DEPARTMENT OF VETERANS AFFAIRS

# OFFICE OF INSPECTOR GENERAL

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

# Comprehensive Healthcare Inspection of the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin

CHIP REPORT | REPORT #20-00075-225 | AUGUST 26, 2020

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***Figure 1.*** *Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin (Source: https://vaww.va.gov/directory/guide/, accessed on January 28, 2020)*

# Abbreviations

| | |
|---|---|
| ADPCS | Associate Director for Patient Care Services |
| CBOC | community-based outpatient clinic |
| CHIP | Comprehensive Healthcare Inspection Program |
| CLC | community living center |
| FPPE | focused professional practice evaluation |
| FY | fiscal year |
| HRS | high risk for suicide |
| LIP | licensed independent practitioner |
| LST | life-sustaining treatments |
| LSTD | life-sustaining treatments decision |
| OIG | Office of Inspector General |
| OPPE | ongoing professional practice evaluation |
| QSV | quality, safety, and value |
| RME | reusable medical equipment |
| SAIL | Strategic Analytics for Improvement and Learning |
| SLB | state licensing board |
| SOP | standard operating procedure |
| SPC | suicide prevention coordinator |
| SPS | Sterile Processing Services |
| TJC | The Joint Commission |
| UM | utilization management |
| VHA | Veterans Health Administration |
| VISN | Veterans Integrated Service Network |
| WH-PCP | women's health primary care provider |

# Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) report provides a focused evaluation of the quality of care delivered in the inpatient and outpatient settings of the Clement J. Zablocki VA Medical Center and multiple outpatient clinics in Wisconsin. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

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

The unannounced visit was conducted during the week of January 27, 2020, at the Clement J. Zablocki VA Medical Center and John H. Bradley Department of Veterans Affairs Outpatient Clinic. The OIG held interviews and reviewed clinical and administrative processes related to specific areas of focus that affect patient outcomes. Although the OIG reviewed a broad spectrum of processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this medical center's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this medical center and other Veterans Health Administration (VHA) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

# Inspection Results

## Leadership and Organizational Risks

At the time of the OIG's visit, the medical center had a leadership team consisting of the Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Deputy Director, and Assistant Director. The Director served as the chairperson of the Zablocki Leadership Council, which has the authority and responsibility for developing annual goals, strategic planning, and performing organizational management. The leaders monitored patient safety and care through the Quality Management Oversight Committee which was responsible for tracking and trending quality of care and patient outcomes.

At the time of the inspection, the medical center's leaders had been working together as a group for over two years. The OIG noted that medical center employees appeared generally satisfied with leaders, but opportunities appeared to exist for the Deputy Director and Assistant Director to decrease employees' feelings of moral distress at work.[1] The patient experience survey scores generally reflected similar or higher ratings than the VHA average. Patients appeared satisfied with the care provided.

The OIG's review of the medical center's accreditation findings did not identify any substantial organizational risk factors. However, the OIG identified concerns with the patient safety program related to identification of sentinel events.[2]

The VA Office of Operational Analytics and Reporting adopted the Strategic Analytics for Improvement and Learning (SAIL) Value Model to help define performance expectations within VA. This model includes "measures on healthcare quality, employee satisfaction, access to care, and efficiency." It does, however, have noted limitations for identifying all areas of clinical risk. The data are presented as one way to "understand the similarities and differences between the top and bottom performers" within VHA.[3]

In individual interviews, the executive leaders were generally able to speak in depth 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

[1] The 2019 All Employee Survey defines moral distress as being "unsure about the right thing to do or could not carry out what you believed to be the right thing."

[2] 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."

[3] VHA Support Service Center (VSSC), *Strategic Analytics for Improvement and Learning (SAIL) Value Model*, http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=9428. (The website was accessed on March 6, 2020, but is not accessible by the public.)

knowledgeable within their scopes of responsibility about selected VHA data used by the SAIL and CLC SAIL models.[4]

The OIG noted opportunities for improvement in seven of eight clinical areas reviewed and issued 28 recommendations that are directed to the Director, Chief of Staff, ADPCS, and Assistant Director. These are briefly described below.

## Quality, Safety, and Value

The medical center complied with requirements for establishing a committee responsible for QSV oversight functions and its review of aggregated data, and most patient safety elements. However, the OIG noted that the Peer Review Committee did not identify improvement actions for any of the Level 2 or 3 cases.[5] The OIG identified weaknesses in the QSV committee's recommendation and implementation of improvement actions, documentation of physician utilization management (UM) advisors' decisions, and interdisciplinary review of UM data.

## Medical Staff Privileging

The OIG identified deficiencies with focused and ongoing professional practice evaluation and healthcare provider exit review processes.[6]

## Environment of Care

The medical center complied with requirements for women veteran accommodations. However, the OIG identified issues with general safety, cleanliness and infection prevention, and privacy. At the time of the on-site visit, the OIG did not note any issues with the availability of medical equipment and supplies; however, during a subsequent review of *VHA's COVID-19 Screening Processes and Pandemic Readiness*, medical center staff reported a need for additional surgical drapes.[7]

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[4] According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers,* June 1, 2017, CLCs, previously known as Nursing Home Care Units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

[5] The definition of utilization management can be found within VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014, amended April 30, 2019. Utilization management involves the "forward-looking evaluation of the appropriateness, medical need, and efficiency of healthcare services according to evidence-based criteria."

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

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

## Medication Management

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

## Mental Health

The medical center complied with requirements for a designated suicide prevention coordinator, appropriate follow-up for no-show high-risk appointments, suicide safety plans, and suicide prevention training. However, the OIG noted a concern with the completion of at least four mental health appointments within 30 days of HRS Patient Record Flag placements.

## Women's Health

The medical center complied with some of the provision of care indicators and staffing elements reviewed. However, the OIG identified weaknesses with gynecologic care coverage, Women Veterans Health Committee meetings and membership, quality assurance data collection and tracking, and women veterans program manager duties.

## High-Risk Processes

The medical center generally complied with the requirements for administrative processes, quality assurance monitoring, and reprocessing area physical inspections. The OIG identified weaknesses with the annual risk analysis, cleaning schedules, and reusable medical equipment storage.

## Conclusion

The OIG conducted a detailed inspection across nine key areas (one nonclinical and eight clinical) and subsequently issued 28 recommendations for improvement to the Medical Center Director, Chief of Staff, ADPCS, and Assistant Director. The number of recommendations should not be used, however, as a gauge for the overall quality provided at this medical center. The intent is for medical center leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address system's issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

## Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the CHIP review findings and recommendations and provided acceptable improvement plans. (See Appendixes G and H, pages 86-87, and the responses within the body of the report for the full

text of the directors' comments.) The OIG considers recommendations 16, 25, and 26 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

# Contents

# Purpose and Scope

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

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change.[1] Investments in a culture of safety and continuous quality improvement, in concert with robust leadership and communication, significantly contribute to positive patient outcomes.[2] Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

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

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

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

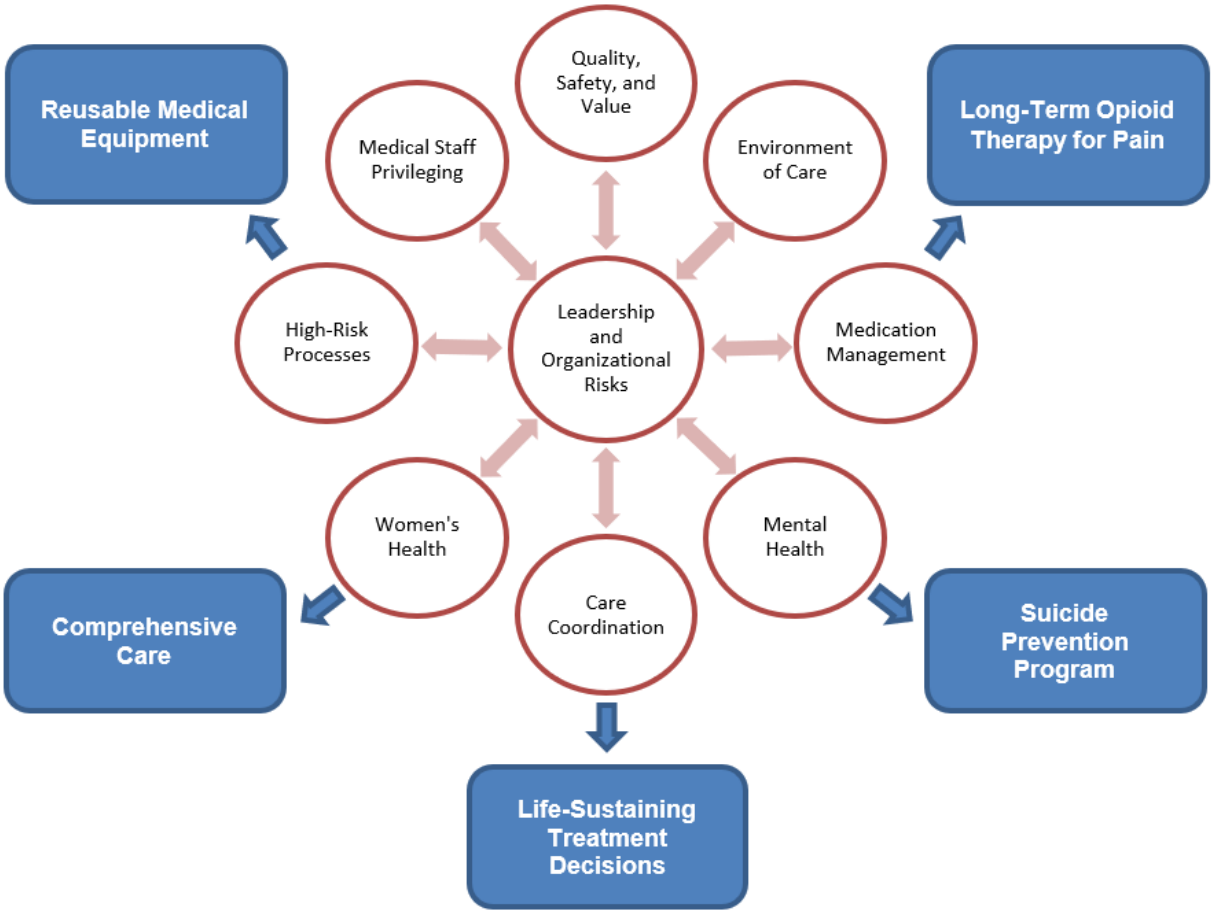


***Figure 2.*** *Fiscal Year (FY) 2020 Comprehensive Healthcare Inspection of Operations and Services*
*Source: VA OIG*

# Methodology

The Clement J. Zablocki VA Medical Center includes multiple outpatient clinics in Wisconsin. Additional details about the types of care provided by the medical center can be found in Appendixes B and C.

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.[4]

The OIG team also selected and physically inspected the John H. Bradley Department of Veterans Affairs Outpatient Clinic and the following areas of the medical center:

- Acute psychiatric unit
- Community living center (CLC)[5]
- Emergency Department
- Intensive care unit
- Medical/surgical inpatient units
- Outpatient clinic
- Post-anesthesia care unit
- Sterile processing services areas

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

The inspection examined operations from July 15, 2017, through January 31, 2020, the last day of the unannounced multiday site visit.[6] While on site, the OIG referred an identified vulnerability beyond the scope of the CHIP inspection to the OIG's hotline management team for further review.

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

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

[5] According to VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers,* June 1, 2017, CLCs, previously known as Nursing Home Care Units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

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

(codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leadership, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

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

# Results and Recommendations

## Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare system. Leadership and organizational risks can impact the healthcare system's ability to provide care in the clinical focus areas.[7] To assess the medical center's risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Employee satisfaction
3. Patient experience
4. Accreditation surveys and oversight inspections
5. Identified factors related to possible lapses in care and medical center's response
6. VHA performance data (medical center)
7. VHA performance data (CLCs)

### Executive Leadership Position Stability and Engagement

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

[7] L. Botwinick, M. Bisognano, and C. Haraden, *Leadership Guide to Patient Safety*, Institute for Healthcare Improvement, Innovation Series White Paper. 2006. www.IHI.org. (The website was accessed on November 6, 2019.)

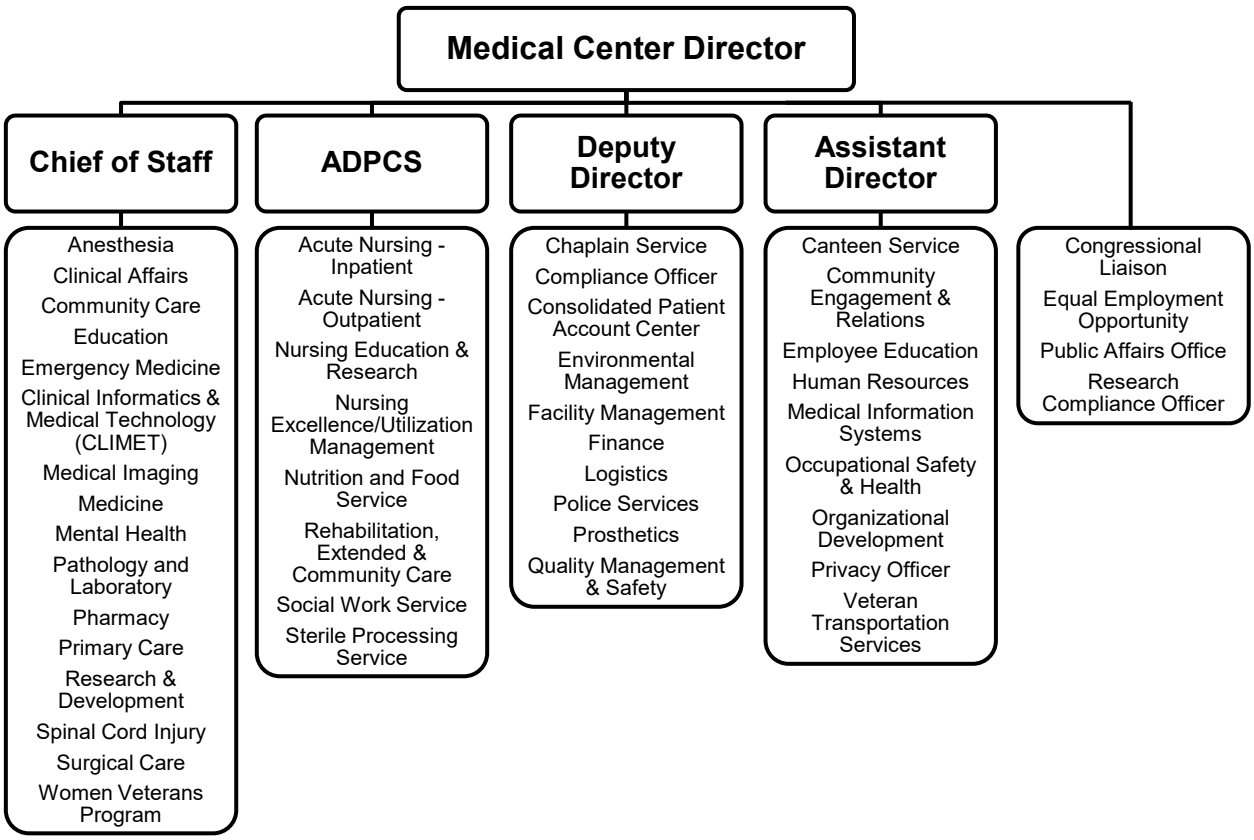


***Figure 3.*** *Medical Center Organizational Chart*
*Source: Clement J. Zablocki VA Medical Center (received January 27, 2020)*

At the time of the OIG site visit, the executive team had been working together as a group for over two years (see Table 1).

**Table 1. Executive Leader Assignments**

| Leadership Position | Assignment Date |
|---|---|
| Medical Center Director | June 26, 2016 |
| Chief of Staff | October 26, 1997 |
| Associate Director for Patient Care Services | May 28, 2017 |
| Deputy Director | October 21, 2012 |
| Assistant Director | October 1, 2017 |

*Source: Clement J. Zablocki VA Medical Center, Human Resources Officer (received January 28, 2020)*

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

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

The Director served as the chairperson of the Zablocki Leadership Council, which has the authority and responsibility for developing annual goals, strategic planning, and performing organizational management.

These leaders monitored patient safety and care through the Quality Management Oversight Committee. The Quality Management Oversight Committee is responsible for tracking and trending quality of care and patient outcomes. See Figure 4.

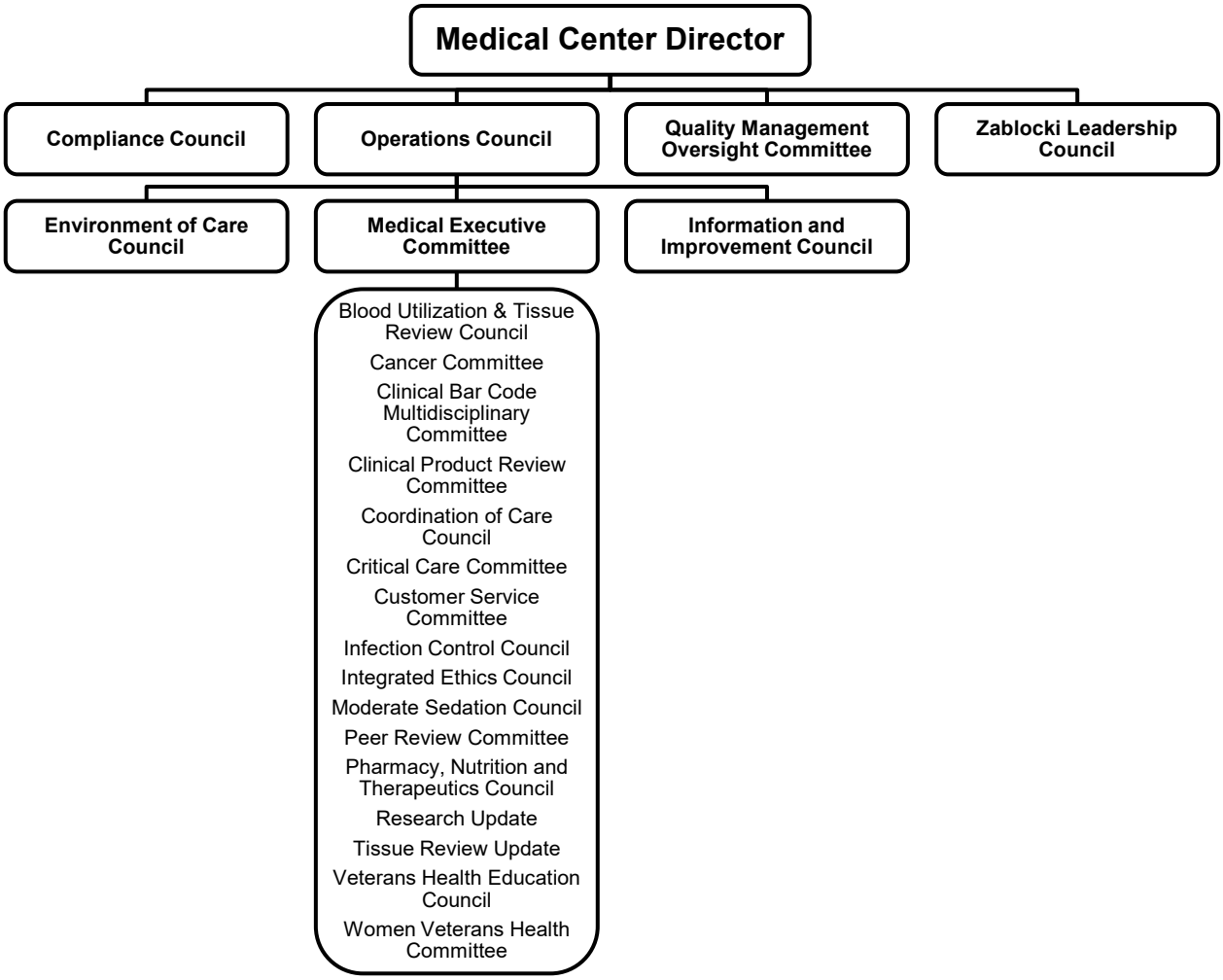


***Figure 4.*** *Medical Center Committee Reporting Structure*
*Source: Clement J. Zablocki VA Medical Center (received January 28, 2020)*

## Employee Satisfaction

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

To assess employee attitudes toward medical center leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of October 1, 2018, through September 30, 2019.[8] Table 2 provides relevant survey results for VHA, the medical center, and selected executive leaders. It summarizes employee attitudes toward the leaders as expressed in VHA's All Employee Survey. The OIG found the medical center's average for the survey leadership questions were similar to the VHA average.[9] Further, the scores for the executive leaders were generally higher than those for VHA and the medical center.

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

| Questions/ Survey Items | Scoring | VHA Average | Medical Center Average | Director Average | Chief of Staff Average | ADPCS Average | Deputy Director Average | Asst. Director Average |
|---|---|---|---|---|---|---|---|---|
| All Employee Survey: *Servant Leader Index Composite*[10] | 0–100 where higher scores are more favorable | 72.6 | 71.7 | 85.9 | 92.9 | 86.9 | 71.0 | 92.2 |

[8] Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Deputy Director, and Assistant Director.

[9] The OIG makes no comment on the adequacy of the VHA average for each selected survey element. The VHA average is used for comparison purposes only.

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

| Questions/ Survey Items | Scoring | VHA Average | Medical Center Average | Director Average | Chief of Staff Average | ADPCS Average | Deputy Director Average | Asst. Director Average |
|---|---|---|---|---|---|---|---|---|
| All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.4 | 3.5 | 4.4 | 4.0 | 4.1 | 3.8 | 4.1 |
| All Employee Survey*: My organization's senior leaders maintain high standards of honesty and integrity.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.6 | 3.7 | 4.7 | 4.3 | 4.5 | 4.1 | 4.3 |
| All Employee Survey: *I have a high level of respect for my organization's senior leaders.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.6 | 3.7 | 4.8 | 4.3 | 4.5 | 3.9 | 4.0 |

*Source: VA All Employee Survey (accessed on December 19 and 23, 2019)*

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey.[11] Note that the medical center's average for the survey questions were similar to the VHA average. Survey scores related to the Director, Chief of Staff, and ADPCS were similar to or better than those for VHA and the medical center. However, opportunities appear to exist for the Deputy Director and Assistant Director to decrease employees' feelings of moral distress at work (uncertainty about the right thing to do or inability to carry out what you believed to be the right thing).

[11] Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, Deputy Director, and Assistant Director.

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

| Questions/ Survey Items | Scoring | VHA Average | Medical Center Average | Director Average | Chief of Staff Average | ADPCS Average | Deputy Director Average | Asst. Director Average |
|---|---|---|---|---|---|---|---|---|
| All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.* | 1 (Strongly Disagree) – 5 (Strongly Agree) | 3.8 | 3.8 | 4.6 | 4.4 | 4.3 | 4.6 | 4.7 |
| 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 | 3.6 | 4.5 | 4.5 | 4.5 | 3.9 | 4.4 |
| 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) | 1.4 | 1.5 | 1.2 | 0.4 | 1.6 | 1.9 | 2.0 |

*Source: VA All Employee Survey (accessed on December 19 and 23, 2019)*

## Patient Experience

To assess patient experiences with the medical center, which directly reflect on its leaders, the OIG team reviewed patient experience survey results that relate to the period of October 1, 2018, through September 30, 2019. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare 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 VHA and the medical center.[12]

VHA also collects SHEP survey data from Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG reviewed responses to four relevant survey questions that reflect patients' attitudes toward their healthcare experiences (see Table 4). For this medical center, the patient survey results reflected higher care ratings than the VHA average. Patients appeared satisfied with the care provided.

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

| Questions | Scoring | VHA Average | Milwaukee Medical Center Average |
|---|---|---|---|
| Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?* | The response average is the percent of "Definitely Yes" responses. | 68.3 | 72.2 |
| 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. | 84.9 | 86.5 |
| 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. | 77.3 | 88.5 |
| 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. | 78.0 | 85.3 |

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

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from

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

2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.[13] For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients' experiences by gender (see Tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care Surveys. The OIG noted that the results for both male and female respondents were generally more favorable than the corresponding VHA averages. Medical center leaders appeared to be actively engaged with male and female patients (for example, conducting patient town hall meetings and managers visiting with newly admitted patients within the first 48 hours).

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

| Questions | Scoring | VHA[14] | | Medical Center[15] | |
|---|---|---|---|---|---|
| | | Male Average | Female Average | Male Average | Female Average |
| *During this hospital stay, how often did doctors treat you with courtesy and respect?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 84.5 | 82.8 | 85.4 | 89.9 |
| *During this hospital stay, how often did nurses treat you with courtesy and respect?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 84.8 | 83.1 | 85.1 | 87.0 |
| *Would you recommend this hospital to your friends and family?* | The measure is calculated as the percentage of responses in the top category (Definitely yes). | 68.7 | 61.8 | 71.6 | 83.9 |

*Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on December 19, 2019)*

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

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

[15] The medical center averages are based on 446–454 male and 20 female respondents, depending on the question.

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

| Questions | Scoring | VHA[16] | | Medical Center[17] | |
|---|---|---|---|---|---|
| | | Male Average | Female Average | Male Average | Female Average |
| *In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 51.2 | 43.3 | 62.5 | 36.2 |
| *In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 59.9 | 49.7 | 72.7 | 75.4 |
| *Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?* | The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10). | 71.6 | 65.7 | 81.4 | 73.5 |

*Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on December 19, 2019)*

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

[17] The medical center averages are based on 478–1,505 male and 41–87 female respondents, depending on the question.

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

| Questions | Scoring | VHA[18] | | Medical Center[19] | |
|---|---|---|---|---|---|
| | | Male Average | Female Average | Male Average | Female Average |
| *In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 48.5 | 44.7 | 57.3 | 62.9 |
| *In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?* | The measure is calculated as the percentage of responses that fall in the top category (Always). | 56.3 | 55.0 | 60.6 | 46.7 |
| *Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?* | The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10). | 70.4 | 70.1 | 75.2 | 70.0 |

*Source: VHA Office of Reporting, Analytics, Performance, Improvement and Deployment (accessed on December 19, 2019)*

## Accreditation Surveys and Oversight Inspections

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

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

[19] The medical center averages are based on 744–2,637 male and 35–126 female respondents, depending on the question.

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

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

recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in July 2017.

At the time of the site visit, the OIG team also noted the medical center's current accreditation by the Commission on Accreditation of Rehabilitation Facilities and the College of American Pathologists.[22] Additional results included the Long-Term Care Institute's inspection of the system's CLCs[23] and the Paralyzed Veterans of America's inspection of the medical center's spinal cord injury/disease unit and related services.[24]

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

| Accreditation or Inspecting Agency | Date of Visit | Number of Recommendations Issued | Number of Recommendations Remaining Open |
|---|---|---|---|
| OIG (*Comprehensive Healthcare Inspection Program Review of the Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin*, Report No. 17-01854-115, March 14, 2018) | July 2017 | 10 | 0 |
| OIG (*Healthcare Inspection – Review of Opioid Prescribing Practices, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin*, Report No. 15-02156-346, August 22, 2017) | April 2015[25] | 5 | 0 |

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

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

[24] The Paralyzed Veterans of America inspection took place August 7–8, 2019. This veterans service organization review does not result in accreditation status.

[25] This OIG report was published after the previous CHIP inspection in July 2017.

| Accreditation or Inspecting Agency | Date of Visit | Number of Recommendations Issued | Number of Recommendations Remaining Open |
|---|---|---|---|
| OIG (*Healthcare Inspection – Management of Mental Health Care Concerns, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin,* Report No. 16-00748-319, July 27, 2017) | February 2016[26] | 5 | 0 |
| TJC Hospital Accreditation | September 2018 | 30 | 0 |
| TJC Behavioral Health Care Accreditation | | 2 | 0 |
| TJC Home Care Accreditation | | 6 | 0 |

*Source: OIG and TJC (inspection/survey results verified with the Manager of the Office of Quality Management and Safety on January 28, 2019)*

## Identified Factors Related to Possible Lapses in Care and Medical Center Response

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

Upon the OIG's request, facility Quality Management staff provided evidence of three sentinel events from July 15, 2017, through January 27, 2020. Medical center staff also reported seven institutional disclosures during the same time period, and the OIG noted that some of the institutional disclosures appeared to meet the definition of a sentinel event and were not identified as such.[27] For example, one event involved a medication error that resulted in the transfer of a patient to a higher level of care for additional treatment. In another incident, a retained object was found following an invasive procedure, and an additional subsequent procedure had to be performed to remove it. Medical center leaders have an opportunity to improve the identification of sentinel events to ensure that timely actions are implemented to mitigate future occurrences.

[26] This OIG report was published after the previous CHIP inspection in July 2017.

[27] The definition of a sentinel event can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. 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."

Table 9 lists the reported patient safety events from July 15, 2017 (the prior OIG comprehensive healthcare inspection), through January 27, 2020.[28]

**Table 9. Summary of Selected Organizational Risk Factors (July 15, 2017, through January 27, 2020)**

| Factor | Number of Occurrences |
|---|---|
| Sentinel Events[29] | 3 |
| Institutional Disclosures[30] | 7 |
| Large-Scale Disclosures[31] | 0 |

*Source: Clement J. Zablocki VA Medical Center's Patient Safety Managers and Manager, Office of Quality Management and Safety (received January 27, 2020)*

## Veterans Health Administration Performance Data

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

[28] 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 Clement J. Zablocki VA Medical Center is a high complexity (1a) affiliated system as described in Appendix B.)

[29] 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."

[30] 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."

[31] 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."

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

Figure 5 illustrates the medical center's quality of care and efficiency metric rankings and performance compared with other VA facilities as of June 30, 2019. Of note, Figure 5 uses blue and green data points to indicate high performance for the medical center (for example, in the areas of patient-centered medical home (PCMH) care coordination, rating (of) specialty care (SC) provider, call responsiveness, and rating (of) hospital). Metrics that need improvement are denoted in orange and red (for example, registered nurse (RN) turnover, adjusted length of stay (LOS), complications, and ambulatory care sensitive conditions (ACSC) hospitalization).[33]

[33] For information on the acronyms in the SAIL metrics, please see Appendix E.

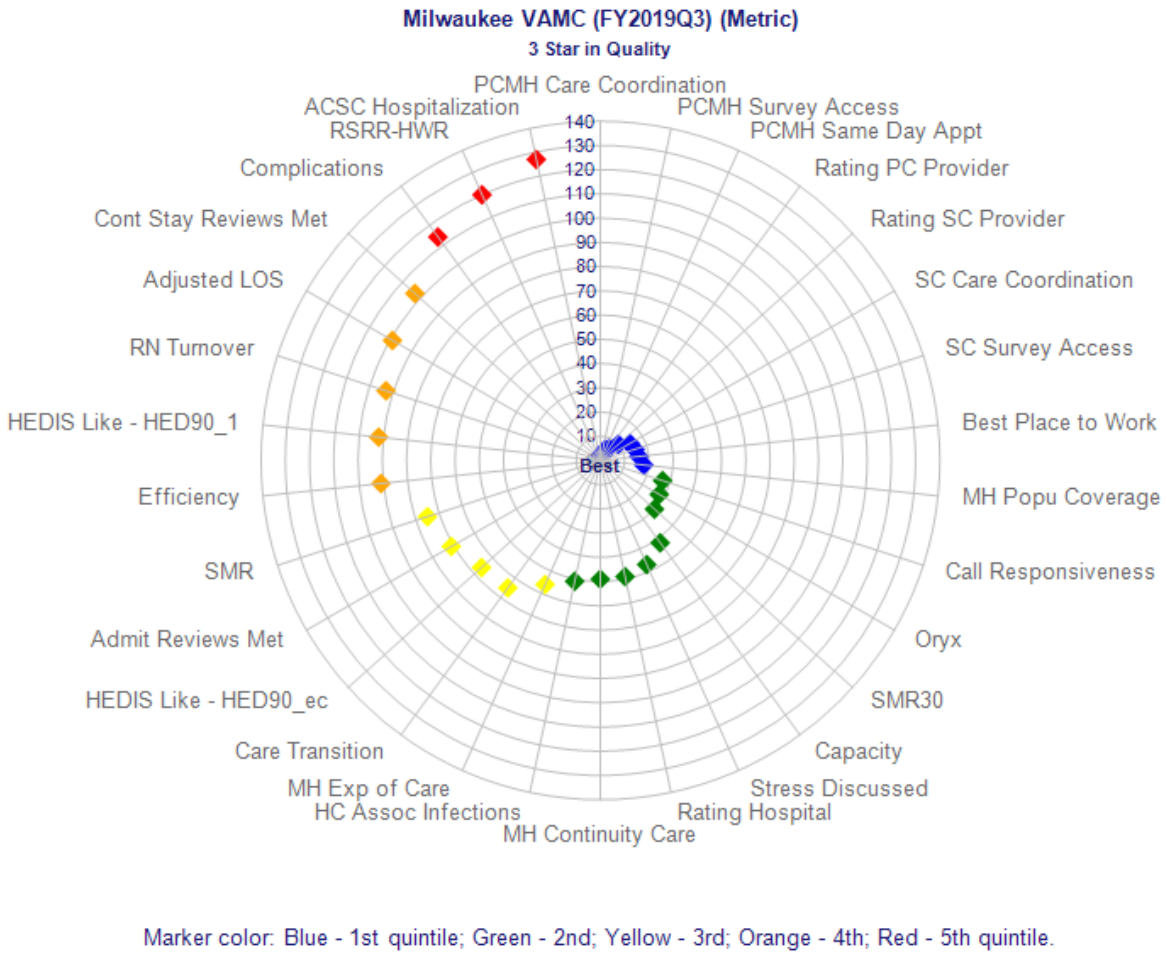


***Figure 5.*** *System Quality of Care and Efficiency Metric Rankings (as of June 30, 2019)*
*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness.*

## Veterans Health Administration Performance Data for Community Living Centers

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

Medicaid Services' (CMS) *Nursing Home Compare* and provides a single resource to review quality measures and health inspection results.[34]

Figure 6 illustrates the medical center's CLC quality rankings and performance compared with other VA CLCs as of September 30, 2019. Figure 6 uses blue and green data points to indicate high performance for the medical center's CLC (physical restraints–long-stay (LS), outpatient emergency department (ED) visit–short-stay (SS), and improvement in function–SS). Metrics that need improvement are denoted in orange and red (for example, falls with major injury–LS, catheter in bladder–LS, and newly received antipsychotic (antipsych) medications (meds)–SS).[35]

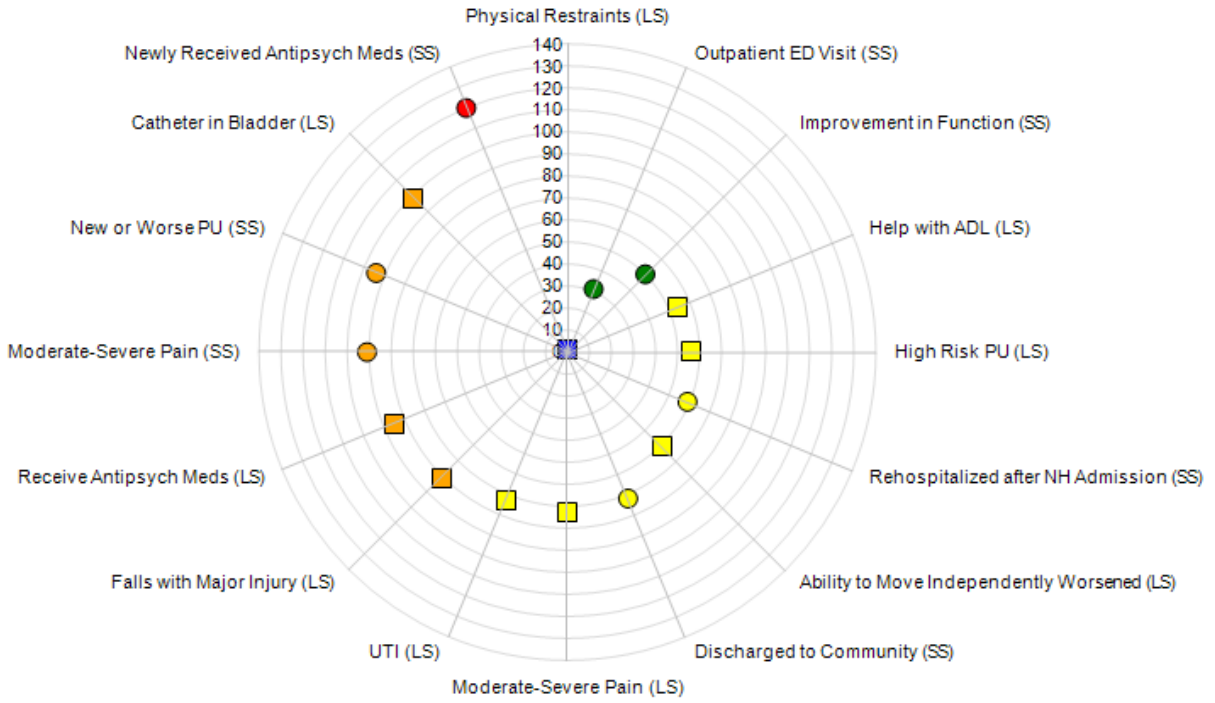


***Figure 6.*** *Clement J. Zablocki VA Medical Center CLC Quality Measure Rankings (as of September 30, 2019)*
*LS = Long-Stay Measure SS = Short-Stay Measure*
*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness.*

[34] According to the Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, November 19, 2018, "In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several "star" ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes."

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

## Leadership and Organizational Risks Conclusion

At the time of the OIG inspection, the medical center's executive leadership team had worked together for over two years. Relevant survey results related to employees' satisfaction with the leaders revealed opportunities for the Deputy Director and Assistant Director to decrease employees' feelings of moral distress at work. Patient experience survey data reflected patient satisfaction with the care provided. Further, the OIG found that selected survey results for male and female respondents were generally more favorable than those for corresponding VHA patients nationally. The OIG's review of the medical center's accreditation findings did not identify any substantial organizational risk factors. However, the OIG identified concerns regarding the patient safety program—specifically, with the identification of sentinel events. In individual interviews, the executive leaders were generally able to speak in depth about actions taken during the previous 12 months to maintain or improve employee satisfaction and patient experiences. In addition, the executive leaders were knowledgeable within their scopes of responsibility about selected VHA data used by the SAIL and CLC SAIL models.

## 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.[36] To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and to maintain Joint Commission accreditation.[37] Many quality-related activities are informed and required by VHA directives, nationally recognized accreditation standards (such as The Joint Commission), and federal regulations. VHA strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.[38]

To determine whether VHA facilities have implemented and incorporated OIG-identified key processes for quality and safety into local activities, the inspection team evaluated the medical center's committee responsible for quality, safety, and value (QSV) oversight functions; its ability to review data, information, and risk intelligence; and its ability to ensure that key QSV functions are discussed and integrated on a regular basis. Specifically, OIG inspectors examined the following requirements:

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

The OIG reviewers also assessed the medical center's processes for conducting protected peer reviews of clinical care.[39] Protected peer reviews, when conducted systematically and credibly, reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[40] The OIG team examined the completion of the following elements:

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)

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

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

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

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

[40] VHA Directive 1190.

- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[41]
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the medical center's utilization management (UM) program, a key component of VHA's framework for quality, safety, and value, which provides vital tools for managing the quality and the efficient use of resources.[42] It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[43] Inspectors reviewed several aspects of the UM program:

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

Finally, the OIG reviewers assessed the medical center's reports of patient safety incidents with related root cause analyses.[44] 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 medical center.[45] The medical center was assessed for its performance on several dimensions:

[41] VHA Directive 1190.

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

[43] VHA Directive 1117(2).

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

[45] VHA Handbook 1050.01.

- Annual completion of a minimum of eight root cause analyses[46]
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of annual patient safety report to medical center leaders

The OIG reviewers interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents.[47]

## Quality, Safety, and Value Findings and Recommendations

The medical center complied with requirements for establishing a committee responsible for QSV oversight functions and review of aggregated data and most patient safety elements. However, the OIG noted that the Peer Review Committee did not identify improvement actions for any of the Level 2 or 3 cases.[48] The OIG also identified significant weaknesses in the QSV committee's recommendation and implementation of improvement actions, documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database, and interdisciplinary review of UM data.

TJC requires that the medical center's governing body provide oversight, structure, and resources to support quality and safety. TJC also requires facilities to measure and analyze performance data so that performance improvement "effectiveness can be sustained, assessed, and measured."[49] The OIG reviewed Quality Management Oversight Committee minutes from March, May, August, and November 2019, and noted a lack of documented action items

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

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

[48] According to VHA Directive 1190, "The PRC provides recommendations for non-punitive, non-disciplinary actions to improve the quality of health care delivered or the utilization of health care resources"; "Levels of Care are to be used in assessing the clinical decisions and actions of the clinician who is the subject of a Peer Review for Quality Management. A Level of Care must be assigned by the initial reviewer(s) and in the evaluation and discussion of the initial review and the episode of care by the multi-disciplinary Peer Review Committee (PRC). (1) Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. (2) Level 2 is the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care. (3) Level 3 is the level at which most experienced and competent clinicians would have managed the case differently."

[49] TJC. Rationale for Leadership standards LD.01.03.01 and 03.05.01; Leadership Introduction to Operations standards LD.03.07.01 through LD.04.03.11; and Performance Improvement standard PI.03.01.01.

developed in response to identified problems and opportunities for improvement. Failure to document performance improvement-based action items may prevent ongoing improvements to the quality of patient care and safety processes. The Medical Center Director stated that discussions about performance-based actions occur in various settings—for example, during other medical center committee meetings and the morning report—and therefore, are not always captured in the Quality Management Oversight Committee meeting minutes.

## Recommendation 1

1. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures specific action items are documented in Quality Management Oversight Committee minutes when problems or opportunities for improvement are identified.

Medical center concurred.

Target date for completion: December 31, 2020

Medical center response: The Medical Center Director is responsible for this action. The Medical Center Director tasked the Manager of the Office of Quality and Safety to ensure that the minutes of the Quality Management Oversight Committee (QMOC) contain actions items when problems or opportunities for improvement are identified. The Medical Center Director/designee will audit minutes for each QMOC meeting to ensure action items are added and tracked appropriately. The numerator will be the number of QMOC meeting minutes that contain tracking of specific action items, and the denominator will be total number of QMOC minutes. Compliance will be reported quarterly to the Medical Center Director and captured in the QMOC minutes. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires that physician UM advisors document, at minimum, 75 percent of their decisions in the National UM Integration database relating to the appropriateness of patient admissions and continued stays.[50] The OIG found that physician UM advisors completed 25 percent of referred reviews from April 1, 2019, through September 30, 2019. These reviews are critical for setting benchmarks; identify trends, actions, and opportunities to improve efficiency; and to monitor outcomes. Incomplete reviews may result in a lack of information available at the national- and medical center-levels. The Assistant Chief of Staff of Clinical Services stated that there are numerous designated physician UM advisors in the medical center; however, staff do not have dedicated administrative time. In addition, the UM nurses interviewed stated that there is an active process to notify the appropriate physician UM advisor when a review is needed however,

[50] VHA Directive 1117(2).

per the UM nurses and Associate Chief of Staff of Clinical Services there was no oversight for missed reviews.

## Recommendation 2

2. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures that physician utilization management advisors consistently document their decisions in the National Utilization Management Integration database.

Medical center concurred.

Target date for completion: August 31, 2020

Medical center response: Medical Center response: The Medical Center Director is responsible for this action. The Utilization Management Program Manager met with the Associate Chief of Staff for Clinical Affairs to identify barriers and best practices used by other facilities. The primary barrier identified was the absence of dedicated administrative time for the Physician Utilization Management Advisors (PUMAs).

On February 1, 2020, the Utilization Management Program Manager reconfirmed the Utilization Management Nurse process for sending reviews to the PUMAs and established a (new) second level review if the PUMA review was not completed within four days of notification. The Utilization Management personnel track completions in real time.

The Utilization Management Program Manager will monitor documentation of the PUMA decisions by utilizing the National Utilization Management Integration database on a weekly basis.

The numerator will be the number of cases referred to the PUMAs that were reviewed timely, and the denominator will be the total number of cases referred to the PUMAs. Compliance will be reported quarterly to the Quality Management Oversight Committee. The recommendation will be considered compliant when 75 percent of PUMA reviews completed timely for two consecutive quarters.

VHA requires that an interdisciplinary group review UM data. This group must include, but not be limited to, "representatives from UM, Medicine, Nursing, Social Work, Case Management, Mental Health, and CBO R-UR [chief business office revenue-utilization review]."[51] The OIG found that from March 2019 through November 2019, the medical center used the Quality Management Oversight Committee to review UM data; however, the committee lacked representation from social work, mental health, and CBO R-UR. As a result, the committee performed reviews and analyses without the perspectives of key staff. The Medical Center

[51] VHA Directive 1117(2).

Director reported that the ADPCS, Chief of Staff, and Assistant Director—who oversee those three departments—could represent the appropriate subject matter experts at Quality Management Oversight Committee meetings.

## Recommendation 3

3. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures all required representatives are assigned and consistently participate in interdisciplinary reviews of utilization management data.

Medical center concurred.

Target date for completion: December 31, 2020

Medical center response: The Medical Center Director is responsible for this action. On February 3, 2020, the Program Manager of the Office of Quality Management and Safety, in collaboration with the Medical Center Director, added the required representatives from Mental Health, Social Work, and Chief Business Office, Revenue-Utilization Resource to the Medical Center's Quality Management Oversight Committee. This committee has oversight of the Utilization Management Program.

Compliance with ensuring each of the required members participate in interdisciplinary reviews of utilization management data will be reported quarterly to the Quality Management Oversight Committee. Utilization Management compliance and attendance will be monitored through review of the Quality Management Oversight Committee meeting minutes. The numerator will be the number of times each of the required members (or alternates) attended the meeting, and the denominator will be the total number of meetings held. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

## 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).[52]

Clinical privileges need to be specific and based on the individual practitioner's clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the Director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo reprivileging prior to their expiration.[53]

VHA defines the focused professional practice evaluation (FPPE) as "a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance." The FPPE process occurs when a provider is hired at the facility and granted initial privileges and before any new clinical privileges are granted. Additionally, VA facilities must continuously monitor the performance of their providers. VHA requirements state that "the on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered."[54] The OIG examined various requirements for FPPEs and OPPEs:

- FPPEs
  - Establishment of criteria in advance
  - Use of minimum criteria for selected specialty LIPs[55]
  - Clear documentation of the results and time frames
  - Evaluation by another provider with similar training and privileges
- OPPEs
  - Application of criteria specific to the service or section
  - Use of minimum criteria for selected specialty LIPs[56]
  - Evaluation by another provider with similar training and privileges

[52] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

[53] VHA Handbook 1100.19.

[54] VHA Handbook 1100.19.

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

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

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

Further, VA must put processes in place to reasonably ensure that its healthcare staff meet or exceed professional practice standards for delivering patient care. When there is a serious concern regarding a current or former licensed practitioner's clinical practice, VA has an obligation to notify state licensing boards (SLBs) and to subsequently respond to inquiries from SLBs concerning the licensed practitioner's clinical practice.[57] Further, "VA medical facility Directors must designate an individual, and backup, to be responsible for the SLB reporting process. This individual will be the subject matter expert (SME) for the facility…and ensure oversight of the exit review process, including receipt, review, and maintenance of the Provider Exit Review Forms."[58] The OIG reviewers assessed whether the medical center's staff

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

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

- No solo/few practitioners underwent initial or reprivileging during the previous 12 months[59]
- Ten LIPs hired within 18 months before the site visit
- Twenty LIPs privileged within 12 months before the visit
- Twenty LIPs who left the medical center within 12 months before the visit

## Medical Staff Privileging Findings and Recommendations

The OIG identified deficiencies with FPPE, OPPE, and provider exit review processes.

VHA requires the criteria for the FPPE process "to be defined in advance, using objective criteria accepted by the practitioner."[60] The OIG reviewed 10 practitioner's profiles and found that all

[57] VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005.

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

[59] VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers few practitioners as being less than three providers in the facility that are privileged in a particular specialty. The 12-month review period was from November 4, 2018, through November 4, 2019.

[60] VHA Handbook 1100.19.

lacked evidence that the LIPs were aware of the evaluation criteria before service chiefs' initiated the FPPE process. This could result in LIPs' misunderstanding of FPPE expectations. The Health Systems Specialist to the Chief of Staff stated that FPPE forms did not previously include a designated signature line for practitioners to acknowledge receipt of criteria in advance of the evaluation but believed that providing LIPs the medical center's bylaws met the intent.

## Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures clinical managers define in advance, communicate, and document criteria in practitioner profiles for focused professional practice evaluations.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. By August 28, 2020, the Chief of Staff, through the Credentialing and Privileging Office, will implement a process during Licensed Independent Practitioner (LIP) onboarding to communicate (in advance of LIP appointment) and document acceptance of focused professional practice evaluation (FPPE) criteria. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of files demonstrating documented acceptance of FPPE criteria, and the denominator will be the total number of files reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA uses the FPPE process as an oversight tool and requires FPPEs be completed for LIPs "when a practitioner does not have the documented evidence of competent performance of the privileges requested." The FPPE must be time-limited and may include "periodic chart review, direct observation, monitoring of diagnostic and treatment techniques, or discussion with other individuals involved in the care of patients." Additionally, results of the review "must be documented in the practitioner's provider profile and reported to the Executive Committee of the Medical Staff."[61]

For 2 of 10 newly hired LIPs, the OIG did not find documented evidence of FPPE results in the practitioners' profile. These newly hired practitioners had been onboard for more than six months, and FPPEs had not been conducted. This may result in practitioners providing patient care without a thorough review of their clinical competencies. The Health Systems Specialist to

[61] VHA Handbook 1100.19.

the Chief of Staff reported that the FPPE results were not available for the practitioners because they were intermittent appointees hired for a provider shortage in cardiology. The Health Systems Specialist also added that the FPPEs had not been initiated because the medical center had not yet needed the intermittent practitioners' services. The OIG remains concerned because facility staff could not provide evidence to demonstrate that FPPEs were ever initiated for these practitioners nor was there evidence of tracking through credentialing process if and when they provided patient care.

The OIG also found that among the eight remaining LIP profiles reviewed, FPPE time frames were not clearly defined. Lack of time limitations may lead to inefficient processes and leave the LIPs unclear about the evaluation period. The Health Systems Specialist stated to the Chief of Staff that the FPPE forms did not include the defined time frame because the division managers believed the medical center's FPPE policy was sufficient documentation for both supervisors and practitioners.

## Recommendation 5

5. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures service chiefs initiate, complete, and document the results of focused professional practice evaluations in practitioner profiles.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff will implement and monitor an audit process through the Professional Standards Board to ensure that results of completed focused professional practice evaluations (FPPEs) are documented in practitioner profiles. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of practitioner profiles which contain documented results of FPPEs, and the denominator will be the number of files reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

## Recommendation 6

6. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that all focused professional practice evaluations include defined time frames.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff, through the Credentialing and Privileging Office, will ensure the facility's focused professional practice evaluation (FPPE) forms include the defined timeframes in which FPPE is required to be completed. The applicable forms will be placed into effect for all clinical services by August 28, 2020. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of completed FPPEs that include the defined timeframes, and the denominator will be number of FPPEs reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires that at the time of reprivileging, service chiefs consider relevant, service- and practitioner-specific data using defined criteria when recommending the continuation of LIPs privileges to the Executive Committee of the Medical Staff. Such data are maintained as part of the practitioner's profile and may include direct observation, clinical discussions, and clinical reviews.[62] For 3 of 20 practitioners reprivileged within the last 12 months, service chiefs could not demonstrate that reprivileging decisions were based upon service-specific OPPE data. In addition, for 20 LIPs practitioners reprivileged within the last 12 months, the OIG found that 12 LIP profiles lacked evidence that the service chief's determination to continue privileges was based, in part, on OPPE results. OPPEs allow the medical center "to identify professional practice trends" impacting "quality of care and patient safety."[63] The Health Systems Specialist reported to the Chief of Staff that the current OPPE forms were not specific to the service but stated clinical service chiefs, Professional Standards Board members, and the Chief of Staff all believed the current forms were sufficient for collecting "meaningful data." The Chief of Staff acknowledged the summary OPPE documents were lacking supporting clinical data but believed the medical center service line managers collect important OPPE components for quality patient care. The Chief of Staff indicated that there is not necessarily "added value to this process."

## Recommendation 7

7. The Chief of Staff evaluates and determines additional reasons for noncompliance and ensures that reprivileging decisions are based on service-specific ongoing professional practice evaluation data.

[62] VHA Handbook 1100.19.

[63] VHA Handbook 1100.19.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff will ensure that re-privileging decisions are based on service-specific ongoing professional practice evaluation (OPPE) data by August 28, 2020. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of completed OPPEs documenting service-specific criteria, and the denominator will be the number of OPPEs reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

## Recommendation 8

8. The Chief of Staff evaluates and determines additional reasons for noncompliance and ensures service chiefs consistently collect and review ongoing professional practice evaluation data for the determination to recommend continuation of privileges.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. By August 28, 2020, the Chief of Staff will ensure that service chiefs consistently collect and review ongoing professional practice evaluation (OPPE) data for the determination to recommend continuation of privileges through implementation and monitoring of an audit process through the Professional Standards Board. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of OPPEs documenting service chief approval, and the denominator will be the number of OPPEs reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires another practitioner with similar training and privileges must complete the professional practice evaluation.[64] The OIG found that OPPE results for two LIPs were not based on an evaluation by another practitioner with similar training and privileges. OPPEs allow the

[64] VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

medical center "to identify professional practice trends" impacting "quality of care and patient safety."[65] The Chief of Staff acknowledged that similarly privileged practitioners were not always able to conduct the evaluations, largely due to working at different medical center locations and indicated that the current reviews had been conducted by appropriately skilled practitioners.

## Recommendation 9

9. The Chief of Staff evaluates and determines additional reasons for noncompliance and ensures that licensed independent practitioners' ongoing professional practice evaluations are completed by providers with similar training and privileges.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff will ensure that Licensed Independent Practitioners' (LIPs) ongoing professional practice evaluations (OPPEs) are completed by providers with similar training and privileges through utilization of other VHA providers, where necessary. Ten credentialing files will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of OPPEs documenting completion by providers with similar training and privileges, and the denominator will be the number of OPPEs reviewed. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires that FPPE and OPPE results be reported to the Executive Committee of the Medical Staff to review and evaluate LIPs' initial and reprivileging requests. Committee minutes must indicate the materials reviewed and the rationale for the privileging determinations.[66]

For 17 practitioners—4 who were granted initial privileges and 13 who were reprivileged—the OIG found that the Medical Executive Committee (the medical center's Executive Committee of the Medical Staff) had not reviewed the FPPE results and the OPPEs did not include a review of clinical data. Failure to use FPPE and OPPE data and appropriately document committee reviews potentially resulted in recommendations based on incomplete evidence to support the Director's approval for continuing clinical privileges.

The Health Systems Specialist reported to the Chief of Staff that two practitioners did not receive FPPEs due to their status as intermittent staff. FPPEs were recently completed for two additional

[65] VHA Handbook 1100.19.

[66] VHA Handbook 1100.19.

practitioners; but, due to a delay in the completion of their evaluations, the results had not yet been presented to the Medical Executive Committee. The Health Systems Specialist to the Chief of Staff stated the Chief of Staff, clinical service chiefs, and Professional Standards Board members believed the current OPPE data were sufficient for quality patient care and safety and that the Medical Executive Committee feels reviewing the Professional Standards Board's discussion and recommendations met the intent of the directive.

## Recommendation 10

10. The Chief of Staff evaluates and determines additional reasons for noncompliance and makes certain that Medical Executive Committee meeting minutes consistently reflect the review of professional practice evaluation results in the decision to recommend continuation of privileges.

Medical center concurred.

Target date for completion March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff will ensure that Medical Executive Committee (MEC) meeting minutes consistently reflect the review of focused professional practice evaluation (FPPE) and ongoing professional practice review (OPPE) results in the decision to recommend continuation of privileges. Resolution of the prior recommendations related to FPPE and OPPE completion (both timeliness and type of data reviewed, i.e. service-specific) will allow for the current process of Medical Executive Committee review of data and provision of recommendations to the Medical Center Director to meet VHA requirements. As MEC meets twice per month, 100 percent of MEC minutes will be audited. The numerator will be the number of MEC minutes containing documentation of review of all FPPE and OPPE results, and the denominator will be the number of MEC minutes audited. Compliance will be reported monthly through Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires that provider exit review forms, which document the review of a provider's clinical practice, are "completed within 7 calendar days of the departure of a licensed health care professional from a VA facility."[67] For the 20 providers who departed the medical center in the previous 12 months, the OIG found that exit review forms for 12 of them were not completed within seven calendar days. Failure to complete exit review forms in a timely manner may delay reporting healthcare professionals' potential substandard care to SLBs. The Health Systems Specialist stated to the Chief of Staff that, due to the size of the organization and decentralized

[67] VHA Notice 2018-05.

stakeholders throughout numerous divisions and clinics, challenges arose when standardizing a process.

## Recommendation 11

11. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that provider exit review forms are completed within seven calendar days of licensed healthcare professionals departing the medical center.

Medical center concurred.

Target date for completion: April 2, 2021

Medical center response: The Medical Director is responsible for this action. The Medical Center Director, through the Health Systems Specialist to the Chief of Staff and Human Resources Officer, will ensure that provider exit review forms are completed within seven calendar days of licensed healthcare professionals departing the medical center through modifications to the electronic employee clearance process. The modifications will be in place by August 28, 2020. Ten exit review forms will be reviewed monthly to determine compliance. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of exit review forms completed within seven calendar days of healthcare professionals departing the medical center, and the denominator will be the number of exit review forms audited. Compliance will be reported monthly through the Medical Executive Committee meetings and quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

## Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct Comprehensive Environment of Care Inspection Rounds and to resolve issues in a timely manner. The goal of the Comprehensive Environment of Care Program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional but should also promote healing.[68]

The purpose of this facet of the OIG inspection was to determine whether the medical center maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the medical center met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the inpatient mental health unit where patients with active suicidal ideation or attempts are treated. Inspectors reviewed several aspects of the medical center's environment:

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

[68] VHA Directive 1608, C*omprehensive Environment of Care (CEOC) Program*, February 1, 2016.

- Environmental cleanliness and infection prevention
- Privacy
- Privacy for women veterans
- Logistics

During its review of the environment of care, the OIG inspected the John H. Bradley Department of Veterans Affairs Outpatient Clinic and the following eight patient care areas of the Clement J. Zablocki VAMC:

- Acute psychiatric unit
- CLC
- Emergency Department
- Intensive care unit
- Medical inpatient unit
- Outpatient clinic (Yellow/Blue)
- Post-anesthesia care unit
- Surgical inpatient unit

The inspection team reviewed relevant documents and interviewed key employees and managers.

## Environment of Care Findings and Recommendations

The medical center complied with requirements for women veteran accommodations. At the time of the on-site visit, the OIG did not note any issues with the availability of medical equipment and supplies; however, during a subsequent review of *VHA's COVID-19 Screening Processes and Pandemic Readiness*, medical center staff reported a need for additional surgical drapes.[69] On one inpatient nursing unit at the medical center, the OIG also observed dirty "plier"-type devices tethered to medication carts which, per the nurse manager, are used by staff to crush pills for patient use.[70] The Chief of Pharmacy stated that the "plier"-type device is older and was unsure why it was still being used on the unit. Additionally, on the same unit, the OIG found unsecured patient health information accessible by patients and visitors.

The OIG identified concerns with general safety, cleanliness and infection prevention, and privacy.

[69] VA OIG, *OIG Inspection of Veterans Health Administration's COVID-19 Screening Processes and Pandemic Readiness March 19–24, 2020*, Report No. 20-02221-120, March 26, 2020.
[70] Unit 7C

TJC requires facilities to minimize "the risk of infection when storing and disposing of infectious waste."[71] The OIG found general cleaning equipment—including a vacuum, mops, brooms, and clean floor signs—in seven biohazardous waste rooms. Additionally, ladders were stored in three biohazard rooms. Failure to follow storage practices may result in potential exposure of patients, staff, and visitors to infectious material. The Chief of Environmental Management Service stated staff are aware that the biohazard rooms are not to be used for general storage but acknowledged that storage is limited.

## Recommendation 12

12. The Assistant Director evaluates and determines any additional reasons for noncompliance and makes sure that biohazardous rooms are not used to store clean items.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Assistant Director is responsible for this action, in collaboration with the Deputy Director who oversees the Manager of Environmental Management Services (EMS). The EMS Manager ensures that biohazard rooms are not used to store clean EMS equipment and supplies. The Manager of EMS developed an audit tool on June 25, 2020.The EMS supervisor/designee will conduct audits to ensure proper storage of clean EMS equipment and supplies. Weekly audits of each area will begin July 1, 2020. The EMS supervisor/designee will collect and collate the audit data weekly and report that data to the EMS manager. The manager. The numerator will be the number of audits which met the criteria for proper storage, and the denominator will be the total number of audits conducted each week. The EMS Manager will report the audit results to the Deputy Director and Environment of Care Council at least monthly and will submit quarterly data summaries to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires restricted access to clean/sterile storerooms and stipulates that the areas must have solid-bottom shelves that are clean, dry, and at least eight inches from the floor.[72] The OIG found bottom shelves that needed cleaning in two of seven patient care areas. This constituted a failure to maintain a generally clean environment and increased the potential for spreading infection. Staff were not able to identify reasons for noncompliance.

[71] TJC. Infection Prevention and Control standard IC.02.01.01.

[72] VHA Directive 1761(2), *Supply Chain Inventory Management*, October 24, 2016, amended on October 26, 2018.

## Recommendation 13

13. The Assistant Director determines the reasons for noncompliance and ensures that clean/sterile storeroom solid-bottom shelves are clean.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Assistant Director is responsible for this action, in collaboration with the Deputy Director who oversees the Division Manager of Logistics. The Division Manager of Logistics/designee is responsible to ensure that all bottom shelves in clean/sterile supply rooms are clean. Monthly audits of each area will begin July 1, 2020. The numerator will be the number of audits which met the criteria for ensuring clean and sterile storeroom solid bottom shelves are clean, and the denominator will be the total number of audits conducted for rooms containing solid bottom shelves. The Division Manager of Logistics will report the audit results to the Deputy Director and the Environment of Care Council at least monthly and will submit quarterly data summaries to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

To meet environmental cleanliness standards, TJC requires that facilities establish and maintain a safe, suitable environment, and that areas used by patients are clean.[73] Of the eight patient areas inspected at the Clement J. Zablocki VA Medical Center, the OIG found five with dirty/dusty heating, ventilation, and air conditioning (HVAC) grills;[74] three with dirty/dusty floors;[75] two with stained ceiling tiles[76] and damaged furniture.[77] Additionally, the OIG noted two areas with dirty/dusty patient equipment.[78] The John H. Bradley VA Outpatient Clinic was generally clean with the exception of stained and damaged ceiling tiles in the main outpatient clinic and dirty/dusty HVAC grills in the mental health annex building.

As a result, the medical center was unable to ensure a safe and functional clinical environment promoting patient and staff safety. The Chief of Environmental Management Service stated that the dust and cleaning issues were related to lack of staff oversight, indicated that some areas like storage and medication rooms were cleaned less regularly, and affirmed that supervisors needed to be more aware in checking those areas. Per the clinic manager at the John H. Bradley VA

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

[74] Units CLC, ICU, 7C, and ED and 6C

[75] Units CLC, 7C, and ED

[76] Units 7C and 6C

[77] Units CLC and Outpatient Yellow/Blue Clinic

[78] Units 6C and ED

Outpatient Clinic, each building had different cleaning contractors and failure to follow up on deficiencies was lack of oversight.

## Recommendation 14

14. The Assistant Director evaluates and determines any additional reasons for noncompliance and ensures that a safe and clean environment is maintained throughout the medical center and outpatient clinic buildings.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Assistant Director is responsible for this action, in collaboration with the Deputy Director who oversees the Manager of Environmental Management Services (EMS) and the Northeast Wisconsin Ambulatory Clinics (NEWAC, which is comprised of the Green Bay, Cleveland, and Appleton clinics). The Manager of Environmental Management Services (EMS) at the Milwaukee campus and the Appleton site Manager are responsible for ensuring a safe and clean environment. An audit tool was developed on June 25, 2020. The EMS supervisor/designee and Appleton site manager/designee will conduct audits to ensure cleanliness of floors, heating, ventilation and air conditioning (HVAC) grills and identification of stained ceiling tiles in the medical center. Weekly audits of each area will begin July 1, 2020. The EMS supervisor/designee and Appleton site manager/designee will collect and collate the audit data weekly. The numerator will be the number of audits which meet the criteria for safe and clean environment, and the denominator will be the total number of audits conducted each week for each of these two sites. The EMS Manager and NEWAC Administrator/designee will report the audit results to the Deputy Director and Environment of Care Council at least monthly and will submit quarterly data summaries to the Quality Management Oversight Committee.

The Milwaukee Facility Management Director initiated work orders on January 31, 2020, to replace the stained ceiling tiles identified by the OIG. The Milwaukee Facility Management Director verified that the stained ceiling tiles had been replaced and closed the work orders on February 6, 2020. The Appleton clinic manager confirmed that the ceiling tiles had been replaced February 3, 2020.

The Managers of the Community Living Centers and the Yellow Clinic had removed all damaged equipment by June 25, 2020. Ongoing compliance and monitoring occur through monthly rounding. The monitoring and auditing will occur monthly and will be reported quarterly to the Quality Management Oversight Committee until 90 percent compliance has been reached for two consecutive quarters.

## Recommendation 15

15. The Associate Director for Patient Care Services evaluates and determines additional reasons for noncompliance and ensures that patient care equipment is clean and ready for use.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Associate Director for Patient Care Services is responsible for this action. The Division Manager for Acute Inpatient Nursing reported that the plier type pill crusher was removed before OIG left the facility on January 31, 2020, and all plier type pill crushers were replaced with the silent knight pill crusher. The Division Manager for Acute Inpatient Nursing / designee will begin weekly audits of each area July 1, 2020, using the audit tool "Cleaning of Non-Critical Reusable Medical Equipment (RME)". The numerator is the number of audits which met the criteria (free from visible soiling) and the denominator is the total number of audits conducted each week. The Division Managers for Acute Inpatient Nursing will report the audit results to the Associate Director Patient Care Services and Environment of Care Council at least monthly and will report compliance quarterly to the Quality Management Oversight Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires facilities to provide security safeguards to control access to areas where information systems reside.[79] The OIG team was able to gain access to the information technology closet on the ninth floor through a door with a functional lock that was not engaged. Doors to secure information technology areas left unlocked may result in unauthorized access and disruption of internal operating systems. Beyond OIG's observation of the door lock, no reason for noncompliance was provided.

## Recommendation 16

16. The Medical Center Director ensures that Office of Information Technology leaders determine the reasons for noncompliance and ensures that access is controlled to information technology rooms.[80]

[79] VHA Handbook 6500, *Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program*, March 10, 2015.

[80] The OIG reviewed evidence that sufficiently demonstrated that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

Medical center concurred.

Target date for completion: Completed

Medical center response: The Information Technology Operations and Services Area Manager is are responsible for controlling access to the information technology rooms. The Milwaukee Veteran Affairs Police Department installed an auto locking door latch on the door to the Information Technology closet on the 9th floor on February 11, 2020. This latch will prevent the door from being unlocked when closed. Based on the evidence provided, we request closure of this recommendation.

## Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.[81] The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.[82] Long-term opioid use is of particular concern in the veteran population where there is a high incidence of posttraumatic stress disorder, major depressive disorder, alcohol use, substance abuse, and suicide attempts.[83] These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.[84]

VHA requires routine assessments of pain and the completion of an opioid risk assessment before initiating patients on long-term opioid therapy and recommends against the therapy for patients with untreated substance use disorders. VHA also recommends avoiding drugs capable of inducing fatal interactions, such as opioids with benzodiazepines.[85] Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.[86] To achieve VHA's vision of providing patient-driven healthcare, providers are also required to obtain informed consent from patients and to provide education about the risks, benefits, and alternatives prior to initiating long-term opioid therapy.[87] VHA recommends evaluating patients receiving continued opioid therapy for improvement of pain and opioid-related adverse events at least every three months and more frequently as doses increase.[88]

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

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

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[81] World Health Organization. "Information sheet on opioid overdose," August 2018. https://www.who.int/substance_abuse/information-sheet/en/. (This website was accessed on November 6, 2019.)

[82] Centers for Disease Control and Prevention. "Opioid Overdose, Understanding the Epidemic," December 19, 2018. https://www.cdc.gov/drugoverdose/epidemic. (The website was accessed on November 6, 2019.)

[83] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. February 2017. https://www.healthquality.va.gov/guidelines/Pain/cot/. (The website was accessed on November 6, 2019.)

[84] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

[85] According to the U.S. Department of Justice's Drug Enforcement Administration, benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety." https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. (The website was accessed on December 1, 2019.)

[86] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

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

[88] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

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

VHA also requires facilities to establish a multidisciplinary pain management committee "to provide oversight, coordination, and monitoring of pain management activities and processes." Monitoring measures include, but are not limited to, adherence to published clinical practice guidelines, timeliness of treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment, patient satisfaction, and quality of life.[89] The OIG examined the following indicators for program oversight and evaluation:

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

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 28 selected outpatients who had newly-dispensed (no VA dispensing in previous six months) long-term opioids for pain, daily or intermittently for 90 or more calendar days through VA from July 1, 2018, through June 30, 2019. The team considered whether providers acted in accordance with guidelines for the provision of pain management and the medical center's oversight process for evaluating pain management outcomes and quality.

## Medication Management Findings and Recommendations

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

VA/DoD clinical practice guidelines recommend completion of an aberrant behavior risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug-related behaviors prior to initiating long-term opioid therapy.[90] The OIG determined that providers assessed patients for a history of personal or family substance abuse in 79 percent of the patients and for a history of psychological disease in 75 percent of patients, based on electronic health records reviewed.[91] This may have resulted in providers prescribing opioids for patients at high-risk for misuse.

[89] VHA Directive 2009-053, *Pain Management*, October 28, 2009.

[90] Examples of aberrant drug related behaviors include "lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents." *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

[91] Confidence intervals are not included because the data represents every patient in the study population.

The Medical Director of Pain Management stated that when a provider follows a patient for years and the patient has no history of psychological or behavioral issues, the provider may choose to not conduct all behavioral risk screenings. Providers often want to direct the visit toward a positive discussion, which at times, means choosing to focus on providing effective treatment versus "checking the box," especially when the patient is extremely low risk and is taking a low-dose medication. Additionally, the Medical Director of Pain Management noted that staff nurses conduct numerous screenings, which providers rely heavily upon to inform treatment decisions, and stated that patients often become irritated when asked the same questions at multiple times. Therefore, to facilitate quality patient care, providers relied on the screening surveys and intake information already collected by nurses whenever possible. OIG noted this response but did not see evidence in the patient records that providers were aware of the relevant patient information collected by the nurses.

## Recommendation 17

17. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures that providers complete an aberrant behavior risk assessment to include a history of substance abuse and psychological disease on all patients prior to initiating long-term opioid therapy.

Medical Center concurred.

Target date for completion: June 1, 2021

Medical Center response: The Chief of Staff is responsible for this corrective action plan. The Chief of Staff will ensure that clinicians complete a behavioral risk assessment that includes a history of substance abuse, psychological disease, and aberrant drug related behaviors on patients prior to initiating long-term opioid therapy. Thirty records will be reviewed monthly to ensure a behavioral risk assessment is completed prior to initiating long-term opioid therapy. If less than thirty records are available, a 100 percent review will be completed. The number of patients newly started on long-term opioid therapy that have behavioral risk assessment will be the numerator, and the number of patients newly started on long-term opioid therapy will be the denominator. Compliance will be reported to the Quality Management Oversight Committee at least quarterly. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VA/DoD clinical practice guidelines recommend that providers "obtain urine drug testing prior to initiating or continuing long-term opioid therapy and periodically thereafter."[92] The OIG found that providers conducted urine drug testing 30 days prior to initial dispensing or after

[92] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

initial dispensing in 46 percent of the patients reviewed.[93] This resulted in providers' inability to identify whether patients had substance use disorders, determine potential diversion, or ensure patients adhered to the prescribed medication regimen. The Physical Medicine and Rehabilitation/Pain Management co-chair stated that urine screenings are often done—although not within the time frame used in the OIG review.

## Recommendation 18

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

Medical center concurred.

Target date for completion: June 1, 2021

Medical center response: The Chief of Staff is responsible for this corrective action plan. The Chief of Staff will ensure that health care providers consistently conduct urine drug testing no more than 30 days before or after starting patients on long-term opioid therapy. Thirty records will be reviewed monthly to ensure urine drug screen testing is completed within the 30-day time frame for patients beginning long-term opioid therapy. If less than thirty records are available, a 100 percent review will be completed. The number of patients starting long-term opioid therapy who have urine drug testing completed no more than 30 days prior to or 30 days following the initial dispensing will be the numerator, and the number of patients newly started on long-term opioid therapy will be the denominator. Compliance will be reported to the Quality Management Oversight Committee at least quarterly. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires providers to obtain and document informed consent prior to the initiation of therapeutic treatments that "have a significant risk of complication or morbidity," including long-term opioid therapy. VHA also recommends that the informed consent conversation covers the risks and benefits of opioid therapy, as well as alternative therapies.[94] The OIG determined that providers documented informed consent prior to initiating long-term opioid therapy in 32 percent of the patient electronic health records reviewed.[95] The remaining patients, therefore, may have received treatment without knowledge of the risks associated with long-term opioid therapy including opioid dependence, tolerance, addiction, and intentional or unintentional fatal overdose.

[93] Confidence intervals are not included because the data represents every patient in the study population.

[94] VHA Directive 1005.

[95] Confidence intervals are not included because the data represents every patient in the study population.

The Physical Medicine and Rehabilitation/Pain Management co-chair stated the informed consents are often done, but not within the time frame used in OIG review. This is because providers typically try to wean the patient to a lower dose or are not anticipating long-term opioid use and obtain patient consent when the need is identified. Additionally, the Medical Director of Pain Management stated that discrepancies in charts are sometimes due to difficulties accessing consent notes, and when consents do not populate correctly or quickly, the providers may try to write their own progress note outside of the required template. In addition, the Medical Director of Pain Management reported time limitations may ultimately result in the patient leaving the visit prior to completing the consent after verbally discussing with the provider the imperative elements of opioid use.

## Recommendation 19

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

Medical center concurred.

Target date for completion: June 1, 2021

Medical center response: The Chief of Staff will ensure that healthcare providers consistently obtain and document informed consent prior to initiating long-term opioid therapy. Thirty records will be reviewed monthly to ensure healthcare providers obtain and document informed consent for patients prior to initiating long-term opioid therapy. If less than thirty records are available, a 100 percent review will be completed. The number of patients newly started on long-term opioid therapy who have documented informed consent will be the numerator, and the number of patients newly started on long-term opioid therapy will be the denominator. Compliance will be reported to the Quality Management Oversight Committee at least quarterly. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VA/DoD clinical practice guidelines recommend that providers evaluate the benefits of continued opioid therapy and risk for opioid-related adverse events at least every three months after initiating long-term opioid therapy.[96] The OIG found that providers conducted follow-ups within three months of initiating therapy, assessed adherence to the pain management plan, and the intervention's effectiveness in 57 percent of the patients, based on the electronic health records reviewed.[97] Failure to conduct timely patient follow-up can result in missed opportunities

[96] *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.*

[97] Confidence intervals are not included because the data represents every patient in the study population.

to assess adherence to the therapy plan, effectiveness of treatment, and risks of continued opioid therapy.

The acting Chief of Pharmacy reported that follow-up is difficult if the patient is coming from outside VA on an established medication and dose. The acting Chief of Pharmacy also felt it may be redundant to follow up, and that providers may elect to focus on finding balance between addressing the patient's concerns and avoiding the perception that the provider does not trust the patient. Additionally, the Physical Medicine and Rehabilitation/Pain Management co-chair reported that patients may travel from a distance to the medical center, thus pain management follow-up care was challenging.

## Recommendation 20

20. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures providers follow up with patients within three months and assess adherence to the pain management plan of care and effectiveness of interventions.

Medical center concurred.

Target date for completion: June 1, 2021

Medical center response: The Chief of Staff will ensure health care providers follow up with patients within the required three-month time frame after initiating long-term opioid-therapy. Thirty records will be reviewed monthly to ensure follow up is completed after initiating long-term opioid therapy. If less than thirty records are available, a 100 percent review will be completed. The number of patients newly started on long-term opioid therapy who have documented health care follow up by their provider within the required three-month time frame will be the numerator, and the number of patients newly started on long-term opioid therapy will be the denominator. We consider compliance within plus or minus 30 days of the three-month time frame. Compliance will be reported to the Quality Management Oversight Committee at least quarterly. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

## Mental Health: Suicide Prevention Program

In 2017, suicide was the 10th leading cause of death, with approximately 47,000 lives lost across the United States.[98] The suicide rate was 1.5 times greater for veterans than for non-veteran adults and estimated to represent approximately 22 percent of all suicide deaths in the United States.[99] Veterans who recently used VHA services had higher rates of suicide than other veterans and non-veterans.[100]

VHA has identified suicide prevention as a top priority and implemented various evidence-based approaches to reduce the veteran suicide rate. In addition to expanded mental health services and community outreach, VHA has developed comprehensive screening and assessment processes to identify at-risk patients.[101]

VHA requires that each medical center and very large CBOC have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.[102] The OIG examined various requirements related to SPCs:

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

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

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

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

[100] Veterans who recently used VHA services are defined as having an encounter in the calendar year of death or in the previous year; Office of Mental Health and Suicide Prevention, *VA National Suicide Data Report 2005-2016.*

[101] *VA Office of Mental Health and Suicide Prevention Guidebook,* June 2018.

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

in his or her electronic health record as soon "as possible but no later than 1 business day after such determination by the SPC."[103] According to VHA, "Some studies indicate that up to two-thirds of patients who commit suicide have seen a physician in the month before their death…The primary purpose of the High Risk for Suicide PRF is to communicate to VA staff that a veteran is at high risk for suicide and the presence of a flag should be considered when making treatment decisions."[104] The HRS PRF is reviewed at least every 90 days and depending on changes to the suicide risk status, the HRS PRF will remain active or be removed.[105] Additionally, VHA requires designated high-risk patients to have a completed suicide safety plan and four face-to-face visits with an acceptable provider within the first 30 days of designation.[106]

The OIG noted that from July 1, 2018, to June 30, 2019 (the time frame for this retrospective review), VHA required that "Any patient determined to be High Risk for Suicide [by the licensed independent provider] must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination."[107] However, on January 16, 2020, the Deputy Undersecretary for Health for Operations and Management changed the requirement for the HRS PRF placement to be "as soon as possible but no later than 1 business day after determination by the SPC."[108] VHA further provided additional clarifying information:

- The "SPC exclusively controls the HRS-PRF and must limit their use to patients who meet the criteria of being placed on the facility high-risk suicide list."
- "The time frame of placing the flag begins once the SPC makes the determination that an HRS-PRF is warranted."
- The SPC's determination process "may be beyond 24 hours after a referral, due to case consultation and review."[109]

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

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

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

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

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

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

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

[109] VHA, *Response to Questions by VA OIG Office of Healthcare Inspections from February 12, 2020*, received February 19, 2020.

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

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRF to "occur no earlier than 10 days before and no later than 10 days after the 90-day due date."[110]

Inspectors examined the completion of several requirements:

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

All VHA employees must complete suicide risk and intervention training within 90 days of entering their position. Clinical staff (including physicians, psychologists, dentists, registered nurses, physician assistants, pharmacists, social workers, case managers, and Vet Center counselors) must complete Suicide Risk Management Training for Clinicians, and nonclinical staff must complete Operation S.A.V.E. training.[111] VHA also requires that all staff receive annual refresher training.[112] In addition, suicide prevention coordinators are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.[113]

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

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

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

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

[113] The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training. Deputy Undersecretary for Health for Operations and Management (DUSHOM) Memorandum, *Suicide Awareness Training*, April 11, 2017.

- Relevant documents;
- The electronic health records of 44 randomly selected outpatients whose electronic health records were flagged as high risk for suicide from July 1, 2018, to June 30, 2019; and
- Staff training records.

## Mental Health Findings and Recommendations

The medical center complied with requirements for a designated SPC, appropriate follow-up for no-show high-risk appointments, suicide safety plans, and suicide prevention training.

However, the OIG found deficiencies. With VHA's original requirement that was in place when these patients received care—that "Any patient determined to be High Risk for Suicide must have a[n] HRS Flag placed in his or her chart as soon as possible but no later than 24 hours after such determination"[114]—the OIG estimated that 89 percent of HRS PRFs were placed within 24 hours of referral to the SPC.[115] Based on the current updated requirement that the SPC be responsible for determining placement of the HRS PRF (without a defined timeframe for doing so), the OIG further calculated that the average time from referral to HRS PRF placement for the patients reviewed was 1 day (observed range was 0–9 days).

Further, the OIG noted concerns with the review of HRS PRFs within the required time frame. VHA required that all patients with an HRS PRF be reevaluated at least every 90 days and there is documented justification for continuing or discontinuing the flag.[116] The OIG estimated that 45 percent of patients with an HRS PRF were reevaluated at least every 90 days.[117] However, based upon the updated requirement that HRS PRFs be reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that 1 of 44 patients did not meet the expected time frame (observed range was 52–100 days).

Additionally, the OIG noted concern with the completion of at least four mental health visits within 30 days of HRS PRF placement.

VHA requires a veteran to have four follow-up visits with a qualified provider within 30 days of the HRS PRF placement. The follow-up visits should be face-to-face unless the veteran requests a telephonic visit, and there must be documentation identifying the patient's preference for a

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

[115] The OIG estimated that 95 percent of the time, the true compliance rate is between 78.7 and 97.6 percent, which is statistically significantly below the 90 percent benchmark.

[116] *VA's Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide.*

[117] The OIG estimated that 95 percent of the time, the true compliance rate is between 31.0 and 60.0 percent, which is statistically significantly below the 90 percent benchmark.

telephone call.[118] The OIG found that 75 percent of the electronic health records reviewed had documentation of four follow-up appointments.[119] Insufficient follow-up on high-risk patients or a lack of documented patient preference may potentially lead to a lack of appropriate and timely care. Of note, the medical center had documented telephone visits for many of the records reviewed; however, the records lacked evidence that the telephonic visit was the patient's preference. The SPCs stated they believed that telephone appointments met the intent of the directive and were unaware that the patient's preference for telephone visits had to be documented in the medical record.

## Recommendation 21

21. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that providers conduct four follow-up appointments within the prescribed time frame and include documentation of the patient's preference for a telephone call, if applicable.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Chief of staff is responsible for this action. The Outpatient Mental Health Program Manager will revise the standard of work by August 3, 2020, to include updated guidance on conducting follow-up appointments and documentation of telephone call preference. The Outpatient Mental Health Program Managers will conduct monthly audits to monitor provider compliance with documentation of the four follow-up appointments within 30 days of high-risk flag placement and the documentation of telephone call preference, if applicable. Ten cases will be reviewed monthly to determine compliance. If less than ten cases are available, a 100 percent review will be completed for the month. The numerator will be the number of patients flagged as high risk for suicide who had documentation of four follow-up appointments within 30 days of the high-risk flag placement and, if contacted by telephone, have documentation of phone contact as a preference. The denominator will be the total number of patients who are 30 days post placement of a high risk for suicide flag.

The Outpatient Mental Health Program Managers will collate and report the results to the Mental Health Division Managers monthly. The Mental Health Division Managers will report the results to the Chief of Staff and Quality Management Oversight Committee on a quarterly basis. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

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

[119] The OIG estimated that 95 percent of the time, the true compliance rate is between 61.5 and 87.2 percent, which is statistically significantly below the 90 percent benchmark.

## Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decisions (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTD. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by "…eliciting, documenting, and honoring patients' values, goals, and preferences."[120]

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD policy by July 12, 2018.[121] Implementation requirements included initiating conversations about the goals of care. A goals of care conversation is a discussion between a healthcare provider and a patient or surrogate to help define the patient's values, goals, and preferences for care and, based on the discussion, make choices about starting, limiting, or ceasing LSTs.[122] VHA requires practitioners to initiate goals of care conversations with high-risk patients—including hospice patients or their surrogates—within a time frame that meets the medical needs of the patient or at the time of a triggering event.[123]

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

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

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

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

[122] According to VHA Handbook 1004.03(1), a surrogate is legally authorized under VA policy to serve as the decision maker on behalf of the patient should the patient lose decision-making capacity.

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

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

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

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

The medical center was assessed for its adherence to requirements for goals of care conversations:

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

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service.[124] Inspectors examined if the medical center established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the medical center complied with the OIG-selected requirements related to LSTD for hospice patients, the inspection team reviewed relevant documents and interviewed key employees. The team also reviewed the electronic health records of 44 hospice patients who had triggering events from July 12, 2018, through June 30, 2019.

## Care Coordination Findings and Recommendations

Generally, the medical center met the above requirements. The OIG made no recommendations.

[124] VHA Handbook 1004.03(1).

## Women's Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.[125] According to data released by the National Center for Veterans Analysis and Statistics in May 2019, the total veteran population and proportion of male veterans are projected to decrease while the proportion of female veterans are anticipated to increase.[126] To help the VA better understand the needs of the growing women's veteran population, efforts have been made by VHA to identify and address the urgent needs "by examining health care use, preferences, and the barriers Women Veterans face in access to VA care."[127] Additionally, a VA report in 2016 on suicide among veterans pointed out concerning trends in suicide among women veterans and discussed "the importance of understanding suicide risk among women veterans and developing gender-tailored suicide prevention strategies."[128]

VHA requires that all eligible and enrolled women veterans have access to timely, high-quality, and comprehensive healthcare services in a sensitive and safe environment. Facilities must, therefore, ensure availability of appropriate resources, services, and staffing ratios.[129] VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veteran health committee that "develops and implements a Women's Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans."[130]

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

- Provision of care requirements

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

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

[127] U.S. Department of Veterans Affairs, "Study of Barriers for Women Veterans to VA Health Care," Final Report, April 2015. https://www.womenshealth.va.gov/docs/Womens%20Health%20Services_Barriers%20to%20Care%20Final%20Report_April2015.pdf. (The website was accessed on September 16, 2019.)

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

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

[130] VHA Directive 1330.01(3).

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

## Women's Health Findings and Recommendations

The medical center complied with requirements for some of the provision of care indicators and staffing elements reviewed. However, the OIG identified weaknesses with gynecologic care coverage, the Women Veterans Health Committee, quality assurance data, and women veterans program manager duties.

VHA requires facilities to have processes and procedures in place for 24 hours a day, 7 days per week coverage in the emergency department and medical center-wide call coverage for gynecologic care.[131] The OIG determined the medical center does not provide 24 hours a day, 7 days per week coverage for gynecological care, potentially resulting in the medical center not providing quality comprehensive women's healthcare. The medical center has a women's health clinic; when the clinic is not open, coverage is provided through a call schedule which only listed the phone number of the resident on call. The OIG requested a call schedule for the attending

[131] VHA Directive 1330.01(3).

providers responsible for supervising the resident staff. The Division Manager for Primary Care provided the schedule for July 2019, through January 2020; however, the call schedule only included two provider names and most days of the months listed no coverage. The Women's Health Medical Director reported that some on-call coverage for Gynecology is provided by practitioners who do not work at the medical center. On such days, the residents would not assume care responsibilities for Gynecology patients, and instead, the patients would be transferred to the community if immediate treatment was needed or referred to the on-site clinic. The medical center managers were unable to provide any policy or procedure describing this coverage process.

## Recommendation 22

22. The Chief of Staff determines the reasons for noncompliance and ensures that processes and procedures are in place to ensure gynecological care is available 24 hours a day, 7 days per week.

Medical center concurred.

Target date for completion: March 5, 2021

Medical center response: The Chief of Staff is responsible for this action. The Women Veterans Program Manager reviewed the facility and Emergency Department Standard Operating Procedures (SOPs) to ensure that there are provisions for after-hours Gynecologic care. The facility policy provided clear guidance for after-hours gynecologic care. The Manager of the Emergency Department will revise the Emergency Department's SOP to include specific language addressing the provision of after-hours gynecologic care. The Emergency Department's SOP will be approved by the Chief of Emergency Medicine, Associate Director for Patient Care Services, Chief of Staff, and Medical Center Director by August 28, 2020.

With respect to ensuring gynecological care is available 24 hours a day, 7 days a week, Milwaukee VA has reviewed the current gynecological care practices and processes in place. As gynecological care is currently provided in-person during part-time, daytime hours to include both outpatient clinics and advanced ambulatory procedures (not requiring inpatient care), the remainder of gynecological care above the level of services currently provided and when there is no gynecology provider present is provided through Community Care. Appropriate gynecological care will be assessed by review of ten emergency room records monthly by a gynecology-trained physician, in collaboration with the Women Veterans Program Manager and Women's Health Medical Director, ensuring that either the gynecological care provide in-house or a decision to refer to Community Care was appropriate. If less than ten records are available, a 100 percent review will be completed for the month. The numerator will be the number of events where appropriate care was rendered, and the denominator will be the number of gynecology records reviewed for the month. Compliance will be reported monthly through the Medical Executive Committee. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership representing multiple disciplines. That membership includes a women veterans program manager; a women's health medical director; "representatives from primary care, mental health, medical and/or surgical subspecialties, gynecology, pharmacy, social work and care management, nursing, ED [emergency department], radiology, laboratory, quality management, business office/Non-VA Medical Care; and a member from executive leadership." [132]

The OIG requested the Women Veterans Health Committee and Medical Executive Board meeting minutes for June through December 2019 and found that the Women Veterans Health Committee had not met during that time. The last meeting was held in May 2019, and during the

[132] VHA Directive 1330.01(3).

same period, the Medical Executive Board received one report in June 2019. Failure to meet quarterly and/or report activities to executive leadership has the potential to impede oversight and support of the women's health program. The Division Manager for Primary Care reported the Women Veterans Program Manager left in August 2019, and the Women's Health Medical Director's priority was ensuring the clinical elements of the program were in place during this transition. In addition, the Division Manager for Primary Care reported a delay in getting the Women Veterans Program Manager vacancy advertised, which delayed the hiring process by an additional five weeks.

In addition, the Women Veterans Health Committee charter did not list required membership from medical and/or surgical subspecialties, Gynecology, Emergency Department, Radiology, Laboratory, Quality Management, Business Office/Non-VA Medical Care, or executive leadership. This could result in a lack of expertise and oversight of data analyses and reviews as the committee planned and carried out improvements for quality and equitable care for women veterans. The Division Manager for Primary Care stated that the prior Women Veterans Program Manager, who left in August 2019, was responsible for sending out meeting invites, and due to the "abrupt timing," a transition with the assigned interim staff was not completed.

## Recommendation 23

23. The Medical Center Director determines the reasons for noncompliance and makes certain that required members are assigned and consistently attend Women Veterans Health Committee meetings and report to executive leaders.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Chief of Staff is responsible for this action. The Women Veterans Program Manager ensures that the Women Veterans Health Committee has required representation at its meetings. The Program Manager/designee will audit for required attendance at the quarterly Women Veterans Health Committee meetings. The numerator will be the number of meetings the required members (or alternates) attend, and the denominator will be the total number of meetings held. Compliance will be reported to the Women Veterans Health Committee, the Medical Executive Committee, and to the Quality Management Oversight Committee on a quarterly basis. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires facilities to collect and track quality assurance data related to appropriate and timely follow-up care of abnormal breast cancer screening results, cervical screening results, customer satisfaction initiatives and outcomes, and access to care.[133] The OIG found the medical

[133] VHA Directive 1330.01(3).

center did not collect and track all the required quality assurance data. This could prevent the medical center from identifying opportunities necessary for practice improvements, ensuring appropriate follow-up, and measuring the effectiveness of actions on a regular basis. As to data and quality improvement, the Deputy Nurse Manager, who was transitioning to the Women Veterans Program Manager position, reported the work is being done; however, documenting improvements through the committee was not occurring.

## Recommendation 24

24. The Chief of Staff evaluates and determines any additional reason(s) for noncompliance and ensures that required quality assurance data related to women veterans' health care services are collected and tracked for improvement opportunities.

Medical center concurred.

Target date for completion: June 30, 2021

Medical center response: The Chief of Staff is responsible for this action. The Women Veterans Program Manager and the Women's Health Medical Director will develop a Women Veterans Health Program Quality Plan by August 1, 2020.

The Women Veterans Health Program leadership will report quality metrics to the Women Veterans Health Committee. The numerator will be the number of Women Veterans Health Committee meeting minutes containing quality data, and the denominator will be the number of meetings. Compliance will be reported to the Medical Executive Committee and the Quality Management Oversight Committee on a quarterly basis. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

VHA requires the facility to have a women veterans program manager who is full-time and free of collateral duties.[134] The OIG found the medical center's interim Women Veterans Program Managers were also serving as the Maternity Care Coordinator. Additionally, the OIG inspectors were informed that beginning in February 2020, the full-time Women Veterans Program Manager would be assigned the role of Maternity Care Coordinator once the position is assumed. This could negatively impact the medical center's ability to deliver the best health care services to their women veteran patients. The OIG was not provided with a reason why the maternity care coordinator responsibilities were being assigned to the Women Veterans Program Manager other than cross-coverage between the positions had always been the practice at the medical center.

[134] VHA Directive 1330.01(3).

## Recommendation 25

25. The Chief of Staff determines the reason(s) for noncompliance and ensures the Women Veterans Program Manager is full-time and free of collateral duties.[135]

Medical center concurred.

Target date for completion: Completed

Medical center response: The Chief of Staff is responsible for this action. The Chief of Staff assigned the collateral duties that had been performed by the Interim Women Veterans Program Manager to the Women's Health Coordinator on February 18, 2020.

The Chief of Staff approved the full-time Women Veterans Program Manager Functional Statement on August 23, 2019. The functional statement does not expect the Women Veterans Program Manager to perform collateral duties. Based on the evidence provided, we request closure of this recommendation.

[135] The OIG reviewed evidence that sufficiently demonstrated that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

## High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have a sterile processing services (SPS) "to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment…"[136] The goal of SPS is to "...provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections."[137] To ensure this, VHA requires facilities to conduct the following activities:

- Maintain a current inventory list of all RME
- Have standard operating procedures (SOPs) that are based on current manufacturer's guidelines and reviewed at least triennially
- Use CensiTrac® Instrument Tracking System for tracking reprocessed instruments[138]
- Perform annual risk analysis and report results to the VISN SPS Management Board
- Monitor data for reprocessing and storing RME
- Conduct annual airflow/ventilation system inspections[139]

VHA requires strict controls that closely monitor climate, storage, and sterilization parameters and additionally requires that quality assurance documentation of this monitoring be maintained for a minimum of three years.[140] The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.[141]

In addition, RME reprocessing areas must be clean, restricted, and airflow-controlled. All areas where RME reprocessing occurs must have safety data sheets, an unobstructed eyewash station, personal protective equipment available for immediate use, and SOPs readily available to guide the reprocessing of RME.[142]

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

[137] Association for Professionals in Infection Control and Epidemiology, *APIC Text of Infection Control and Epidemiology,* Chapter 107: Sterile Processing, April 26, 2019. https://text.apic.org/toc/infection-prevention-for-support-services-and-the-care-environment/sterile-processing#book_section_17348. (The website was accessed on May 14, 2019.)

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

[139] VHA Directive 1116(2).

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

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

[142] VHA Directive 1116(2).

VHA also requires facilities to provide training for staff who reprocess RME; this training must be provided and documented prior to the reprocessing of equipment. The required training includes mandatory initial competencies, continued annual and essential staff competency assessments, and monthly continuing education. This ensures that staff have sufficient aptitude, knowledge, and skills to effectively and safely reprocess and sterilize RME.[143]

To determine whether the medical center complied with OIG-selected requirements, the inspection team examined relevant documents and training records; conducted physical inspections of the SPS, Gastroenterology SPS, and sterile storage areas; and interviewed key managers and staff on the following:

- Requirements for administrative processes
  - RME inventory file is current
  - SOPs are based on current manufacturer's guidelines and reviewed at least triennially
  - CensiTrac® System used
  - Risk analysis performed and results reported to the VISN SPS Management Board
  - Airflow checks made
  - Eyewash station checked
  - Daily cleaning schedule maintained
- Monitoring of quality assurance
  - High-level disinfectant solution tested
  - Bioburden tested
- Physical inspections of reprocessing and storage areas
  - Traffic restricted
  - Airflow monitored
  - Personal protective equipment available
  - Area is clean
  - Eating or drinking in the area prohibited
  - Equipment properly stored
  - Required temperature and humidity maintained

[143] VHA Directive 1116(2).

- Completion of staff training, competency, and continuing education
  - Required training completed in a timely manner
  - Competency assessments performed
  - Monthly continuing education received

## High-Risk Processes Findings and Recommendations

The medical center generally complied with the requirements for the administrative processes, quality assurance monitoring, and reprocessing area physical inspections. During review of SOPs and manufacturer's instructions for use (IFU), the IFU referenced by the medical center cited a different version number than the most current one. The SPS Chief and Re-usable Medical Equipment (RME) Coordinator stated that although the IFU version numbers were different, the manufacturer's print dates were the same. In addition, the OIG noted that a portion of the colonoscope SOP manual flushing section did not align with the IFU. This was corrected while OIG was on site. There were no other SOP/IFU discrepancies noted. However, the OIG identified deficiencies with the annual risk analysis, cleaning schedules, and equipment storage.

VHA requires that the SPS Chief performs an annual risk analysis and report the results to the VISN SPS Management Board.[144] The OIG found evidence that a risk analysis was completed for FY 2019; however, the results were not reported the VISN SPS Board. Failure to report the risk analysis may delay or prevent the identification of problems or process failures and result in missed opportunities for mitigation. The SPS Chief reported this was an oversight due, in part, to collateral duties while assisting other medical centers with VISN SPS reviews and not receiving the annual VISN action item prompting the report.

## Recommendation 26

26. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and makes certain that the Sterile Processing Services Chief consistently performs and documents an annual risk analysis and reports the results to the Veterans Integrated Service Network Sterile Processing Services Management Board.[145]

[144] VHA Directive 1116(2).

[145] The OIG reviewed evidence that sufficiently demonstrated that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

Medical center concurred.

Target date for completion: Completed

Medical center response: The Associate Director for Patient Care Services is responsible for this action. The Chief of Sterile Processing Services (SPS) and Infection Control reviewed and approved the Sterile Processing Risk Analysis in a multi-disciplinary manner on February 21, 2020. The Chief of SPS submitted the Sterile Processing Risk Analysis to VISN 12 on February 28, 2020, for out of cycle review by the VISN 12 Sterile Processing Service Chief Board. The Sterile Processing Risk Analysis was acknowledged in the VISN SPS Board minutes on May 14, 2020. Based on the evidence provided, we request closure of this recommendation.

Additionally, according to VHA, the Chief of SPS must "develop, implement and enforce a written daily cleaning schedule for all SPS areas…"[146] Although evidence of a written cleaning schedule for Environmental Management Service (EMS) was posted and included all three shift responsibilities, the schedule had only one EMS signature covering Monday through Friday and no documentation for weekends. A written cleaning schedule aids in achieving and maintaining a clean environment. The EMS Supervisor and SPS Chief stated the EMS staff and supervisors were aware of the expectations; however, inconsistent oversight and monitoring of the cleaning schedules contributed to the lack of compliance.

## Recommendation 27

27. The Assistant Director evaluates and determines any additional reasons for noncompliance and ensures that the written cleaning schedule for Sterile Processing Services is enforced.

Medical center concurred.

Target date for completion: March 31, 2021

Medical center response: The Deputy Director is responsible for this action. The Manager of Environmental Management Services (EMS) / designee will conduct weekly cleaning compliance audits. The numerator will be the number of audits which meet the criteria of adherence to the cleaning schedule, and the denominator will be the total number of weekly audits of the Sterile Processing Services (SPS). The Manager of EMS will report the audit results to the Deputy Director, Chief of Sterile Processing Services, and the Environment of Care Committee at least monthly, with quarterly data summaries sent to the Quality Management Oversight Committee. The SPS Chief will report the compliance data to the Associate Director for Patient Care Services on a monthly basis. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

[146] VHA Directive 1116(2).

Additionally, VHA requires that high-level disinfected endoscopes "…are to be hung so that no part of the scope touches the bottom of the cabinet and in sufficient space for storage of multiple endoscopes without touching."[147] The OIG found that three high-level disinfected endoscopes were touching either the sides or bottom of the cabinet. Correct storage of endoscopes reduces the risk of contamination or damage to equipment. The SPS Chief stated larger cabinets were purchased specifically for endoscopes; however, upon delivery, there was a need to use the cabinets for bronchoscope storage. The Assistant Nurse Manager for the gastrointestinal area and the SPS Chief reported additional cabinets were approved and were in the process of being purchased. Both managers stated that the staff were aware of the expectation to send the scopes for reprocessing when they are found not hanging freely.

## Recommendation 28

28. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that high-level disinfected scopes are stored properly.

Medical center concurred.

Target date for completion: February 28, 2021

Medical center response: The Associate Director for Patient Care Services is responsible for this action. The Sterile Processing Service (SPS) Chief, in collaboration with the Gastroenterology Laboratory (GI Lab) Program Manager, purchased and installed larger endoscope storage cabinets for the GI Lab. The cabinets were installed the week of June 15, 2020. The endoscope cabinets are constructed and configured to prevent scopes from touching the sides and the bottom of the cabinet. On May 28, 2020 the Olympus representative provided education to the staff responsible for handing and managing the endoscopes on the proper handling and storage of the endoscopes in the new cabinets. The GI Program Manager ensured that all responsible staff completed the competency assessment titled SOP #069 Flexible Scope Management. The competencies were completed by June 5, 2020.

The GI Lab manager/designee will conduct weekly audits. The numerator will be the number of audits which meet the criteria of proper handling and storage of endoscopes, and the denominator will be the total number of scopes audited weekly.

The GI Lab Manager will report the audit results to the Acute Outpatient Division Manager, at least monthly, and will submit quarterly data summaries to the Quality Management Oversight Committee. The Acute Outpatient Division Manager will report the results to the Associate Director for Patient Care Services monthly. The monitoring and auditing will continue until 90 percent compliance has been reached for two consecutive quarters.

[147] VHA Directive 1116(2).

# Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

| Healthcare Processes | Requirements | Conclusion |
|---|---|---|
| Leadership and Organizational Risks | • Executive leadership position stability and engagement<br>• Employee satisfaction<br>• Patient experience<br>• Accreditation surveys and oversight inspections<br>• Factors related to possible lapses in care and medical center response<br>• VHA performance data (facility or system)<br>• VHA performance data for CLCs | Twenty-eight OIG recommendations ranging from documentation concerns to noncompliance that can lead to patient and staff safety issues or adverse events are attributable to the Director, Chief of Staff, ADPCS, and Assistant Director. See details below. |

| Healthcare Processes | Requirements | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Quality, Safety, and Value | • QSV Committee<br>• Protected peer reviews<br>• UM reviews<br>• Patient safety | • Specific action items are documented in Quality Management Oversight Committee minutes when problems or opportunities for improvement are identified. | • Physician utilization management advisors consistently document their decisions in the National Utilization Management Integration database.<br>• Required representatives are assigned and consistently participate in interdisciplinary reviews of utilization management data. |

| Healthcare Processes | Requirements | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Medical Staff Privileging | • FPPEs<br>• OPPEs<br>• Provider exit reviews and reporting to state licensing boards | • Clinical managers define in advance, communicate, and document criteria in practitioner profiles for focused professional practice evaluations.<br>• Service chiefs initiate, complete, and document the results of focused professional practice evaluations in practitioner profiles.<br>• Focused professional practice evaluations include defined time frames.<br>• Reprivileging decisions are based on service-specific ongoing professional practice evaluation data.<br>• Service chiefs collect and review ongoing professional practice evaluation data for determination to recommend continuation of privileges.<br>• Licensed independent practitioners are evaluated by providers with similar training and privileges.<br>• Medical Executive Committee meeting minutes consistently reflect the review of professional practice evaluation results in the decision to recommend continuation of privileges. | • Provider exit review forms are completed within seven calendar days of licensed healthcare professionals departing the medical center. |

| Healthcare Processes | Requirements | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Environment of Care | • Medical center<br>  ○ General safety<br>  ○ Special use spaces<br>  ○ Environmental cleanliness and infection prevention<br>  ○ Privacy<br>  ○ Accommodation and privacy for women veterans<br>  ○ Logistics<br>• Inpatient mental health unit<br>  ○ General safety<br>  ○ Special use spaces<br>  ○ Environmental cleanliness and infection prevention<br>  ○ Privacy<br>  ○ Accommodation for women veterans<br>  ○ Logistics<br>• Community-based outpatient clinic<br>  ○ General safety<br>  ○ Special use spaces<br>  ○ Environmental cleanliness and infection prevention<br>  ○ Privacy<br>  ○ Privacy for women veterans<br>  ○ Logistics | • Biohazardous rooms are not used to store clean items.<br>• Safe and clean environment is maintained throughout the medical center and outpatient clinic buildings.<br>• Patient care equipment is clean and ready for patient use. | • Clean/sterile storeroom solid-bottom shelves are clean.<br>• Access is controlled to information technology rooms. |

| Healthcare Processes | Requirements | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Medication Management: Long-Term Opioid Therapy | • Provision of pain management using long-term opioid therapy<br>• Program oversight and evaluation | • Providers complete aberrant behavior risk assessments to include a history of substance abuse and psychological disease on all patients prior to initiating long-term opioid therapy.<br>• Providers consistently conduct urine drug testing for patients on long-term opioid therapy.<br>• Providers obtain and document informed consent consistently for patients who are initiating long-term opioid therapy.<br>• Providers follow up with patients within three months and assess adherence to pain management plan of care and effectiveness of the intervention. | • None |
| Mental Health: Suicide Prevention Program | • Designated facility suicide prevention coordinator<br>• Provision of suicide prevention care<br>• Completion of suicide prevention training requirements | • Providers conduct four follow-up appointments within prescribed time frame and include documentation of the patient's preference for a telephone call. | • None |
| Care Coordination: Life-Sustaining Treatment Decisions | • LSTD multidisciplinary committee<br>• Goals of care conversation documentation<br>• LSTD note/orders completed by an authorized provider or delegated | • None | • None |

| Healthcare Processes | Requirements | Critical Recommendations for Improvement | Recommendations for Improvement |
|---|---|---|---|
| Women's Health: Comprehensive Care | • Provision of care<br>• Program oversight and performance improvement data monitoring<br>• Staffing requirements | • Processes and procedures are in place to ensure gynecological care is available 24 hours a day, 7 days per week. | • Required members are assigned and consistently attend Women Veterans Health Committee meetings and report to executive leaders.<br>• Quality assurance data related to women veterans' health care services are collected and tracked for improvement opportunities.<br>• The Women Veterans Program Manager is full-time and free of collateral duties. |
| High-Risk Processes: Reusable Medical Equipment | • Administrative processes<br>• Data monitoring<br>• Physical inspection<br>• Staff training | • High-level disinfected scopes are stored properly. | • Sterile Processing Services Chief performs and documents an annual risk analysis and reports the results to the VISN Sterile Processing Services Management Board.<br>• Written cleaning schedule for the Sterile Processing Services is enforced. |

# Appendix B: Medical Center Profile

The table below provides general background information for this high complexity (1a) affiliated[1] medical center reporting to VISN 12.[2]

**Table B.1. Profile for Clement J. Zablocki VA Medical Center (695) (October 1, 2016, through September 30, 2019)**

| Profile Element | Medical Center Data FY 2017[3] | Medical Center Data FY 2018[4] | Medical Center Data FY 2019[5] |
|---|---|---|---|
| Total medical care budget in dollars | $659,069,474 | $701,146,290 | $730,511,040 |
| Number of: | | | |
| • Unique patients | 63,955 | 64,350 | 63,937 |
| • Outpatient visits | 818,682 | 824,165 | 819,053 |
| • Unique employees[6] | 3,399 | 3,509 | 3,596 |
| Type and number of operating beds: | | | |
| • Community living center | 113 | 113 | 113 |
| • Domiciliary | 150 | 150 | 125 |
| • Medicine | 81 | 81 | 81 |
| • Mental health | 34 | 34 | 34 |
| • Rehabilitation medicine | 11 | 11 | 11 |
| • Residential rehabilitation | 9 | 9 | 9 |
| • Spinal cord injury | 38 | 38 | 38 |
| • Surgery | 32 | 32 | 32 |
| Average daily census: | | | |
| • Community living center | 89 | 87 | 92 |
| • Domiciliary | 116 | 111 | 96 |
| • Medicine | 71 | 66 | 70 |
| • Mental health | 21 | 21 | 18 |
| • Rehabilitation medicine | 7 | 6 | 7 |

[1] Associated with a medical residency program.

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

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

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

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

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

| Profile Element | Medical Center Data FY 2017[3] | Medical Center Data FY 2018[4] | Medical Center Data FY 2019[5] |
|---|---|---|---|
| • Residential rehabilitation | 7 | 7 | 7 |
| • Spinal cord injury | 18 | 19 | 18 |
| • Surgery | 21 | 21 | 17 |

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

# Appendix C: VA Outpatient Clinic Profiles[1]

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

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

| Location | Station No. | Primary Care Workload/ Encounters | Mental Health Workload/ Encounters | Specialty Care Services[3] Provided | Diagnostic Services[4] Provided | Ancillary Services[5] Provided |
|---|---|---|---|---|---|---|
| Cleveland, WI | 695GC | 7,735 | 2,401 | Dermatology<br>Endocrinology<br>Gastroenterology<br>Infectious disease<br>Pulmonary/Respiratory disease | EKG | Pharmacy<br>Weight management |

[1] Includes all outpatient clinics in the community that were in operation as of August 27, 2019. The OIG omitted Milwaukee, WI (695QA) as no workload/encounters or services were reported.

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

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

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

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

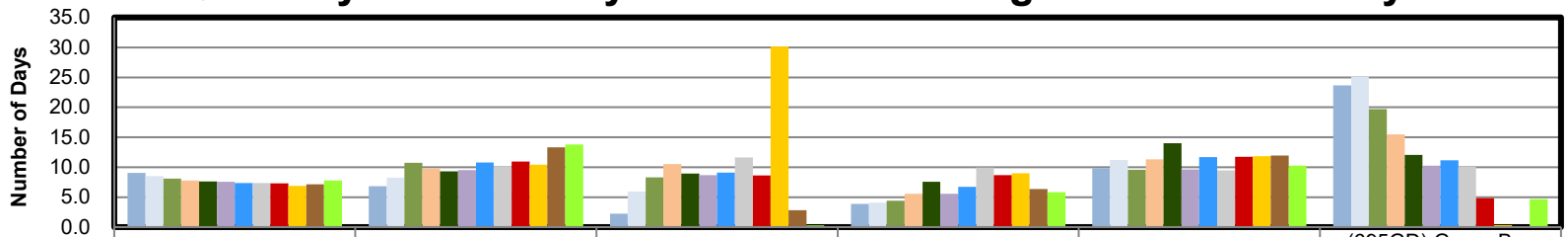
| Location | Station No. | Primary Care Workload/ Encounters | Mental Health Workload/ Encounters | Specialty Care Services[3] Provided | Diagnostic Services[4] Provided | Ancillary Services[5] Provided |
|---|---|---|---|---|---|---|
| Appleton, WI | 695BY | 33,551 | 12,696 | Dermatology<br>Endocrinology<br>Eye<br>Gastroenterology<br>General surgery<br>Infectious disease<br>Poly-Trauma<br>Podiatry<br>Pulmonary/Respiratory disease<br>Urology | EKG<br>Laboratory & Pathology<br>Radiology | Pharmacy<br>Social work<br>Weight management |
| Union Grove, WI | 695GA | 7,188 | 3,003 | Dermatology<br>Infectious disease<br>Pulmonary/Respiratory disease | EKG | Pharmacy<br>Weight management |

| Location | Station No. | Primary Care Workload/ Encounters | Mental Health Workload/ Encounters | Specialty Care Services[3] Provided | Diagnostic Services[4] Provided | Ancillary Services[5] Provided |
|---|---|---|---|---|---|---|
| Green Bay, WI | 695GD | 28,295 | 9,930 | Allergy<br>Cardiology<br>Dermatology<br>Endocrinology<br>Eye<br>Gastroenterology<br>General surgery<br>Hematology/Oncology<br>Infectious disease<br>Nephrology<br>Orthopedics<br>Otolaryngology<br>Podiatry<br>Poly-Trauma<br>Pulmonary/Respiratory disease<br>Rheumatology<br>Urology | EKG<br>Laboratory & Pathology<br>Radiology<br>Vascular lab | Dental<br>Pharmacy<br>Prosthetics<br>Social work<br>Weight management |

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

# Appendix D: Patient Aligned Care Team Compass Metrics[1]

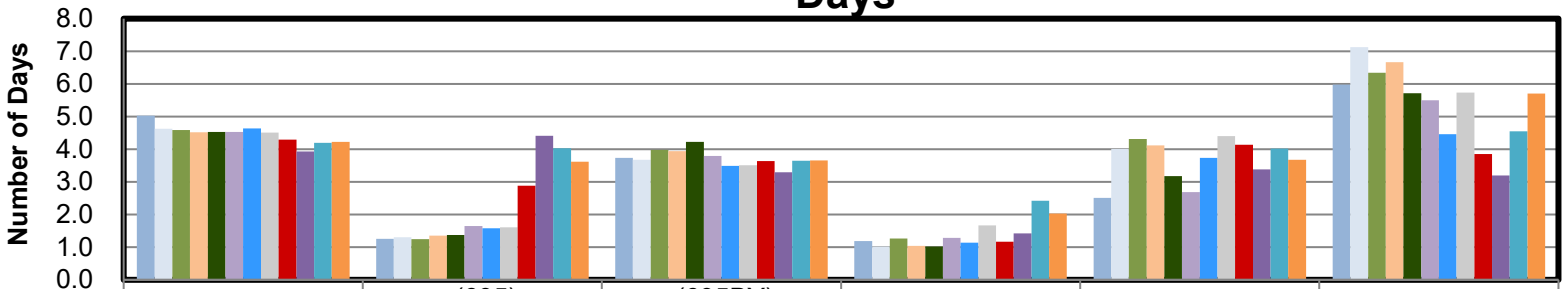
## Quarterly New Primary Care Patient Average Wait Time in Days




| | VHA Total | (695) Milwaukee, WI (Clement J. Zablocki) | (695BY) Appleton, WI (John H. Bradley) | (695GA) Union Grove, WI | (695GC) Cleveland, WI | (695GD) Green Bay, WI (Milo C. Huempfner) |
|---|---|---|---|---|---|---|
| JAN-FY19 | 9.0 | 6.8 | 2.2 | 3.9 | 9.8 | 23.7 |
| FEB-FY19 | 8.5 | 8.3 | 5.9 | 4.1 | 11.2 | 25.1 |
| MAR-FY19 | 8.1 | 10.7 | 8.3 | 4.4 | 9.6 | 19.7 |
| APR-FY19 | 7.8 | 9.8 | 10.5 | 5.6 | 11.3 | 15.5 |
| MAY-FY19 | 7.6 | 9.3 | 8.9 | 7.6 | 14.0 | 12.1 |
| JUN-FY19 | 7.6 | 9.5 | 8.7 | 5.5 | 9.6 | 10.3 |
| JUL-FY19 | 7.3 | 10.8 | 9.1 | 6.7 | 11.7 | 11.2 |
| AUG-FY19 | 7.4 | 10.1 | 11.6 | 9.9 | 9.4 | 10.1 |
| SEP-FY19 | 7.3 | 10.9 | 8.6 | 8.7 | 11.7 | 4.8 |
| OCT-FY20 | 6.9 | 10.4 | 30.1 | 9.0 | 11.9 | 0.3 |
| NOV-FY20 | 7.1 | 13.3 | 2.8 | 6.4 | 11.9 | 0.1 |
| DEC-FY20 | 7.8 | 13.8 | 0.3 | 5.8 | 10.3 | 4.7 |

*Source: VHA Support Service Center*
*Note: The OIG did not assess VA's data for accuracy or completeness The OIG omitted Milwaukee, WI (695QA), as no workload/encounters or services 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.*

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




| | VHA Total | (695) Milwaukee, WI (Clement J. Zablocki) | (695BY) Appleton, WI (John H. Bradley) | (695GA) Union Grove, WI | (695GC) Cleveland, WI | (695GD) Green Bay, WI (Milo C. Huempfner) |
|---|---|---|---|---|---|---|
| JAN-FY19 | 5.0 | 1.3 | 3.7 | 1.2 | 2.5 | 6.0 |
| FEB-FY19 | 4.6 | 1.3 | 3.7 | 1.0 | 4.0 | 7.1 |
| MAR-FY19 | 4.6 | 1.2 | 4.0 | 1.3 | 4.3 | 6.3 |
| APR-FY19 | 4.5 | 1.4 | 3.9 | 1.0 | 4.1 | 6.7 |
| MAY-FY19 | 4.5 | 1.4 | 4.2 | 1.0 | 3.2 | 5.7 |
| JUN-FY19 | 4.5 | 1.6 | 3.8 | 1.3 | 2.7 | 5.5 |
| JUL-FY19 | 4.6 | 1.6 | 3.5 | 1.1 | 3.7 | 4.5 |
| AUG-FY19 | 4.5 | 1.6 | 3.5 | 1.7 | 4.4 | 5.7 |
| SEP-FY19 | 4.3 | 2.9 | 3.6 | 1.2 | 4.1 | 3.9 |
| OCT-FY20 | 3.9 | 4.4 | 3.3 | 1.4 | 3.4 | 3.2 |
| NOV-FY20 | 4.2 | 4.0 | 3.6 | 2.4 | 4.0 | 4.6 |
| DEC-FY20 | 4.2 | 3.6 | 3.7 | 2.0 | 3.7 | 5.7 |

*Source: VHA Support Service Center*

*Note: The OIG did not assess VA's data for accuracy or completeness. The OIG omitted Milwaukee, WI (695QA), as no workload/encounters or services 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 E: Strategic Analytics for Improvement and Learning (SAIL) Metric Definitions[1]

| Measure | Definition | Desired Direction |
|---|---|---|
| ACSC hospitalization | Ambulatory care sensitive conditions hospitalizations | A lower value is better than a higher value |
| Adjusted LOS | Acute care risk adjusted length of stay | A lower value is better than a higher value |
| Admit reviews met | Percent acute admission reviews that meet interqual criteria | A higher value is better than a lower value |
| Best place to work | All employee survey best places to work score | A higher value is better than a lower value |
| Call responsiveness | Call center speed in picking up calls and telephone abandonment rate | A lower value is better than a higher value |
| Care transition | Care transition (inpatient) | A higher value is better than a lower value |
| Complications | Acute care risk adjusted complication ratio (observed to expected ratio) | A lower value is better than a higher value |
| Cont stay reviews met | Percent acute continued stay reviews that meet interqual criteria | A higher value is better than a lower value |
| Efficiency | Overall efficiency measured as 1 divided by SFA (Stochastic Frontier Analysis) | A higher value is better than a lower value |
| HC assoc infections | Health care associated infections | A lower value is better than a higher value |
| HEDIS like – HED90_1 | HEDIS-EPRP based PRV TOB BHS | A higher value is better than a lower value |
| HEDIS like – HED90_ec | HEDIS-eOM based DM IHD | A higher value is better than a lower value |
| MH continuity care | Mental health continuity of care (FY14Q3 and later) | A higher value is better than a lower value |
| MH exp of care | Mental health experience of care (FY14Q3 and later) | A higher value is better than a lower value |

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

| Measure | Definition | Desired Direction |
|---|---|---|
| MH popu coverage | Mental health population coverage (FY14Q3 and later) | A higher value is better than a lower value |
| Oryx | ORYX | A higher value is better than a lower value |
| PCMH care coordination | PCMH care coordination | A higher value is better than a lower value |
| PCMH same day appt | Days waited for appointment when needed care right away (PCMH) | A higher value is better than a lower value |
| PCMH survey access | Timely appointment, care and information (PCMH) | A higher value is better than a lower value |
| Rating hospital | Overall rating of hospital stay (inpatient only) | A higher value is better than a lower value |
| Rating PC provider | Rating of PC providers (PCMH) | A higher value is better than a lower value |
| Rating SC provider | Rating of specialty care providers (specialty care) | A higher value is better than a lower value |
| RN turnover | Registered nurse turnover rate | A lower value is better than a higher value |
| RSRR-HWR | Hospital wide readmission | A lower value is better than a higher value |
| SC care coordination | SC (specialty care) care coordination | A higher value is better than a lower value |
| SC survey access | Timely appointment, care and information (specialty care) | A higher value is better than a lower value |
| SMR | Acute care in-hospital standardized mortality ratio | A lower value is better than a higher value |
| SMR30 | Acute care 30-day standardized mortality ratio | A lower value is better than a higher value |
| Stress discussed | Stress discussed (PCMH Q40) | A higher value is better than a lower value |

*Source: VHA Support Service Center*

# Appendix F: Community Living Center (CLC) Strategic Analytics for Improvement and Learning (SAIL) Measure Definitions[1]

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

[1] *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, Center for Innovation & Analytics (last updated December 12, 2019). http://vaww.vssc.med.va.gov/VSSCEnhancedProductManagement/DisplayDocument.aspx?DocumentID=7410. (The website was accessed on January 13, 2020, but is not accessible by the public.)

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

# Appendix G: VISN Director Comments

## Department of Veterans Affairs Memorandum

Date: July 8, 2020

From: Director, Great Lakes Health Care System (10N12)

Subj: Comprehensive Healthcare Inspection of the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin

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

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

1. I have reviewed the Comprehensive Healthcare Inspection draft report of the Clement J. Zablocki VA Medical Center, Milwaukee, WI.
2. I concur with the findings and recommendations proposed.
3. I concur with the submitted action plans from the facility.
4. I would like to thank the OIG inspection team for a thorough review of the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin.

*(Original signed by:)*

Lynette J. Taylor for Victoria P. Brahm

# Appendix H: Medical Center Director Comments

## Department of Veterans Affairs Memorandum

Date: June 26, 2020

From: Director, Clement J. Zablocki VA Medical Center (695/00)

Subj: Comprehensive Healthcare Inspection of the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin

To: Director, Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the draft report titled *Comprehensive Healthcare Inspection of the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin* resulting from the January 2020 onsite review. I concur with all recommendations.
2. Please see the attached response to the recommendations identified in the review. Reasons for noncompliance were considered as action plans were developed. I remain committed to ensuring that these efforts enhance the services and care provided to Veterans.
3. As recognized by the Office of the Inspector General (OIG), shortly after the inspection, the landscape of healthcare was changed by the COVID-19 pandemic. Our facility activated its Emergency Operations Plan on March 1, 2020, shifting the prioritization of resources to addressing this novel disease. Despite this unprecedented impact, progress to address recommendations continued.
4. Additional information or further clarification will be provided as needed.

*(Original signed by:)*

James McLain for Daniel Zomchek

# OIG Contact and Staff Acknowledgments

| | |
|---|---|
| **Contact** | For more information about this report, please contact the Office of Inspector General at (202) 461-4720. |
| **Inspection Team** | Tasha Felton Williams, DNP, ACNP, Team Leader<br>Melinda Alegria, AUD, CCC-A<br>Patricia Calvin, RN, MBA<br>Beth DiGiammarino, MSN, APRN<br>Donna Murray, MSN, RN<br>Michelle (Shelly) Wilt, MBA, BSN |
| **Other Contributors** | Elizabeth Bullock<br>Shirley Carlile, BA<br>Alicia Castillo-Flores, MBA, MPH<br>Limin Clegg, PhD<br>Jennifer Frisch, MSN, RN<br>Justin Hanlon, BS<br>LaFonda Henry, MSN, RN-BC<br>Erin Johnson, BA<br>Susan Lott, MSA, RN<br>Scott McGrath, BS<br>Larry Ross, Jr., MS<br>Krista Stephenson, MSN, RN<br>Robyn Stober, JD, MBA<br>Marilyn Stones, BS<br>Caitlin Sweany-Mendez, MPH, BS<br>Robert Wallace, ScD, MPH |

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