of long-term opioid orders risk assessment completion each month until 90 percent or greater compliance is achieved for six consecutive months. The results will be reported monthly in Medical Staff Executive Council meetings, which the Chief of Staff chairs.

VA/DoD clinical practice guidelines recommend avoiding coadministration of medications such as opioids and benzodiazepines that could induce fatal drug-drug interactions.⁷⁸ The OIG determined that providers documented justification for prescribing the medications concurrently

⁷⁷ The OIG estimated that 95 percent of the time, the true compliance rate is between 60.0 and 87.5 percent, which is statistically significantly below the 90 percent benchmark.

⁷⁸ VA/DoD Clinical Practice Guidelines for Opioid Therapy for Chronic Pain.

in two of seven (29 percent) patients' electronic health records. This may have resulted in an increased risk of harm from potentially fatal drug interactions for the remaining patients. The Chief of Physical Medicine and Rehabilitation Services (chair of the Pain Committee), the acting Chief of Staff, and the Associate Chief of Staff–Primary Care stated that providers did not pay attention to opioid and benzodiazepine coadministration requirements.

Recommendation 11

11. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain providers document justification for prescribing opioids and benzodiazepines concurrently.

Medical center concurred.

Target date for completion: February 1, 2021

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. A Controlled Substance One Note was implemented in January 2020. This note must be completed when initiating long-term opioid therapy. The Controlled Substance One Note requires the provider to select one of two options for the rationale of the concomitant use of opioids and benzodiazepines: 1) risk outweighs benefit or 2) will discuss taper plan with co-prescribing provider.

One Note training was completed from October 2019 through March 2020 with providers who prescribe controlled substances throughout the facility and Community Based Outpatient Clinics. Additional One Note screen shot guidance was shared with providers one week prior to note activation.

The Chief of Physical Medicine and Rehabilitation Service will review 100 percent of new long-term opioid orders monthly until 90 percent or greater compliance of justification when prescribing opioids and benzodiazepines concurrently documentation is met for six consecutive months. The results will be reported monthly in Medical Staff Executive Council meetings, which the Chief of Staff chairs.

VA/DoD clinical practice guidelines recommend that providers "obtain UDT [urine drug testing] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter." The OIG estimated that providers conducted initial urine drug testing in 54 percent of patient electronic health records reviewed. This may have resulted in providers' inability to identify the remaining patients who had active substance use disorders, determine drug diversion, or

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

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

⁸¹ The OIG estimated that 95 percent of the time, the true compliance rate is between 37.8 and 69.5 percent, which is statistically significantly below the 90 percent benchmark.

ensure patients adhered to the prescribed medication regimen. The Chief of Physical Medicine and Rehabilitation Services, the acting Chief of Staff, and the Associate Chief of Staff–Primary Care stated that the medical center policy—which did not align with VHA guidance—required urine drug testing every six months.

Recommendation 12

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

Medical center concurred.

Target date for completion: February 1, 2021

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. A Controlled Substance One Note was implemented in January 2020. This note must be completed when initiating long-term opioid therapy. The Controlled Substance One Note contains a urine drug testing order. One Note training was completed from October 2019 through March 2020 with providers who prescribe controlled substances throughout the facility and Community Based Outpatient Clinics. One week prior to implementation an email was shared with providers containing screen shot guidance of the Controlled Substance One Note.

The Chief of Physical Medicine and Rehabilitation Service will review 100 percent of long-term opioid orders monthly until 90 percent or greater compliance of urine drug testing is met for six consecutive months. The results will be reported monthly in Medical Staff Executive Council meetings, which the Chief of Staff chairs.

Note: At the time of this response, due to coronavirus disease (COVID) 19, VHA issued guidance regarding controlled substance prescribing through telehealth modalities during the COVID-19 public health emergency. (Ref. Deputy Under Secretary for Health for Operations and Management (10N) COVID-19: Controlled Substance Prescribing Through Telehealth During the COVID-19 Public Health Emergency, dated March 21, 2020.)

VHA states that "opioid prescribers are responsible for completing the informed consent process" prior to initiating long-term opioid therapy. 82 Long-term therapy begins after 90 or more calendar days of consistent or intermittent opioid use. 83 The OIG estimated that providers documented informed consent prior to initiating long-term opioid therapy in 74 percent of

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⁸² VHA Directive 1005.

⁸³ VHA Directive 1005.

patients, based upon the electronic health records reviewed.⁸⁴ The remaining patients may have been receiving treatment without knowledge of the risks associated with long-term opioid therapy, including opioid dependence, tolerance, addiction, and intentional or unintentional fatal overdose. The Chief of Physical Medicine and Rehabilitation Services, the acting Chief of Staff, and the Associate Chief of Staff–Primary Care stated that providers followed the medical center policy for obtaining informed consent when there were four or more consecutive months of opioid prescriptions.

Recommendation 13

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

Medical center concurred.

Target date for completion: February 1, 2021.

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. A Controlled Substance One Note was implemented in January 2020. This note must be completed when initiating long-term opioid therapy. The Controlled Substance One Note contains an order set to obtain and document informed consent for patients prior to initiating long-term opioid therapy. One Note training was completed from October 2019 through March 2020 with providers who prescribe controlled substances throughout the facility and Community Based Outpatient Clinics. One week prior to implementation an email was shared with providers containing screen shot guidance of the Controlled Substance One Note.

The Chief of Physical Medicine and Rehabilitation Service will review 100 percent of long-term opioid orders monthly until 90 percent or greater compliance of documentation of long-term opioid therapy consent is met for six consecutive months. The results will be reported monthly in the Medical Staff Executive Council meetings which the Chief of Staff chairs.

Note: At the time of this response, due to coronavirus disease (COVID)-19, VHA issued guidance regarding controlled substance prescribing through telehealth modalities during the COVID-19 public health emergency. (Ref. Deputy Under Secretary for Health for Operations and Management (10N) COVID-19: Controlled Substance Prescribing Through Telehealth During the COVID-19 Public Health Emergency, dated March 21, 2020.)

⁸⁴ The OIG estimated that 95 percent of the time, the true compliance rate is between 60.5 and 87.5 percent, which is statistically significantly below the 90 percent benchmark.

Mental Health: Suicide Prevention Program

In 2017, suicide was the 10th leading cause of death, with approximately 47,000 lives lost across the United States.⁸⁵ The suicide rate was 1.5 times greater for veterans than for non-veteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States.⁸⁶ Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.⁸⁷

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.⁸⁸

VHA requires that each medical center and very large CBOC have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities. ⁸⁹ The OIG examined various requirements related to SPCs:

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

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

⁸⁵ Centers for Disease Control and Prevention. *Preventing Suicide*. https://www.cdc.gov/violenceprevention/suicide/fastfact.html. (The website was accessed on March 4, 2020.)

⁸⁶ Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*, September 2018; Department of Veterans Affairs, *National Strategy for Preventing Veteran Suicide 2018-2028*.

⁸⁷ Veterans who recently used VHA services are defined as having an encounter in the calendar year of death or in the previous year; Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*.

⁸⁸ VA Office of Mental Health and Suicide Prevention Guidebook, June 2018.

⁸⁹ According to VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015, very large CBOCs are those that serve more than 10,000 unique veterans each year. The Veterans Crisis Line connects veterans with qualified responders through a confidential toll-free hotline, online chat, and text-messaging service to receive confidential support 24 hours a day. Community outreach activities are described in VHA Handbook 1160.01.

in his or her electronic health record "as soon as possible but no later than 1 business day after such determination by the SPC." According to VHA, "Some studies indicate that up to two-thirds of patients who commit suicide have seen a physician in the month before their death... The primary purpose of the High Risk for Suicide PRF is to communicate to VA staff that a veteran is at high risk for suicide and the presence of a flag should be considered when making treatment decisions." The HRS PRF is reviewed at least every 90 days and depending on changes to the suicide risk status, will remain active or be removed. Additionally, VHA requires designated high-risk patients to have a completed suicide safety plan and four face-to-face visits with an acceptable provider within the first 30 days of designation.

The OIG noted that from July 1, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA required that "Any patient determined to be High Risk for Suicide [by the licensed independent provider] must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination." However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management changed the requirement for the HRS PRF placement to be "as soon as possible but no later than 1 business day after determination by the SPC." VHA further provided additional clarifying information:

- The "SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list."
- "The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted."
- The SPC's determination process "may be beyond 24 hours after a referral, due to case consultation and review." 96

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

⁹⁰ VHA DUSHOM Memorandum, Update to High Risk for Suicide Patient Record Flag Changes, January 16, 2020.

⁹¹ VHA Directive 2008-036, Use of Patient Record Flags to Identify Patients at High Risk for Suicide, July 18, 2008.

⁹² 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.

⁹³ A safety plan is a written list of coping strategies and support sources for use during or preceding suicidal crises. Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide.

⁹⁴ VHA DUSHOM Memorandum, High Risk for Suicide Patient Record Flag Changes, October 3, 2017.

⁹⁵ VHA DUSHOM Memorandum, Update to High Risk for Suicide Patient Record Flag Changes, January 16, 2020.

⁹⁶ VHA, Response to Questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received on February 19, 2020.

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

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRF to "occur no earlier than 10 days before and no later than 10 days after the 90-day due date." ⁹⁷

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

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

Relevant documents;

⁹⁷ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

⁹⁸ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym "S.A.V.E" summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for non-clinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

⁹⁹ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

¹⁰⁰ The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training. VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017.

- The electronic health records of 42 randomly selected outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The medical center complied with requirements for a designated SPC and patient appointment tracking.

The OIG noted concerns with the review of HRS PRFs within the required time frame. VHA required that all patients with an HRS PRF be evaluated at least every 90 days and there is documented justification for continuing or discontinuing the flag. ¹⁰¹ The OIG estimated that 36 percent of patients with an HRS PRF were evaluated at least every 90 days. ¹⁰² 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 34 of 42 patients (81 percent) were reviewed within the expected time frame (observed range was 7–108 days). ¹⁰³

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

VHA requires "that for patients with a new or reactivated HRS-PRF, the safety plan should be completed within 7 days before or after the current HRS-PRF date." The OIG estimated that 76 percent of patients had a safety plan completed within seven days before or after the high-risk designation, based on electronic health records reviewed. When safety plans are not completed in a timely manner for the remaining patients, they may not be able find critical resources when needed. The Chief of Mental Health stated that attempts by providers to contact patients were not always successful and supervisors did not ensure that suicide safety plans were completed in a timely fashion and had no contingency plans in place to reach difficult-to-contact patients.

¹⁰¹ VHA Directive 2008-036; VHA Directive 2010-053, Patient Record Flags, December 3, 2010.

¹⁰² The OIG estimated that 95 percent of the time, the true compliance rate is between 21.9 and 50.0 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰³ VHA Notice 2020-13.

¹⁰⁴ VHA subject matter expert response to timing of safety plan completion, July 8, 2019.

¹⁰⁵ The OIG estimated that 95 percent of the time, the true compliance rate is between 60.8. and 89.5 percent, which is statistically significantly below the 90 percent benchmark.

Recommendation 14

14. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that suicide prevention safety plans are completed within seven days before or after the High Risk for Suicide Patient Record Flag designation.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. The Suicide Prevention Coordinator provided education to 126 of 138 (91.3 percent) mental health staff, on safety plans for high risk Veterans on April 15, 2020. Safety plan education will be completed for all mental health staff by August 19, 2020.

The Suicide Prevention Coordinator will review safety plans weekly to ensure all plans are completed within seven days and to ensure that all elements are completed in the safety plans. The Chief of Mental Health Services will monitor compliance and audit results will be reported to the Medical Staff Executive Council, chaired by the Chief of Staff, until 90 percent or greater compliance is maintained for six consecutive months.

VHA requires that suicide prevention safety plans include contact information for professionals and agencies as well as assessments of patients' access to opioids ¹⁰⁶ The OIG estimated that 33 percent of patients' electronic health records reviewed contained professionals' and agencies' contact information in the safety plan. ¹⁰⁷ Additionally, the OIG estimated that 13 percent of providers asked about access to opioids. ¹⁰⁸ Failure to complete safety plans with all required elements may hinder patients' access to appropriate care and treatment when needed and pose a significant danger to vulnerable patients. The Chief of Mental Health reported that an updated electronic health record suicide prevention template was not installed, which led to the omission of prompts for providers to enter all required information.

¹⁰⁶ VHA DUSHOM memo *SP Safety Plan National CPRS Note Templates Implementation*, June 1, 2018 and V*A Safety Plan treatment Manual to Reduce Suicide Risk*: Veteran Version, August 20, 2008.

¹⁰⁷ The OIG estimated that 95 percent of the time, the true compliance rate is between 17.7 and 50.0 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰⁸ The OIG estimated that 95 percent of the time, the true compliance rate is between 0.0 and 27.3 percent, which is statistically significantly below the 90 percent benchmark.

Recommendation 15

15. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that suicide prevention safety plans include all required elements for patients with High Risk for Suicide Patient Record Flags.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Chief of Staff determined the reason for non-compliance and considered this when developing the action plan. The Suicide Prevention Coordinator provided education to 126 of 138 (93.1 percent) mental health staff on safety plans for high risk Veterans on April 15, 2020. Safety plan education will be completed for all mental health staff by August 19, 2020. The Mental Health Services providers began exclusive utilization of the updated safety plan template which includes all required elements on March 12, 2020.

The Suicide Prevention Coordinator will review safety plans weekly to ensure all plans include required elements for patients with High Risk for Suicide Patient Record Flags. The Chief of Mental Health Services will monitor compliance and audit results will be reported to the Medical Staff Executive Council, which the Chief of Staff chairs, until 90 percent or greater compliance is maintained for six consecutive months.

VHA requires that all staff, clinical and nonclinical, receive annual suicide prevention refresher training. The OIG found that 12 of 20 staff completed the required annual training. Failure to complete training requirements could lead to less than optimal intervention(s) for patients at risk for suicide. The Accreditation Manager reported that due to administrative vacancies, there had been a lack of oversight.

Recommendation 16

16. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that clinical and nonclinical staff complete annual suicide prevention refresher training.

¹⁰⁹ VHA Directive 1071.

Medical center concurred.

Target date for completion: October 1, 2020

Medical center response: The Medical Center Director determined the reason for non-compliance and considered this when developing the action plan. The Domain Manager verified that each service has a trained Talent Management System (TMS) administrator.

Monthly compliance reports will be generated by the service line TMS administrator and sent to service line chiefs to monitor and address deficiencies. In addition, the Domain Manager will provide quarterly compliance reports to the executive leadership team for review and action. The Chief of Mental Health Services will provide monthly updates to Medical Staff Executive Council on the percentage of compliance for the required annual suicide prevention refresher training until 90 percent or greater compliance is maintained for six consecutive months. The Medical Staff Executive Committee reports monthly to the Facility Leadership Board which the Medical Center Director chairs.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the Life-Sustaining Treatment Decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "…eliciting, documenting, and honoring patients' values, goals, and preferences." 110

VA healthcare medical centers were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018. Implementation requirements included initiating conversations about the goals of care. A goals of care conversation is a discussion between a healthcare provider and a patient or surrogate to help define the patient's values, goals, and preferences for care and, based on the discussion, make choices about starting, limiting, or ceasing LSTs. VHA requires practitioners to initiate goals of care conversations with high-risk patients—including hospice patients or their surrogates—within a time frame that meets the medical needs of the patient or at the time of a triggering event. Is

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

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

¹¹¹ According to VHA Handbook 1004.03(1), the medical facility must fully implement handbook requirements within 18 months of publication.

¹¹² According to VHA Handbook 1004.03(1), a surrogate is legally authorized under VA policy to serve as the decision maker on behalf of the patient should the patient lose decision-making capacity.

¹¹³ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017, defines hospice patients as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. According to VHA Handbook 1004.03(1), triggering events requiring goals of care conversations include those "prior to referral or following admission (e.g., within 24 hours) to VA or non-VA hospice."

• Informed consent for the LST plan.

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

To determine whether the medical center complied with the OIG-selected requirements related to LSTD for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 48 randomly selected hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

¹¹⁴ VHA Handbook 1004.03(1).

Care Coordination Findings and Recommendations

Generally, the medical center achieved the requirements listed above. The OIG made no recommendations.

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹¹⁵ 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.¹¹⁶ To help the VA better understand the needs of the growing women's veteran population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."¹¹⁷ 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."¹¹⁸

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. ¹¹⁹ 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." ¹²⁰

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

¹¹⁵ National Center for Veterans Analysis and Statistics, "VETPOP2016 LIVING VETERANS BY AGE GROUP, GENDER, 2015-2045," Table 1L. https://www.va.gov/vetdata/Veteran_Population.asp. (The website was accessed on November 14, 2019.)

¹¹⁶ National Center for Veterans Analysis and Statistics, "Veteran Population," May 3, 2019. https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf. (The website was accessed on September 16, 2019.)

¹¹⁷ U.S. Department of Veterans Affairs, "Study of Barriers for Women Veterans to VA Health Care," Final Report, April 2015.

https://www.womenshealth.va.gov/docs/Womens%20Health%20Services_Barriers%20to%20Care%20Final%20Re port April2015.pdf. (The website was accessed on September 16, 2019.)

¹¹⁸ U.S. Department of Veterans Affairs, Health Services Research & Development, Forum, *Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions*, Suicide Prevention, Spring 2018. https://www.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5. (The website was accessed on September 16, 2019.)

¹¹⁹ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020.

¹²⁰ VHA Directive 1330.01(3).

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

Women's Health Findings and Recommendations

The medical center complied with most of the requirements for women's health including program oversight and performance improvement data monitoring. However, the OIG identified deficiencies with designated women's health primary care providers at CBOCs.

VHA requires that each CBOC has at least two designated women's health primary care providers. ¹²¹ The OIG identified that four CBOCs (Bessemer, Childersburg, Gadsden, and Jasper) had more than one provider at each location. However, these clinics did not have at least two designated women's health primary care providers, which could limit the medical center's ability to provide comprehensive healthcare services to women veterans. The Women's Health Medical Director reported that some primary care providers opted not to pursue women's health

¹²¹ VHA Directive 1330.01(3).

designation training and additionally cited challenges for providers to maintain competencies when the volume of female patients seen at the CBOCs is low.

Recommendation 17

17. The Medical Center Director 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.

Medical center concurred.

Target date for completion: February 1, 2021

Medical center response: The Medical Center Director determined the reason for non-compliance and considered this when developing the action plan. The Women's Health Medical Director (WHMD) will continue to identify existing providers who are interested in becoming designated women's health providers. Associate Chief of Staff for Primary Care will continue to make a priority the recruitment of providers with women's health experience or interest in pursuing training. Due to coronavirus diease-19, VHA cancelled the in-person 20-hour Women's Health Mini Residencies. The WHMD will explore alternative trainings that would allow designation of providers. The WHMD will seek Community Based Outpatient Clinic waivers for qualifying clinics having less than 160 women veterans per the National Women's Health Services by August 28, 2020. Compliance of two designated women's health primary care providers per community- based outpatient clinic will be completed monthly by the WHMD. Audit results will be reported to the Medical Staff Executive Council that reports to the Facility Leadership Board which is chaired by the Medical Center Director until six months of 90 percent or greater compliance is met.

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

- Maintain a current inventory list of all RME
- Have standard operating procedures (SOPs) that are based on current manufacturer's guidelines and reviewed at least triennially
- Use CensiTrac[®] Instrument Tracking System for tracking reprocessed instruments¹²⁴
- 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 inspections¹²⁵

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. ¹²⁶ The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization. ¹²⁷

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,

¹²² VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016.

¹²³ Association for Professionals in Infection Control and Epidemiology, *APIC Text of Infection Control and Epidemiology*, Chapter 107: Sterile Processing, April 26, 2019. https://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing#book_section_17348. (The website was accessed on May 14, 2019.)

¹²⁴ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.

¹²⁵ VHA Directive 1116(2).

¹²⁶ 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.

¹²⁷ VHA Directive 7704(1), Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment, February 16, 2016.

personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME. ¹²⁸

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. 129

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

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

-

¹²⁸ VHA Directive 1116(2).

¹²⁹ VHA Directive 1116(2).

- o Eating or drinking in the area prohibited
- Equipment properly stored
- Required temperature and humidity maintained
- Completion of staff training, competency, and continuing education
 - o Required training completed in a timely manner
 - Competency assessments performed
 - Monthly continuing education received

High-Risk Processes Findings and Recommendations

The medical center met the requirements for quality assurance monitoring; reprocessing and storage area physical inspections; and staff training, competency, and continuing education. However, the OIG identified a deficiency with the annual risk analysis.

VHA requires the SPS Chief to perform an annual risk analysis and report the results to the VISN SPS Management Board. The OIG found that the SPS Chief performed a fiscal year 2019 risk analysis but did not report the results to the VISN SPS Management Board. Failure to report the risk analysis could result in missed opportunities to identify potential problems or process failures. The VISN SPS Lead reportedly believed that the results did not need to be sent to the VISN SPS Management Board because the VISN developed the standardized risk assessment tool—which was approved by the VISN on the front end—and did not see the need to send the completed risk assessment.

Recommendation 18

18. The Associate Director for Patient/Nursing Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Services Chief reports the annual risk analysis results to the Veterans Integrated Service Network Sterile Processing Services Management Board.

¹³⁰ VHA Directive 1116(2).

Medical center concurred.

Target date for completion: September 1, 2020

Medical center response: The Associate Director for Patient/Nursing Services determined the reason for noncompliance and considered this when developing the action plan. The Surgery and Sterile Processing Services Chief will provide the completed annual risk assessment results to the VISN Sterile Processing Services Management Board annually. The 2020 Sterile Processing Services risk assessment results were shared with the VISN 7 Sterile Processing Services Management Board on June 18, 2020.

The Surgery and Sterile Processing Services Chief will report the compliance of transmission of the annual risk assessment results to the VISN Sterile Processing Services Management Board to the Medical Staff Executive Council annually. The Sterile Processing Services risk assessment results transmission to the VISN Sterile Processing Services Management Board will be added to the Medical Staff Executive Council reporting calendar to ensure annual result transmission to the VISN board. The Medical Staff Executive Council reports to the Facility Leadership Board in which the Associate Director for Patient/Nursing Services is a member.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

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) 	Eighteen OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Medical Center Director, Chief of Staff, ADPNS, and Associate Director. See details below.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	 QSV Committee Protected peer reviews UM reviews Patient safety	• None	Root cause analyses include all required review content and are properly documented in the VHA Patient Safety Information System.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	 FPPEs OPPEs Provider exit reviews and reporting to SLBs 	 Service chief includes the minimum pathology-specific criteria for focused professional practice evaluations. Reprivileging decisions are based on service-specific criteria for ongoing professional practice evaluations. Providers with similar training and privileges complete ongoing professional practice evaluations of licensed independent practitioners. 	Healthcare practitioners' supervisor completes and signs the exit review form within seven calendar days of departure from the medical center.
Environment of Care	Medical center General safety Special use spaces Environmental cleanliness and infection prevention Privacy Accommodation and privacy for women veterans Logistics Community-based outpatient clinic General safety Special use spaces Environmental cleanliness and infection prevention Privacy Privacy Privacy for women veterans Logistics	 Furnishings and equipment are safe and in good repair. Clean and dirty equipment, devices, and supplies are kept separate. A safe, functional, and clean patient care area is maintained. 	Protected health information is properly secured when transported.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	 Provision of pain management using long-term opioid therapy Program oversight and evaluation 	 Aberrant behavior risk assessments are completed on patients prior to initiating long-term opioid therapy. Justification for prescribing opioids and benzodiazepines concurrently is documented in the electronic health record. Urine drug testing is conducted as required for patients on long-term opioid therapy. Informed consent is obtained and documented consistently for patients prior to initiating long-term opioid therapy. 	• None
Mental Health: Suicide Prevention Program	 Designated suicide prevention coordinator Provision of suicide prevention care Completion of suicide prevention training requirements 	 Suicide prevention safety plans are completed within seven days before or after the High Risk for Suicide Patient Record Flag designation. Suicide prevention safety plans include all required elements. 	All staff receive annual suicide prevention refresher training.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Care Coordination: Life-Sustaining Treatment Decisions	 LSTD multidisciplinary committee Goals of care conversation documentation LSTD note/orders completed by an authorized provider or delegated 	• None	• None
Women's Health: Comprehensive Care	 Provision of care Program oversight and performance improvement data monitoring Staffing requirements 	Each community- based outpatient clinic has at least two designated women's health primary care providers.	• None
High-Risk Processes: Reusable Medical Equipment	Administrative processesData monitoringPhysical inspectionStaff training	• None	An annual risk analysis is reported to the VISN Sterile Processing Services Management Board.

Appendix B: Medical Center Profile

The table below provides general background information for this high complexity (1a) affiliated¹ medical center reporting to VISN 7.²

Table B.1. Profile for Birmingham VA Medical Center (521) (October 1, 2016, through September 30, 2019)

Profile Element	Medical Center Data FY 2017 ³	Medical Center Data FY 2018 ⁴	Medical Center Data FY 2019 ⁵
Total medical care budget in dollars	\$509,786,669	\$526,193,473	\$588,364,088
Number of:			
Unique patients	65,935	67,794	67,222
Outpatient visits	837,412	869,615	862,170
Unique employees ⁶	2,309	2,305	2,428
Type and number of operating beds: • Blind Rehabilitation	24	20	20
Medicine	69	83	83
Neurology	4	4	4
Residential rehabilitation	12	12	12
Surgery	34	22	22
Average daily census:			
Blind Rehabilitation	14	14	14
Medicine	60	57	55
Neurology	3	3	2
Residential rehabilitation	10	12	12
Surgery	13	14	13

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

¹ Associated with a medical residency program.

² The VHA medical centers are classified according to a facility complexity model; a designation of "1a" indicates a facility with high volume, high risk patients, most complex clinical programs, and large research and teaching programs."

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

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

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

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

Appendix C: VA Outpatient Clinic Profiles¹

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Huntsville, AL	521GA	35,599	17,259	Anesthesia Cardiology Dermatology Endocrinology Eye Gastroenterology Infectious disease Neurology	Radiology	Nutrition Pharmacy

¹ Includes all outpatient clinics in the community that were in operation as of August 27, 2019. The OIG omitted (521QA) Callahan, AL, as no workload/encounters or services were reported.

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

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

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

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

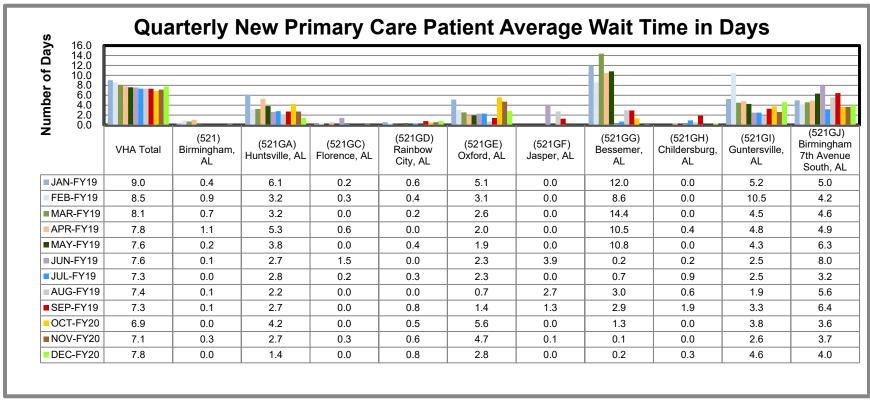
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Sheffield, AL	521GC	11,282	5,854	Anesthesia Dermatology Endocrinology Infectious disease Neurology	n/a	Nutrition Social work Weight management
Gadsden, AL	521GD	8,708	5,247	Anesthesia Dermatology Endocrinology Infectious disease Neurology	n/a	Nutrition Pharmacy
Oxford, AL	521GE	12,857	8,160	Anesthesia Dermatology Endocrinology Infectious disease Neurology	n/a	Nutrition
Jasper, AL	521GF	4,300	3,951	Anesthesia Dermatology Endocrinology Eye	n/a	Nutrition Pharmacy Weight management
Bessemer, AL	521GG	4,967	3,827	Anesthesia Dermatology Eye	n/a	Nutrition Pharmacy Social work Weight management
Childersburg, AL	521GH	7,736	4,325	Dermatology Endocrinology	n/a	Nutrition

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Guntersville, AL	521GI	9,496	5,081	Anesthesia Dermatology Endocrinology Eye Nephrology Neurology	n/a	Nutrition
Birmingham, AL	521GJ	34,611	1,957	Anesthesia Endocrinology GYN Poly-Trauma Rehab Physician Spinal cord injury	Radiology	Nutrition Pharmacy Social work Weight management

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

n/a = not applicable

Appendix D: Patient Aligned Care Team Compass Metrics¹

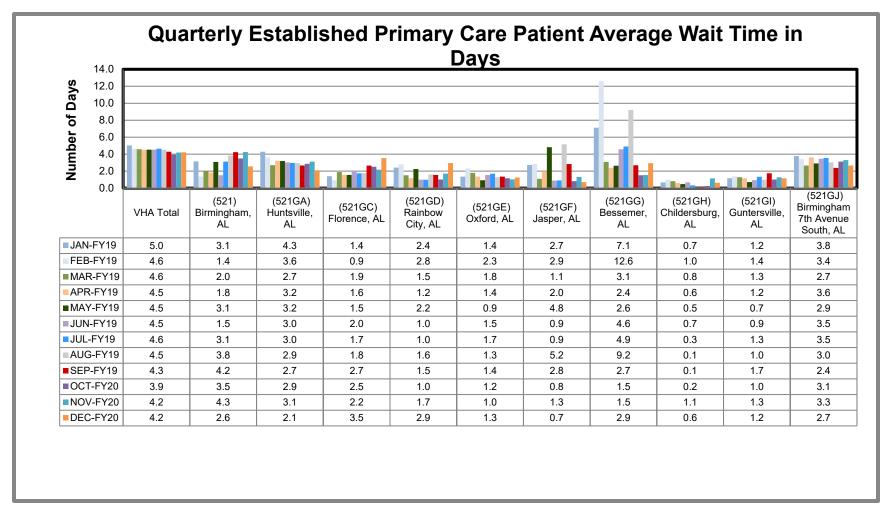


Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (521QA) Callahan, AL, as no data were reported.

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

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



Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (521QA) Callahan, AL, 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 Definitions¹

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

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

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

Source: VHA Support Service Center

Appendix F: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: July 22, 2020

From: Interim Director, VA Southeast Network (VISN 7) (10N7)

Subj: Draft Report: Comprehensive Healthcare Inspection of the Birmingham VA Medical Center, AL

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

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

- 1. I have had the opportunity to review the Draft Report: Comprehensive Healthcare Inspection of the Birmingham Veterans Affairs Medical Center, Birmingham, AL.
- 2. VISN 7 submits concurrence to recommendations 1-18, and with the attached Birmingham Veterans Affairs Medical Center submission.
- 3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.
- 4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

Original signed by:

Joe D. Battle

Appendix G: Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: July 20, 2020

From: Director, Birmingham VA Medical Center (521/00)

Subj: Comprehensive Healthcare Inspection of the Birmingham VA Medical Center, AL

To: Director, VA Southeast Network (10N7)

- I would like to express my appreciation to the Office of Inspector General (OIG), Comprehensive Healthcare Inspection Program (CHIP) review team for their professional and excellent feedback provided to our employees during the CHIP review of the Birmingham Health VA Care System (BVAHCS) conducted the week of March 2, 2020.
- 2. I have reviewed the draft report for the BVAHCS, Birmingham, AL and concur with the responses and action plans.
- Please express my thanks to the team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our Veterans. Should you have any questions or concerns, please feel free to contact my office at 205-933-4515.

Original signed by:

Stacy J. Vasquez

Medical Center Director

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