

# DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Ralph H. Johnson VA Medical Center in Charleston, South Carolina

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*Figure 1.* Ralph H. Johnson VA Medical Center in Charleston, South Carolina (Source: https://vaww.va.gov/directory/guide/, accessed on February 20, 2020)

### **Abbreviations**

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



### **Report Overview**

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Ralph H. Johnson VA Medical Center and multiple outpatient clinics in Georgia and South Carolina. 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 February 24, 2020, at the Ralph H. Johnson VA Medical Center and Hinesville VA Clinic. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this medical center's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this medical center and other Veterans Health Administration (VHA) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

### **Inspection Results**

### Leadership and Organizational Risks

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

When the team conducted this inspection, the medical center's leaders had worked together for five months in their current roles. In September 2019, the permanent Director was detailed as the acting Veterans Integrated Service Network (VISN) 7 Director. As a result, the Associate and Assistant Directors were appointed as the acting Director and acting Associate Director, respectively. The permanent Director, ADNPCS, and Chief of Staff had worked together since 2016.

The OIG noted that selected employee satisfaction survey results indicated satisfaction with medical center leadership. Further, patient experience survey scores for healthcare system leaders generally reflected similar or higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and did not identify any substantial organizational risk factors.<sup>1</sup>

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

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 executive leaders were also

<sup>&</sup>lt;sup>1</sup> 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."

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

knowledgeable within their scopes of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing SAIL and Community Living Center (CLC) measures but should continue to take actions to sustain and improve performance.<sup>3</sup>

The OIG noted opportunities for improvement in six clinical areas reviewed and issued 13 recommendations that are directed to the Medical Center Director, Chief of Staff, ADNPCS, and Associate Director and are briefly described below.

### Quality, Safety, and Value

The medical center complied with requirements for a committee responsible for quality, safety, and value oversight functions and review of aggregated data, as well as most patient safety elements. However, the OIG identified concerns with protected peer reviews.

### Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluations and healthcare provider exit review processes.<sup>4</sup>

### **Environment of Care**

The medical center largely met compliance with requirements for special use spaces, privacy, accommodations for women veterans, and logistics. However, the OIG identified issues with patient safety in the inpatient behavioral health unit and cleanliness in the medical/surgical inpatient units.

### **Mental Health**

The medical center complied with the requirements for a designated suicide prevention coordinator, suicide safety plans, patient follow-up, and community outreach activities. However, the OIG identified a deficiency with suicide prevention annual training requirements.

<sup>&</sup>lt;sup>3</sup> According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

<sup>&</sup>lt;sup>4</sup> The definitions of focused professional practice evaluation and ongoing professional practice evaluations can be found within the 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."

### Women's Health

The medical center complied with requirements for most of the provision of care indicators. The OIG noted concerns with community-based outpatient clinic-designated women's health primary care providers, the Women Veterans Health Committee, and a designated maternity care coordinator.

#### **High-Risk Processes**

The medical center met many of the requirements for the proper operations and management of reprocessing reusable medical equipment (RME). The OIG identified a deficiency with airflow testing.

#### Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 13 recommendations for improvement to the Medical Center Director, Chief of Staff, ADNPCS, and Associate Director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this medical center. The intent is for medical center leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

#### Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the CHIP review findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 70–71, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendations 10, 12, and 13 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

John V. Vaigh. M.

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

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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 facilities providing healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Ralph H. Johnson 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.<sup>5</sup> Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes.<sup>6</sup> 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:

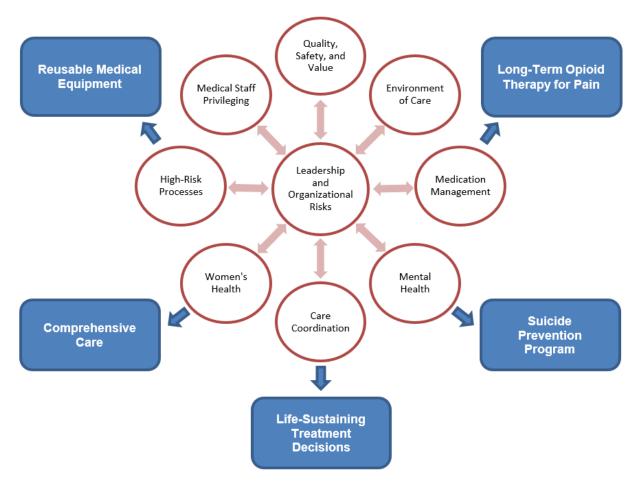
- 1. Leadership and organizational risks
- 2. Quality, safety, and value (QSV)
- 3. Medical staff privileging
- 4. Environment of care
- 5. Medication management (targeting long-term opioid therapy for pain)
- 6. Mental health (focusing on the suicide prevention program)
- 7. Care coordination (spotlighting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

<sup>&</sup>lt;sup>5</sup> 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.) <sup>6</sup> 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.

<sup>&</sup>lt;sup>7</sup> 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 Ralph H. Johnson VA Medical Center includes multiple outpatient clinics in Georgia and South Carolina. 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.<sup>8</sup>

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

- Community living center (CLC)<sup>9</sup>
- Critical care stepdown unit
- Dental clinic
- Dialysis unit
- Emergency Department
- Gastroenterology suite
- Inpatient behavioral health unit
- Intensive care units (medical and surgical)
- Medical/surgical inpatient units
- Outpatient primary care clinic
- Post-anesthesia care unit
- Specialty clinic
- Sterile processing services areas
- Women's health clinic

<sup>&</sup>lt;sup>8</sup> The OIG did not review VHA's internal survey results, instead focused on OIG inspections and external surveys that affect facility accreditation status.

<sup>&</sup>lt;sup>9</sup> According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017, CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

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

The inspection examined operations from January 27, 2018, through February 28, 2020, the last day of the unannounced multiday site visit.<sup>10</sup> While on site, the OIG referred concerns beyond the scope of the CHIP inspection to the OIG's hotline management team for further review.

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.

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

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

<sup>&</sup>lt;sup>10</sup> The range represents the time period from the prior CHIP inspection to the completion of the unannounced, multiday CHIP site visit in February 2020.

### **Results and Recommendations**

#### Leadership and Organizational Risks

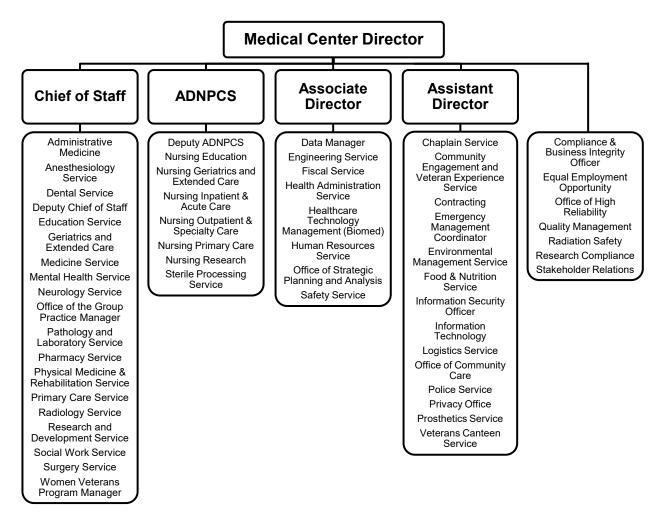
Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare system. Leadership and organizational risks can affect the healthcare system's ability to provide care in the clinical focus areas.<sup>11</sup> To assess the medical center's risks, the OIG considered the following indicators:

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

#### **Executive Leadership Position Stability and Engagement**

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

<sup>&</sup>lt;sup>11</sup> 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: Ralph H. Johnson VA Medical Center (received February 24, 2020)

At the time of the OIG's visit, the medical center's executive leadership team had worked together for five months in their current roles. In September 2019, the permanent Director was detailed as the acting VISN 7 Director. At that time, the Associate and Assistant Directors were appointed as the acting Director and acting Associate Director, respectively. The permanent Director, ADNPCS, and Chief of Staff had worked together since 2016 (see table 1).

Leadership Position	Assignment Date
Medical Center Director	November 2, 2014 (permanent) September 23, 2019 (acting
	VISN Director)
Chief of Staff	November 5, 2000
Associate Director for Nursing and Patient Care Services	April 3, 2016
Associate Director	August 4, 2019 (permanent)
	September 23, 2019 (acting Medical Center Director)
Assistant Director	August 4, 2019 (permanent)
	September 23, 2019 (acting Associate Director)

Table 1. Executive Leader Assignments

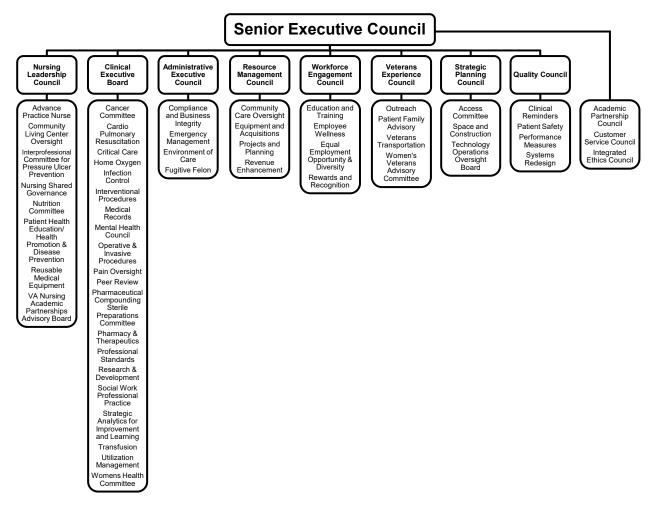
Source: Ralph H. Johnson VA Medical Center Supervisory Human Resources Specialist (received February 25, 2020)

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

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

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

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



*Figure 4.* Medical Center Committee Reporting Structure Source: Ralph H. Johnson VA Medical Center (received February 24, 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.<sup>12</sup> Table 2 provides relevant survey results for VHA, the medical center, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found the medical center average for the selected survey questions was similar to the VHA average.<sup>13</sup> The leaders' averages for the selected questions were often notably higher than both the VHA and medical center averages.<sup>14</sup>

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADNPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: Servant Leader Index Composite. <sup>15</sup>	0–100 where higher scores are more favorable	72.6	73.7	81.7	91.8	83.0	85.8	75.6
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	3.4	3.9	4.5	3.6	3.8	3.7

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

<sup>&</sup>lt;sup>12</sup> Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADNPCS, Associate Director, and Assistant Director.

<sup>&</sup>lt;sup>13</sup> 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.

<sup>&</sup>lt;sup>14</sup> It is important to note that the 2019 All Employee Survey results are not reflective of employee satisfaction with the current acting Medical Center Director, acting Associate Director, or acting Assistant Director, who assumed the roles after the survey was administered.

<sup>&</sup>lt;sup>15</sup> According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, the Servant Leader Index "is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others' contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others' needs before their own."

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADNPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: My organization's senior leaders maintain high standards of honesty and integrity.	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	3.6	4.2	4.7	4.0	4.3	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	3.6	4.1	4.8	4.2	4.1	4.0

Source: VA All Employee Survey (accessed January 21, 2020)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.<sup>16</sup> Note that the medical center averages for the selected survey questions were similar to the VHA averages, while those for the leaders were generally better than those for VHA and the medical center.

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADNPCS 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	4.2	4.6	3.8	4.3	4.3

<sup>&</sup>lt;sup>16</sup> Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADNPCS, Associate Director, and Assistant Director.

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADNPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.8	4.2	4.5	4.2	4.1	3.8
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	1.3	0.8	0.9	2.0	1.7	1.4

Source: VA All Employee Survey (accessed January 21, 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, 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.<sup>17</sup>

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

<sup>&</sup>lt;sup>17</sup> Ratings are based on responses by patients who received care at this medical center.

reflect patients' attitudes toward their healthcare experiences (see table 4). For this medical center, the patient survey results generally reflected similar or higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): <i>Would you recommend this hospital to your friends and family?</i>	The response average is the percent of "Definitely Yes" responses.	68.3	73.2
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	85.0
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): <i>I felt like a valued customer.</i>	The response average is the percent of "Agree" and "Strongly Agree" responses.	77.3	82.1
Survey of Healthcare Experiences of Patients (outpatient specialty care): <i>I felt like a valued customer.</i>	The response average is the percent of "Agree" and "Strongly Agree" responses.	78.0	78.5

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

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed December 23, 2019)

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from 2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.<sup>18</sup> For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that the results for male respondents were generally better than corresponding VHA averages, while those for female respondents

<sup>&</sup>lt;sup>18</sup> VA National Center for Veterans Analysis and Statistics, *The Past, Present and Future of Women Veterans*, February 2017.

were generally similar to or better than those for female VHA patients nationally. Medical center leaders appeared to be actively engaged with male and female patients.

Questions	Scoring	VHA <sup>19</sup>		Medical Center <sup>20</sup>		
		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	87.3	82.6	
During this hospital stay, how often did nurses treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	88.3	92.6	
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	74.7	60.8	

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

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed January 21, 2020)

<sup>&</sup>lt;sup>19</sup> The VHA averages are based on 48,259–48,798 male and 2,342–2,359 female respondents, depending on the question.

<sup>&</sup>lt;sup>20</sup> The medical center averages are based on 402–410 male and 37 female respondents, depending on the question.

Questions	Scoring	VHA <sup>21</sup>		Medical Center <sup>22</sup>		
		Male Average	Female Average	Male Average	Female Average	
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	57.9	68.0	
In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	67.0	46.5	
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	73.9	70.0	

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

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed January 21, 2020)

<sup>&</sup>lt;sup>21</sup> The VHA averages are based on 79,450–241,828 male and 5,762–13,041 female respondents, depending on the question.

 $<sup>^{22}</sup>$  The medical center averages are based on 425–1,216 male and 58–106 female respondents, depending on the question.

Questions	Scoring	VHA <sup>23</sup>		Medical Center <sup>24</sup>		
		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	47.6	41.2	
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	60.0	59.3	
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	73.0	75.7	

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

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed January 21, 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.<sup>25</sup> Table 8 summarizes the relevant medical center inspections most recently performed by the OIG and The Joint Commission (TJC).<sup>26</sup> Of note, at the time of the OIG visit, the medical center had

<sup>&</sup>lt;sup>23</sup> The VHA averages are based on 65,968–208,722 male and 3,460–11,072 female respondents, depending on the question.

<sup>&</sup>lt;sup>24</sup> The medical center averages are based on 455–1,636 male and 35–123 female respondents, depending on the question.

<sup>&</sup>lt;sup>25</sup> 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.

<sup>&</sup>lt;sup>26</sup> 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 comprehensive healthcare inspection conducted in January 2018.

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.<sup>27</sup> Additional results included the Long Term Care Institute's inspection of the medical center's CLC.<sup>28</sup>

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Comprehensive Healthcare Inspection Program Review of the Ralph H. Johnson VA Medical Center, Charleston, South Carolina, Report No.18-0600-259, August 22, 2018)	January 2018	4	0
TJC Hospital Accreditation	March 2019	32	0
TJC Behavioral Health Care Accreditation		5	0
TJC Home Care Accreditation		6	0

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

Source: OIG and TJC (inspection/survey results verified with the Chief of Quality Management on February 25, 2020)

# Identified Factors Related to Possible Lapses in Care and Medical Center Response

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be

<sup>&</sup>lt;sup>27</sup> 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.

<sup>&</sup>lt;sup>28</sup> The Long Term Care Institute states that it has been to over 4,000 healthcare facilities conducting quality reviews and over 1,145 external regulatory surveys since 1999. The Long Term Care Institute is "focused on long-term care quality and performance improvement; compliance program development; and review in long-term care, hospice, and other residential care settings." Long Term Care Institute. http://www.ltciorg.org/about-us/. (The website was accessed on March 6, 2019.)

able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms.

The patient safety coordinator and risk managers provided details regarding the nature of events that led to nine institutional disclosures and two sentinel events along with details on the reviews and administrative controls implemented to mitigate future risks to the facility. Table 9 lists the reported patient safety events from January 27, 2018 (the prior OIG comprehensive healthcare inspection), through February 25, 2020.<sup>29</sup>

(January 27, 2018, through February 25, 2020)			
Factor	Number of Occurrences		
Sentinel Events <sup>30</sup>	2		
Institutional Disclosures <sup>31</sup>	9		
Large-Scale Disclosures <sup>32</sup>	0		

# Table 9. Summary of Selected OrganizationalRisk Factors

Source: Ralph H. Johnson VA Medical Center's Patient Safety Coordinator and Risk Managers (received February 25, 2020)

#### Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted

<sup>&</sup>lt;sup>29</sup> 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 Ralph H. Johnson VA Medical Center is a high complexity (1a) affiliated system as described in Appendix B.)

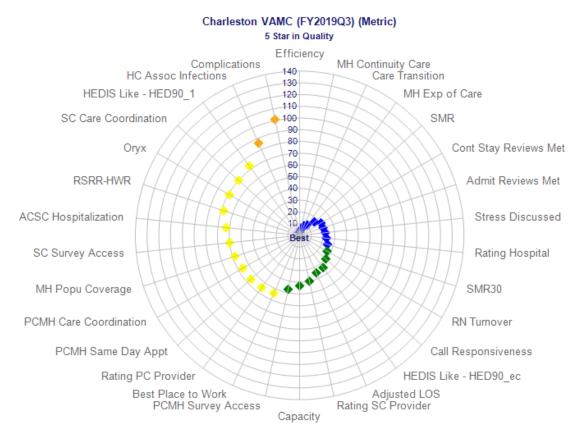
<sup>&</sup>lt;sup>30</sup> The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

<sup>&</sup>lt;sup>31</sup> 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."

<sup>&</sup>lt;sup>32</sup> 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."

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.<sup>33</sup>

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, figure 5 uses blue and green data points to indicate high performance for the Ralph H. Johnson VA Medical Center (Charleston VAMC) (for example, in the areas of mental health (MH) continuity (of) care, rating (of) hospital, registered nurse (RN) turnover, and capacity). Metrics that need improvement are denoted in orange (health care (HC) associated infections and complications).<sup>34</sup>



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

*Figure 5.* System 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.

<sup>&</sup>lt;sup>33</sup> VHA Support Service Center, *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

 $<sup>^{34}</sup>$  For information on the acronyms in the SAIL metrics, please see Appendix E.

# Veterans Health Administration Performance Data for Community Living Centers

The "CLC SAIL" Value Model is a tool to summarize and compare the performance of CLCs in the VA. The model leverages much of the same data used in the Centers for Medicare & Medicaid Services' (CMS) *Nursing Home Compare* and provides a single resource to review quality measures and health inspection results.<sup>35</sup>

Figure 6 illustrates the medical center's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2019. Figure 6 uses blue and green data points to indicate high performance for the Charleston CLC (for example, in the areas of physical restraints–long-stay (LS), falls with major injury (LS), and receive antipsychotic meds (LS)). Metrics that need improvement are denoted in red (urinary tract infection (UTI) (LS)).<sup>36</sup>

<sup>&</sup>lt;sup>35</sup> According to the Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, November 19, 2018, "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

<sup>&</sup>lt;sup>36</sup> For data definitions of acronyms in the SAIL CLC measures, please see Appendix F.

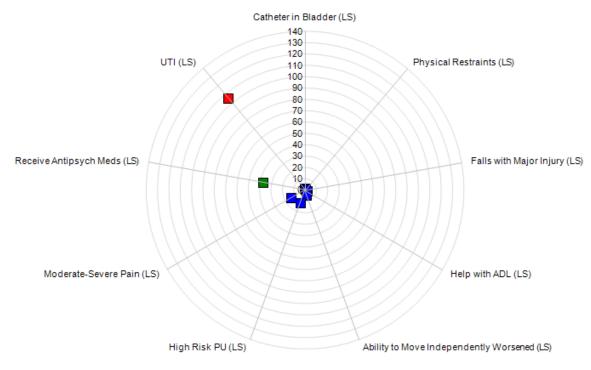


Figure 6. Charleston CLC Quality Measure Rankings (as of September 30, 2019)LS = Long-Stay MeasureSS = Short-Stay MeasureSource: VHA Support Service CenterNote: The OIG did not assess VA's data for accuracy or completeness.

### Leadership and Organizational Risks Conclusion

At the time of the OIG's visit, the medical center's leadership team had worked together in their current positions for five months, although three of the five leaders had worked together for several years. Survey scores related to employee satisfaction with the executive leaders were generally better than those for VHA and the medical center. Patient experience survey data revealed satisfaction with the care provided. The medical center's leaders appeared actively engaged with employees and patients and were working to sustain and further improve employee and patient engagement and satisfaction. The leaders also appeared to support efforts to improve and maintain patient safety, quality care, and other positive outcomes. The OIG's review of the medical center's accreditation findings and disclosures did not identify any substantial organizational risk factors. The executive leadership team was knowledgeable within their scope of responsibility about SAIL and CLC SAIL measures but 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.<sup>37</sup> 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.<sup>38</sup> 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.<sup>39</sup>

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

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

The OIG reviewers also assessed the medical center's processes for conducting protected peer reviews of clinical care.<sup>40</sup> 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.<sup>41</sup> The OIG team examined the completion of the following elements:

<sup>&</sup>lt;sup>37</sup> Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence, September 2014.

<sup>&</sup>lt;sup>38</sup> VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs, May 9, 2017.

<sup>&</sup>lt;sup>39</sup> Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence.

<sup>&</sup>lt;sup>40</sup> 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."

<sup>&</sup>lt;sup>41</sup> VHA Directive 1190.

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

Next, the inspection team assessed the medical center's utilization management (UM) program, a key component of VHA's framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.<sup>43</sup> 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.<sup>44</sup> 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.<sup>45</sup> 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

<sup>&</sup>lt;sup>42</sup> VHA Directive 1190.

<sup>&</sup>lt;sup>43</sup> 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."

<sup>&</sup>lt;sup>44</sup> VHA Directive 1117(2).

<sup>&</sup>lt;sup>45</sup> 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."

communicate potential and actual causes of harm to patients throughout the medical center.<sup>46</sup> The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses<sup>47</sup>
- 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.<sup>48</sup>

### **Quality, Safety, and Value Findings and Recommendations**

The medical center complied with requirements for the establishment of a committee responsible for QSV oversight functions and review of aggregated data, as well as most patient safety elements. The OIG identified significant weaknesses in protected peer reviews.

VHA requires peer reviewers to use at least one of the nine aspects of care to evaluate level two or three peer review findings.<sup>49</sup> The OIG found that 14 of 16 cases had evidence that the reviewer used at least one of the nine aspects of care. Failure to use an aspect of care may impact the ability to determine if appropriate care was provided. The Chief of Quality Management was unable to validate that the aspects of care were used but maintained that the requirement was met.

<sup>&</sup>lt;sup>46</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>47</sup> 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]."

<sup>&</sup>lt;sup>48</sup> For CHIP inspections, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

<sup>&</sup>lt;sup>49</sup> VHA Directive 1190. A level two peer review finding is defined as "the level at which most experienced and competent clinicians might have managed the case differently but it remains within the standard of care." A level three peer review "is the level at which most experienced and competent clinicians would have managed the case differently."

### **Recommendation 1**

1. The Chief of Staff determines the reasons for noncompliance and ensures that peer reviewers consistently use at least one of the nine aspects of care for evaluations.

Medical center concurred.

Target date for completion: November 30, 2020

Medical center response: The Chief of Quality Management attests that reasons for noncompliance were considered when developing this action plan. The Chief of Quality Management developed an electronic form with a forced function to ensure the "aspects of care" checkboxes would be populated. This form is now distributed to all reviewers electronically for completion. Completed peer reviews will be monitored in the Peer Review committee for 6 months for 90% compliance.

### **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).<sup>50</sup>

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.<sup>51</sup>

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."<sup>52</sup> The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
  - o Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs<sup>53</sup>
  - Clear documentation of the results and time frames
  - Evaluation by another provider with similar training and privileges
- OPPEs
  - Application of criteria specific to the service or section
  - Use of minimum criteria for selected specialty LIPs<sup>54</sup>
  - Evaluation by another provider with similar training and privileges

<sup>&</sup>lt;sup>50</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

<sup>&</sup>lt;sup>51</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>52</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>53</sup> VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

<sup>&</sup>lt;sup>54</sup> VHA Acting DUSHOM Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

The OIG also determined whether service chiefs recommended continuing the LIPs' current privileges based in part on the results of OPPE activities and if the medical center's Executive Committee of the Medical Staff 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.<sup>55</sup> 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."<sup>56</sup> 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:

- Three solo/few practitioners who underwent initial or reprivileging during the previous 12 months<sup>57</sup>
- 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 professional practice evaluations and provider exit review processes.

<sup>&</sup>lt;sup>55</sup> VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005.

<sup>&</sup>lt;sup>56</sup> VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018.

<sup>&</sup>lt;sup>57</sup> VHA 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 November 4, 2018, through November 4, 2019.

VHA requires that LIPs are evaluated on an ongoing basis by providers with similar training and privileges.<sup>58</sup> Of the 30 profiles reviewed, the OIG found that FPPE and OPPE for psychiatrists were reviewed by psychologists. This resulted in LIPs providing care without a thorough evaluation of their competencies, which could impact quality of care and patient safety. The Chief of Staff attributed the noncompliance to the similarity in services provided at the medical center (such as cognitive behavior treatment and suicidality assessments). However, the Chief of Staff also acknowledged that psychologist and psychiatrist privileges are not identical.

#### **Recommendation 2**

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

Medical center concurred.

Target date for completion: December 30, 2020

Medical center response: The Chief of Staff [COS] attests that reasons for noncompliance were considered when developing this action plan. The COS educated service chiefs to ensure they are aware FPPE/OPPE completed on providers is done by a provider with similar or like privileges. OPPE/FPPE will be monitored for 90% compliance for 6 consecutive months. The Professional Standards Board will monitor ongoing compliance.

OPPE Review for May, June and July were in 100% compliance

FPPE Review for May – 100%, June indicated 87% compliance and July 100%

VHA requires that service chiefs include the minimum specialty-specific criteria for OPPEs of gastroenterology, nuclear medicine, pathology, and radiation oncology practitioners.<sup>59</sup> The OIG found that a nuclear medicine practitioner's OPPE lacked the required specialty-specific criteria.<sup>60</sup> This resulted in the nuclear medicine practitioner providing care without a thorough evaluation. The Community-Based Program Supervisor (previously the Assistant Chief of Quality Management) reported being aware of the criteria and posting an updated nuclear medicine OPPE form on the medical center's SharePoint site in January 2019. However, the older form was not deleted and was therefore inadvertently selected for OPPE documentation.

<sup>&</sup>lt;sup>58</sup> VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

<sup>&</sup>lt;sup>59</sup> VHA Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

<sup>&</sup>lt;sup>60</sup> VHA Memorandum, Requirements for Peer Review of Solo Practitioners, August 29, 2016.

## **Recommendation 3**

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

Medical center concurred.

Target date for completion: January 30, 2021

Medical center response: The Chief of Staff attests that reasons for noncompliance were considered when developing this action plan. The medical center identified this recommendation as an issue in January 2020 and took corrective action in order to correct the issue. The Chief of Staff reviewed the standard forms, added specific criteria suggested by Directive and sent to Service Chiefs for review and approval. These updated forms were routed through CEB [Clinical Executive Board] for final approval in June and July of 2020. We will monitor for 90% compliance for 6 months.

Additionally, VHA requires that reprivileging decisions are based on OPPE information specific to the service and practitioner.<sup>61</sup> The OIG found that service chiefs made reprivileging decisions based upon service-specific data for 19 of 23 practitioners. This resulted in inadequate data to support continuation of clinical privileges for the remaining LIPs. The Chief of Quality Management reported being aware of this deficiency subsequent to a VHA review conducted in January 2020 and provided documentation of an action plan submitted to VHA in February 2020 to ensure each service develops specific criteria for OPPE evaluations.

#### **Recommendation 4**

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

<sup>&</sup>lt;sup>61</sup> VHA Handbook 1100.19.

Medical center concurred.

Target date for completion: December 30, 2020

Medical center response: The Chief of Staff attests that reasons for noncompliance were considered when developing this action plan. The medical center identified this recommendation as an issue in January 2020 and took corrective action in order to correct the issue. The Chief of Staff reviewed the standard forms, added specific criteria suggested by Directive and sent to Service Chiefs for review and approval. These updated forms were routed through CEB for final approval in June and July of 2020. We will monitor for 90% compliance for 6 months.

VHA requires the Executive Committee of the Medical Staff's review and evaluation of LIPs' initial privileging requests. Committee minutes must include the materials reviewed and the rational of the conclusion reached. The committee's recommendation is then submitted to the Medical Center Director for approval.<sup>62</sup> For 6 of 10 practitioners who were granted initial privileges, the OIG found that the Clinical Executive Board (the medical center's Executive Committee of the Medical Staff) documented their recommendations. Failure to appropriately document committee reviews and recommendations resulted in incomplete evidence to support the Medical Center Director's privileging decisions. The Chief of Quality Management reported that a temporary recorder, who was unaware of the documentation requirement, completed the Clinical Executive Board for Credentialing and Privileging (a subcommittee of the Clinical Executive Board) minutes and omissions were overlooked by the Chief of Staff upon approval.

#### **Recommendation 5**

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

<sup>&</sup>lt;sup>62</sup> VHA Handbook 1100.19.

Medical center concurred.

Target date for completion: November 30, 2020

Medical center response: The Chief of Staff attests that reasons for noncompliance were considered when developing this action plan. The Chief of Quality Management ensured credentialing staff reverted to their previous process to add FPPE completions for review and discussion in the CEB minutes. Quality Management completed an audit to correct previous minutes not reflecting PSB [Professional Standards Board] discussions regarding FPPE completions reviewed in CEB. No harm or safety issues were identified. We will monitor for 6 months for 90% compliance.

VHA requires provider exit review forms, which document the review of a provider's clinical practice, to "be completed within 7-calendar days of the departure of a licensed health care professional from a VA facility."<sup>63</sup> Of the 20 providers who departed the medical center in the previous 12 months, the OIG found that 17 exit review forms were completed within the required time frame. Inconsistent performance of this process could result in delayed reporting of potential substandard care to SLBs. The Community-Based Program Supervisor (previously the Assistant Chief of Quality Management) did not provide any reasons for noncompliance but reported previous efforts at improving communication between Human Resource and Credentialing staff and documentation oversight since January 2019.

#### **Recommendation 6**

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

Medical center concurred.

Target date for completion: November 30, 2020

Medical center response: The Chief of Quality Management attests that reasons for noncompliance were considered when developing this action. Even though there was a short delay in completion of the exit reviews, all providers met the standard of care, therefore no harm came to any patients and reporting to the State Licensing board was not warranted. The Chief of Quality Management designed an electronic Exit Review form which was incorporated into the facility electronic clearing process in June 2020. The medical center will monitor for >90% compliance for 6 consecutive months.

<sup>&</sup>lt;sup>63</sup> VHA Notice 2018-05.

## **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.<sup>64</sup>

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

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

<sup>&</sup>lt;sup>64</sup> VHA Directive 1608, Comprehensive Environment of Care (CEOC) Program, February 1, 2016.

- o General safety
- Special use spaces
- Environmental cleanliness and infection prevention
- o Privacy
- Privacy for women veterans
- Logistics

During its review of the environment of care, the OIG team inspected the Hinesville VA Clinic and the following 16 patient care areas at the medical center:

- CLC (Patriots Harbor)
- Critical care stepdown unit
- Dental clinic
- Dialysis unit
- Emergency Department
- Gastroenterology suite
- Inpatient behavioral health unit
- Intensive care units (medical and surgical)
- Medical/surgical inpatient units (3B North, 4B North, 4B South)
- Outpatient primary care clinic (Green Team)
- Post-anesthesia care unit
- Specialty clinic
- Women's health clinic

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

#### **Environment of Care Findings and Recommendations**

The inspection team observed general compliance with requirements for special use spaces, privacy, accommodations for women veterans, and logistics. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified vulnerabilities with patient safety in the inpatient behavioral health unit and environmental cleanliness at the medical center.

VHA requires that flooring material in the inpatient behavioral health unit seclusion room provide adequate cushioning in the event of a fall.<sup>65</sup> The OIG found that the seclusion room had a hard floor. This could potentially affect the safety and physical well-being of patients and staff. The Chief of Engineering did not provide a reason for noncompliance and stated that work orders were approved prior to the inspection, and renovations were planned for August 2020.

#### **Recommendation 7**

7. The Associate Director for Nursing and Patient Care Services determines the reasons for noncompliance and makes certain that flooring in the inpatient behavioral health unit seclusion room is made of material that provides cushioning.

Medical center concurred.

Target date for completion: November 30, 2020

Medical center response: The Chief of Engineering attests that reasons for noncompliance were considered when developing this action plan. The Chief of Engineering collaborated with VHA National Center for Patient Safety Field Office, Interior Design, Mental Health, and Patient Safety to purchase and install padded floor mats to protect the area surrounding the seclusion room bed. A quote has been obtained, ordered to be placed on August 6 and will be ordered August 2020. The Chief of Engineering will report during Mental Health EOC [Environment of Care] rounds when completed.

The flooring in the Inpatient Behavioral Health Unit Seclusion rooms will be replaced with adequately cushioned flooring via Project #534-18-107 (Mechanical Upgrades). Flooring will meet or exceed standards set forth in the Mental Health Environment of Care Guidebook.

TJC requires facilities to maintain a clean environment, continually monitor environmental conditions, and remediate conditions not meeting this requirement.<sup>66</sup> The OIG found soiled floors in medical/surgical units 3B North, 4B North, and 4B South, especially between corridors and rooms. This presented a potential risk of infection to both patients and staff. The Environmental Management Service Manager indicated that the age of flooring prevented proper maintenance and cleaning.

<sup>&</sup>lt;sup>65</sup> VHA Directive 1167.

<sup>&</sup>lt;sup>66</sup> TJC. Infection Prevention and Control standard IC.02.01.01, EP 1; and Environment of Care standard EC.02.06.01, EP 26.

### **Recommendation 8**

8. The Associate Director evaluates and determines any additional reasons for noncompliance and makes certain that managers maintain a safe and clean environment.

Medical center concurred.

Target date for completion: November 30, 2020

Medical center response: The Chief of Environmental Management Services attests that reasons for noncompliance were considered when developing this action plan. In March 2020, The Chief of Environmental Management Service (EMS) implemented a detailed cleaning plan for the three Medical/Surgical Units (3BN, 4BN, 4BS). Focused cleaning of transitions, corners, edges, and walls occur weekly on these units and have been incorporated into the EMS floor cleaning plans. Strip and wax completed in March and April and autoscrub occurs daily. The planned work will be monitored through a tracker developed by EMS Leadership and monitored by Nursing and EMS leadership. The QA [Quality Assurance] employee was vacant but was posted and closed on August 11, 2020. A supplemental cleaning contractor changed from one vendor to another in May 2020. A license to utilize Salesforce as our QA monitoring software has been purchased. We will monitor for 6 months for 90% compliance.

### Medication Management: Long-Term Opioid Therapy for Pain

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

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.<sup>71</sup> Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.<sup>72</sup> 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.<sup>73</sup> 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.<sup>74</sup>

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

<sup>&</sup>lt;sup>67</sup> 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.)

<sup>&</sup>lt;sup>68</sup> 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.)

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

<sup>&</sup>lt;sup>70</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

<sup>&</sup>lt;sup>71</sup> 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.)

<sup>&</sup>lt;sup>72</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

<sup>&</sup>lt;sup>73</sup> VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, May 13, 2020.

<sup>&</sup>lt;sup>74</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

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

VHA also requires facilities to establish a multidisciplinary pain management committee "to provide oversight, coordination, and monitoring of pain management activities and processes." Monitoring measures include, but are not limited to, adherence to published clinical practice guidelines, timeliness of treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment, patient satisfaction, and quality of life.<sup>75</sup> 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 19 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 many of the indicators of expected performance, including pain screening, documented justification for concurrent therapy with benzodiazepines, and quality measure oversight. However, the OIG found deficiencies with aberrant behavior risk assessments, urine drug testing, informed consent, and patient follow-up.

VA/DoD clinical practice guidelines recommend completion of an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors<sup>76</sup> prior to initiating long-term opioid therapy.<sup>77</sup> The OIG determined that providers completed aberrant behavior risk assessments for 74 percent of the patients reviewed.<sup>78</sup>

<sup>&</sup>lt;sup>75</sup> VHA Directive 2009-053, Pain Management, October 28, 2009.

<sup>&</sup>lt;sup>76</sup> "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.

<sup>&</sup>lt;sup>77</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. For the purpose of this review, the OIG considers aberrant behavior risk assessments completed up to 30 days prior to initial dispensing as compliant.

<sup>&</sup>lt;sup>78</sup> Confidence intervals are not included because the data represents every patient in the study population.

Failure to complete behavior risk assessments may have allowed providers to prescribe opioids for patients at high risk for misuse. The Assistant Chief of Primary Care stated that a provider documented one patient's assessment at a previous visit, which was three months prior to the initial dispensing date, and assumed this met the requirement. The Chief also stated that another patient was initially prescribed an opioid for short-term use; long-term opioid therapy was not anticipated, and the required screening was inadvertently omitted.

VA/DoD clinical practice guidelines also recommend that providers conduct "UDT [urine drug testing] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter."<sup>79</sup> The OIG determined that providers conducted initial urine drug testing in 79 percent of the patients reviewed.<sup>80</sup> This resulted in providers' inability to identify whether the remaining patients had substance use disorders, determine potential diversion, or ensure adherence to the prescribed medication regimen. The Assistant Chief of Primary Care reported that providers determine the frequency for urine drug testing based on the overall patient assessment.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy.<sup>81</sup> VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.<sup>82</sup> The OIG determined that providers documented informed consent prior to initiating long-term opioid therapy in 74 percent of the patients reviewed.<sup>83</sup> The remaining patients, therefore, were potentially receiving treatment without documented knowledge of the associated risks, including opioid dependence, tolerance, addiction, and fatal overdose. The Chief of Primary Care explained that the controlled substance prescribing note used during the OIG review period did not include a prompt to complete the informed consent, which resulted in omissions.

VA/DoD clinical practice guidelines recommend providers follow up with patients within three months after initiating long-term opioid therapy.<sup>84</sup> The OIG determined that providers followed up within three months after initiating long-term opioid therapy for 84 percent of the patients reviewed.<sup>85</sup> For the remaining patients, failure to conduct follow-ups can result in missed opportunities to assess adherence to the therapy plan, effectiveness of treatment, or risks of continued opioid therapy. The Assistant Chief of Primary Care acknowledged the requirement and stated that performing monthly risk reviews, in combination with

<sup>&</sup>lt;sup>79</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

<sup>&</sup>lt;sup>80</sup> Confidence intervals are not included because the data represents every patient in the study population.

<sup>&</sup>lt;sup>81</sup> VHA Directive 1005.

<sup>&</sup>lt;sup>82</sup> VHA Directive 1005.

<sup>&</sup>lt;sup>83</sup> Confidence intervals are not included because the data represents every patient in the study population.

<sup>&</sup>lt;sup>84</sup> VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

<sup>&</sup>lt;sup>85</sup> Confidence intervals are not included because the data represents every patient in the study population.

patient feedback, are inherent in the opioid refill process and should suffice for frequent follow-up evaluations.

The OIG made no recommendations related to aberrant behavior risk assessments, urine drug testing, informed consent, or patient follow-up due to the low number of identified outpatients who had newly-dispensed long-term opioids for pain during the review period.

#### 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.<sup>86</sup> 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.<sup>87</sup> Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.<sup>88</sup>

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.<sup>89</sup>

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.<sup>90</sup> The OIG examined various requirements related to SPCs:

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

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

https://www.cdc.gov/violenceprevention/suicide/fastfact.html. (The website was accessed on March 4, 2020.)

<sup>&</sup>lt;sup>86</sup> Centers for Disease Control and Prevention. *Preventing Suicide*.

<sup>&</sup>lt;sup>87</sup> 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*.

<sup>&</sup>lt;sup>88</sup> 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*.

<sup>&</sup>lt;sup>89</sup> VA Office of Mental Health and Suicide Prevention Guidebook, June 2018.

<sup>&</sup>lt;sup>90</sup> 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 tollfree 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."<sup>91</sup> 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."<sup>92</sup> 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.<sup>93</sup> 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.<sup>94</sup>

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."<sup>95</sup> 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."<sup>96</sup> 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."<sup>97</sup>

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

 <sup>&</sup>lt;sup>91</sup> VHA DUSHOM Memorandum, Update to High Risk for Suicide Patient Record Flag Changes, January 16, 2020.
 <sup>92</sup> VHA Directive 2008-036, Use of Patient Record Flags to Identify Patients at High Risk for Suicide, July 18, 2008.

<sup>&</sup>lt;sup>93</sup> 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.

<sup>&</sup>lt;sup>94</sup> 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 faceto-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.* 

<sup>&</sup>lt;sup>95</sup> VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

<sup>&</sup>lt;sup>96</sup> VHA DUSHOM Memorandum, Update to High Risk for Suicide Patient Record Flag Changes, January 16, 2020.

<sup>&</sup>lt;sup>97</sup> VHA, Response to Questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

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." <sup>98</sup>

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

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

<sup>&</sup>lt;sup>98</sup> VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

<sup>&</sup>lt;sup>99</sup> 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.

<sup>&</sup>lt;sup>100</sup> VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

<sup>&</sup>lt;sup>101</sup> 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.

- Relevant documents;
- The electronic health records of 44 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, suicide safety plans, patient follow-up, and community outreach activities. However, the OIG noted concerns with annual refresher training.

VHA requires all employees to complete suicide risk and intervention training within 90 days of entering their position.<sup>102</sup> Additionally, VHA mandates that all employees receive annual refresher training.<sup>103</sup> The OIG found that 15 of 17 newly-hired employees completed training within the expected timeframe, and 17 of 20 employees who had been in their positions for more than a year had evidence of annual refresher training. Lack of training could prevent employees from providing optimal treatment to veterans who are at risk for suicide. The Suicide Prevention Coordinator and Associate Chief of Mental Health attributed the deficiency to reliance on the VA Talent Management System alerts to prompt staff to complete the required training, as well as lack of supervisory oversight.

#### **Recommendation 9**

9. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures employees complete suicide risk and intervention training within 90 days of entering their position and annual training thereafter.

<sup>&</sup>lt;sup>102</sup> VHA Directive 1071.

<sup>&</sup>lt;sup>103</sup> VHA Directive 1071.

Medical center concurs.

Target date for completion: November 30, 2020

Medical center response: The Chief of Mental Health attests that reasons for noncompliance were considered when developing this action plan. The Chief of Mental Health has determined that initial training for new employees will be monitored for completion within 90 days. It was determined annual training was not completed for 3 staff who were hired prior to the 2017 directive. The SPC will obtain a TMS [Talent Management System] report for all outstanding annual training and coordinate with Designated Learning Officer (DLO) to ensure annual TMS training is assigned to all deficient and upon hire for all employees. Initial and annual training will be monitored for 90% compliance for 6 consecutive months. Facility achieved the following: Annual Training, May 96%, June 97% and July 97%; Initial Clinician Training – received a TMS Moratorium due to COVID 19 from April 3- August 2 for May, June and July and Initial Non-Clinician Training- May 93%, June 97% and July 93%.

#### **Care Coordination: Life-Sustaining Treatment Decisions**

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. Life-sustaining treatments may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "…eliciting, documenting, and honoring patients' values, goals, and preferences."<sup>104</sup>

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.<sup>105</sup> 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.<sup>106</sup> 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.<sup>107</sup>

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

<sup>&</sup>lt;sup>104</sup> 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.

<sup>&</sup>lt;sup>105</sup> According to VHA Handbook 1004.03(1), the medical facility must fully implement handbook requirements within 18 months of publication.

<sup>&</sup>lt;sup>106</sup> 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.

<sup>&</sup>lt;sup>107</sup> 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 facility's Ethics Consultation Service.<sup>108</sup> 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 35 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

<sup>&</sup>lt;sup>108</sup> VHA Handbook 1004.03(1).

## **Care Coordination Findings and Recommendations**

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

#### Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.<sup>109</sup> 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.<sup>110</sup> To help the VA better understand the needs of the growing women veterans population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."<sup>111</sup> 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."<sup>112</sup>

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.<sup>113</sup> VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veterans health committee that "develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."<sup>114</sup>

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:

<sup>&</sup>lt;sup>109</sup> 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.)

<sup>&</sup>lt;sup>110</sup> 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.)

<sup>&</sup>lt;sup>111</sup> 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.)

<sup>&</sup>lt;sup>112</sup> 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.)

<sup>&</sup>lt;sup>113</sup> VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020.

<sup>&</sup>lt;sup>114</sup> VHA Directive 1330.01(3).

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

#### Women's Health Findings and Recommendations

The medical center complied with requirements for most of the provision of care indicators. However, the OIG identified weaknesses with CBOC-designated women's health primary care providers, the Women Veterans Health Committee, and a designated maternity care coordinator.

VHA requires that each CBOC has at least two designated women's health primary care providers (WH-PCPs).<sup>115</sup> The OIG found that one of six CBOCs had only one designated WH-PCP, which could limit the system's ability to provide comprehensive healthcare services to women veterans.<sup>116</sup> The Assistant Chief of Primary Care reported that the CBOC has providers with women's health training who can deliver care and thought that the staffing requirement was

<sup>&</sup>lt;sup>115</sup> VHA Directive 1330.01(3).

<sup>&</sup>lt;sup>116</sup> VHA Directive 1330.01(3).

met. The Chief of Primary Care did not provide any other reason for not designating two WH-PCPs.

#### **Recommendation 10**

10. 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.<sup>117</sup>

Medical center concurs.

Target date for completion: Completed

Medical center response: The medical center concurs with this finding. Three staff members completed the WH training. There is a Board-Certified Family Medicine Physician who is available to address WH issues in the Same Day Provider (SDP) Clinic. In January 2020, we designated a second Women's Health Provider at the Beaufort CBOC. September 24, 2020, we received an email response from Central Office indicating we met the intent of this policy.

We request closure for this recommendation based on the evidence provided.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership. That membership includes a women veterans program manager; a women's health medical director; "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership."<sup>118</sup>

The OIG reviewed the Women Veterans Health Committee and Clinical Executive Board meeting minutes from June 2019, through December 2019, and found that the committee did not report to executive leaders or have consistent representation by medical and/or surgical subspecialties, gynecology, ED, radiology, laboratory, quality management, business office/non-VA medical care, or executive leadership. This resulted in a lack of expert oversight as the committee planned and carried out improvements for quality and equitable women veterans care. The Women Veterans Program Manager reported being unaware of the requirement for core membership and was not invited to report or provide documentation to executive leaders.

 <sup>&</sup>lt;sup>117</sup> The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.
 <sup>118</sup> VHA Directive 1330.01(3).

#### **Recommendation 11**

11. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that the Women Veterans Health Committee reports to executive leaders and is comprised of required core members who consistently attend meetings.

Medical center concurred.

Target date for completion: December 1, 2020

Medical center response: The Chief of Staff attests that reasons for noncompliance were considered when developing this action plan. The Chief of Staff ensured the required members were reviewed and added. The assigned members will attend or send a surrogate. COS will schedule Women's Health as required to report to CEB. A CEB reporting schedule was developed for the Women's Veteran Health Committee to ensure quarterly reporting to executive leadership. The committee leadership will provide 6 months of attendance reports and evidence of 90% attendance of the appointed member or surrogate for 6 consecutive meetings and quarterly presentation at CEB.

VHA requires the medical center to have a designated maternity care coordinator.<sup>119</sup> The OIG found no evidence of a formal maternity care coordinator; however, the medical center provided documentation that staff monitored and coordinated the delivery of care, and tracked outcomes of services that had been furnished through maternity purchased care.<sup>120</sup> The absence of a maternity care coordinator poses a risk of fragmented care and the inability to report cumulative tracking data to executive leaders.<sup>121</sup> The Women Veterans Program Manager stated that several requests for a maternity care coordinator were not approved by the resource board.

#### **Recommendation 12**

12. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures the medical center has a designated maternity care coordinator.<sup>122</sup>

<sup>&</sup>lt;sup>119</sup> VHA Directive 1330.01(3).

<sup>&</sup>lt;sup>120</sup> Purchased care is provided by non-VA clinicians.

<sup>&</sup>lt;sup>121</sup> VHA Directive 1330.03, *Maternity Health Care and Coordination*, October 5, 2012.

<sup>&</sup>lt;sup>122</sup> The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

Medical center concurred.

Target date for completion: Completed

Medical center response: The Chief of Staff attests that reasons for noncompliance were considered when developing this action plan. The Chief of staff evaluated the Maternity Care Program and designated a Maternity Care Coordinator May 6, 2020.

We request closure for this recommendation based on the evidence provided.

#### High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have sterile processing services (SPS) "to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment..."<sup>123</sup> The goal of SPS is to "...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."<sup>124</sup> 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<sup>®</sup> Instrument Tracking System for tracking reprocessed instruments<sup>125</sup>
- Perform annual risk analysis and report results to the VISN SPS Management Board
- Monitor data for reprocessing and storing RME
- Conduct annual airflow/ventilation system inspections<sup>126</sup>

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.<sup>127</sup> The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.<sup>128</sup>

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,

<sup>&</sup>lt;sup>123</sup> VHA Directive 1116(2), Sterile Processing Services (SPS), March 23, 2016.

<sup>&</sup>lt;sup>124</sup> 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.)

 <sup>&</sup>lt;sup>125</sup> VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.
 <sup>126</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>127</sup> 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.

<sup>&</sup>lt;sup>128</sup> 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.<sup>129</sup>

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.<sup>130</sup>

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

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

<sup>&</sup>lt;sup>129</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>130</sup> VHA Directive 1116(2).

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

#### **High-Risk Processes Findings and Recommendations**

The medical center met many of the requirements for the proper operations and management of reprocessing RME. However, the OIG identified a deficiency with airflow testing.

Despite VHA's requirement for strict airflow control in SPS, the OIG found that the annual airflow testing for FY 2018 and 2019 in the gastroenterology suite was not conducted.<sup>131</sup> Failure to evaluate and maintain air-quality standards can lead to the spread of healthcare-associated infections.<sup>132</sup> The Chief of SPS was unaware that the contract vendor had not performed annual airflow testing.

#### **Recommendation 13**

13. The Associate Director for Nursing and Patient Care Services determines the reasons for noncompliance and ensures that annual airflow testing is conducted in all areas where reusable medical equipment is stored.<sup>133</sup>

<sup>&</sup>lt;sup>131</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>132</sup> Centers for Disease Control and Prevention, *Guidelines for Environmental Infection Control in Health-Care Facilities, July 2019.* https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf. (The website was accessed on August 15, 2019.)

<sup>&</sup>lt;sup>133</sup> The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

Medical center concurred.

Target date for completion: Completed

Medical center response: The Chief of Engineering attests that reasons for noncompliance were considered when developing this action plan. The Chief of Engineering discovered the previous contract was initiated prior to the Gastrointestinal Suite's move to its current location, causing the GI [Gastrointestinal] Suite to be inadvertently not tested for annual airflow testing. The contract was updated to include the GI Suite and both the preliminary and annual airflow testing was completed by the vendor March 2020. Airflow testing is now on an annual schedule for all SPS areas to include the GI Suite and results are communicated to SPS Leadership.

We request closure for this recommendation based on the evidence provided.

## 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	<ul> <li>Executive leadership position stability and engagement</li> <li>Employee satisfaction</li> <li>Patient experience</li> <li>Accreditation surveys and oversight inspections</li> <li>Factors related to possible lapses in care and medical center response</li> <li>VHA performance data (facility or system)</li> <li>VHA performance data for CLCs</li> </ul>	Thirteen OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, ADNPCS, and Associate Director. See details below.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement	
Quality, Safety, and Value	<ul> <li>QSV Committee</li> <li>Protected peer reviews</li> <li>UM reviews</li> <li>Patient safety</li> </ul>	• None	• Peer reviewers consistently use at least one of the nine aspects of care for evaluations.	

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	<ul> <li>FPPEs</li> <li>OPPEs</li> <li>Provider exit reviews and reporting to state licensing boards</li> </ul>	<ul> <li>Practitioners with similar training and privileges complete focused and ongoing professional practice evaluations.</li> <li>Service chiefs include the minimum nuclear medicine- specific criteria for ongoing professional practice evaluations of licensed independent practitioners.</li> <li>Reprivileging decisions are based on service-specific ongoing professional practice evaluation data.</li> </ul>	<ul> <li>Clinical Executive Board meeting minutes consistently reflect the review of professional practice evaluation results in the decision to recommend continuation of privileges.</li> <li>Provider exit review forms are completed within seven calendar days of licensed healthcare professionals' departure from the medical center.</li> </ul>

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Environment of Care	<ul> <li>Medical center         <ul> <li>General safety</li> <li>Special use spaces</li> <li>Environmental cleanliness and infection prevention</li> <li>Privacy</li> <li>Accommodation and privacy for women veterans</li> <li>Logistics</li> </ul> </li> <li>Inpatient mental health unit         <ul> <li>General safety</li> <li>Special use spaces</li> <li>Environmental cleanliness and infection prevention</li> <li>Privacy</li> <li>Accommodation for women veterans</li> <li>Logistics</li> </ul> </li> <li>Community-based outpatient clinic</li> <li>General safety</li> <li>Special use spaces</li> <li>Environmental cleanliness and infection prevention</li> <li>Privacy</li> </ul> <li>Accommodation for women veterans</li> <li>Logistics</li> <li>Community-based outpatient clinic</li> <li>General safety</li> <li>Special use spaces</li> <li>Environmental cleanliness and infection prevention</li> <li>Privacy</li> <li>Privacy for women veterans</li> <li>Logistics</li>	<ul> <li>Flooring in the inpatient behavioral health unit seclusion room is cushioned.</li> <li>Managers maintain a safe and clean environment.</li> </ul>	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	<ul> <li>Provision of pain management using long- term opioid therapy</li> <li>Program oversight and evaluation</li> </ul>	• None	• None
Mental Health: Suicide Prevention Program	<ul> <li>Designated facility suicide prevention coordinator</li> <li>Provision of suicide prevention care</li> <li>Completion of suicide prevention training requirements</li> </ul>	• None	• Employees complete suicide risk and intervention training within 90 days of hire and annual training thereafter.
Care Coordination: Life-Sustaining Treatment Decisions	<ul> <li>LSTD multidisciplinary committee</li> <li>Goals of care conversation documentation</li> <li>LSTD note/orders completed by an authorized provider or delegated</li> </ul>	• None	• None
Women's Health: Comprehensive Care	<ul> <li>Provision of care</li> <li>Program oversight and performance improvement data monitoring</li> <li>Staffing requirements</li> </ul>	CBOCs have at least two designated women's health primary care providers.	<ul> <li>The Women Veterans Health Committee reports to executive leaders and is comprised of required members who consistently attend meetings.</li> <li>The medical center has a designated maternity care coordinator.</li> </ul>
High-Risk Processes: Reusable Medical Equipment	<ul> <li>Administrative processes</li> <li>Quality assurance monitoring</li> <li>Physical inspection</li> <li>Staff training</li> </ul>	Annual airflow testing is conducted in all areas where reusable medical equipment is stored.	None

## **Appendix B: Medical Center Profile**

The table below provides general background information for this high complexity (1a) affiliated<sup>1</sup> medical center reporting to VISN 7.<sup>2</sup>

Brofile Element Escility Data Escility Data					
Profile Element	Facility Data FY 2017 <sup>3</sup>	Facility Data FY 2018⁴	Facility Data FY 2019⁵		
Total medical care budget	\$525,706,712	\$573,093,023	\$587,519,366		
Number of:					
Unique patients	74,533	77,781	79,896		
Outpatient visits	934,308	960,019	1,022,540		
Unique employees <sup>6</sup>	2,285	2,362	2,577		
Type and number of operating beds:					
Community living center	28	28	28		
Medicine	47	50	53		
Mental health	25	25	25		
Neurology	3	3	3		
Surgery	27	27	27		
Average daily census:					
Community living center	19	19	18		
Medicine	38	40	39		
Mental health	18	18	20		
Neurology	1	1	2		
Surgery	13	15	14		

#### Table B.1. Profile for Ralph H. Johnson VA Medical Center (534) (October 1, 2016, through September 30, 2019)

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.

<sup>&</sup>lt;sup>1</sup> Associated with a medical residency program.

<sup>&</sup>lt;sup>2</sup> 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."

<sup>&</sup>lt;sup>3</sup> October 1, 2016, through September 30, 2017.

<sup>&</sup>lt;sup>4</sup> October 1, 2017, through September 30, 2018.

<sup>&</sup>lt;sup>5</sup> October 1, 2018, through September 30, 2019.

<sup>&</sup>lt;sup>6</sup> Unique employees involved in direct medical care (cost center 8200).

## Appendix C: VA Outpatient Clinic Profiles<sup>1</sup>

The VA outpatient clinics in communities within the catchment area of the healthcare system provide primary care integrated with women's health, mental health, and telehealth services. Some also provide specialty care, diagnostic, and ancillary services. Table C.1. provides information relative to each of the clinics.

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services <sup>3</sup> Provided	Diagnostic Services⁴ Provided	Ancillary Services⁵ Provided
Savannah, GA	534BY	44,027	21,015	Cardiology	EKG	Nutrition
				Dermatology	Radiology	Pharmacy
				Endocrinology	Vascular lab	Prosthetics
				Eye		Social work
				Nephrology		Weight
				Podiatry		management
				Pulmonary/ Respiratory disease		

<sup>&</sup>lt;sup>1</sup> Includes all outpatient clinics in the community that were in operation as of August 27, 2019.

<sup>&</sup>lt;sup>2</sup> 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."

<sup>&</sup>lt;sup>3</sup> Specialty care services refer to non-primary care and non-mental health services provided by a physician.

<sup>&</sup>lt;sup>4</sup> Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

<sup>&</sup>lt;sup>5</sup> 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 <sup>3</sup> Provided	Diagnostic Services <sup>4</sup> Provided	Ancillary Services⁵ Provided
Myrtle Beach, SC	534GB	37,335	1,894	Cardiology Dermatology Endocrinology Nephrology	EKG Radiology	Nutrition Pharmacy Prosthetics Social work Weight management
Beaufort, SC	534GC	14,545	6,313	Cardiology Dermatology Endocrinology	Radiology	Nutrition Pharmacy Social work Weight management
Goose Creek, SC	534GD	26,925	10,263	Anesthesia Cardiology Dermatology Endocrinology Eye Orthopedics	Radiology	Nutrition Pharmacy Social work Weight management
Hinesville, GA	534GE	20,579	15,574	Dermatology Endocrinology Eye Podiatry	EKG Radiology	Nutrition Pharmacy Prosthetics Social work Weight management
North Charleston, SC	534GF	22,845	n/a	Dermatology Endocrinology	n/a	Nutrition Pharmacy Social work Weight management

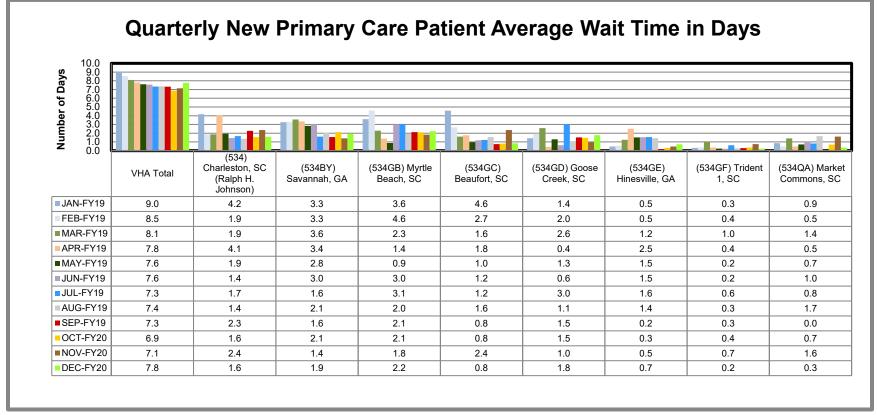
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services <sup>3</sup> Provided	Diagnostic Services⁴ Provided	Ancillary Services⁵ Provided
Myrtle Beach, SC	534QA	8,241	16,536	Dermatology Eye Podiatry	n/a	n/a
North Charleston, SC	534QB	n/a	8,663	Anesthesia	n/a	n/a
North Charleston, SC	534QC	n/a	174	n/a	n/a	n/a

Source: VHA Support Service Center and VA Corporate Data Warehouse

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

n/a = not applicable

## **Appendix D: Patient Aligned Care Team Compass Metrics**<sup>1</sup>

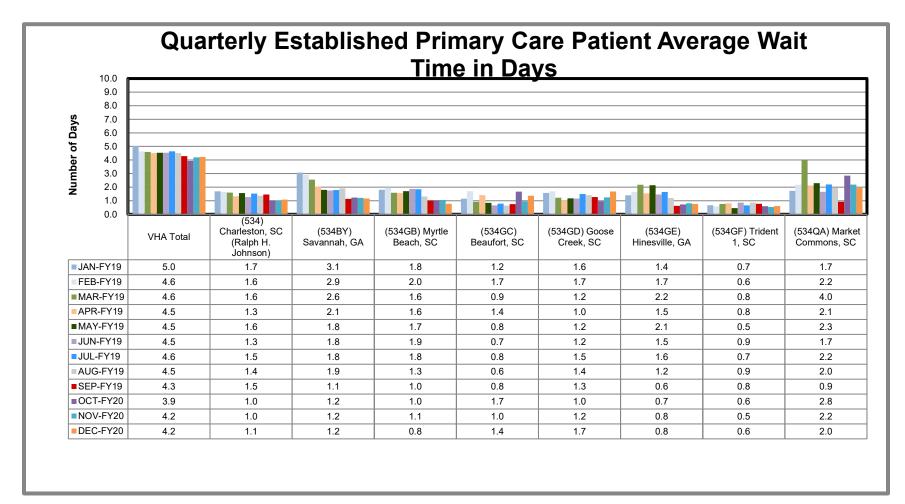


Source: VHA Support Service Center

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

Data Definition: "The average number of calendar days between 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.

<sup>&</sup>lt;sup>1</sup> 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.

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

## Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions<sup>1</sup>

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

<sup>&</sup>lt;sup>1</sup> VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL)* (last updated September 30, 2019). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

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

Source: VHA Support Service Center

# Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions<sup>1</sup>

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

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

Measure	Definition
Outpatient ED visit (SS)	Short-stay measure: percent of short-stay residents who have had an outpatient emergency department (ED) visit.
Physical restraints (LS)	Long-stay measure: percent of residents who were physically restrained.
Receive antipsych meds (LS)	Long-stay measure: percent of residents who received an antipsychotic medication.
Rehospitalized after NH Admission (SS)	Short-stay measure: percent of residents who were re-hospitalized after a nursing home admission.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

# **Appendix G: VISN Director Comments**

#### **Department of Veterans Affairs Memorandum**

- Date: October 7, 2020
- From: Interim Director, VA Southeast Network (VISN 7) (10N7)
- Subj: Draft Report: Comprehensive Healthcare Inspection of the Ralph H. Johnson VAMC, Charleston, SC.
- To: Director, Office of Healthcare Inspections (54CH02) 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 Ralph H. Johnson VAMC, Charleston, SC.
  - 2. VISN 7 submits concurrence to recommendations 1-13 and the attached Ralph H. Johnson 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 H: Medical Center Director Comments**

#### **Department of Veterans Affairs Memorandum**

- Date: October 6, 2020
- From: Director, Ralph H. Johnson VA Medical Center (534/00)
- Subj: Comprehensive Healthcare Inspection of the Ralph H. Johnson VA Medical Center in Charleston, South Carolina
- To: InterimDirector, VA Southeast Network (10N7)
  - 1. Thank you for the opportunity to review the draft of the Inspector General report from the Comprehensive Healthcare Inspection of the Ralph H. Johnson Veterans Medical Center.
  - 2. I reviewed findings 1-13 and concur with the recommendations and submitted action plans.

(Original signed by:)

Scott R. Isaacks, FACHE Medical Center Director

## **OIG Contact and Staff Acknowledgments**

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