



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare
Inspection of the Richard L.
Roudebush VA Medical
Center

Indianapolis, Indiana



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Figure 1. *Richard L. Roudebush VA Medical Center, Indianapolis, IN*
(Source: <https://vaww.va.gov/directory/guide/>, accessed on May 16, 2019)

Abbreviations

ADPCS	associate director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
FPPE	focused professional practice evaluation
FY	fiscal year
LIP	licensed independent practitioner
MST	military sexual trauma
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
SAIL	Strategic Analytics for Improvement and Learning
TJC	The Joint Commission
UCC	urgent care center
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) provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Richard L. Roudebush VA Medical Center (the facility). The inspection covers key clinical and administrative processes that are associated with promoting quality care.

CHIP inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The reviews 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 as well as areas affecting quality patient care. At the time of the review, the clinical areas of focus were

1. Quality, safety, and value;
2. Medical staff privileging;
3. Environment of care;
4. Medication management (specifically the controlled substances inspection program);
5. Mental health (focusing on military sexual trauma follow-up and staff training);
6. Geriatric care (spotlighting antidepressant use for elderly veterans);
7. Women's health (particularly abnormal cervical pathology result notification and follow-up); and
8. High-risk processes (specifically the emergency department and urgent care center operations and management).

This unannounced visit was conducted during the week of January 28, 2019. The OIG held interviews and reviewed clinical and administrative processes related to areas of focus that affect patient care outcomes. Although the OIG reviewed a broad spectrum of clinical and administrative 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 facility's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this facility and other Veterans Health Administration (VHA) facilities to identify areas of vulnerability or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results and Inspection Impact

Leadership and Organizational Risks

At the time of the OIG's visit, the facility leadership team consisted of the director, chief of staff, associate director for Patient Care Services (ADPCS), associate director (primarily nonclinical), and assistant director (primarily nonclinical). Organizational communications and accountability were managed through a committee reporting structure, with the Leadership Council having oversight for several working groups. The chief of staff and chief of Quality, Safety & Value were the co-chairs of the Clinical and Performance Board/Quality, Safety & Value Committee, which was responsible for tracking, identifying trends in, and monitoring quality of care and patient outcomes.

The facility's leadership team was relatively new, having worked together for four months as of the week of the OIG site visit. The ADPCS, appointed in September 2018, was the newest member of the team while the assistant director was the most tenured member, having been in the position since January 2012.

The OIG noted that selected employee satisfaction survey results indicated that opportunities appear to exist to for the ADPCS to improve employee satisfaction and provide a safe workplace environment where employees feel comfortable bringing forth issues or ethical concerns. However, it is important to note that the scores are not reflective of this leader, who assumed the role in September 2018. The selected patient experience survey scores for facility leaders were better than the VHA average, and facility leaders appeared to be actively engaged with patients.

Additionally, the OIG reviewed accreditation agency findings, sentinel events,¹ disclosures of adverse patient events, and patient safety indicator data and identified organizational risk factors that may contribute to future issues of lapses in patient safety unless corrective processes are implemented and continuously monitored.

The OIG recognizes that the Strategic Analytics for Improvement and Learning (SAIL) model has limitations for identifying all areas of clinical risk but is "a way to understand the similarities and differences between the top and bottom performers" within VHA.² Although the leadership

¹ The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

² VHA's Office of Operational Analytics and Reporting developed a model for understanding a facility's performance in relation to nine quality domains and one efficiency domain. The domains within SAIL are made up of multiple composite measures, and the resulting scores permit comparison of facilities within a Veterans Integrated Service Network or across VHA. The SAIL model uses a "star rating" system to designate a facility's performance in individual measures, domains, and overall quality.

<http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938>. (The website was accessed on March 6, 2019, but is not accessible by the public.)

team members, with the exception of the recently-appointed ADPCS, were knowledgeable within their areas of responsibility about selected SAIL metrics, the leaders should continue to take actions to sustain and improve performance of the quality of care metrics and measures likely contributing to the facility's SAIL "3-star" quality rating.³

The OIG noted deficiencies in six of the eight clinical areas reviewed and issued 13 recommendations that are attributable to the director, chief of staff, and associate director. These are briefly described below.

Quality, Safety, and Value

The facility complied with the requirements for some of the performance indicators. However, the OIG identified deficiencies with quarterly summary report submission for protected peer reviews, the interdisciplinary reviews of UM data,⁴ inclusion of required review elements in root cause analyses, resuscitation episode reviews, and implementation and monitoring of corrective actions for effectiveness to improve quality assurance and clinical outcomes.

Medical Staff Privileging

The OIG found general compliance with requirements for privileging and ongoing professional practice evaluations. However, the OIG identified concerns with focused professional practice evaluations for cause.⁵

Environment of Care

Generally, the OIG found compliance with many of the performance indicators including safety, privacy, and women veterans program requirements. The OIG did not note any issues with the

³ Based on fiscal year 2018, quarter 3 ratings at the time of the site visit.

⁴ The definition of utilization management can be found within VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018). Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria." The January 2018 version of the directive was in effect at the time of the January 2019 review. Subsequently, the directive was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019), which expired on July 31, 2019. The utilization management definition remained consistent in both versions of the directive.

⁵ The definitions of ongoing professional practice evaluation and focused professional practice evaluations can be found within Office of Safety and Risk Awareness, Office of Quality and Performance, *Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance*, July 2016 (Revision 2). An ongoing professional practice evaluation is "the ongoing monitoring of privileged providers to confirm the quality of care delivered and ensures patient safety." A focused professional practice evaluation is "a time-limited process whereby the clinical leadership evaluates the privilege-specific competence of a provider who does not yet have documented evidence of competently performing the requested privilege(s) at the facility." A focused professional practice evaluation for cause is "a time-limited period during which the medical staff leadership assesses the provider's professional performance to determine if any action should be taken on the provider's privileges."

availability of medical equipment and supplies. However, the OIG identified a deficiency in infection prevention procedures for damaged wheelchairs.

Medication Management

The OIG found general compliance with requirements for most of the performance indicators evaluated, including the controlled substances coordinator reports, pharmacy operations, requirements for controlled substances inspectors, and pharmacy inspections. However, the OIG identified noncompliance with the review of monthly and quarterly trend reports, verification of controlled substances orders, and review of medication override reports.

Geriatric Care

Generally, the OIG found compliance with documenting justification for initiating the medication. However, the OIG identified that clinicians did not provide adequate patient and/or caregiver education about the safe and effective use of newly prescribed medication nor did they reconcile the patients' medication relevant to the episode of care.

Women's Health

Generally, the OIG found compliance with many of the performance indicators, including requirements for a designated women veterans program manager and clinical champion, clinical oversight of the women's health program, tracking of data related to cervical cancer screenings, communication of results to patients within the required time frame, and follow-up care when indicated. The OIG noted a concern with the core membership of the Women Veterans Health Committee that warranted a recommendation for improvement.

Summary

In reviewing key healthcare processes, the OIG issued 13 recommendations for improvement directed to the facility director, chief of staff, and associate director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this facility. The intent is for facility 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 eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network director and acting facility director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes E and F, pages 69–70, and the responses within the body of the report for the full text of the directors’ comments.) The OIG will follow up on the planned actions for the open recommendations until they are completed.



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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to provide oversight of healthcare services to veterans. This focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Richard L. Roudebush VA Medical Center (the facility) is accomplished by examining a broad overview of key clinical and administrative processes associated with quality care and positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and facility leaders so that informed decisions can be made on improving care.

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting the quality agenda; and promoting a culture to sustain positive change.⁶ Investments in a culture of safety and quality improvement with robust communications and leadership significantly contribute to positive patient outcomes in healthcare organizations.⁷ Figure 2 shows the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

To examine risks to patients and the organization when core processes are not performed well, the OIG focused on the following nine areas of clinical and administrative operations that support quality care at the facility:⁸

1. Leadership and organizational risks
2. Quality, safety, and value (QSV)
3. Medical staff privileging
4. Environment of care
5. Medication management (specifically the controlled substances inspection program)
6. Mental health (focusing on military sexual trauma follow-up and staff training)
7. Geriatric care (spotlighting antidepressant use for elderly veterans)
8. Women's health (particularly abnormal cervical pathology results notification and follow-up)

⁶ Anam Parand, Sue Dopson, Anna Renz, and Charles Vincent, "The role of hospital managers in quality and patient safety: a systematic review," *British Medical Journal*, 4, no. 9 (September 5, 2014): e005055. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4158193/>. (The website was accessed on January 24, 2019.)

⁷ Institute for Healthcare Improvement, "How risk management and patient safety intersect: Strategies to help make it happen," March 24, 2015. <http://www.npsf.org/blogpost/1158873/211982/How-Risk-Management-and-Patient-Safety-Intersect-Strategies-to-Help-Make-It-Happen>. (The website was accessed on January 24, 2019.)

⁸ See Figure 2. CHIP inspections address these processes during FY 2019 (October 1, 2018, through September 30, 2019); they may differ from prior years' focus areas.

9. High-risk processes (specifically the emergency department and urgent care center operations and management).

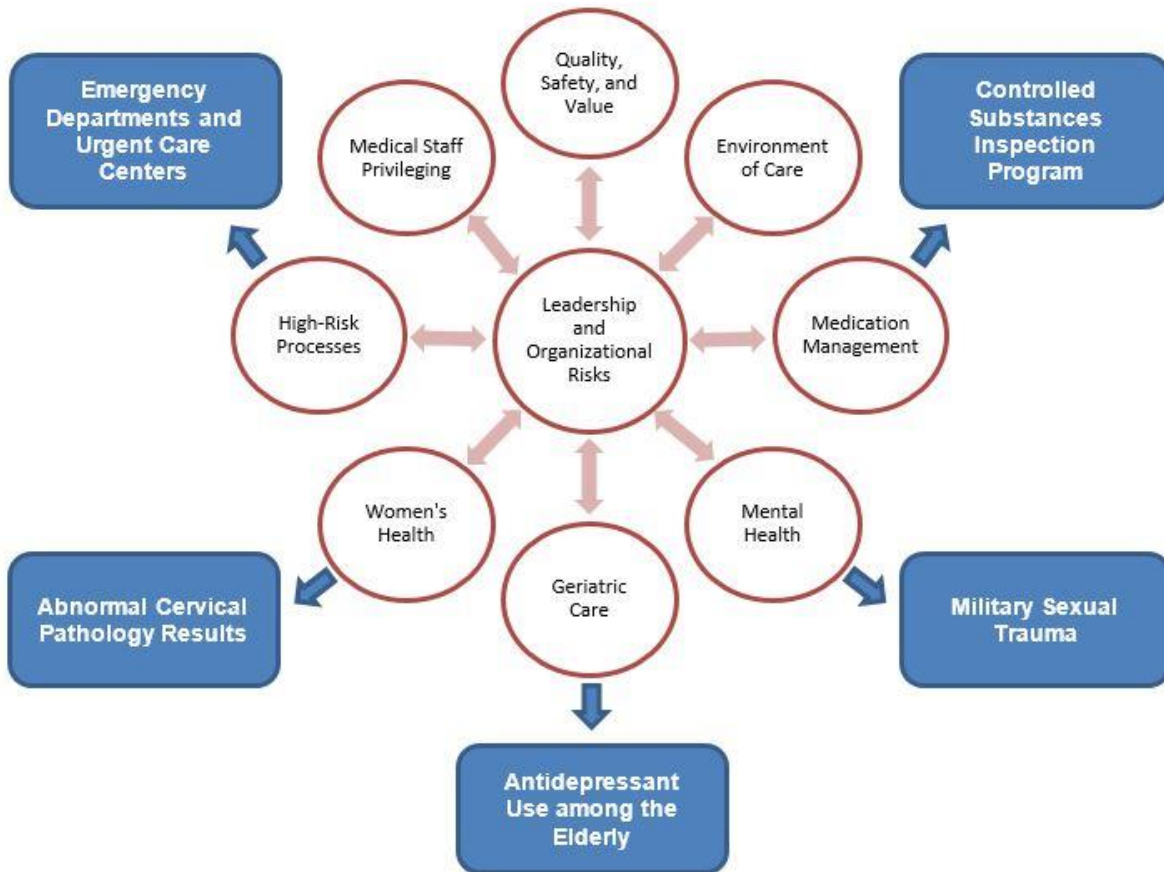


Figure 2. Fiscal Year (FY) 2019 Comprehensive Healthcare Inspection of Operations and Services
Source: VA OIG

Methodology

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports;⁹ physically inspected OIG-selected areas; and discussed processes and validated findings with managers and employees. The OIG also interviewed members of the executive leadership team.

The inspection period examined operations from March 12, 2016, through February 1, 2019, the last day of the unannounced week-long site visit.¹⁰ While on site, the OIG referred issues and concerns beyond the scope of the CHIP review to our Hotline management team for further evaluation.

This report's recommendations for improvement target problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the facility completes corrective actions. The facility director's comments submitted in response to the report recommendations appear within each topic area.

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

⁹ The OIG did not review VHA's internal survey results, instead focusing on OIG inspections and external surveys that affect facility accreditation status.

¹⁰ The range represents the time period from the last Clinical Assessment Program review, which was performed prior to the comprehensive healthcare inspection, to the completion of the unannounced week-long CHIP site visit.

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare facility. Leadership and organizational risks can impact the facility's ability to provide care in all of the selected clinical areas of focus.¹¹ To assess the facility's risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation and/or for-cause surveys and oversight inspections
5. Factors related to possible lapses in care
6. VHA performance data

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 facility's reported organizational structure. The facility has a leadership team consisting of the director, chief of staff, associate director for Patient Care Services (ADPCS), associate director (primarily nonclinical), and assistant director (primarily nonclinical). The chief of staff and ADPCS oversee patient care, which requires managing service directors and chiefs of programs and practices.

¹¹ L. Botwinick, M. Bisognano, and C. Haraden, "Leadership Guide to Patient Safety," *Institute for Healthcare Improvement*, Innovation Series White Paper. 2006. www.IHI.org. (The website was accessed on February 2, 2017.)

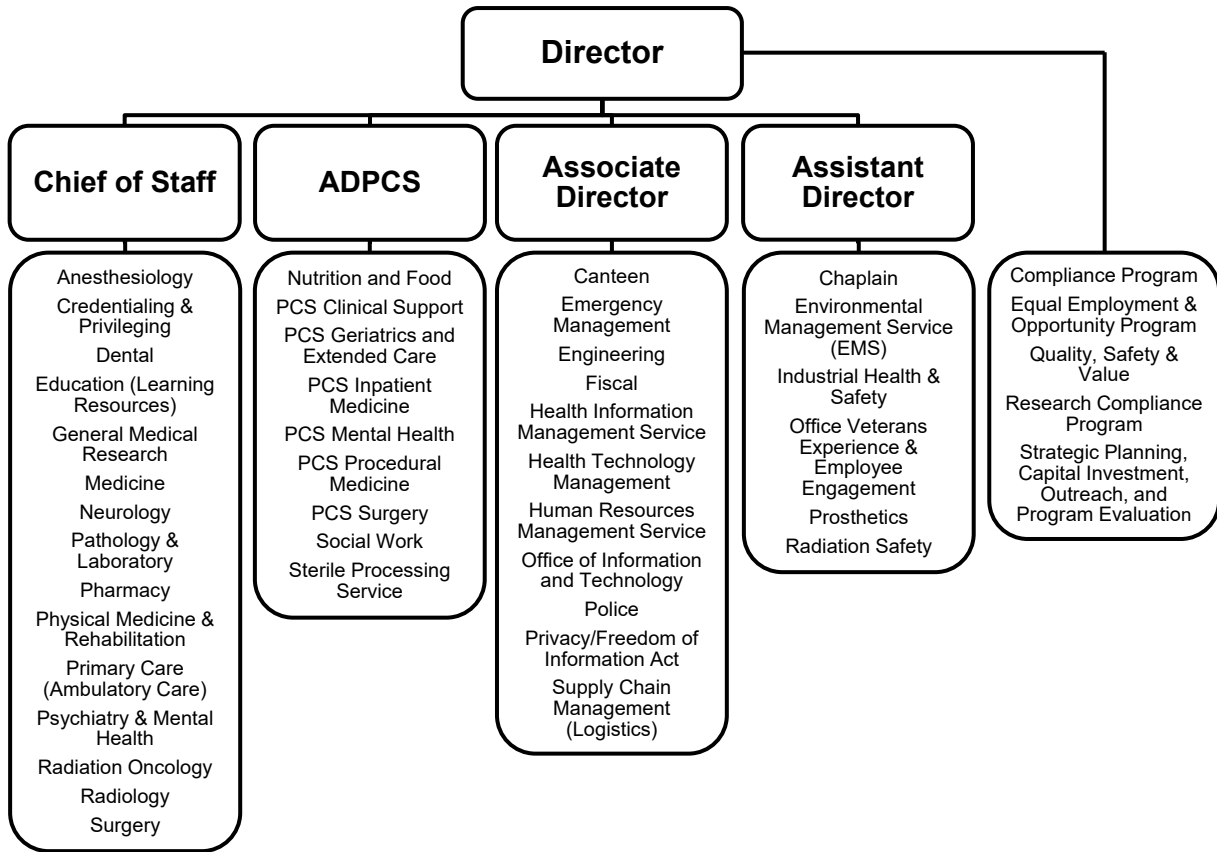


Figure 3. Facility Organizational Chart¹²

Source: Richard L. Roudebush VA Medical Center System (received January 29, 2019)

At the time of the OIG site visit, the executive team had been working together for four months, although several team members have been in their position for many years (see Table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Facility director	May 1, 2016
Chief of staff	December 10, 2017
Associate director for Patient Care Services	September 16, 2018
Associate director	December 25, 2016
Assistant director	January 1, 2012

Source: Richard L. Roudebush VA Medical Center human resources officer (received January 28, 2019)

¹² At this facility, the director is responsible for the Compliance Program, Equal Employment and Opportunity Program; Quality, Safety, and Value; Research Compliance Program; and Strategic Planning, Capital Investment, Outreach, and Program Evaluation.

To help assess facility executive leaders' engagement, the OIG interviewed the director, chief of staff, ADPCS, and associate director regarding their knowledge of various performance metrics and their involvement and support of actions to improve or sustain performance.

In individual interviews, these executive leadership team members, except for the recently-appointed ADPCS, generally were able to speak knowledgeably about actions taken during the previous 12 months in order to maintain or improve performance, as well as employee and patient survey results. In addition, the executive leaders were generally knowledgeable, within their scope of responsibilities, about selected Strategic Analytics for Improvement and Learning (SAIL) metrics. These are discussed in greater detail below.

These leaders are also engaged in monitoring patient safety and care through formal mechanisms. The Clinical and Performance Board/Quality, Safety and Value Committee, co-chaired by the chief of staff and chief of Quality, Safety, and Value (QSV), is responsible for focusing on health care delivery, patient care programs, performance improvement and clinical administration, education, and research and reports to the Leadership Council. The director serves as the chairperson of the Leadership Council, with the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Leadership Council also oversees various working groups, such as the Resources and Planning Board, Executive Committee of the Medical Staff, and Integrated Ethics Board. The OIG noted that although facility policy requires the Leadership Council to meet monthly, minutes for meetings held from May through August 2018 were not available for review when requested. See Figure 4.

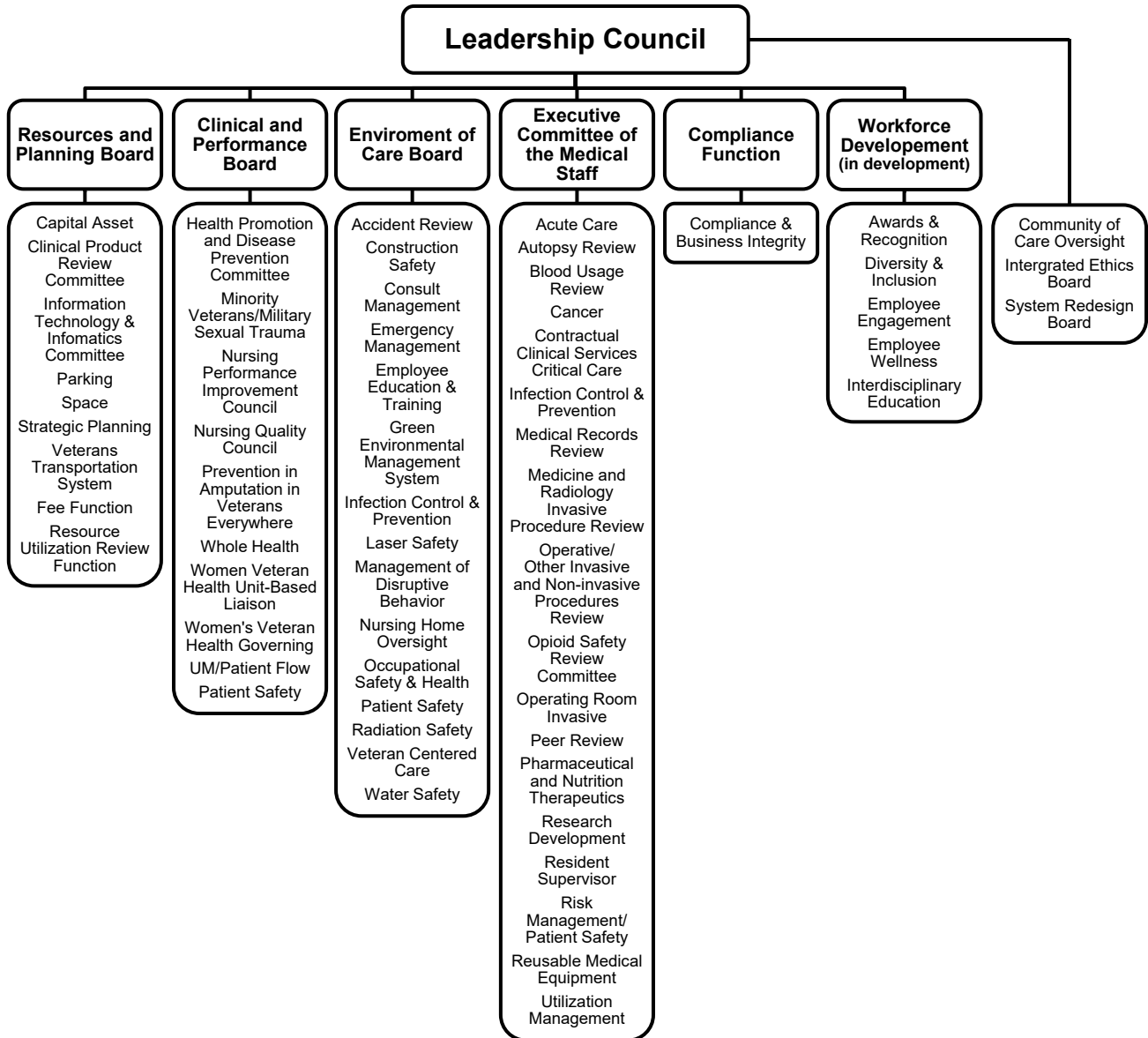


Figure 4. Facility Committee Reporting Structure¹³
Source: Richard L. Roudebush VA Medical Center (received January 29, 2019)

Employee Satisfaction

The All Employee Survey is an “annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential.” Since 2001, the instrument has been refined several times in response to VA leaders’ inquiries on VA culture and organizational health. Although the

¹³ The Leadership Council oversees the Community of Care Oversight, Integrated Ethics Board, and System Redesign Board.

OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on facility leadership.

To assess employee attitudes toward facility leaders, the OIG reviewed employee satisfaction survey results from VHA’s All Employee Survey that relate to the period of October 1, 2017, through September 30, 2018.¹⁴ Table 2 provides relevant survey results for VHA, the facility, and selected facility executive leaders. It summarizes employee attitudes toward these selected facility leaders as expressed in VHA’s All Employee Survey. The OIG found the facility average for selected survey leadership questions was similar to or lower than the VHA average.¹⁵ The executive leader scores were above the VHA averages, with the exception of the ADPCS whose results were generally lower than the facility and VHA averages.¹⁶ Although opportunities appear to exist to improve employee satisfaction with the ADPCS, it is important to note that the scores are not reflective of the current ADPCS, who assumed the role in September 2018.

**Table 2. Survey Results on Employee Attitudes toward Facility Leadership
(October 1, 2017, through September 30, 2018)**

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
All Employee Survey: <i>Servant Leader Index Composite</i> ¹⁷	0–100 where HIGHER scores are more favorable	71.7	71.3	90.4	76.4	75.0	79.6	91.7
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)	3.3	3.2	4.0	3.7	2.7	3.5	4.0

¹⁴ Ratings are based on responses by employees who report to or are aligned under the director, chief of staff, ADPCS, and associate director.

¹⁵ 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.

¹⁶ The ADPCS scores are not reflective of the current ADPCS, who assumed the role after the survey was administered in June 2018.

¹⁷ According to the 2018 VA All Employee Survey Questions by Organizational Health Framework, Servant Leader Index “is a summary measure of the work environment being a place where organizational goals are achieved by empowering others. This includes focusing on collective goals, encouraging contribution from others, and then positively reinforcing others’ contributions. Servant Leadership occurs at all levels of the organization, where individuals (supervisors, staff) put others’ needs before their own.”

Questions/ Survey Items	Scoring	VHA Average	Facility 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)	3.5	3.4	3.9	3.8	2.8	3.9	4.1
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	3.9	3.9	2.8	3.9	4.4

Source: VA All Employee Survey (accessed January 11, 2019)

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. The OIG noted that the facility averages for the selected survey questions were similar to the VHA average and that those for the executive leaders, with the exception of the ADPCS, were generally similar to or better than both the VHA and facility averages.¹⁸ Again, opportunities appear to exist for the current ADPCS to provide a safe workplace environment where employees feel comfortable bringing forth issues or ethical concerns. Facility leaders verbalized ongoing efforts to improve the culture of the organization.

**Table 3. Survey Results on Employee Attitudes toward the Workplace
(October 1, 2017, through September 30, 2018)**

Questions/ Survey Items	Scoring	VHA Average	Facility 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	4.5	3.8	3.3	3.9	4.3
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	3.6	4.1	4.0	3.0	3.6	4.5

¹⁸ The ADPCS scores are not reflective of the current ADPCS, who assumed the role after the survey was administered in June 2018.

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average	Asst. Director Average
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)	1.5	1.5	1.5	1.2	1.6	1.4	0.5

Source: VA All Employee Survey (accessed January 11, 2019)

Patient Experience

To assess patient attitudes toward facility leaders, the OIG reviewed patient experience survey results that relate to the period of October 1, 2017, through September 30, 2018. VHA’s Patient Experiences Survey Reports provide results from the Survey of Healthcare Experience of Patients (SHEP) program. VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients’ experiences with their health care and to support benchmarking its performance against the private sector. Table 4 provides relevant survey results for facility leadership and compares the results to the overall VHA averages.¹⁹

VHA also collects SHEP survey data from Patient-Centered Medical Home, Specialty Care, and Inpatient Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients’ attitudes toward facility leaders (see Table 4). For this facility, the selected survey results reflected higher ratings than the VHA average. Patients appear generally satisfied with the leadership and care provided, and facility leaders appeared to be actively engaged with patients.

Table 4. Survey Results on Patient Attitudes toward Facility Leadership (October 1, 2017, through September 30, 2018)

Questions	Scoring	VHA Average	Facility 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.	66.9	73.8

¹⁹ Ratings are based on responses by patients who received care at this facility.

Questions	Scoring	VHA Average	Facility Average
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.	84.2	84.7
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.	76.3	77.0
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.	76.5	80.3

Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed January 11, 2019)

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys, including those conducted for cause, by oversight and accrediting agencies to gauge how well leaders respond to identified problems.²⁰ Table 5 summarizes the relevant facility inspections most recently performed by the OIG and The Joint Commission (TJC).²¹ During the on-site review, the OIG noted that the facility had two open recommendations from a Hotline report that was published 12 days prior.²² Actions to address these recommendations were in progress.

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

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

²² A closed status indicates that the facility has implemented corrective actions and improvements to address findings and recommendations, not by self-certification, but as determined by the accreditation organization or inspecting agency.

At the time of the site visit, the OIG also noted the facility’s current accreditation status with the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.²³

Table 5. 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 Richard L. Roudebush VA Medical Center, Indianapolis, Indiana, Report No. 16-00111-310, May 19, 2016</i>)	March 2016	30	0
OIG (<i>Review of Community Based Outpatient Clinics and Other Outpatient Clinics of the Richard L. Roudebush VA Medical Center, Indianapolis, Indiana, Report No. 16-00020-303, May 11, 2016</i>)	March 2016	8	0
OIG (<i>Concerns Related to the Management of a Patient’s Medication at Three VA Medical Centers and Inaccurate Response to a Congressional Inquiry at the VA Illiana Health Care System, Orlando, Florida, Indianapolis, Indiana, Danville, Illinois, Report No. 18-02056-54, January 16, 2019</i>)	Not applicable	2 ²⁴	2

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

²⁴ Although eight recommendations are made in the report, only recommendations three and four are directed to the Richard L. Roudebush VA Medical Center.

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
TJC Hospital Accreditation	March 2018	32	0
TJC Behavioral Health Care Accreditation		9	0
TJC Home Care Accreditation	June 2018	10	0
TJC Behavioral Health: Opioid Substitution Program		8	0
TJC Disease Specific Care: Advanced Primary Stroke Center	June 2018	5	0

Source: OIG and TJC (inspection/survey results verified with the chief of Quality Management on January 29, 2019)

Factors Related to Possible Lapses in Care

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. Table 6 lists the reported patient safety events from March 12, 2016 (the prior comprehensive OIG inspection), through February 1, 2019.²⁵

²⁵ It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the Richard L. Roudebush VA Medical Center is a highest complexity (1a) affiliated facility as described in Appendix B.)

**Table 6. Summary of Selected Organizational Risk Factors
(March 12, 2016, through February 1, 2019)**

Factor	Number of Occurrences
Sentinel Events ²⁶	13
Institutional Disclosures ²⁷	3
Large-Scale Disclosures ²⁸	0

Source: Richard L. Roudebush VA Medical Center System's assistant chief of Quality Management (received January 29, 2019)

The OIG also reviewed patient safety indicators developed by the Agency for Healthcare Research and Quality within the U.S. Department of Health and Human Services. These provide information on potential in-hospital complications and adverse events following surgeries and procedures.²⁹ The rates presented are specifically applicable for this facility, and lower rates indicate lower risks. Table 7 summarizes patient safety indicator data from October 1, 2016, through September 30, 2018.

**Table 7. Patient Safety Indicator Data
(October 1, 2016, through September 30, 2018)**

Indicators	Reported Rate per 1,000 Hospital Discharges		
	VHA	VISN 10	Facility
Pressure ulcer	0.74	0.45	0.26
Death among surgical inpatients with serious treatable conditions	113.42	135.14	163.79

²⁶ The definition of sentinel event can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient “death, permanent harm, or severe temporary harm and intervention required to sustain life.”

²⁷ According to VHA Directive 1004.08, *Disclosure of Adverse Events To Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an “administrative disclosure”) as “a formal process by which VA medical facility leaders together with clinicians and others, as appropriate, inform the patient or [his or her] personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse.”

²⁸ According to VHA Directive 1004.08, VHA defines large-scale disclosures of adverse events (sometimes referred to as “notifications”) as “a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they may have been affected by an adverse event resulting from a systems issue.”

²⁹ Agency for Healthcare Research and Quality. <https://www.qualityindicators.ahrq.gov/>. (The website was accessed on December 11, 2017.)

Indicators	Reported Rate per 1,000 Hospital Discharges		
	VHA	VISN 10	Facility
Iatrogenic pneumothorax ³⁰	0.17	0.17	0.16
Central venous catheter-related bloodstream infection	0.16	0.16	0.13
In-hospital fall with hip fracture	0.09	0.12	0.09
Perioperative hemorrhage or hematoma	2.61	3.55	2.44
Postoperative acute kidney injury requiring dialysis	0.89	1.06	2.02
Postoperative respiratory failure	4.54	5.52	8.22
Perioperative pulmonary embolism or deep vein thrombosis	2.97	2.19	2.31
Postoperative sepsis	3.55	3.16	5.25
Postoperative wound dehiscence (rupture along incision)	0.82	0.91	1.10
Unrecognized abdominopelvic accidental puncture or laceration	1.00	0.82	0.95

Source: VHA Support Service Center

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

The patient safety indicator measure for death among surgical inpatients with serious treatable conditions, postoperative acute kidney injury requiring dialysis, postoperative respiratory failure, postoperative sepsis, and postoperative wound dehiscence (rupture along incision) show a higher reported rate than VISN 10 and VHA. The patient safety indicator measures for perioperative pulmonary embolism or deep vein thrombosis and unrecognized abdominopelvic accidental puncture or laceration show a higher reported rate than VISN 10.

The OIG also reviewed patient safety indicator data for FY 2018, quarter 4 (the most recent data) and the previous four quarters to identify any potential trends that may impact patient safety or increase the risk for patient harm. It is important to note that although the data are collected and reported by quarter, each set of quarterly data represents potential complications or patient safety events over an eight-quarter or two-year period. Further, it is possible for a facility measure to exceed the VHA rate due to a single incident and for that measure to vary above or below the VHA rate over time due to differences in the number of patients treated. Figure 5 illustrates the time frames covered by the data reviewed.

³⁰ According to Northwestern Memorial Hospital, “A Pneumothorax is a type of lung injury that allows air to leak into the area between the lungs and the chest wall, which causes mild to severe chest pain and shortness of breath. An Iatrogenic Pneumothorax is caused by medical treatment, often as an incidental event during a procedure such as a pacemaker insertion.” Northwestern Medicine. <http://www.nmh.org/nm/quality-lung-injury-due-to-medical-care>. (The website was accessed on March 6, 2019.)

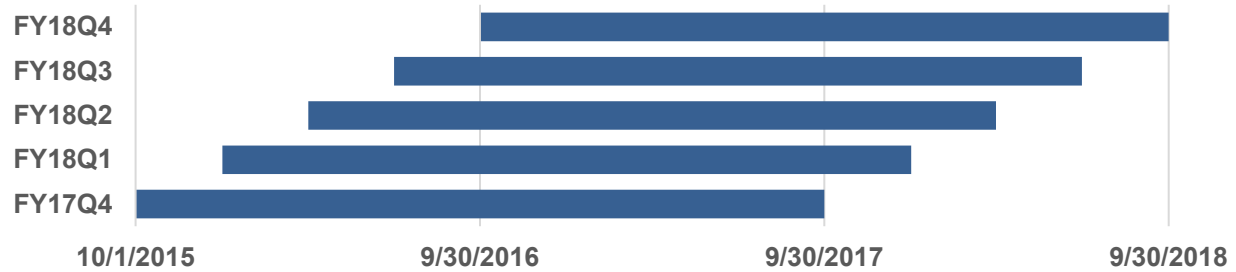


Figure 5. Associated Time Frames for Quarterly Patient Safety Indicator Data

Source: VA OIG

FY18Q4 = fiscal year 2018, quarter 4

FY18Q3 = fiscal year 2018, quarter 3

FY18Q2 = fiscal year 2018, quarter 2

FY18Q1 = fiscal year 2018, quarter 1

FY17Q4 = fiscal year 2017, quarter 4

Table 8 summarizes patient safety indicator data for FY 2017, quarter 4 (FY17Q4) through FY 2018, quarter 4 (FY18Q4), which includes potential complications from October 1, 2015, through September 30, 2018.

**Table 8. Patient Safety Indicator Data Trending
(October 1, 2015, through September 30, 2018)**

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Pressure ulcer	VHA	0.60	0.88	— ³¹	0.76	0.74
	Facility	0.43	0.55	—	0.38	0.26
Death among surgical inpatients with serious treatable conditions	VHA	100.97	118.96	113.92	114.89	113.42
	Facility	178.57	182.48	161.29	173.55	163.79
Iatrogenic pneumothorax	VHA	0.19	0.19	0.17	0.15	0.17
	Facility	0.16	0.14	0.16	0.08	0.16
Central venous catheter-related bloodstream infection	VHA	0.15	0.14	0.15	0.16	0.16
	Facility	0.13	0.11	0.13	0.13	0.13
In-hospital fall with hip fracture	VHA	0.08	0.09	0.08	0.09	0.09
	Facility	0.00	0.00	0.09	0.09	0.09
Perioperative hemorrhage or hematoma	VHA	1.94	2.58	2.62	2.59	2.61
	Facility	2.86	3.17	3.40	3.12	2.44

³¹ According to VHA’s Inpatient Evaluation Center, pressure ulcer data are not available for the time frame of April 1, 2016, through March 31, 2018.

Indicators	Site	Reported Rate per 1,000 Hospital Discharges				
		FY17Q4	FY18Q1	FY18Q2	FY18Q3	FY18Q4
Postoperative acute kidney injury requiring dialysis	VHA	0.88	0.80	0.65	0.96	0.89
	Facility	2.21	2.01	1.42	1.96	2.02
Postoperative respiratory failure	VHA	5.55	5.34	5.11	4.88	4.54
	Facility	11.13	9.97	8.98	7.26	8.22
Perioperative pulmonary embolism or deep vein thrombosis	VHA	3.29	3.26	3.09	3.05	2.97
	Facility	3.34	3.03	2.90	3.28	2.31
Postoperative sepsis	VHA	4.00	3.96	3.72	3.70	3.55
	Facility	6.40	6.24	5.41	5.62	5.25
Postoperative wound dehiscence (rupture along incision)	VHA	0.52	1.04	1.00	0.93	0.82
	Facility	3.22	2.58	3.07	3.13	1.10
Unrecognized abdominopelvic accidental puncture or laceration	VHA	0.53	1.21	1.02	1.07	1.00
	Facility	0.00	0.43	0.50	0.94	0.95

Source: VHA Support Service Center

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

Five measures (death among surgical inpatients with serious treatable conditions, postoperative acute kidney injury requiring dialysis, postoperative respiratory failure, postoperative sepsis, postoperative wound dehiscence) have trended above the VHA average. Most recently, perioperative hemorrhage or hematoma and perioperative pulmonary embolism or deep vein thrombosis measures improved to below the VHA rate.

Facility staff reported that there was no single point of contact within the facility responsible for the cyclical review of patient safety indicator scores, so no one could speak to potential trends or improvement actions taken in response to specific indicators. The chief of Surgery and chief of QSV shared that similar indicators are reviewed through the VA Surgical Quality Improvement Program and other data repositories. Additionally, the chief of QSV verbalized concerns regarding the accuracy of coding patient events in the electronic health record and timeliness of patient safety indicator data. During the OIG site visit, facility staff provided limited information, and the OIG could not determine if trends, process changes, or risk mitigation activities existed in response to the patient safety indicators. As a result, the OIG is concerned that the facility had not monitored its patient safety indicators and did not take action to evaluate and correct coding issues and address timeliness of the data.

Veterans Health Administration Performance Data

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

limitations for identifying all areas of clinical risk. The data are presented as one way to “understand the similarities and differences between the top and bottom performers” within VHA.³²

VA also uses a star rating system where facilities with a “5-star” rating are performing within the top 10 percent of facilities and “1-star” facilities are performing within the bottom 10 percent of facilities. Figure 6 describes the distribution of facilities by star rating.³³ As of June 30, 2018, the facility was rated as “3-star” for overall quality.

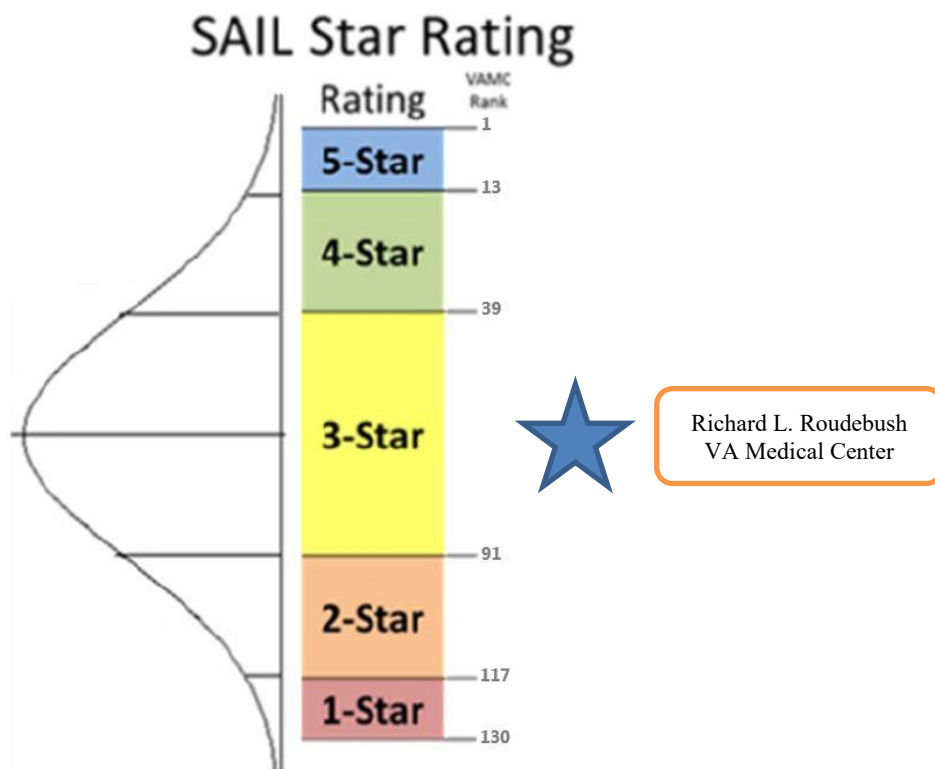


Figure 6. Strategic Analytics for Improvement and Learning Star Rating Distribution (as of June 30, 2018)

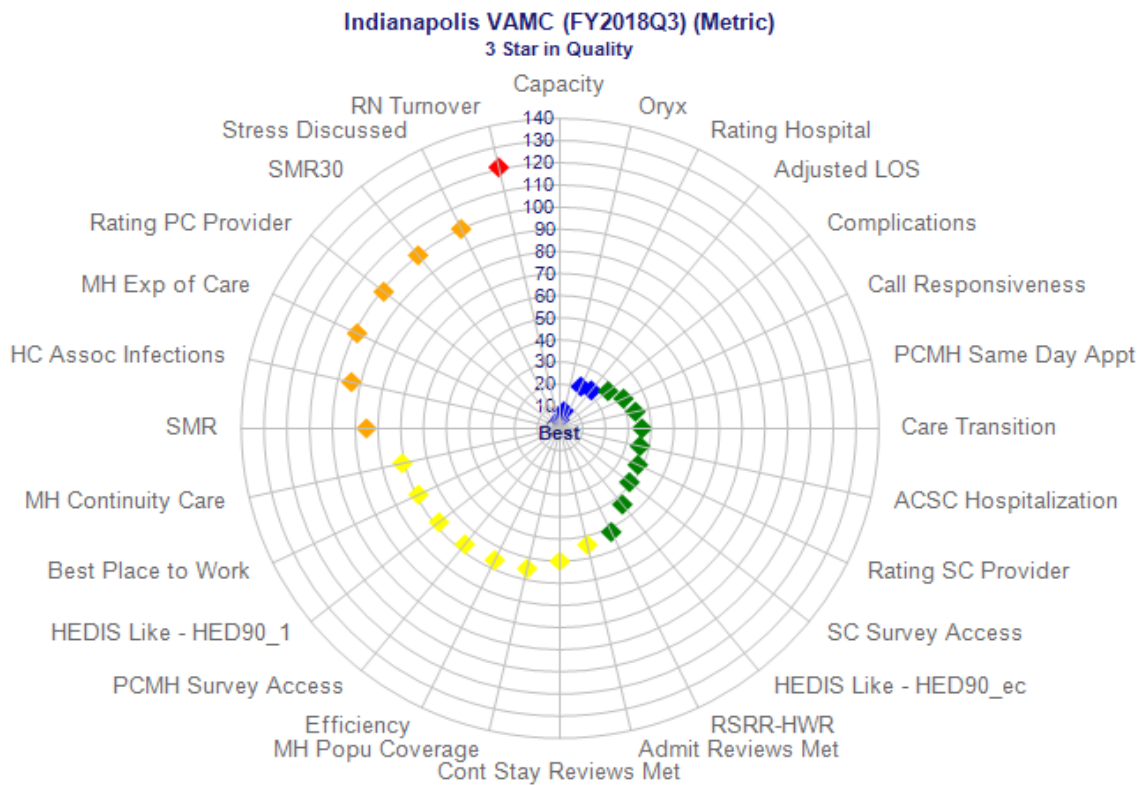
Source: VA Office of Informatics and Analytics Office of Operational Analytics and Reporting (accessed December 28, 2018)

Figure 7 illustrates the facility’s quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2018. Of note, the figure uses blue and green

³² VHA Support Service Center (VSSC), *The Strategic Analytics for Improvement and Learning (SAIL) Value Model*, <http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938>. (The website was accessed on March 7, 2019, but is not accessible by the public.)

³³ According to the methods established by the SAIL Model, this is based on normal distribution ranking of the quality domain for 130 VA Medical Centers.

data points to indicate high performance (for example, in the areas of capacity, patient centered medical home (PCMH) same day appointment (appt), and rating (of) specialty care (SC) provider). Metrics that need improvement are denoted in orange and red (for example, mental health (MH) experience (exp) of care, rating (of) primary care (PC) provider, stress discussed, and registered nurse (RN) turnover).³⁴



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

Figure 7. Facility Quality of Care and Efficiency Metric Rankings (as of June 30, 2018)

Source: VHA Support Service Center

Note: The OIG did not assess VA's data for accuracy or completeness. Also see Appendix C for sample outpatient performance measures that feed into these data points (such as wait times, discharge contacts, and where patient care is received). Data definitions are provided in Appendix D.

Leadership and Organizational Risks Conclusion

The facility's executive leadership team appeared relatively stable, with four positions permanently filled for over one year prior to the OIG's on-site visit. Selected survey scores related to employee satisfaction and trust in the facility's executive leaders were generally higher

³⁴ For information on the acronyms in the SAIL metrics, please see Appendix D.

than VHA averages; however, opportunities appear to exist for the current ADPCS to improve employee satisfaction and to provide a safe workplace environment where employees feel comfortable bringing forth issues or ethical concerns. In the OIG's review of patient experience survey data, patients appear generally satisfied with the leadership and care provided, and facility leaders appeared to be actively engaged with patients. The leaders appeared to support efforts to improve and maintain patient safety, quality care, and other positive outcomes; however, the organizational risk factors detailed in this report, as evidenced by sentinel events, institutional disclosures, and selected patient safety indicators may contribute to future issues of noncompliance and/or lapses in patient safety unless corrective processes are implemented and continuously monitored. The leadership team, with the exception of the recently-appointed ADPCS, were knowledgeable within their scope of responsibility about selected SAIL metrics but should continue to take actions to sustain and improve performance of measures contributing to the SAIL "3-star" quality rating.

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 that involves coordinating care among members of the healthcare team. To meet this goal, VHA must foster a culture of integrity and accountability in which personnel are vigilant and mindful, proactively risk-aware, and committed to consistently providing quality care, while seeking continuous improvement.³⁵ VHA also strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.³⁶ VHA requires that its facilities operate a quality, safety, and value (QSV) program to monitor the quality of patient care and performance improvement activities.³⁷

In determining whether the facility implemented and incorporated several OIG-selected key functions of VHA's Enterprise Framework for QSV into local activities, the inspection team evaluated protected peer reviews of clinical care,³⁸ utilization management (UM) reviews,³⁹ patient safety incident reporting with related root cause analyses,⁴⁰ and cardiopulmonary resuscitation (CPR) episode reviews.⁴¹

When conducted systematically and credibly, protected peer reviews reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and

³⁵ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. (This VHA directive was scheduled for recertification on or before the last working day of August 2018 but was rescinded on October 24, 2019.)

³⁶ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

³⁷ VHA Directive 1026.

³⁸ The definition of a peer review can be found within VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a critical review of care, performed by a peer, to evaluate care provided by a clinician for a specific episode of care, to identify learning opportunities for improvement, to provide confidential communication of the results back to the clinician, and to identify potential system or process improvements.

³⁹ The definition of utilization management can be found within VHA Directive 1117(1), *Utilization Management Program*, July 9, 2014 (amended January 18, 2018). Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria." The January 2018 version of the directive was in effect at the time of the January 2019 review. Subsequently, the directive was replaced by VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019), which expired on July 31, 2019. The utilization management definition remained consistent in both versions of the directive.

⁴⁰ The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. (This VHA handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.) 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."

⁴¹ VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.

nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.⁴²

The UM program, a key component of VHA's framework for quality, safety, and value, provides vital tools for managing the quality and the efficient use of resources. 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.⁴³

Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the facility.⁴⁴

VHA has also issued guidance to support its strategic priority of providing personalized, proactive, patient-driven care and to ensure that the provision of life-sustaining treatments, including CPR, is aligned with patients' values, goals, and preferences. VHA requires that each facility establishes a CPR Committee or equivalent that fully reviews each episode of care in which resuscitation was attempted. The ongoing review and analysis of high-risk healthcare processes is essential for ensuring patient safety and the provision of high-quality care. VHA also has established requirements for basic life support and advanced cardiac life support training and certification for clinicians responsible for administering life-sustaining treatments.⁴⁵

The OIG 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. Specifically, OIG inspectors evaluated the following performance indicators:⁴⁶

- Protected peer reviews
 - Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
 - Implementation of improvement actions recommended by the Peer Review Committee
 - Completion of final reviews within 120 calendar days

⁴² VHA Directive 1190.

⁴³ VHA Directive 1117(1).

⁴⁴ VHA Handbook 1050.01.

⁴⁵ VHA Directive 1177, VHA Handbook 1004.03, *Life-Sustaining Treatment Decisions: Eliciting, Documenting and Honoring Patients' Values, Goals and Preferences*, January 11, 2017.

⁴⁶ For CHIP reviews, the OIG selects performance indicators based on VHA or regulatory requirements or accreditation standards and evaluates these for compliance.

- Quarterly review of Peer Review Committee’s summary analysis by the Medical Executive Committee
- 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 unit⁴⁷
- UM
 - Completion of at least 75 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
- Patient safety
 - Annual completion of a minimum of eight root cause analyses⁴⁸
 - Inclusion of required content in root cause analyses (generally)
 - Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
 - Provision of feedback about root cause analysis actions to reporting employees
 - Submission of annual patient safety report to facility leaders
- Resuscitation episode review
 - Evidence of a committee responsible for reviewing resuscitation episodes
 - Confirmation of actions taken during resuscitative events being consistent with patients’ wishes
 - Evidence of basic or advanced cardiac life support certification for code team responders
 - Evaluation of each resuscitation episode by the CPR Committee or equivalent

⁴⁷ VHA Directive 1190.

⁴⁸ According to VHA Handbook 1050.01, “the requirement for a total of eight [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of [root cause analyses] is driven by the events that occur and the [Safety Assessment Code] SAC score assigned to them. At least four analyses per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses].”

Quality, Safety, Value Conclusion

The OIG found general compliance with requirements for some of the performance indicators. However, the OIG identified deficiencies with submitting a quarterly summary report for protected peer reviews, the interdisciplinary review of UM data, root cause analyses including all review elements, the review of each resuscitation episode, and implementing and monitoring corrective actions for effectiveness to improve quality assurance and clinical outcomes that warranted recommendations for improvement.

Specifically, VHA requires that the Peer Review Committee submit a quarterly summary report, including trends and analysis of aggregate data, for review by the Executive Committee of the Medical Staff. The peer review summary includes, at a minimum, the number of peer reviews, assigned levels by the initial reviewer and PRC, and changes in assignment levels. The Executive Committee of the Medical Staff is then responsible for utilizing the data to determine the need for further action.⁴⁹

From January 1, 2018, through December 19, 2018, the Executive Committee of the Medical Staff documented their review of two of four required quarterly reports. The risk manager provided documentation to the OIG to show that two missing quarterly reports were submitted as required; however, the chief of staff and chief of QSV asserted that the meeting recorder did not insert the missing reports or notate the risk manager's presentation in the committee minutes. Inconsistent reviews of quarterly Peer Review Committee summary reports by the Executive Committee of the Medical Staff may result in the committee's failure to determine the need for further action, follow up on identified trends that needs improvement, and monitor the effectiveness of quality improvement initiatives. The chief of QSV and chief of staff cited a lack of oversight as the reason for noncompliance.

Recommendation 1

1. The chief of staff ensures the Executive Committee of the Medical Staff reviews quarterly Peer Review Committee summary reports with trends and analysis of aggregate data and monitors the committee's compliance.

Facility concurred.

Target date for completion: December 1, 2019

Facility response: The Risk Manager will continue to provide quarterly reports to the Executive Committee of the Medical Staff and the Chief of Staff will assure the report is documented in the minutes appropriately. The quarterly reports will be monitored for compliance until 100% compliance is maintained for six consecutive months.

⁴⁹ VHA Directive 1190.

VHA requires that an interdisciplinary group review the UM data. This process must include “representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [chief Business Office revenue-utilization review].”⁵⁰ From December 2017 through December 2018, the Executive Committee of the Medical Staff, the facility group that reviews UM data, lacked representation from the CBO R-UR. As a result, the Executive Committee of the Medical Staff performed reviews and analyses of UM data without the perspectives of key utilization review colleagues.⁵¹ The CBO R-UR representative was notified in July 2018 by facility leaders that a business representative was required to review UM data with the interdisciplinary team but was unable to attend meetings due to collateral duties.

Recommendation 2

2. The chief of staff makes certain that all required representatives consistently participate in interdisciplinary reviews of utilization management data and monitors the representatives’ compliance.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: Utilization Management Data is presented at the Executive Committee of the Medical Staff quarterly. The required staff have been sent invitations for the meetings to satisfy the attendance requirements per the directive. Compliance will be monitored until 90% attendance is met for two (2) consecutive quarters. Compliance will be presented monthly to the Clinical and Performance Board/Quality Safety Value Committee.

To ensure credibility, VHA requires root cause analysis to include several factors, such as participation by leadership, exclusion of individuals involved in the event under review, consideration of relevant literature, and identification of at least one root cause with a corresponding action and outcome measure.⁵² In four of five root cause analyses, the OIG found no evidence that the patient safety manager included consideration of relevant literature. This resulted in insufficient evaluation of patient safety events and limited the analysis of system vulnerabilities that may lead to patient harm. Although aware of the literature review requirement, the patient safety manager cited lack of attention to detail as the reason for noncompliance.

⁵⁰ VHA Directive 1117(1).

⁵¹ VHA Directive 1117(1).

⁵² VHA Handbook 1050.01.

Recommendation 3

3. The facility director makes sure the patient safety manager includes a review of relevant literature in the root cause analysis and monitors the patient safety manager's compliance.

Facility concurred.

Target date for completion: September 30, 2019

Facility response: The Chief of Quality Safety and Value (QSV) discussed with all members of the Patient Safety Program the requirement to include relevant literature in each Root Cause Analysis. Each RCA will be reviewed by the Chief of QSV prior to director signature to confirm compliance. Audits will be conducted until 100% compliance is achieved for six consecutive months.

In accordance with TJC standards, VHA requires that the facility Code Blue Committee (known as the CPR Committee at this facility and a subcommittee of the Acute Care Committee) reviews each resuscitative episode of care under the facility's responsibility.⁵³ There was no evidence that the CPR Committee reviewed the ten OIG-selected resuscitative episodes at the facility. This likely resulted in missed opportunities for the identification of errors or deficiencies in technique or procedures; availability or malfunction of equipment; and clinical issues or patient care issues, such as failure to rescue, that can contribute to the occurrence of a cardiopulmonary event. The CPR Committee coordinator reported submitting each resuscitative episode event to the committee for review subsequent to assuming the position in November 2018. Facility managers were unaware of the CPR Committee's requirement to review each resuscitative episode of care.

Recommendation 4

4. The facility director confirms that the Cardiopulmonary Resuscitation Committee reviews each resuscitative episode under the facility's responsibility and monitors the committee's compliance.

⁵³ VHA Directive 1177.

Facility concurred.

Target date for completion: June 1, 2020

Facility response: The Code Blue Committee will continue to review 100% of resuscitative episodes on a monthly basis and will report trended data to the Acute Care Committee quarterly. The Acute Care Committee reports quarterly trended data to Executive Committee of the Medical Staff. Compliance will be monitored and reported at Clinical and Performance Board/Quality Safety Value Committee, which is chaired by the Chief of Staff and the Chief of QSV. Compliance with monitoring and reporting will continue until 90% compliance is reached for six consecutive months.

Additionally, VHA requires that enterprise framework activity documents generated from quality assurance reviews must involve primary service and program monitoring activities.⁵⁴ When problems or opportunities for improvement are identified, facility clinical leaders must ensure that corrective actions are implemented and monitored for effectiveness.⁵⁵ The facility's governance structure is composed of committees that conduct quality assurance reviews without establishing corrective actions or monitoring effectiveness on a consistent basis. This could result in the inability to set benchmarks, identify trends, and take action to improve patient outcomes. Although clinical managers reported reorganizing the committee structure to improve quality assurance reviews and clinical outcomes, the chief of QSV cited lack of oversight as the reason for noncompliance.

Recommendation 5

5. The facility director ensures that clinical managers implement corrective actions and monitor for effectiveness when problems or opportunities for improvement are identified and monitors the clinical managers' compliance.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: Under the direction of Executive Leadership, Quality Safety and Value Service will complete the Committee Governance Structure re-organization and will ensure the mandatory reporting and improvement activities are monitored for sustained improvement. Audits of meeting minutes will be conducted until 90% compliance is maintained for six consecutive months. Results from the audits will be documented in the Executive Leadership Committee minutes, which is chaired by the Facility Director.

⁵⁴ VHA Directive 1026.

⁵⁵ VHA Directive 1026.

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).⁵⁶

Clinical privileges need to be specific, based on the individual’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.⁵⁷

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 typically occurs at the time of initial appointment to the medical staff or the granting of new, additional privileges.” “The on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered.”⁵⁸

According to TJC, the “FPPE for Cause” should be used when a question arises regarding a privileged provider’s ability to deliver safe, high-quality patient care. The “FPPE for Cause” is limited to a particular time frame and customized to the specific provider and related clinical concerns.⁵⁹ Federal law requires VA facilities to report to the National Practitioner Data Bank when facilities take adverse clinical privileging actions, accept the surrender of clinical privileges, or restrict clinical privileges when the action is related to professional competence or professional conduct of LIPs.⁶⁰

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

⁵⁶ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (This VHA handbook was scheduled for recertification on or before the last working date of October 2017 and has not been recertified.)

⁵⁷ VHA Handbook 1100.19.

⁵⁸ VHA Handbook 1100.19.

⁵⁹ 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).

⁶⁰ VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. (This VHA handbook was scheduled for recertification on or before the last working date of December 2014 and has not been recertified.)

- No solo few (less than two in a specialty) practitioners were hired within 18 months before the site visit or were privileged within the prior 12 months⁶¹
- Ten LIPs hired within 18 months before the site visit⁶²
- Twenty LIPs re-privileged within 12 months before the visit⁶³
- Seven providers who underwent a FPPE for cause within 12 months prior to the visit.

The OIG evaluated the following performance indicators:

- Privileging
 - Privileges requested by the provider
 - Facility-specific
 - Service-specific
 - Provider-specific⁶⁴
 - Approval of privileges for a period of less than, or equal to, two years
- Focused professional practice evaluations
 - Criteria defined in advance
 - Use of required criteria in FPPEs for selected specialty LIPs
 - Results and time frames clearly documented
 - Evaluation by another provider with similar training and privileges
 - Executive Committee of the Medical Staff's consideration of FPPE results in its decision to recommend continuing the initially granted privileges
- Ongoing professional practice evaluations
 - Criteria specific to the service or section

⁶¹ The 18-month period was from July 29, 2017, through January 29, 2019. The 12-month review period covered January 29, 2018, through January 29, 2019; VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers "few practitioners" as being fewer than three providers in the facility that are privileged in a particular specialty.

⁶² The 18-month period was from July 29, 2017, through January 29, 2019.

⁶³ The 12-month review period was from January 29, 2018, through January 29, 2019.

⁶⁴ According to VHA Handbook 1100.19, facility-specific means that privileges are granted only for procedures and types of services performed at the facility; service-specific refers to privileges being granted in a specific clinical service, such as neurology; and provider-specific means that the privileges should be granted to the individual provider based on their clinical competence and capabilities.

- Use of required criteria in OPPEs for selected specialty LIPs
- Service chief's determination to recommend continuation of current privileges was based in part on the results of OPPE activities
- Evaluation by another provider with similar training and privileges
- Executive Committee of the Medical Staff's decision to recommend continuing privileges based on OPPE results
- Focused professional practice evaluations for cause
 - Clearly defined expectations/outcomes
 - Time-limited
 - Provider's ability to practice independently not limited for more than 30 days
 - Shared with the provider in advance⁶⁵

Medical Staff Privileging Conclusion

The facility generally complied with requirements for privileging and OPPEs. However, the OIG identified a concern with the FPPE for cause process that warranted a recommendation for improvement.

Specifically, VHA requires FPPEs for cause to be time limited with clearly defined expectations and outcomes that are accepted by the provider in advance of the evaluation.⁶⁶ The OIG reviewed the profiles of seven providers who underwent an FPPE for cause and found two of seven FPPEs lacked defined expectations and outcomes, were not time limited, and restricted the providers' ability to practice independently for more than 30 days; and three of seven were not shared with the provider in advance. The chief of credentialing and privileging stated that the clinical service chiefs are responsible for complying with the requirement. Failure to clearly define expectations can hinder the evaluation of the provider. The chief of staff and chief of credentialing and privileging were aware of the requirement, however, lack of attention to detail was cited as the reason for noncompliance.

⁶⁵ 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).

⁶⁶ Office of Safety and Risk Awareness, Office of Quality and Performance.

Recommendation 6

6. The chief of staff confirms that clinical service chiefs clearly define and share in advance the expectations and outcomes for focused professional practice evaluations for cause that do not restrict the providers' ability to practice independently for more than 30 days with providers and monitors the clinical service chiefs' compliance.

Facility concurred.

Target date for completion: October 31, 2019

Facility response: The facility instituted a standardized template as recommended in a guidance document provided by Office of Medical Staff Affairs "Provider Competency and Clinical Care Concerns" in March 2019. All prior templates have been removed and the new template was shared with all Service Chiefs and discussed at Professional Standards Board [a subcommittee of the Executive Committee of the Medical Staff]. Any FPPE for cause will be monitored by the Professional Standards Board for compliance with the template. Audits will be completed until 100% compliance is achieved for six consecutive months.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct environment of care inspection rounds and resolve issues in a timely manner. The goal of the environment of care program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.⁶⁷

The purpose of this facet of the OIG inspection was to determine whether the facility maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the facility met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the locked inpatient mental health unit. The inspection team also looked at facility compliance with emergency management processes.⁶⁸

VHA requires its facilities to have the “capacity for [providing] mental health services for veterans with acute and severe emotional and/or behavioral symptoms causing a safety risk to self or others, and/or resulting in severely compromised functional status. This level of care is typically provided in an inpatient setting;” however, for facilities that do not have inpatient mental health services, that “capacity” could mean facilitating care at a nearby VA or non-VA facility.⁶⁹

VHA requires managers to establish a comprehensive emergency management program to ensure the continuity of patient care and hospital operations in the event of a natural disaster or other emergency. This includes conducting a hazard vulnerability analysis and developing an emergency operations plan. These requirements are meant to support facilities’ efforts to identify and minimize harm from potential hazards, threats, incidents, and events related to healthcare and other essential services.⁷⁰ Managers must also develop utility management plans to increase reliability and reduce failures of electrical power distribution systems in accordance with TJC,

⁶⁷ VHA Directive 1608, *Comprehensive Environment of Care, (CEOC Program)*, February 1, 2016.

⁶⁸ Applicable requirements for high-risk areas and emergency management include those detailed in or by various VHA Directives, Joint Commission hospital accreditation standards, Occupational Safety and Health Administration, American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI), and National Fire Protection Association (NFPA).

⁶⁹ VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013. (This VHA handbook was scheduled for recertification on or before the last working date of September 2018 and has not been recertified.)

⁷⁰ VHA Directive 0320.01, *Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures*, April 6, 2017.

Occupational Safety and Health Administration,⁷¹ and National Fire Protection Association standards.⁷² The provision of sustained electrical power during disasters or emergencies is critical to healthcare facility operations.⁷³

In all, the OIG team inspected 20 areas—medical/surgical 7-north, 7-south, 8-north, and 8-south; medical intensive care; medical-telemetry/step-down; surgical intensive care; surgical step-down; poly-trauma; mental health and post-anesthesia care units; emergency department; physical therapy department; women’s health clinic; specialty clinic; orthopedic clinic; and primary care clinics blue, green, gold, and purple. The team also inspected the Indianapolis-West VA Clinic and reviewed the emergency management program. The inspection team reviewed relevant documents and interviewed key employees and managers. The OIG evaluated the following location-specific performance indicators:

- Parent facility
 - General safety
 - Environmental cleanliness and infection prevention
 - General privacy
 - Women veterans program
 - Availability of medical equipment and supplies
- Community based outpatient clinic
 - General safety
 - Environmental cleanliness and infection prevention
 - General privacy
 - Women veterans program
 - Availability of medical equipment and supplies
- Locked inpatient mental health unit
 - Mental health environment of care rounds

⁷¹ The Occupational Safety and Health Administration (OSHA) is part of the US Department of Labor. OSHA’s mission is to assure safe and healthy working conditions “by setting and enforcing standards and by providing training, outreach, education, and assistance.” <https://www.osha.gov/about.html>. (This website was accessed on June 28, 2018.)

⁷² The National Fire Protection Association (NFPA) is a global nonprofit organization “devoted to eliminating death, injury, property, and economic loss due to fire, electrical, and related hazards.” <https://www.nfpa.org/About-NFPA>. (This website was accessed on June 28, 2018.)

⁷³ TJC. Environment of Care standard EC.02.05.07.

- Nursing station security
- Public area and general unit safety
- Patient room safety
- Infection prevention
- Availability of medical equipment and supplies
- Emergency management
 - Hazard vulnerability analysis (HVA)
 - Emergency operations plan (EOP)
 - Emergency power testing and availability

Environment of Care Conclusion

Generally, the OIG found compliance with many of the performance indicators including safety, privacy, and women veterans program requirements. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified a deficiency in infection prevention procedures for damaged wheelchairs.

Specifically, TJC requires hospitals to minimize the possibility of transmitting infections by ensuring that furnishings and equipment are safe and in good repair.⁷⁴ The OIG found wheelchairs with damaged or missing armrests in five patient care units and in lobbies or corridors in four locations.⁷⁵ Vinyl coverings on armrests were cracked and torn and prevented effective cleaning or disinfection. This resulted in a lack of assurance of a clean and safe patient care environment that minimizes the spread of infection. Facility managers were uncertain who was responsible for wheelchair maintenance or if a facility policy existed.⁷⁶

Recommendation 7

7. The associate director assures managers remove damaged wheelchairs from service and send them for repair or replacement and monitors managers' compliance.

⁷⁴ TJC. Infection Prevention and Control standard IC.02.02.01, EP 1 and Environment of Care standard EC.02.06.01, EP 26.

⁷⁵ Medical/surgical in-patient 7N and 8S, medical step-down 6A, physical therapy, Emergency Department, corridors adjacent to radiology, patient transportation office, mental health and the main lobby.

⁷⁶ Chief of Engineering Services; chief of Environmental Management Services; and infection preventionist.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: The wheelchair management policy was updated and responsibility for oversight of the process was delineated. All wheelchairs procured by the medical center are numbered and inventoried. Each wheelchair will have a color-coded tag indicating the month the wheelchair will receive cleaning. Each month Environmental Management Service (EMS) staff make rounds and gather the corresponding color-tagged wheelchairs due to be washed. Any wheelchairs with gross contamination are washed as needed. Damaged chairs found by facility staff will be directed to Engineering Service for major repairs and the Office of Veteran Experience and Employee Engagement for minor repairs. The Associate Director/Assistant Director will ensure monthly wheelchair cleaning and repair volume reports are presented at the Safety and Health Leadership Committee (formerly Environment of Care Board, now a subcommittee of Healthcare Services Operations Committee which ultimately reports to Executive Leadership Committee [previously known as the Leadership Council]) by both EMS and Engineering respectfully to monitor throughput. EOC weekly rounding tool will add a specific line item for damaged wheelchairs instead of utilizing the “other” category to better track activity specific to this issue. Focused tracers will be conducted by Quality Safety and Value staff to evaluate compliance with the policy. The number of wheelchairs without damage (numerator)/total number of wheelchairs inspected during the tracer (denominator) will be monitored until greater than 90% compliance is sustained for six consecutive months. Data will be reported monthly to the Safety and Health Leadership Committee.

Medication Management: Controlled Substances Inspections

The Controlled Substances Act divides controlled drugs into five categories based on whether they have an accepted medical treatment use in the United States, their relative potential for abuse, and the likelihood of causing dependence if abused.⁷⁷ Diversion of controlled substances by healthcare workers—the transfer of legally prescribed controlled substances from the prescribed individual to others for illicit use—remains a serious problem that can increase patient safety issues and elevate the liability risk to healthcare facilities.⁷⁸

VHA requires that facility managers implement and maintain a controlled substances inspection program to minimize the risk for loss and diversion and to enhance patient safety. Requirements include the appointment of controlled substances coordinator(s) and controlled substances inspectors, implementation of procedures for inventory control, and inspections of the pharmacy and clinical areas with controlled substances.⁷⁹

To determine whether the facility complied with requirements related to controlled substances security and inspections, the OIG team interviewed key managers and reviewed inspection reports; monthly summaries of findings, including discrepancies, provided to the facility director; inspection quarterly trend reports for the prior two completed quarters;⁸⁰ and other relevant documents. The OIG evaluated the following performance indicators:

- Controlled substances coordinator reports
 - Monthly summary of findings to the director
 - Quarterly trend reports to the director
 - Quality Management Committee’s review of monthly and quarterly trend reports
 - Actions taken to resolve identified problems
- Pharmacy operations
 - Staff restrictions for monthly review of balance adjustments⁸¹
- Requirements for controlled substances inspectors

⁷⁷ Drug Enforcement Agency Controlled Substance Schedules. <https://www.deadiversion.usdoj.gov/schedules/>. (The website was accessed on March 7, 2019.)

⁷⁸ American Society of Health-System Pharmacists, “ASHP Guidelines on Preventing Diversion of Controlled Substances,” *American Journal of Health-System Pharmacists*, 74, no. 5 (March 1, 2017): 325-348.

⁷⁹ VHA Directive 1108.02(1), *Inspection of Controlled Substances*, November 28, 2016 (amended March 6, 2017).

⁸⁰ The two quarters were from July 1, 2018, through December 31, 2018.

⁸¹ Controlled substances balance adjustment reports list transactions in which the pharmacy vault inventory balance was manually adjusted.

- No conflicts of interest
- Appointed in writing by the director for a term not to exceed three years
- Hiatus of one year between any reappointment
- Completion of required annual competency assessment
- Controlled substances area inspections
 - Completion of monthly inspections
 - Rotations of controlled substances inspectors
 - Patterns of inspections
 - Completion of inspections on day initiated
 - Reconciliation of dispensing between pharmacy and each dispensing area
 - Verification of controlled substances orders
 - Performance of routine controlled substances inspections
- Pharmacy inspections
 - Monthly physical counts of the controlled substances in the pharmacy
 - Completion of inspections on day initiated
 - Security and verification of drugs held for destruction⁸²
 - Accountability for all prescription pads in pharmacy
 - Verification of hard copy controlled substances prescriptions
 - Verification of 72-hour inventories of the main vault
 - Quarterly inspections of emergency drugs
 - Monthly checks of locks and verification of lock numbers
- Facility review of override reports⁸³

Medication Management Conclusion

The OIG found general compliance with requirements for most of the performance indicators evaluated, including the controlled substances coordinator reports, pharmacy operations,

⁸² According to VHA Directive 1108.02(1), the Destructions File Holding Report “lists all drugs awaiting local destruction or turn-over to a reverse distributor.” Controlled substances inspectors “must verify there is a corresponding sealed evidence bag containing drug(s) for each destruction holding number on the report.”

⁸³ When automated dispensing cabinets are used, nursing staff can override and remove medications prior to the pharmacists’ review of medications ordered by the providers.

requirements for controlled substances inspectors, and pharmacy inspections. However, the OIG identified deficiencies with the Quality Management Committee's review of monthly and quarterly trend reports, verifying controlled substances orders, and reviewing medication override reports that warranted recommendations for improvement.

Specifically, VHA requires monthly and quarterly controlled substance inspection program reports be reviewed at least quarterly by the Quality Management (QM) Committee for adherence with controlled substance inspection program requirements.⁸⁴ The OIG reviewed the Clinical and Performance Board (the facility's Quality Management Committee) monthly meeting minutes for July through December 2018 but did not find evidence that the committee reviewed monthly and quarterly controlled substance inspection program reports. Failure to review quarterly reports can result in missed opportunities to identify areas for improvement and implement corrective actions. The controlled substance coordinator cited a lack of attention to detail for not reviewing the minutes.

Recommendation 8

8. The facility director makes certain that the facility quality manager ensures the Clinical and Performance Board reviews the monthly and quarterly controlled substance inspection program reports at least quarterly and monitors the quality manager's compliance.

Facility concurred.

Target date for completion: February 1, 2020

Facility response: The Chief of Quality Safety and Value (QSV) will assure the required monthly and quarterly reports are presented to the Quality Safety and Value Committee (formerly Clinical and Performance Board), which is chaired by the Chief of Staff and Chief of QSV and reports to Executive Leadership Committee. Compliance will be monitored with monthly audits until 90% compliance is maintained for six consecutive months.

VHA requires that controlled substance inspectors verify during controlled substances inspections that there is evidence of documentation of two signatures for any partial dose wastage for five randomly selected dispensing activities.⁸⁵ The OIG reviewed six months of documentation for controlled substances inspections for 10 areas. In 3 of 10 areas, the OIG found that the controlled substance inspectors did not consistently verify documentation of two signatures for waste when partial doses were administered. This may result in the inability to

⁸⁴ VHA Directive 1108.02(1).

⁸⁵ VHA Directive 1108.02(1).

account for all controlled substances. The controlled substance coordinator reported the noncompliance was due to the shortage and continuous training of inspectors.

Recommendation 9

9. The facility director makes certain that the controlled substances inspectors verify documentation for two signatures for any waste of partial doses of controlled substances and monitors inspectors' compliance.

Facility concurred.

Target date for completion: September 30, 2019

Facility response: The Controlled Substance Coordinator will monitor inspector's compliance with the verification and documentation of two signatures for waste of partial doses of controlled substances. Non-Compliance will be monitored by the Chief of QSV and will be addressed with each inspector. Compliance will be monitored with monthly audits until 90% compliance is maintained for six consecutive months. Results from the audits will be included in the monthly Controlled Substance inspector reports and submitted to the Quality Safety Value Committee (formerly Clinical and Performance Board), which is chaired by the Chief of Staff and Chief of QSV and reports to the Executive Leadership Committee.

Additionally, TJC requires that when automatic dispensing cabinets are used, the hospital has a policy that describes the types of medication overrides that will be reviewed for appropriateness and the frequency of the reviews.⁸⁶ The OIG did not find that the facility reviewed Omnicell[®] override reports on a quarterly basis as required by hospital policy. Failure to review override reports could result in missed opportunities to identify appropriateness and frequency of reviews. The controlled substance coordinator stated a lack of oversight as the reason for noncompliance.

Recommendation 10

10. The facility director ensures that a pharmacist reviews the Omnicell[®] override report for appropriateness and frequency as required and monitors the pharmacist's compliance.

⁸⁶ TJC. Medication Management standard MM.08.01.01, EP16.

Facility concurred.

Target date for completion: June 1, 2020

Facility response: The Facility Medication Safety Pharmacist will continue to review quarterly override reports and discuss trends and discrepancies with the Medication Safety Committee, a sub-committee of Pharmacy Nutrition and Therapeutics. Pharmacy Nutrition and Therapeutics reports to Healthcare Delivery Committee (formerly Executive Committee of the Medical Staff). Healthcare Delivery Committee reports to Executive Leadership Committee. All controlled substance discrepancies or concerns will be sent to the Controlled Substance Coordinator for investigation and documented in the Controlled Substance Inspection reports. Compliance will be presented monthly to the Quality Safety Value Committee (formerly Clinical and Performance Board) which reports to Executive Leadership Committee. Monitoring will continue until 90% compliance is reached for two consecutive quarters.

Mental Health: Military Sexual Trauma Follow-Up and Staff Training

The Department of Veterans Affairs uses the term “military sexual trauma” (MST) to refer to a “psychological trauma, which in the judgment of a mental health professional employed by the Department [of Veterans Affairs], resulted from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while the Veteran was serving on active duty, active duty for training, or inactive duty training.”⁸⁷ MST is an experience, not a diagnosis or a mental health condition. Although posttraumatic stress disorder is commonly associated with MST, other frequently associated diagnoses include depression and substance use disorders.⁸⁸

VHA requires that the facility director designates an MST coordinator to support national and VISN-level policies related to MST-related care and serve as a source of information; establish and monitor MST-related staff training and informational outreach; and communicate MST-related issues, services, and initiatives with leadership.⁸⁹ Additionally, the facility director is responsible for ensuring that MST-related data are tracked and monitored.⁹⁰

VHA requires that all veterans and potentially eligible individuals seen in VHA facilities be screened for experiences of MST with the required MST clinical reminder in the computerized patient record system.⁹¹ Those who screen positive must have access to appropriate MST-related care.⁹² VHA also requires that evidence-based mental health care be available to all veterans with mental health conditions related to MST. Patients requesting or referred for mental health services must receive an initial evaluation within 24 hours of the referral to identify urgent care needs and a more comprehensive diagnostic evaluation within 30 days.⁹³

The MST coordinator may provide clinical care to individuals experiencing MST and is thus subject to the same mandatory training requirements as mental health and primary care providers.⁹⁴ All mental health and primary care providers must complete MST mandatory

⁸⁷ VHA Directive 1115, *Military Sexual Trauma (MST) Program*, May 8, 2018.

⁸⁸ Military Sexual Trauma. https://www.mentalhealth.va.gov/docs/mst_general_factsheet.pdf. (The website was accessed on November 17, 2017.)

⁸⁹ VHA Directive 1115.

⁹⁰ VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008 (amended November 16, 2015). (This VHA handbook was scheduled for recertification on or before the last working date of September 2013 and has not been recertified.)

⁹¹ VHA Directive 1115 states that “MST-related care is not subject to the minimum active duty service requirement set forth in 38 U.S.C. 5303A; Veterans may therefore be able to receive MST-related care even if they are not eligible for VA health care under other treatment authorities.”

⁹² VHA Directive 1115.

⁹³ VHA Handbook 1160.01.

⁹⁴ VHA Directive 1115.

training; for those hired after July 1, 2012, this training must be completed no later than 90 days after assuming their position.⁹⁵

To determine whether the facility complied with the requirements related to MST follow-up and training, the OIG inspection team reviewed relevant documents and staff training records and interviewed key employees. The team also reviewed the electronic health records of 49 outpatients who had a positive MST screen from July 1, 2017, through June 30, 2018. The OIG evaluated the following performance indicators:

- Designated facility MST coordinator
 - Establishes and monitors MST-related staff training
 - Establishes and monitors informational outreach
 - Communicates MST-related issues, services, and initiatives with local leaders
- Evidence of tracking MST-related data
- Provision of clinical care
 - Referral for MST-related care to patients with positive MST screens
 - Initial evaluation within 24 hours of referral for mental health services
 - Comprehensive diagnostic and treatment planning evaluation within 30 days of referral for mental health services
- Completion of MST mandatory training requirement for mental health and primary care providers

Mental Health Conclusion

Generally, the facility met requirements with the above performance indicators. The OIG made no recommendations.

⁹⁵ VHA Directive 1115.01, *Military Sexual Trauma (MST) Mandatory Training and Reporting Requirements for VHA Mental Health and Primary Care Providers*, April 14, 2017; Acting Deputy Under Secretary for Health for Operations and Management Memorandum, *Compliance with Military Sexual Trauma (MST) Mandatory Training for Mental Health and Primary Care Providers*, February 2, 2016.

Geriatric Care: Antidepressant Use among the Elderly

VA's National Registry for Depression reported that "11 [percent] of veterans aged 65 years and older have a diagnosis of major depressive disorder."⁹⁶ The VA/DoD Clinical Practice Guideline (CPG) describes depression as "a common mental disorder that presents with depressed mood, loss of interest or pleasure in regular activities, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration." This can lead to poor quality of life, decreased productivity, and increased mortality from suicide.⁹⁷

According to the Centers for Disease Control and Prevention, older adults are at increased risk for experiencing depression because "80 [percent] of older adults have at least one chronic health condition and 50 [percent] have two or more." Further, "most older adults see an improvement in [their] symptoms when treated with antidepressant drugs, psychotherapy, or a combination of both."⁹⁸

The American Geriatrics Society revised the Beers Criteria in 2015 to include lists of potentially inappropriate medications to be avoided. Potentially inappropriate medication use in older adults continues to be associated with confusion, falls, and mortality.⁹⁹ The criteria provide guidelines that help to improve the safety of prescribing certain medications including antidepressants for older adults.

TJC requires clinicians to educate patients and families about the "safe and effective use of medications."¹⁰⁰ In 2015, VHA outlined essential medical information "necessary for review, management, and communication of medication information" with patients, caregivers, and their healthcare teams.¹⁰¹ Further, TJC requires clinicians to perform medication reconciliation by comparing the medication a patient is actually taking to the new medications that are ordered for the patient and resolving any discrepancies.¹⁰² The CPG recommends that clinicians monitor patients monthly after therapy initiation or a change in treatment until the patient achieves

⁹⁶ Hans Peterson, "Late Life Depression," *U.S. Department of Veterans Affairs, Mental Health Featured Article*, March 1, 2011. https://www.mentalhealth.va.gov/featureArticle_Mar11LateLife.asp. (The website was accessed on March 8, 2019.)

⁹⁷ *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, April 2016. <https://www.healthquality.va.gov/guidelines/MH/mdd/VADoDMDDCPGFINAL82916.pdf> (The website was accessed November 20, 2018.)

⁹⁸ Centers for Disease Control and Prevention, "Depression is Not a Normal Part of Growing Older," January 31, 2017. <https://www.cdc.gov/aging/mentalhealth/depression.htm>. (The website was accessed on March 8, 2019.)

⁹⁹ American Geriatrics Society 2015 Beers Criteria Update Expert Panel, "American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults." http://www.sgot.org/allegato_docs/1057_Beers-Criteria.pdf (The website was accessed on March 22, 2018.)

¹⁰⁰ TJC. Provision of Care, Treatment, and Services standard PC.02.03.01.

¹⁰¹ VHA Directive 1164, *Essential Medication Information Standards*, June 26, 2015.

¹⁰² TJC. National Patient Safety Goal standard NPSG.03.06.01.

remission. Monitoring includes assessment of symptoms, adherence to medication and psychotherapy, and any adverse effects. The CPG also recommends that treatment planning includes patient education about treatment options, including risks and benefits.¹⁰³

To determine whether the facility complied with requirements concerning use of antidepressants among the elderly, the OIG inspection team interviewed key employees and managers. The team also reviewed the electronic health records of 44 randomly selected patients, ages 65 and older, who were newly prescribed one of seven selected antidepressant medications from July 1, 2017, through June 30, 2018.¹⁰⁴ The OIG evaluated the following performance indicators:

- Justification for medication initiation
- Evidence of patient and/or caregiver education specific to the medication prescribed
- Clinician evaluation of patient and/or caregiver understanding of the education provided
- Medication reconciliation

Geriatric Care Conclusion

Generally, the OIG found compliance with providers justifying the reason for medication initiation. However, the OIG identified inadequate patient and/or caregiver education related to newly prescribed medications and medication reconciliation processes that warranted recommendations for improvement.

Specifically, TJC requires that clinicians educate patients and families about safe and effective use of medications.¹⁰⁵ The OIG estimated that clinicians provided this education to 20 percent of the patients at the facility, based on electronic health records reviewed.¹⁰⁶ Providing medication education is critical to ensuring that patients or their caregivers have the information they need to manage their health at home.¹⁰⁷ The chief of primary care and the older adult mental health program manager reported inadequate staff within the pharmacy and mental health services, leading to inconsistency in providing education.

¹⁰³ VA/DoD Clinical Practice Guidelines for the Management of Major Depressive Disorder.

¹⁰⁴ The seven selected antidepressant medications are amitriptyline, clomipramine, desipramine, doxepin (>6mg/day), imipramine, nortriptyline, and paroxetine.

¹⁰⁵ TJC. Provision of Care standard PC.02.03.01 and Record of Care, Treatment, and Services standard RC.02.01.01.

¹⁰⁶ The OIG is 95 percent confident that the true compliance rate is somewhere between 9.2 and 33.4 percent, which is statistically significantly below the 90 percent benchmark.

¹⁰⁷ TJC. Introduction to Provision of Care standard PC.02.03.01.

Recommendation 11

11. The chief of staff ensures that clinicians provide and document patient/caregiver education about the safe and effective use of newly prescribed medications and monitors clinicians' compliance.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: A report will be generated on a monthly basis to review antidepressants newly prescribed for depression in the elderly population for documentation of patient/caregiver education. 100% charts meeting criteria will be audited, and audits will continue until 90% compliance is sustained for six consecutive months. Results of the audits will be presented monthly to the Quality Safety Value Committee (formerly Clinical and Performance Board) which is chaired by the Chief of Staff and Chief QSV and reports to the Executive Leadership Committee.

According to TJC, the required process of medication reconciliation is when “a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolve any discrepancies.”¹⁰⁸ TJC also requires patients' medical records contain information that reflects the patient's care, treatment, and services.¹⁰⁹ Additionally, VHA requires that clinicians review and reconcile medications relevant to the episode of care.¹¹⁰

The OIG estimated that providers performed medication reconciliation for 61 percent of the patients at the facility, based on electronic health records reviewed.¹¹¹ Failure to reconcile medications increases the risk for duplications, omissions, and interactions in the patient's actual drug regimen.¹¹² The chief of primary care stated that lack of oversight and attention to details led to inconsistent documentation for medication reconciliation.

Recommendation 12

12. The chief of staff ensures clinicians review and reconcile medications and monitors the clinicians' compliance.

¹⁰⁸ TJC. National Patient Safety Goal standard NPSG.03.06.01.

¹⁰⁹ TJC. Record of Care, Treatment, and Services standard RC.02.01.01.

¹¹⁰ VHA Directive 1164.

¹¹¹ The OIG is 95 percent confident that the true compliance rate is somewhere between 46.7 and 75.5 percent, which is statistically significantly below the 90 percent benchmark.

¹¹² TJC. Rationale for NPSG.03.06.01.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: A report will be generated on a monthly basis to review antidepressants newly prescribed for depression in the elderly population for documentation of medication reconciliation education. 100% of charts meeting criteria will be audited, and audits will continue until 90% compliance is sustained for six consecutive months. Results of the audits will be presented monthly to the Quality Safety Value Committee (formerly Clinical and Performance Board) which is chaired by the Chief of Staff and Chief QSV and reports to the Executive Leadership Committee.

Women’s Health: Abnormal Cervical Pathology Results Notification and Follow-Up

Each year, about 12,000 women in the United States are diagnosed with cervical cancer.¹¹³ Human papillomavirus (HPV) can be transmitted during sexual contact and is the main cause of cervical cancer.¹¹⁴ In addition to HPV infection, other risk factors for cervical cancer include smoking, human immunodeficiency virus (HIV) infection, use of oral contraceptives for five or more years, and having given birth to three or more children.¹¹⁵ Cervical cancer is highly preventable through diligent screening and vaccination efforts. With early detection, it is very treatable and associated with optimal patient outcomes.¹¹⁶

VA is authorized to provide “gender-specific services, such as Papanicolaou tests (Pap smears),” to eligible women veterans. Further, VHA requires that all eligible and enrolled women veterans have access to appropriate services and preventative care. That care would include age-appropriate screening for cervical cancer.¹¹⁷

VHA requires that each facility have a “full-time Women Veterans Program Manager (WVPM) to execute comprehensive planning for women’s health care.” VHA also requires a medical director or clinical champion to be responsible for the clinical oversight of the women’s health program. Each facility must also have a “Women Veterans Health Committee (WVHC) comprised of appropriate facility leaders and program directors, which develops and implements a Women’s Health Program strategic plan.” The Women Veterans Health Committee must meet at least quarterly and report to the executive leaders. The facility must also have a process to ensure the collecting and tracking of data related to cervical cancer screenings.¹¹⁸

VHA has established time frames for notifying patients of abnormal cervical pathology results. Abnormal cervical pathology results must be communicated to patients within seven calendar days from the date the results are available to the ordering provider. Communication of the results to patients must be documented. The facility must ensure that appropriate follow-up care is provided to patients with abnormal results.¹¹⁹

¹¹³ Centers for Disease Control and Prevention. “Cervical Cancer” *Inside Knowledge* fact sheet, December 2016. https://www.cdc.gov/cancer/cervical/pdf/cervical_facts.pdf. (The website was accessed on February 28, 2018.)

¹¹⁴ Centers for Disease Control and Prevention. *Basic Information About Cervical Cancer*, February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on March 8, 2019.)

¹¹⁵ Centers for Disease Control and Prevention. *What Are the Risk Factors for Cervical Cancer?* February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/risk_factors.htm. (The website was accessed on March 8, 2019.)

¹¹⁶ Centers for Disease Control and Prevention. *Basic Information About Cervical Cancer*, February 13, 2017. https://www.cdc.gov/cancer/cervical/basic_info/index.htm. (The website was accessed on February 28, 2018.)

¹¹⁷ VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017 (amended July 24, 2018).

¹¹⁸ VHA Directive 1330.01(2).

¹¹⁹ VHA Directive 1330.01(2).

To determine whether the facility complied with selected VHA requirements for the notification and follow-up care of abnormal cervical pathology results, the OIG inspection team reviewed relevant documents and interviewed selected employees and managers. The team also reviewed the electronic health records of 20 women veteran patients, between ages 21 and 65, who had an abnormal pap smear or test from July 1, 2017, through June 30, 2018. The OIG evaluated the following performance indicators:

- Appointment of a women veterans program manager
- Appointment of a women’s health medical director or clinical champion
- Facility Women Veterans Health Committee
 - Core membership
 - Quarterly meetings
 - Reports to clinical executive leaders
- Collection and tracking of cervical cancer screening data
 - Notification of patients due for screening
 - Completed screenings
 - Results reporting
 - Follow-up care
- Communication of abnormal results to patients within required time frame

Women’s Health Conclusion

Generally, the OIG found compliance with many of the performance indicators, including requirements for a designated women veterans program manager and clinical champion, clinical oversight of the women’s health program, tracking of data related to cervical cancer screenings, communication of results to patients within the required time frame, and follow-up care when indicated. The OIG identified a concern with the core membership of the Women Veterans Health Committee that warranted a recommendation for improvement.

Specifically, VHA requires that the core membership of the Women Veterans Health Committee includes a women veterans program manager; a women’s health medical director; “representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/non-VA medical care; and a member from executive leadership.”¹²⁰ From October 2017 through December 2018, the committee

¹²⁰ VHA Directive 1330.01(2).

lacked representation from mental health, pharmacy, social work, nursing, emergency department, radiology, laboratory, quality management, business office, and a member from executive leadership. This resulted in a lack of expertise in the review and analysis of data as the committee planned and carried out improvements for quality and equitable care for women veterans. The women veterans program manager acknowledged the requirements for representation and stated that senior leaders were aware of the committee's lack of attendance; however, no actions were taken to improve the committee's attendance prior to the OIG site visit.

Recommendation 13

13. The facility director confirms that the Women Veterans Health Committee is comprised of the required core members and monitors committee's compliance.

Facility concurred.

Target date for completion: September 30, 2020

Facility response: The Woman Veterans Health Committee, subcommittee to Primary Care Integrated Community Committee who reports to Healthcare Delivery Committee ultimately reporting to Executive Leadership Committee, evaluated the required members and updated the attendance rosters. The Committee Charter provides clear definition of the mandatory members as well as the expectation for 75% attendance for required members. If unable to attend the expectation was outlined to send a representative if the regularly assigned member is unable to attend. The meeting day and time will also be evaluated to assure required member attendance. Reminders will be sent to those members not meeting expectations with escalation to executive leadership as warranted. Compliance will be presented monthly to the Quality Safety Value Committee (formerly Clinical and Performance Board) which reports to Executive Leadership Committee. Compliance will be monitored until 90% compliance is reached for six consecutive months.

High-Risk Processes: Operations and Management of Emergency Departments and Urgent Care Centers

VHA defines an emergency department as a “unit in a VA medical facility that has acute care medical and/or surgical inpatient beds and whose primary responsibility is to provide resuscitative therapy and stabilization in life-threatening situations.” An urgent care center (UCC) “provides acute medical care for patients without a scheduled appointment who are in need of immediate attention for an acute medical or mental health illness and/or minor injuries.”¹²¹ A variety of emergency services may exist, dependent on “capability, capacity, and function of the local VA medical facility;” however, emergency care must be uniformly available in all VHA emergency departments and UCCs.¹²²

Because the emergency department or UCC is often the first point of contact for patients seeking treatment of unexpected medical issues, a care delivery system with appropriate resources and services must be available to deliver prompt, safe, and appropriate care. VHA requires that each emergency department provide “unrestricted access to appropriate and timely emergency medical and nursing care 24 hours a day, 7 days a week.” VHA UCCs are also required to provide access and timely care during established operational hours. VHA also requires that “evaluation, management, and treatment [are] provided by qualified personnel with the knowledge and skills appropriate to treat those seeking emergency care.”¹²³

TJC noted that patient flow problems pose a persistent risk to quality and safety and established standards for the management of the flow of patients in the emergency department and the rest of the hospital. Managing the flow of patients prevents overcrowding, which can “undermine the timeliness of care and, ultimately, patient safety.” Effective management processes that “support patient flow [in the emergency department or UCC settings] (such as admitting, assessment and treatment, patient transfer, and discharge) can minimize delays in the delivery of care.”¹²⁴

The VHA national director of Emergency Medicine developed the Emergency Medicine Improvement initiative to improve the quality of emergent and urgent care provided through VA emergency departments and UCCs. As part of this initiative, all VA emergency departments and UCCs must use the Emergency Department Integration Software (EDIS) tracking program to document and manage the flow of patients.¹²⁵

¹²¹ VHA Directive 1101.05(2), *Emergency Medicine*, September 2, 2016 (amended March 7, 2017).

¹²² VHA Directive 1101.05(2).

¹²³ VHA Directive 1101.05(2).

¹²⁴ TJC. Leadership standard LD.04.03.11.

¹²⁵ VHA Directive 1101.05(2); the Emergency Medicine Management Tool (EMMT) uses data collected from EDIS to generate productivity metrics. The use of EDIS and EMMT are key tools in accomplishing Emergency Medicine Improvement initiative goals.

VA emergency departments and UCCs must also be designed to promote a safe environment of care.¹²⁶ Managers must ensure medications are securely stored,¹²⁷ a psychiatric intervention room is available,¹²⁸ and equipment and supplies are readily accessible to provide gynecologic and resuscitation services. VHA also requires emergency departments to have communication systems available to accept requests by local emergency medical services for transporting unstable patients to VA emergency departments.¹²⁹

The OIG examined the clinical risks of the emergency department/UCC areas by evaluating the staffing; the provision of care, including selected aspects of mental health and women's health; and the reduction of patient safety risks to optimize quality care and outcomes in those areas. In addition to conducting manager and staff interviews, the OIG team reviewed emergency department staffing schedules, committee minutes, and other relevant documents. The OIG evaluated the following performance indicators:

- General
 - Presence of an emergency department or UCC
 - Availability of acute care medical and/or surgical inpatient beds in facilities with emergency departments
 - Emergency department/UCC operating hours
 - Workload capture process
- Staffing for emergency department/UCC
 - Dedicated medical director
 - At least one licensed physician privileged to staff the department at all times
 - Minimum of two registered nurses on duty during all hours of operation
 - Backup call schedules for providers
- Support services for emergency department/UCC
 - Access during regular hours, off hours, weekends, and holidays
 - On-call list for staff required to respond

¹²⁶ VHA Directive 1101.05(2).

¹²⁷ TJC. Medication Management standard MM.03.01.01.

¹²⁸ A psychiatric intervention room is where individuals experiencing a behavioral health crisis, including serious disturbances, agitation, or intoxication may be taken immediately on arrival.

¹²⁹ VHA Directive 1101.05(2).

- Licensed independent mental health provider available as required for the facility's complexity level
- Telephone message system during non-operational hours¹³⁰
- Inpatient provider available for patients requiring admission
- Patient flow
 - EDIS tracking program
 - Emergency department patient flow evaluation
 - Diversion policy
 - Designated bed flow coordinator
- General safety
 - Directional signage to after-hours emergency care
 - Fast tracks¹³¹
- Medication security and labeling
- Management of patients with mental health disorders
- Emergency department participation in local/regional emergency medical services (EMS) system, if applicable
- Women veteran services
 - Capability and equipment for gynecologic examinations
- Life support equipment

High-Risk Processes Conclusion

Generally, the facility met requirements with the above performance indicators. The OIG made no recommendations.

¹³⁰ Not applicable; this facility operates a 24-hour full-service emergency department.

¹³¹ The emergency department fast track is a designated care area within the emergency department domain where lower acuity patients are assessed and treated.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

Healthcare Processes	Performance Indicators	Conclusion
Leadership and Organizational Risks	<ul style="list-style-type: none">• Executive leadership position stability and engagement• Employee satisfaction• Patient experience• Accreditation and/or for-cause surveys and oversight inspections• Factors related to possible lapses in care• VHA performance data	Thirteen OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the director, chief of staff, and associate director. See details below.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	<ul style="list-style-type: none"> • Protected peer reviews • UM reviews • Patient safety • Resuscitation episode review 	<ul style="list-style-type: none"> • The Cardiopulmonary Resuscitation Committee reviews each resuscitative episode under the facility's responsibility. 	<ul style="list-style-type: none"> • The Executive Committee of the Medical Staff reviews quarterly Peer Review Committee summary reports with trends and analysis of aggregate data. • All required representatives consistently participate in interdisciplinary reviews of UM data. • The patient safety manager includes a review of relevant literature in the root cause analysis. • Clinical managers implement corrective actions and monitor for effectiveness when problems or opportunities for improvement are identified.
Medical Staff Privileging	<ul style="list-style-type: none"> • Privileging • FPPEs • OPPEs • FPPEs for cause • Reporting of privileging actions to National Practitioner Data Bank 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Clinical service chiefs clearly define and share in advance the expectations and outcomes for FPPEs for cause that do not restrict the providers' ability to practice independently for more than 30 days with providers.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
<p>Environment of Care</p>	<ul style="list-style-type: none"> • Parent facility <ul style="list-style-type: none"> ○ General safety ○ Environmental cleanliness and infection prevention ○ General privacy ○ Women veterans program ○ Availability of medical equipment and supplies • Community based outpatient clinic <ul style="list-style-type: none"> ○ General safety ○ Environmental cleanliness and infection prevention ○ General privacy ○ Women veterans program ○ Availability of medical equipment and supplies • Locked inpatient mental health unit <ul style="list-style-type: none"> ○ Mental health environment of care rounds ○ Nursing station security ○ Public area and general unit safety ○ Patient room safety ○ Infection prevention ○ Availability of medical equipment and supplies • Emergency management <ul style="list-style-type: none"> ○ Hazard vulnerability analysis (HVA) ○ Emergency operations plan (EOP) ○ Emergency power testing and availability 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Managers remove damaged wheelchairs from service and send them for repair or replacement.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Controlled Substances Inspections	<ul style="list-style-type: none"> • Controlled substances coordinator reports • Pharmacy operations • Controlled substances inspector requirements • Controlled substances area inspections • Pharmacy inspections • Facility review of override reports 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • The Clinical and Performance Board reviews the monthly and quarterly controlled substance inspection program reports at least quarterly. • The controlled substances inspectors verify documentation for two signatures for any waste of partial doses of controlled substances. • A pharmacist reviews the Omnicell® override report for appropriateness and frequency as required.
Mental Health: Military Sexual Trauma (MST) Follow-Up and Staff Training	<ul style="list-style-type: none"> • Designated facility MST coordinator • Evidence of tracking MST-related data • Provision of clinical care • Completion of MST mandatory training requirement for mental health and primary care providers 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None
Geriatric Care: Antidepressant Use among the Elderly	<ul style="list-style-type: none"> • Justification for medication initiation • Evidence of patient and/or caregiver education specific to the medication prescribed • Clinician evaluation of patient and/or caregiver understanding of the education provided • Medication reconciliation 	<ul style="list-style-type: none"> • Clinicians provide and document patient and/or caregiver education about the safe and effective use of newly prescribed medications. 	<ul style="list-style-type: none"> • Clinicians review and reconcile medications.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
<p>Women's Health: Abnormal Cervical Pathology Results Notification and Follow-Up</p>	<ul style="list-style-type: none"> • Appointment of a women veterans program manager • Appointment of a women's health medical director or clinical champion • Facility Women Veterans Health Committee • Collection and tracking of cervical cancer screening data • Communication of abnormal results to patients within required time frame • Provision of follow-up care for abnormal cervical pathology results, if indicated 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • The Women Veterans Health Committee is comprised of the required core members.
<p>High-Risk Processes: Operations and Management of Emergency Departments and UCCs</p>	<ul style="list-style-type: none"> • General • Staffing for emergency department/UCC • Support services for emergency department/UCC • Patient flow • General safety • Medication security and labeling • Management of patients with mental health disorders • Emergency department participation in local/regional EMS system • Women veteran services • Life support equipment 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None

Appendix B: Facility Profile and VA Outpatient Clinic Profiles

Facility Profile

The table below provides general background information for this highest complexity (1a) affiliated¹³² facility reporting to VISN 10.¹³³

**Table B.1. Facility Profile for Richard L. Roudebush VA Medical Center (583)
(October 1, 2015, through September 30, 2018)**

Profile Element	Facility Data FY 2016 ¹³⁴	Facility Data FY 2017 ¹³⁵	Facility Data FY 2018 ¹³⁶
Total medical care budget in dollars	\$574,208,654	\$584,803,748	\$574,427,496
Number of:			
• Unique patients	61,988	62,511	62,763
• Outpatient visits	770,353	775,317	736,282
• Unique employees ¹³⁷	2,627	2,628	2,680
Type and number of operating beds:			
• Domiciliary	50	50	50
• Intermediate	7	7	7
• Medicine	83	83	83
• Mental health	15	15	15
• Neurology	3	3	3
• Rehabilitation medicine	8	8	8
• Surgery	43	43	43
Average daily census:			
• Domiciliary	42	42	45
• Intermediate	0	0	0

¹³² Associated with a medical residency program.

¹³³ The VHA medical centers are classified according to a facility complexity model; a designation of “1a” indicates a facility with “high volume, high-risk patients, most complex clinical programs, and large research and teaching programs.”

¹³⁴ October 1, 2015, through September 30, 2016.

¹³⁵ October 1, 2016, through September 30, 2017.

¹³⁶ October 1, 2017, through September 30, 2018.

¹³⁷ Unique employees involved in direct medical care (cost center 8200).

Profile Element	Facility Data FY 2016¹³⁴	Facility Data FY 2017¹³⁵	Facility Data FY 2018¹³⁶
• Medicine	62	66	62
• Mental health	14	13	13
• Neurology	1	1	1
• Rehabilitation medicine	6	6	7
• Surgery	23	20	17

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.

VA Outpatient Clinic Profiles¹³⁸

The VA outpatient clinics in communities within the catchment area of the facility provide primary care integrated with women’s health, mental health, and telehealth services. Some also provide specialty care, diagnostic, and ancillary services. Table B.2. provides information relative to each of the clinics.

Table B.2. VA Outpatient Clinic Workload/Encounters and Specialty Care, Diagnostic, and Ancillary Services Provided (October 1, 2017, through September 30, 2018)¹³⁹

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ¹⁴⁰ Provided	Diagnostic Services ¹⁴¹ Provided	Ancillary Services ¹⁴² Provided
Bloomington, IN	583QA	n/a	3,662	n/a	n/a	n/a
Bloomington, IN	583GB	8,653	450	Cardiology Dermatology Endocrinology Anesthesia General surgery Orthopedics Urology	Radiology	Pharmacy Prosthetics Weight management Nutrition

¹³⁸ Includes all outpatient clinics in the community that were in operation as of August 15, 2018. The OIG omitted Indianapolis-Meridian Street, IN (583QB) and Indianapolis, IN (583QE), as no data were reported.

¹³⁹ The definition of an “encounter” can be found in VHA Directive 2010-049, *Encounter and Workload Capture for Therapeutic and Supported Employment Services Vocational Programs*, October 14, 2010. (This directive expired on October 31, 2015, and has not been updated.) An encounter is a “professional contact between a patient and a practitioner vested with responsibility for diagnosing, evaluating, and treating the patient’s condition.”

¹⁴⁰ Specialty care services refer to non-primary care and non-mental health services provided by a physician.

¹⁴¹ Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory, nuclear medicine, radiology, and vascular lab services.

¹⁴² Ancillary services include chiropractic, dental, nutrition, pharmacy, prosthetic, social work, and weight management services.

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ¹⁴⁰ Provided	Diagnostic Services ¹⁴¹ Provided	Ancillary Services ¹⁴² Provided
Edinburgh, IN	583GF	4,737	1,555	Cardiology Dermatology Eye General surgery Orthopedics Urology Vascular	n/a	Pharmacy Prosthetics Weight management Nutrition
Indianapolis, IN	583GD	11,189	1,173	Dermatology Eye General surgery	n/a	Pharmacy Social work Weight management Nutrition
Martinsville, IN	583GC	4,606	1,321	Cardiology Dermatology Endocrinology General surgery Orthopedics	n/a	Pharmacy Prosthetics Weight management Nutrition
Shelbyville, IN	583GG	396	165	Cardiology Dermatology Urology	n/a	Pharmacy Weight management Nutrition

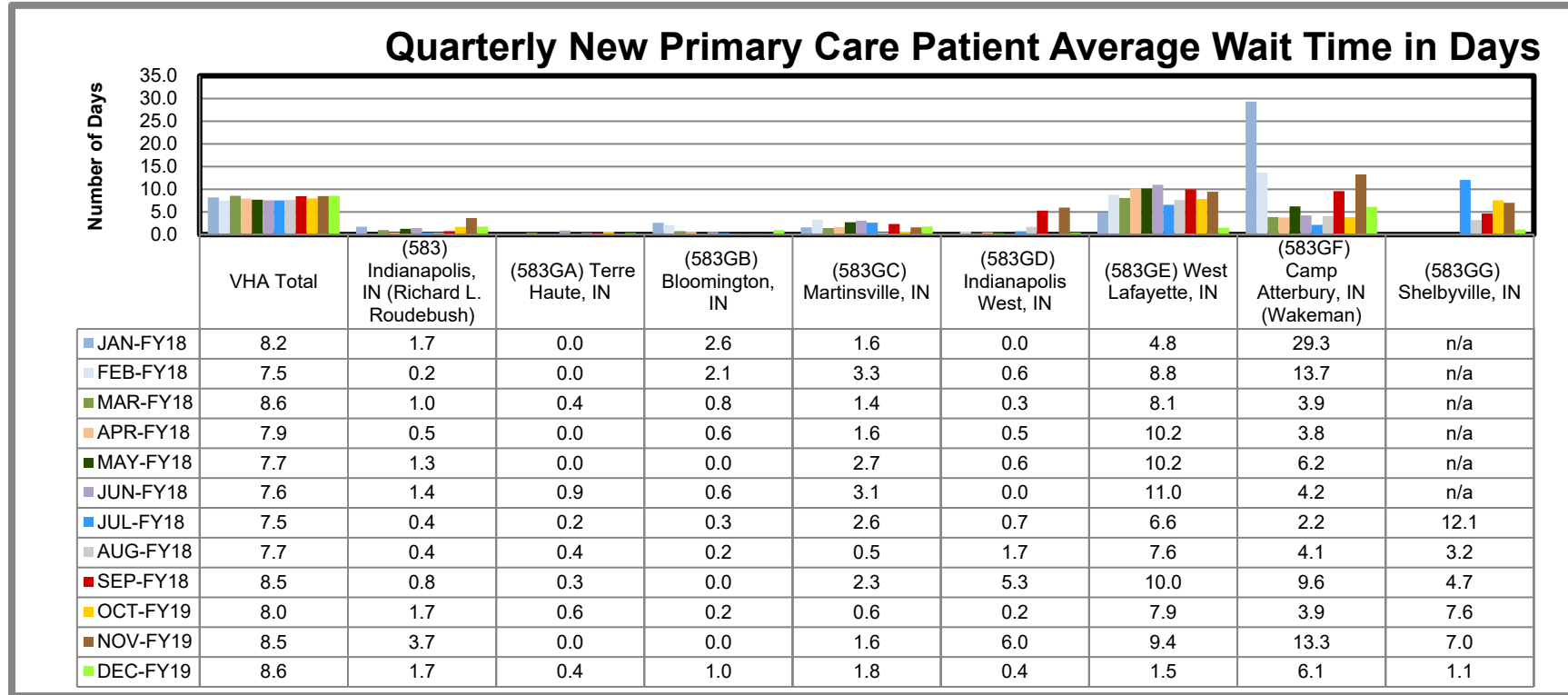
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services ¹⁴⁰ Provided	Diagnostic Services ¹⁴¹ Provided	Ancillary Services ¹⁴² Provided
Terre Haute, IN	583GA	9,160	6	Cardiology Dermatology Endocrinology Hematology/ Oncology Poly-trauma Anesthesia General surgery Orthopedics Urology	Radiology Nuclear medicine	Pharmacy Prosthetics Social work Weight management Nutrition
Terre Haute, IN	583QC	n/a	4,340	n/a	n/a	n/a
West Lafayette, IN	583GE	5,153	3,396	Cardiology Dermatology Endocrinology General surgery Orthopedics	n/a	Pharmacy Weight management Nutrition

Source: VHA Support Service Center and VA Corporate Data Warehouse

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

n/a = not applicable

Appendix C: Patient Aligned Care Team Compass Metrics¹⁴³



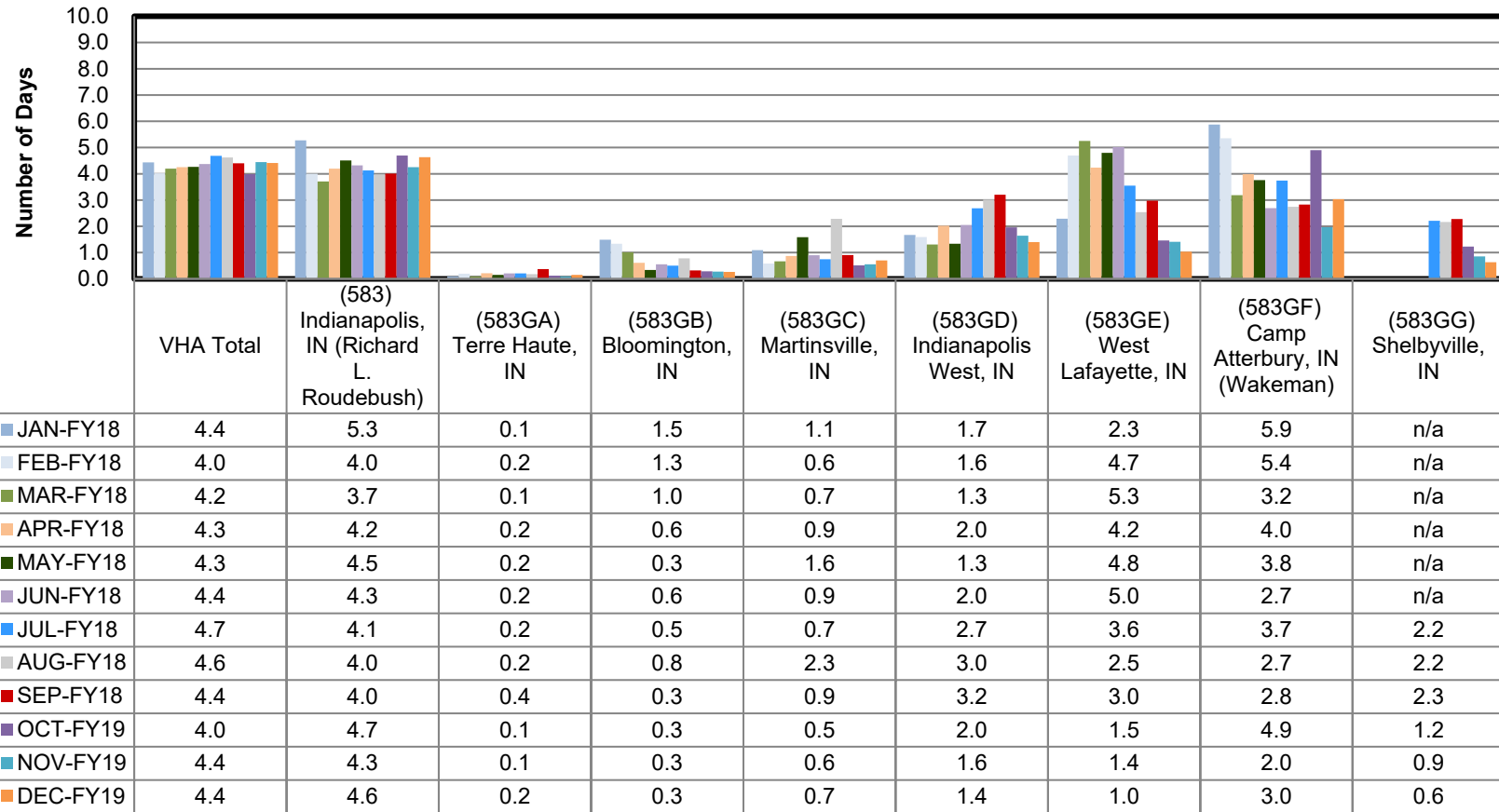
Source: VHA Support Service Center

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted Monroe County, IN (583QA); Indianapolis-Meridian Street, IN (583QB); Vigo County, IN (583QC); and Indianapolis, IN (Cold Spring Road) (583QE), as no data were reported.

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

¹⁴³ Department of Veterans Affairs, Patient Aligned Care Teams Compass Data Definitions, accessed September 13, 2018.

Quarterly Established Primary Care Patient Average Wait Time in Days



Source: VHA Support Service Center

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted Monroe County, IN (583QA); Indianapolis-Meridian Street, IN (583QB); Vigo County, IN (583QC); and Indianapolis, IN (Cold Spring Road) (583QE), as no data were reported.

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

Appendix D: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions¹⁴⁴

Measure	Definition	Desired Direction
ACSC hospitalization	Ambulatory care sensitive conditions hospitalizations	A lower value is better than a higher value
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
Admit reviews met	Percent acute admission reviews that meet interqual criteria	A higher value is better than a lower value
APP capacity	Advanced practice provider capacity	A lower value is better than a higher value
Best place to work	All employee survey best places to work score	A higher value is better than a lower value
Call responsiveness	Call center speed in picking up calls and telephone abandonment rate	A lower value is better than a higher value
Care transition	Care transition (Inpatient)	A higher value is better than a lower value
Complications	Acute care risk adjusted complication ratio (observed to expected ratio)	A lower value is better than a higher value
Comprehensiveness	Comprehensiveness (PCMH)	A higher value is better than a lower value
Cont stay reviews met	Percent acute continued stay reviews that meet interqual criteria	A higher value is better than a lower value
Efficiency	Overall efficiency measured as 1 divided by SFA (Stochastic Frontier Analysis)	A higher value is better than a lower value
Efficiency/capacity	Efficiency and physician capacity	A higher value is better than a lower value
Employee satisfaction	Overall satisfaction with job	A higher value is better than a lower value

¹⁴⁴ VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL)* (last updated December 26, 2018). <http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=8938>. (The website was accessed on March 7, 2019, but is not accessible by the public.)

Measure	Definition	Desired Direction
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like	Outpatient performance measure (HEDIS)	A higher value is better than a lower value
HEDIS like – HED90_1	HEDIS-EPRP based PRV TOB BHS	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS-eOM based DM IHD	A higher value is better than a lower value
MH wait time	Mental health care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx	ORYX	A higher value is better than a lower value
PC routine care appt	Timeliness in getting a PC routine care appointment (PCMH)	A higher value is better than a lower value
PC urgent care appt	Timeliness in getting a PC urgent care appointment (PCMH)	A higher value is better than a lower value
PCMH care coordination	PCMH care coordination	A higher value is better than a lower value
PCMH same day appt	Days waited for appointment when needed care right away (PCMH)	A higher value is better than a lower value
PCMH survey access	Timely appointment, care and information (PCMH)	A higher value is better than a lower value
Physician capacity	Physician capacity	A lower value is better than a higher value
PC wait time	PC wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
PSI	Patient safety indicator (observed to expected ratio)	A lower value is better than a higher value

Measure	Definition	Desired Direction
Rating hospital	Overall rating of hospital stay (inpatient only)	A higher value is better than a lower value
Rating PC provider	Rating of PC providers (PCMH)	A higher value is better than a lower value
Rating SC provider	Rating of specialty care providers (specialty care)	A higher value is better than a lower value
RN turnover	Registered nurse turnover rate	A lower value is better than a higher value
RSMR-AMI	30-day risk standardized mortality rate for acute myocardial infarction	A lower value is better than a higher value
RSMR-CHF	30-day risk standardized mortality rate for congestive heart failure	A lower value is better than a higher value
RSMR-COPD	30-day risk standardized mortality rate for COPD	A lower value is better than a higher value
RSMR-pneumonia	30-day risk standardized mortality rate for pneumonia	A lower value is better than a higher value
RSRR-AMI	30-day risk standardized readmission rate for acute myocardial infarction	A lower value is better than a higher value
RSRR-cardio	30-day risk standardized readmission rate for cardiorespiratory patient cohort	A lower value is better than a higher value
RSRR-CHF	30-day risk standardized readmission rate for congestive heart failure	A lower value is better than a higher value
RSRR-COPD	30-day risk standardized readmission rate for COPD	A lower value is better than a higher value
RSRR-CV	30-day risk standardized readmission rate for cardiovascular patient cohort	A lower value is better than a higher value
RSRR-HWR	Hospital wide readmission	A lower value is better than a higher value
RSRR-med	30-day risk standardized readmission rate for medicine patient cohort	A lower value is better than a higher value
RSRR-neuro	30-day risk standardized readmission rate for neurology patient cohort	A lower value is better than a higher value
RSRR-pneumonia	30-day risk standardized readmission rate for pneumonia	A lower value is better than a higher value
RSRR-surg	30-day risk standardized readmission rate for surgery patient cohort	A lower value is better than a higher value

Measure	Definition	Desired Direction
SC care coordination	SC (specialty care) care coordination	A higher value is better than a lower value
SC routine care appt	Timeliness in getting a SC routine care appointment (specialty care)	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
SC urgent care appt	Timeliness in getting a SC urgent care appointment (specialty care)	A higher value is better than a lower value
Seconds pick up calls	Average speed of call center responded to calls in seconds	A lower value is better than a higher value
SMR	Acute care in-hospital standardized mortality ratio	A lower value is better than a higher value
SMR30	Acute care 30-day standardized mortality ratio	A lower value is better than a higher value
Specialty care wait time	Specialty care wait time for new patient completed appointments within 30 days of preferred date	A higher value is better than a lower value
Stress discussed	Stress discussed (PCMH Q40)	A higher value is better than a lower value
Telephone abandonment rate	Telephone abandonment rate	A lower value is better than a higher value

Source: VHA Support Service Center

Appendix E: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: November 27, 2019

From: Director, VA Healthcare System (10N10)

Subj: Comprehensive Healthcare Inspection of the Richard L. Roudebush VA Medical Center, Indianapolis, IN

To: Director, Chicago Office of Healthcare Inspections (54CH02)

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

1. I have reviewed the draft report of the Comprehensive Healthcare Inspection of the Richard L. Roudebush VA Medical Center, Indianapolis, IN.
2. I concur with the responses and action plans submitted by the Richard L. Roudebush VA Medical Center Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

Lisa A. Pyle

For RimaAnn O. Nelson

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Appendix F: Acting Facility Director Comments

Department of Veterans Affairs Memorandum

Date: November 22, 2019

From: Acting Director, Richard L. Roudebush VA Medical Center (583/00)

Subj: Comprehensive Healthcare Inspection of the Richard L. Roudebush VA Medical Center, Indianapolis, IN

To: Director, VA Healthcare System (10N10)

1. I have reviewed the VA OIG's draft report of the CHIP review conducted at the Richard L. Roudebush VA Medical Center in Indianapolis, Indiana. I concur with the OIG's recommendations.
2. I am submitting my plan to comply with the recommendations to include timeline for completion and sustainment of improvements.
3. I appreciate the OIG's partnership in our continuous improvement efforts.

(Original signed by:)

Laura E. Ruzick, FACHE

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