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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Bay Pines VA Healthcare System in Florida

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Figure 1. Bay Pines VA Healthcare System in Florida.

Source: https://vaww.va.gov/directory/guide (accessed March 8, 2021).

Abbreviations

ADPCS Associate Director for Patient Care Services

CHIP Comprehensive Healthcare Inspection Program

CLC community living center

COVID-19 coronavirus disease

FDA Food and Drug Administration

FY fiscal year

OIG Office of Inspector General

QSV quality, safety, and value

RN registered nurse

SAIL Strategic Analytics for Improvement and Learning

TJC The Joint Commission

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Bay Pines VA Healthcare System, which includes the C.W. Bill Young VA Medical Center and eight outpatient clinics in Florida. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

- 1. COVID-19 pandemic readiness and response¹
- 2. Quality, safety, and value
- 3. Registered nurse credentialing
- 4. Medication management (targeting remdesivir use)
- 5. Mental health (focusing on emergency department and urgent care center suicide risk screening and evaluation)
- 6. Care coordination (spotlighting inter-facility transfers)
- 7. High-risk processes (examining the management of disruptive and violent behavior)

The OIG conducted an unannounced virtual review of the Bay Pines VA Healthcare System during the week of March 15, 2021. 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 the healthcare system's performance within the identified focus areas at the time of the OIG review. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this healthcare system and other Veterans Health Administration (VHA)

¹ "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," World Health Organization, accessed August 25, 2020, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. COVID-19 (coronavirus disease) is an infectious disease caused by the "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)."

facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

The OIG noted opportunities for improvement in several areas reviewed and issued five recommendations to the System Director, Chief of Staff, and Associate Director for Patient Care Services. These opportunities for improvement are briefly described below.

Leadership and Organizational Risks

At the time of the OIG's virtual review, the healthcare system's leadership team consisted of the System Director, Chief of Staff, Associate Director for Patient Care Services, Deputy Director, Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure, with Executive Leadership Board oversight of several working groups. Leaders monitored patient safety and care through the Organizational Excellence Council, which was responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this inspection, the executive team had worked together for nine months. The newest member of the team, the Associate Director for Patient Care Services, was assigned in June 2020. The most tenured leader, the Deputy Director, was assigned in October 2017.

During an interview with the OIG, the Director indicated that the system had sufficient funding prior to the pandemic but would need more funding for the salaries of over 200 staff hired to support pandemic efforts.

The OIG reviewed survey results and concluded that the responses demonstrated satisfaction with leadership and maintenance of an environment where staff felt respected, and discrimination was not tolerated. However, responses also pointed to opportunities to reduce feelings of moral distress at work.² Patient experience survey data implied satisfaction with the care provided. Further, the OIG found that selected survey results for female respondents were generally more favorable than those for female VHA patients nationally.

² "2020 VA All Employee Survey (AES): Questions by Organizational Health Framework," VA Workforce Surveys Portal, VHA Support Service Center, accessed July 29, 2021, http://aes.vssc.med.va.gov/SurveyInstruments/_layouts/15/DocIdRedir.aspx?ID=QQVSJ65U5ZMQ-229890423-174. (This is an internal website not publicly accessible.) The 2020 All Employee Survey defines moral distress as being "unsure about the right thing to do or could not carry out what you believed to be the right thing."

The inspection team also reviewed accreditation agency findings and sentinel events and did not identify any substantial organizational risk factors.³ However, the OIG identified an opportunity to strengthen the institutional disclosure process.

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.⁵

The executive leaders were knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to poor performance on specific SAIL measures. Leaders also understood Community Living Center SAIL measures.⁶ In individual interviews, the executive leadership team members could speak about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences.

COVID-19 Pandemic Readiness and Response

The OIG will report the results of the COVID-19 pandemic readiness and response evaluation for this healthcare system and other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

Quality, Safety, and Value

The healthcare system complied with most of the requirements for a committee responsible for quality, safety, and value oversight functions; protected peer reviews; and the System Redesign and Improvement Program. However, the OIG identified a weakness with the Surgical Work Group review of surgical deaths.

³ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

⁴ "Strategic Analytics for Improvement and Learning (SAIL) Value Model," VHA Support Service Center, accessed March 6, 2020, https://vssc.med.va.gov. (This is an internal website not publicly accessible.)

⁵ "Strategic Analytics for Improvement and Learning (SAIL) Value Model."

⁶ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers,* June 1, 2017. Community living centers, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

Medication Management

The healthcare system complied with many of the indicators of expected performance, including staff availability to receive remdesivir shipments, provision of required testing prior to remdesivir administration, and reporting adverse events. However, the OIG identified deficiencies with patient or caregiver education prior to remdesivir administration.

Mental Health

The healthcare system complied with requirements related to suicide prevention screening within emergency departments and urgent care centers. However, the OIG identified a deficiency with staff training.

Care Coordination

The OIG observed compliance with most of the requirements for inter-facility transfers. However, the OIG identified a deficiency with documented transmission of patients' advance directives to receiving facilities.

High-Risk Processes

The healthcare system met many of the requirements for the management of disruptive and violent behavior. However, the OIG identified deficiencies with Disruptive Behavior Committee attendance and patient notification of an Order of Behavioral Restriction.

Conclusion

The OIG conducted a detailed inspection across eight key areas (two administrative and six clinical) and subsequently issued five recommendations for improvement to the System Director, Chief of Staff, and Associate Director for Patient Care Services. However, the number of recommendations should not be used as a gauge for the overall quality of care provided at this system. The intent is for system leaders to use these recommendations to help guide improvements in operations and clinical care. The recommendations address issues that may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and System Director agreed with the comprehensive healthcare inspection findings and recommendations and provided acceptable improvement plans (see appendixes G and H, pages 58–59, and the responses within the body of the report for the full text of the directors' comments.) The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Assistant Inspector General

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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 that provide healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Bay Pines VA Healthcare System 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 healthcare system leaders so that informed decisions can be made to improve care.¹

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

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

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

- 1. Leadership and organizational risks
- 2. COVID-19 pandemic readiness and response⁵
- 3. Quality, safety, and value (QSV)
- 4. Registered nurse credentialing

¹ VA administers healthcare services through a network of 18 regional offices nationwide referred to as the Veterans Integrated Service Network.

² Anam Parand et al., "The role of hospital managers in quality and patient safety: a systematic review," *British Medical Journal*, 4, no. 9 (September 5, 2014): https://doi.org/10.1136/bmjopen-2014-005055.

³ Danae Sfantou et al., "Importance of Leadership Style Towards Quality of Care Measures in Healthcare Settings: A Systematic Review," *Healthcare (Basel)* 5, no. 4, (October 14, 2017): 73, https://doi.org/10.3390/healthcare5040073.

⁴ Virtual CHIP site visits address these processes during fiscal year 2021 (October 1, 2020, through September 30, 2021); they may differ from prior years' focus areas.

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

- 5. Medication management (targeting remdesivir use)
- 6. Mental health (focusing on emergency department and urgent care center suicide risk screening and evaluation)
- 7. Care coordination (spotlighting inter-facility transfers)
- 8. High-risk processes (examining the management of disruptive and violent behavior)

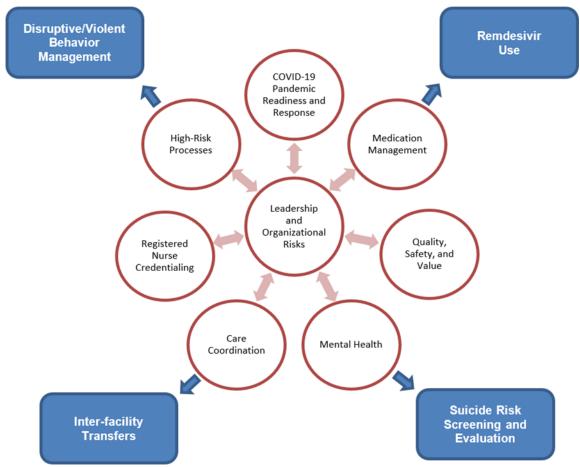


Figure 2. Fiscal year (FY) 2021 comprehensive healthcare inspection of operations and services. Source: VA OIG.

Methodology

The Bay Pines VA Healthcare System includes the C. W. Bill Young VA Medical Center and eight outpatient clinics in Florida. Additional details about the types of care provided by the healthcare system can be found in appendixes B and C.

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality and clinical functions, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.⁶ The team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

The inspection examined operations from December 16, 2017, through March 19, 2021, the last day of the unannounced multiday evaluation.⁷ During the virtual review, the OIG did not receive any complaints beyond the scope of the inspection.

The OIG will report the results of the COVID-19 pandemic readiness and response evaluation for this healthcare system and other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

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

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

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

⁶ The OIG did not review VHA's internal survey results and instead focused on OIG inspections and external surveys that affect facility accreditation status.

⁷ The range represents the time period from the prior CHIP site visit to the completion of the unannounced, multiday virtual CHIP visit in March 2021.

⁸ Pub. L. No. 95-452, 92 Stat 1101, as amended (codified at 5 U.S.C. App. 3).

Results and Recommendations

Leadership and Organizational Risks

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

- 1. Executive leadership position stability and engagement
- 2. Budget and operations
- 3. Staffing
- 4. Employee satisfaction
- 5. Patient experience
- 6. Accreditation surveys and oversight inspections
- 7. Identified factors related to possible lapses in care and the healthcare system response
- 8. VHA performance data (healthcare system)
- 9. VHA performance data (community living center (CLC))¹⁰

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 healthcare system's reported organizational structure. The healthcare system had a leadership team consisting of the System Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Deputy Director, Associate Director, and Assistant Director. The Chief of Staff and ADPCS oversaw patient care, which required managing service directors and chiefs of programs and practices.

⁹ Laura Botwinick, Maureen Bisognano, and Carol Haraden, *Leadership Guide to Patient Safety*, Institute for Healthcare Improvement, Innovation Series White Paper, 2006.

¹⁰ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017. CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

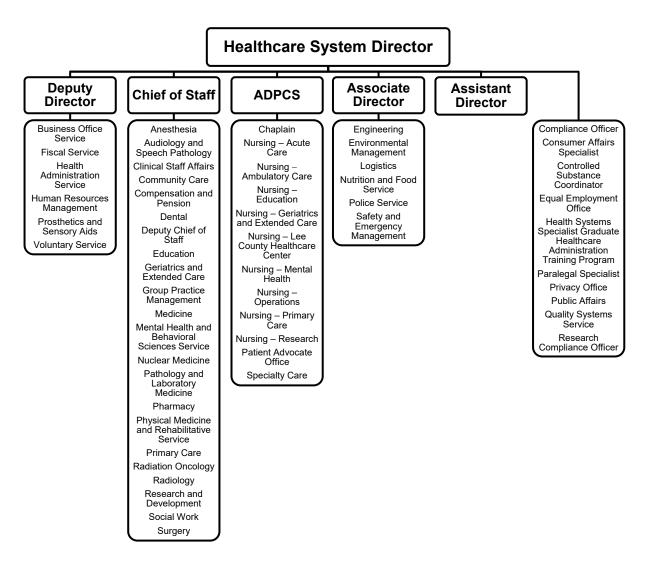


Figure 3. Healthcare system organizational chart.

Source: Bay Pines VA Healthcare System (received March 15, 2021).

At the time of the OIG inspection, the executive team had worked together for nine months. The newest member of the team, the ADPCS, was assigned in June 2020. The most tenured leader, the Deputy Director, was assigned in October 2017 (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
System Director	September 16, 2018
Chief of Staff	April 28, 2019
Associate Director for Patient Care Services	June 21, 2020
Deputy Director	October 1, 2017
Associate Director	June 24, 2018
Assistant Director	November 11, 2018

Source: Bay Pines VA Healthcare System Senior Strategic Business Partner (received March 16, 2021).

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

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

The System Director served as the chairperson of the Executive Leadership Board, which had the authority and responsibility to establish policy, maintain quality care standards, and perform organizational management and strategic planning. The Executive Leadership Board oversaw various working groups such as the Patient-Centered Care, Medical Executive, and Resources and Operations Councils. These leaders monitored patient safety and care through the Organizational Excellence Council, which was responsible for tracking and trending quality of care and patient outcomes and reported to the Executive Leadership Board (see figure 4).

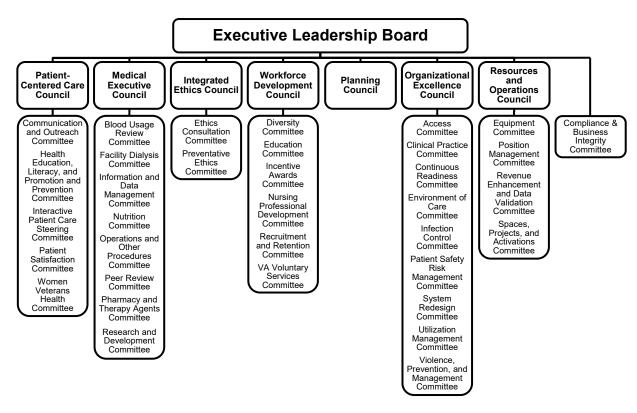


Figure 4. Healthcare system committee reporting structure.

Source: Bay Pines VA Healthcare System (received March 15, 2021).

Budget and Operations

The healthcare system's FY 2020 annual medical care budget of \$1,108,367,452 increased almost 27 percent compared to the previous year's budget of \$875,407,659. When asked about the effect of this change on the healthcare system's operations, the System Director indicated that the budget was adequate with the additional COVID-19 funding. The System Director reported hiring over 200 staff to support pandemic efforts and shared that the system would need more money to continue their salaries. The Director also reported that funds were used for increases in cost-of-living allowances, retirement adjustments, and nurse salaries. The Chief of Staff described using the funding increase to also implement a pay-for-performance initiative for physicians.

Staffing

The Veterans Access, Choice, and Accountability Act of 2014 required the OIG to determine, on an annual basis, the VHA occupations with the largest staffing shortages. ¹² Under the authority

¹¹ VHA Support Service Center.

¹² Veterans Access, Choice, and Accountability Act of 2014, Pub. L. No. 113-146 (2014).

of the VA Choice and Quality Employment Act of 2017, the OIG conducts annual determinations of clinical and nonclinical VHA occupations with the largest staffing shortages within each medical facility.¹³ In addition, the OIG has demonstrated a linkage between staffing shortages and negative effects on patient care delivery.¹⁴

Table 2 provides the top facility-reported clinical and nonclinical occupational shortages as reported in the *OIG Determination of Veterans Health Administration's Occupational Staffing Shortages, Fiscal Year 2020.*¹⁵ The System Director confirmed that psychiatrists and general practice providers remained in the top clinical shortages. The System Director also shared that the system had hired contract staff and used financial incentives and retention bonuses.

Table 2. Top Facility-Reported Clinical and Nonclinical Staffing Shortages

Top Clinical Staffing Shortages	Top Nonclinical Staffing Shortages
1. Psychiatry*	Medical Records Technician
2. General Practice*	2. –
3. Hospitalist*	3. –
4. Radiation Oncology*	4. –
5. Emergency Medicine*	5. –

Source: VA OIG.

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 healthcare system leaders.

^{*}Represents assignment codes within the Medical Officer occupational series.

¹³ VA Choice and Quality Employment Act of 2017, Pub. L. No. 115-46 (2017); VA OIG, *OIG Determination of Veterans Health Administration's Occupational Staffing Shortages, Fiscal Year 2020*, Report No. 20-01249-259, September 23, 2020.

¹⁴ VA OIG, *Critical Deficiencies at the Washington DC VA Medical Center*, Report No. 17-02644-130, March 7, 2018.

¹⁵ VA OIG, OIG Determination of Veterans Health Administration's Occupational Staffing Shortages, Fiscal Year 2020.

¹⁶ "AES Survey History," VA Workforce Surveys Portal, VHA Support Service Center, accessed May 3, 2021, http://aes.vssc.med.va.gov/Documents/04_AES_History_Concepts.pdf. (This is an internal website not publicly accessible.)

¹⁷ "AES Survey History."

To assess employee attitudes toward healthcare system leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey from October 1, 2019, through September 30, 2020. Table 3 provides relevant survey results for VHA, the healthcare system, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found the healthcare system averages for the selected survey leadership questions were similar to or higher than the VHA averages. Scores related to the Director, Chief of Staff, and ADPCS were consistently higher than those for VHA and the healthcare system. Scores for the Deputy and Associate Directors were generally similar to the scores for VHA and the healthcare system.

Table 3. Survey Results on Employee Attitudes toward Healthcare System Leaders (October 1, 2019, through September 30, 2020)

Questions/ Survey Items	Scoring	VHA Average	Health- care System Average	Director Average	Chief of Staff Average	ADPCS Average*	Deputy Director	Assoc. Director Average
All Employee Survey: Servant Leader Index Composite.†	0–100 where higher scores are more favorable	73.8	74.7	74.6	85.2	90.0	72.8	75.1
All Employee Survey: In my organization, senior leaders generate high levels of motivation and commitment in the workforce.	1 (Strongly Disagree) –5 (Strongly Agree)	3.5	3.5	3.7	4.3	4.5	3.4	3.5
All Employee Survey: My organization's senior leaders maintain high standards of honesty and integrity.	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.7	4.0	4.4	4.6	3.7	3.6

¹⁸ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Deputy Director, and Associate Director. Data were not available for the Assistant Director.

¹⁹ 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.

Questions/ Survey Items	Scoring	VHA Average		Director Average		ADPCS Average*	Director	Assoc. Director Average
All Employee Survey: I have a high level of respect for my organization's senior leaders.	1 (Strongly Disagree) -5 (Strongly Agree)	3.7	3.8	3.9	4.4	4.8	3.7	3.7

Source: VA All Employee Survey (accessed January 4 and February 16, 2021).

Table 4 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.²⁰ The healthcare system average for the selected survey questions was similar to the VHA average. Scores related to the Director and Chief of Staff were consistently better than those for VHA and the healthcare system for all three selected survey questions. The ADPCS scores were better than those for VHA and the healthcare system for two of the selected survey questions. However, opportunities may exist for the ADPCS and Deputy Director to reduce employee feelings of moral distress at work (uncertainty about the right thing to do or inability to carry out what you believed to be the right thing). The ADPCS believed that the changing guidance early in the pandemic, coupled with uncertainty, likely contributed to the moral distress score.

Table 4. Survey Results on Employee Attitudes toward the Workplace (October 1, 2019, through September 30, 2020)

Questions/ Survey Items	Scoring	VHA Average	Health- care System Average	Director Average	Chief of Staff Average	ADPCS Average*		Assoc. Director Average
All Employee Survey: I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.	1 (Strongly Disagree) –5 (Strongly Agree)	3.8	3.8	4.1	4.4	4.5	3.7	3.8

²⁰ Ratings are based on responses by employees who report to or are aligned under the System Director, Chief of Staff, ADPCS, Deputy Director, and Associate Director. Data were not available for the Assistant Director.

^{*}ADPCS scores include the results for all respondents aligned under patient care services.

[†]The Servant Leader Index is a summary measure based upon respondents' assessments of their supervisors' listening, respect, trust, favoritism, and response to concerns.

Questions/ Survey Items	Scoring	VHA Average	Health- care System Average	Director Average	Chief of Staff Average	ADPCS Average*	Deputy Director	Assoc. Director Average
All Employee Survey: Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).	Ägree)	3.8	3.7	4.0	4.2	4.1	3.5	3.6
All Employee Survey: In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?	0 (Never)– 6 (Every Day)	1.4	1.4	1.3	1.1	1.8	1.8	1.2

Source: VA All Employee Survey (accessed January 4 and February 16, 2021).

VHA leaders have articulated that the agency "is committed to a harassment-free health care environment." To this end, leaders initiated the "End Harassment" and "Stand Up to Stop

^{*}ADPCS scores include the results for all respondents aligned under patient care services.

²¹ "Stand Up to Stop Harassment Now!" Department of Veterans Affairs, accessed December 8, 2020, https://vaww.insider.va.gov/stand-up-to-stop-harassment-now/; Executive in Charge, Office of Under Secretary for Health Memorandum, *Stand Up to Stop Harassment Now*, October 23, 2019.

Harassment Now!" campaigns to help create a culture of safety where staff and patients feel secure and respected.²²

The System Director reported implementing strategies to support VA's commitment that included operational messaging for the system to maintain a harassment-free, non-hostile environment and initiation of investigations as needed.

Table 5 summarizes employee perceptions related to respect and discrimination based on VHA's All Employee Survey responses. The healthcare system and leader averages for the selected survey questions were generally similar to or better than the VHA averages. Leaders appeared to maintain an environment where staff felt respected and safe, and discrimination was not tolerated.

Table 5. Survey Results on Employee Attitudes toward Workgroup Relationships (October 1, 2019, through September 30, 2020)

Questions/ Survey Items	Scoring	VHA Average	Health- care System Average	Director Average	Chief of Staff Average	ADPCS Average*	Deputy Director	Assoc. Director Average
All Employee Survey: People treat each other with respect in my workgroup.	1 (Strongly Disagree)– 5 (Strongly Agree)		3.9	4.0	4.4	4.5	3.7	3.8
All Employee Survey: Discrimination is not tolerated at my workplace.	1 (Strongly Disagree)– 5 (Strongly Agree)	4.1	4.1	4.3	4.5	4.4	4.0	4.1
All Employee Survey: Members in my workgroup are able to bring up problems and tough issues.	1 (Strongly Disagree)– 5 (Strongly Agree)	3.8	3.8	3.8	4.4	4.1	3.7	3.8

Source: VA All Employee Survey (accessed January 4 and February 16, 2021).

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^{*}ADPCS scores include the results for all respondents aligned under patient care services.

²² "Stand Up to Stop Harassment Now!"

Patient Experience

To assess patient experiences with the healthcare system, which directly reflect on its leaders, the OIG team reviewed survey results from October 1, 2019, through September 30, 2020. 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 support benchmarking its performance against the private sector.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The OIG reviewed responses to three relevant survey questions that reflect patients' attitudes toward their healthcare experiences. Table 6 provides relevant survey results for VHA and the healthcare system. ²³ For this system, the overall patient satisfaction survey results reflected similar or higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

Table 6. Survey Results on Patient Experience (October 1, 2019, through September 30, 2020)

Questions	Scoring	VHA Average	Healthcare System
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.	69.5	73.8
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?	The response average is the percent of "Very satisfied" and "Satisfied" responses.	82.5	82.5
Survey of Healthcare Experiences of Patients (outpatient specialty care): Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?	The response average is the percent of "Very satisfied" and "Satisfied" responses.	84.8	86.2

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed December 21, 2020).

In 2019, women were estimated to represent 10.1 percent of the total veteran population in the United States, and it is projected that women will represent 17.8 percent of living veterans by

²³ Ratings are based on responses by patients who received care at this healthcare system.

2048.²⁴ For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant questions that reflect patients' experiences by gender, including those for Inpatient, Patient-Centered Medical Home, and Specialty Care surveys (see tables 7–9). The results for male respondents were generally similar to the corresponding VHA averages, while those for female respondents were often more positive than female VHA patients nationally. System leaders appeared to be actively engaged with male and female patients (for example, by conducting veteran town hall meetings and asking for patient feedback while on rounds).

Table 7. Inpatient Survey Results on Experiences by Gender (October 1, 2019, through September 30, 2020)

Questions	Scoring	VHA*		Healthcare System [†]	
		Male Average	Female Average	Male Average	Female Average
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).	69.8	64.5	73.9	71.7
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	84.8	79.3	86.7
During this hospital stay, how often did nurses treat you with courtesy and respect?	The measure is calculated as the percentage of responses that fall in the top category (Always).	85.1	83.3	84.9	81.1

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed December 20, 2020).

^{*}The VHA averages are based on 48,907–49,521 male and 2,395–2,423 female respondents, depending on the question.

[†]The healthcare system averages are based on 596–603 male and 30–33 female respondents, depending on the question.

²⁴ "Veteran Population," Table 1L: VetPop2018 Living Veterans by Age Group, Gender, 2018-2048, National Center for Veterans Analysis and Statistics, accessed November 30, 2020, https://www.va.gov/vetdata/Veteran Population.asp.

Table 8. Patient-Centered Medical Home Survey Results on Patient Experiences by Gender (October 1, 2019, through September 30, 2020)

Questions	Scoring	VHA*		Healthcare System [†]		
		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).	51.3	44.0	51.9	57.7	
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).	59.5	53.0	60.7	62.7	
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).	74.0	68.9	74.8	76.5	

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed December 20, 2020).

^{*}The VHA averages are based on 74,278–223,617 male and 6,158–13,836 female respondents, depending on the question.

[†]The healthcare system averages are based on 878–2,797 male and 65–170 female respondents, depending on the question.

Table 9. Specialty Care Survey Results on Patient Experiences by Gender (October 1, 2019, through September 30, 2020)

Questions Scoring		VHA*		Healthcare System [†]	
		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).	50.5	47.3	49.8	56.9
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).	57.4	54.3	56.9	55.3
Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	75.1	72.2	75.3	72.5

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed December 20, 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 responded to identified problems.²⁵ Table 10 summarizes the relevant system inspections most recently performed by the OIG and The Joint

^{*}The VHA averages are based on 63,661–187,441 male and 3,777–10,616 female respondents, depending on the question.

[†]The healthcare system averages are based on 841–2,567 male and 70–191 female respondents, depending on the question.

²⁵ "Profile Definitions and Methodology: Joint Commission Accreditation," *American Hospital Directory*, accessed December 12, 2020, https://www.ahd.com/definitions/prof_accred.html. "The Joint Commission conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization."

Commission (TJC).²⁶ At the time of the OIG review, the system had closed all recommendations for improvement issued since the previous CHIP site visit conducted in December 2017. Quality System Services staff reported that the system had completed some actions related to the open thoracic surgery quality of care hotline recommendations but had not yet submitted the actions to the OIG for closure because the report was published only two months before the CHIP review.²⁷

The OIG team also noted the system's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²⁸ An additional result included the Long Term Care Institute's inspection of the system's CLCs.²⁹

Table 10. Office of Inspector General Inspections/The Joint Commission Survey

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Comprehensive Healthcare Inspection Program Review of the Bay Pines VA Healthcare System, Florida, Report No. 17-01857-264, August 28, 2018)	December 2017	4	0
OIG (Thoracic Surgery Quality of Care Issues and Facility Leaders' Response at the C.W. Bill Young VA Medical Center in Bay Pines, Florida, Report No. 18-01321-56, January 13, 2021)	July 2018	10	10*

²⁶ 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."

²⁷ VA OIG, *Thoracic Surgery Quality of Care Issues and Facility Leaders' Response at the C.W. Bill Young VA Medical Center in Bay Pines, Florida*, Report No. 18-01321-56, January 13, 2021.

²⁸ 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 CARF [Commission on Accreditation of Rehabilitation Facilities] to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs." "About the College of American Pathologists," College of American Pathologists, accessed February 20, 2019, https://www.cap.org/about-the-cap. According to the College of American Pathologists, for 75 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." Additionally, as stated in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

²⁹ "About Us," Long Term Care Institute, accessed December 8, 2020, http://www.ltciorg.org/about-us/. The Long Term Care Institute is "focused on long term care quality and performance improvement; compliance program development; and review in long term care, hospice, and other residential care settings."

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (Alleged Inadequate Response to a Missing Patient and Safety Concerns at the Bay Pines VA Healthcare System, Florida, Report No. 18-04132-163, July 18, 2019)	January 2019	3	0
TJC Hospital Accreditation	March 2019	34	0
TJC Behavioral Health Care Accreditation		6	0
TJC Home Care Accreditation		5	0

Source: OIG and TJC (inspection/survey results received from the Supervisory Program Analyst on March 15, 2021).

Identified Factors Related to Possible Lapses in Care and Healthcare System Responses

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms.

Table 11 lists the reported patient safety events from December 16, 2017 (the prior OIG CHIP site visit), through March 15, 2021.³⁰

^{*}As of October 2021, two recommendations remained open.

³⁰ 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 Bay Pines VA Healthcare System is a highest complexity (1a) affiliated system as described in appendix B.) According to VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018, a sentinel event is

an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life." Additionally, as stated in VHA Directive 1004.08, *Disclosure of Adverse Events To Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an "administrative disclosure") as "a formal process by which VA medical facility leaders together with clinicians and others, as appropriate, inform the patient or personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse." Lastly, in VHA Directive 1004.08, VHA defines 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."

Table 11. Summary of Selected Organizational Risk Factors (December 16, 2017, through March 15, 2021)

Factor	Number of Occurrences
Sentinel Events	9
Institutional Disclosures	19
Large-Scale Disclosures	0

Source: Bay Pines VA Healthcare System Patient Safety Specialist and Risk Manager (received March 16, 2021).

The OIG's review of the system's accreditation findings and sentinel events did not identify any substantial organizational risk factors. The System Director shared that sentinel events are reported through emails, phone calls, patient safety reports, briefings, and face-to-face interactions. The System Director was generally able to speak knowledgeably about the status of root cause analysis actions to improve the quality and safety of care. This included knowledge of implementation progress, outcomes monitoring, and action item closure. However, the OIG identified an opportunity to strengthen the institutional disclosure process (see Leadership and Organizational Risks Findings and Recommendation).

Veterans Health Administration Performance Data for the Healthcare System

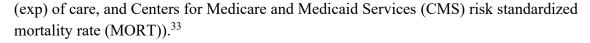
The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with "measures on healthcare quality, employee satisfaction, access to care, and efficiency." Despite limitations for identifying all areas of clinical risk the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.³²

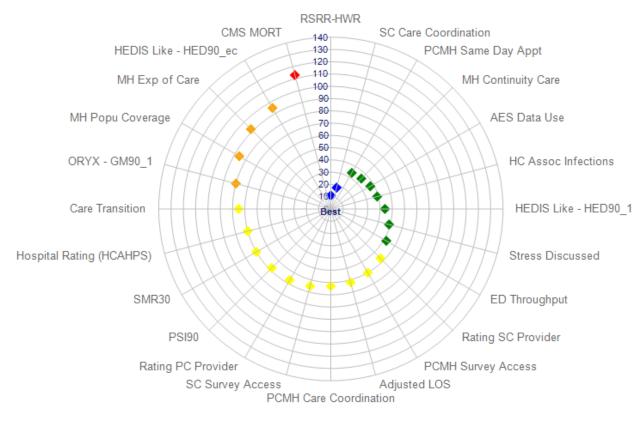
Figure 5 illustrates the system's quality of care and efficiency metric rankings and performance compared with other VA facilities as of September 30, 2020. Figure 5 shows the Bay Pines VA Healthcare System's performance in the first through fifth quintiles. Those in the first and second quintiles (blue and green data points, respectively) are better-performing measures (for example, in the areas of specialty care (SC) care coordination, patient-centered medical home (PCMH) same day appointment (appt), and health care (HC) associated (assoc) infections). Metrics in the fourth and fifth quintiles are those that need improvement and are denoted in orange and red, respectively (for example, mental health (MH) population (popu) coverage, MH experience

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³¹ "Strategic Analytics for Improvement and Learning (SAIL) Value Model," VHA Support Service Center, accessed March 6, 2020, https://vssc.med.va.gov. (This is an internal website not publicly accessible.)

³² "Strategic Analytics for Improvement and Learning (SAIL) Value Model."





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

Figure 5. Bay Pines VA Healthcare System quality of care and efficiency metric rankings for fiscal year 2020 quarter 4 (as of September 30, 2020).

Source: VHA Support Service Center.

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

³³ For information on the acronyms in the SAIL metrics, please see appendix E.

Veterans Health Administration Performance Data for the Community Living Center

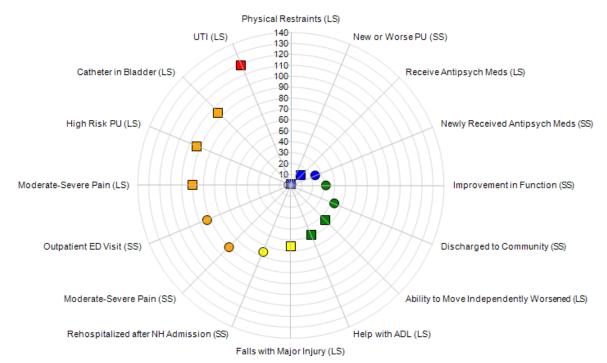
The CLC SAIL Value Model is a tool to "summarize and compare performance of CLCs in the VA."³⁴ The model "leverages much of the same data" used in CMS's *Nursing Home Compare* and provides a single resource "to review quality measures and health inspection results."³⁵

Figure 6 illustrates the system's CLC quality rankings and performance compared with other VA CLCs as of June 30, 2020. Figure 6 displays the Bay Pines VA Healthcare System's CLC metrics with high performance (blue and green data points) in the first and second quintiles (for example, in the areas new or worse pressure ulcer (PU)–short-stay (SS), receive antipsychotic (antipsych) medications (meds)–long-stay (LS), and improvement in function (SS)). Metrics in the fourth and fifth quintiles need improvement and are denoted in orange and red (for example, moderate-severe pain (LS), catheter in bladder (LS), and urinary tract infection (UTI) (LS)).

³⁴ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC): A tool to examine Quality Using Internal VA Benchmarks*, July 16, 2021.

³⁵ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC): A tool to examine Quality Using Internal VA Benchmarks.* "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."

³⁶ For data definitions of acronyms in the SAIL CLC measures, please see appendix F.



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

Figure 6. Bay Pines CLC quality measure rankings for fiscal year 2020 quarter 3 (as of June 30, 2020).

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 Findings and Recommendation

At the time of the OIG inspection, the executive team had worked together for nine months. The newest member of the team, the ADPCS, was assigned in June 2020. The most tenured leader, the Deputy Director, was assigned in October 2017. The executive leaders were able to discuss interim strategies to address clinical occupational shortages.

Selected employee satisfaction survey responses demonstrated satisfaction with leadership and maintenance of an environment where staff felt respected, and discrimination was not tolerated. However, responses also pointed to opportunities to reduce feelings of moral distress at work. Patient experience survey data implied satisfaction with the care provided. Further, the OIG found that selected survey results for female respondents were generally more favorable than those for female VHA patients nationally.

The OIG's review of the system's accreditation findings and sentinel events did not identify any substantial organizational risk factors. In addition, the executive leaders were knowledgeable within their scope of responsibilities about selected VHA data used by the SAIL and CLC SAIL

models. However, the OIG identified an opportunity to strengthen the institutional disclosure process.

VHA requires its facility directors to ensure that an institutional disclosure is performed when an adverse event occurs during patient care that "resulted in, or is reasonably expected to result in, death or serious injury."³⁷ VHA states "serious injury may include significant or permanent disability, injury that leads to prolonged hospitalization, injury requiring life-sustaining intervention, or intervention to prevent impairment or damage, including, for example sentinel events as defined by The Joint Commission."³⁸ The OIG found that four patients who experienced sentinel event falls from January 1, through March 15, 2021, did not receive the required institutional disclosure. The Chief of Staff reported institutional disclosures were not completed due to a lack of awareness of the requirement.

Recommendation 1

1. The System Director evaluates and determines any additional reasons for noncompliance and ensures disclosure of adverse events that require an institutional disclosure.

Healthcare system concurred.

Target date for completion: December 21, 2021

Healthcare system response: The System Director evaluated reasons for noncompliance and determined no additional reasons. An Institutional Disclosure Tracking Log was created and implemented April 2, 2021. The log captures all relevant information about an event that meets the definition for institutional disclosure per VHA Directive 1004.08—Disclosure of Adverse Events to Patients. The log was developed and is maintained by the Risk Manager. The Risk Manager reviews all potential events received from Patient Safety Manager or delegate, peer review specialists, or other sources, including issue briefs and leadership communications, to determine whether they meet criteria for institutional disclosure and confers with the Chief of Staff for concurrence, as needed. The Risk Manager will report monthly Institutional Disclosure Tracking Log results, on a quarterly basis for six months, to the Organizational Excellence Council. The System Director is the Chair of the Organizational Excellence Council. Compliance will be achieved when 90 percent of institutional disclosures logged for adverse events were completed or declined within the six-month period. Compliance will also be achieved when 90 percent of institutional disclosures for adverse events are completed or declined within 72 hours of discovery or after a thorough quality review or investigation into the facts are completed, and contact is made with the patient and/or family.

³⁷ VHA Directive 1004.08.

³⁸ VHA Directive 1004.08.

COVID-19 Pandemic Readiness and Response

On March 11, 2020, due to the "alarming levels of spread and severity" of COVID-19, the World Health Organization declared a pandemic.³⁹ VHA subsequently issued its *COVID-19 Response Plan* on March 23, 2020, which presents strategic guidance on prevention of viral transmission among veterans and staff and appropriate care for sick patients.⁴⁰

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

Due to VHA's mission-critical work in supporting both veteran and civilian populations during the pandemic, the OIG conducted an evaluation of the pandemic's effect on the healthcare system and its leaders' subsequent responses. The OIG analyzed performance in the following domains:

- Emergency preparedness
- Supplies, equipment, and infrastructure
- Staffing
- Access to care
- CLC patient care and operations

The OIG also surveyed healthcare system staff to solicit their feedback and potentially identify any problematic trends and/or issues that may require follow-up.

The OIG will report the results of the COVID-19 pandemic readiness and response evaluation for this healthcare system and other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

³⁹ "WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020," World Health Organization, accessed December 8, 2020, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

⁴⁰ VHA, Office of Emergency Management, COVID-19 Response Plan, March 23, 2020.

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

⁴² VA OIG, OIG Inspection of Veterans Health Administration's COVID-19 Screening Processes and Pandemic Readiness, March 19–24, 2020, Report No. 20-02221-120, March 26, 2020.

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. ⁴³ To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation. ⁴⁴ 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." ⁴⁵

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 healthcare system's committee responsible for 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 healthcare system's processes for its Systems Redesign and Improvement Program, which support "VHA's transformation journey to become a High Reliability Organization." Systems redesign and improvement processes drive organizational change toward the goal of "zero harm" and can create strong cultures of safety. VHA implemented systems redesign and improvement programs to "optimize Veterans' experience by providing services to develop self-sustaining improvement capability." The OIG team examined various requirements related to systems redesign and improvement:

- Designation of a systems redesign and improvement coordinator
- Tracking of facility-level performance improvement capability and projects
- Participation on the facility quality management committee and VISN Systems Redesign Review Advisory Group
- Staff education on performance improvement principles and techniques

⁴³ Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence, September 21, 2014.

⁴⁴ VHA Directive 1100.16, Accreditation of Medical Facility and Ambulatory Programs, May 9, 2017.

⁴⁵ Department of Veterans Affairs, Veterans Health Administration Blueprint for Excellence.

⁴⁶ VHA Directive 1026.01, VHA Systems Redesign and Improvement Program, December 12, 2019.

⁴⁷ VHA Directive 1026.01.

Next, the OIG assessed the healthcare system's processes for conducting protected peer reviews of clinical care. ⁴⁸ 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." ⁴⁹ Peer reviews are "intended to promote confidential and non-punitive" processes that consistently contribute to quality management efforts at the individual provider level. ⁵⁰ The OIG team examined the completion of the following elements:

- 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 unit⁵¹
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee for Level 3 peer reviews⁵²
- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Finally, the OIG assessed the healthcare system's surgical program. The VHA National Surgery Office provides oversight for surgical programs and "promotes systems and practices that enhance high quality, safe, and timely surgical care." The National Surgery Office's principles, which guide the delivery of comprehensive surgical services at local, regional, and national levels, include "(1) Operational oversight of surgical services and quality improvement activities; (2) Policy development; (3) Data stewardship; and (4) Fiduciary responsibility for select

⁴⁸ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a "critical review of care, performed by a peer," to evaluate care provided by a clinician for a specific episode of care, identify learning opportunities for improvement, provide confidential communication of the results back to the clinician, and identify potential system or process improvements. In the context of protected peer reviews, "protected" refers to the designation of review as a confidential quality management activity under 38 U.S.C. § 5705 as "a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or improving the utilization of health-care resources in VA facilities."

⁴⁹ VHA Directive 1190.

⁵⁰ VHA Directive 1190.

⁵¹ VHA Directive 1190.

⁵² VHA Directive 1190. A peer review is assigned a Level 3 when "most experienced and competent clinicians would have managed the case differently."

⁵³ "NSO Reporting, Resources, & Tools," VA Surgical Quality Improvement Program, accessed November 21, 2020, https://vaww.nso.med.va.gov/apps/VASQIP/Pages/Default.aspx. (This is an internal VA website not publicly accessible.)

specialty programs."⁵⁴ The healthcare system's performance was assessed on several dimensions:

- Assignment and duties of a chief of surgery
- Assignment and duties of a surgical quality nurse (registered nurse)
- Establishment of a surgical work group with required members who meet at least monthly
- Surgical work group tracking and review of quality and efficiency metrics
- Investigation of adverse events⁵⁵

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, systems redesign and improvement documents and reports, protected peer reviews, National Surgery Office reports, and other relevant information.⁵⁶

Quality, Safety, and Value Findings and Recommendations

The healthcare system complied with most of the requirements for a committee responsible for QSV oversight functions, protected peer reviews, and the System Redesign and Improvement Program. However, the OIG identified a deficiency with the Surgical Work Group review of surgical deaths.

VHA requires the medical facility director to ensure the facility has a surgical work group responsible for the "[m]onthly review of surgical deaths, [a]n analysis of efficiency and utilization metrics...[a] review of NSO [National Surgery Office] surgical quality reports, and [a]n evaluation of critical surgical events."⁵⁷ The OIG interviewed leaders and reviewed the Surgical Work Group meeting minutes from March 1, 2020, through February 28, 2021. The OIG found that the Surgical Work Group did not review surgical deaths in 9 of 11 meeting minutes reviewed. The failure to review surgical deaths monthly could result in missed opportunities to identify problematic surgical processes or issues in the practice of one or more providers. The Chief of Staff reported that surgical deaths were reviewed during monthly surgical mortality and morbidity conferences and believed this met the requirement.

⁵⁴ "NSO Reporting, Resources, & Tools."

⁵⁵ VHA Directive 1102.01(1), National Surgery Office, April 24, 2019, amended May 22, 2019.

⁵⁶ For CHIP visits, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁵⁷ VHA Directive 1102.01(1).

Recommendation 2

2. The System Director evaluates and determines any additional reasons for noncompliance and ensures that the Surgical Work Group reviews surgical deaths monthly.

Healthcare system concurred.

Target date for completion: November 30, 2021

Healthcare system response: The System Director evaluated reasons for noncompliance and determined no additional reasons. The Chair, Facility Surgical Work Group, who reports to the Organizational Excellence Council, is responsible for ensuring that monthly surgical death reviews are conducted in workgroup meetings. In February 2021, the Chair, Facility Surgical Work Group instituted the required VISN 8 Chief Surgical Consultant's Morbidity and Mortality All Outcomes Tool to present monthly surgical death reviews. The Chief, Surgery Service will provide Facility Surgical Work Group minutes from April 2021 through September 2021 to the Quality Systems Supervisory Program Analyst. The Quality Systems Supervisory Program Analyst will report monthly aggregate metric compliance to the Continuous Readiness Committee. The Quality Systems Supervisory Program Analyst will additionally report quarterly metrics to the Organizational Excellence Council chaired by the System Director. The numerator will be the number of monthly Facility Surgical Work Group meetings minutes with documentation of surgical death reviews. The denominator will be the number of Facility Surgical Work Group is responsible for the monthly compliance rate of at least 90 percent for two consecutive quarters.

Registered Nurse Credentialing

VHA has defined procedures for the credentialing of registered nurses (RNs) that include verification of "professional education, training, licensure, certification, registration, previous experience, including documentation of any gaps (greater than 30 days) in training and employment, professional references, adverse actions, or criminal violations, as appropriate." Licensure is defined by VHA as "the official or legal permission to practice in an occupation, as evidenced by documentation issued by a State in the form of a license and/or registration." ⁵⁹

VA requires all RNs to hold at least one active, unencumbered license.⁶⁰ Individuals who hold a license in more than one state are not eligible for RN appointment if a state has terminated the license for cause or if the RN voluntarily relinquished the license after written notification from the state of potential termination for cause.⁶¹ When an action has been "taken against [an] applicant's sole license or against any of the applicant's licenses, a review by the Chief, Human Resources Management Service, or the Regional Counsel, must be completed to determine whether the applicant satisfies VA's licensure requirements," and documented as required.⁶² Additionally, all current and previously held licenses must be verified from the primary or original source and documented in VetPro, VHA's electronic credentialing system, prior to appointment to a VA medical facility.⁶³

The OIG assessed compliance with VA licensure requirements by conducting interviews with key managers and reviewing relevant documents for 156 RNs who were hired from January 1, 2020, through February 13, 2021. The OIG determined whether

- the RNs were free from potentially disqualifying licensure actions, or
- the Chief, Human Resources Management Service or Regional Counsel determined that the RNs met VA licensure requirements.

The OIG also reviewed the credentialing files for 32 of the 156 RNs to determine whether healthcare system staff completed primary source verification prior to the appointment.

⁶² VHA Directive 2012-030.

⁵⁸ VHA Directive 2012-030, Credentialing of Health Care Professionals, October 11, 2012.

⁵⁹ VHA Directive 1100.18, Reporting and Responding to State Licensing Boards, January 28, 2021.

⁶⁰ VA Directive 2012-030. "Definition of *Unencumbered license*," Law Insider, accessed December 3, 2020, https://www.lawinsider.com/dictionary/unencumbered-license. An unencumbered license is "a license that is not revoked, suspended, or made probationary or conditional by the licensing or registering authority in the respective jurisdiction as a result of disciplinary action."

⁶¹ 38 U.S.C. § 7402.

⁶³ VHA Directive 2012-030.

Registered Nurse Credentialing Findings and Recommendations

The healthcare system generally met the requirements listed above. The OIG made no recommendations.

Medication Management: Remdesivir Use in VHA

On May 1, 2020, the Food and Drug Administration (FDA) authorized the emergency use of remdesivir. At that time, remdesivir was an unapproved, investigational antiviral medication for the treatment of adults and children hospitalized with severe COVID-19.⁶⁴ The FDA provided information on specific laboratory tests to be ordered prior to and during the administration of remdesivir. Additionally, the FDA required providers to report potentially related adverse events.⁶⁵

VA issued a memorandum on May 8, 2020, which outlined the use of remdesivir under the FDA's Emergency Use Authorization criteria. ⁶⁶ Due to the limited supply and specific storage requirements of remdesivir, VA needed someone to be available 24 hours a day, 7 days a week to accept overnight, cold-chain shipments of the drug and report any unused medication to the Emergency Pharmacy Services group. ⁶⁷

On August 28, 2020, the FDA amended the Emergency Use Authorization criteria for remdesivir to include "suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients." The FDA subsequently approved remdesivir on October 22, 2020, for use in adult patients requiring hospitalization for the treatment of COVID-19.69

To determine whether VHA facilities complied with requirements related to the administration of remdesivir, the OIG interviewed key employees and managers and reviewed electronic health records of the 40 patients who were administered remdesivir under Emergency Use Authorization from May 8 through October 21, 2020. The OIG assessed the following performance indicators:

• Staff availability to receive medication shipments

⁶⁴ Gilead Sciences, Fact Sheet for Health Care Providers: Emergency use Authorization (EUA) of Veklury (remdesivir), May 1, 2020, revised August 2020. Food and Drug Administration, Frequently Asked Questions for Veklury (remdesivir), updated February 4, 2021.

⁶⁵ Gilead Sciences, Fact Sheet for Health Care Providers: Emergency use Authorization (EUA) of Veklury (remdesivir).

⁶⁶ Assistant Under Secretary for Health for Operations Memorandum, *Remdesivir Distribution for Department of Veterans Affairs (VA) Patients*, May 8, 2020.

⁶⁷ Centers for Disease Control and Prevention, *Vaccine Storage and Handling Kit*, May 2014. "The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccine(s) to the distributor, then delivery and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage conditions must be maintained at every link in the cold chain." Assistant Under Secretary for Health for Operations Memorandum, *Remdesivir Distribution for Department of Veterans Affairs (VA) Patients*.

⁶⁸ Food and Drug Administration, "FDA News Release: COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19," August 28, 2020.

⁶⁹ Food and Drug Administration, "FDA News Release: FDA Approves First Treatment for COVID-19," October 22, 2020.

- Medication orders used proper name
- Staff determined patients met criteria for receiving medication prior to administration
- Required testing completed prior to medication administration for
 - Potential pregnancy
 - Kidney assessment (estimated glomerular filtration rate)⁷⁰
 - o Liver assessment (alanine transferase or serum glutamic pyruvic transaminase)⁷¹
- Patient/caregiver education provided
- Staff reported any adverse events to the FDA

Medication Management Findings and Recommendations

The healthcare system complied with many of the indicators of expected performance, including staff availability to receive remdesivir shipments, provision of required testing prior to remdesivir administration, and reporting adverse events. However, the OIG identified deficiencies with patient or caregiver education prior to remdesivir administration.

Under the Emergency Use Authorization, the VA Pharmacy Benefits Management Services required healthcare providers to provide the *Fact Sheet for Patients and Parents/Caregivers* and inform patients or caregivers that remdesivir was not an FDA-approved medication prior to the administration. The OIG determined that 100 percent of the electronic health records lacked evidence the patients or caregivers were provided with the required education prior to remdesivir administration. Specifically, the OIG found 38 percent of electronic health records lacked evidence the patient or caregivers were given the *Fact Sheet for Patients and Parents/Caregivers*; 80 percent lacked evidence the patient or caregivers were informed that remdesivir was not an FDA-approved drug; 75 percent lacked evidence the patient or caregivers were informed of the significant known and potential risks and benefits; and 100 percent lacked evidence that patients or caregivers were informed of alternatives to receiving remdesivir prior to administration. This could have resulted in patients or caregivers lacking the information needed

⁷⁰ "Estimated Glomerular Filtration Rate (eGFR)," National Kidney Foundation, accessed December 9, 2020, https://www.kidney.org/atoz/content/gfr. "Estimated glomerular filtration rate [eGFR] is the best test to measure your level of kidney function and determine your stage of kidney disease."

⁷¹ "Alanine transferase," National Cancer Institute, accessed December 9, 2020, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/alanine-transferase. Alanine transferase also referred to as serum glutamate pyruvate transaminase, is "an enzyme found in the liver and other tissues," of which a high level may be indicative of liver damage.

⁷² VA Pharmacy Benefits Management Services, *Remdesivir Emergency Use Authorization (EUA) Requirements*, May 2020.

to make a fully informed decision to receive the medication. Both the Chief, Pulmonary and Supervisor, Pharmacy, reported believing providers communicated all required patient/caregiver education prior to remdesivir treatment despite lacking awareness of the requirement to document each patient education element.

Given the FDA's approval of remdesivir for use in adult patients requiring hospitalization for the treatment of COVID-19 on October 22, 2020, the OIG made no recommendations related to the requirements under the Emergency Use Authorization.⁷³

⁷³ Food and Drug Administration, "FDA News Release: FDA Approves First Treatment for COVID-19."

Mental Health: Emergency Department and Urgent Care Center Suicide Risk Screening and Evaluation

Suicide prevention remains a top priority for VHA. Suicide is the 10th leading cause of death, with over 47,000 lives lost across the United States in 2019.⁷⁴ The suicide rate for veterans was 1.5 times greater than for nonveteran adults and estimated to represent approximately 13.8 percent of all suicide deaths in the United States during 2018.⁷⁵ However, suicide rates among veterans who recently used VHA services decreased by 2.4 percent between 2017 and 2018.⁷⁶

VHA has implemented various evidence-based approaches to reduce veteran suicides. In addition to expanded mental health services and community outreach, VHA has adopted a three-phase process to screen and assess for suicide risk in most clinical settings. The phases include primary and secondary screens and a comprehensive assessment. However, screening for patients seen in emergency departments or urgent care centers begins with the secondary screen, the Columbia-Suicide Severity Rating Scale, and subsequent completion of the Comprehensive Suicide Risk Assessment when screening is positive. The OIG examined whether staff initiated the Columbia-Suicide Severity Rating Scale and completed all required elements.

Additionally, VHA requires intermediate, high-acute, or chronic risk for suicide patients to have a suicide safety plan completed or updated prior to discharge from the emergency department or urgent care center.⁷⁸ The healthcare system was assessed for its adherence to the following requirements for suicide safety plans:

- Completion of suicide safety plans by required staff
- Completion of mandatory training by staff who develop suicide safety plans

To determine whether VHA facilities complied with selected requirements for suicide risk screening and evaluation within emergency departments and urgent care centers, the OIG inspection team interviewed key employees and reviewed

• relevant documents;

⁷⁴ "Suicide Prevention: Facts About Suicide," Centers for Disease Control and Prevention, accessed December 9, 2020, https://www.cdc.gov/violenceprevention/suicide/fastfact.html.

⁷⁵ Office of Mental Health and Suicide Prevention, *2020 National Veteran Suicide Prevention Annual Report*, November 2020.

⁷⁶ Office of Mental Health and Suicide Prevention, 2020 National Veteran Suicide Prevention Annual Report.

⁷⁷ Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Suicide Risk Screening and Assessment Requirements*, May 23, 2018; Department of Veterans Affairs, *Department of Veterans Affairs (VA) Suicide Risk Identification Strategy: Minimum Requirements by Setting*, December 18, 2019.

⁷⁸ DUSHOM Memorandum, *Eliminating Veteran Suicide: Implementation Update on Suicide Risk Screening and Evaluation (Risk ID Strategy) and the Safety Planning for Emergency Department (SPED) Initiatives*, October 17, 2019.

- the electronic health records of 50 randomly selected patients who were seen in the emergency department/urgent care center from December 1, 2019, through August 31, 2020; and
- staff training records.

Mental Health Findings and Recommendations

The healthcare system complied with requirements related to suicide prevention screening within emergency departments and urgent care centers. However, the OIG did not find evidence that the staff responsible for suicide safety plan development consistently completed the required training.

VHA requires staff to complete mandatory suicide safety plan training prior to developing suicide safety plans with patients. The OIG reviewed the training records for 10 staff responsible for suicide prevention safety plan development and found that 70 percent lacked evidence that the staff completed the mandatory training. Lack of training could prevent employees from providing optimal treatment to veterans who are at risk for suicide. The acting Chief, Mental Health and Behavioral Sciences Service and the Chief, Social Work reported that some fee-basis providers and social workers were inadvertently omitted on the email groups used to assign the training.

Recommendation 3

3. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that staff complete mandatory suicide safety plan training prior to developing suicide prevention safety plans.

⁷⁹ DUSHOM Memorandum, Eliminating Veteran Suicide: Implementation Update on Suicide Risk Screening and Evaluation (Risk ID Strategy) and the Safety Planning for Emergency Department (SPED Initiative); Department of Veterans Affairs (VA) Suicide Prevention Safety Plan and Suicide Behavior and Overdose Report (SBOR) Templates: Staff Specific Guidance, April 17, 2019.

Healthcare system concurred.

Target date for completion: April 30, 2022

Healthcare system response: The Chief of Staff evaluated the reasons for noncompliance and determined there were no additional reasons. The Education Program Specialist, who reports to the Supervisor, Healthcare Education Officer, who reports to the Associate Chief of Staff (who is the Chief of Education), will assign Talent Management System course VA-36232, Suicide Safety Planning Training, to all psychiatrists, psychologists, psychiatric nurse practitioners, social workers, and licensed mental health counselors (to include fee basis providers) from the Mental Health and Behavioral Sciences Service, as well as to all social workers providing services and/or coverage in the Emergency Department with completion date to be within 30 days of their Entrance on Duty date. The Suicide Prevention Coordinator will retrieve Talent Management System training compliance reports for this demographic and provide it along with the compliance rate to the Acting Chief, Mental Health and Behavioral Sciences Service and the Chief, Social Work monthly. The Acting Chief, Mental Health and Behavioral Sciences Service and Chief, Social Work will monitor the reports and follow up with any non-compliant staff to ensure the required training is completed within 30 days of the employees' Entrance on Duty date. As of October 1, 2021, the Suicide Prevention Coordinator or designee will email monthly aggregate suicide safety plan training compliance rates for the previously identified demographic to the Supervisory Program Analyst, who reports to the Chief, Quality Systems Service. This same Supervisory Program Analyst will report monthly aggregate compliance metrics to the Continuous Readiness Committee and quarterly metrics to the Organizational Excellence Council, of which the Chief of Staff is a required member. The compliance numerator will be the number of Mental Health and Behavioral Sciences Service providers (to include fee basis providers), and social workers providing services and/or coverage in the Emergency Department, who completed Talent Management System course VA-36232 within 30 days of their Entrance on Duty date. The compliance denominator will be the number of Mental Health and Behavioral Sciences Service providers (including fee basis providers) and social workers required to complete the suicide safety plan training. The goal is a 90 percent or greater compliance for six consecutive months.

Care Coordination: Inter-facility Transfers

Inter-facility transfers are necessary to provide access to specific providers, services, or levels of care. While there are inherent risks in moving an acutely ill patient between facilities, there is also risk in not transferring the patient when his or her needs can be better managed at another facility.⁸⁰

VHA medical facility directors are "responsible for ensuring that a written policy is in effect that ensures the safe, appropriate, orderly, and timely transfer of patients." Further, VHA staff are required to use the VA *Inter-Facility Transfer Form* or a facility-defined equivalent note in the electronic health record to monitor and evaluate all transfers. 82

The healthcare system was assessed for its adherence to various requirements:

- Existence of a facility policy for inter-facility transfers
- Monitoring and evaluation of inter-facility transfers
- Completion of all required elements of the *Inter-Facility Transfer Form* or facility-defined equivalent by the appropriate provider(s) prior to patient transfer
- Transmission of patient's active medication list and advance directive to the receiving facility
- Communication between nurses at sending and receiving facilities

To determine whether the healthcare system complied with OIG-selected inter-facility transfer requirements, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 43 patients who were transferred from the healthcare system due to urgent needs to a VA or non-VA facility from July 1, 2019, through June 30, 2020.

Care Coordination Findings and Recommendations

The OIG observed general compliance with most of the expectations for inter-facility transfers. However, the OIG identified a deficiency with documented transmission of patients' advance directives to receiving facilities.

VHA requires facilities to "send all pertinent medical records available, including an active patient medication list and any medications given to the patient prior to transfer with the patient,

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⁸⁰ VHA Directive 1094, Inter-Facility Transfer Policy, January 11, 2017.

⁸¹ VHA Directive 1094.

⁸² VHA Directive 1094. A completed VA *Inter-Facility Transfer Form* or an equivalent note communicates critical information to facilitate and ensure safe, appropriate, and timely transfer. Critical elements include documentation of patients' informed consent, medical and/or behavioral stability, mode of transportation and appropriate level of care required, identification of transferring and receiving physicians, and proposed level of care after transfer.

including documentation of the patient's advance directive made prior to transfer, if any."⁸³ The OIG determined that providers did not send a copy of the advance directive to the receiving facility for the 15 applicable patients. As a result, there was no assurance that the receiving facility could determine patient preferences regarding future healthcare decisions in the event the patient no longer had decision-making capability.⁸⁴ The Chief, Health Administration Service stated a packet with the required information was sent with transferred patients but was not documented in the electronic health records as required.

Due to the small number of patients identified for this requirement, the OIG made no recommendation.

⁸³ VHA Directive 1094.

⁸⁴ VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives, December 24, 2013.

High-Risk Processes: Management of Disruptive and Violent Behavior

VHA defines disruptive behavior as "behavior by any individual that is intimidating, threatening, dangerous, or that has, or could, jeopardize the health or safety of patients, Department of Veterans Affairs (VA) employees, or individuals at the facility." Balancing the rights and healthcare needs of violent and disruptive patients with the health and safety of other patients, visitors, and staff poses a significant challenge for VHA facilities. VHA has "committed to reducing and preventing disruptive behaviors and other defined acts that threaten public safety through the development of policy, programs, and initiatives aimed at patient, visitor, and employee safety." The OIG examined various requirements for the management of disruptive and violent behavior:

- Development of a policy for reporting and tracking disruptive behavior
- Implementation of an employee threat assessment team⁸⁷
- Establishment of a disruptive behavior committee or board that holds consistently attended meetings⁸⁸
- Use of the Disruptive Behavior Reporting System to document the decision to implement an Order of Behavioral Restriction⁸⁹
- Patient notification of an Order of Behavioral Restriction
- Completion of the annual Workplace Behavioral Risk Assessment with involvement from required participants⁹⁰

⁸⁷ VHA Directive 2012-026. An employee threat assessment team is "a facility-level, interdisciplinary team whose primary charge is using evidence-based and data-driven practices for addressing the risk of violence posed by employee-generated behavior(s), that are disruptive or that undermine a culture of safety."

⁸⁵ VHA Directive 2012-026, Sexual Assaults and Other Defined Public Safety Incidents in Veterans Health Administration (VHA) Facilities, September 27, 2012.

⁸⁶ VHA Directive 2012-026.

⁸⁸ VHA Directive 2012-026. VHA defines a disruptive behavior committee or board as "a facility-level, interdisciplinary committee whose primary charge is using evidence-based and data-driven practices for preventing, identifying, assessing, managing, reducing, and tracking patient-generated disruptive behavior."

⁸⁹ DUSHOM Memorandum, *Actions Needed to Ensure Medical Facility Workplace Violence Prevention Programs* (WVPP) Meet Agency Requirements, July 20, 2018. VA requires each medical facility's disruptive behavior committee "to use the Disruptive Behavior Reporting System (DBRS) to document a decision to implement an Order of Behavioral Restriction (OBR) and to document notification of a patient when an OBR is issued."

⁹⁰ DUSHOM Memorandum, *Workplace Behavioral Risk Assessment (WBRA)*, October 19, 2012. The Workplace Behavioral Risk Assessment is a "data-driven process that evaluates the unique constellation of factors that affect workplace safety. It enables facilities to make informed, supportable decisions regarding the level of PMDB [Prevention and Management of Disruptive Behavior] training needed to sustain a culture of safety in the workplace."

VHA also requires that all staff complete part 1 of the prevention and management of disruptive behavior training within 90 days of hire. The Workplace Behavioral Risk Assessment results are used to assign additional levels of training. When the assessment results deem a facility location as low or moderate risk, staff working in the area are also required to complete part 2 of the training. When results indicate high-risk, staff are required to complete parts 1, 2, and 3 of the training. VHA also requires that employee threat assessment team members complete the appropriate team-specific training. The OIG assessed staff compliance with the completion of required training.

To determine whether VHA facilities implemented and incorporated OIG-identified key processes for the management of disruptive and violent behavior, the inspection team examined relevant documents and training records and interviewed key managers and staff.

High-Risk Processes Findings and Recommendations

The OIG found the healthcare system addressed many of the indicators of expected performance for the management of disruptive and violent behavior. However, the OIG found deficiencies with Disruptive Behavior Committee attendance and patient notification of an Order of Behavioral Restriction that included the required elements.

VHA requires that the Chief of Staff and Nurse Executive (ADPCS) establish a disruptive behavior committee or board that includes a senior clinician as the chairperson; administrative support staff; a patient advocate; and representatives from the Prevention and Management of Disruptive Behavior Program, VA police, patient safety or risk management, and the Union Safety Committee. The OIG found that from March 1, 2020, through February 28, 2021, representatives from the Prevention and Management of Disruptive Behavior Program and patient safety or risk management did not attend 2 of 12 meetings. This could result in a lack of knowledge and expertise when assessing patients' disruptive behavior. The Chair, Disruptive Behavior Committee reported not being aware that a new Prevention and Management of Disruptive Behavior Program Coordinator had been assigned. Additionally, the chairperson stated that a staffing vacancy and competing priorities also contributed to the deficiency.

⁹¹ DUSHOM Memorandum, *Update to Prevention and Management of Disruptive Behavior (PMDB) Training Assignments*, February 24, 2020.

⁹² DUSHOM Memorandum, Actions Needed to Ensure Medical Facility Workplace Violence Prevention Programs (WVPP) Meet Agency Requirements.

⁹³ VHA Directive 2010-053.

Recommendation 4

4. The Chief of Staff and Associate Director for Patient Care Services evaluate and determine any additional reasons for noncompliance and ensure all required members attend Disruptive Behavior Committee meetings.

Healthcare system concurred.

Target date for completion: April 30, 2022

Healthcare system response: The Chief of Staff and Associate Director for Patient Care Services evaluated reasons for noncompliance and determined no additional reasons. The Chair, Disruptive Behavior Committee is responsible for Disruptive Behavior Committee attendance oversight and monitoring attendance at all meetings to ensure attendance by required members or their designated representative, the Chair, Disruptive Behavior Committee, prevention management of disruptive behavior program representative, VA police, health administration and/or privacy officer, patient safety/risk management, and patient advocate. The Disruptive Behavior Committee reports to the Violence Prevention Management Committee. As of September 1, 2021, the Chair, Disruptive Behavior Committee will monitor and report monthly aggregate meeting attendance metrics to the Quality Systems Supervisory Program Analyst. The Quality Systems Supervisory Program Analyst will report aggregate metric compliance to the Continuous Readiness Committee and report quarterly metrics to the Organizational Excellence Council, chaired by the System Director. The Chief of Staff and Associate Director, Patient Care Services are required members of this Council. The Chair, Disruptive Behavior Committee will determine meeting attendance metrics through reviews of the Disruptive Behavior Committee minutes attendance rosters. The aggregated attendance metric numerator is the number of required members attended. The aggregated attendance metric denominator is the total number attendance by each required member. Attendance metrics shall be reported monthly until 90 percent compliance is sustained for two consecutive quarters (six months).

VHA requires the Disruptive Behavior Committee to document patient notification of Orders of Behavioral Restriction, with information regarding the patient's right to appeal the order and the appeal process, in the Disruptive Behavior Reporting System. ⁹⁴ The OIG reviewed 30 entries of Orders of Behavioral Restriction from March 1, 2020, through February 28, 2021. The OIG determined all notifications lacked information regarding the right to appeal and the appeal process. This could result in missed opportunities for patients to be fully informed of their right to appeal the decision and the appeal process. The Chair, Disruptive Behavior Committee reported being aware that the patient notification letters lacked the mandatory appeal

⁹⁴ DUSHOM Memorandum, Actions Needed to Ensure Medical Facility Workplace Violence Prevention Programs (WVPP) Meet Agency Requirements.

information. Additionally, the Chief of Staff stated that the Disruptive Behavior Committee had not followed the formal healthcare system process to request a revision to the notification letter.

Recommendation 5

5. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures patient notification of Orders of Behavioral Restriction in the Disruptive Behavior Reporting System include information regarding patients' right to appeal the orders and the appeals process.

Healthcare system concurred.

Target date for completion: April 30, 2022

Healthcare system response: The Chief of Staff evaluated reasons for noncompliance and determined no additional reasons. The Chair, Disruptive Behavior Committee is responsible for Disruptive Behavior Committee oversight and the monitoring of Order of Behavioral Restriction letters to ensure patients are informed of their right to appeal the Order of Behavioral Restriction and the appeals process. On March 26, 2021, a Mental Health and Behavioral Sciences Service social worker updated the patient notifications of Order of Behavioral Restriction in the Disruptive Behavior Reporting System to include an additional instruction page addressing "How to Appeal a Patient Record Flag Order of Behavioral Restrictions" which clarifies the 30day timeframe the patient may use to appeal the restriction. As of September 1, 2021, the Chair, Disruptive Behavior Committee, will monitor and report the right to appeal the Order of Behavioral Restriction and the appeal process aggregate monthly metrics for Order of Behavioral Restriction letters to the Quality Systems Supervisory Program Analyst with a goal of 90 percent of Order of Behavioral Restriction letters to include the appeals process and instructions. Monthly, the Quality Systems Supervisory Program Analyst will report aggregate metric compliance to the Continuous Readiness Committee and report compliance data to the Organizational Excellence Council that is chaired by the System Director and the Chief of Staff is a required member. The compliance numerator is the number of Order of Behavioral Restriction letters including the appeals process information that are completed as evidence by audit conducted by the Chair, Disruptive Behavior Committee. The process compliance denominator is the number of Patient Record Flag Order of Behavioral Restrictions assigned during the month. The Chair, Disruptive Behavior Committee is responsible for Order of Behavioral Restriction notification and appeals process letter metrics reporting monthly until 90 percent compliance is sustained for two consecutive quarters (six months).

Report Conclusion

The OIG acknowledges the inherent challenges of operating VA medical facilities, especially during times of unprecedented stress on the U.S. healthcare system. To assist leaders in evaluating the quality of care at their healthcare system, the OIG conducted a detailed review of eight clinical and administrative areas and provided five recommendations on issues that may adversely affect patients. While the OIG's recommendations are not a comprehensive assessment of the caliber of services delivered at this healthcare system, they illuminate areas of concern and guide improvement efforts. A summary of recommendations is presented in appendix A.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

The table below outlines five OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events. The recommendations are attributable to the System Director, Chief of Staff, and Associate Director for Patient Care Services. The intent is for these leaders to use these recommendations to guide improvements in operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if left unattended, may potentially interfere with the delivery of quality health care.

Table A.1. Summary Table of Recommendations

Healthcare Processes	Review Elements	Critical Recommendations for Improvement	Recommendations for Improvement
Leadership and Organizational Risks	 Executive leadership position stability and engagement Budget and operations Staffing Employee satisfaction Patient experience Accreditation surveys and oversight inspections Identified factors related to possible lapses in care and healthcare system response VHA performance data (healthcare system) VHA performance data (CLC) 	The system discloses adverse events that require an institutional disclosure.	• None
COVID-19 Pandemic Readiness and Response	 Emergency preparedness Supplies, equipment, and infrastructure Staffing Access to care CLC patient care and operations Staff feedback 	The OIG will report the repandemic readiness and this healthcare system as separate publication to pa more comprehensive pathallenges and ongoing of the original systems.	response evaluation for nd other facilities in a rovide stakeholders with icture of regional VHA

Healthcare Processes	Review Elements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	 QSV committee Systems redesign and improvement Protected peer reviews Surgical program 	• None	The Surgical Work Group reviews surgical deaths monthly.
RN Credentialing	RN licensure requirementsPrimary source verification	• None	• None
Medication Management: Remdesivir Use in VHA	 Staff availability for medication shipment receipt Medication order naming Satisfaction of inclusion criteria prior to medication administration Required testing prior to medication administration Patient/caregiver education Adverse event reporting to the FDA 	• None	• None
Mental Health: Emergency Department and Urgent Care Center Suicide Risk Screening and Evaluation	 Columbia-Suicide Severity Rating Scale initiation and note completion Suicide safety plan completion Staff training requirements 	Staff complete mandatory suicide safety plan training prior to developing suicide prevention safety plans.	• None

Healthcare Processes	Review Elements	Critical Recommendations for Improvement	Recommendations for Improvement
Care Coordination: Inter-facility Transfers	 Inter-facility transfer policy Inter-facility transfer monitoring and evaluation Inter-facility transfer form/facility-defined equivalent with all required elements completed by the appropriate provider(s) prior to patient transfer Patient's active medication list and advance directive sent to receiving facility Communication between nurses at sending and receiving facilities 	• None	• None
High-Risk Processes: Management of Disruptive and Violent Behavior	 Policy for reporting and tracking of disruptive behavior Employee threat assessment team implementation Disruptive behavior committee or board establishment Disruptive Behavior Reporting System use Patient notification of an Order of Behavioral Restriction Annual Workplace Behavioral Risk Assessment with involvement from required participants Mandatory staff training 	Patient notification of Orders of Behavioral Restriction in the Disruptive Behavior Reporting System include information regarding patients' right to appeal the orders and the appeals process.	All required members attend Disruptive Behavior Committee meetings.

Appendix B: Healthcare System Profile

The table below provides general background information for this highest complexity (1a) affiliated healthcare system reporting to VISN 8.¹

Table B.1. Profile for Bay Pines VA Healthcare System (516) (October 1, 2017, through September 30, 2020)

Profile Element	Healthcare System Data FY 2018*	Healthcare System Data FY 2019 [†]	Healthcare System Data FY 2020 [‡]
Total medical care budget	\$837,798,688	\$875,407,659	\$1,108,367,452
Number of:	109,473	111,092	109,417
Unique patients			
 Outpatient visits 	1,453,832	1,433,267	1,379,807
• Unique employees§	3,461	3,516	3,949
Type and number of operating beds:			
Community living center	112	112	112
Domiciliary	99	99	99
Medicine	106	106	106
Mental health	33	33	33
Rehabilitation medicine	8	8	8
Surgery	39	35	35
Average daily census:			
 Community living center 	87	79	54
Domiciliary	76	76	54
Medicine	81	90	82
Mental health	29	25	20
Rehabilitation medicine	6	7	4

¹ "Facility Complexity Model," VHA Office of Productivity, Efficiency & Staffing (OPES), accessed August 20, 2021, http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx. (This is an internal website not publicly accessible.) VHA medical centers are classified according to a facility complexity model; a designation of "1a" indicates a facility with "high volume, high risk patients, most complex clinical programs, and large research and teaching programs." An affiliated healthcare system is associated with a medical residency program.

Profile Element	Healthcare	Healthcare	Healthcare
	System Data	System Data	System Data
	FY 2018*	FY 2019 [†]	FY 2020 [‡]
 Surgery 	18	16	12

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

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

^{*}October 1, 2017, through September 30, 2018.

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

[‡]October 1, 2019, through September 30, 2020.

[§]Unique employees involved in direct medical care (cost center 8200).

Appendix C: VA Outpatient Clinic Profiles

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

Table C.1. VA Outpatient Clinic Workload/Encounters and Specialty Care, Diagnostic, and Ancillary Services Provided (October 1, 2019, through September 30, 2020)

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Cape Coral, FL	516BZ	40,328	12,931	Cardiology Cardio thoracic Dermatology Eye Gastroenterology General surgery GYN Nephrology Neurosurgery Orthopedics Otolaryngology	EKG Laboratory & Pathology Nuclear med Radiology Vascular lab	Dental Nutrition Pharmacy Prosthetics Social work Weight management

¹ VHA Directive 1230(4), *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended June 17, 2021. An encounter is a "professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient's condition." Specialty care services refer to non-primary care and non-mental health services provided by a physician.

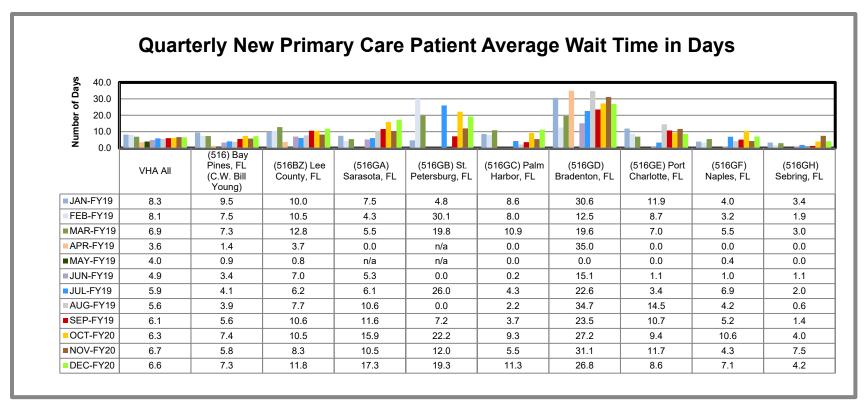
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Cape Coral, FL (continued)				Podiatry Pulmonary/ Respiratory disease Rehab physician Urology		
Sarasota, FL	516GA	12,950	4,583	Cardiology Dermatology Gastroenterology GYN Nephrology	EKG Laboratory & Pathology Nuclear med	Nutrition Pharmacy Social work Weight management
St. Petersburg, FL	516GB	3,926	916	Cardiology	EKG Laboratory & Pathology	Nutrition Pharmacy Social work Weight management
Palm Harbor, FL	516GC	11,572	3,383	Cardiology Gastroenterology	EKG Laboratory & Pathology	Nutrition Pharmacy Weight management
Bradenton, FL	516GD	13,890	3,863	Cardiology Dermatology Eye Gastroenterology GYN Nephrology Pulmonary/ Respiratory disease	EKG Laboratory & Pathology Nuclear med Radiology	Dental Nutrition Pharmacy Social work Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Port Charlotte, FL	516GE	14,702	3,346	Cardiology Dermatology Eye Nephrology	Laboratory & Pathology Nuclear med	Nutrition Pharmacy Social work Weight management
Naples, FL	516GF	12,592	2,219	Cardiology Dermatology	Laboratory & Pathology Nuclear med	Nutrition Pharmacy Weight management
Sebring, FL	516GH	8,774	1,966	Dermatology Nephrology Pulmonary/ Respiratory disease	Laboratory & Pathology Nuclear med	Nutrition Pharmacy Weight management

Source: VHA Support Service Center and VA Corporate Data Warehouse.

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

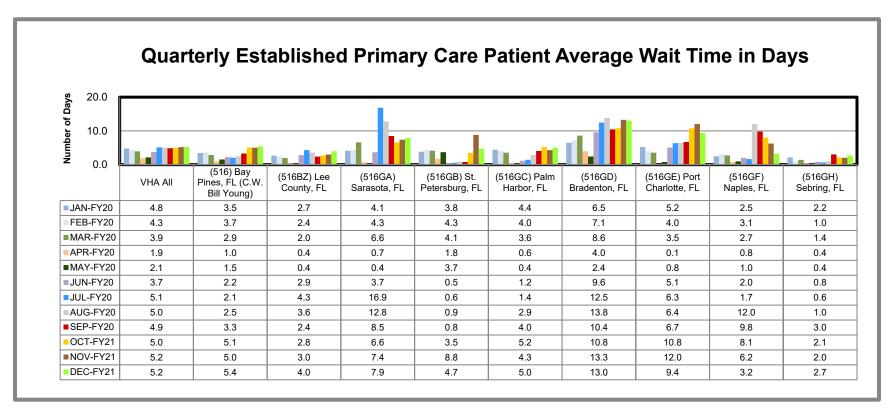
Appendix D: Patient Aligned Care Team Compass Metrics



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

Note: The OIG did not assess VA's data for accuracy or completeness. The OIG has on file the healthcare system's explanation for the increased wait times for the community-based outpatient clinics in Bradenton, Florida.

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



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

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

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

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

Measure	Definition	Desired Direction
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
AES data use	Composite measure based on three individual All Employee Survey (AES) data use and sharing questions	A higher value is better than a lower value
Care transition	Care transition (inpatient)	A higher value is better than a lower value
CMS MORT	Centers for Medicare and Medicaid Services (CMS) risk standardized mortality rate	A lower value is better than a higher value
ED throughput	Composite measure for timeliness of care in the emergency department	A lower value is better than a higher value
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like – HED90_1	Healthcare Effectiveness Data and Information Set (HEDIS) composite score related to outpatient behavioral health screening, prevention, immunization, and tobacco	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS composite score related to outpatient care for diabetes and ischemic heart disease	A higher value is better than a lower value
Hospital Rating (HCAHPS)	Overall rating of hospital stay (inpatient only)	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

Measure	Definition	Desired Direction
Oryx – GM90_1	ORYX inpatient composite of global measures	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
PSI90	Patient Safety and Adverse Events Composite (PSI90) focused on potentially avoidable complications and events	A lower value is better than a higher value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value

Source: VHA Support Service Center.

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

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

Measure	Definition
Receive antipsych meds (LS)	Long-stay measure: percent of residents who received an antipsychotic medication.
Rehospitalized after NH Admission (SS)	Short-stay measure: percent of residents who were re-hospitalized after a nursing home admission.
UTI (LS)	Long-stay measure: percent of residents with a urinary tract infection.

Source: VHA Support Service Center.

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: September 15, 2021

From: Director, VA Sunshine Healthcare Network (10N8)

Subj: Comprehensive Healthcare Inspection of the Bay Pines VA Healthcare System in

Florida

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

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

I have reviewed the VAOIG's report as well as the Bay Pines VA Healthcare System response and concur with the findings, recommendations, and corrective action plans that have been submitted.

(Original signed by:)

Miguel H. LaPuz, M.D., MBA

Network Director, VISN 8

Appendix H: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: September 14, 2021

From: Director, Bay Pines VA Healthcare System (516/00)

Subj: Comprehensive Healthcare Inspection of the Bay Pines VA Healthcare System in

Florida

To: Director, VA Sunshine Healthcare Network (10N8)

 Thank you for the opportunity to provide a response to the findings from the Comprehensive Healthcare Inspection of the Bay Pines VA Healthcare System.

2. I concur with the recommendations and will ensure the actions to correct the findings are completed and sustained as described in the responses. I appreciate the opportunity for this review as a continuing process to improve the care to our Veterans.

(Original signed by:)

Paul M. Russo, MHSA, FACHE, RD

Healthcare System Director/CEO

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Director, Bay Pines VA Healthcare System (516/00)

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