



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare
Inspection of the VA
Northern Indiana Health
Care System in Marion



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Figure 1. VA Northern Indiana Health Care System in Marion.

Source: <https://vaww.va.gov/directory/guide/> (accessed July 23, 2020).

Abbreviations

ADPCS	Associate Director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
COVID-19	coronavirus disease
FPPE	focused professional practice evaluation
FY	fiscal year
HRS	high risk for suicide
LIP	licensed independent practitioner
LST	life-sustaining treatment
LSTD	life-sustaining treatment decision
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
RME	reusable medical equipment
SAIL	Strategic Analytics for Improvement and Learning
SLB	state licensing board
SPC	suicide prevention coordinator
SPS	Sterile Processing Services
TJC	The Joint Commission
UM	utilization management
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 VA Northern Indiana Health Care System, which includes campuses in Fort Wayne and Marion, and multiple outpatient clinics in Indiana. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

1. COVID-19 pandemic readiness and response¹
2. Quality, safety, and value
3. Medical staff privileging
4. Medication management (targeting long-term opioid therapy for pain)
5. Mental health (focusing on the suicide prevention program)
6. Care coordination (spotlighting life-sustaining treatment decisions)
7. Women's health (examining comprehensive care)
8. High-risk processes (emphasizing reusable medical equipment)

The unannounced virtual review was conducted during the week of July 27, 2020. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this 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) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

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](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)."

Inspection Results

The OIG noted opportunities for improvement in several areas reviewed and issued 20 recommendations that are directed 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 Director, acting Chief of Staff, Associate Director for Patient Care Services, Associate Director, and Assistant Director. Organizational communications and accountability were managed through a committee reporting structure, with the Executive Council overseeing several working groups. The leaders monitor patient safety and care through the Quality Executive Board, which is responsible for tracking and trending quality of care and patient outcomes.

When the team conducted this review, the healthcare system's leaders had worked together as a group for nine months, although several had served in their positions for more than a year. The Associate Director for Patient Care Services was the most tenured leader, permanently assigned in August 1998. The Director was assigned in September 2016; the chief of staff position had been vacant since October 2019, with the Deputy Chief of Staff serving in the role in an acting capacity. The Associate Director had served in the position since December 2018 and the Assistant Director was the newest member of the leadership team, assigned in October 2019.

The OIG reviewed employee satisfaction survey results and concluded that employees were generally satisfied, and leaders maintained an environment where employees felt safe bringing forth issues and concerns. However, the selected Inpatient, Patient-Centered Medical Home, and Specialty Care survey questions highlighted opportunities to improve patient satisfaction in the inpatient and outpatient settings.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events, and did not identify any substantial organizational risk factors.² However, the OIG noted that the healthcare system disclosed 114 adverse events to patients and their families. Of those, 109 involved substandard care delivered by a single physician who reportedly left the system in 2017.

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

² 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."

way to understand the similarities and differences between the top and bottom performers within VHA.³

The executive leaders, except for the recently hired Assistant Director, were knowledgeable within their scope of responsibilities about VHA data and/or system-level factors contributing to specific poorly performing Strategic Analytics for Improvement and Learning quality and efficiency measures. In individual interviews, the executive leadership team members were able to speak in depth about actions taken during the previous 12 months to maintain or improve organizational performance, employee satisfaction, or patient experiences.

COVID-19 Pandemic Readiness and Response

The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.⁴

Medical Staff Privileging

The healthcare system complied with the requirements for focused professional practice evaluations. However, the OIG identified deficiencies with ongoing professional practice evaluations, healthcare provider exit review processes, and state licensing board reporting.⁵

Medication Management

The system addressed some of the elements of expected performance, including initial pain screening, documented justification for concurrent therapy with benzodiazepines, patient follow-up, and establishment of a multidisciplinary pain management committee to oversee and monitor required quality measures. However, the OIG identified deficiencies with aberrant behavior risk assessments, urine drug testing, and informed consent.

³ "Strategic Analytics for Improvement and Learning (SAIL) Value Model," VHA Support Service Center, accessed March 6, 2020, <https://vssc.med.va.gov>. (This is an internal VA website not publicly accessible.)

⁴ VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

⁵ Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility."

Mental Health

The healthcare system complied with requirements for a designated suicide prevention coordinator. However, the OIG had concerns with the completion of at least four mental health visits within 30 days of High Risk for Suicide Patient Record Flag placement, suicide safety plans, and staff refresher training.

Women's Health

The healthcare system complied with many of the requirements reviewed for women's health. However, the OIG noted concerns with gynecologic care coverage and the Women Veterans Health Committee.

High-Risk Processes

Generally, the healthcare system met many of the requirements for the proper operations and management of reprocessing reusable medical equipment. However, the OIG noted concerns with the annual risk analysis; daily cleaning schedule; and staff training, competency, and continuing education.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two administrative and seven clinical) and subsequently issued 20 recommendations for improvement to the System Director, Chief of Staff, and Associate Director for Patient Care Services. The number of recommendations should not be used, however, as a gauge for the overall quality of care provided at this system. The intent is for system leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and System Director agreed with the comprehensive healthcare inspection program findings and recommendations and provided acceptable improvement plans. (See appendixes G and H, pages 77–78, and the responses within the body of the report for the full text of the directors’ comments.) The OIG considers recommendations 14, 16, 17, 19, and 20 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.



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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities providing healthcare services to veterans. This report’s evaluation of the quality of care delivered in the inpatient and outpatient settings of the VA Northern Indiana Health Care 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.”³ Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

1. Leadership and organizational risks
2. COVID-19 pandemic readiness and response⁵
3. Quality, safety, and value (QSV)
4. Medical staff privileging

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

² Anam Parand et al., “The Role of Hospital Managers in Quality and Patient Safety: a Systematic Review,” *British Medical Journal*, 4, no. 9 (September 5, 2014), <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, (December 2017): 73, <https://doi.org/10.3390/healthcare5040073>.

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

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

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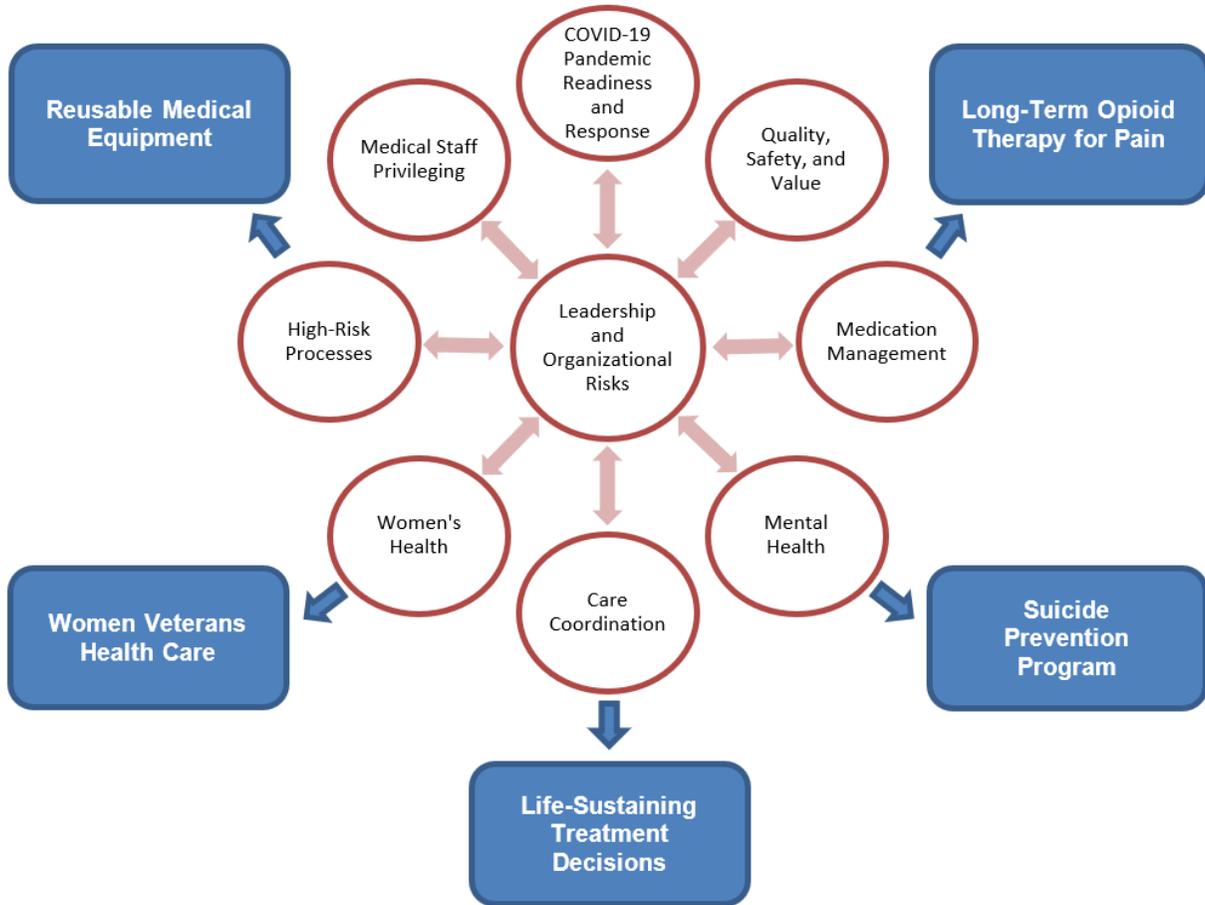


Figure 2. Fiscal year (FY) 2020 comprehensive healthcare inspection of operations and services.

Source: VA OIG.

Methodology

The VA Northern Indiana Health Care System includes inpatient facilities in Marion and Fort Wayne and multiple outpatient clinics in Indiana. 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 March 11, 2017, through July 31, 2020, the last day of the unannounced multiday evaluation.⁷ During the virtual site visit, the OIG did not receive any complaints beyond the scope of the inspection.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.⁹ The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

This report's recommendations for improvement address problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the 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 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 Clinical Assessment Program site visit to the completion of the unannounced, multiday virtual CHIP visit in July 2020.

⁸ VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

⁹ Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3).

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare system. Leadership and organizational risks can affect the healthcare system's ability to provide care in the clinical focus areas.¹⁰ To assess the healthcare system's risks, the OIG considered several indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation surveys and oversight inspections
5. Identified factors related to possible lapses in care and healthcare system response
6. VHA performance data (healthcare system)
7. VHA performance data (community living centers (CLCs))¹¹

Executive Leadership Position Stability and Engagement

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

¹⁰ Laura Botwinick, Maureen Bisognano, and Carol Haraden, *Leadership Guide to Patient Safety*, Institute for Healthcare Improvement, Innovation Series White Paper, 2006.

¹¹ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017. CLCs, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

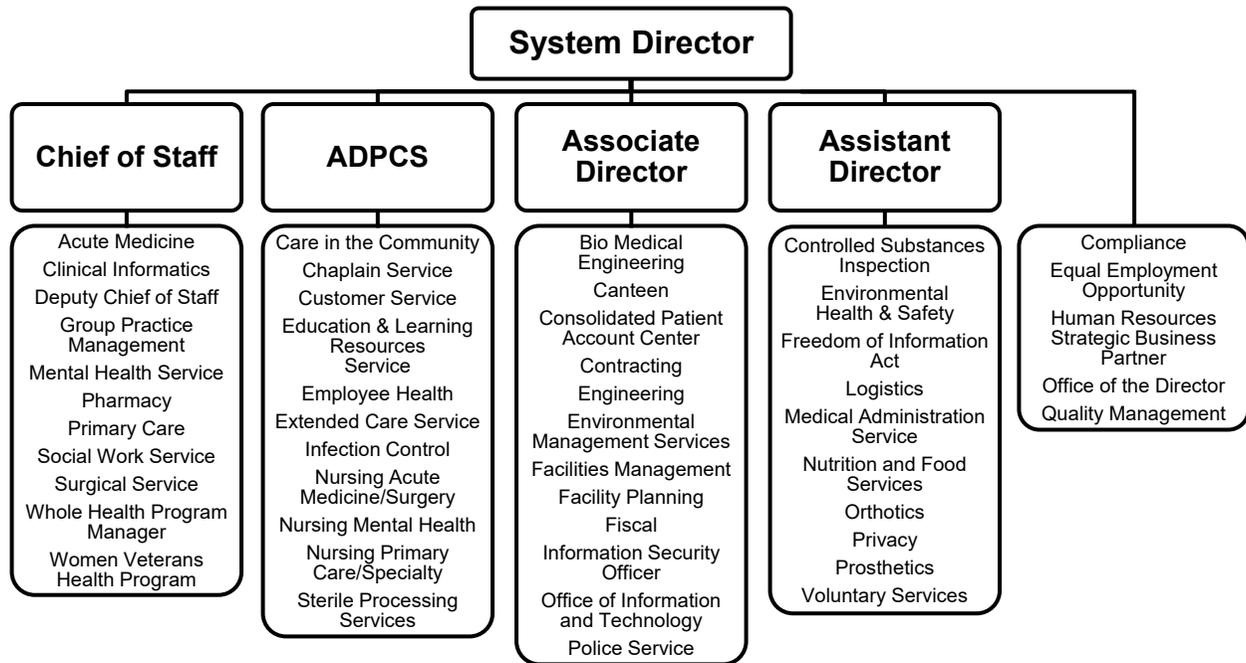


Figure 3. Healthcare system organizational chart.

Source: VA Northern Indiana Health Care System (received July 27, 2020).

At the time of the OIG virtual review, the permanently assigned executive team members had worked together for nine months. The System Director and ADPCS had served in their roles since 2016 and 1998, respectively. The Associate Director had been in the position for more than one year, and the Assistant Director was assigned in October 2019. The chief of staff position had been vacant since October 2019. The Deputy Chief of Staff had been acting in that role since then (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
System Director	September 4, 2016
Chief of Staff	October 11, 2019 (acting)
Associate Director for Patient Care Services	August 2, 1998
Associate Director	December 23, 2018
Assistant Director	October 13, 2019

Source: VA Northern Indiana Health Care System Senior Strategic Business Partner (received July 27, 2020).

To help assess the healthcare system executive leaders’ engagement, the OIG interviewed the Director, acting Chief of Staff, ADPCS, Associate Director, and Assistant Director regarding

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

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

The Director serves as the chairperson of the Executive Council, which has the authority and responsibility to establish policy, maintain quality care standards, and perform organizational management and strategic planning. The Executive Council oversees various working groups including the Clinical Executive, Administrative Executive, Organizational Safety, and Customer Service Boards.

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

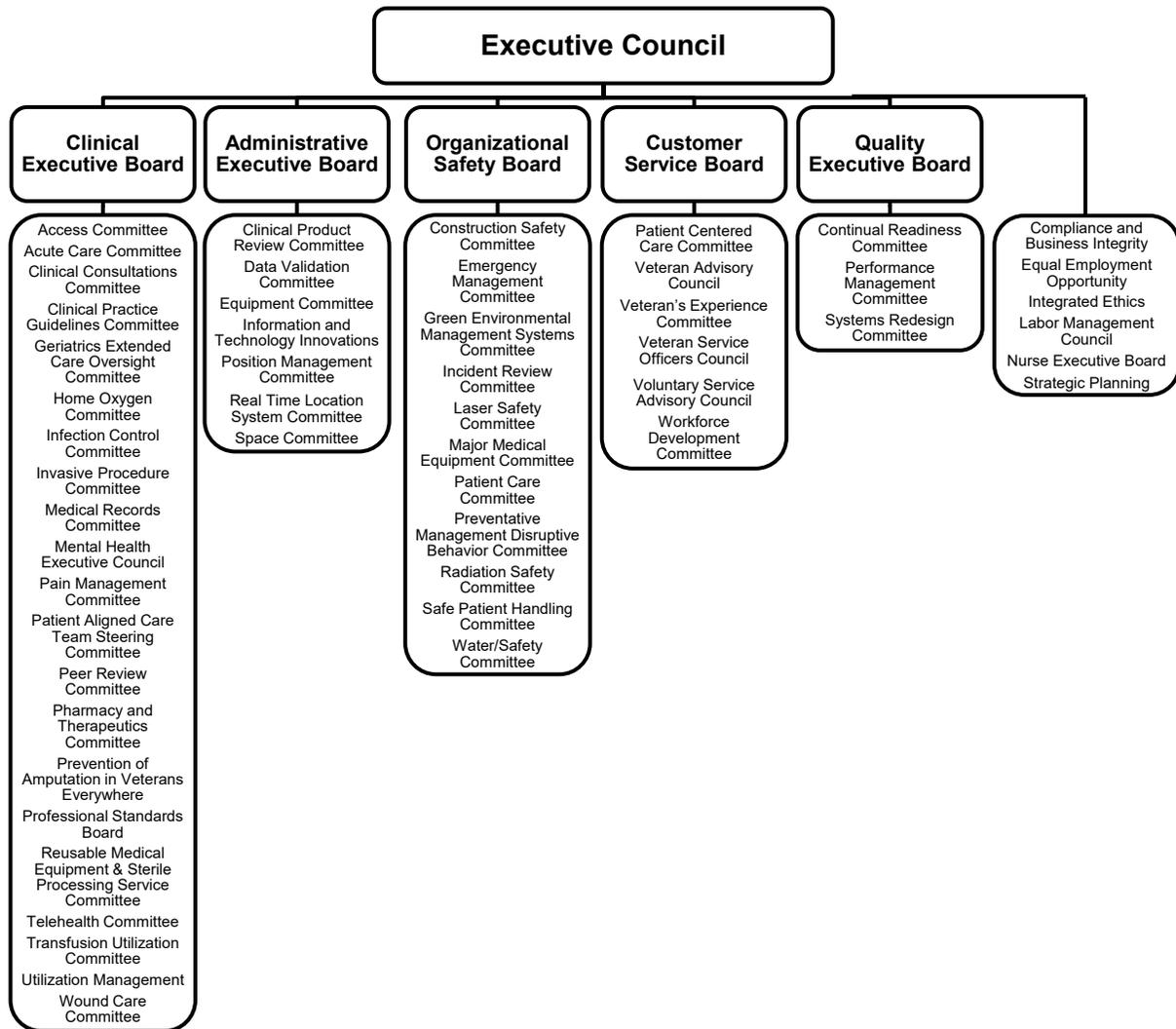


Figure 4. Healthcare system committee reporting structure.

Source: VA Northern Indiana Health Care System (received July 27, 2020).

Employee Satisfaction

The All Employee Survey “is an annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential.” Since 2001, the instrument has been refined several times in response to VA leaders’ inquiries on VA culture and organizational health.¹² Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting

¹² “Survey Instruments” VA Workforce Surveys Portal, VHA Support Service Center, accessed May 3, 2021, <http://aes.vssc.med.va.gov/SurveyInstruments/Pages/default.aspx>. (This is an internal website not publicly accessible.)

point for discussions, indicate areas for further inquiry, and be considered along with other information on healthcare system leadership.

To assess employee attitudes toward healthcare system leaders, the OIG reviewed employee satisfaction survey results from VHA’s All Employee Survey from October 1, 2018, through September 30, 2019.¹³ Table 2 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 questions were lower than the VHA average even though scores for the executive leaders, except the Assistant Director, were similar to or higher than those for VHA and the healthcare system.¹⁴

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

Questions/Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: <i>Servant Leader Index Composite.*</i>	0–100 where higher scores are more favorable	72.6	71.9	95.0	77.9	81.3	73.7	64.1
All Employee Survey: <i>In my organization, senior leaders generate high levels of motivation and commitment in the workforce.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.4	3.2	4.7	3.7	3.6	3.4	3.1

¹³ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Associate Director, and Assistant Director.

¹⁴ 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. It is important to note that the 2019 All Employee Survey results are not reflective of employee satisfaction with the current Assistant Director, who assumed the role after the survey was administered.

Questions/Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: <i>My organization's senior leaders maintain high standards of honesty and integrity.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.4	4.7	3.8	3.8	3.5	3.2
All Employee Survey: <i>I have a high level of respect for my organization's senior leaders.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.4	4.6	3.9	3.6	3.5	3.1

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

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

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA’s All Employee Survey.¹⁵ The healthcare system average for the selected survey questions was similar to the VHA average; the scores for the executive leaders, except the Assistant Director, were generally better than those for VHA and the healthcare system. Leaders appeared to be maintaining an environment where employees feel safe bringing forth issues and concerns.

¹⁵ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Associate Director, and Assistant Director.

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

Questions/Survey Items	Scoring	VHA Average	Health-care System Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: <i>I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.8	3.7	4.9	4.1	4.5	3.8	3.4
All Employee Survey: <i>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).</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.7	3.7	4.6	4.1	3.9	3.7	3.3
All Employee Survey: <i>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)?</i>	0 (Never) – 6 (Every Day)	1.4	1.4	0.8	1.0	1.1	1.2	2.6

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

Patient Experience

To assess patient experiences with the healthcare system, which directly reflect on its leaders, the OIG team reviewed survey results that relate to the period of October 1, 2018, through September 30, 2019. VHA’s Patient Experiences Survey Reports provide results from the Survey of Healthcare Experiences of Patients program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients’ experiences with their health care and to support benchmarking its performance against the private sector.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The OIG reviewed responses to four relevant survey questions that reflect patients’ attitudes toward their healthcare experiences. Table 4 provides relevant survey results for VHA and the healthcare system.¹⁶ For this system, patient survey results—except for one inpatient question (“Would you recommend this hospital to your friends and family?”)—reflected higher ratings than the VHA average. Patients generally appeared satisfied with the care provided.

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

Questions	Scoring	VHA Average	Healthcare System Average
Survey of Healthcare Experiences of Patients (inpatient): <i>Would you recommend this hospital to your friends and family?</i>	The response average is the percent of “Definitely Yes” responses.	68.3	64.3
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	84.9	88.0
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	77.3	78.1

¹⁶ Ratings are based on responses by patients who received care at this healthcare system.

Questions	Scoring	VHA Average	Healthcare System Average
Survey of Healthcare Experiences of Patients (outpatient specialty care): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	78.0	81.4

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

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from 2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.¹⁷ For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients’ experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The results highlight opportunities to improve patient satisfaction in the inpatient and outpatient settings, despite system leaders reporting active engagement with both male and female patients (for example, by providing dedicated providers and space for female veterans, conducting quarterly town hall meetings, and establishing an “open-door” policy for veterans to share their concerns with the Director about what the system can do to improve services).

¹⁷ VA National Center for Veterans Analysis and Statistics, *The Past, Present and Future of Women Veterans*, February 2017.

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

Questions	Scoring	VHA*		Healthcare System †	
		Male Average	Female Average	Male Average	Female Average
<i>During this hospital stay, how often did doctors treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	81.6	-‡
<i>During this hospital stay, how often did nurses treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	85.9	-‡
<i>Would you recommend this hospital to your friends and family?</i>	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	64.2	-‡

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

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

†The healthcare system averages are based on 291–294 male respondents, depending on the question.

‡Data are not available due to a low number of respondents.

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

Questions	Scoring	VHA*		Healthcare System †	
		Male Average	Female Average	Male Average	Female Average
<i>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?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	42.3	39.5
<i>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?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	62.5	56.3
<i>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?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	67.0	67.8

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

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

†The healthcare system averages are based on 521–1,809 male and 23–85 female respondents, depending on the question.

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

Questions	Scoring	VHA*		Healthcare System [†]	
		Male Average	Female Average	Male Average	Female Average
<i>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?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	50.7	‡
<i>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?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	55.0	57.2	69.8
<i>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?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	67.5	87.5

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

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

†The healthcare system averages are based on 362–1,431 male and 5–28 female respondents, depending on the question.

‡Data are not available due to a low number of respondents.

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys—including those conducted for cause—by oversight and accrediting agencies to gauge how well leaders respond to identified problems.¹⁸ Table 8 summarizes the relevant system inspections most recently performed by the OIG and The Joint

¹⁸ “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).¹⁹ Of note, at the time of the OIG virtual review, the system had closed all recommendations for improvement issued since the previous Clinical Assessment Program inspection conducted in March 2017. The Quality Manager reported continuing to work with system managers to address the three open recommendations resulting from a prior focused OIG report on pain management, which was published on July 16, 2019.²⁰

At the time of the virtual review, the OIG team also noted the system’s current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²¹ Additional results included the Long Term Care Institute’s inspection of the system’s CLCs.²²

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

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (<i>Clinical Assessment Program Review of the VA Northern Indiana Health Care System, Fort Wayne, Indiana, Report No. 16-00577-335, August 15, 2017</i>)	March 2017	19	0

¹⁹ 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.”

²⁰ VA OIG. *Alleged Interference and Failure to Comply with the Pain Management Directive and the Opioid Safety Initiative at the VA Northern Indiana Health Care System, Fort Wayne, Indiana, Report No. 17-05835-165*, July 16, 2019.

²¹ VHA Directive 1170.01, *Accreditation of Veterans Health Administration Rehabilitation Programs*, May 9, 2017. The Commission on Accreditation of Rehabilitation Facilities “provides an international, independent, peer review system of accreditation that is widely recognized by Federal agencies.” VHA’s commitment is supported through a system-wide, long-term joint collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs. “About the College of American Pathologists,” College of American Pathologists, accessed April 26, 2021, <https://www.cap.org/about-the-cap>. According to the College of American Pathologists, for 75 years it has “fostered excellence in laboratories and advanced the practice of pathology and laboratory science.” Additionally, as stated in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

²² “About Us,” Long Term Care Institute, accessed March 6, 2019, <http://www.ltciorg.org/about-us/>. The Long-Term Care Institute states that it has been to over 4,000 healthcare facilities conducting quality reviews and over 1,145 external regulatory surveys since 1999. The Long-Term Care Institute is “focused on long term care quality and performance improvement; compliance program development; and review in long term care, hospice, and other residential care settings.”

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (<i>Alleged Interference and Failure to Comply with the Pain Management Directive and the Opioid Safety Initiative at the VA Northern Indiana Health Care System, Fort Wayne, Indiana, Report No. 17-05835-165, July 16, 2019</i>)	June 2018	12	3*
TJC Hospital Accreditation	February 2018	37	0
TJC Behavioral Health Care Accreditation		8	0
TJC Home Care Accreditation		7	0

Source: OIG and TJC (inspection/survey results verified with the Quality Manager on July 28, 2020).

*As of December 2020, no recommendations issued to the healthcare system remained open.

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

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. The OIG’s review of the system’s accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, the OIG noted that the healthcare system disclosed 114 adverse events to patients and their families. Of those, 109 involved substandard care delivered by a single physician. System leaders reportedly reviewed a total of 415 surgeries performed by the physician, and for cases determined not to meet the standard of care, clinical managers conducted institutional disclosures in early 2018. The physician reportedly left the system in 2017.

Table 9 lists the reported sentinel events and disclosures from March 11, 2017 (the prior OIG Clinical Assessment Program visit), through July 28, 2020.²³

Table 9. Summary of Selected Organizational Risk Factors (March 11, 2017, through July 28, 2020)

Factor	Number of Occurrences
Sentinel Events	5
Institutional Disclosures	114
Large-Scale Disclosures	0

Source: VA Northern Indiana Health Care System’s Quality Management Supervisor (received July 27, 2020).

Veterans Health Administration Performance Data

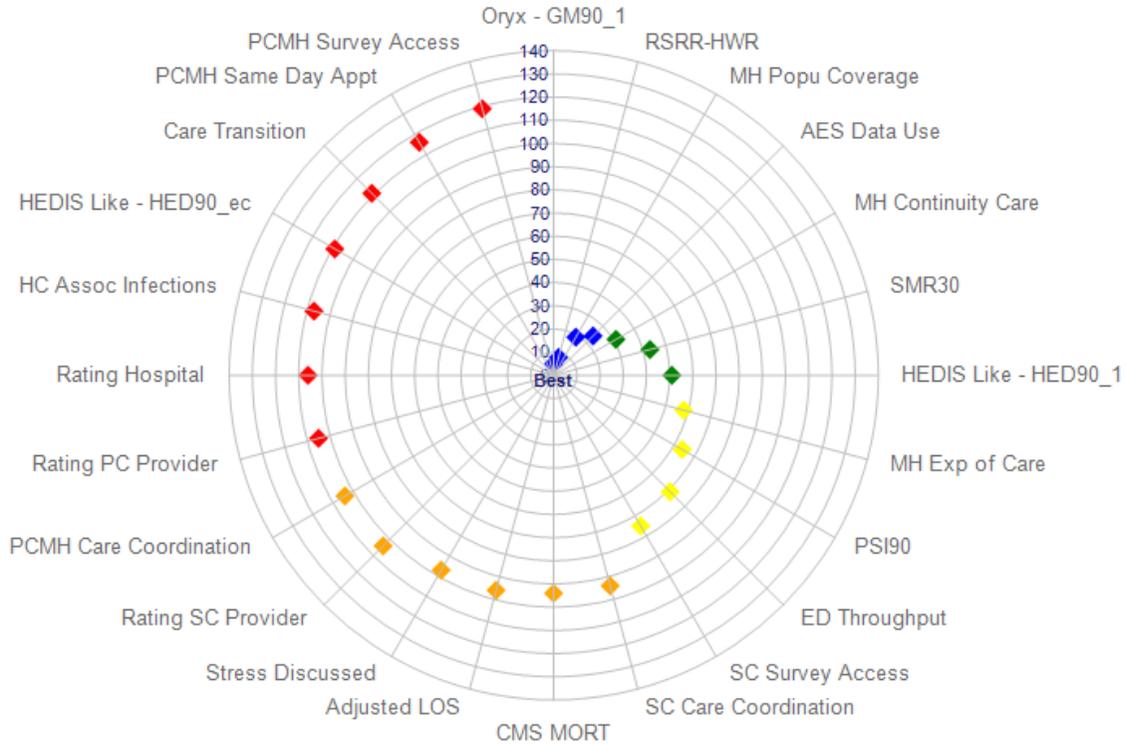
The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with “measures on healthcare quality, employee satisfaction, access to care, and efficiency.” Despite noted limitations for identifying all areas of clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.²⁴

Figure 5 illustrates the system’s quality of care and efficiency metric rankings and performance compared with other VA facilities as of December 31, 2019. Of note, figure 5 uses blue and green data points to indicate high performance (for example, in the areas of hospital wide readmission (RSRR-HWR), mental health population (MH popu) coverage, and acute care 30-

²³ 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. (The OIG noted that the VA Northern Indiana Health Care System is a medium complexity (2) 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 leader(s), together with clinicians and others as appropriate, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse.” Lastly, in VHA Directive 1004.08, VHA defines a large-scale disclosure of adverse events (sometimes referred to as a “notification”) as “a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue.”

²⁴ “Strategic Analytics for Improvement and Learning (SAIL) Value Model,” VHA Support Service Center, accessed March 6, 2020, <https://vssc.med.va.gov>. (This is an internal VA website not publicly accessible.)

day standardized mortality ratio (SMR30)). Metrics that need improvement are denoted in orange and red (for example, rating (of) specialty care (SC) provider, health care associated (HC assoc) infections, and patient-centered medical home same day appointment (PCMH appt)).²⁵



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

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

Source: VHA Support Service Center.

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

Veterans Health Administration Performance Data for Community Living Centers

The CLC SAIL Value Model is a tool to “summarize and compare the performance of CLCs in the VA.” The model “leverages much of the same data” used in the Centers for Medicare &

²⁵ For information on the acronyms in the SAIL metrics, please see appendix E.

Medicaid Services’ (CMS) *Nursing Home Compare* and provides a single resource “to review quality measures and health inspection results.”²⁶

Figure 6 illustrates the system’s CLC quality rankings and performance compared with other VA CLCs as of December 31, 2019. Figure 6 uses blue and green data points to indicate high performance (for example, in the areas of physical restraints–long-stay (LS), new or worse pressure ulcer (PU)–short-stay (SS), and falls with major injury (LS)). Metrics that need improvement are denoted in orange and red (for example, urinary tract infections (UTI) (LS), catheter in bladder (LS), and moderate-severe pain (SS)).²⁷

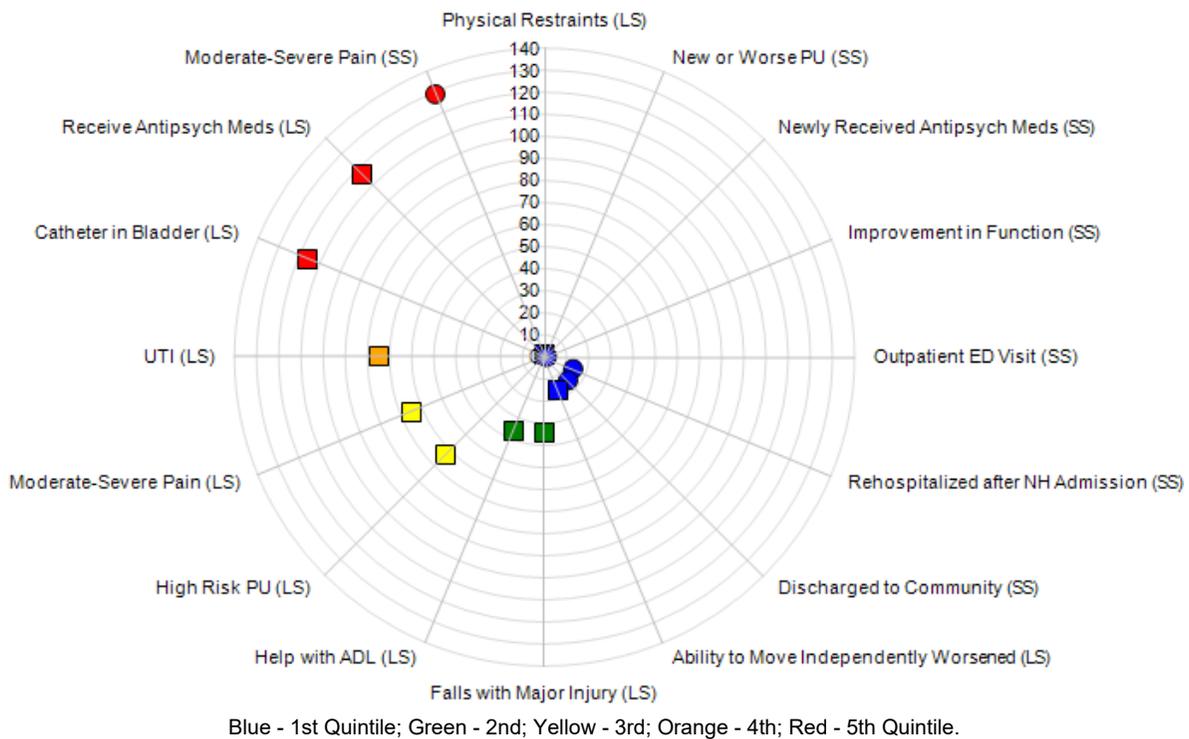


Figure 6. Marion CLC quality measure rankings FY 2020 quarter 1 (as of December 31, 2019).

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

Source: VHA Support Service Center.

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

²⁶ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, July 23, 2020. “In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several “star” ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes.”

²⁷ For data definitions of acronyms in the SAIL CLC measures, please see appendix F.

Leadership and Organizational Risks Conclusion

At the time of the OIG virtual review, the executive leaders, including the acting Chief of Staff, had worked together as a team for nine months. The Deputy Chief of Staff had served as the acting Chief of Staff since October 2019. Survey results related to employees' satisfaction with the system executive leaders, except for the recently hired Assistant Director, were similar to or better than VHA averages. Although system leaders appeared to be actively engaged with patients, the selected Inpatient, Patient-Centered Medical Home, and Specialty Care survey questions highlighted opportunities to improve patient satisfaction in the inpatient and outpatient settings. The OIG's review of the system's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, the OIG noted that the healthcare system disclosed 114 adverse events to patients and their families. Of those, 109 involved substandard care delivered by a single physician who reportedly left the system in 2017. In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve employee satisfaction and patient experiences. In addition, the executive leaders were generally knowledgeable within their scope of responsibilities about selected VHA data used by the SAIL models.

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.²⁸ 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.²⁹

During this time, VA continued providing for veterans’ healthcare needs and engaged its fourth mission, “the provision of hospital care and medical services during certain disasters and emergencies” to persons “who would otherwise not have eligibility to receive such care and services.”³⁰ “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.”³¹

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

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

The OIG also surveyed healthcare system staff to solicit their feedback and potentially identify any problematic trends and/or issues that may require follow-up. The results of the OIG’s evaluation of the healthcare system’s COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.³²

²⁸ “WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19 - 11 March 2020,” World Health Organization, accessed March 23, 2020, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19--11-march-2020>.

²⁹ VHA Office of Emergency Management, *COVID-19 Response Plan*, March 23, 2020.

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

³¹ 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.

³² VA OIG, *Comprehensive Healthcare Inspection of Facilities’ COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

Quality, Safety, and Value

VHA’s goal is to serve as the nation’s leader in delivering high-quality, safe, reliable, and veteran-centered care.³³ 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.³⁴ 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.”³⁵

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 quality, safety, and value (QSV) oversight functions; its ability to review data, information, and risk intelligence; and its ability to ensure that key QSV functions are discussed and integrated on a regular basis. Specifically, OIG inspectors examined the following requirements:

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

The OIG reviewers also assessed the healthcare system’s processes for conducting protected peer reviews of clinical care.³⁶ 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.”³⁷ Peer reviews are “intended to promote confidential and non-punitive” processes that consistently contribute to quality management efforts at the individual provider level.³⁸ The OIG team examined the completion of the following elements:

³³ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 21, 2014.

³⁴ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

³⁵ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*.

³⁶ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a “critical review of care, performed by a peer,” to evaluate care provided by a clinician for a specific episode of care, identify learning opportunities for improvement, provide confidential communication of the results back to the clinician, and identify potential system or process improvements. In the context of protected peer reviews, “protected” refers to the designation of review as a confidential quality management activity under 38 U.S.C. § 5705 as “a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or the utilization of health-care resources in VA facilities.”

³⁷ VHA Directive 1190.

³⁸ VHA Directive 1190.

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit³⁹
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of the Peer Review Committee’s summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the healthcare system’s utilization management (UM) program, a key component of VHA’s framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.⁴⁰ It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.⁴¹ Inspectors reviewed several aspects of the UM program:

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

Finally, the OIG reviewers assessed the healthcare system’s reports of patient safety incidents with related root cause analyses.⁴² Among VHA’s approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root

³⁹ VHA Directive 1190.

⁴⁰ VHA Directive 1117, *Utilization Management Program*, July 9, 2014, amended on April 30, 2019. UM reviews include evaluating the “appropriateness, medical necessity and the efficiency of health care services according to evidence-based criteria.” (This directive was rescinded and replaced with VHA Directive 1117, *Utilization Management Program*, October 8, 2020.)

⁴¹ VHA Directive 1117(2).

⁴² VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is “a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls.”

cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the healthcare system.⁴³ The healthcare system was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses⁴⁴
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of an annual patient safety report to healthcare system leaders

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents.⁴⁵

Quality, Safety, and Value Findings and Recommendations

The healthcare system complied with requirements for the establishment of a committee responsible for QSV oversight functions, review of aggregated data, and many of the peer review elements.

At the time of the OIG inspection, VHA required the System Director to ensure that an interdisciplinary group review UM data on an ongoing basis. This group included, but was not limited to, “representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [chief business office revenue-utilization review].”⁴⁶ From January through December 2019, the UM Committee met monthly but did not have representation from chief business office revenue-utilization review until December 2019.⁴⁷ As a result, the group performed UM data reviews and analyses without the perspectives of a key colleague.

⁴³ VHA Handbook 1050.01.

⁴⁴ VHA Handbook 1050.01, “The requirement for a total of eight RCAs [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of RCAs is driven by the events that occur and the SAC [Safety Assessment Code] score assigned to them...At least four analysis per fiscal year must be individual RCAs, with the balance being Aggregated Reviews or additional individual RCAs.”

⁴⁵ For CHIP visits, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

⁴⁶ VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. (This directive was rescinded on October 8, 2020, and replaced with VHA Directive 1117.)

⁴⁷ The UM Committee met monthly except for November 2019.

The Chief of Quality Management stated that prior to September 2019, the UM Committee was unaware of the requirement. On October 8, 2020, VHA changed the requirement for the review of UM data to be completed by a “multidisciplinary committee, which may include representatives from” various services. Therefore, the OIG made no recommendation.⁴⁸

⁴⁸ VHA Directive 1117, *Utilization Management Program*, October 8, 2020.

Medical Staff Privileging

VHA has defined procedures for the clinical privileging of “all healthcare professionals who are permitted by law and the facility to practice independently”—“without supervision or direction, within the scope of the individual’s license, and in accordance with individually-granted clinical privileges.” These healthcare professionals are also referred to as licensed independent practitioners (LIPs).⁴⁹

Clinical privileges need to be specific and based on the individual practitioner’s clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the Director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo reprivileging prior to their expiration.⁵⁰

VHA defines the focused professional practice evaluation (FPPE) as “a time-limited period during which the medical staff leadership evaluates and determines the practitioner’s professional performance.” The FPPE process occurs when a provider is hired at the facility and granted initial privileges and before any new clinical privileges are granted. VA facilities must continuously monitor the performance of their providers. VHA requirements state that “the on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered.”⁵¹ The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
 - Establishment of criteria in advance
 - Use of minimum criteria for selected specialty LIPs⁵²
 - Clear documentation of the results and time frames
 - Evaluation by another provider with similar training and privileges
- OPPEs
 - Application of criteria specific to the service or section
 - Use of minimum criteria for selected specialty LIPs⁵³
 - Evaluation by another provider with similar training and privileges

⁴⁹ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

⁵⁰ VHA Handbook 1100.19.

⁵¹ VHA Handbook 1100.19.

⁵² VHA Acting Deputy Under Secretary for Health for Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁵³ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*.

The OIG determined whether service chiefs recommended continuing the LIPs' current privileges based in part on the results of OPPE activities and if the healthcare system's Executive Committee of the Medical Staff decided to recommend continuing privileges based on FPPE and OPPE results.

VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.⁵⁴ Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process. This individual will be the subject matter expert (SME) for the facility...and ensure oversight of the exit review process, including receipt, review, and maintenance of the Provider Exit Review Forms."⁵⁵ The OIG reviewers assessed whether the healthcare system's staff

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

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

- Eight solo/few practitioners who underwent initial or reprivileging during calendar year 2019⁵⁶
- Four LIPs who completed an FPPE in calendar year 2019
- Ten LIPs privileged during calendar year 2019
- Eighteen LIPs who left the healthcare system in calendar year 2019

⁵⁴ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. (This handbook was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18. The two documents contain similar language related to state licensing board reporting requirements.)

⁵⁵ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (VHA Directive 1100.18 requires the "Credentialing and Privileging program manager to be responsible for the [state licensing board] reporting process and oversight of timely completion of exit reviews." The new directive also revises the requirement for exit review forms to be completed within seven calendar days to seven business days.)

⁵⁶ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*. This memorandum refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers few practitioners as being less than three providers in the facility that are privileged in a particular specialty.

Medical Staff Privileging Findings and Recommendations

The OIG found general compliance with the requirements for FPPEs but identified deficiencies with OPPEs, provider exit review processes, and SLB reporting. Of note, credentialing and privileging program staff reported that the VISN conducted two reviews of the healthcare system's credentialing and privileging procedures in 2018 and 2019 and found multiple deficiencies with the program. As a result, in late 2019, program staff reportedly made numerous changes to processes and forms in order to address these deficiencies.

VHA requires that reprivileging decisions are based on OPPE criteria that are specific to the service or section.⁵⁷ VHA also requires that service chiefs include the minimum specialty-specific criteria for OPPEs of gastroenterology, nuclear medicine, pathology, and radiation oncology LIPs.⁵⁸ The OIG found that for 4 of 17 LIPs who were reprivileged in calendar year 2019, the service chief could not provide evidence that the decision was based on service-specific OPPE criteria. In addition, a radiation oncologist's OPPE did not include the minimum specialty-specific criteria. This resulted in the LIPs practicing without thorough competency evaluations, which could have affected quality of care and patient safety. Credentialing and privileging staff attributed the noncompliance to deficiencies in forms and processes which had been previously identified during the 2018 and 2019 VISN reviews.

Recommendation 1

1. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that service chiefs base reprivileging decisions on service-specific criteria for ongoing professional practice evaluations of licensed independent practitioners.

⁵⁷ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

⁵⁸ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff evaluated reasons for noncompliance and ensures that the Service Chiefs include service specific criteria for reprivileging decisions. The facility service chiefs utilize a standardized facility ongoing professional practice evaluations form with providers evaluated in each of the general competencies with criteria tailored for the specific service by the service chief. In October 2020, the Medical Executive Board has implemented new processes to ensure service specific data is included in the ongoing professional practice evaluations data established by each service chief and included in the service chief Credentialing and Privileging ongoing professional practice evaluation report. The data will be tracked by the number of providers reviewed in committee demonstrating the above compliance divided by the number of renewals completed at the committee with the compliance tracked until 90% or greater compliance is established for six consecutive months.

Compliance Monitor: Numerator equals the number of ongoing professional practice evaluations reviewed with the service specific criteria. Denominator equals the number of total ongoing professional practice evaluations reviewed by the Medical Executive Board.

Compliance Goal: 90% or greater for 6 consecutive months

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective 08/21/20.

Recommendation 2

2. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that service chiefs ensure that ongoing professional practice evaluations for radiation oncologists include the minimum radiation oncology-specific criteria.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Associate Chief of Staff of Acute Medicine reviewed reasons for noncompliance and ensures that required Radiation Oncologist specific criteria are included in ongoing professional practice evaluations and monitors compliance.

Compliance Monitor: The facility service chief utilizes a standardized national ongoing professional practice evaluation form with providers evaluated in each of the general competencies with criteria tailored for the specific service by the service chief. The service chief responsible for the radiation oncologists will use the national ongoing professional practice evaluation form.

Responsibility: The Associate Chief of Staff of Acute Medicine will ensure implementation for all impacted providers until 100% compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective 08/21/20.

VHA requires that LIPs are evaluated by providers with similar training and privileges.⁵⁹ The OIG found that two LIPs, an anesthesiologist and obstetrician/gynecologist, were not evaluated by providers with similar training or privileges. As a result, the two LIPs provided care without a thorough evaluation of their competencies. Again, credentialing and privileging staff attributed the noncompliance to deficiencies in forms and processes which had been reportedly identified previously during the 2018 and 2019 VISN reviews.

Recommendation 3

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

⁵⁹ VHA Acting DUSHOM Memorandum, *Requirements for Peer Review of Solo Practitioners*.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff evaluated reasons for noncompliance and ensures providers with similar training and privileges complete ongoing professional practice evaluations. The facility service chiefs utilize a standardized facility ongoing professional practice evaluation form with providers evaluated in each of the general competencies with criteria tailored for the specific service and reviews by providers with similar training and privileges. In October 2020, the Medical Executive Board has included the ongoing professional practice evaluations with reviews by providers with similar training and privileges in the minutes. Providers are assigned by each service chief and included in the service chief ongoing professional practice evaluation report to [the] Medical Executive Board. The data is tracked by the number of providers reviewed in committee demonstrating the above compliance divided by the number of renewals completed at the committee with the compliance tracked until 90% or greater compliance is established for six consecutive months.

Compliance Monitor: Numerator equals the number of ongoing professional practice evaluations reviewed which documents providers' evaluations by providers of similar training and privileges. Denominator equals the number of total ongoing professional practice evaluations reviewed by the Medical Executive Board Compliance Goal: 90% or greater compliance established for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective August 21, 2020.

VHA requires that service chiefs' determination to continue current privileges are based, in part, on OPPE activities such as direct observation, clinical pertinence reviews, and clinical discussions. VHA also requires the Executive Committee of the Medical Staff (locally known as the Clinical Executive Board) to recommend continuation of privileges based on OPPE results.⁶⁰ For four of ten general LIPs reviewed who were repriviledged in calendar year 2019, the service chiefs and the Clinical Executive Board recommended continuation of privileges but could not provide evidence that the decisions were based on OPPE results. One OPPE was not completed or signed, one lacked supporting data, and two were missing required forms and supporting data. This resulted in inadequate data to support decisions to continue clinical privileges.

⁶⁰ VHA Handbook 1100.19.

Credentialing and privileging staff attributed the noncompliance to deficiencies in forms and processes which, again, were identified previously by VISN 10 reviewers in 2018 and 2019.

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that service chiefs' determinations to continue privileges are based, in part, on results of ongoing professional practice evaluation activities.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff evaluated reasons for noncompliance and ensures that Service Chiefs' determinations to continue privileges are based, in part, on results of ongoing professional practice evaluation activities. The service chief reviews and includes the results of ongoing professional practice evaluation activities in their determination to recommend the continuation of clinical privileges.

Compliance Monitor: Numerator equals the number of those providers reviewed that have evidence that the results of the ongoing professional practice evaluation activities were used in the determination to recommend the renewal of privileges. Denominator equals the number of total reprivileging request approved by [the] Medical Executive Board.

Compliance Goal: 90% compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective 08/21/2020.

Recommendation 5

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

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff evaluated reasons for noncompliance and ensures [the] Medical Executive Board's decision to recommend continuation of privileges is based on ongoing professional practice evaluation results. The Medical Executive Board reviews and includes the results of ongoing professional practice evaluation activities in their determination to recommend the continuation of clinical privileges.

Compliance Monitor: Numerator equals the number of those reviewed that have evidence that the results of the ongoing professional practice evaluation activities were used in the determination to recommend the renewal of privileges. Denominator equals the number of total reprivileging request approved by [the] Medical Executive Board.

Compliance Goal: 90% compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective 08/21/2020.

At the time of the OIG visit, VHA required the System Director to “designate an individual, and backup, to be responsible for the SLB reporting process.”⁶¹ Credentialing and Privileging program staff indicated that the healthcare system did not have a designated backup individual for the reporting process. This could have resulted in delayed reporting of LIPs that are identified as providing substandard care. Credentialing and privileging staff attributed the noncompliance to short staffing in the department.

On January 28, 2021, VHA amended the requirement for a designee and backup to oversee the SLB reporting process and assigned responsibility to the credentialing and privileging program manager.⁶² Therefore, the OIG made no recommendation.

Further, VHA required provider exit review forms, which document the review of a provider's clinical practice, to “be completed within 7 calendar days of the departure of a licensed health care professional from a VA facility.”⁶³ For the 18 LIPs who departed the healthcare system in 2019, the OIG found that 8 exit review forms were not completed within 7 calendar days.

⁶¹ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (VHA Handbook 1100.18 was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18.)

⁶² VHA Directive 1100.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021.

⁶³ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18*.

As of January 28, 2021, VHA requires exit forms to be completed within 7 business days.⁶⁴ Based on this updated requirement, none of the 8 exit review forms were completed on time. This could have resulted in delayed reporting of healthcare professionals' substandard care to SLBs. Credentialing and privileging staff cited poor communication between the service chiefs and an affiliated facility as a contributing factor to untimely exit form completion.

Recommendation 6

6. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven business days of licensed independent practitioners' departure from the healthcare system.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff and Associate Director of Patient Care Services evaluated reasons for noncompliance and will complete education on the importance of exit reviews, and completion of exit reviews will be added to the service line employee clearance processes. Designated staff have updated the exit review forms to provide clarity on the signatures needed. Designated staff will monitor and report compliance of completed exit reviews within seven business days, monthly to the Medical Executive Board until a 90% compliance rate for a rolling six month has been met.

Compliance Monitor: Numerator will be the number of exit review forms completed for licensed independent practitioners within seven calendar days and include signature of the first- or second-line supervisor. Denominator will be the number of licensed independent practitioners that left the system.

Compliance Goal: 90% compliance for a rolling six months.

Responsibility: The Chief of Staff and Associate Director of Patient Care Services will ensure compliance. The results will be reported through [the] Medical Executive Board which was previously [the] Clinical Executive Board. The Clinical Executive Board was converted to [the] Medical Executive Board effective 08/21/2020.

⁶⁴ VHA Directive 1100.18.

VHA also requires that facilities initiate the SLB reporting process when a provider fails to meet generally accepted standards of practice.⁶⁵ Credentialing and privileging staff stated that one of three LIPs who failed to meet generally accepted standards of practice was reported to the National Practitioner Data Bank but not to the SLB as required. This resulted in a safety concern for patients who could have been treated by the provider. Credentialing and privileging staff attributed the noncompliance to a misunderstanding of the reporting requirements.

Recommendation 7

7. The System Director evaluates and determines any additional reasons for noncompliance and ensures state licensing board reporting is initiated when a provider fails to meet generally accepted standards of practice.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Staff reviewed reasons for noncompliance and determined that a written procedure was needed to support the compliance of ensuring state licensing board providers were reported when a provider failed to meet generally accepted standards of practice. A Standard Operating Procedure (SOP) has been developed and is currently in the process of being finalized. The SOP will ensure the process and responsibilities of state licensing board reporting and compliance. The facility also follows VHA Handbook 1100.18, Reporting and Responding to the State Licensing Board. The Chief of Staff and Associate Director of Patient Care Services will ensure compliance if a provider fails to meet generally accepted standards of practice, any adverse clinical privileging action, or restriction of clinical privileges related to professional competency or professional conduct of a provider needing to be reported to the State Licensing Board.

Compliance monitor: Numerator is the number of providers that have been reported to the State Licensing Board. Denominator is the total number of providers that required reporting to the State Licensing Board.

Compliance goal: 90% compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance when a provider fails to meet generally accepted standards of practice.

⁶⁵ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. (This directive was in place for the time frame of the documents reviewed in this report. It was rescinded and replaced with VHA Directive 1100.18 on January 28, 2021. The handbook and directive contain the same or similar language regarding the SLB reporting process.)

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁶⁶ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁶⁷ Long-term opioid use is of particular concern in the veteran population where there is a high incidence of posttraumatic stress disorder, major depressive disorder, alcohol use, substance abuse, and suicide attempts.⁶⁸ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁶⁹

VHA requires routine assessments of pain and the completion of an opioid risk assessment before initiating patients on long-term opioid therapy and recommends against the therapy for patients with untreated substance use disorders. VHA also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines.⁷⁰ Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.⁷¹ To achieve VHA's vision of providing patient-driven healthcare, providers are also required to obtain informed consent from patients and to provide education about the risks, benefits, and alternatives prior to initiating long-term opioid therapy.⁷² VHA recommends evaluating patients receiving continued opioid therapy for improvement of pain and opioid-related adverse events at least every three months and more frequently as doses increase.⁷³

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

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

⁶⁶ "Information Sheet on Opioid Overdose," World Health Organization, accessed November 6, 2019, https://www.who.int/substance_abuse/information-sheet/en/.

⁶⁷ "Opioid Overdose, Understanding the Epidemic," Centers for Disease Control and Prevention, accessed November 6, 2019, <https://www.cdc.gov/drugoverdose/epidemic>.

⁶⁸ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0, February 2017.

⁶⁹ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁷⁰ "Benzodiazepines, Street Names: Benzos, Downers, Nerve Pills, Tranks," U.S. Drug Enforcement Administration, accessed December 20, 2020, https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. Benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety."

⁷¹ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁷² VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020.

⁷³ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

- Documentation of informed consent
- Timely follow-up with patients included required elements

VHA also requires facilities to establish a multidisciplinary pain management committee “to provide oversight, coordination, and monitoring of pain management activities and processes.” Monitoring measures include, but are not limited to, “adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment...patient satisfaction, physical and psychosocial functioning, and quality of life.”⁷⁴ The OIG examined indicators for program oversight and evaluation:

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

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 41 selected outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The team considered whether providers acted in accordance with guidelines for the provision of pain management and the healthcare system’s oversight process for evaluating pain management outcomes and quality.

Medication Management Findings and Recommendations

The system addressed some of the indicators of expected performance, including initial pain screening, documented justification for concurrent therapy with benzodiazepines, patient follow-up, and establishment of a multidisciplinary pain management committee to oversee and monitor required quality measures. However, the OIG identified deficiencies with aberrant behavior risk assessments, urine drug testing, and informed consent.

VA/DoD clinical practice guidelines recommend that providers complete an aberrant behavior risk assessment that includes a history of substance abuse, mental health problems or disorders, and aberrant drug-related behaviors prior to initiating long-term opioid therapy.⁷⁵ The OIG determined that providers did not document aberrant drug-related behaviors in 17 percent of the patient electronic health records reviewed.⁷⁶ Failure to conduct risk assessments may have resulted in providers prescribing opioids for patients at high risk for misuse. The Pain Management Committee chairperson stated that providers completed risk assessments in

⁷⁴ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

⁷⁵ *Pain Management, Opioid Safety, VA Educational Guide (2014)*, July 2014. Examples of aberrant drug related behaviors include “lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents.” *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁷⁶ Confidence intervals are not included because the data represents every patient in the study population.

accordance with the State of Indiana’s pain management requirements and reported that inconsistencies with assessment and documentation were due to providers’ lack of awareness of the VA/DoD clinical practice guidelines.

Recommendation 8

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

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) evaluated reasons for noncompliance and implemented through the Opioid Safety Initiative (OSI) Committee along with the Pain Management Committee reviewed and enhanced the long-term opioid therapy documentation process with a standardized facility electronic medical record template titled, “Provider Pain Management Note.” The updated note was modified to include all the required fields for documenting an opioid behavior risk assessment including a history of substance abuse, psychological disease, and aberrant drug-related behaviors.

Compliance monitor: The OSI Committee Chair will conduct 10 monthly random chart audits for the use of the note. Numerator is the number of patients screened prior to initiating long-term opioid therapy who had a completed behavior risk assessment that included a history of substance abuse, psychological disease, and aberrant drug-related behaviors. Denominator is 10 random chart audits of patients on newly initiated long-term opioid therapy.

Compliance goal: 90% compliance is demonstrated for 6 consecutive months.

Responsible: Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) will ensure compliance. Audits will be reported to the Pain Management Committee.

VA/DoD clinical practice guidelines also recommend that providers “obtain UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter.”⁷⁷ The OIG found that providers did not conduct initial urine drug testing for 20 percent of patients, based on the electronic health records reviewed.⁷⁸ This may have resulted in providers’ inability to identify whether these patients had substance use disorders, determine

⁷⁷ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0, February 2017.

⁷⁸ Confidence intervals are not included because the data represents every patient in the study population.

potential diversion, or ensure adherence to the prescribed medication regimen. The Pain Management Committee chairperson stated that providers completed urine drug testing in accordance with the State of Indiana’s pain management requirements and attributed inconsistencies with assessment and documentation to providers’ lack of awareness of the VA/DoD clinical practice guidelines.

Recommendation 9

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

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) evaluated reasons for noncompliance and implemented through the Opioid Safety Initiative (OSI) Committee along with the Pain Management Committee reviewed and enhanced the long-term opioid therapy documentation process with a standardized facility electronic medical record template titled, “Provider Pain Management Note.” The updated note was modified to include all the required fields for documenting consistent orders for urine drug testing as recommended for patients who are initiated on long-term opioid therapy.

Compliance monitor: The OSI Committee Chair will conduct 10 monthly random chart audits of patients on long-term opioid therapy validating that healthcare providers conduct urine drug testing. Numerator is the number of patients with completed urine drug testing. Denominator is 10 random chart audits of patients on newly initiated long-term opioid therapy.

Compliance goal: 90% compliance is demonstrated for 6 consecutive months. Responsible: Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) will ensure compliance. Audits will be reported to the Pain Management Committee.

VHA requires that providers obtain and document informed consent prior to the initiation of long-term opioid therapy. VHA also recommends that the informed consent conversation cover the risks and benefits of opioid therapy, as well as alternative therapies.⁷⁹ The OIG determined that providers did not document informed consent prior to initiating long-term opioid therapy in 31 percent of the electronic health records reviewed.⁸⁰ Therefore, patients may have received

⁷⁹ VHA Directive 1005(1), *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014, amended November 13, 2018. (This directive was in place for the time frame of the electronic health records reviewed in this report. It was rescinded and replaced with VHA Directive 1005 on May 13, 2020. Both directives contain the same or similar language regarding the informed consent process.)

⁸⁰ Confidence intervals are not included because the data represents every patient in the study population.

treatment without knowledge of the associated risks, including opioid dependence, tolerance, addiction, and fatal overdose. The Pain Management Committee chairperson stated providers obtained consent in accordance with the State of Indiana’s pain management requirements and reported that inconsistencies with documentation were due to providers’ lack of awareness of the requirement.

Recommendation 10

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

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) evaluated reasons for noncompliance and implemented through the Opioid Safety Initiative (OSI) Committee along with the Pain Management Committee reviewed and enhanced the long-term opioid therapy documentation process with a standardized facility electronic medical record template titled, “Provider Pain Management Note.” The updated note was modified to include all the required fields for documenting informed consents for patients who are initiated on long-term opioid therapy.

Compliance monitor: The OSI Committee Chair will conduct 10 monthly random chart audits of patients on long-term opioid therapy validating that healthcare providers received informed consents from patients. Numerator is the number of patients who are initiated on long-term opioid therapy with an informed consent. Denominator is 10 random chart audits of patients on newly initiated long-term opioid therapy.

Compliance goal: 90% compliance is demonstrated for 6 consecutive months. Responsible: Chief of Pain Management, Rehabilitation and Extended Care (PMR/EC) will ensure compliance. Audits will be reported to the Pain Management Committee.

Mental Health: Suicide Prevention Program

Suicide prevention remains a top priority for VHA. Suicide is the 10th leading cause of death, with over 47,000 lives lost across the United States in 2019.⁸¹ The suicide rate for veterans was 1.5 times greater than for nonveteran adults and estimated to represent approximately 13.8 percent of all suicide deaths in the United States during 2018. However, suicide rates among veterans who recently used VHA services decreased by 2.4 percent between 2017 and 2018.⁸²

VHA has identified suicide prevention as a top priority and implemented various evidence-based approaches to reduce the veteran suicide rate. In addition to expanded mental health services and community outreach, VHA has developed comprehensive screening and assessment processes to identify at-risk patients.⁸³

VHA requires that each medical center and very large community-based outpatient clinic have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.⁸⁴ The OIG examined various requirements related to SPCs:

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

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

⁸¹ "Preventing Suicide," Centers for Disease Control and Prevention, accessed December 9, 2020, <https://www.cdc.gov/violenceprevention/suicide/fastfact.html>.

⁸² VA Office of Mental Health and Suicide Prevention, *2020 National Veteran Suicide Prevention Annual Report*, November 2020.

⁸³ VA Office of Mental Health and Suicide, *VA Office of Mental Health and Suicide Prevention Guidebook*, June 2018.

⁸⁴ VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. "Very large CBOCs [community-based outpatient clinics] are those that serve more than 10,000 unique veterans each year." The Veterans Crisis Line connects veterans with qualified responders through a confidential toll-free hotline, online chat, and text-messaging service to receive confidential support 24 hours a day. Community outreach activities are described in VHA Handbook 1160.01.

in his or her electronic health record “as soon as possible but no later than 1 business day after such determination by the SPC.”⁸⁵ According to VHA, “Some studies indicate that up to two-thirds of patients who commit suicide have seen a physician in the month before their death...The primary purpose of the High Risk for Suicide PRF is to communicate to VA staff that a veteran is at high risk for suicide and the presence of a flag should be considered when making treatment decisions.”⁸⁶ The HRS PRF is reviewed at least every 90 days and depending on changes to the suicide risk status, will remain active or be removed.⁸⁷ Additionally, VHA requires designated high-risk patients to have a completed suicide safety plan and four face-to-face visits with an acceptable provider within the first 30 days of designation.⁸⁸

The OIG noted that from July 1, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA required that “Any patient determined to be High Risk for Suicide [by the licensed independent provider] must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination.”⁸⁹ However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management changed the requirement for the HRS PRF placement to be “as soon as possible but no later than 1 business day after determination by the SPC.”⁹⁰ VHA further provided additional clarifying information:

- The “SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list.”
- “The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted.”
- The SPC’s determination process “may be beyond 24 hours after a referral, due to case consultation and review.”⁹¹

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

⁸⁵ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

⁸⁶ VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008.

⁸⁷ *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*, January 5, 2018; VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

⁸⁸ VA Manual, *Safety Plan Treatment Manual to Reduce Suicide Risk: Veteran Version*, August 20, 2008. A safety plan is a “written list of coping strategies and sources of support that patients can use during or preceding suicidal crises.” Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

⁸⁹ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

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

⁹¹ VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

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

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRF to “occur no earlier than 10 days before and no later than 10 days after the 90-day due date.”⁹²

Inspectors examined the completion of several requirements:

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

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training.⁹³ VHA also requires that all staff receive annual refresher training.⁹⁴ In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.⁹⁵

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

- Relevant documents;

⁹² VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

⁹³ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym “S.A.V.E” summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

⁹⁴ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

⁹⁵ VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

- The electronic health records of 40 outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

Mental Health Findings and Recommendations

The healthcare system complied with requirements for a designated SPC. However, the OIG noted concerns.

With VHA’s original requirement that was in place when these patients received care—that “Any patient determined to be High Risk for Suicide must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination”⁹⁶—the OIG estimated that 27 percent of HRS PRFs were not placed within 24 hours of referral to the SPC.⁹⁷ Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined time frame for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was 2 days (observed range was 0–14 days).⁹⁸

The OIG also noted concerns with reviewing HRS PRFs within the required time frame. VHA required the System Director to ensure that all patients with an HRS PRF were reevaluated at least every 90 days.⁹⁹ The OIG estimated that 25 percent of patients with an HRS PRF were not reevaluated at least every 90 days.¹⁰⁰ However, based on the updated requirement that the SPC ensure HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that clinical staff reviewed 95 percent of patients within the new time frame (observed range was 35–95 days).¹⁰¹

Additionally, the OIG noted concerns with the completion of at least four mental health visits within 30 days of HRS PRF placement, suicide safety plans, and staff refresher training.

⁹⁶ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

⁹⁷ The OIG estimated that 95 percent of the time, the true compliance rate is between 57.9 and 85.7 percent, which is statistically significantly below the 90 percent benchmark.

⁹⁸ VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020; VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

⁹⁹ VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008.

¹⁰⁰ The OIG estimated that 95 percent of the time, the true compliance rate is between 61.4 and 87.8 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰¹ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

VHA requires a veteran to have four follow-up visits with a qualified provider within 30 days of HRS PRF placement. The follow-up visits should be face-to-face unless the veteran requests a telephonic visit, and there must be documentation identifying the patient's preference for a telephone call.¹⁰² The OIG estimated that providers did not conduct four mental health visits for 25 percent of patients reviewed.¹⁰³ This resulted in insufficient follow-up of high-risk patients. The Chief of Mental Health reported that conflicting VHA guidance led to the belief that telephonic contacts, without documented patient preference for a telephone visit, met the follow-up visit requirement.

Recommendation 11

11. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers conduct four follow-up visits, either face-to-face or telephonic with documented consent, within the required time frame.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Chief of Mental Health evaluated reasons for noncompliance and along with the Mental Health leadership team reviewed processes to ensure optimal management of the Veterans' care after identification of high suicide risk. Mental Health leadership has implemented enhanced processes including use of expanded technology to accommodate individual preferences for completing the follow-up visits with Veterans as well as ensuring capturing modality consent where indicated.

The Mental Health leadership has identified a point of contact, the Suicide Prevention Coordinator (SPC), who will track each high-risk Veteran case to ensure the Veteran receives the required follow up visits. The SPC will review the compliance in the daily Suicide Prevention huddle and proactively identify any Veterans needing special focus to meet the requisite 4 visits timely.

Compliance monitor: Numerator is the number of newly high-risk flagged Veterans who received the required 4 mental health visits in 30 days post HRF [high risk flag] placement. Denominator is 100% of all newly flagged Veteran cases with high-risk for suicide.

Compliance goal: The Chief of Mental Health will ensure all newly flagged high-risk Veterans receive the requisite visits at 90% compliance for 6 consecutive months and report the results to the Suicide Prevention Committee.

¹⁰² VA's *Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*, January 5, 2018.

¹⁰³ The OIG estimated that 95 percent of the time, the true compliance rate is between 61.1 and 87.7 percent, which is statistically significantly below the 90 percent benchmark.

VHA also states that any patient with a high-risk designation should have a completed suicide prevention safety plan “within 7 days before or after the current HRS-PRF date.”¹⁰⁴ The OIG estimated that 27 percent of safety plans were not completed on time.¹⁰⁵ Failure to complete safety plans on time may have limited patients’ awareness of available resources when in crisis. The Chief of Mental Health, Assistant Chief of Mental Health, and Suicide Prevention Coordinator stated that providers did not understand the safety plan documentation requirement.

Recommendation 12

12. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that suicide prevention safety plans are completed within the required time frame.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Mental Health leadership team reviewed processes to ensure safety plans were in place for Veterans after identification of high suicide risk. Mental Health leadership expanded education of staff to understand the role of safety planning. Enhanced data tracking and outreach by Suicide Prevention Coordinator (SPC) and staff to enhance outreach to Veterans to facilitate effective timely safety planning. The SPC and QM [Quality Manager] will track the Safety Plans within 7 days before or after designation of the HRF in the month the Veteran was flagged. The compliance will be reviewed in Suicide Prevention daily huddles to facilitate compliance.

Compliance monitor: Numerator is all newly flagged high-risk Veterans who have a Safety Plan placed within 7 days before or after designation of HRF in the month the Veteran was flagged. Denominator is the total number of Veterans flagged for high risk in a month.

Compliance goal: The Chief of Mental Health will ensure all newly flagged high-risk Veterans will have a Safety Plan completed timely at 90% compliance for 6 consecutive months and report the results to the Suicide Prevention Committee.

VHA requires that all employees complete suicide risk and intervention training “within 90 days of entering their position” and annual refresher training thereafter.¹⁰⁶ The OIG found that 5 of the 18 employee records reviewed lacked evidence of annual refresher training. Lack of training could have prevented employees from providing optimal care to veterans who were at risk for

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

¹⁰⁵ The OIG estimated that 95 percent of the time, the true compliance rate is between 57.9 and 86.7 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰⁶ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

suicide. The Chief of Education, Assistant Chief of Mental Health, and Chief Nurse of Mental Health attributed the noncompliance to managers' insufficient oversight of mandatory training completion and employees' lack of responsiveness to training alerts.

Recommendation 13

13. The System Director evaluates and determines any additional reasons for noncompliance and ensures employees complete annual suicide prevention refresher training.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Mental Health leadership team has reviewed and enhanced the process to monitor compliance with the annual staff refresher training. Mental Health leadership focused on ensuring staff compliance by prospectively reviewing organizational training by reviewing upcoming deadlines and notification processes.

The Mental Health Leadership team provides a separate reminder with the automated Talent Management System (TMS) message reminder and partners with facility leadership to ensure employee compliance. Mental Health leadership and Suicide Prevention continue to review compliance with the training.

Compliance Monitor: Numerator will be all applicable employees for annual required suicide prevention refresher training who complete the training by their assigned date. Denominator is the total number of staff in a given month that are due for the TMS training.

Compliance Goal: Mental Health Leadership team will monitor until 90 percent compliance is demonstrated for 6 consecutive months and report the results to Suicide Prevention Committee.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decision (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTDs. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by “eliciting, documenting, and honoring patients’ values, goals, and preferences.”¹⁰⁷

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018.¹⁰⁸ Implementation requirements included initiating conversations about the goals of care. A goals of care conversation is a discussion between a healthcare provider and a patient or surrogate to help define the patient’s values, goals, and preferences for care and, based on the discussion, make choices about starting, limiting, or ceasing LSTs.¹⁰⁹ VHA requires practitioners to initiate goals of care conversations with high-risk patients—including hospice patients or their surrogates—within a time frame that meets the medical needs of the patient or at the time of a triggering event.¹¹⁰

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

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

¹⁰⁷ VHA Handbook 1004.03(1), *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients’ Values, Goals and Preferences*, January 11, 2017, amended March 19, 2020.

¹⁰⁸ VHA Handbook 1004.03(1). The medical facility must fully implement handbook requirements within 18 months of publication.

¹⁰⁹ VHA Handbook 1004.03(1). A surrogate is legally authorized under VA policy to serve as the decision maker on behalf of the patient should the patient lose decision-making capacity.

¹¹⁰ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017. Hospice patients are defined as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. VHA Handbook 1004.03(1). Triggering events requiring goals of care conversations include those “prior to referral or following admission (e.g., within 24 hours) to VA or non-VA hospice.”

However, on March 19, 2020, VHA amended the requirements related to documenting patients' goals of care. Although the elements of the goals of care conversation are still required, the LST progress note must include at a minimum

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

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

The healthcare system was assessed for its adherence to requirements for goals of care conversations:

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

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service.¹¹¹ Inspectors examined if the healthcare system established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from the Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the healthcare system complied with the OIG-selected requirements related to LSTD for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 42 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

Care Coordination Findings and Recommendations

The healthcare system generally complied with requirements for the LSTD committee and supervision of designees. With VHA's original requirements that were in place when these

¹¹¹ VHA Handbook 1004.03(1).

patients received care, the OIG estimated that 38 percent of patients' LST progress notes did not address previous advance directive(s), state-authorized portable orders, and/or LST notes.¹¹² However, VHA deleted requirements for the documentation of these elements in the LST progress note.¹¹³ The OIG made no recommendation but remains concerned that this change could result in practitioners not addressing these important goals of care conversation elements.

¹¹² VHA Handbook 1004.03(1), *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017. The OIG estimated that 95 percent of the time, the true compliance rate is between 46.7 and 76.2 percent, which is statistically significantly below the 90 percent benchmark.

¹¹³ VHA Handbook 1004.03(1).

Women’s Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹¹⁴ According to data released by the National Center for Veterans Analysis and Statistics in May 2019, the total veteran population and proportion of male veterans are projected to decrease while the proportion of female veterans are anticipated to increase.¹¹⁵ To help the VA better understand the needs of the growing women veterans population, efforts have been made by VHA to identify and address the urgent needs “by examining health care use, preferences, and the barriers Women Veterans face in access to VA care.”¹¹⁶ Additionally, a VA report in 2016 on suicide among veterans pointed out concerning trends in suicide among women veterans and discussed “the importance of understanding suicide risk among women veterans and developing gender-tailored suicide prevention strategies.”¹¹⁷

VHA requires that all eligible and enrolled women veterans have access to timely, high-quality, and comprehensive healthcare services in a sensitive and safe environment. Facilities must, therefore, ensure availability of appropriate resources, services, and staffing ratios.¹¹⁸ VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veterans health committee that “develops and implements a Women’s Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans.”¹¹⁹

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

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

¹¹⁴ “Veteran Population,” Table 1L: VetPop2016 Living Veterans by Age Group, Gender, 2015–2045, National Center for Veterans Analysis and Statistics, accessed November 14, 2019, https://www.va.gov/vetdata/Veteran_Population.asp.

¹¹⁵ “Veteran Population,” National Center for Veterans Analysis and Statistics, accessed September 16, 2019, https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf.

¹¹⁶ Department of Veterans Affairs, *Study of Barriers for Women Veterans to VA Health Care, Final Report*, April 2015.

¹¹⁷ Claire Hoffmire, “Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions,” *Suicide Prevention, Forum*, Spring 2018, <https://www.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5>.

¹¹⁸ VHA Directive 1330.01(4), *Health Care Services for Women Veterans*, February 15, 2017, amended January 8, 2021.

¹¹⁹ VHA Directive 1330.01(4).

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

Women's Health Findings and Recommendations

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

VHA requires the Chief of Staff to ensure that gynecological care coverage is available 24 hours a day, 7 days per week.¹²⁰ The Women Veterans Program Manager reported that the healthcare system had no full-time gynecologist on staff. The OIG also noted that the Emergency Department's policy did not specifically address patients requiring gynecologic care. This limited the availability of comprehensive women's health services. The Women Veterans Program Manager reported that a meeting with the Chief of Acute Medicine led to the belief that the policy to transfer stable patients requiring care outside the Emergency Department's scope of service, such as gynecologic care, met the requirement.

¹²⁰ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020. (This directive was in place for the time frame of the virtual review. It was amended on January 8, 2021 (1330.01(4)). Both directives contain the same or similar language regarding gynecological care coverage.)

Recommendation 14

14. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that gynecological care coverage is available 24 hours a day, 7 days per week.¹²¹

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Chief of Staff reviewed reasons for noncompliance and determined that a written procedure was needed to support gynecological care coverage for 24 hours a day, 7 days per week. A Standard Operating Procedure (SOP) was developed regarding local guidance on the care of emergent obstetrical and gynecological care of women veterans. VANIHCS [VA Northern Indiana Health Care System] also follows local policy on Inter-Facility Patient Transfers which addresses Women Veterans presenting with gynecology and/or obstetrical emergencies. The Women's Veteran Program will ensure that women veterans are either referred to our partnering community providers for care, when we can't provide onsite care with a designated women's health provider in the Health System. This will occur according to patient preference and in compliance with VHA guidelines to ensure comprehensive care is delivered. The SOP has been approved and education has been provided to the Emergency Department and Urgent Care staff. 22/22 (100%) Emergency Department staff and 12/12 (100%) Urgent Care staff have been educated on the approved SOP.

Request closure of this recommendation based on supporting documentation.

VHA also requires the Women Veterans Health Committee to have a core membership with a women veterans program manager, a women's health medical director, "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care, and a member from executive leadership."¹²² The OIG reviewed the Women Veterans Health Committee minutes for meetings held between July 1 and December 31, 2019, and found that a representative from executive leadership had not attended any of the meetings.¹²³ This may have resulted in a lack of expertise and oversight in the review and analysis of data as the committee planned and carried out

¹²¹ The OIG reviewed evidence sufficient to demonstrate that the healthcare system had completed improvement actions and therefore closed the recommendation before publication of the report.

¹²² VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018. (This directive was in place for the time frame of the minutes reviewed in this report. It was amended on June 29, 2020 (1330.01(3)) and again on January 8, 2021 (1330.01(4)). All three directives contain the same or similar language regarding the Women Veterans Health Committee.)

¹²³ At the time of the OIG review, the Women Veterans Health Committee reported to the Patient Aligned Care Team Steering Committee.

improvements for quality and equitable care for women veterans. The Women Veterans Program Manager cited scheduling conflicts for the lack of attendance from an executive leader.

Recommendation 15

15. The System Director evaluates and determines any additional reasons for noncompliance and makes certain that required members consistently attend Women Veterans Health Committee meetings.

Healthcare system concurred.

Target date for completion: October 31, 2021

Healthcare system response: The Women Veterans Health Committee Chair reviewed reasons for noncompliance and will ensure ongoing compliance of the core members assigned consistently attend the Women Veterans Health Committee meetings. The Women's Veterans Health Program Manager has revised the meeting date and times to ensure compliance of attendance and continue to meet at a minimum quarterly. Core members were advised of meeting expectations.

Compliance monitor: Numerator is the total number of Women Veterans Health Committee core members or their designees that were in attendance. Denominator is the total number of Women Veterans Health Committee core members.

Compliance goal: 90% or greater compliance for 2 consecutive quarters.

Responsibility: The Women Veterans Health Committee Chair is responsible for compliance with attendance at quarterly meetings. Results will be reported to the Medical Executive Board.

High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have Sterile Processing Services (SPS) “to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment.”¹²⁴ The goal of SPS is to “provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections.”¹²⁵ To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME
- Have standard operating procedures that are based on current manufacturers’ guidelines and reviewed at least triennially
- Use CensiTrac[®] Instrument Tracking System for tracking reprocessed instruments¹²⁶
- Perform annual risk analysis and report results to the VISN SPS Management Board
- Monitor data for reprocessing and storing RME
- Conduct annual airflow/ventilation system inspections¹²⁷

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

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station, personal protective equipment available for immediate use, and standard operating procedures readily available to guide the reprocessing of RME.¹³⁰

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

¹²⁵ Julie Jefferson, Martha Young. *APIC Text of Infection Control and Epidemiology*. Association for Professionals in Infection Control and Epidemiology, 2019. “Chapter 108: Sterile Processing.”

¹²⁶ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.

¹²⁷ VHA Directive 1116(2).

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

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

¹³⁰ VHA Directive 1116(2).

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

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

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

¹³¹ VHA Directive 1116(2).

High-Risk Processes Findings and Recommendations

Generally, the healthcare system met many of the requirements for the proper operations and management of reprocessing RME. However, the OIG noted concerns with the annual risk analysis; daily cleaning schedule; and staff training, competency, and continuing education.

VHA requires that the SPS Chief perform an annual risk analysis and report the results to the VISN SPS Management Board.¹³² The Chief of SPS reported that the FY 2019 annual risk analysis was not performed. Failure to conduct a risk analysis could have delayed or prevented the identification and mitigation of problems or process failures. The ADPCS stated that the Chief of SPS believed documenting the review of the individual RME risk level in the standard operating procedure met the requirement for an annual risk analysis.

Recommendation 16

16. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Services Chief performs an annual risk analysis and reports the results to the Veterans Integrated Service Network Sterile Processing Services Management Board.¹³³

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Sterile Processing Services (SPS) Chief evaluated reasons for noncompliance and determined the process of providing the completed annual risk assessment results to the VISN Sterile Processing Services Management Board annually. The Sterile Processing Services risk assessment results were shared with the VISN 10 Sterile Processing Services Management Board on November 17, 2020. The SPS Chief will report compliance of transmission of the annual risk assessment results to the VISN Sterile Processing Services Board thru the RME and SPS Committee.

Request closure of this recommendation based on supporting documentation.

Additionally, VHA requires that the Chief of SPS “must develop, implement and enforce a written daily cleaning schedule for all SPS areas.”¹³⁴ The OIG reviewed SPS daily cleaning schedules from July 15 to July 28, 2020; the SPS and Environmental Management Services Chiefs reported that they were unable to verify if employees followed the schedule at the Fort

¹³² VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

¹³³ The OIG reviewed evidence sufficient to demonstrate that the healthcare system had completed improvement actions and therefore closed the recommendation before publication of the report.

¹³⁴ VHA Directive 1116(2).

Wayne campus. Adhering to a written cleaning schedule ensures a clean environment is achieved and maintained. The Chief of Environmental Management Services attributed the noncompliance to a new supervisor who had not been instructed to ensure the completion of the daily cleaning log.

Recommendation 17

17. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures the Sterile Processing Services supervisor enforces the daily cleaning schedule at the Fort Wayne campus.¹³⁵

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Sterile Processing Chief reviewed reasons for noncompliance and implemented a process for improvement. The Environmental Management Services (EMS) Chief will ensure monitoring of the daily cleaning logs for compliance at the Fort Wayne Campus. The EMS Chief will provide evidence of adherence to the cleaning schedule to the RME Committee on a monthly basis.

Compliance monitor: The department will be cleaned per guidance at 100%.

Compliance goal: 100% compliance of cleaning schedule completed for 2 consecutive quarters.

Responsible: The SPS Chief will ensure compliance and report compliance data to RME and SPS Committee monthly.

Request closure of this recommendation based on supporting documentation.

Since March 23, 2016, VHA has required that “all new SPS employees must complete the SPS Level 1 training program within 90 days of hire.”¹³⁶ The OIG found that 2 of 10 selected employees lacked evidence of completed Level 1 training within the required time frame. Failure to complete training in a timely manner could have resulted in improper cleaning of the RME and compromised patient safety. The Chief of SPS stated that Level 1 training for one employee was completed; however, the evidence of completion was not maintained. Further, the other employee needed additional preparation time to ensure successful completion of Level 1 training.

¹³⁵ The OIG reviewed evidence sufficient to demonstrate that the healthcare system had completed improvement actions and therefore closed the recommendation before publication of the report.

¹³⁶ VHA Directive 1116(2).

Recommendation 18

18. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that all new Sterile Processing Services employees complete Level 1 training within 90 days of hire.

Healthcare system concurred.

Target date for completion: August 2021

Healthcare system response: The Sterile Processing Services (SPS) Chief reviewed reasons for noncompliance and will ensure all new SPS employees complete the Talent Management System (TMS) Level 1 training within 90 days of hire. The SPS Educator will conduct a review of the new employee's orientation records to ensure that all TMS Level 1 training modules have been completed within 90 days of hire and prior to starting on-the-job training in restricted areas.

Compliance monitor: Numerator is the total number of new SPS employees hired who completed the TMS Level 1 training within 90 days of hire. Denominator is the total number of newly hired SPS employees during the same review period. No new staff have been hired since the review.

Compliance goal: 100%

Responsible: The SPS Chief will ensure compliance and provide monthly compliance reports quarterly to [the] RME and SPS Committee to be documented in the minutes.

VHA also requires SPS employees who reprocess RME to complete competency assessments.¹³⁷ The OIG found that 2 of 10 selected SPS employees had expired competency assessments for reprocessing endoscopes. This could have resulted in improper cleaning of the RME and may have compromised patient safety. The Chief of SPS stated that the competency assessments were not prioritized since the endoscopes were temporarily not in use.

Recommendation 19

19. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that Sterile Processing Services employees who reprocess reusable medical equipment complete competency assessments.¹³⁸

¹³⁷ VHA Directive 1116(2).

¹³⁸ The OIG reviewed evidence sufficient to demonstrate that the healthcare system had completed improvement actions and therefore closed the recommendation before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Sterile Processing Services (SPS) Chief reviewed reasons for noncompliance and will ensure that SPS staff properly complete competency assessments for reprocessing reusable medical equipment. The SPS Educator will perform monthly competency trainings for staff reprocessing medical equipment for completeness. The SPS Education will report the to the Reusable Medical Equipment Committee monthly.

Compliance monitor: Numerator is the total number of SPS employees who reprocess RME that completed the competency assessments. Denominator is the number of SPS [employees] who reprocess RME that should complete the competency assessments.

Compliance goal: 100% compliance is sustained for 6 consecutive months.

Responsible: The SPS Chief will monitor to ensure compliance monthly. The results of the monitoring will be reported to the RME and SPS Committee monthly.

Request closure of this recommendation based on supporting documentation.

VHA requires SPS employees to receive monthly continuing education.¹³⁹ The OIG reviewed training records of nine selected staff from October through December 2019, and found that eight applicable employees hired before January 2020 did not receive continuing education in October, and two employees did not receive education in December. This resulted in a potential knowledge gap in the technical aspects of reprocessing duties. The Chief of SPS reported being unaware of the monthly education requirement.

Recommendation 20

20. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures Sterile Processing Services employees receive monthly continuing education.¹⁴⁰

¹³⁹ VHA Directive 1116(2).

¹⁴⁰ The OIG reviewed evidence sufficient to demonstrate that the healthcare system had completed improvement actions and therefore closed the recommendation before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Sterile Processing Services (SPS) Chief reviewed reasons for noncompliance and will ensure implementation and sustainment of this corrective action to ensure that all staff complete the required monthly continuing education. The SPS Educator will log staff compliance monthly for continuing education.

Compliance monitor: Numerator is the number of SPS who completed the required monthly continuing education. Denominator is the total number of who should complete the required monthly continuing education.

Compliance goal: 100% compliance is sustained for six consecutive months.

Responsible: The SPS Chief will ensure compliance and provide monthly compliance to the RME and SPS Committee to be documented in the minutes.

Request closure of this recommendation based on supporting documentation.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

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

Table A.1. Summary Table of Recommendations

Healthcare Processes	Requirements	Conclusion
Leadership and Organizational Risks	<ul style="list-style-type: none"> • Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation surveys and oversight inspections • Factors related to possible lapses in care and healthcare system response • VHA performance data (system) • VHA performance data for CLCs 	Twenty OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, and ADPCS. See details below.
COVID-19 Readiness and Response	<ul style="list-style-type: none"> • Emergency preparedness • Supplies, equipment, and infrastructure • Staffing • Access to care • CLC patient care and operations • Staff feedback 	The results of the OIG's evaluation of the healthcare system's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	<ul style="list-style-type: none"> • QSV Committee • Protected peer reviews • UM reviews • Patient safety 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None
Medical Staff Privileging	<ul style="list-style-type: none"> • FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards 	<ul style="list-style-type: none"> • Service chiefs base reprivileging decisions on service-specific criteria for OPPEs of LIPs. • Service chiefs include the minimum radiation oncology-specific criteria for OPPEs. • Providers with similar training and privileges complete OPPEs. • Service chiefs' determinations to continue privileges are based, in part, on results of OPPE activities. • Clinical Executive Board's decision to recommend continuation of privileges is based on OPPE results. 	<ul style="list-style-type: none"> • Provider exit review forms are completed within seven business days of licensed independent practitioners' departure from the healthcare system. • State licensing board reporting is initiated when a provider fails to meet generally accepted standards of practice.

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Long-Term Opioid Therapy	<ul style="list-style-type: none"> • Provision of pain management using long-term opioid therapy • Program oversight and evaluation 	<ul style="list-style-type: none"> • Providers complete an aberrant behavior risk assessment that includes a history of substance abuse, mental health problems or disorders, and aberrant drug-related behaviors for all patients prior to initiating long-term opioid therapy. • Providers conduct urine drug testing as recommended for patients on long-term opioid therapy. • Providers obtain and document informed consent for patients prior to initiating long-term opioid therapy. 	<ul style="list-style-type: none"> • None
Mental Health: Suicide Prevention Program	<ul style="list-style-type: none"> • Designated facility suicide prevention coordinator • Tracking and follow-up of high-risk veterans • Provision of suicide prevention care • Completion of suicide prevention training requirements 	<ul style="list-style-type: none"> • Providers conduct four follow-up visits, either face-to-face or telephonic with documented consent, within the required time frame. • Suicide prevention safety plans are completed within the required time frame. 	<ul style="list-style-type: none"> • Employees complete annual suicide prevention refresher training.
Care Coordination: Life-Sustaining Treatment Decisions	<ul style="list-style-type: none"> • LSTD multidisciplinary committee • LSTD progress note documentation • LSTD note/orders completed by an authorized provider or delegated 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Women's Health: Comprehensive Care	<ul style="list-style-type: none"> • Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements 	<ul style="list-style-type: none"> • Gynecological care coverage is available 24 hours a day, 7 days per week. 	<ul style="list-style-type: none"> • Required members consistently attend Women Veterans Health Committee meetings.
High-Risk Processes: Reusable Medical Equipment	<ul style="list-style-type: none"> • Administrative processes • Quality assurance • Staff training 	<ul style="list-style-type: none"> • SPS employees who reprocess RME complete competency assessments. 	<ul style="list-style-type: none"> • SPS Chief performs an annual risk analysis and reports the results to the VISN SPS Management Board. • The daily cleaning schedule is enforced at the Fort Wayne campus. • SPS employees complete Level 1 training within 90 days of hire. • SPS employees receive monthly continuing education.

Appendix B: Healthcare System Profile

The table below provides general background information for this medium complexity (2) healthcare system reporting to VISN 10.¹

**Table B.1. Profile for VA Northern Indiana Health Care System (610/00)
(October 1, 2016, through September 30, 2019)**

Profile Element	Healthcare System Data FY 2017*	Healthcare System Data FY 2018 [†]	Healthcare System Data FY 2019 [‡]
Total medical care budget	\$331,312,545	\$365,005,340	\$362,581,759
Number of:			
• Unique patients	44,930	45,223	45,331
• Outpatient visits	496,416	493,124	504,767
• Unique employees	1,412	1,464	1,495
Type and number of operating beds:			
• Community living center	180	180	180
• Domiciliary	30	30	30
• Medicine	26	26	26
• Mental Health	65	65	65
Average daily census:			
• Community living center	97	89	96
• Domiciliary	24	26	25
• Medicine	13	15	13
• Mental health	40	23	20
• Surgery	–	0	–

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

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

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

[†]October 1, 2017, through September 30, 2018.

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

¹ The VHA medical centers are classified according to a facility complexity model; a designation of “2” indicates a facility with “medium volume, low-risk patients, few complex clinical programs, and small or no research and teaching programs.”

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, 2018, through September 30, 2019)

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Mishawaka, IN	610BY	24,956	9,765	Anesthesia Cardiology Dermatology Endocrinology Eye Gastroenterology General surgery Hematology/ Oncology	Laboratory & Pathology Nuclear med Radiology	Nutrition Pharmacy Prosthetics Weight management

¹ Includes outpatient clinics in the community that were in operation as of August 27, 2019. The OIG omitted (610QB) South Bend, IN as no workload/encounters or services were reported. VHA Directive 1230(3), *Outpatient Scheduling Processes And Procedures*, July 15, 2016, amended January 7, 2021. An encounter is a “professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient’s condition.” Specialty care services refer to non-primary care and non-mental health services provided by a physician. Diagnostic services include laboratory, nuclear medicine, and radiology. Ancillary services include nutrition, pharmacy, prosthetics, social work, and weight management services.

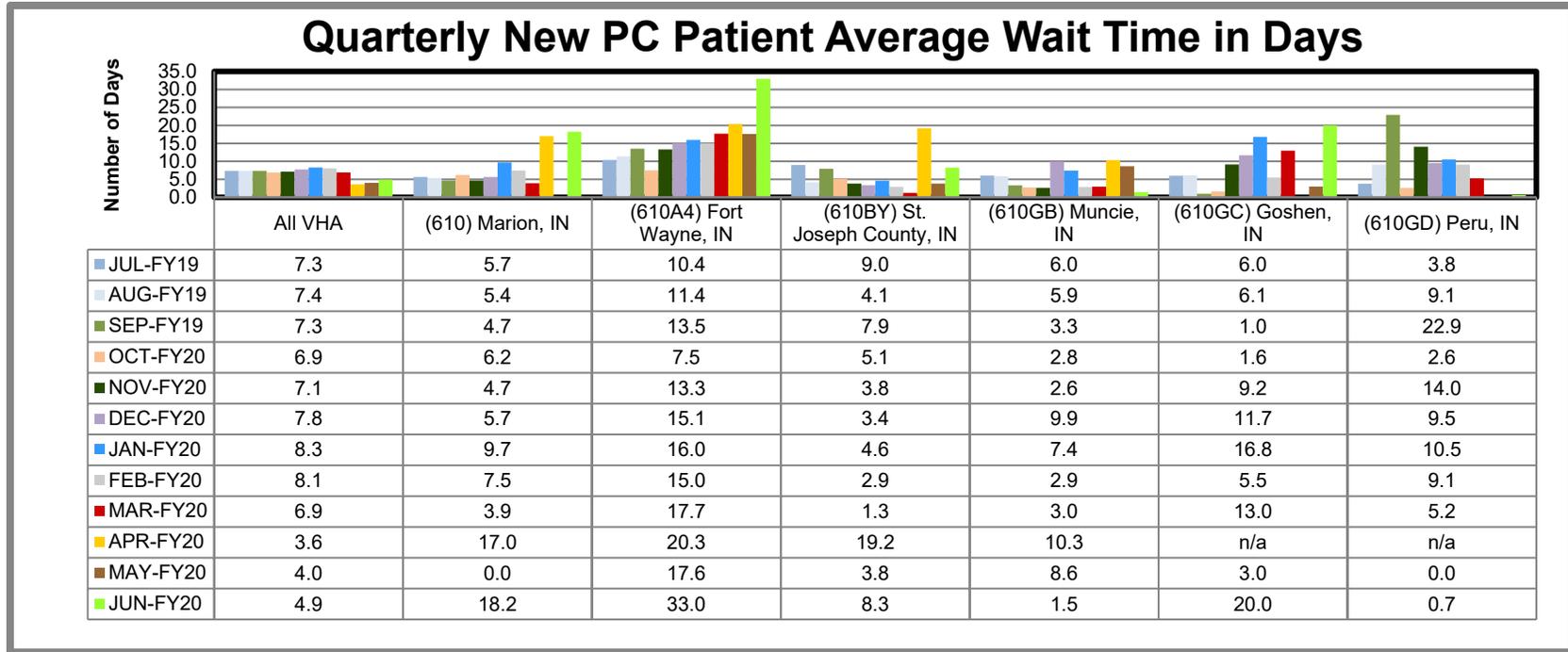
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Mishawaka, IN, cont.				Neurology Orthopedics Podiatry Urology Vascular		
Muncie, IN	610GB	10,188	4,188	Cardiology Dermatology Endocrinology Gastroenterology General surgery Neurology Orthopedics Urology Vascular	Radiology	Nutrition Pharmacy Prosthetics Weight management
Goshen, IN	610GC	7,598	3,030	Anesthesia Cardiology Dermatology Endocrinology Gastroenterology General surgery GYN Hematology/ Oncology Infectious disease Neurology Urology Vascular	Radiology	Pharmacy Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Peru, IN	610GD	6,317	2,478	Cardiology Dermatology Endocrinology Gastroenterology General surgery Hematology/ Oncology Neurology Orthopedics Urology Vascular	Radiology	Nutrition Pharmacy Prosthetics Weight management
Fort Wayne, IN	610QA	–	15,126	Endocrinology	–	Nutrition Pharmacy Social Work

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

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

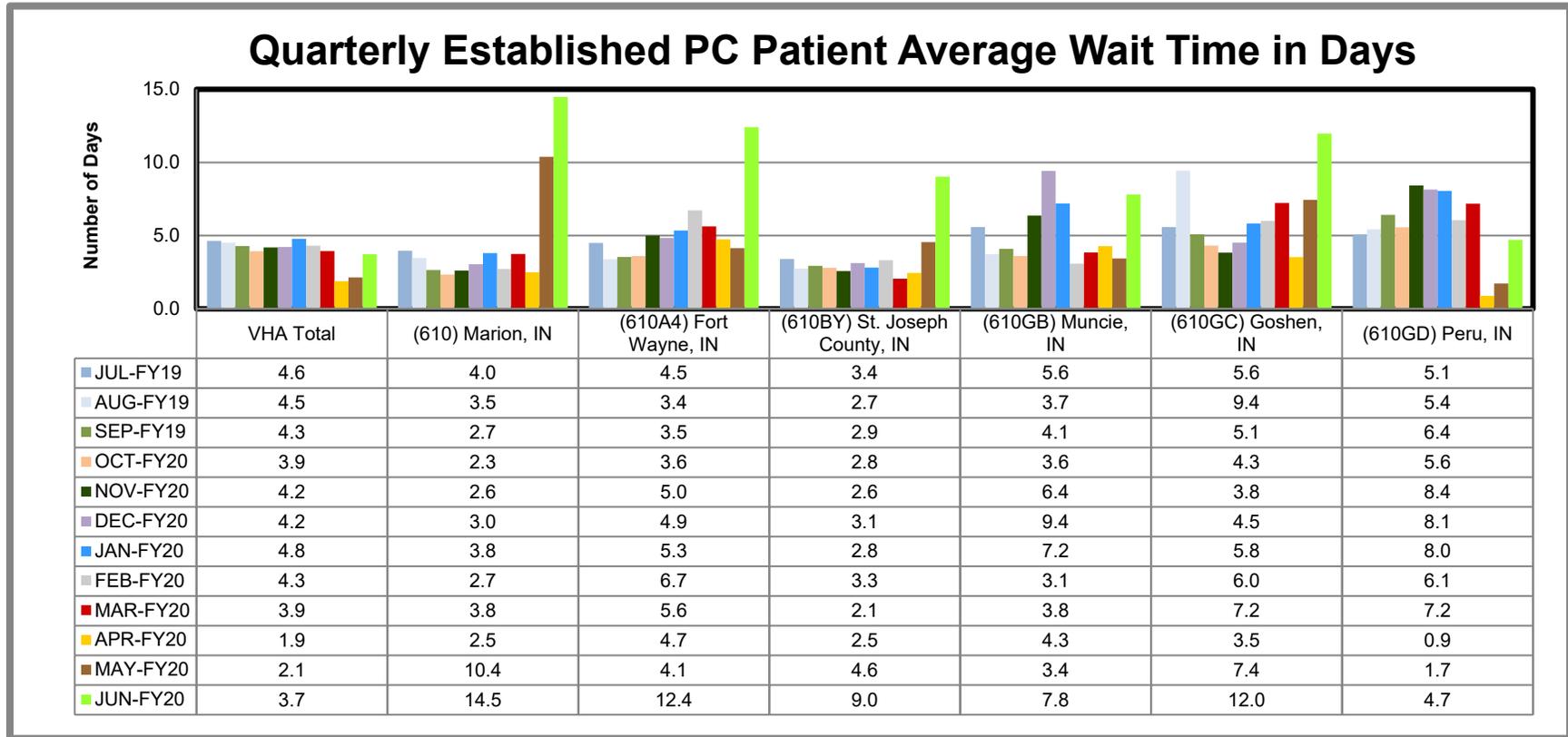
Appendix D: Patient Aligned Care Team Compass Metrics



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 Fort Wayne Clinic. The OIG omitted (610QA) Fort Wayne East State Boulevard, IN and (610QB) Columbia Place, IN as no data was reported.

Data Definition. "The average number of calendar days between a New Patient's Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date." 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. Patient Aligned Care Teams Compass Data Definitions, <https://vssc.med.va.gov>, accessed October 21, 2019.

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted (610QA) Fort Wayne East State Boulevard, IN and (610QB) Columbia Place, IN as no data was reported.

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

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

Measure	Definition	Desired Direction
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
AES Data Use	Composite measure based on three individual All Employee Survey (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
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx – GM90_1	ORYX inpatient composite of global measures	A higher value is better than a lower value

Measure	Definition	Desired Direction
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
PSI90	Patient Safety and Adverse Events Composite (PSI90) focused on potentially avoidable complications and events	A lower value is better than a higher value
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC survey access	Timely appointment, care and information (specialty care)	A higher value is better than a lower value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value

Source: VHA Support Service Center.

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

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

Source: VHA Support Service Center.

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: April 26, 2021

From: Network Director, VA Healthcare System (10N10)

Subj: Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion

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

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

1. I have reviewed and concur with the response for the draft report of our Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion.
2. I concur with the responses and action plans submitted by the VA Northern Indiana Health Care System Executive Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson

Appendix H: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: April 22, 2021

From: Executive Director, VA Northern Indiana Health Care System (610/00)

Subj: Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion

To: Network Director, VA Healthcare System (10N10)

1. Attached is a status update as a result of VA Northern Indiana Health Care System's OIG CHIP review that was conducted the week of July 27, 2020.
2. We have provided narrative responses along with supporting documentation for each recommendation for consideration with planned completion dates outlined in this report.

(Original signed by:)

Michael E. Hershman, MHA, FACHE

Executive Director

OIG Contact and Staff Acknowledgments

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