VETERANS HEALTH ADMINISTRATION

# Comprehensive Healthcare Inspection of the VA Western New York Healthcare System

# Buffalo, New York

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***Figure 1.*** *VA Western New York Health Care System, Buffalo, New York (Source: https://vaww.va.gov/directory/guide/, accessed on December 5, 2019)*

# Abbreviations

| | |
|---|---|
| ADPNS | associate director for Patient Nursing Services |
| CHIP | Comprehensive Healthcare Inspection Program |
| CLC | community living center |
| 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 VA Western New York Healthcare System (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 March 18, 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 Nursing Services (ADPNS), associate director, and assistant director. Organizational communications and accountability were managed through a committee reporting structure, with the Local Leadership Committee having oversight for several working groups. The director is the chair of both the Local Leadership Committee and the Quality Committee, which was responsible for tracking, identifying trends in, and monitoring quality of care and patient outcomes.

The facility's leadership team had been working together since June 2018, although several team members had been in their position for many years. The director and ADPNS were permanently assigned August 6, 2018, and June 4, 2018, respectively. The chief of staff was permanently assigned March 20, 2016. The associate director and assistant director positions were permanently assigned April 17, 2016 and November 27, 2016, respectively. The facility's executive leadership team appeared relatively stable, despite the assistant director serving as both the assistant director and acting associate director for over a year.

The OIG noted that selected employee satisfaction survey results were similar to or worse than the VHA average. Although employees appear generally satisfied with the director, ADPNS, assistant director, and associate director, opportunities exist for the chief of staff and facility leaders together to improve facility-wide employee satisfaction. Facility leaders had implemented processes and plans to maintain positive patient experiences.

The OIG reviewed accreditation agency findings, sentinel events,[1] disclosures of adverse patient events, and patient safety indicator data and identified opportunities for the facility to review the process for evaluating cases for possible institutional disclosure as well as the patient safety indicator data and other sources of data to identify trends/frequently occurring events to mitigate future risks. Additionally, the OIG identified that the Credentialing and Privileging Committee periodically made recommendations to the director to approve medical staff privileges instead of the recommendation coming from the Executive Committee of Medical Staff.

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

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[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."

and differences between the top and bottom performers" within VHA.[2] Although the leadership team members were knowledgeable within their areas of responsibility about selected SAIL metrics and SAIL community living center (CLC) measures, 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 "4-star," Buffalo CLC's "1-star," and Batavia CLC's "2-star" quality ratings.[3]

The OIG noted findings in all eight clinical areas reviewed and issued 18 recommendations that are attributable to the director, associate director, and chief of staff. These are briefly described below.

## Quality, Safety, and Value

The OIG found general compliance with requirements for protected peer reviews, UM, and patient safety.[4] However, the OIG identified concerns with code team physician responders lacking evidence of basic or advanced cardiac life support certification.

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[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.)

[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 March 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.

## Medical Staff Privileging

The facility generally complied with requirements for privileging and focused professional practice evaluations for cause. However, the OIG identified noted concerns in the focused and ongoing professional practice evaluation processes.[5]

## Environment of Care

Generally, the facility met privacy measures at the parent facility and the representative VA Clinic. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified deficiencies with environment of care cleanliness, inpatient mental health floor cushioning, and the required review of inventory of assets and resources for emergency management**.**

## Medication Management

Overall, the facility complied with requirements for some of the performance indicators evaluated for medication management, including controlled substances inspector's requirements for appointment and competencies. However, the OIG identified deficiencies in staff restrictions for monthly review of balance adjustments, completion of controlled substances area monthly inspections on day initiated, and verification of 72-hour inventories of the pharmacy main vault.

## Mental Health

The OIG team also found the facility complied with many of the performance indicators, including the designation of a military sexual trauma (MST) coordinator, tracking of MST-related data, and initial evaluations within 24 hours for patients referred to mental health services. However, the OIG noted noncompliance with the requirement that providers complete MST mandatory training within the required time frame.

## Geriatric Care

For geriatric patients, clinicians followed requirements for justifying the reason for medication initiation and validating general patient/caregiver understanding after educating them about

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[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."

newly prescribed medications. However, the OIG identified inadequate patient and/or caregiver education specific to the newly prescribed antidepressant drug and medication reconciliation relevant to the episode of care.

## Women's Health

Overall, the OIG team noted facility compliance with many of the performance indicators, including those related to requirements for a designated women's health medical director, communication of results to patients within the required time frame, and follow-up care if indicated. However, the OIG noted concerns that the facility had no full-time women veterans program manager and that the Women Veterans Health Committee lacked required membership and meetings and did not report to the Clinical Executive Board.

## High-Risk Processes

The facility generally complied with many of the performance indicators used to assess the operations and management of the emergency department. However, the OIG identified a deficiency with licensed physician staffing.

## Incidental Findings

The OIG noted that the emergency department had the capability and equipment for gynecologic examinations but did not have resources readily available to evaluate victims of sexual assaults.

## Summary

In reviewing key healthcare processes, the OIG issued 18 recommendations for improvement directed to the facility director, associate director, and chief of staff. 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 facility director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes F and G, pages 83–84, and the responses within the body of the report for the full text of the directors' comments.) The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Assistant Inspector General
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# Contents

# 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 VA Western New York Healthcare System (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:

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)

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[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.)

9. High-risk processes (specifically the emergency department and urgent care center operations and management).[8]
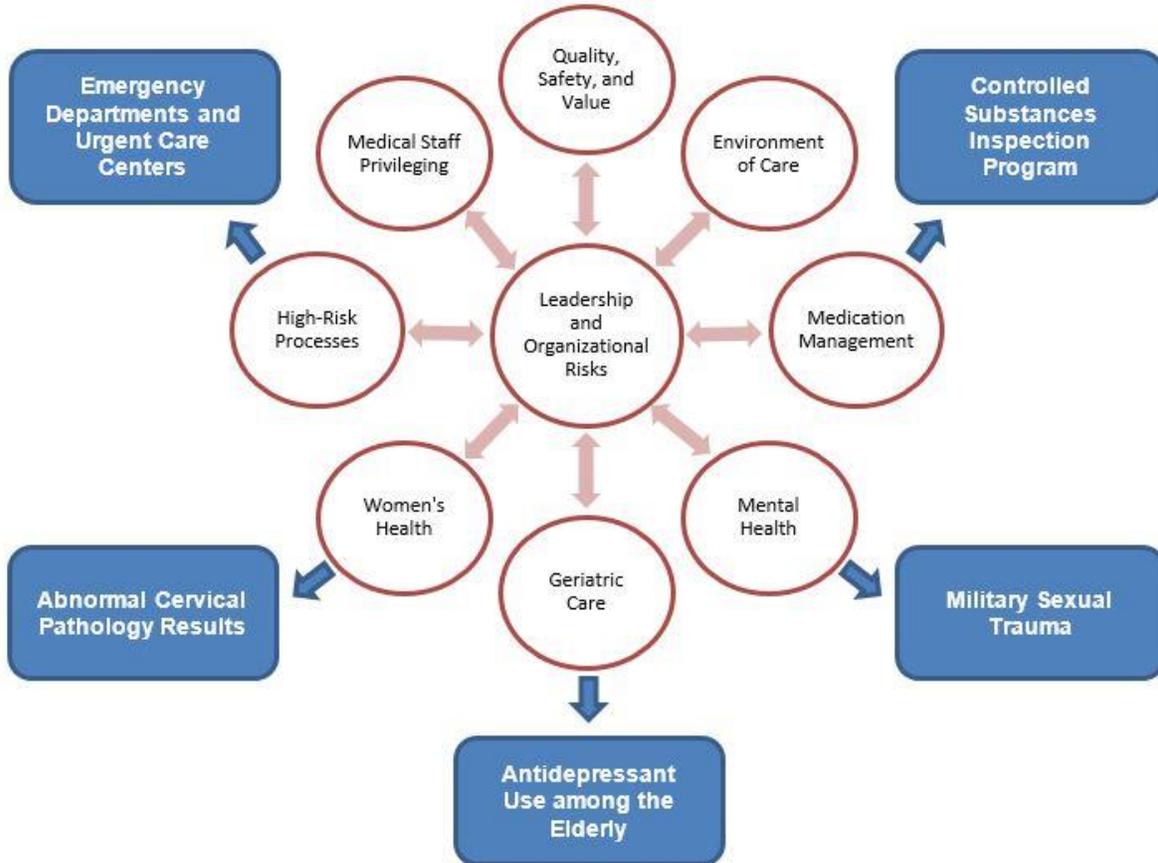


*Figure 2.* Fiscal Year (FY) 2019 Comprehensive Healthcare Inspection of Operations and Services
*Source: VA OIG*

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[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.

# 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 November 7, 2015, through March 22, 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.

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[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 Nursing Services (ADPNS), associate director, and assistant director. The chief of staff and ADPNS oversee patient care, which involves managing service directors and chiefs of programs and practices.

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[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.)

**Director**

**Chief of Staff**
- Anesthesiology
- Behavioral Health
- Care in the Community
- Clinical Application Coordinators
- Dental
- Extended Care and Rehabilitation Medicine
- Graduate Medical Education
- Group Practice Manager
- Healthcare Administrative Service
- Medicine
- Nuclear Medicine
- Pathology and Laboratory Medicine
- Primary Care
- Pharmacy
- Radiology
- Research
- Social Work
- Surgical
- Virtual Care

**ADPNS**
- Associate Chief Nurse of:
  - Acute Medical and Surgical
  - Ambulatory Care
  - Behavioral Health
  - Long Term Care
- Education
- Nurse Recruiter
- Nursing Office
- Sterile Processing Service

**Associate Director**
- Biomedical Engineering
- Engineering
- Environmental Management Service
- Human Resources
- Logistics
- Police

**Assistant Director**
- Green Environmental Management System
- Health Information Management
- Nutrition and Food Service
- Privacy
- Public Affairs
- Safety
- Veterans Service Center
- Voluntary and Recreation Services

- Compliance and Business Integrity Program
- Equal Employment Office
- Quality Management
- Research Compliance

***Figure 3.** Facility Organizational Chart[12]*
*Source: VA Western New York Healthcare System (received March 18, 2019)*

At the time of the OIG site visit, the executive team had been working together since June 2018, although several team members have been in their position for many years (see Table 1). It is important to note that although the associate director was assigned in April 2016, the assistant director had served as the acting associate director for over a year while the permanently assigned associate director was reassigned to another position within the facility.

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[12] At this facility, the director is responsible for the Compliance and Business Integrity Program, Equal Employment Office, Quality Management, and Research Compliance.

**Table 1. Executive Leader Assignments**

| Leadership Position | Assignment Date |
|---|---|
| Facility director | January 2018 (interim); August 6, 2018 (permanent) |
| Chief of staff | March 20, 2016 |
| Associate director for Patient Care Services | June 4, 2018 |
| Associate director | April 17, 2016 |
| Assistant director | November 27, 2016 |

*Source: VA Western New York Healthcare System supervisory human resource specialist (received March 18, 2019)*

To help assess facility executive leaders' engagement, the OIG interviewed the director, chief of staff, ADPNS, and assistant/acting 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 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 and SAIL community living center (CLC) measures. These are discussed in greater detail below.

The director serves as the chairperson of the Local Leadership Committee, with the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Local Leadership Committee oversees various working groups, such as the Executive Committee of Medical Staff, Administrative Executive Board, Executive Committee of Nursing Staff, and Resource Management Committee.

These facility leaders are also engaged in monitoring patient safety and care through the Quality Committee, for which the director is the chair. The Quality Committee is responsible for tracking and identifying trends and monitoring quality of care and patient outcomes, and it reports to the Local Leadership Committee. See Figure 4.

**Figure 4.** *Facility Committee Reporting Structure[13]*
*Source: VA Western New York Healthcare System (received March 18, 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 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 and summarizes employee attitudes for VHA, the facility, and selected facility executive leaders. The OIG found

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[13] The Local Leadership Committee directly oversees the Compliance Advisory Board and Quality Committee.

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

the facility average for selected survey leadership questions was worse than the VHA average.[15] Although employees appear generally satisfied with the director, ADPNS, assistant director, and associate director, opportunities exist for the chief of staff and the facility leaders as a group to improve facility-wide employee satisfaction.

**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 | ADPNS Average | Assoc. Director Average | Asst. Director |
|---|---|---|---|---|---|---|---|---|
| All Employee Survey: *Servant Leader Index Composite[16]* | 0–100 where HIGHER scores are more favorable | 71.7 | 68.7 | 63.8 | 57.8 | 63.1 | 83.3 | 77.7 |
| All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.3 | 3.0 | 3.5 | 2.6 | 3.5 | 3.2 | 3.5 |
| All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.5 | 3.2 | 3.6 | 3.1 | 3.5 | 3.5 | 4.0 |
| All Employee Survey: *I have a high level of respect for my organization's senior leaders.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.6 | 3.3 | 3.7 | 2.9 | 3.3 | 3.7 | 4.1 |

*Source: VA All Employee Survey (accessed February 14, 2019)*

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[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] 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."

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. Note that the facility averages for the selected survey questions were similar to or worse than the VHA average. Additionally, the facility leadership team's scores related to how often employees experience moral distress at work were worse than the VHA average for all members, and their scores for employees doing what is right were lower than the VHA average for all leaders except for the ADPNS. Opportunities exist to improve facility-wide employee workplace attitudes by providing an environment where employees feel encouraged to do the right thing.

**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 | ADPNS Average | Assoc. Director Average | Asst. Director |
|---|---|---|---|---|---|---|---|---|
| All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.8 | 3.5 | 3.3 | 3.7 | 3.9 | 4.5 | 3.7 |
| All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.7 | 3.4 | 3.2 | 3.6 | 4.0 | 3.3 | 3.4 |
| All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?* | 0 (Never) – 6 (Every Day) | 1.5 | 1.6 | 1.9 | 2.0 | 1.8 | 2.0 | 1.9 |

*Source: VA All Employee Survey (accessed February 14, 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.[17]

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 two outpatient survey results reflected higher care ratings than the VHA average, and the two inpatient results were slightly lower than VHA average. Patients appeared to be generally satisfied with the leadership and care provided. Facility leaders seemed to be actively engaged with patients as they were currently focused on increasing staff support to provide a refreshed patient environment at the time of the site visit. The leaders also offered a child care program for the veterans to use during their outpatient appointments.

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[17] Ratings are based on responses by patients who received care at this facility.

**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): *Would you recommend this hospital to your friends and family?* | The response average is the percent of "Definitely Yes" responses. | 66.9 | 66.2 |
| Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.* | The response average is the percent of "Agree" and "Strongly Agree" responses. | 84.2 | 82.9 |
| Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.* | The response average is the percent of "Agree" and "Strongly Agree" responses. | 76.3 | 78.5 |
| Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.* | The response average is the percent of "Agree" and "Strongly Agree" responses. | 76.5 | 82.0 |

*Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment
(accessed December 28, 2018)*

## Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys, including those conducted for cause, by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[18] Table 5 summarizes the relevant facility inspections most recently performed by the OIG and The Joint Commission (TJC).[19] During the on-site review, the OIG noted that the OIG Hotline report had

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[18] 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.

[19] 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."

one open recommendation; however, this recommendation was addressed to the VA Office of General Counsel.[20]

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.[21] Additional results included the Long Term Care Institute's inspection of the facilities.[22]

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[20] 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.

[21] 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.

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

**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 (*Combined Assessment Program Review of the VA Western New York Healthcare System, Buffalo, New York, Report No. 15-04698-99, January 28, 2016*) | November 2015 | 12 | 0 |
| OIG (*Review of Community Based Outpatient Clinics and Other Outpatient Clinics of VA Western New York Healthcare System, Buffalo, New York, Report No. 15-05155-89, January 28, 2016*) | November 2015 | 13 | 0 |
| OIG (*Healthcare Inspection – Mismanagement of a Resuscitation and Other Concerns Buffalo VA Medical Center, Buffalo, New York, Report No. 17-01485-128, March 12, 2018*) | January 2017 | 10[23] | 1 |
| TJC Hospital Accreditation | March 2018 | 23 | 0 |
| TJC Behavioral Health Care Accreditation | | 6 | 0 |
| TJC Home Care Accreditation | | 13 | 0 |

*Source: OIG and TJC (Inspection/survey results received from the quality management staff on March 20, 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 November 7, 2015 (the prior comprehensive OIG inspection), through March 21, 2019.[24]

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[23] Although Report No. 17-01485-128 includes 10 recommendations, one was directed to the VA Office of General Counsel (open at the time of the OIG's site visit), and one was directed to the Veterans Integrated Service Network director.

[24] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the VA Western New York Healthcare System is a high complexity (1b) affiliated facility as described in Appendix B.)

**Table 6. Summary of Selected Organizational Risk Factors
(November 7, 2015 through March 21, 2019)**

| Factor | Number of Occurrences |
|---|---|
| Sentinel Events[25] | 0 |
| Institutional Disclosures[26] | 1 |
| Large-Scale Disclosures[27] | 2 |

*Source: VA Western New York Healthcare System risk manager (received March 18, 2019), health system specialist (received March 18, 2019) and chief of Quality Management (received March 20, 2019)*

Although the facility reported one institutional disclosure, the OIG identified five patients with an institutional disclosure note entered in the patient's records for the time frame reviewed. During OIG interviews, the facility staff stated that they performed a "humanistic risk review" for four of the five patients, in lieu of completing institutional disclosures. A humanistic risk review is not defined by VHA or facility policy. Further, the OIG had conducted a hotline inspection of the facility in 2017, which concluded with a recommendation that the "Veterans Integrated Service Network Director conduct an evaluation of the Facility's quality management practices (including but not limited to Institutional Disclosures) to ensure that they align with Veterans Health Administration policies and also address…(e) the failure to make an Institutional Disclosure consistent with Veterans Health Administration Policy."[28] Although the VISN conducted a visit in February 2018 and the OIG determined that the action was adequate to close the recommendation on October 2, 2018, the facility appears to lack processes to provide institutional disclosures consistent with VHA policy.

The facility had two large-scale disclosures. The first disclosure followed an alert from the Food and Drug Administration and the Centers for Disease Control to hospitals nationwide about

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

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

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

[28] Office of Inspector General, *Healthcare Inspection–Mismanagement of a Resuscitation and Other Concerns VA Western New York Healthcare System, Buffalo, New York*, Report No. 17-01485-128, March 12, 2018.

potential infection risks related to open-heart surgery and heater-cooler units connected to heart lung bypass machines. The facility conducted a five-year look back of patients who underwent open-heart surgery using this equipment and contacted 312 patients during FY 2017, quarter 1.

The second large-scale disclosure occurred in FY 2018, quarter 1 after Sterile Processing Service management discovered that an employee might not have followed, in some cases, the manufacturer's instructions for cleaning reusable medical equipment. The facility contacted 504 patients and offered free screening for hepatitis B, hepatitis C, and human immunodeficiency virus (HIV).

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 2 | Facility |
| Pressure ulcer | 0.74 | 0.46 | 0.00 |
| Death among surgical inpatients with serious treatable conditions | 113.42 | 126.64 | 158.73 |
| Iatrogenic pneumothorax[30] | 0.17 | 0.18 | 0.13 |
| Central venous catheter-related bloodstream infection | 0.16 | 0.04 | 0.00 |
| In-hospital fall with hip fracture | 0.09 | 0.12 | 0.00 |
| Perioperative hemorrhage or hematoma | 2.61 | 3.24 | 1.12 |
| Postoperative acute kidney injury requiring dialysis | 0.89 | 1.23 | 0.89 |
| Postoperative respiratory failure | 4.54 | 4.68 | 13.40 |
| Perioperative pulmonary embolism or deep vein thrombosis | 2.97 | 3.11 | 2.19 |
| Postoperative sepsis | 3.55 | 3.21 | 0.91 |

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

[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.)

| Indicators | Reported Rate per 1,000 Hospital Discharges | | |
|---|---|---|---|
| | VHA | VISN 2 | Facility |
| Postoperative wound dehiscence (rupture along incision) | 0.82 | 0.75 | 0.00 |
| Unrecognized abdominopelvic accidental puncture or laceration | 1.00 | 1.18 | 0.84 |

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

As noted, two of the 12 patient safety indicator measures (death among surgical inpatients with serious treatable conditions and postoperative respiratory failure) showed a higher reported rate than VHA and VISN 2, and one patient safety indicator (postoperative acute kidney injury requiring dialysis) rate was equal to VHA and lower than VISN 2. The nine remaining patient safety indicator measures show a lower reported rate than VHA and VISN 2.

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.
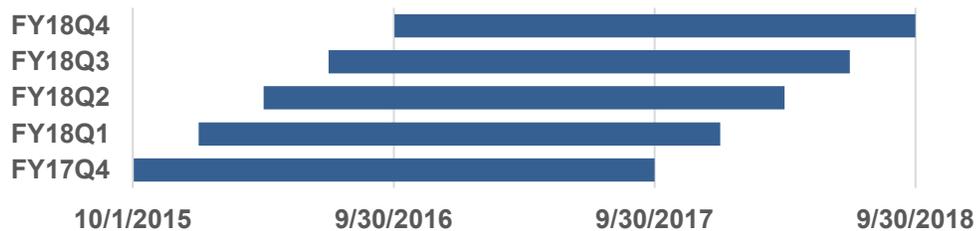
***Figure 5.*** *Associated Time Frames for Quarterly Patient Safety Indicator Data*
*Source: VA OIG*
*FY18Q4 = fiscal year 2018, quarter 4*
*FY18Q3 = fiscal year 2018, quarter 3*
*FY18Q2 = fiscal year 2018, quarter 2*
*FY18Q1 = fiscal year 2018, quarter 1*
*FY17Q4 = fiscal year 2017, quarter 4*

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 | 0.00 | 0.00 | — | 0.00 | 0.00 |
| Death among surgical inpatients with serious treatable conditions | VHA | 100.97 | 118.96 | 113.92 | 114.89 | 113.42 |
| | Facility | 160.00 | 142.86 | 185.19 | 185.19 | 158.73 |
| Iatrogenic pneumothorax | VHA | 0.19 | 0.19 | 0.17 | 0.15 | 0.17 |
| | Facility | 0.25 | 0.22 | 0.25 | 0.38 | 0.13 |
| Central venous catheter-related bloodstream infection | VHA | 0.15 | 0.14 | 0.15 | 0.16 | 0.16 |
| | Facility | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| In-hospital fall with hip fracture | VHA | 0.08 | 0.09 | 0.08 | 0.09 | 0.09 |
| | Facility | 0.00 | 0.11 | 0.00 | 0.00 | 0.00 |
| Perioperative hemorrhage or hematoma | VHA | 1.94 | 2.58 | 2.62 | 2.59 | 2.61 |
| | Facility | 0.58 | 0.50 | 0.58 | 0.58 | 1.12 |
| Postoperative acute kidney injury requiring dialysis | VHA | 0.88 | 0.80 | 0.65 | 0.96 | 0.89 |
| | Facility | 0.98 | 0.83 | 0.91 | 0.91 | 0.89 |
| Postoperative respiratory failure | VHA | 5.55 | 5.34 | 5.11 | 4.88 | 4.54 |
| | Facility | 10.46 | 11.25 | 12.59 | 15.26 | 13.40 |
| Perioperative pulmonary embolism or deep vein thrombosis | VHA | 3.29 | 3.26 | 3.09 | 3.05 | 2.97 |
| | Facility | 1.15 | 0.99 | 1.13 | 1.70 | 2.19 |
| Postoperative sepsis | VHA | 4.00 | 3.96 | 3.72 | 3.70 | 3.55 |
| | Facility | 0.00 | 0.00 | 0.93 | 0.94 | 0.91 |
| Postoperative wound dehiscence (rupture along incision) | VHA | 0.52 | 1.04 | 1.00 | 0.93 | 0.82 |
| | Facility | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Unrecognized abdominopelvic accidental puncture or laceration | VHA | 0.53 | 1.21 | 1.02 | 1.07 | 1.00 |
| | Facility | 0.00 | 1.61 | 1.18 | 1.72 | 0.84 |

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

Two measures (death among surgical inpatients with serious treatable conditions and postoperative respiratory failure) have trended above the VHA average for all five quarters.

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[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.

Three measures (iatrogenic pneumothorax, postoperative acute kidney injury requiring dialysis, and unrecognized abdominopelvic accidental puncture/laceration) have trended near or above VHA until most recently when the three measures improved to below or equal to the VHA rate.

For FY 2018, quarter 4, there were ten patients in the death among surgical inpatients with serious treatable condition measure. Eight of the patients were reviewed by the Peer Review Committee and two cases were reviewed by the risk manager. No opportunities for improvement were identified, and no aggregate review for trends were conducted.

Ten patients had postoperative respiratory failure. Again, no opportunities for improvement were identified, and no aggregate review for trends conducted.

During an on-site discussion, quality leaders and staff confirmed the lack of a defined process for reviewing patient safety indicator data beyond checking the SAIL G-Chart Rare Events tool[32] each day and sending the cases for evaluation and follow-up. Further, the facility did not have a tracking process to follow up on referred cases.

## 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.[33]

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.[34] As of June 30, 2018, the facility was rated as "4-star" for overall quality.

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[32] G-Charts are available for the following outcome measures: in-hospital complications, in-hospital mortality, and Agency for Healthcare Research & Quality (AHRQ) Provider level Patient Safety Indicators (PSI). Data are processed to calculate the opportunities (days) between incidences in the last 12 months for each facility providing acute inpatient medical/surgical services.

[33] 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.)

[34] 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.
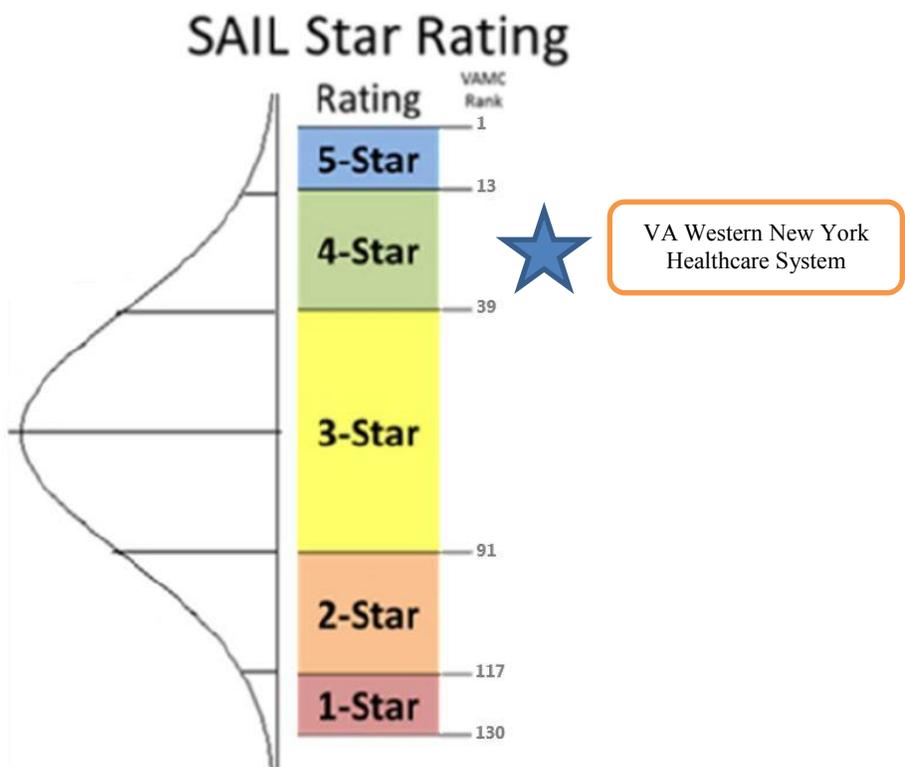
*Figure 6.* *Strategic Analytics for Improvement and Learning Star Rating Distribution (as of June 30, 2018) Source: VA Office of Informatics and Analytics Office of Operational Analytics and Reporting (accessed February 14, 2019)*

Figure 7 illustrates the facility's quality of care and efficiency metric rankings and performance compared with other VA facilities as of September 30, 2018. Of note, the figure uses blue and green data points to indicate high performance (for example, in the areas of stress discussed, mental health (MH) continuity (of) care, and rating (of) primary care (PC) provider). Metrics that need improvement are denoted in orange and red (for example, call responsiveness, rating (of) hospital, and best place to work).[35]

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[35] For information on the acronyms in the SAIL metrics, please see Appendix D.

**Buffalo VAMC (FY2018Q4) (Metric)**

Marker color: Blue - 1st quintile; Green - 2nd; Yellow - 3rd; Orange - 4th; Red - 5th quintile.
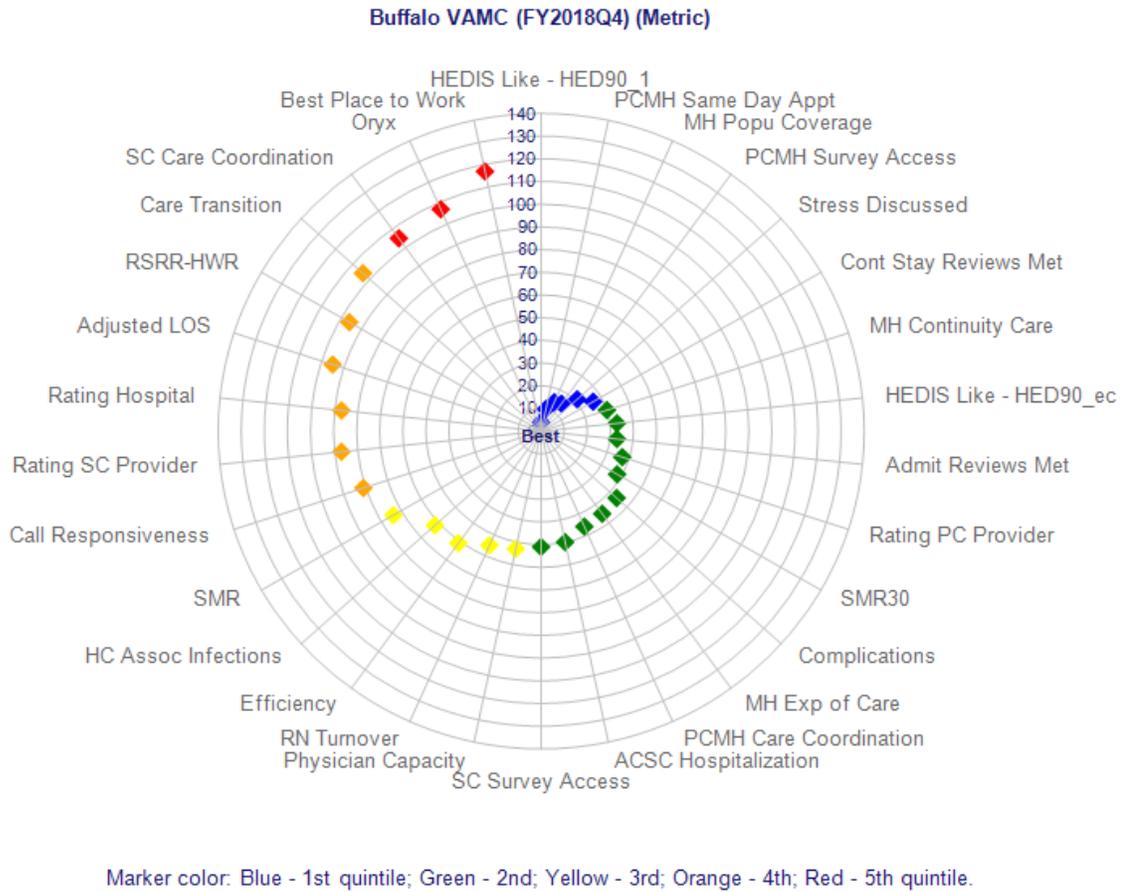
*Figure 7.* *Facility Quality of Care and Efficiency Metric Rankings (as of September 30, 2018)*
*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness. Also see Appendix C for sample outpatient performance measures that feed into these data points (such as wait times, discharge contacts, and where patient care is received). Data definitions are provided in Appendix D.*

The SAIL Value Model also includes "SAIL CLC," which is a tool to summarize and compare the performance of CLCs in the VA. The SAIL model leverages much of the same data used in The Centers for Medicare & Medicaid Services' (CMS) *Nursing Home Compare*.[36] The SAIL CLC provides a single resource to review quality measures and health inspection results. It

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[36] According to the Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, August 22, 2019, "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

includes star ratings for an unannounced survey, staffing, quality, and overall results.[37] Table 9 summarizes the rating results for the facility's CLCs as of September 30, 2018. Although the Batavia site has an overall "5-star" rating, its rating for quality is only a "2-star," and the Buffalo site with an overall rating of "3-star" has a quality rating of "1-star."

**Table 9. Facility CLC Star Ratings
(as of September 30, 2018)**

| Domain | Buffalo Division Star Rating | Batavia Division Star Rating |
|---|---|---|
| Unannounced Survey | 3 | 4 |
| Staffing | 5 | 5 |
| Quality | 1 | 2 |
| **Overall** | 3 | 5 |

*Source: VHA Support Service Center*

In exploring the reasons for the "2-star" Batavia and "1-star" Buffalo quality ratings, the OIG considered the radar diagrams showing CLC performance relative to other CLCs for all 13 quality measures. Figures 8 and 9 illustrates the facility's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2018. For the Buffalo division, Figure 8 uses blue and green data points to indicate high performance (for example, in the areas of falls with major injury (LS) and high risk pressure ulcer (LS)). Metrics that need improvement and were likely the reasons why the facility had a "1-star" for quality are denoted in orange and red (for example, moderate-severe pain (SS), improvement in function (SS), newly received antipysch meds (SS), and catheter in bladder (LS)).[38] For the Batavia division, Figure 9 uses blue and green data points to indicate high performance (for example, in the areas of falls with major injury– long stay (LS), newly received antipysch meds–short stay (SS), and moderate-severe pain (SS)). Metrics that need improvement and were likely the reasons why the facility had a "2-star" for quality are denoted in orange and red (for example, urinary tract infection (UTI) (LS), help with activities of daily living (ADL) (LS), new or worse pressure ulcer (PU) (SS), and improvement in function–short stay (SS)).[39]

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[37] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated August 22, 2019). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on September 3, 2019, but is not accessible by the public.)

[38] For data definitions of acronyms in the SAIL CLC measures, please see Appendix E.

[39] For data definitions of acronyms in the SAIL CLC measures, please see Appendix E.
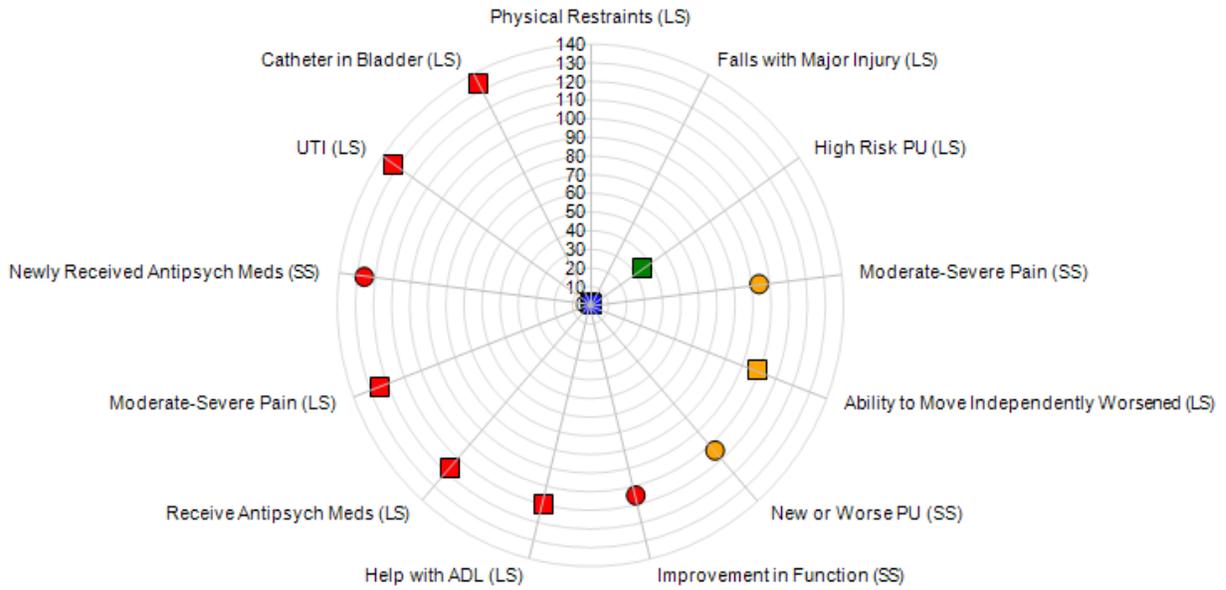
*Figure 8. Buffalo CLC Quality Measure Rankings (as of September 30, 2018)*
*LS = Long-Stay Measure                SS = Short-Stay Measure*
*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix E.*
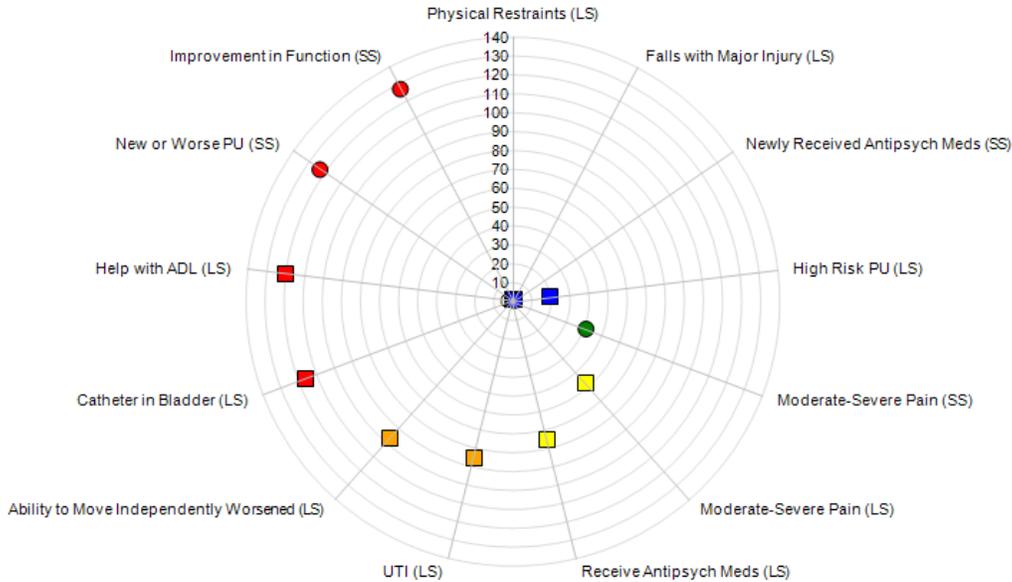


*Figure 9. Batavia CLC Quality Measure Rankings (as of September 30, 2018)*
*LS = Long-Stay Measure                SS = Short-Stay Measure*
*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness. For data definitions, see Appendix E.*

## Leadership and Organizational Risks Conclusion

The facility's executive leadership team appeared relatively stable, despite the assistant director serving as both the assistant director and acting associate director for over a year. Selected survey scores related to employees' satisfaction with the facility executive leaders revealed opportunities to improve facility-wide employee satisfaction and to provide an environment where employees feel encouraged to do the right thing. Patient experience survey data suggested that patients were generally satisfied with the leadership and care provided. The facility leaders appeared actively engaged with employees and patients and were working to sustain and further improve employee and patient engagement and satisfaction. The leaders appeared to support efforts to improve and maintain patient safety, quality care, and other positive outcomes (such as initiating plans to maintain positive perceptions of the facility through active stakeholder engagement). The OIG's review of the facility's accreditation findings, sentinel events, and disclosures identified opportunities for the facility to review the process for evaluating cases for possible institutional disclosure. The OIG's review of patient safety indicator data also identified opportunities for the facility leaders to define a process to monitor for trends/frequently occurring events to mitigate future risks. The senior leadership team appeared actively engaged and generally knowledgeable about selected SAIL metrics within their scope of responsibility and should continue to take actions to improve care and performance of metrics likely contributing to the facility SAIL "4-star," Buffalo CLC "1-star," and Batavia CLC "2-star" quality ratings.

## 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.[40] VHA also strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.[41] VHA requires that its facilities operate a quality, safety, and value (QSV) program to monitor the quality of patient care and performance improvement activities.[42]

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,[43] utilization management (UM) reviews,[44] patient safety incident reporting with related root cause analyses,[45] and cardiopulmonary resuscitation (CPR) episode reviews.[46]

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

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[40] 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.)

[41] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 2014.

[42] VHA Directive 1026.

[43] 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.

[44] 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 March 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.

[45] 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."

[46] VHA Directive 1177, *Cardiopulmonary Resuscitation*, August 28, 2018.

nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[47]

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.[48]

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.[49]

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.[50]

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:[51]

- 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

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[47] VHA Directive 1190.

[48] VHA Directive 1117(1).

[49] VHA Handbook 1050.01.

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

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

- o Quarterly review of Peer Review Committee's summary analysis by the Medical Executive Committee

- o Peer review of all applicable deaths within 24 hours of admission to the hospital

- o Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[52]

- UM

  - o Completion of at least 75 percent of all required inpatient reviews

  - o Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database

  - o Interdisciplinary review of UM data

- Patient safety

  - o Annual completion of a minimum of eight root cause analyses[53]

  - o Inclusion of required content in root cause analyses (generally)

  - o Submission of completed root cause analyses to the National Center for Patient Safety within 45 days

  - o Provision of feedback about root cause analysis actions to reporting employees

  - o Submission of annual patient safety report to facility leaders

- Resuscitation episode review

  - o Evidence of a committee responsible for reviewing resuscitation episodes

  - o Confirmation of actions taken during resuscitative events being consistent with patients' wishes

  - o Evidence of basic or advanced cardiac life support certification for code team responders

  - o Evaluation of each resuscitation episode by the CPR Committee or equivalent

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[52] VHA Directive 1190.

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

## Quality, Safety, Value Conclusion

The OIG found general compliance with requirements for protected peer reviews, UM, and patient safety. Approximately seven months prior to the OIG's visit, the peer review coordinator identified a deficiency with implementation of improvement actions recommended by the Peer Review Committee and changed the process. The OIG found that peer reviews completed after the implementation were compliant. The facility continued to be compliant with implementation of improvement actions recommended by the Peer Review Committee. However, the OIG identified concerns with basic or advanced cardiac life support certification for code team physician responders which warranted a recommendation for improvement.

Specifically, VHA requires that all members of a team responding to a resuscitation code must have basic or advanced cardiac life support certification.[54] The OIG found that in four of eight resuscitative events reviewed, three resident physicians did not have required basic or advanced cardiac life support certification. This resulted in the lack of assurance that physician providers responding to resuscitation events were trained and certified. The quality staff member reported that a former internal medicine residency program director misinformed the resident physicians that the certifications were not required. The OIG noted that there was no facility awareness regarding the misinformation and lack of oversight and adherence to facility policy regarding physician code leaders being advanced cardiac life support certified at the time of the code.

## Recommendation 1

1. The chief of staff confirms that all team members responding to resuscitation events have basic or advanced cardiac life support certification and monitors compliance.

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[54] VHA Directive 1177.

Facility concurred.

Target date for completion: May 30, 2020

Facility response: The facility requires that staff responding to resuscitation events have basic or advanced cardiac life support certification. The information below provides how this information is monitored based on the discipline.

Facility Providers: All members of the code team are required to maintain basic or advanced cardiac life support certification including physician, nurse practitioners, physician assistants and nurses.

Residents: The trainee coordinator in the VA academic affiliation office in conjunction with the University of Buffalo (UB) monitors all residents who rotate through the facility to ensure that they have a current advanced cardiac life support certification. Due to varying schedules, all residents advanced cardiac life support certification status is tracked, and email notification goes to the resident as well as their Program Administrator at UB and their VA Program Site Director prior to their recertification expiring. Those that are already non-compliant have been suspended from training at our site until recertification card is provided. All residents are notified at minimum, 60 days prior to expiration of advanced cardiac life support certification allowing time for completion of the advanced cardiac life support certification course prior to their first rotation day.

Compliance Monitoring: Numerator is the number of codes each month with team members in compliance with required certification. Denominator is the total number of Code Team Events.

Compliance Goal: 100% compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. Compliance will be monitored at Quality Committee through the Cardiopulmonary Resuscitation Committee until compliant for 6 months with compliance of 100%.

## 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).[55]

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 re-privileging prior to their expiration.[56]

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."[57]

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.[58] 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.[59]

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:

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[55] 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.)

[56] VHA Handbook 1100.19.

[57] VHA Handbook 1100.19.

[58] 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).

[59] 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.)

- Four solo "few" (less than two in a specialty) practitioners[60] hired within 18 months before the site visit or were privileged within the prior 12 months[61]

- Ten LIPs hired within 18 months before the site visit

- Twenty LIPs re-privileged within 12 months before the visit

- Two providers who underwent a FPPE for cause within 12 months prior to the visit.

The OIG evaluated the following performance indicators:

- Privileging

  o Privileges requested by the provider

    - Facility-specific

    - Service-specific

    - Provider-specific[62]

  o Approval of privileges for a period of less than, or equal to, two years

- Focused professional practice evaluations

  o Criteria defined in advance

  o Use of required criteria in FPPEs for selected specialty LIPs

  o Results and time frames clearly documented

  o Evaluation by another provider with similar training and privileges

  o Executive Committee of the Medical Staff consideration of FPPE results in its decision to recommend continuing the initially granted privileges

- Ongoing professional practice evaluations

  o Criteria specific to the service or section

  o Use of required criteria in OPPEs for selected specialty LIPs

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[60] This refers to circumstances where there are two or less practitioners in a particular specialty.

[61] The 18-month period was from September 18, 2017, through March 18, 2019. The 12-month review period covered March 18, 2018, through March 18, 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] 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.

- o Service chief's determination to recommend continuation of current privileges was based in part on the results of OPPE activities

- o Evaluation by another provider with similar training and privileges

- o Executive Committee of the Medical Staff's decision to recommend continuing privileges based on OPPE results

- Focused professional practice evaluations for cause

  - o Clearly defined expectations/outcomes

  - o Time-limited

  - o Provider's ability to practice independently not limited for more than 30 days

  - o Shared with the provider in advance

- Reporting of privileging actions to National Practitioner Data Bank

## Medical Staff Privileging Conclusion

The OIG team found there was general compliance with requirements for privileging and FPPE for cause. However, the team identified deficiencies with FPPE and OPPE processes that warranted recommendations for improvement.

VHA requires each service chief "establish additional criteria for granting of clinical privileges within the service consistent with the needs of the service and the facility as well as within the available resources to provide these services."[63] The OIG found that in 19 of 24 OPPEs reviewed, four of which were solo providers, there was insufficient evidence of service-specific criteria. This resulted in inadequate data to support decisions to grant clinical privileges to these LIPs. The chief of staff reported all providers are only evaluated on core competencies.[64]

## Recommendation 2

2. The chief of staff ensures the service chiefs include service-specific criteria in ongoing professional practice evaluations and monitors compliance.

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[63] VHA Handbook 1100.19.

[64] According to VHA Handbook 1100.19, "[t]he term "competency" is a documented demonstration of an individual having the requisite or adequate abilities or qualities capable to perform up to a defined expectation." The providers were evaluated on the following competencies: patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice.

Facility concurred.

Target date for completion: March 30, 2020

Facility response: The facility service chiefs utilize a standardized facility ongoing professional practice evaluations form with providers evaluated in each of the general competencies with criteria tailored for the specific service by the service chief. The Credentialing and Privileging Committee has implemented new processes to ensure service specific data is included in the ongoing professional practice evaluations data established by each service chief and included in the service chief Credentialing and Privileging ongoing professional practice evaluations report. The data will be tracked by the number of providers reviewed in committee demonstrating the above compliance divided by the number of renewals completed at the committee with the compliance tracked until 90% or great compliance established for six consecutive months.

Compliance Monitor: Numerator = # ongoing professional practice evaluations reviewed with the service specific criteria. Denominator = # of total ongoing professional practice evaluations reviewed by the Credentialing and Privileging Committee.

Compliance Goal: 90% or greater for 6 months

Responsibility: The Chief of Staff will ensure compliance. Audits will be conducted monthly to ensure compliance for 6 months with 90% or greater compliance. The results will be reported to the Executive Committee of the Medical Staff through the Credentialing and Privileging Committee.

In addition, VHA has defined specialty-specific elements to be used, where appropriate, for gastroenterology, pathology, nuclear medicine, and radiation oncology specialties.[65] The OPPE process ensures a consistent approach for evaluating providers in these specialties and "is essential to confirm the quality of care delivered."[66]

The OIG found that the OPPEs for all three of the specialty providers reviewed (one gastroenterologist and two pathologists) did not contain the specialty-specific elements required by VHA. This resulted in insufficient evidence to confirm the quality of care delivered by the provider. The medicine service chief reported the elements are included in the supporting documentation, and OIG observed the elements were not on the OPPE form.

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[65] VHA Deputy Under Secretary for Health Operations and Management (DUSHOM) Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.
[66] VHA Handbook 1100.19.

## Recommendation 3

3. The chief of staff ensures that service chiefs include required gastroenterology and pathology specific criteria for those specialties in ongoing professional practice evaluations and monitors service chiefs' compliance.

Facility concurred.

Target date for completion: March 30, 2020

Facility response: The chief of staff ensures that service chiefs include required gastroenterology and pathology specific criteria for those specialties in ongoing professional practice evaluations and monitors service chiefs' compliance.

Compliance Monitor: The facility service chiefs utilize a standardized facility ongoing professional practice evaluations form with providers evaluated in each of the general competencies with criteria tailored for the specific service by the service chief. The service chiefs responsible for gastroenterology and pathology will use the national ongoing professional practice evaluations form rather than the standardized form tailored to include the elements of the national form.

The Chief of Staff will ensure compliance through audits which will be completed on all impacted providers until 100% compliance. The results will be reported to the Executive Committee of the Medical Staff through the Credentialing and Privileging Committee.

Regarding OPPEs, VHA requires providers with "similar training and privileges evaluate the privilege-specific competence of the practitioner and document evidence of competently performing the requested privileges of the facility."[67] In 5 of 23 practitioners' profiles, two of which were solo providers, the OIG found that the evaluations were conducted by a provider who did not have similar training and privileges. This resulted in providers practicing without a comprehensive evaluation of their specialty practice. The chief of staff reported that providers are evaluated on the core competencies and, because most of the work done by providers at the facility was similar to the provider undergoing review, believed that the facility met the requirement.

## Recommendation 4

4. The chief of staff ensures that ongoing professional practice evaluations are completed by providers with similar training and privileges and monitors compliance.

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[67] VHA DUSHOM Memorandum.

Facility concurred.

Target date for completion: March 30, 2020

Facility response: The facility service chiefs utilize a standardized facility ongoing professional practice evaluations form with providers evaluated in each of the general competencies with criteria tailored for the specific service by the service chief. The Credentialing and Privileging Committee has implemented new processes to ensure the providers completing evaluations have similar training and privileges and is included in the ongoing professional practice evaluations data established by each service chief and included in the service chief Credentialing and Privileging ongoing professional practice evaluations report. The data will be tracked by the number of providers reviewed in committee demonstrating the above compliance divided by the number of renewals completed at the committee with the compliance tracked until 90% or greater compliance established for six consecutive months.

Compliance Monitor: Numerator = # ongoing professional practice evaluations s reviewed which document providers completing evaluations have similar training and privileges. Denominator = # of total ongoing professional practice evaluations reviewed by the Credentialing and Privileging Committee.

Compliance Goal: 90% or great compliance established for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. Audits will be conducted monthly to ensure 90% or greater compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Credentialing and Privileging Committee.

VHA requires that "the applicable Service Chief reviews the credentialing file and requested privileges and makes recommendations regarding the appointment. The folder and recommendations are [then] reviewed by the credentialing committee and then submitted with recommendations to the medical staff's Executive Committee." VHA also states that this "Executive Committee of the Medical Staff must consider all information available…prior to making their recommendation for the granting of privileges to the Director. This deliberation must be clearly documented in the minutes."[68]

The OIG reviewed 12 months of the Executive Committee of Medical Staff minutes and found that for all 10 providers' FPPE profiles and 6 of 24 providers' OPPE profiles reviewed, three of which were solo providers, there was insufficient evidence that the committee considered, reviewed, discussed, or recommended privileging actions. The OIG noted that the facility's Credentialing and Privileging Committee was reviewing and voting on privileging actions and then sending the results to the director for signature. The lack of input from the Executive Committee of Medical Staff to the director resulted in incomplete reviews to support the facility

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[68] VHA Handbook 1100.19.

director's approval for granting or continuing privileges. Since the Credentialing and Privileging Committee and the Executive Committee of the Medical Staff committees had the same membership, with the exception of one additional member—the chief of staff believed it was appropriate to allow the Credentialing and Privileging Committee to periodically make initial and re-privileging recommendations and submit directly to the director for approval.

## Recommendation 5

5. The chief of staff ensures that the Executive Committee of the Medical Staff reviews and evaluates licensed independent practitioners' initial and re-privileging requests prior to making recommendations to the facility director and monitors compliance.

Facility concurred.

Target date for completion: December 20, 2019

Facility response: The Executive Committee of the Medical Staff reviews and evaluates licensed independent practitioners' initial and re-privileging requests prior to making recommendations to the facility director and monitors compliance.

Compliance Monitor: Numerator = # of total initial and re-privileging request reviewed by Credentialing and Privileging Committee and approved by the Executive Committee of the Medical Staff.

Denominator = # of total initial and re-privileging request approved by Credentialing and Privileging Committee.

Compliance Goal: 100% compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. Audits will be conducted monthly to ensure 100% compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Credentialing and Privileging Committee.

## 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.[69]

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.[70]

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.[71]

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.[72] Managers must also develop utility management plans to increase reliability and reduce failures of electrical power distribution systems in accordance with TJC,[73]

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

[70] 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).

[71] 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.)

[72] VHA Directive 0320.01, *Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures*, April 6, 2017; TJC Emergency Management standard EM.01.01.01; TJC Emergency Management standard EM.2.01.01; TJC Emergency Management standard EM.03.01.01; and TJC Emergency Management standard EM.03.01.03.

[73] TJC Emergency Management standard EM.01.01.01; TJC Emergency Management standard EM.2.01.01; TJC Emergency Management standard EM.03.01.01; and TJC Emergency Management standard EM.03.01.03.

Occupational Safety and Health Administration,[74] and National Fire Protection Association standards.[75] The provision of sustained electrical power during disasters or emergencies is critical to healthcare facility operations.[76]

In all, the OIG team inspected 10 units at the Buffalo and Batavia divisions—Buffalo – intensive care unit (2D), community living center (9A), medicine unit (9D), surgical unit (8D), post-anesthesia care unit (205D), outpatient clinic (1A), and emergency department (1D); and Batavia – outpatient clinic (Bldg. 1), community living center (2B), inpatient mental health (10A). The team also reviewed the emergency management program and the Dunkirk VA Clinic. 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
  - Nursing station security

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[74] 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.)

[75] 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.)

[76] TJC. Environment of Care standard EC.02.05.07.

- o Public area and general unit safety

- o Patient room safety

- o Infection prevention

- o Availability of medical equipment and supplies

- Emergency management

- o Hazard vulnerability analysis (HVA)

- o Emergency operations plan (EOP)

- o Emergency power testing and availability

## Environment of Care Conclusion

Generally, the facility met privacy measures at the parent facility and the representative VA Clinic. The OIG did not note any issues with the availability of medical equipment and supplies. However, the OIG identified deficiencies with environment of care cleanliness, inpatient mental health floor cushioning, and the required review of inventory of emergency management assets and resources that warranted recommendations for improvement.

Specifically, TJC requires hospitals to identify environmental deficiencies, hazards, and unsafe practices and to keep "furnishings and equipment safe and in good repair."[77] Of the 11 patient care areas inspected, the OIG noted six areas with dusty, damaged, or stained ceiling tiles; damaged, dirty, or stained floor tiles; dirty or dusty heating, ventilation, and air conditioning exterior grills; dirty, damaged, or stained light fixtures; and damaged or stained walls. Additionally, two areas had dusty fire sprinkler heads and lower storage shelves that were not solid, and in three areas, the shelves were less than 8 inches above the floor. These conditions resulted in a lack of assurance of a clean and safe patient care environment. The chief of Environmental Management Service and the assistant chief of Engineering Service cited a shortage of staff and inattention to detail as reasons for noncompliance.

## Recommendation 6

6. The associate director ensures that a safe and clean environment is maintained throughout the facility and monitors compliance.

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[77] TJC. Environment of Care standard EC.02.06.01.

Facility concurred.

Target date for completion: January 31, 2020

Facility response: This process is ongoing daily and is a focus topic on Environment of Care (EOC) rounding conducted bi-annually on patient care areas and annually in all other areas. New processes and training for EMS staff were implemented to address deficient areas. This also included education of staff to enter work orders if cleanliness and repairs are needed within the facility, off-site clinics, or CBOC clinics. Corrective action is taken within 14 days and the finding is closed out in Performance Logic software and briefed in the Environment of Care Committee.

Compliance Monitoring: Compliance will be monitored based on the percentage of EOC rounds findings completed within the 14-day window.

Numerator - # of findings completed within 14-days or have an action plan established in 14-days.

Denominator - # of EOC rounds findings.

Compliance Goal: monthly compliance of 90% or greater. Audits are conducted monthly to ensure compliance.

Responsibility: Assistant Director. The results will be reported to the Environment of Care Committee.

VHA requires that inpatient mental health seclusion rooms be designed to prevent patient injury; this includes floors which must be made "of a material that provides cushioning."[78] The OIG found that the floor in two inspected seclusion rooms lacked cushioning. This could result in harm to patients or staff in the event of a fall while in the seclusion room. The OIG team noted that the mental health environment of care rounds team also identified the flooring as appropriate during July 2018 and January 2019 inspections, and facility engineer staff provided no reason for noncompliance since they believed that current flooring was compliant.

## Recommendation 7

7. The associate director makes certain mental health seclusion room floors are cushioned.

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[78] VHA Mental Health Environment of Care Checklist, December 8, 2016.

Facility concurred.

Target date for completion: April 30, 2020

Facility response: The facility selected a cushioned material to replace the existing flooring in the inpatient mental health unit. The Statement of Work was completed and forwarded to contracting on October 29, 2019. Construction specifications are available for review if needed.

Compliance Monitor: The construction phase will be monitored for timeliness and completion.

Compliance Goal: Installation completion by April 30, 2020

Responsibility: Assistant Director. The results will be reported to Environment of Care Committee.

Also, VHA[79] and TJC[80] require facilities to have a comprehensive emergency management plan that includes an annual review of inventory of assets and resources that may be needed during emergencies. The OIG reviewed selected sections of the facility's emergency operations plan and found no evidence of an inventory of assets and resources. This resulted in a lack of assurance that the facility is prepared for contingency operations during emergencies. The emergency manager reported being in the role for almost two years and had been working on updating the emergency operations plan but had not created the required inventory.

## Recommendation 8

8. The associate director ensures the required inventory of assets and resources is created and reviewed annually by the Emergency Management Committee and approved by executive leaders and monitors compliance.

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[79] VHA Directive 0320.01.

[80] TJC Emergency Management standard EM.01.01.01; TJC Emergency Management standard EM.03.01.01.

Facility concurred.

Target date for completion: November 30, 2019

Facility response: The Emergency Manager completed the assets and resources inventory and it was approved by the Emergency Management Steering Committee on April 19, 2019. This inventory will be reviewed annually in the month of November.

Compliance Monitor: The Emergency Management Committee meeting minutes will be monitored to ensure that the assets and resources inventory is reviewed annually and will be reported to the Environment of Care Committee.

Compliance Goal: Review of inventory annually

Responsibility: Assistant Director

## 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.[81] 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.[82]

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.[83]

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;[84] 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 adjustments[85]
- Requirements for controlled substances inspectors

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

[82] 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.

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

[84] The two quarters were from July 1, 2018, through December 31, 2018.

[85] 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 destruction[86]

  - 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 reports[87]

## Medication Management Conclusion

The OIG found there was general compliance with some of the performance indicators evaluated, including controlled substances inspector's requirements for appointment and

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[86] 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."

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

competencies. However, the OIG identified deficiencies in staff restrictions for monthly review of balance adjustments, completion of controlled substances area monthly inspections on day initiated, and verification of 72-hour inventories of the pharmacy main vault that warranted recommendations for improvement.

Despite VHA's requirement that pharmacy staff assigned to review controlled substances inventory balance adjustments not be the same staff who perform and document the balance adjustments, the OIG found that one pharmacy staff member assigned to monitor controlled substance inventory balance adjustments also had access to electronically perform controlled substance adjustments to the pharmacy vault inventory.[88] This increases the potential for controlled substances diversions. The pharmacy chief thought the pharmacy staff member only had the supervisor key and did not realize that the staff member also had the ability to make balance adjustments.

## Recommendation 9

9. The facility director ensures that staff who conduct monthly review of balance adjustments not be the same staff that perform and document the balance adjustments and monitors compliance.

Facility concurred.

Target date for completion: December 31, 2019

Facility response: The Associate Chief of Pharmacy makes a formal request to an Automated Data Processing Application Coordinator pharmacist to run the report of all employees that have the VistA Key. The Associate Chief of Pharmacy references the report that provides the names of the staff that audit balance adjustments. The cross reference verifies that staff who hold the balance adjustment key do not have the ability to audit balance adjustments.

Compliance Monitor: Report generated quarterly.

Compliance Goal: No Pharmacy staff will have the ability to audit balance adjustments and enter balance adjustments.

Responsibility: Associate Chief of Pharmacy will ensure audits will be conducted quarterly to ensure compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Pharmacy and Therapeutics Committee.

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[88] VHA Directive 1108.02(1).

VHA requires that controlled substances inspectors conduct monthly physical inventory of the controlled substances storage area and complete these inventories on the day initiated.[89] VHA also requires that records are retained to include inspector worksheets and supporting documentation.[90] For all 10 non-pharmacy areas reviewed, the OIG did not find evidence of required physical inventories and completion on the day initiated. This resulted in the potential lack of accountability for controlled substances. The co-controlled substances coordinators reported the automatic dispensing cabinets did not allow inventory logs to be printed past 90 days, and there was not a process to collect inventories at the time of the controlled substances inspection. In addition, with 10 automated dispensing cabinets in the operating room, there were times when the controlled substances inspectors had not completed the reviews on the same day.

## Recommendation 10

10. The facility director makes certain that controlled substances coordinators maintain necessary records and controlled substance inspectors conduct monthly physical inventory of the controlled substances storage area that are completed on the day initiated and monitors controlled substance coordinator's compliance.

Facility concurred.

Target date for completion: March 31, 2020

Facility response: All inspections will be completed on the day initiated. The area identified (Operating Room) during the review has been addressed by the initiation of an earlier start time for all inspections. This change began in September with no missed pyxis machines and will continue until March.

Compliance Monitor: Controlled Substance Coordinators monitor the inspection documentation to ensure inspection was completed on day of initiation. Numerator = # of Pyxis inspections on day of initiation. Denominator = # total of pyxis machine to be inspected.

Compliance Goal: 100% of Pyxis machines will be inspected within the day initiated.

Responsibility: Facility director or designee will ensure audits will be conducted monthly to ensure compliance for six months. The results will be reported to the Quality Committee.

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[89] VHA Directive 1108.02(1).
[90] VHA Directive 1108.02(1).

VHA requires that controlled substances inspectors verify and document that twice a week (three days apart) pharmacy inventory checks have been completed.[91] The OIG found the controlled substances inspectors documented verification of completed 72-hour pharmacy inventory checks; however, in the OIG's review of the pharmacy inventory logs, the 72-hour or twice a week inventory was not being completed. This could potentially delay identification of discrepancies and potential drug diversions. The chief of Pharmacy cited lack of staffing as the reason the pharmacy inventory logs had not been completed.

## Recommendation 11

11. The facility director makes certain that the pharmacy staff complete the pharmacy inventory checks as required and monitors staff compliance.

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Facility concurred.

Target date for completion: December 2019

Facility response: The pharmacy staff are currently completing the inventory checks daily (Monday thru Friday) to ensure that the twice weekly requirement is maintained.

Compliance Monitor: Numerator = # of days inventory checks occurred; Denominator = # of days counts should occur.

Compliance Goal: 90% or greater compliance

Responsibility: Associate Chief of Pharmacy ensures audits will be conducted to ensure compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Pharmacy and Therapeutics Committee.

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[91] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. (This Handbook was in effect at the time of the review but was rescinded on May 1, 2019, and replaced by VHA Directive 1108.01, *Controlled Substances Management*.)

# 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."[92] 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.[93]

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.[94] Additionally, the facility director is responsible for ensuring that MST-related data are tracked and monitored.[95]

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.[96] Those who screen positive must have access to appropriate MST-related care.[97] 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.[98]

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.[99] All mental health and primary care providers must complete MST mandatory

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

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

[94] VHA Directive 1115.

[95] 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.)

[96] 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."

[97] VHA Directive 1115.

[98] VHA Handbook 1160.01.

[99] 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.[100]

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

  o Establishes and monitors MST-related staff training

  o Establishes and monitors informational outreach

  o Communicates MST-related issues, services, and initiatives with local leaders

- Evidence of tracking MST-related data

- Provision of clinical care

  o Referral for MST-related care to patients with positive MST screens

  o Initial evaluation within 24 hours of referral for mental health services

  o 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 OIG found compliance with many of the performance indicators, including the designation of an MST coordinator, tracking of MST-related data, and initial evaluations within 24 hours for patients referred to mental health services. However, the OIG noted noncompliance with providers completing MST mandatory training within the required time frame that warranted a recommendation for improvement.

Specifically, VHA requires that all mental health and primary care providers complete the MST mandatory training; for those hired after July 1, 2012, this training must be completed no later than 90 days after entering their position and those hired prior to July 1, 2012, to complete

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[100] 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.

training no later than September 30, 2012.[101] The OIG found two of five providers hired after July 1, 2012, did not complete training within 90 days of their hire date nor had they completed it by the time of the OIG site visit. In addition, two of 15 clinicians hired before July 1, 2012, had no record of training completion at the time of OIG's site visit. This could potentially result in providers being responsible for counseling, care, and services without the required MST training. The MST coordinator reported a failure to validate completion of required training and a lack of a process to capture employees transferring from areas without the MST training requirement.

## Recommendation 12

12. The chief of staff ensures mental health and primary care providers complete military sexual trauma mandatory training within the required time frame and monitors providers' compliance.

Facility concurred.

Target date for completion: March 30, 2020

Facility response: New staff are provided Talent Management System training on hire and current staff are assigned training as needed. The Military Sexual Trauma Coordinator monitors this on a monthly basis.

Compliance Monitor: The Military Sexual Coordinator Monitors Talent Management System reports of employees to maintain competency and staff will receive training upon hire or appointment. MST Coordinator will alert respective supervisors to any staff nearing a deficient status to encourage compliance.

Compliance Goal: 90% or greater compliance; Numerator = # staff compliant; Denominator = # staff assigned MST training.

Responsibility: The Military Sexual Coordinator will ensure audits will be conducted monthly to ensure 90% or greater compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Behavioral Health Council minutes.

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[101] VHA Directive 1115.01; Acting Deputy Under Secretary for Health for Operations and Management Memorandum.

## 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."[102] 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.[103]

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 antidepression drugs, psychotherapy, or a combination of both."[104]

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.[105] 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."[106] In 2015, VHA outlined essential medical information "necessary for review, management, and communication of medication information" with patients, caregivers, and their healthcare teams.[107] 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.[108] The CPG recommends that clinicians monitor patients monthly after therapy initiation or a change in treatment until the patient achieves

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[102] 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.)

[103] *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.)

[104] 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.)

[105] 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.sigot.org/allegato_docs/1057_Beers-Criteria.pdf. (The website was accessed on March 22, 2018.)

[106] TJC. Provision of Care, Treatment, and Services standard PC.02.03.01.

[107] VHA Directive 1164, *Essential Medication Information Standards*, June 26, 2015.

[108] 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.[109]

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 32 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.[110] 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

The OIG inspection revealed providers followed requirements for justifying the reason for medication initiation and validating general patient/caregiver understanding after educating them about newly prescribed medications. However, the OIG identified inadequate patient and/or caregiver education specific to the newly prescribed antidepressant drug and medication reconciliation relevant to the episode of care, which warranted recommendations for improvement.

Specifically, TJC requires that clinicians educate patients and families about "safe and effective use of medications" and that the patient's "medical record contains information that reflects the patient's care, treatment, and services."[111] The OIG estimated that clinicians documented medication education in 34 percent of the electronic health records reviewed.[112] Providing medication education is important for patients to be able to manage their health at home.[113] The chief of Geriatrics stated that clinicians provided education to the patient and/or caregiver, however the discussion was not documented.

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[109] *VA/DoD Clinical Practice Guidelines for the Management of Major Depressive Disorder*.

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

[111] TJC Provision of Care, Treatment, and Services standard PC.02.03.01; TJC Record of Care, Treatment, and Services standard RC.02.01.01.

[112] The OIG is 95 percent confident that the true compliance rate is somewhere between 18.4 and 51.5 percent, which is statistically significantly below the 90 percent benchmark.

[113] TJC. Provision of Care standard PC.02.03.01.

## Recommendation 13

13. The chief of staff makes certain that clinicians provide education to the patient and/or caregiver about the safe and effective use of newly prescribed medications and monitors the clinicians' compliance.

Facility concurred.

Target date for completion: May 31, 2020

Facility response: The facility implemented a dashboard prior to the OIG CHIP review. This dashboard allows individual providers to review their prescribing of targeted anticholinergic medications. Additionally, a progress note entitled "Anticholinergic Medications" was developed following the review to document prescribing and education regarding these medications. The progress note may be populated either with (1) an "initiation" template for the prescribing provider to document diagnosis, baseline data, risk/benefit and patient agreement to therapy, (2) a "follow-up within 30-days" template for the provider to document follow up on effects, side effects and any safety concerns, and (3) a "initial education" template for the pharmacist to document initial education.

Compliance Monitor: Pharmacy will use the dashboard to identify providers prescribing new anticholinergic medications for patients > 65 years old each month. This list will be used to determine Provider compliance with use of the note for initiation and follow-up. It will be used to determine Pharmacist compliance with documentation of education. 100% of impacted patients will be reviewed.

Compliance Goal: Numerator = # of patients >65 years old initiated on the target anticholinergics with appropriate documentation. Denominator = # of patients >65 years old initiated on the target anticholinergics on or after 12/1/2019. The 100% audits of impacted patients will be conducted monthly to ensure compliance of 90% or greater average for six consecutive months.

Responsibility: The Associate Chief of Pharmacy will ensure compliance. Audits will be conducted to ensure 90% or great compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Pharmacy and Therapeutics Committee.

According to TJC, in medication reconciliation, a clinician compares the medications a patient should be taking and is actually taking to the new medications that are ordered for the patient and resolve any discrepancies.[114] TJC also requires patients' "medical record[s] contain[]information that reflects the patient's care, treatment, and services."[115] Furthermore, VHA requires that clinicians review and reconcile medications relevant to the episode of care.[116] The OIG estimated that medication reconciliation was performed for 59 percent of the patients at the facility, based on electronic health records reviewed.[117] Failure to maintain and communicate accurate patient medication information and reconcile medications increases the risk of duplications, omissions, and negative interactions in the patient's actual drug regimen.[118] The chief of Pharmacy reported that when a progress note is started prior to entering a new prescription, the new medication does not appear in the medication reconciliation segment of the progress note.

## Recommendation 14

14. The chief of staff ensures clinicians review and reconcile patients' medications and maintain and communicate accurate patient medication information in patients' electronic health records and monitors the clinicians' compliance.

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[114] TJC. National Patient Safety Goal standard NPSG.03.06.01.

[115] TJC. Record of Care, Treatment, and Services standard RC.02.01.01.

[116] VHA Directive 1164.

[117] The OIG is 95 percent confident that the true compliance rate is between 42.3 and 75.9 percent, which is statistically significantly below the 90 percent benchmark.

[118] TJC. National Patient Safety Goal standard NPSG.03.06.01.

Facility concurred.

Target date for completion: May 31, 2020

Facility response: A progress note entitled "Anticholinergic Medications" was developed following the review to document prescribing and education regarding these medications. The progress note may be populated either with (1) an "initiation" template for the prescribing provider to document diagnosis, baseline data, risk/benefit and patient agreement to therapy which includes medication reconciliation information.

Compliance Monitor: Pharmacy will use the dashboard to identify providers prescribing new anticholinergic medications for patients ≥ 65 years old each month. This list will be used to determine Provider compliance with completion of medication reconciliation. 100% of impacted patients will be reviewed.

Compliance Goal: Numerator = # of patients >65 years old initiated on the target anticholinergics with appropriate medication reconciliation. Denominator = # of patients >65 years old initiated on the target anticholinergics on or after 12/1/2019. The 100% audits of the impacted patients will be conducted monthly to ensure compliance 90% or greater average for six consecutive months.

Responsibility: The Associate Chief of Pharmacy will ensure compliance.

Audits will be conducted to ensure 90% or great compliance for six months. The results will be reported to the Executive Committee of the Medical Staff through the Pharmacy and Therapeutics 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.[119] Human papillomavirus (HPV) can be transmitted during sexual contact and is the main cause of cervical cancer.[120] 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.[121] Cervical cancer is highly preventable through diligent screening and vaccination efforts. With early detection, it is very treatable and associated with optimal patient outcomes.[122]

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.[123]

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 leadership 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.[124]

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

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[119] 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.)

[120] 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.)

[121] 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.)

[122] 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.)

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

[124] VHA Directive 1330.01(2).

results to patients must be documented. The facility must ensure that appropriate follow-up care is provided to patients with abnormal results.[125]

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 40 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

- Facilitte Women Veterans Health Committee

   o Core membership

   o Quarterly meetings

   o Reports to clinical executive leaders

- Collection and tracking of cervical cancer screening data

   o Notification of patients due for screening

   o Completed screenings

   o Results reporting

   o Follow-up care

- Communication of abnormal results to patients within required time frame

- Provision of follow-up care for abnormal cervical pathology results, if indicated

## Women's Health Conclusion

Overall, the OIG team noted facility compliance with many of the performance indicators, including those related to requirements for a designated women's health medical director, communication of results to patients within the required time frame, and follow-up care if indicated. However, the OIG noted noncompliance with the requirements for a full-time women veterans program manager and the Women Veterans Health Committee meetings, membership, and reporting to the Clinical Executive Board that warranted recommendations for improvement.

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[125] VHA Directive 1330.01(2).

Although VHA requires each facility to "have a full-time [w]omen [v]eterans [p]rogram [m]anager to [ensure] comprehensive planning for women's health care,"[126] the OIG found the acting women veterans program manager was not in a dedicated full-time position. This could result in lack of adequate and timely care coordination for women veterans at the facility. The acting women veterans program manager stated the former manager retired in September 2018, and the position was combined with another role until the full-time position is filled.

## Recommendation 15

15. The facility director confirms that the facility has a full-time women veterans program manager and monitors compliance.

Facility concurred.

Target date for completion: September 30, 2019

Facility response: The Chief of Staff will monitor compliance. Prior to the OIG CHIP, the staff selected for the Women Veterans Program Manager position had continued coverage for the position vacated by the selection. On March 25, 2019 the Women Veterans Program Manager assumed full duties with official transfer on March 31, 2019. Official notification designating the full-time Women Veterans Program Manager was received from Human Resources on March 31, 2019.

Regarding the Women Veterans Health Committee, VHA requires that the core membership includes the women veterans program manager; the 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."[127] VHA also requires that the committee meets quarterly and reports to leadership at the Clinical Executive Board level.

The OIG found that from May 2018 through March 2019, the committee met once and lacked representation from medical and/or surgical subspecialties, pharmacy, radiology, laboratory, quality management, business office, and executive leadership. The OIG also noted that due to lack of meeting the committee had not provided a report to the Clinical Executive Board level. This resulted in a lack of expertise and oversight in the review and analysis of data to ensure availability of appropriate clinical services for women veterans. The acting women veterans program manager was aware of the requirements but could not find an active committee charter specifying membership and frequency of meetings. The OIG also noted in the February 2019 Health Systems Committee meeting minutes that its subcommittee, the Women Veterans Health

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[126] VHA Directive 1330.01(2).
[127] VHA Directive 1330.01(2).

Committee, planned to not review the charter or meet until a permanent women veterans program manager was in place.

## Recommendation 16

16. The facility director makes certain that the Women Veterans Health Committee meets quarterly, is comprised of required core members, reports to executive quadrad leadership with signed minutes, and monitors the committee's compliance.

Facility concurred.

Target date for completion: November 30, 2019

Facility response: The Women Veterans Health Committee has met monthly since April 2019 and reports to Executive Committee of the Medical Staff through Health Systems Committee. The Charter was reviewed and approved in March 2019.

Compliance Monitor: Women Veterans Health Committee minutes will be monitored to ensure that the Women Veterans Health Committee meets quarterly and includes required membership.

Compliance Goal: Quarterly meetings

Responsibility: The Chief of Staff is responsible for ensuring compliance with quarterly meetings. The results will be reported to the Executive Committee of the Medical Staff through Health Systems Committee.

# 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."[128] 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.[129]

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."[130]

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 ED or UCC settings] (such as admitting, assessment and treatment, patient transfer, and discharge) can minimize delays in the delivery of care."[131]

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.[132]

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

[129] VHA Directive 1101.05(2).

[130] VHA Directive 1101.05(2).

[131] TJC. Leadership standard LD.04.03.11.

[132] 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 Medincine Improvement initiative goals.

VA emergency departments and UCCs must also be designed to promote a safe environment of care.[133] Managers must ensure medications are securely stored,[134] a psychiatric intervention room is available,[135] 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.[136]

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 ED 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

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[133] VHA Directive 1101.05(2).

[134] TJC. Medication Management standard MM.03.01.01.

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

[136] VHA Directive 1101.05(2).

- o Licensed independent mental health provider available as required for the facility's complexity level

- o Telephone message system during non-operational hours

- o Inpatient provider available for patients requiring admission

- Patient flow

  - o EDIS tracking program

  - o Emergency department patient flow evaluation

  - o Diversion policy

  - o Designated bed flow coordinator

- General safety

  - o Directional signage to after-hours emergency care

  - o Fast tracks[137]

- 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

  - o Capability and equipment for gynecologic examinations

- Life support equipment

## High-Risk Processes Conclusion

The facility generally complied with many of the performance indicators used to assess the operations and management of the emergency department. The OIG noted that the emergency department had the capability and equipment for gynecologic examinations but did not have resources readily available to provide evaluation for sexual assaults. The OIG also identified a deficiency with licensed physician staffing that warranted a recommendation for improvement.

Specifically, VHA requires that an emergency department have appropriately educated and qualified emergency care professionals physically present in the emergency department during

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

all hours of operation. This includes a licensed physician.[138] The OIG found the emergency department was staffed by at least one licensed physician during all hours of operation; however, the emergency department's physician also had collateral responsibility to respond to patient emergencies within the facility and was not always present in the emergency department during evenings, weekends, and holidays. This could result in a lack of appropriate care for patients presenting for emergency care. The associate director of the emergency department reported that when an emergency department physician leaves to respond to codes, the emergency department is staffed with a physician assistant or nurse practitioner and believed this met the requirements of the directive.

## Recommendation 17

17. The facility director makes certain that the emergency department has a licensed physician privileged to staff the department during all hours of operation and monitors the department's compliance.

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[138] VHA Directive 1101.05(2).

Facility concurred.

Target date for completion: December 27, 2019

Facility response: Veterans Affairs Western New York Health Care System contacted the VHA Chief Consultant for Emergency Medicine and guidance was provided that the national VHA Emergency Department Directive is in the process of being updated and the language that the Emergency Department physician shall not leave the Emergency Department is being omitted from the policy for consistency with other VHA Directives and to provide additional flexibility to sites. The Chief Consultant indicated concurrence with Veterans Affairs Western New York Health Care System facility approach and of the Emergency Department physician may respond to cardiopulmonary or respiratory emergencies that arise outside of the Emergency Department if the emergency is beyond the capabilities of the normal response team, the Emergency Department physician is the most knowledgeable or experienced physician available to manage the emergency, and the response will not jeopardize the care of patients in the Emergency Department. A waiver request has been requested to formalize Veterans Affairs Western New York Health Care System process for Emergency Department physicians leaving the Emergency Department to respond to cardiopulmonary or respiratory emergencies will be submitted thru the VISN 2 Network Director to the Deputy Under Secretary for Health for Operation and Management.

Compliance Monitor: Numerator = # adverse events due to Emergency Department physician out of Emergency Department managing cardiopulmonary or respiratory emergencies. Denominator = # total number of cardiopulmonary or respiratory emergencies that required Emergency Department physician to leave Emergency Department.

Compliance Goal: There will be no adverse events in the ED while the ED physician is out of the ED managing cardiopulmonary or respiratory emergencies.

Responsibility: Emergency Department Service Chief will report the results to the Executive Committee of the Medical Staff.

## Incidental Finding

### Equipment and Supplies

Lastly, VHA requires equipment and supplies, including women's health supplies, necessary for patient care be readily available in the emergency department at all times.[139] The OIG found that the facility lacked a rape evaluation kit or access to community resources to conduct an evaluation should a patient remain too unstable to transfer. This may result in a lack of timely and appropriate treatment for patients presenting for care. The emergency department's associate director and department manager acknowledged the absence of the required rape evaluation kit and stated a policy had been drafted and was pending implementation while undergoing legal review.

## Recommendation 18

18. The facility director makes certain the emergency department has the necessary resources readily available to treat sexual assault patients and monitors compliance.

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[139] VHA Directive 1101.05(2).

Facility concurred.

Target date for completion: December 27, 2019

Facility response: It is the practice that Veterans Affairs Western New York Health Care System assess and stabilize sexual assault patients as necessary and transfer to the local trauma center, Erie County Medical Center for completion of a sexual assault examination and complete rape exam. Veterans Affairs Western New York Health Care System Emergency Department will transfer patients with the complaint of rape after the medical screening exam and assessment for stability. When deemed stable by the Emergency Department Provider, the patient will be transferred to the local trauma facility which has on-site sexual assault nurse examiners (SANE) for the completion of the rape exam. (The Erie County Medical Center is the present facility). The Emergency Department Provider will perform a medical screening exam and stabilize the patient for airway, breathing and circulation if needed (cardiac monitor, oximetry, IV access etc.). Initiate workup/intervention for other injuries and concerns as per the patient's presentation (labs, imaging etc.) Place a call to the Erie County Medical Center Emergency Department Attending to discuss and arrange emergent transfer once the patient has been deemed stable and agrees to the transfer. Complete COBRA form and place routine community care consult Emergency Department and special travel request in the patient's record. The Emergency Department Nurse will ensure the patient has privacy, ensure the patients clothing is not disrupted unless treatment requires, and provide SBAR to Erie County Medical Center Emergency Department receiving nurse if transferring patient.

Compliance Monitor: Numerator = # number of patients transferred to a local trauma facility Denominator = # number of patients presenting with chief complaint of sexual assault.

Compliance Goal: All sexual assault victims will be stabilized prior to transfer to a trauma facility for care if needed. The results will be reported to the Executive Committee of the Medical Staff through the Chief of the Emergency Department.

Responsibility: The Emergency Department Service Chief will ensure compliance with the results reported to the Executive Committee of the Medical Staff.

# 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 | • Executive leadership position stability and engagement<br>• Employee satisfaction<br>• Patient experience<br>• Accreditation and/or for-cause surveys and oversight inspections<br>• Factors related to possible lapses in care<br>• VHA performance data | Eighteen 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, associate director, and chief of staff. See details below. |

| Healthcare Processes | Performance Indicators | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Quality, Safety, and Value | • Protected peer reviews<br>• UM reviews<br>• Patient safety<br>• Resuscitation episode review | • All team members responding to resuscitation events have basic or advanced cardiac life support certification. | • None |

| Healthcare Processes | Performance Indicators | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Medical Staff Privileging | • Privileging<br>• FPPEs<br>• OPPEs<br>• FPPEs for cause<br>• Reporting of privileging actions to National Practitioner Data Bank | • Service chiefs include service-specific criteria in OPPEs.<br>• Service chiefs include required gastroenterology and pathology specific criteria in OPPEs.<br>• OPPE evaluations are completed by providers with similar training and privileges. | • The Executive Committee of Medical Staff reviews and evaluates LIPs' initial and re-privileging requests prior to making recommendations to the facility director. |

| Healthcare Processes | Performance Indicators | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Environment of Care | • Parent facility<br>  ○ General safety<br>  ○ Environmental cleanliness and infection prevention<br>  ○ General privacy<br>  ○ Women veterans program<br>  ○ Availability of medical equipment and supplies<br>• Community based outpatient clinic<br>  ○ General safety<br>  ○ Environmental cleanliness and infection prevention<br>  ○ General privacy<br>  ○ Women veterans program<br>  ○ Availability of medical equipment and supplies<br>• Locked inpatient mental health unit<br>  ○ Mental health environment of care rounds<br>  ○ Nursing station security<br>  ○ Public area and general unit safety<br>  ○ Patient room safety<br>  ○ Infection prevention<br>• Emergency management<br>  ○ Hazard vulnerability analysis (HVA)<br>  ○ Emergency operations plan (EOP)<br>  ○ Emergency power testing and availability | • A safe and clean environment is maintained throughout the facility.<br>• Mental health seclusion room floors are cushioned.<br>• The required inventory of assets and resources is created and reviewed annually by the Emergency Management Committee and approved by executive leaders. | • None |

| Healthcare Processes | Performance Indicators | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Medication Management: Controlled Substances Inspections | • Controlled substances coordinator reports<br>• Pharmacy operations<br>• Controlled substances inspector requirements<br>• Controlled substances area inspections<br>• Pharmacy inspections<br>• Facility review of override reports | • Controlled substances coordinator maintains necessary records and inspectors conduct monthly physical inventory that are completed on the day initiated.<br>• Pharmacy inventory checks are completed as required. | • Staff who conduct monthly review of balance adjustment are not the same staff that perform and document the balance adjustments. |
| Mental Health: Military Sexual Trauma (MST) Follow-Up and Staff Training | • Designated facility MST coordinator<br>• Evidence of tracking MST-related data<br>• Provision of clinical care<br>• Completion of MST mandatory training requirement for mental health and primary care providers | • None | • Primary care and mental health providers complete MST mandatory training within the required time frame. |
| Geriatric Care: Antidepressant Use among the Elderly | • Justification for medication initiation<br>• Evidence of patient and/or caregiver education specific to the medication prescribed<br>• Clinician evaluation of patient and/or caregiver understanding of the education provided<br>• Medication reconciliation | • Clinicians provide education to the patient and/or caregiver about the newly prescribed medication.<br>• Clinicians review and reconcile patients' medications and maintain and communicate accurate patient medication information in patients' electronic health records. | • None |

| Healthcare Processes | Performance Indicators | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Women's Health: Abnormal Cervical Pathology Results Notification and Follow-Up | • Appointment of a women veterans program manager<br>• Appointment of a women's health medical director or clinical champion<br>• Facility Women Veterans Health Committee<br>• Collection and tracking of cervical cancer screening data<br>• Communication of abnormal results to patients within required time frame<br>• Provision of follow-up care for abnormal cervical pathology results, if indicated | • None | • The facility has a full-time women veterans program manager.<br>• The Women Veterans Health Committee meets quarterly, is comprised of required core members, and reports to the Clinical Executive Board. |
| High-Risk Processes: Operations and Management of Emergency Departments and UCCs | • General<br>• Staffing for emergency department/UCC<br>• Support services for emergency department/UCC<br>• Patient flow<br>• General safety<br>• Medication security and labeling<br>• Management of patients with mental health disorders<br>• Emergency department participation in local/regional EMS system<br>• Women veteran services<br>• Life support equipment | • The emergency department has a licensed physician privileged to staff the department during all hours of operation. | • None |
| Incidental Finding | • Availability of necessary equipment and supplies. | • The emergency department has the necessary resources readily available to treat sexual assault patients. | • None |

# Appendix B: Facility Profile and VA Outpatient Clinic Profiles

## Facility Profile

The table below provides general background information for this high complexity (1b) affiliated[140] facility reporting to VISN 2.[141]

**Table B.1. Facility Profile for VA Western New York Healthcare System (528)**
**(October 1, 2015, through September 30, 2018)**

| Profile Element | Facility Data FY 2016[142] | Facility Data FY 2017[143] | Facility Data FY 2018[144] |
|---|---|---|---|
| Total medical care budget in dollars | $356,095,037 | $381,495,787 | $393,682,928 |
| Number of: | | | |
| • Unique patients | 54,385 | 56,311 | 61,687 |
| • Outpatient visits | 558,619 | 569,341 | 579,079 |
| • Unique employees[145] | 1,831 | 1,833 | 1,834 |
| Type and number of operating beds: | | | |
| • Community living center | 120 | 120 | 120 |
| • Domiciliary | 52 | 52 | 52 |
| • Medicine | 65 | 65 | 65 |
| • Mental health | 15 | 15 | 15 |
| • Surgery | 24 | 24 | 24 |
| Average daily census: | | | |
| • Community living center | 87 | 80 | 81 |
| • Domiciliary | 35 | 39 | 43 |
| • Medicine | 54 | 50 | 50 |
| • Mental health | 15 | 12 | 12 |

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[140] Associated with a medical residency program.

[141] The VHA medical centers are classified according to a facility complexity model; a designation of "1b" indicates a facility with "medium-high volume, high risk patients, many complex clinical programs, and medium-large research and teaching programs."

[142] October 1, 2015, through September 30, 2016.

[143] October 1, 2016, through September 30, 2017.

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

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

| Profile Element | Facility Data FY 2016[142] | Facility Data FY 2017[143] | Facility Data FY 2018[144] |
|---|---|---|---|
| • Surgery | 14 | 14 | 12 |

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

## VA Outpatient Clinic Profiles[146]

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)[147]**

| Location | Station No. | Primary Care Workload/ Encounters | Mental Health Workload/ Encounters | Specialty Care Services[148] Provided | Diagnostic Services[149] Provided | Ancillary Services[150] Provided |
|---|---|---|---|---|---|---|
| Jamestown, NY | 528GB | 4,240 | 2,479 | Cardiology Dermatology Endocrinology Gastroenterology Infectious disease Neurology Anesthesia General surgery Otolaryngology Vascular | n/a | Nutrition Pharmacy Prosthetics Weight management |

[146] Includes all outpatient clinics in the community that were in operation as of August 15, 2018. The OIG omitted Buffalo-Main Street, NY (528QA); and Packard, NY (528QB), as no data were reported.

[147] 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."

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

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

[150] 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[148] Provided | Diagnostic Services[149] Provided | Ancillary Services[150] Provided |
|---|---|---|---|---|---|---|
| Dunkirk, NY | 528GC | 4,649 | 1,460 | Cardiology<br>Dermatology<br>Endocrinology<br>Gastroenterology<br>Infectious disease<br>Neurology<br>Anesthesia | n/a | Pharmacy<br>Prosthetics<br>Weight management<br>Nutrition |
| Niagara Falls, NY | 528GD | 4,018 | 1,390 | Dermatology<br>Endocrinology<br>Gastroenterology<br>Hematology/ Oncology<br>Infectious disease | n/a | Pharmacy<br>Weight management<br>Nutrition |
| Lockport, NY | 528GK | 4,011 | 596 | Cardiology<br>Dermatology<br>Gastroenterology<br>Infectious disease | n/a | Pharmacy<br>Weight management<br>Nutrition |
| Lackawanna, NY | 528GQ | 6,693 | 1,783 | Cardiology<br>Dermatology<br>Endocrinology<br>Infectious disease<br>Neurology<br>General surgery | n/a | Pharmacy<br>Prosthetics<br>Nutrition |

| Location | Station No. | Primary Care Workload/ Encounters | Mental Health Workload/ Encounters | Specialty Care Services[148] Provided | Diagnostic Services[149] Provided | Ancillary Services[150] Provided |
|---|---|---|---|---|---|---|
| Olean, NY | 528GR | 4,673 | 2,578 | Allergy<br>Cardiology<br>Dermatology<br>Endocrinology<br>Gastroenterology<br>Hematology/ Oncology<br>Infectious disease<br>Neurology<br>Anesthesia<br>General surgery<br>Otolaryngology | EKG | Pharmacy<br>Prosthetics<br>Social work<br>Weight management<br>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 Metrics[151]

## Quarterly New Primary Care Patient Average Wait Time in Days

| | VHA Total | (528) Buffalo, NY | (528GB) Jamestown, NY | (528GC) Dunkirk, NY | (528GD) Niagara Falls, NY | (528GK) Lockport, NY | (528GQ) Lackawanna, NY | (528GR) Olean, NY | (528QB) Packard, NY |
|---|---|---|---|---|---|---|---|---|---|
| JAN-FY18 | 8.2 | 11.8 | 0.0 | 3.5 | 7.7 | 0.9 | 5.1 | 1.7 | 0.0 |
| FEB-FY18 | 7.5 | 12.6 | 0.0 | 2.6 | 9.2 | 1.3 | 3.5 | 0.0 | n/a |
| MAR-FY18 | 8.6 | 6.2 | 0.0 | 2.5 | 1.5 | 2.5 | 3.2 | 1.7 | n/a |
| APR-FY18 | 7.9 | 5.4 | 0.0 | 1.4 | 0.8 | 2.8 | 3.6 | 0.0 | n/a |
| MAY-FY18 | 7.7 | 9.5 | 0.0 | 2.4 | 3.4 | 0.9 | 9.9 | 1.1 | 0.0 |
| JUN-FY18 | 7.6 | 8.6 | 1.9 | 1.8 | 2.5 | 1.5 | 3.7 | 6.1 | n/a |
| JUL-FY18 | 7.5 | 7.8 | 0.0 | 5.4 | 5.2 | 1.5 | 4.6 | 9.0 | 0.0 |
| AUG-FY18 | 7.7 | 6.5 | 0.0 | 5.8 | 9.6 | 1.9 | 4.2 | 1.9 | 0.0 |
| SEP-FY18 | 8.5 | 4.8 | 1.1 | 0.4 | 4.4 | 1.3 | 4.5 | 12.9 | 0.0 |
| OCT-FY19 | 8.0 | 8.5 | 0.5 | 2.3 | 5.1 | 2.1 | 5.4 | 12.7 | n/a |
| NOV-FY19 | 8.5 | 4.0 | 0.0 | 3.0 | 4.3 | 0.8 | 1.8 | 11.9 | 0.0 |
| DEC-FY19 | 8.6 | 11.8 | 0.0 | 1.9 | 10.5 | 0.8 | 7.5 | 2.9 | 0.0 |

*Source: VHA Support Service Center*

*Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted (528QA) Buffalo-Main Street, NY, 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 is indicated by "n/a."*

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[151] 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
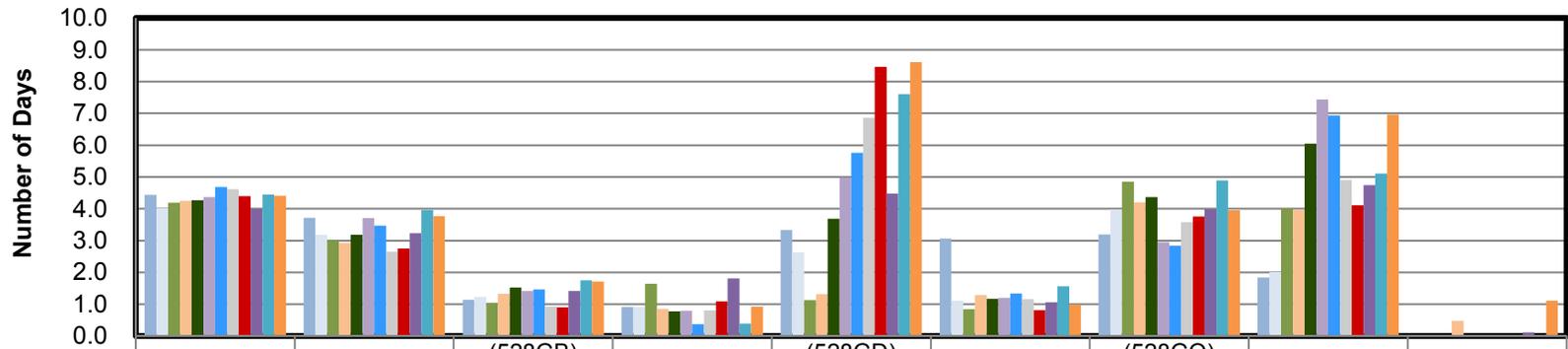


| | VHA Total | (528) Buffalo, NY | (528GB) Jamestown, NY | (528GC) Dunkirk, NY | (528GD) Niagara Falls, NY | (528GK) Lockport, NY | (528GQ) Lackawanna, NY | (528GR) Olean, NY | (528QB) Packard, NY |
|---|---|---|---|---|---|---|---|---|---|
| JAN-FY18 | 4.4 | 3.7 | 1.1 | 0.9 | 3.3 | 3.1 | 3.2 | 1.8 | 0.0 |
| FEB-FY18 | 4.0 | 3.2 | 1.2 | 0.9 | 2.6 | 1.1 | 4.0 | 2.0 | 0.0 |
| MAR-FY18 | 4.2 | 3.0 | 1.0 | 1.6 | 1.1 | 0.8 | 4.8 | 4.0 | 0.0 |
| APR-FY18 | 4.3 | 2.9 | 1.3 | 0.9 | 1.3 | 1.3 | 4.2 | 4.0 | 0.5 |
| MAY-FY18 | 4.3 | 3.2 | 1.5 | 0.8 | 3.7 | 1.2 | 4.4 | 6.0 | 0.0 |
| JUN-FY18 | 4.4 | 3.7 | 1.4 | 0.8 | 5.0 | 1.2 | 2.9 | 7.4 | 0.0 |
| JUL-FY18 | 4.7 | 3.5 | 1.5 | 0.4 | 5.8 | 1.3 | 2.8 | 6.9 | 0.0 |
| AUG-FY18 | 4.6 | 2.7 | 0.9 | 0.8 | 6.9 | 1.2 | 3.6 | 4.9 | 0.0 |
| SEP-FY18 | 4.4 | 2.7 | 0.9 | 1.1 | 8.5 | 0.8 | 3.8 | 4.1 | 0.0 |
| OCT-FY19 | 4.0 | 3.2 | 1.4 | 1.8 | 4.5 | 1.1 | 4.0 | 4.7 | 0.1 |
| NOV-FY19 | 4.4 | 4.0 | 1.8 | 0.4 | 7.6 | 1.6 | 4.9 | 5.1 | 0.0 |
| DEC-FY19 | 4.4 | 3.8 | 1.7 | 0.9 | 8.6 | 1.0 | 4.0 | 7.0 | 1.1 |

*Source: VHA Support Service Center*

*Note: The OIG did not assess VA's data for accuracy or completeness The OIG omitted (528QA) Buffalo-Main Street, NY, 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."*

# Appendix D: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions[152]

| 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 |

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[152] 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: Strategic Analytics for Improvement and Learning (SAIL) Community Living Center (CLC) Measure Definitions[153]

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

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[153] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated August 22, 2018). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on September 3, 2019, but is not accessible by the public.)

# Appendix F: VISN Director Comments

## Department of Veterans Affairs Memorandum

Date: November 21, 2019

From: Director, New York/New Jersey Health Care Network (10N2)

Subj: Comprehensive Healthcare Inspection of the VA Western New York Healthcare System, Buffalo, NY

To: Director, Bay Pines Office of Healthcare Inspections (54CH03)

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

1. Thank you for the opportunity to review the draft report of the Comprehensive Healthcare Inspection of the VA Western New York Healthcare System, Buffalo, New York. I appreciate the Office of Inspector General's oversight and the extensive work done as part of this review. We acknowledge there are improvements to be made and we are committed to ensuring correction of identified opportunities for improvement.

2. I have reviewed the Healthcare System Director's action plan and projected completion dates. I concur with the plan and have complete confidence that the plan will be effective. VISN 2 will assist the Healthcare System's leadership in reaching full compliance in a timely manner.

*(Original signed by:)*

Joan E. McInerney, MD, MBA, MA, FACEP
Network Director, VISN 2

*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 G: Facility Director Comments

## Department of Veterans Affairs Memorandum

Date: November 20, 2019

From: Director, VA Western New York Healthcare System (528/00)

Subj: Comprehensive Healthcare Inspection of the VA Western New York Healthcare System, Buffalo, NY

To: Director, New York/New Jersey Health Care Network (10N2)

1. I have reviewed and concur with the findings and recommendations in the report of the Comprehensive Healthcare Inspection Review that was conducted the week of March 18, 2019 at the VA Western New York Healthcare System.

2. Corrective action plans have been established with planned completion dates, as detailed in the attached report.

*(Original signed by:)*

Michael J. Swartz, FACHE
Executive Director
VA Western New York Healthcare System

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

# OIG Contact and Staff Acknowledgments

| | |
|---|---|
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