

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Wm. Jennings Bryan Dorn VA Medical Center in Columbia, South Carolina

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Figure 1. Wm. Jennings Bryan Dorn VA Medical Center in Columbia, South Carolina

Source: https://vaww.va.gov/directory/guide/, (accessed

February 27, 2020)

Abbreviations

ADPC/NS Associate Director Patient Care/Nursing Service

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 treatment decisions

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 Wm. Jennings Bryan Dorn VA Medical Center and multiple outpatient clinics in 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 looks at leadership and organizational risks and at the time of the inspection, focused on the following clinical areas:

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

The unannounced visit was conducted during the week of March 2, 2020, at the Wm. Jennings Bryan Dorn VA Medical Center and Anderson 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 Director, Chief of Staff, Associate Director Patient Care/Nursing Service (ADPC/NS), Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure, with the Executive Leadership Council overseeing several working groups. The leaders monitor patient safety and care through the Quality Improvement Board, which is responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this inspection, the medical center leaders had worked together as a group for almost two years. The Director was permanently assigned in March 2017. The ADPC/NS, the most tenured member, was assigned in May 2006. The Chief of Staff and Associate Director had served in their positions since January 2014 and July 2017, respectively. The Assistant Director was appointed in March 2018.

The OIG reviewed employee satisfaction survey results and concluded that employees were generally satisfied, and leaders had maintained an environment where employees felt safe bringing forth issues and concerns. Of the selected Inpatient, Patient-Centered Medical Home, and Specialty Care Survey questions reviewed, results for the medical center were similar to or lower than the corresponding VHA averages. Patient experience survey data indicated opportunities for medical center leaders to improve patient satisfaction 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.¹

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.²

The executive leaders, except for the Chief of Staff, were knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly-

¹ 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."

² VHA Support Service Center, *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, https://vaww.vssc.med.va.gov/vsscenhancedproductmanagement/displaydocument.aspx?documentid=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

performing SAIL and Community Living Center SAIL quality and efficiency measures. In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences.

The OIG noted opportunities for improvement in six of eight clinical areas reviewed and issued 14 recommendations that are directed to the Director, Chief of Staff, ADPC/NS, and Associate Director. These are briefly described below.

Medical Staff Privileging

The OIG found compliance with requirements for focused professional practice evaluations but identified deficiencies with ongoing professional practice evaluations and provider exit reviews.³

Environment of Care

The inspection team observed general compliance with requirements reviewed for the medical center and the inpatient mental health unit. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified issues with environmental cleanliness and infection prevention, and privacy at the Anderson VA Clinic.

Medication Management

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

Mental Health

The OIG found compliance with the requirements for a suicide prevention coordinator, suicide prevention training for new nonclinical employees, and monthly outreach activities. However, areas for improvement included patient follow-up for no-show high-risk appointments and annual suicide prevention training.

³ The definitions of focused professional practice evaluation and ongoing professional practice evaluations can be found within Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility."

Women's Health

The medical center complied with many of the requirements for women's health, including most provision of care indicators and each of the selected staffing elements reviewed. The OIG noted concerns with gynecologic care coverage and the Women Veterans Health Committee.

High-Risk Processes

Generally, the medical center met proper operations and management of reprocessing reusable medical equipment. However, the OIG identified a deficiency with the storage of reusable medical equipment.

Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 14 recommendations for improvement to the Director, Chief of Staff, ADPC/NS, and Associate Director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this system. 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 not addressed, may eventually interfere with the delivery of quality health care.

Comments

The interim Veterans Integrated Service Network Director and Medical Center Director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans (see appendixes G and H, pages 73–74, and the responses within the body of the report for the full text of the directors' comments). The OIG has received evidence of compliance and considers recommendations 6, 11, and 12 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Purpose and Scope

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

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change. Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes. Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

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

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

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

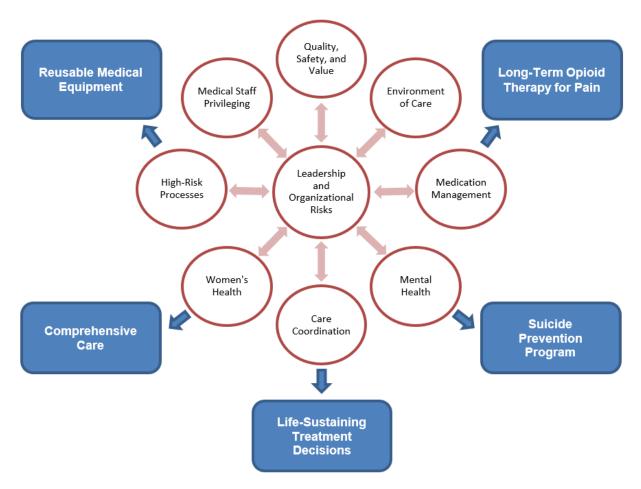


Figure 2. Fiscal year (FY) 2020 comprehensive healthcare inspection of operations and services Source: VA OIG

Methodology

The Wm. Jennings Bryan Dorn VA Medical Center includes an inpatient facility and multiple outpatient clinics in 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.⁴

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

- Acute mental health unit
- Community living centers (CLCs)⁵
- Emergency Department
- Medical and surgical inpatient units
- Medical and surgical intensive care units
- Outpatient clinic
- Post-anesthesia care unit
- Sterile processing services areas

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

The inspection examined operations from January 27, 2018, through March 6, 2020, the last day of the unannounced multiday site visit.⁶ While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, §7, 92 Stat 1105, as amended

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

⁵ 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.

⁶ The range represents the time period from the prior CHIP inspection to the completion of the unannounced, multiday CHIP site visit in March 2020.

(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 Director's responses to the report recommendations appear within each topic area. The OIG accepted the action plans that medical center leaders developed based on the reasons for noncompliance.

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

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA medical center. Leadership and organizational risks can affect the medical center's ability to provide care in the clinical focus areas.⁷ 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 (CLC)

Executive Leadership Position Stability and Engagement

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

⁷ 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.)

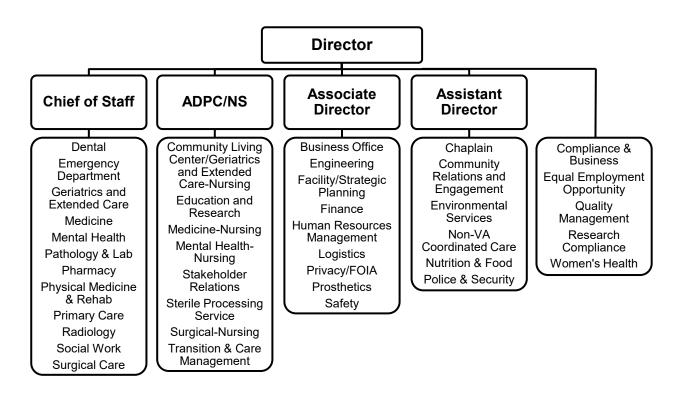


Figure 3. Medical center organizational chart

Source: Wm. Jennings Bryan Dorn VA Medical Center (received March 2, 2020)

FOIA = Freedom of Information Act

At the time of the OIG site visit, the executive team had been working together as a group for nearly two years, although the Director had served since 2017 and the other team members had been in their positions for multiple years (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Director	March 19, 2017
Chief of Staff	January 26, 2014
Associate Director Patient Care/Nursing Service	May 14, 2006
Associate Director	July 9, 2017
Assistant Director	March 18, 2018

Source: Wm. Jennings Bryan Dorn VA Medical Center Supervisory Human Resources Specialist (received March 2, 2020)

To help assess the medical center executive leaders' engagement, the OIG interviewed the Director, Chief of Staff, ADPC/NS, Associate Director, and Assistant Director regarding their

knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance.

The executive leaders, except for the Chief of Staff, were knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly-performing quality and efficiency measures. In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, and patient experiences. These are discussed in greater detail below.

The Director serves as the chairperson of the Executive Leadership Council, which has the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Executive Leadership Council oversees various working groups such as the Nurse Executive, Medical Executive, Quality Improvement, Resource Management, and Environment of Care Boards, as well as the Veteran Employee Experience Council.

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

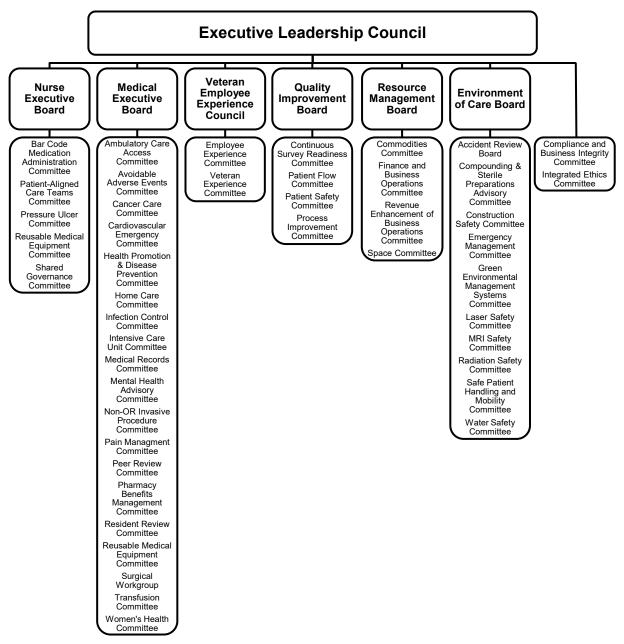


Figure 4. Medical center committee reporting structure Source: Wm. Jennings Bryan Dorn VA Medical Center (received March 2, 2020)

Employee Satisfaction

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

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of October 1, 2018, through September 30, 2019.⁸ 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 that medical center average scores for the selected survey leadership questions were similar to the VHA average.⁹ Scores for the executive leaders were consistently higher than those for VHA and the medical center.

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPC/NS Average	Assoc Director Average	Asst. Director Average
All Employee Survey: Servant Leader Index Composite ¹⁰	0–100 where higher scores are more favorable	72.6	72.0	90.3	86.5	91.0	85.5	90.0
All Employee Survey: In my organization, senior leaders generate high levels of motivation and commitment in the workforce.	1 (Strongly Disagree) – 5 (Strongly Agree)	3.4	3.3	4.4	3.7	4.5	4.3	4.3

⁸ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPC/NS, Associate Director, and Assistant Director.

⁹ 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.

¹⁰ 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	ADPC/NS 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	3.5	4.5	3.8	4.5	4.3	4.5
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	4.5	3.9	4.6	4.4	4.5

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

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. ¹¹ Note that the medical center averages for the selected survey questions were again similar to the VHA average and the scores related to the executive leaders were consistently better than those for VHA and the medical center. Leaders appeared to be maintaining an environment where employees felt safe bringing forth issues and concerns.

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

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPC/NS 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	3.7	4.7	4.1	4.8	4.5	4.2

¹¹ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPC/NS, Associate Director, and Assistant Director.

Questions/ Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPC/NS 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	3.7	4.4	4.6	4.9	4.0	4.2
All Employee Survey: In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?	0 (Never) – 6 (Every Day)	1.4	1.4	0.4	0.6	1.2	0.9	0.3

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

Patient Experience

To assess patient experiences with the medical center, which directly reflect on its leaders, the OIG 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 Experiences of Patients program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for VHA and the medical center. 12

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

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

table 4). For this medical center, patient survey results generally reflected lower ratings than the VHA average. Patients appeared less than satisfied with specific aspects of their experience at the medical center. Executive leaders acknowledged an increase in patients and reported that they had conducted townhall meetings with veterans to address issues, received funding to expand clinic space, and focused on hiring specialized staff.

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

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): Would you recommend this hospital to your friends and family?	The response average is the percent of "Definitely Yes" responses.	68.3	66.6
Survey of Healthcare Experiences of Patients (inpatient): I felt like a valued customer.	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.9	83.5
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	71.4
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	75.4

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

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

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that the results for the Inpatient and Patient-Centered Medical Home questions were generally similar to or lower than the corresponding VHA averages for both male and female respondents. In the outpatient specialty care setting, both male and female patients' experiences were generally less positive than all VHA patients nationally, indicating opportunities for improvement for medical center leaders.

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

Questions	Scoring	VHA ¹⁴		Medical Center ¹⁵		
		Male Average	Female Average	Male Average	Female Average	
During this hospital stay, how often did doctors treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	84.4	78.9	
During this hospital stay, how often did nurses treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	83.4	85.1	
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	67.0	59.6	

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

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

¹⁵ The medical center averages are based on 404–405 male and 19 female respondents, depending on the question.

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

Questions	Scoring	VHA ¹⁶		Medical Center ¹⁷		
		Male Average	Female Average	Male Average	Female Average	
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	49.2	34.5	
In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	55.2	46.1	
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	71.7	65.6	

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

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

 $^{^{17}}$ The medical center averages are based on 575–1,766 male and 50–108 female respondents, depending on the question.

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

Questions	Scoring	VHA ¹⁸		Medical Center ¹⁹		
		Male Average	Female Average	Male Average	Female Average	
In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	41.8	32.5	
In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	55.0	52.6	47.4	
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	67.5	66.2	

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

Accreditation Surveys and Oversight Inspections

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

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

¹⁹ The medical center averages are based on 657–2,177 male and 32–102 female respondents, depending on the question.

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

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

recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in January 2018.

At the time of the site visit, the OIG also noted the medical center's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²² Additional results included the Long Term Care Institute's inspection of the medical center's CLCs.²³

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Comprehensive Healthcare Inspection Program Review of the William Jennings Bryan Dorn VA Medical Center, Columbia, South Carolina, Report No. 18-00412-173, May 17, 2018)	January 2018	8	0
TJC Hospital Accreditation	January 2019	37	0
TJC Behavioral Health Care Accreditation		1	0
TJC Home Care Accreditation		8	0

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

²² 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.

²³ 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 OIG's review of the medical center's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors.

Table 9 lists the reported patient safety events from January 27, 2018 (the prior OIG comprehensive healthcare inspection), through March 2, 2020.²⁴

Table 9. Summary of Selected Organizational Risk Factors (January 27, 2018, through March 2, 2020)

Factor	Number of Occurrences	
Sentinel Events ²⁵	6	
Institutional Disclosures ²⁶	3	
Large-Scale Disclosures ²⁷	0	

Source: Wm. Jennings Bryan Dorn VA Medical Center's Quality Management Supervisor (received March 2, 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 limitations for identifying all areas of clinical risk. The data are presented as one way to

²⁴ It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the Wm Jennings Bryan Dorn VA Medical Center is a mid-high complexity (1c) affiliated system as described in appendix B.)

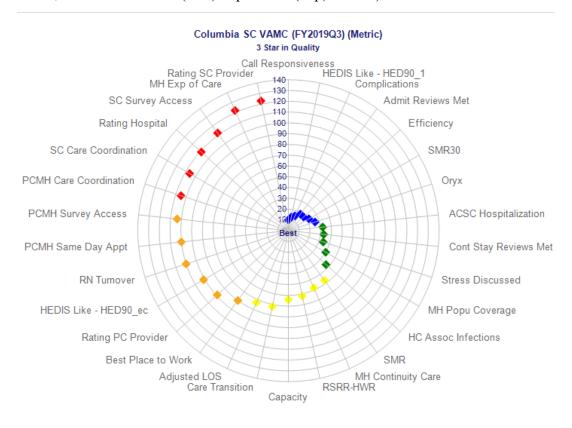
²⁵ The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

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

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

"understand the similarities and differences between the top and bottom performers" within VHA.²⁸

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, figure 5 uses blue and green data points to indicate high performance (for example, in the areas of call responsiveness, complications, stress discussed, and healthcare (HC) associated (assoc) infections). Metrics that need improvement are denoted in orange and red (for example, rating (of) primary care (PC) provider, registered nurse (RN) turnover, specialty care (SC) care coordination, and mental health (MH) experience (exp) of care).²⁹



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

Figure 5. Medical center quality of care and efficiency metric rankings (as of June 30, 2019) Source: VHA Support Service Center

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

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

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

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.³⁰

Figure 6 illustrates the medical center's CLC quality rankings and performance compared with other VA CLCs as of December 30, 2019. Figure 6 uses blue and green data points to indicate high performance (for example, in the areas of falls with major injury–long-stay (LS), moderate-severe pain–short-stay (SS), and urinary tract infections (UTI) (LS)). Metrics that need improvement are denoted in orange and red (for example, catheter in bladder (LS), help with activities of daily living (ADL) (LS), and high risk pressure ulcer (PU) (LS)). ³¹

³⁰ 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."

³¹ For data definitions of acronyms in the SAIL CLC measures, please see appendix F.

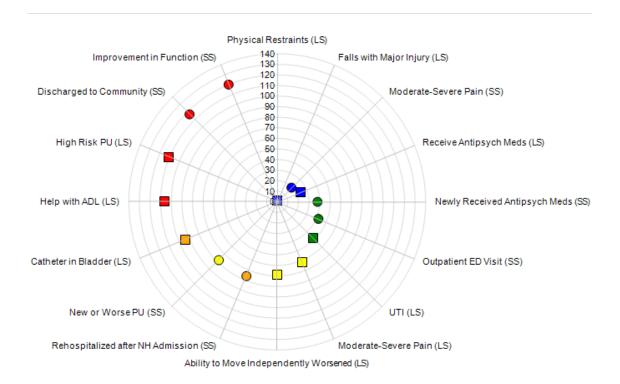


Figure 6. Medical center CLC quality measure rankings (as of September 30, 2019)

LS = Long-Stay Measure SS = Short-Stay Measure

Source: VHA Support Service Center

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

Leadership and Organizational Risks Conclusion

The medical center's executive leadership team had been working together as a team for nearly two years at the time of the OIG's on-site inspection. Specific survey results indicated that employees were generally satisfied and that leaders appeared to be maintaining an environment where employees feel safe bringing forth issues and concerns. Of the selected Inpatient, Patient-Centered Medical Home, and Specialty Care patient experience survey questions reviewed, the OIG noted that results were similar to or lower than the corresponding VHA averages. The OIG's review of the medical center's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. Medical center leaders interviewed—except for the Chief of Staff—were knowledgeable within their scope of responsibilities about employee/patient satisfaction survey results and VHA data and/or factors contributing to specific poorly-performing quality and efficiency measures, as well as actions taken to maintain or 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. ³² 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. ³³ 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. ³⁴

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.³⁵ 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.³⁶ The OIG team examined the completion of the following elements:

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

³³ VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs, May 9, 2017.

³⁴ Veterans Health Administration Blueprint for Excellence.

³⁵ 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."

³⁶ 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 unit³⁷
- 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.³⁸ 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.³⁹ 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. ⁴⁰ Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual

³⁸ According to VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019, UM reviews include evaluating the "appropriateness, medical need, and efficiency of health care services according to evidence-based criteria."

³⁷ VHA Directive 1190.

³⁹ VHA Directive 1117(2).

⁴⁰ The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

causes of harm to patients throughout the medical center.⁴¹ The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses⁴²
- 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.⁴³

Quality, Safety, and Value Findings and Recommendations

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

⁴¹ VHA Handbook 1050.01.

⁴² 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]."

⁴³ For CHIP inspections, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for 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).⁴⁴

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.⁴⁵

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

FPPEs

- o Establishment of criteria in advance
- o Use of minimum criteria for selected specialty LIPs⁴⁷
- o Clear documentation of the results and time frames
- o Evaluation by another provider with similar training and privileges

OPPEs

- o Application of criteria specific to the service or section
- Use of minimum criteria for selected specialty LIPs⁴⁸
- o Evaluation by another provider with similar training and privileges

⁴⁴ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

⁴⁵ VHA Handbook 1100.19.

⁴⁶ VHA Handbook 1100.19.

⁴⁷ VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁴⁸ 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.⁴⁹ Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process. This individual will be the subject matter expert (SME) for the facility...and ensure oversight of the exit review process, including receipt, review, and maintenance of the Provider Exit Review Forms." The OIG reviewers assessed whether the medical center's staff

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

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

- Eleven solo/few practitioners who underwent initial or reprivileging during the previous 12 months⁵¹
- 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 found compliance with the requirements for FPPEs but identified deficiencies with OPPE and provider exit review processes.

⁴⁹ VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards, December 22, 2005.

⁵⁰ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18*, *Reporting and Responding to State Licensing Boards*, February 5, 2018.

⁵¹ 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 the determination to continue current privileges is based, in part, on OPPE activities such as direct observation, clinical pertinence reviews, and clinical discussions.⁵² VHA also requires the Executive Committee of the Medical Staff to recommend continuing privileges based on OPPE results. Committee minutes must indicate the materials reviewed and the rationale for the conclusion. The committee's recommendation is then submitted to the Medical Center Director for approval.⁵³ For 22 of 28 LIPs who were reprivileged within the last 12 months, the OIG found that service chiefs' determination to continue current privileges was based in part on OPPE activities. For the remaining six LIPs—including one solo LIP (a thoracic surgeon)—the Executive Committee of the Medical Staff, locally referred to as the Medical Executive Board, recommended continuation of privileges but could not provide evidence that the decisions were made based on OPPE results; in fact, of these six practitioners' OPPEs, two were incomplete, two had missing forms, and two lacked supporting data. This resulted in inadequate data to support decisions to continue clinical privileges. The Chief of Quality Management stated that surgery, dental, medicine, and primary care service chiefs believed current practices met requirements and reported that changes in leadership led to misplaced or unretained documents.

Recommendation 1

 The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that service chiefs' reprivileging recommendations are based on ongoing professional practice evaluation activities and licensed independent practitioner files contain properly completed evaluation forms with supporting data.

⁵² VHA Handbook 1100.19.

⁵³ VHA Handbook 1100.19.

Target date for completion: February 28, 2021

Medical center response: The Chief of Staff determined the reason for noncompliance and considered this when developing the action plan. The Chief of Staff educated service chiefs to ensure they are aware that they must maintain service level files for credentialed providers and these files must contain complete files with all forms and the clinical reviews with supporting data. Services have developed an internal tracking mechanism for all Ongoing Professional Practice Evaluations (OPPE) to include completed clinical reviews with supporting data. Physical copies are placed in the providers' credentialing file and maintained by the service Administrative Officer. The Medical Staff Office Supervisor in coordination with the service Administrative Officer will review service chiefs' documentation and supporting clinical review form to ensure compliance prior to submission to the Medical Executive Board (MEB) for Credentialing and Privileging (C&P).

Numerator = number of complete OPPE packages submitted by service chief to include all areas complete, signatures and supporting clinical review data.

Denominator = number of OPPEs submitted to the MEB for C&P each month

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

Recommendation 2

 The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that the Medical Executive Board's decision to recommend continuation of privileges is based on complete ongoing professional practice evaluation results.

Target date for completion: February 28, 2021

Medical center response: The Chief of Staff determined the reason for noncompliance and considered this when developing the action plan. The Chief of Staff educated service chiefs to ensure they are aware that they must maintain service level files for credentialed providers and these files must contain complete files with all forms and the clinical reviews with supporting data. Services have developed an internal tracking mechanism for all Ongoing Professional Practice Evaluations (OPPE) to include completed clinical reviews with supporting data. Physical copies are placed in the providers' credentialing file and maintained by the service Administrative Officer. The Medical Staff Office Supervisor in coordination with the service Administrative Officer will review service chiefs' documentation and supporting clinical review form to ensure compliance prior to submission to the Medical Executive Board (MEB) for Credentialing and Privileging (C&P).

Numerator = number of complete OPPE packages submitted by service chief to include all areas complete, signatures and supporting clinical review data.

Denominator = number of OPPEs submitted to the MEB for C&P each month

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

VHA also 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." For the 20 providers who departed the medical center in the previous 12 months, the OIG found that 12 exit forms were completed within seven calendar days. Of the eight exit forms that did not meet the VHA requirement, the OIG found that three were completed prior to the last day that the LIP provided care to patients. A delay in completing exit forms or completing the forms in advance of the LIP's departure could result in untimely or missed reporting of healthcare professionals' potentially substandard care to SLBs. The Chief of Quality Management stated that medicine, primary care, and surgery service chiefs provided several reasons for noncompliance, including the failure of prior service chiefs to complete forms in a timely manner, inability to contact LIPs to complete the forms, lack of awareness of official LIP resignation dates, and competing priorities.

⁵⁴ VHA Notice 2018-05.

Recommendation 3

3. The Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven calendar days of licensed health care professionals' departure from the medical center.

Medical center concurred.

Target date for completion: December 31, 2020

Medical center response: The Chief of Staff determined the reason for noncompliance and considered this when developing the action plan. Quality Management initiated an electronic Exit Review form. The Medical Staff Office will utilize the gains and losses report against the exit review forms received as an ongoing tracking system to enhance compliance. The Medical Staff Office Supervisor will audit Exit Review forms completion within 7 days.

Numerator = number of exit review forms returned within 7 days.

Denominator = number of exit review forms required

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

Environment of Care

Any facility, 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.⁵⁵

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

⁵⁵ VHA Directive 1608, Comprehensive Environment of Care (CEOC) Program, February 1, 2016.

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

During its review of the environment of care, the OIG team inspected the Anderson VA Clinic and the following 10 patient care areas at the medical center:

- Acute mental health unit
- CLCs (1 and 2)
- Emergency Department
- Medical and surgical inpatient units
- Medical and surgical intensive care units
- Outpatient clinic
- Post-anesthesia care unit

The OIG reviewed relevant documents and interviewed key employees and managers.

Environment of Care Findings and Recommendations

The inspection team observed general compliance with requirements reviewed for the medical center and the inpatient mental health unit and did not note any issues with the availability of medical equipment and supplies. However, the OIG identified vulnerabilities with environmental cleanliness and infection prevention, and privacy.

TJC requires that facilities minimize "the risk of infection when storing and disposing of infectious waste" and drug administration errors when storing and removing "expired, damaged, and/or contaminated medications." The OIG found a contaminated disposable scalpel and an open, partially-used vial of gentian violet in an empty podiatry procedure room at the Anderson VA Clinic. Failure to properly dispose of instruments and medications presents a risk of exposure to infectious materials and potential administration of contaminated medications.

⁵⁶ TJC Infection Prevention and Control standard IC.02.01.01.

⁵⁷ TJC Medication Management standard MM.03.01.01; EP8.

⁵⁸ Gentian violet is an antiseptic dye that has antifungal and antibacterial activity. Alexander M. Maley and Jack L. Arbiser, "Gentian Violet: A 19th Century Drug Re-Emerges in the 21st Century," *Exp Dermatol*. 12 (December 22, 2013): 775–780.

The clinic Administrative Officer was aware of the requirement and cited lack of provider oversight as the reason for noncompliance.

Recommendation 4

4. The Associate Director evaluates and determines any additional reasons for noncompliance and makes certain that staff dispose of contaminated instruments and used medications appropriately.

Medical center concurred.

Target date for completion: March 31, 2021

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

The identified item was removed and properly disposed of by the Podiatry RN. The medical solution was also secured as it is a multi-use medication. The Podiatry provider, leadership, and staff reviewed the issue with their team to prevent the potential of future occurrences.

The team developed and implemented the following new process March 9, 2020: Podiatry staff ensure that all items are disposed of or secured at the completion of each patient visit before the patient is released. The process has been hard wired into daily operations and eliminates the opportunity for recurrence of this finding.

The Surgery Clinic Nurse Manager will conduct 100 percent audits after every case to monitor compliance.

Numerator = number of podiatry cases where no instruments or medications were found improperly disposed or left out after a procedure.

Denominator = number of podiatry procedures monitored

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

VHA requires environmental control and inventory management procedures to minimize the risk of cross-contamination when storing patient care supplies. Clean or sterile packaged items must not be stored in shipping cartons or corrugated boxes and must be removed from these containers before being brought into clean or sterile storage. Shipping cartons may harbor microorganisms and are considered contaminated. The OIG found full and empty corrugated cardboard boxes in several areas—audiology, biohazard room, and durable medical equipment storage room—at the

⁵⁹ VHA Directive 1761(2), Supply Chain Inventory Management, October 24, 2016, amended October 26, 2018.

⁶⁰ VHA Directive 1116(2), Sterile Processing Services, March 23, 2016.

Anderson VA Clinic. This caused an increased risk of cross-contamination of supplies. The clinic Administrative Officer was aware of the requirement and cited a lack of oversight as the reason for noncompliance.

Recommendation 5

5. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures managers remove patient care supplies from shipping cartons and all corrugated boxes prior to putting items in clean storage areas.

Medical center concurred.

Target date for completion: March 31, 2021

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

The corrugated cardboard items identified were addressed at the time of the site visit. The durable medical equipment storage area was reorganized to further meet storage requirements. The equipment items (wheelchairs, patient scooter, and recumbent bike) were removed from the storage area.

Beginning in March, janitor staff monitor for corrugated cardboard daily and remove empty containers. In April 2020, the Upstate Logistics Team implemented weekly monitoring for distribution and removal of corrugated cardboard items. Long range monitoring was established via biannual environment of care rounds.

Numerator = number of weekly rounds resulting in no deficiencies identified.

Denominator = number of weekly rounds.

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

TJC requires protection of patient information "against unauthorized access, use, and disclosure of health information." The OIG found that Anderson VA Clinic staff did not secure bags containing patient information when transporting laboratory specimens to the parent facility. This may have resulted in unauthorized access to protected health information. The clinic Administrative Officer was aware of the requirement but stated a belief that using a contracted courier service met general privacy requirements.

⁶¹ The Joint Commission IM 02.01.03, EP 5.

Recommendation 6

6. The Associate Director evaluates and determines any additional reasons for noncompliance and ensures that staff secure protected health information when transporting laboratory specimens from the clinic to the medical center.⁶²

Medical center concurred.

Target date for completion: Completed

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

The contracted courier service was immediately made aware of the preliminary finding as well as our Privacy Officer. The vendor reviewed their equipment and ordered new biohazard transport bags on March 6, 2020. Attached are the purchase orders and photos of the new bags as supporting evidence.

The change in process was implemented in April 1, 2020.

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

⁶² 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.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁶³ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁶⁴ 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.⁶⁵ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁶⁶

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

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

- Completion of initial screening for pain
- Assessment of aberrant behavior risk

⁶³ 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.)

⁶⁴ 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.)

⁶⁵ 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.)

⁶⁶ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁶⁷ 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.)

⁶⁸ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁶⁹ VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, May 13, 2020.

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

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

Medication Management Findings and Recommendations

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

Despite VA/DoD clinical practice guidelines stating that "clinicians should obtain UDT [urine drug testing] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter," medical center leaders indicated that providers followed local medical center memorandum requirements to obtain UDTs twice a year to assess compliance with therapy. 73

⁷¹ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

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

⁷³ Columbia Health Care System Medical Center Memorandum 544-11-50, *Long-Term Opioid Therapy For Non-Cancer Pain Policy*, November 15, 2018.

The OIG did not make a recommendation but is concerned that the local medical center memorandum does not require UDTs prior to initiation and could mislead providers to only obtain UDTs periodically. This may result in providers' inability to identify whether patients had substance use disorders prior to initiating long-term opioid therapy.

VA/DoD clinical practice guidelines recommend that providers complete an aberrant behavior risk assessment that includes a history of substance abuse, mental health problems or disorders, and aberrant drug-related behaviors prior to initiating long-term opioid therapy. The OIG estimated that clinical staff completed an aberrant behavior risk assessment for 45 percent of the patients reviewed. This may have resulted in providers prescribing opioids for patients at high risk for misuse. Medical center pain management leaders reportedly believed that when any clinician completed a behavior risk assessment, the intent of the requirement was met.

Recommendation 7

7. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers complete an aberrant behavior risk assessment that includes a history of substance abuse, mental health problems or disorders, and aberrant drug-related behaviors on all patients prior to initiating long-term opioid therapy.

⁷⁴ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Examples of aberrant drug related behaviors include "lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents." Pain Management, Opioid Safety, VA Educational Guide (2014), July 2014. https://www.va.gov/PAINMANAGEMENT/docs/OSI_1_Tookit_Provider_AD_Educational_Guide_7_17.pdf. (The website was accessed on September 17, 2019.)

⁷⁵ The OIG estimated that 95 percent of the time, the true compliance rate is between 30.4 and 58.7 percent, which is statistically significantly below the 90 percent benchmark.

⁷⁶ Medical center pain management leaders include the Chief of Pharmacy, Associate Chief of Clinical Pharmacy, Quality Management Pharmacy and Controlled Substance Coordinator, Clinical Pharmacy Specialist Outpatient Supervisor, Pharmacy Benefits Management Committee Chair, Pain Committee Chair, and Chief of Primary Care.

Target date for completion: May 30, 2021

Medical center response: This recommendation is based on the VA's pain Management, Opioid Safety Education Guide which is not enforceable by law/VA policy/Licensure requirements. The Columbia VA HCS [Health Care System] conducted a secondary review post survey and found an increased percentage of compliance. The medical center agreed there are areas of opportunity to increase compliance to the OIG CHIP adherence standard.

We have incorporated the Prescription Drug Monitoring Program checks into the Controlled Substance note that was implemented in September 2019 as another means of monitoring aberrant behaviors, but this note was implemented after the review period covered by this OIG CHIP Survey. Beginning in October, Primary Care will monitor for aberrant behavior risk assessments monthly. Numerator = number of monthly aberrant behavior risk assessments resulting in no deficiencies identified. Denominator = number of Veterans prescribed opioids. Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

VHA requires providers to obtain and document informed consent prior to the initiation of long-term opioid therapy. WHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies. The OIG estimated that providers documented informed consent prior to initiating long-term opioid therapy in 44 percent of the patients reviewed. The remaining 56 percent of patients, therefore, may have received treatment without knowledge of the risks associated with long-term opioid therapy, including dependence, tolerance, addiction, and fatal overdose. Medical center pain management leaders stated that providers overlooked the need to obtain informed consent.

Recommendation 8

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

⁷⁷ VHA Directive 1005.

⁷⁸ VHA Directive 1005.

⁷⁹ The OIG estimated that 95 percent of the time, the true compliance rate is between 29.8 and 58.0 percent, which is statistically significantly below the 90 percent benchmark.

⁸⁰ Medical center pain management leaders included the Chief of Pharmacy, Associate Chief of Clinical Pharmacy, Quality Management Pharmacy and Controlled Substance Coordinator, Clinical Pharmacy Specialist Outpatient Supervisor, Pharmacy Benefits Management Committee Chair, Pain Committee Chair, and Chief of Primary Care.

Target date for completion: March 31, 2021

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

Provider education with each new provider orientation and all staff primary care meeting September 1, 2020. Providers will be educated on consent. Primary Care Data Analyst will pull prescription data by provider for primary care to share with clinic leadership beginning September 11, 2020. Primary Care leadership and CBOC physician leads will distribute reports, request providers to discuss in huddles, and ensure patients are contacted for consent. Data will be pulled every month for new start long term opioid after report distribution to evaluate compliance of >90% compliance for six consecutive months.

*COVID pandemic may interfere with timeliness as patients must sign consent in person.

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

VA/DoD clinical practice guidelines also recommend providers follow up with patients within three months after initiating long-term opioid therapy and assess patients' adherence to their pain management plan of care and the effectiveness of interventions. The OIG estimated that providers followed up within the required time frame for 64 percent of the patients reviewed. For the remaining patients, failure to conduct the required assessments could have resulted in missed opportunities to determine the benefits of continued opioid therapy. Medical center pain management leaders reportedly believed that subsequent assessments were performed as required. 83

Recommendation 9

9. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers conduct follow-up assessments that include adherence to the plan of care and effectiveness of interventions within three months of initiating long-term opioid therapy.

⁸¹ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁸² The OIG estimated that 95 percent of the time, the true compliance rate is between 50.0 and 77.6 percent, which is statistically significantly below the 90 percent benchmark.

⁸³ Medical center pain management leaders consisted of the Chief of Pharmacy, Associated Chief of Clinical Pharmacy, Quality Management Pharmacy and Controlled Substance Coordinator, Clinical Pharmacy Specialist Outpatient Supervisor, Pharmacy Benefits Management Committee Chair, Pain Committee Chair, and Chief of Primary Care.

Target date for completion: May 30, 2021

Medical center response: The Columbia VA HCS conducted a secondary review post survey and found an increased percentage of compliance. The medical center agreed there are areas of opportunity to increase compliance to the OIG CHIP adherence standard.

Data will be pulled every month for Veterans due for 3-month follow up to evaluate compliance of >90% for six consecutive months.

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

Mental Health: Suicide Prevention Program

In 2017, suicide was the 10th leading cause of death, with approximately 47,000 lives lost across the United States. ⁸⁴ The suicide rate was 1.5 times greater for veterans than for non-veteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States. ⁸⁵ Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans. ⁸⁶

VHA has identified suicide prevention as a top priority and implemented various evidence-based approaches to reduce the veteran suicide rate. In addition to expanded mental health services and community outreach, VHA has developed comprehensive screening and assessment processes to identify at-risk patients.⁸⁷

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

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

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

⁸⁴ Centers for Disease Control and Prevention. *Preventing Suicide*. https://www.cdc.gov/violenceprevention/suicide/fastfact.html. (The website was accessed on March 4, 2020.)

⁸⁵ Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016*, September 2018; Department of Veterans Affairs, *National Strategy for Preventing Veteran Suicide 2018-2028*.

⁸⁶ 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*.

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

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

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

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

- The "SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list."
- "The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted."
- The SPC's determination process "may be beyond 24 hours after a referral, due to case consultation and review." 95

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

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

⁹⁰ VHA Directive 2008-036, Use of Patient Record Flags to Identify Patients at High Risk for Suicide, July 18, 2008.

⁹¹ VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide, January 5, 2018; VHA DUSHOM Memorandum, High Risk for Suicide Patient Record Flag Changes, October 3, 2017.

⁹² A safety plan is a written list of coping strategies and support sources for use during or preceding suicidal crises. Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide.

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

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

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

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

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

Inspectors examined the completion of several requirements:

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

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training. ⁹⁷ VHA also requires that all staff receive annual refresher training. ⁹⁸ In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees. ⁹⁹

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

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

⁹⁷ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym "S.A.V.E" summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for 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.

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

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

Mental Health Findings and Recommendations

The medical center complied with many of the requirements reviewed, including designation of an SPC, suicide prevention training for new nonclinical employees, and community outreach.

The OIG noted concerns with reviewing HRS PRFs within the mandated time frame. VHA required that all patients with an HRS PRF be reevaluated at least every 90 days and justification for continuing or discontinuing the flag is documented. The OIG estimated that 61 percent of patients with an HRS PRF were reevaluated at least every 90 days. Based on the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that five patients were not reviewed within the expected time frame (observed range was 66–184 days). 102

The OIG also noted concerns with patient follow-up for no-show high-risk appointments and annual suicide prevention training.

For patients with an HRS PRF who miss or fail to attend mental health or substance abuse appointments, VHA requires that a mental health provider contact, or attempt to contact, the patient. Further, when attempted contact is unsuccessful, "the suicide prevention coordinator will collaborate with the treatment provider(s) to determine the next appropriate step utilizing clinical judgment and the pre-developed Safety Plan." Although the OIG found documented contact attempts for eight of the nine patients who missed or failed to attend a mental health appointment after PRF placement, six patient contacts were unsuccessful and required the provider to collaborate with the SPC. The OIG did not find evidence of provider and SPC collaboration for all six patients. Failure to follow up with a patient who is at high risk for suicide could result in missed opportunities to identify potential life-saving interventions. The SPC stated the requirements were met because in most cases, the provider noted that the patient was either assessed as "safe" earlier the same day or there was recent documentation that the patient was

¹⁰⁰ VHA Directive 2008-036; VHA Directive 2010-053, Patient Record Flags, December 3, 2010.

¹⁰¹ The OIG estimated that 95 percent of the time, the true compliance rate is between 46.7 and 75.0 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰² VHA Notice 2020-13.

 $^{^{103}}$ VHA DUSHOM Memorandum, *Guidance on Patients Failure to Attend Appointments (No Shows)*, August 6, 2013.

improving and in no distress. The SPC also stated that providers typically contact the SPC team via phone or instant message, so consultation with the SPC was not always documented in the record.

Recommendation 10

10. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that mental health providers collaborate with the Suicide Prevention Coordinator after unsuccessful contact attempts with patients flagged as high risk for suicide who miss mental health appointments and properly document those efforts.

Medical center concurred.

Target date for completion: November 30, 2020

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

The Suicide Prevention Coordinator (SPC) Team worked with the Clinical Application Coordinators (CACs). Effective February 3, 2020, the SPC Team receive view alerts whenever a Suicide Risk Evaluation – Comprehensive (CSRE) is completed and the "Alert Suicide Prevention for consideration of High-Risk Flag" indicator is checked. Suicide Prevention Team members rotate on a schedule to ensure alerts are reviewed on a daily basis. If a Veteran is being hospitalized, SPC Team notes deferment of HRF to consultation with inpatient providers. In any case, SPC Team policy is now to document review of HRF consideration within 1 business day. Additionally, SPC Team is working with CACs to develop an HRF e-consult for providers to use when requesting HRF consideration rather than relying on CSRE or being designated as an additional signer.

Additionally, SPC Team now consults weekly on HRF Veterans for which no guidance from Treatment Team has been provided and will make a decision based on chart review. This is usually unnecessary due to SPC Team's weekly HRF consultation with each OPMH [Outpatient Mental Health] Treatment team. This data is monitored at a National level by the Office of Mental Health Suicide Prevention (OMHSP) through Strategic Analytics for Improvement and Learning (SAIL) Continuity of Care Metric HRF5: percent of Veterans with a new assignment, reactivated, or continued HRF who received cased review within 100 days after flag initiation. The facility has excelled in this area for FY20 exceeding National scores. The data definitions are from SAIL.

Starting on March 25, 2020 the Suicide Prevention Coordinators educate all new providers during orientation that all high-risk Veterans who no-show for their appointments must initiate a consultation with the SPC. The SPC will collaborate with providers on care plan decisions and

determine if a welfare check is warranted. Additionally, the SPC has worked with Informatic Technology to implement a high-risk no-show dashboard that is consulted daily.

Numerator = Inclusion in the numerator of this measure requires that a HRF has been reviewed, based on note titles, within 100 days of the HRF initiation or continuation. The note titles were defined based on field review of note titles used locally and were assigned by each facility locally

Denominator = Veterans who are assigned a new assignment or reactivated high risk flag (HRF) for suicide (all constituent measures), and Veterans whose HRF was continued (for constituent measure HRF5 only)

FY20Q2: 349/352 = 99.15% FY20Q3: 348/350 = 99.43%

FY20Q2 data includes 2 months preceding the VA OIG CHIP review and the OMHSP SAIL data is only available on a quarterly basis. While the facility has demonstrated significant improvement and sustained compliance, we will monitor for an additional quarter to demonstrate 6 months of sustained compliance.

Compliance data will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

VHA requires that all employees complete suicide risk and intervention training within 90 days of entering their position. VHA mandates that all staff, clinical and nonclinical, receive annual refresher training thereafter. ¹⁰⁴ The OIG found that only 5 of 14 staff completed annual refresher training at or within one year of initial training. Lack of training could prevent staff from providing optimal care to veterans who are at risk for suicide. The SPC attributed the noncompliance to reliance on Talent Management System alerts to prompt staff to complete the required training and lack of monitoring by service lines.

Recommendation 11

11. The Director evaluates and determines any additional reasons for noncompliance and ensures all staff complete annual suicide prevention refresher training. 105

¹⁰⁴ VHA Directive 1071.

¹⁰⁵ 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.

Target date for completion: Completed

Medical center response: The medical center educated supervisory staff during morning report on the importance of compliance with TMS [Talent Management System] mandatory training and incorporated a weekly monitor for compliance. Specific for Suicide Prevention, beginning March 2, 2020, the TMS Coordinator tracked all Suicide Prevention Training across the Health Care System via TMS course completion. At the end of the month, a compliance report is sent to the Suicide Prevention Coordinator. The monthly report includes a detail listing (by name) of all staff currently not compliant with the required training. Monitoring for March-September 2020 is included to demonstrate sustained compliance.

Numerator = number of staff who have completed the training

Denominator = number of staff required to complete the training

3/2020: 3334/3475 = 95.9%

4/2020: 3369/3464 = 97.2%

5/2020: 3205/3246 = 98.7%

6/2020: 3122/3150 = 99.1%

7/2020: 3101/3128 = 99.1%

8/2020: No data due to an upgrade to TMS

9/2020: 3098/3153 = 98.2%

Supporting documents include the monthly deficient report and the TMS monthly compliance report. While we do not have data specifically for the month of August, the reports for July and September demonstrate sufficient compliance to infer that August compliance is comparable and above the 90% threshold. The TMS upgrade that occurred in August took reports offline for 2-3 weeks.

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

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "eliciting, documenting, and honoring patients' values, goals, and preferences." ¹⁰⁶

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018. ¹⁰⁷ 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. ¹⁰⁸ 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. ¹⁰⁹

The OIG noted that from July 12, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA policy defined the elements of a goals of care conversation to be documented in an LST progress note in the electronic health record, which included

- Decision-making capacity,
- Identification of a surrogate if the patient loses decision-making capacity,
- Patient or surrogate understanding of the patient's condition,
- Goals of care,
- Plan of care for the use of LST, including whether cardiopulmonary resuscitation will be attempted in the event of cardiac arrest, and
- Informed consent for the LST plan.

¹⁰⁶ 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.

¹⁰⁷ According to VHA Handbook 1004.03(1), the medical facility must fully implement handbook requirements within 18 months of publication.

 $^{^{108}}$ 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.

¹⁰⁹ 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."

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. 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 45 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

The medical center generally complied with requirements for goals of care conversations, including LSTD notes that were entered, documented timely, and completed by an authorized

¹¹⁰ VHA Handbook 1004.03(1).

provider. Requirements for the LSTD committee and supervision of designees were also found to be generally compliant.

Additionally, with VHA's original requirements that were in place when these patients received care, ¹¹¹ the OIG estimated that providers documented all required elements for 60 percent of the electronic health records reviewed. ¹¹² Specifically, 68 percent of patients' LST progress notes addressed previous advance directive(s), state-authorized portable orders, and/or LST notes. ¹¹³ However, VHA no longer requires this element to be documented in the LST progress note. ¹¹⁴ The OIG remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements. The OIG made no recommendations.

¹¹¹ VHA Handbook 1004.03(1).

¹¹² The OIG estimated that 95 percent of the time, the true compliance rate is between 44.7 and 75.6 percent, which is statistically significantly below the 90 percent benchmark.

¹¹³ The OIG estimated that 95 percent of the time, the true compliance rate is between 52.6 and 81.6 percent, which is statistically significantly below the 90 percent benchmark.

¹¹⁴ VHA Handbook 1004.03(1).

Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹¹⁵ According to data released by the National Center for Veterans Analysis and Statistics in May 2019, the total veteran population and proportion of male veterans are projected to decrease while the proportion of female veterans are anticipated to increase.¹¹⁶ To help the VA better understand the needs of the growing women's veteran population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."¹¹⁷ Additionally, a VA report in 2016 on suicide among veterans pointed out concerning trends in suicide among women veterans and discussed "the importance of understanding suicide risk among women veterans and developing gender-tailored suicide prevention strategies."¹¹⁸

VHA requires that all eligible and enrolled women veterans have access to timely, high-quality, and comprehensive healthcare services in a sensitive and safe environment. Facilities must, therefore, ensure availability of appropriate resources, services, and staffing ratios. ¹¹⁹ VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women 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." ¹²⁰

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

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

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

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

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

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

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

¹²⁰ VHA Directive 1330.01(3).

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

Women's Health Findings and Recommendations

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

VHA requires that facilities have gynecological care available 24 hours a day, 7 days per week. 121 The OIG noted that the medical center had only one gynecologist on staff. The Women's Health Medical Director reported that one specific community hospital is contacted when the on-call gynecologist is unavailable; however, the medical center had no written procedure or service agreement in place for this alternate coverage. This limited the availability

¹²¹ VHA Directive 1330.01(3).

of (and in this case, coordination of) comprehensive women's health care. Although the medical center had only one gynecologist, the Women's Health Medical Director believed that the current call procedure met requirements.

Recommendation 12

12. The Chief of Staff determines the reasons for noncompliance and ensures that gynecological care coverage is available 24 hours a day, 7 days per week. 122

Medical center concurred.

Target date for completion: Completed

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

The medical center believes the call schedule and the collaboration with our third-party vendor meets the requirements for gynecological care coverage. However, the medical center recognizes that the Women Veterans Health Program staff were not educated to availability of coverage for gynecological care 24 hours a day, 7 days per week. At the time of the site visit, we did not provide documented evidence of an agreement with a community provider. The Chief of Staff has ensured the Women Veterans Health Program staff were educated. The facility obtained from the Vice President of Program Management for OptumServe an attestation that Prisma Health as well as several Health Care Systems have over 50 gynecologists that are available to meet our Veterans' needs from the Community Care Network contract. Prisma Health partners with USC [the University of South Carolina] to directly oversee our residency program and provide clinical services. A copy of attestations is included as supporting documentation.

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

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

From July through December 2019, the OIG did not find the Emergency Department was represented with a member on the committee, nor was there evidence of consistent meeting

¹²² 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.

¹²³ VHA Directive 1330.01(3).

attendance by radiology, laboratory, and executive leadership representatives based on Women Veterans Health Committee meeting minutes reviewed. This resulted in a lack of expertise and oversight in the review and analysis of data as the committee planned and carried out improvements for quality and equitable care for women veterans. The Women Veterans Program Manager was aware of the requirement and attributed the noncompliance to staffing constraints and competing priorities.

Recommendation 13

13. The Director evaluates and determines any additional reasons for noncompliance and makes certain that required members are appointed and attend Women Veterans Health Committee meetings.

Medical center concurred.

Target date for completion: December 30, 2020

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

The Chief of Staff in collaboration with the Chief, Radiology and the Chief, ED identified members to attend meetings. Effective September 2020, meeting attendance recorded in the minutes will reflect required core members by position, their membership status (voting), and the required core member they are representing, e.g., WHMD, PC rep, etc.

For existing minutes, the Women Veterans Program Manager will utilize a membership designation form to document the names of the required attendees. Monitoring will be for 6 months beginning with June 2020

N = number of required members attending

D = number of required members

Compliance must be >90%

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

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

- Maintain a current inventory list of all RME
- Have standard operating procedures (SOPs) that are based on current manufacturer's guidelines and reviewed at least triennially
- Use CensiTrac® Instrument Tracking System for tracking reprocessed instruments 126
- 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 ¹²⁷

VHA requires strict controls that closely monitor climate, storage, and sterilization parameters and additionally requires that quality assurance documentation of this monitoring be maintained for a minimum of three years. ¹²⁸ The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization. ¹²⁹

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station,

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

¹²⁵ 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.)

¹²⁶ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019. ¹²⁷ VHA Directive 1116(2).

¹²⁸ VHA Directive 1116(2); VHA DUSHOM Memorandum, *Interim Guidance for Heating, Ventilation and Air Conditioning (HVAC) Requirements Related to Reusable Medical Equipment (RME) Reprocessing and Storage*, September 5, 2017.

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

personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME.¹³⁰

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

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

¹³⁰ VHA Directive 1116(2).

¹³¹ VHA Directive 1116(2).

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

High-Risk Processes Findings and Recommendations

Generally, the medical center met the above requirements for the proper operations and management of reprocessing RME. However, the OIG identified a deficiency with the storage of endoscopes.

VHA requires that high-level disinfected endoscopes "are to be hung so that no part of the scope touches the bottom of the cabinet and in sufficient space for storage of multiple endoscopes without touching." The OIG found three high-level disinfected endoscopes touching other scopes in the gastroenterology scope room storage cabinet. Correct storage of endoscopes reduces the risk of contamination or damage to equipment. The SPS Chief reported awareness of the requirement and stated that the touching was caused by internal coiling of the scopes.

Recommendation 14

14. The Associate Director Patient Care/Nursing Service evaluates and determines the reasons for noncompliance and ensures that high-level disinfected endoscopes are stored properly.

¹³² VHA Directive 1116(2).

Target date for completion: February 28, 2021

Medical center response: The Associate Director Patient Care/Nursing Service determined the reason for noncompliance and considered this when developing the action plan.

The Sterile Processing Service (SPS) Chief, SPS Supervisor, and GI [Gastrointestinal] Nurse Manager will conduct quality assurance monitoring of cabinets monthly.

N = #rounds with HLD [high-level disinfected] scopes stored appropriately

D = #rounds of HLD scopes

Audit results will be reported to Quality Management until six consecutive months of 90 percent or greater compliance is achieved.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

Healthcare Processes	Requirements	Conclusion
Leadership and Organizational Risks	 Executive leadership position stability and engagement Employee satisfaction Patient experience Accreditation surveys and oversight inspections Factors related to possible lapses in care and medical center response VHA performance data (medical center) VHA performance data for CLCs 	Fourteen 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, ADPC/NS, and Associate Director. See details below.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	 QSV Committee Protected peer reviews UM reviews Patient safety	• None	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medical Staff Privileging	 FPPEs OPPEs Provider exit reviews and reporting to state licensing boards 	Service chiefs' reprivileging recommendations are based on OPPE activities, with properly completed OPPE forms and supporting data. The Medical Executive Board's decision to recommend continuation of privileges is based on OPPE results.	Provider exit review forms are completed within seven calendar days of licensed healthcare professionals' departure from the medical center.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Environment of Care	Medical center General safety Special use spaces Environmental cleanliness and infection prevention Privacy Accommodation for women veterans Logistics Inpatient mental health unit General safety Special use spaces Environmental cleanliness and infection prevention Privacy Accommodation for women veterans Logistics Community-based outpatient clinic General safety Special use spaces Environmental cleanliness and infection prevention Privacy Special use spaces Environmental cleanliness and infection prevention Privacy Privacy Privacy for women veterans Logistics	Clinic staff appropriately dispose of contaminated instruments and used medications.	 Clinic managers remove clean and sterile items from shipping cartons and corrugated boxes prior to putting items in clean storage areas. Clinic staff secure protected health information when transporting laboratory specimens from the clinic to the medical center.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	 Provision of pain management using long-term opioid therapy Program oversight and evaluation 	 Providers complete an aberrant behavior risk assessment on all patients prior to initiating long-term opioid therapy. Providers obtain and document informed consent prior to initiating long-term opioid therapy. Providers conduct follow-up assessments that include adherence to the plan of care and effectiveness of interventions within three months of initiating long-term opioid therapy. 	• None
Mental Health: Suicide Prevention Program	 Designated suicide prevention coordinator Tracking and follow-up of high-risk veterans Provision of suicide prevention care Completion of suicide prevention training requirements 	Mental health providers collaborate with the Suicide Prevention Coordinator after unsuccessful contact attempts with patients flagged as high risk for suicide who miss mental health appointments.	All staff receive annual suicide prevention refresher training.
Care Coordination: Life-Sustaining Treatment Decisions	 LSTD multidisciplinary committee Goals of care conversation documentation LSTD note/orders completed by an authorized provider or delegated appropriately 	• None	• None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement	
Women's Health: Comprehensive Care	 Provision of care Program oversight and performance improvement data monitoring Staffing requirements 	Gynecological care coverage is available 24 hours a day, 7 days per week.	Required members are appointed and attend Women Veterans Health Committee meetings.	
High-Risk Processes: Reusable Medical Equipment	 Administrative processes Quality assurance monitoring Physical inspection Staff training 	High-level disinfected endoscopes are stored properly.	• None	

Appendix B: Medical Center Profile

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

Table B.1. Profile for Wm. Jennings Bryan Dorn VA Medical Center (544) (October 1, 2016, through September 30, 2019)

Profile Element	Medical Center Data FY 2017 ³	Medical Center Data FY 2018 ⁴	Medical Center Data FY 2019 ⁵
Total medical care budget in dollars	\$532,664,910	\$549,817,084	\$584,030,311
Number of:			
Unique patients	82,475	81,895	84,300
Outpatient visits	1,078,839	1,132,711	1,159,081
Unique employees ⁶	2,239	2,291	2,395
Type and number of operating beds:			
 Community living center 	94	94	94
Medicine	72	69	69
Mental health	17	17	17
Surgery	23	23	21
Average daily census:			
 Community living center 	63	73	66
Medicine	39	43	40
Mental health	16	15	16
Surgery	7	7	6

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

¹ Associated with a medical residency program.

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

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

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

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

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

Appendix C: VA Outpatient Clinic Profiles¹

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Greenville, SC	544BZ	31,037	12,655	Anesthesia Dermatology Eye Gastroenterology Pulmonary/ Respiratory Spinal cord injury	Radiology	Dental Pharmacy Nutrition Social work Weight management
Florence, SC	544GB	18,396	8,809	Nephrology	n/a	Nutrition Pharmacy Social work

¹ Includes all outpatient clinics in the community that were in operation as of August 27, 2019.

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

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

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

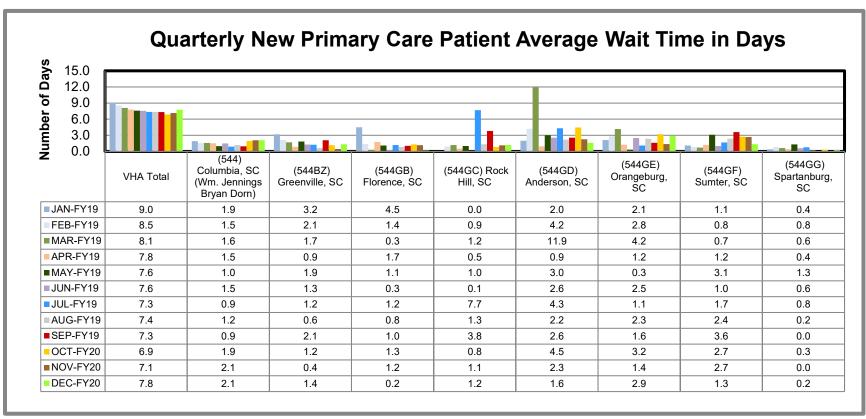
⁵ Ancillary services include chiropractic, dental, nutrition, pharmacy, prosthetic, social work, and weight management services.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ³ Provided	Diagnostic Services ⁴ Provided	Ancillary Services ⁵ Provided
Rock Hill, SC	544GC	14,129	11,470	Dermatology Gastroenterology Nephrology	n/a	Pharmacy
Anderson, SC	544GD	15,034	6,244	Dermatology Nephrology Podiatry	Radiology	Pharmacy Nutrition Weight management
Orangeburg, SC	544GE	10,414	5,088	n/a	n/a	Pharmacy
Sumter, SC	544GF	14,651	5,604	n/a	n/a	Pharmacy
Spartanburg, SC	544GG	13,593	6,440	Dermatology	Radiology	Pharmacy Nutrition

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

n/a = not applicable

Appendix D: Patient Aligned Care Team Compass Metrics¹

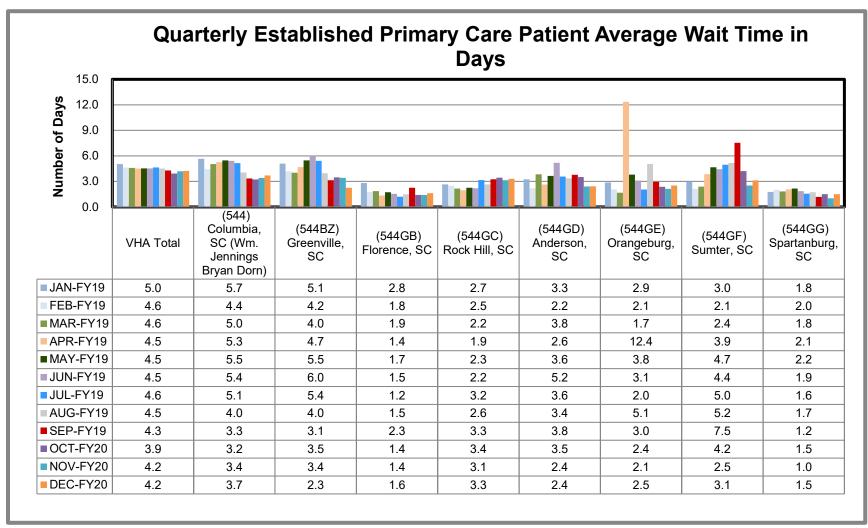


Source: VHA Support Service Center

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

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

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



Source: VHA Support Service Center

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

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

Appendix E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions¹

Measure	Definition	Desired Direction
ACSC hospitalization	Ambulatory care sensitive conditions hospitalizations	A lower value is better than a higher value
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
Admit reviews met	Percent acute admission reviews that meet interqual criteria	A higher value is better than a lower value
Best place to work	All employee survey best places to work score	A higher value is better than a lower value
Call responsiveness	Call center speed in picking up calls and telephone abandonment rate	A lower value is better than a higher value
Capacity	Percent increase in current physician and advanced practice provider capacity, based on productivity; capacity is not calculated for sites with above average productivity for their medical center group	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

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

Measure	Definition	Desired Direction
HEDIS like – HED90_ec	HEDIS-eOM based DM IHD	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
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 Definitions¹

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.

¹ 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 rehospitalized after a nursing home admission.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

Appendix G: Interim VISN Director Comments

Department of Veterans Affairs Memorandum

Date: October 29, 2020

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

Subj: OIG Draft Report: CHIP [Comprehensive Healthcare Inspection Program] of the Wm Jennings Bryan Dorn VAMC [Medical Center], Columbia VA Health Care System, South Carolina

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

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

- I have had the opportunity to review the Draft Report: CHIP Review of the Wm Jennings Bryan Dorn VAMC, Columbia VA Health Care System.
- 2. VISN 7 submits concurrence with the attached Wm Jennings Bryan Dorn VA Medical Center action plan. VISN 7 concurs with Recommendations 1-14.
- 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 29, 2020

From: Medical Center Director, Columbia VA Health Care System [Wm. Jennings Bryan Dorn VA Medical Center] (544/00)

Subj: Comprehensive Healthcare Inspection of the Columbia VA Health Care System [William Jennings Bryan Dorn VA Medical Center], Columbia, South Carolina

To: Director, Southeast Network (10N7)

- 1. The Columbia VA Health Care System would like to thank the Office of the Inspector General Team for the thorough review and assessment during the Comprehensive Healthcare Inspection Program review.
- I have reviewed each recommendation and concur with the findings, recommendations and submitted action plans. The plans have been carefully analyzed and will be implemented and monitored through satisfactory completion.

(Original signed by:)

David L. Omura, DPT, MHA, MS

Medical center Director

OIG Contact and Staff Acknowledgments

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