



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare
Inspection of the Battle Creek
VA Medical Center in
Michigan



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Figure 1. Battle Creek VA Medical Center in Michigan.

Source: <https://vaww.va.gov/directory/guide/> (accessed July 24, 2020).

Abbreviations

ADPCS	Associate Director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
COVID-19	coronavirus disease
DoD	Department of Defense
FPPE	focused professional practice evaluation
FY	fiscal year
HRS	high risk for suicide
LIP	licensed independent practitioner
LST	life-sustaining treatment
LSTD	life-sustaining treatment decision
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
RME	reusable medical equipment
SAIL	Strategic Analytics for Improvement and Learning
SLB	state licensing board
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



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 Battle Creek VA Medical Center and outpatient clinics in Michigan. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

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

The unannounced virtual review was conducted during the week of July 27, 2020, at the Battle Creek VA Medical Center. 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 review. 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

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

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

Inspection Results

The OIG noted opportunities for improvement in several areas reviewed and issued 11 recommendations to the Director, Chief of Staff, and Associate Director for Patient Care Services. These opportunities for improvement are briefly described below.

Leadership and Organizational Risks

At the time of the OIG's virtual review, the medical center's leadership team consisted of the acting Director, Chief of Staff, acting Associate Director for Patient Care Services, and acting Associate Director. Organizational communications and accountability were managed through a committee reporting structure, with the Executive Leadership Quality Board overseeing several working groups. The Executive Leadership Quality Board also monitors performance and quality improvement activities.

When the team conducted this inspection, the medical center's leaders had worked together as a team for less than a month. Three of the four leaders were serving in an acting capacity; the Chief of Staff, permanently assigned in April 2013, was the most tenured leader.

The OIG reviewed selected All Employee Survey results and concluded that the Associate Director for Patient Care Services, who assumed the role just prior to the survey's administration, appeared to have opportunities to improve employee satisfaction. Similarly, the OIG's review of selected patient experience survey scores highlighted various opportunities to improve patient satisfaction.

The inspection team also reviewed accreditation agency findings, sentinel events, and disclosures of adverse patient events and did not identify any substantial organizational risk factors.²

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

² VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A sentinel event is an incident or condition that results in patient "death, permanent harm, or severe temporary harm and intervention required to sustain life."

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

The executive leaders were knowledgeable within their scope of responsibilities about VHA data and/or medical center-level factors contributing to specific poorly performing SAIL measures. Leaders also understood Community Living Center SAIL measures.⁴ In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve employee satisfaction and patient experiences.

COVID-19 Pandemic Readiness and Response

The results of the OIG's evaluation of the medical center's COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.⁵

Quality, Safety, and Value

The medical center complied with requirements for a committee responsible for quality, safety, and value oversight functions, protected peer reviews, and most patient safety elements reviewed. However, the OIG identified weaknesses in the recommendation, implementation, and monitoring of action items in response to opportunities for improvement and the review of utilization management data.

Medical Staff Privileging

The medical center generally complied with requirements for focused and ongoing professional practice evaluations.⁶ However, the OIG identified a deficiency in the provider exit review process.

Medication Management

The OIG observed compliance with some of the indicators of expected performance, including pain screening and justification for concurrent therapy with benzodiazepines. However, the OIG

⁴ VHA Directive 1149, *Criteria for Authorized Absence, Passes, and Campus Privileges for Residents in VA Community Living Centers*, June 1, 2017. Community living centers, previously known as nursing home care units, provide a skilled nursing environment and a variety of interdisciplinary programs for persons needing short- and long-stay services.

⁵ VA OIG, *Comprehensive Healthcare Inspection of Facilities' COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

⁶ 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."

identified weaknesses in aberrant behavior risk assessments, urine drug testing, informed consent, patient follow-up, and pain management oversight and evaluation.

Mental Health

The inspection team found compliance with the requirements for a suicide prevention coordinator, monthly outreach activities, and suicide prevention training. However, one area for improvement was mental health follow-up appointment completion.

Women's Health

The medical center complied with requirements for designated women's health primary care providers and Primary Care Mental Health Integration services. However, the OIG identified concerns with Women Veterans Health Advisory Committee membership and meeting attendance, Women Veterans Program Manager duties, and a designated maternity care coordinator.

High-Risk Processes

The medical center met some of the requirements for the proper operations and management of reprocessing reusable medical equipment. The OIG identified deficiencies with standard operating procedures, staff training, and competency assessments.

Conclusion

The OIG conducted a detailed inspection across nine key areas (two administrative and seven clinical) and subsequently issued 11 recommendations for improvement to the Director, Chief of Staff, and Associate Director for Patient Care Services. The number of recommendations should not be used, however, as a gauge for the overall quality of care provided at this 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 systems issues as well as other less-critical findings that, if not addressed, may eventually interfere with the delivery of quality health care.

Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the comprehensive healthcare inspection findings and recommendations and provided acceptable improvement plans. (See appendixes G and H, pages 64–65, and the responses within the body of the report for the full text of the directors’ comments.) The OIG considers recommendations 7 and 8 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

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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities providing healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Battle Creek 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.¹

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting expectations for quality care delivery; and promoting a culture to sustain positive change.² Effective leadership has been cited as “among the most critical components that lead an organization to effective and successful outcomes.”³ Figure 2 illustrates the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

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

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

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

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

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

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

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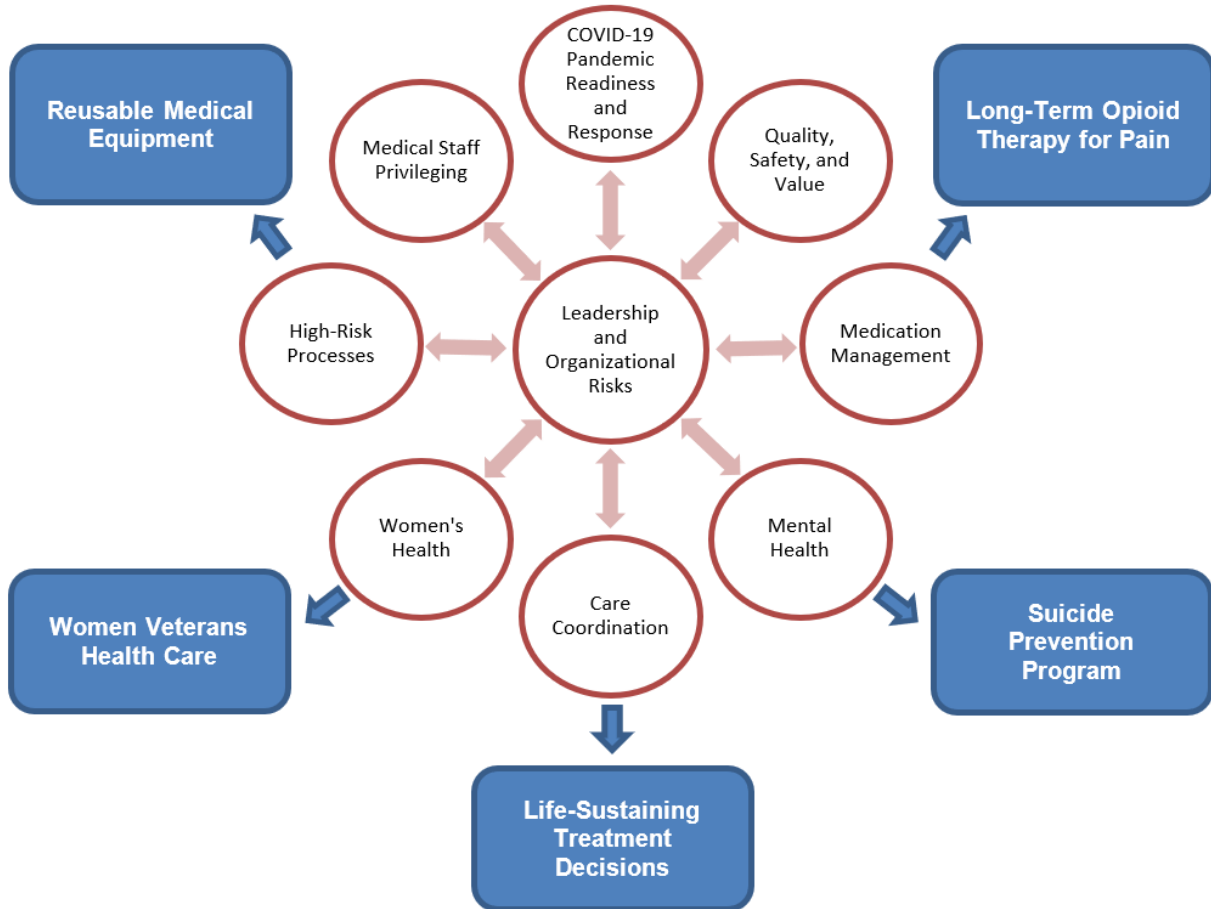


Figure 2. Fiscal year (FY) 2020 comprehensive healthcare inspection of operations and services.

Source: VA OIG.

Methodology

The Battle Creek VA Medical Center also provides care through multiple VA outpatient clinics in Michigan. 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 and clinical functions, the inspection team reviewed OIG-selected clinical records, administrative and performance measure data, and accreditation survey reports.⁶ The OIG team also interviewed executive leaders and discussed processes, validated findings, and explored reasons for noncompliance with staff.

The inspection examined operations from May 26, 2018, through July 31, 2020, the last day of the unannounced multiday evaluation.⁷ During the virtual review, the OIG did not receive any complaints beyond the scope of the inspection.

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

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

This report's recommendations for improvement address problems that can influence the quality of patient care significantly enough to warrant OIG follow-up until the 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 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.

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

⁷ The range represents the time period from the prior CHIP site visit to the completion of the unannounced, multiday virtual CHIP visit in July 2020.

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

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

Results and Recommendations

Leadership and Organizational Risks

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

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

Executive Leadership Position Stability and Engagement

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

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

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

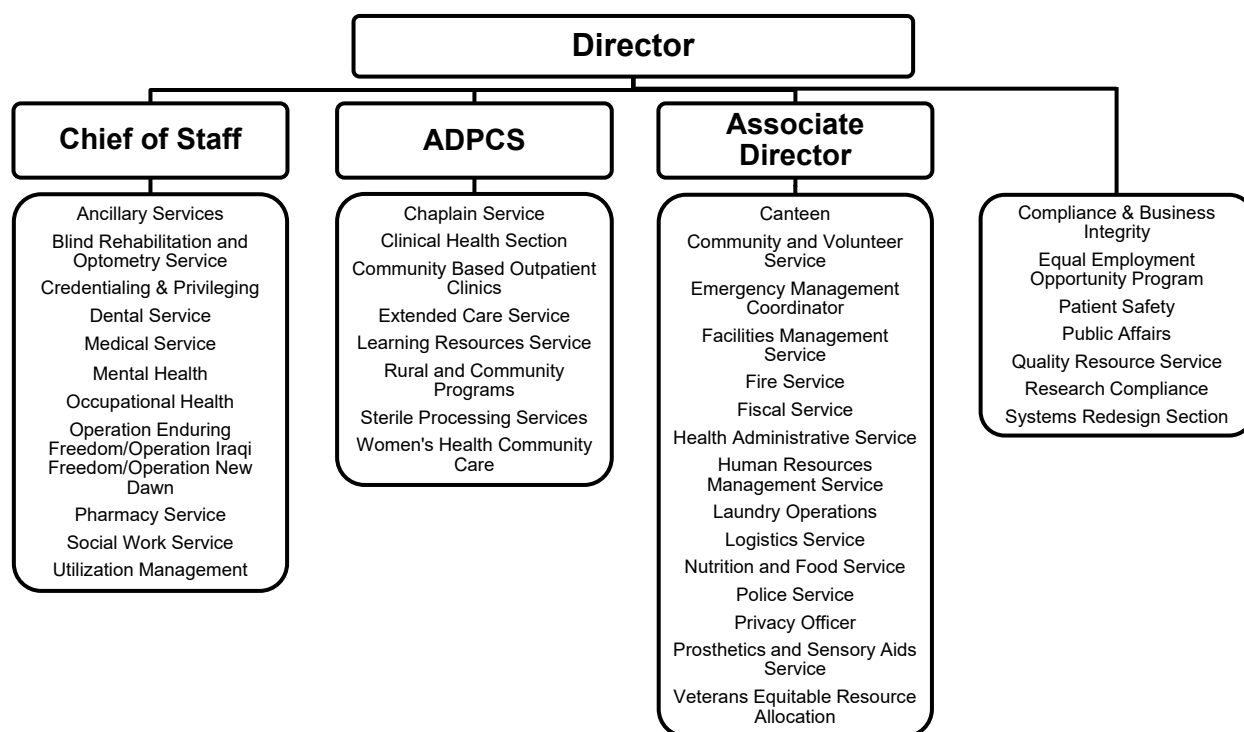


Figure 3. Medical center organizational chart.

Source: Battle Creek VA Medical Center (received July 28, 2020).

At the time of the OIG virtual review, the executive team had one leader serving in a permanent role while the other three leaders were serving in acting capacities. The acting Director is the permanent ADPCS, assigned May 26, 2019. The Chief of Staff had served in the role since 2013, and the acting ADPCS and acting Associate Director had served in their roles since May 25 and July 23, 2020, respectively (see table 1).

Table 1. Executive Leader Assignments

Leadership Position	Assignment Date
Director	March 25, 2020 (acting)
Chief of Staff	April 12, 2013
Associate Director for Patient Care Services	May 26, 2019 (permanent) May 25, 2020 (acting)
Associate Director	July 23, 2020 (acting)

Source: Battle Creek Strategic Business Partner (received July 27, 2020).

To help assess the medical center executive leaders’ engagement, the OIG interviewed the acting Director, Chief of Staff, acting ADPCS, and acting Associate Director regarding their knowledge

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

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

The Director serves as the chairperson of the Executive Leadership Quality Board, which has the authority and responsibility to establish policy, maintain quality care standards, perform organizational management and strategic planning, and monitor performance and quality improvement activities. The Executive Leadership Quality Board oversees various working groups such as the Administrative, Nurse, and Clinical Executive Boards (see figure 4).

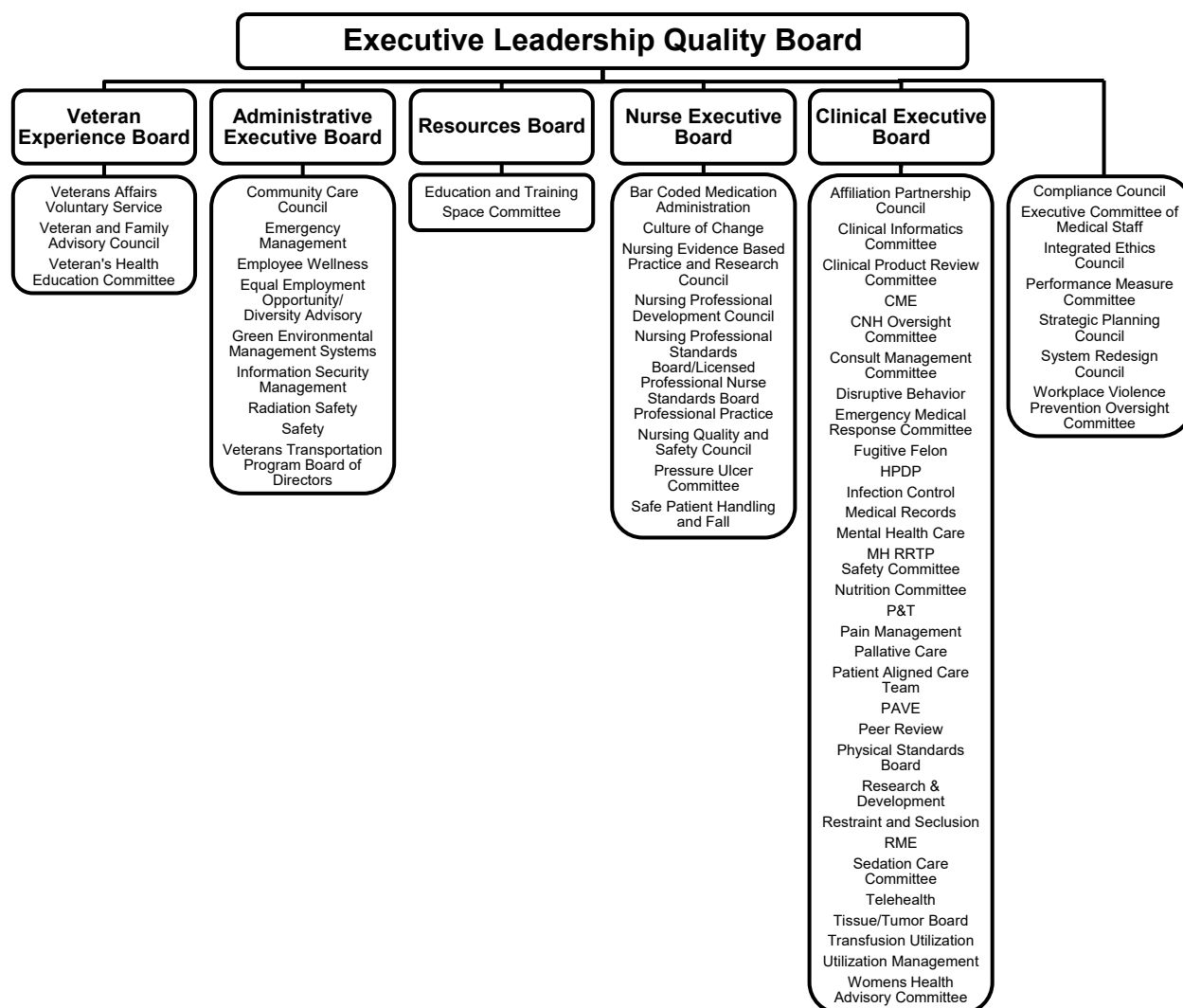


Figure 4. Medical center committee reporting structure.

Source: Battle Creek VA Medical Center (received July 29, 2020).

CME = Continuing Medical Education

CNH = Community Nursing Home

HPDP = Health Promotion Disease Prevention

MH RRTP = Mental Health Residential Rehabilitation Treatment Program

P&T = Pharmacy & Therapeutics

PAVE = Prevention of Amputation in Veterans Everywhere

RME = Reusable Medical Equipment

Employee Satisfaction

The All Employee Survey “is an annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential.” Since 2001, the instrument has been refined several

times in response to VA leaders’ inquiries on VA culture and organizational health.¹² Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting 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 from October 1, 2018, through September 30, 2019.¹³ 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 average for the selected survey leadership questions was similar to the VHA average.¹⁴ Scores related to the Director, Chief of Staff, and Associate Director were consistently higher than those for VHA and the medical center; however scores specifically related to the ADPCS were consistently lower than those for VHA and the medical center.¹⁵ Opportunities appear to exist for the ADPCS to improve employee attitudes toward medical center leaders.

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	Assoc. Director Average
All Employee Survey: <i>Servant Leader Index Composite</i> .*	0–100 where higher scores are more favorable	72.6	72.7	87.5	77.9	63.9	86.3

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

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

¹⁴ The OIG makes no comment on the adequacy of the VHA average for each selected survey element. The VHA average is used for comparison purposes only.

¹⁵ The OIG notes that the 2019 All Employee Survey results are not reflective of employee satisfaction with the acting Director and acting Associate Director. The results are also not reflective of the current ADPCS, who assumed the ADPCS role just prior to the survey’s administration.

Questions/Survey Items	Scoring	VHA Average	Medical Center Average	Director Average	Chief of Staff Average	ADPCS Average	Assoc. Director Average
All Employee Survey: <i>In my organization, senior leaders generate high levels of motivation and commitment in the workforce.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.4	3.3	4.3	4.1	3.0	4.3
All Employee Survey: <i>My organization's senior leaders maintain high standards of honesty and integrity.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.5	4.2	4.2	3.0	4.4
All Employee Survey: <i>I have a high level of respect for my organization's senior leaders.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.6	3.6	4.3	4.1	3.3	4.4

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

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

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA’s All Employee Survey.¹⁶ The OIG noted that the medical center average for the selected survey questions was similar to the VHA average. Scores for the Director, Chief of Staff, and Associate Director were consistently better than those for VHA and the healthcare system. However, the results also highlight opportunities for the ADPCS to improve employee attitudes toward the workplace.¹⁷

¹⁶ Ratings are based on responses by employees who report to or are aligned under the Director, Chief of Staff, ADPCS, and Associate Director.

¹⁷ The OIG notes that the 2019 All Employee Survey results are not reflective of employee satisfaction with the acting Director and acting Associate Director. The results are also not reflective of the current ADPCS, who assumed the ADPCS role just prior to the survey’s administration.

**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	Assoc. Director Average
All Employee Survey: <i>I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.8	3.8	4.6	4.4	3.1	4.4
All Employee Survey: <i>Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).</i>	1 (Strongly Disagree) –5 (Strongly Agree)	3.7	3.8	4.6	4.3	3.4	4.0
All Employee Survey: <i>In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?</i>	0 (Never) – 6 (Every Day)	1.4	1.4	1.3	0.9	2.4	0.7

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

Patient Experience

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

experiences with their health care and to support benchmarking its performance against the private sector.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The OIG reviewed responses to four relevant survey questions that reflect patients’ attitudes toward their healthcare experiences. Table 4 provides relevant survey results for VHA and the medical center.¹⁸ For this medical center, the inpatient and outpatient specialty care survey results generally reflected lower care ratings than the VHA average. There appear to be opportunities for leaders to improve patient experience and satisfaction.

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

Questions	Scoring	VHA Average	Medical Center Average
Survey of Healthcare Experiences of Patients (inpatient): <i>Would you recommend this hospital to your friends and family?</i>	The response average is the percent of “Definitely Yes” responses.	68.3	50.9
Survey of Healthcare Experiences of Patients (inpatient): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	84.9	78.0
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	77.3	80.1
Survey of Healthcare Experiences of Patients (outpatient specialty care): <i>I felt like a valued customer.</i>	The response average is the percent of “Agree” and “Strongly Agree” responses.	78.0	69.9

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

¹⁸ Ratings are based on responses by patients who received care at this medical center.

In 2015, women represented 9.4 percent of the total veteran population in the United States, and it is projected that women will represent 16.3 percent of living veterans by 2043. Further, from 2005 to 2015, the number of women veterans using VA health care increased by 46.4 percent, from almost 240,000 to 455,875.¹⁹ For these reasons, it is important for VHA to provide accessible and inclusive care for women veterans.

The OIG reviewed selected responses to several additional relevant survey questions that reflect patients’ experiences by gender (see tables 5–7), including those for Inpatient, Patient-Centered Medical Home, and Specialty Care surveys. The results highlight opportunities to improve patient satisfaction, despite medical center leaders reporting active engagement with both male and female patients.

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>During this hospital stay, how often did doctors treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.5	82.8	88.0	– [‡]
<i>During this hospital stay, how often did nurses treat you with courtesy and respect?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	84.8	83.1	88.4	–
<i>Would you recommend this hospital to your friends and family?</i>	The measure is calculated as the percentage of responses in the top category (Definitely yes).	68.7	61.8	51.4	–

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

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

The medical center averages are based on 94–96 male respondents, depending on the question.

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

¹⁹ VA National Center for Veterans Analysis and Statistics, *The Past, Present and Future of Women Veterans*, February 2017.

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

Questions	Scoring	VHA*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	51.2	43.3	40.3	31.5
<i>In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	59.9	49.7	59.7	58.5
<i>Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	71.6	65.7	65.5	55.4

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

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

The medical center averages are based on 421–1,456 male and 34–73 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*		Medical Center	
		Male Average	Female Average	Male Average	Female Average
<i>In the last 6 months, when you contacted this provider's office to get an appointment for care you needed right away, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	48.5	44.7	49.1	45.1
<i>In the last 6 months, when you made an appointment for a check-up or routine care with this provider, how often did you get an appointment as soon as you needed?</i>	The measure is calculated as the percentage of responses that fall in the top category (Always).	56.3	55.0	54.5	64.1
<i>Using any number from 0 to 10, where 0 is the worst provider possible and 10 is the best provider possible, what number would you use to rate this provider?</i>	The reporting measure is calculated as the percentage of responses that fall in the top two categories (9, 10).	70.4	70.1	71.7	87.7

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

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

The medical center averages are based on 356–1,197 male and 14–39 female respondents, depending on the question.

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

²⁰ “Profile Definitions and Methodology: Joint Commission Accreditation,” *American Hospital Directory*, accessed December 12, 2020, https://www.ahd.com/definitions/prof_accred.html. “The Joint Commission conducts for-cause unannounced surveys in response to serious incidents relating to the health and/or safety of patients or staff or other reported complaints. The outcomes of these types of activities may affect the accreditation status of an organization.”

Joint Commission (TJC).²¹ Of note, at the time of the OIG virtual review, the medical center had closed all recommendations for improvement issued since the previous comprehensive healthcare inspection conducted in May 2018.

At the time of the virtual review, the OIG team also noted the medical center’s current accreditation by the College of American Pathologists.²² Additional results included the Long-Term Care Institute’s inspection of the medical center’s CLCs.²³

Table 8. Office of Inspector General Inspection/The Joint Commission Surveys

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (<i>Comprehensive Healthcare Inspection Program Review of the Battle Creek VA Medical Center, Michigan, Report No. 18-01139-267, September 12, 2018</i>)	May 2018	3	0
TJC Hospital Accreditation	June 2018	29	0
TJC Behavioral Health Care Accreditation		10	0
TJC Home Care Accreditation		3	0
TJC Hospital Follow-up Inspection	January 2019	1	0

Source: OIG and TJC (inspection/survey results verified with the Chief of Quality Resource Service on July 30, 2020).

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

²² 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 collaboration with the Commission on Accreditation of Rehabilitation Facilities to achieve and maintain national accreditation for all appropriate VHA rehabilitation programs. “About the College of American Pathologists,” College of American Pathologists, accessed April 26, 2021, <https://www.cap.org/about-the-cap>. According to the College of American Pathologists, for 75 years it has “fostered excellence in laboratories and advanced the practice of pathology and laboratory science.” Additionally, as stated in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

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

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.

Table 9 lists the reported sentinel events and disclosures from May 26, 2018 (the prior OIG comprehensive healthcare inspection), through July 27, 2020.²⁴

Table 9. Summary of Selected Organizational Risk Factors (May 26, 2019, through July 27, 2020)

Factor	Number of Occurrences
Sentinel Events	1
Institutional Disclosures	1
Large-Scale Disclosures	0

Source: Battle Creek VA Medical Center's Quality Management Supervisor (received July 30, 2020).

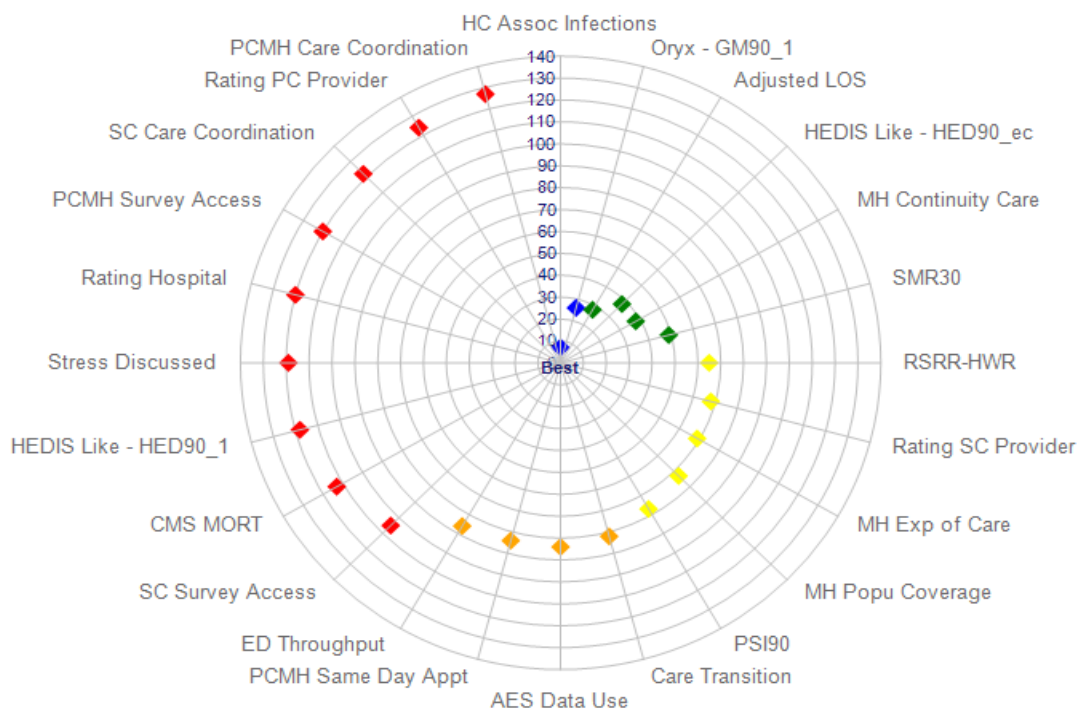
Veterans Health Administration Performance Data

The VA Office of Operational Analytics and Reporting adopted the SAIL Value Model to help define performance expectations within VA with “measures on healthcare quality, employee satisfaction, access to care, and efficiency.” Despite noted limitations for identifying all areas of

²⁴ It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (The OIG noted that the Battle Creek VA Medical Center is a low complexity (3) system as described in appendix B.) According to VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018, a sentinel event is an incident or condition that results in patient “death, permanent harm, or severe temporary harm and intervention required to sustain life.” Additionally, as stated in VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018, VHA defines an institutional disclosure of adverse events (sometimes referred to as an “administrative disclosure”) as “a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient’s personal representative that an adverse event has occurred during the patient’s care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient’s rights and recourse.” Lastly, in VHA Directive 1004.08, VHA defines a large-scale disclosure of adverse events (sometimes referred to as a “notification”) as “a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue.”

clinical risk, the data are presented as one way to understand the similarities and differences between the top and bottom performers within VHA.²⁵

Figure 5 illustrates the medical center’s quality of care and efficiency metric rankings and performance compared with other VA facilities as of December 31, 2019. Of note, figure 5 uses blue and green data points to indicate high performance for the Battle Creek VA Medical Center (for example, in the areas of health care associated (HC assoc) infections, adjusted length of stay (LOS), and mental health (MH) continuity (of) care). Metrics that need improvement are denoted in orange and red (for example, care transition, rating (of) hospital, and rating (of) primary care (PC) provider).²⁶



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

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

Source: VHA Support Service Center.

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

²⁵ “Strategic Analytics for Improvement and Learning (SAIL) Value Model,” VHA Support Service Center, accessed on November 12, 2020, <https://vssc.med.va.gov>. (This is an internal VA website not publicly accessible.)

²⁶ For information on the acronyms in the SAIL metrics, please see appendix E.

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.”²⁷

Figure 6 illustrates the medical center’s CLC quality rankings and performance compared with other VA CLCs as of December 31, 2019. Figure 6 uses blue and green data points to indicate high performance for the Battle Creek CLC (for example, in the areas of physical restraints–long-stay (LS), new or worse pressure ulcer (PU)–short-stay (SS), and falls with major injury (LS)). Metrics that need improvement are denoted in orange and red (for example, discharged to community (SS) and improvement in function (SS)).²⁸

²⁷ Center for Innovation and Analytics, *Strategic Analytics for Improvement and Learning (SAIL) for Community Living Centers (CLC)*, July 23, 2020. “In December 2008, The Centers for Medicare & Medicaid Services (CMS) enhanced its *Nursing Home Compare* public reporting site to include a set of quality ratings for each nursing home that participates in Medicare or Medicaid. The ratings take the form of several “star” ratings for each nursing home. The primary goal of this rating system is to provide residents and their families with an easy way to understand assessment of nursing home quality; making meaningful distinctions between high and low performing nursing homes.”

²⁸ For data definitions of acronyms in the SAIL CLC measures, please see appendix F.

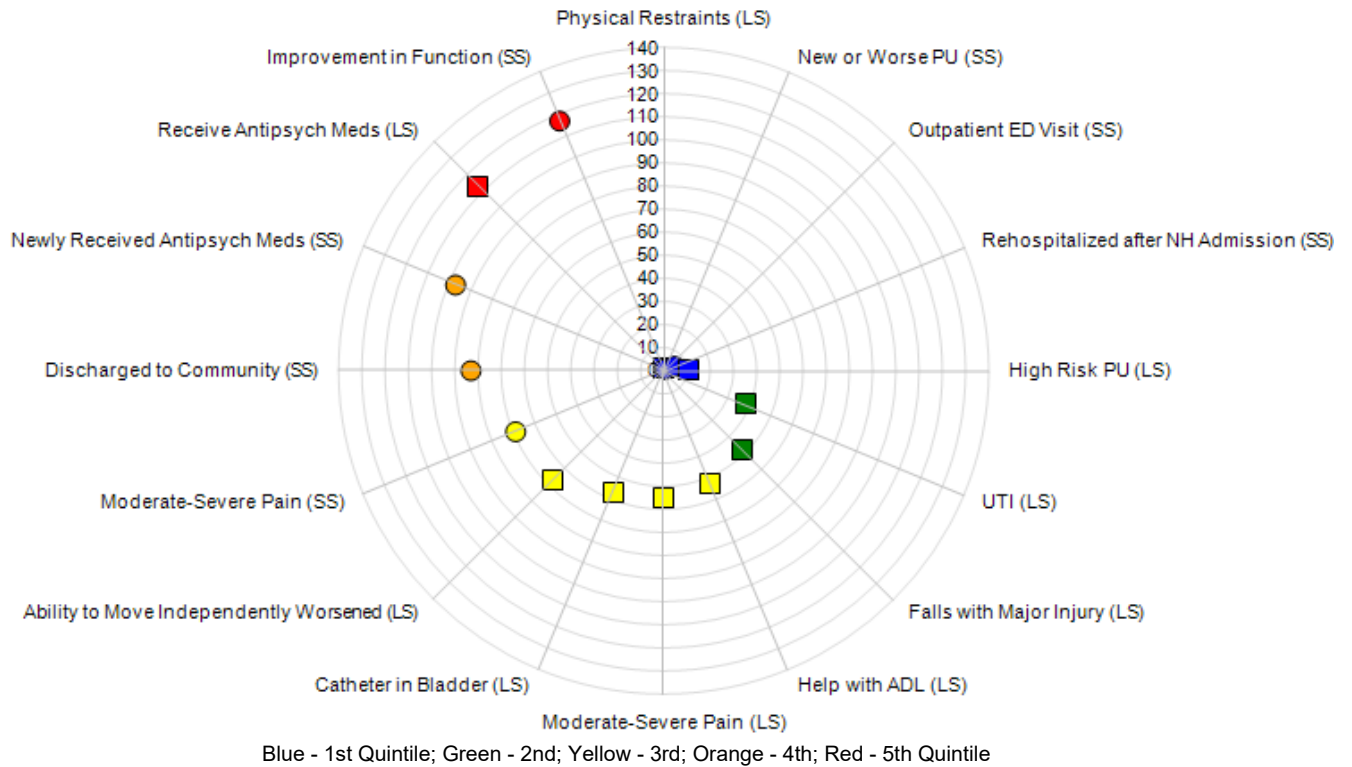


Figure 6. Battle Creek CLC quality measure rankings, FY 2020 quarter 1 (as of December 31, 2019).

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

Source: VHA Support Service Center.

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

Leadership and Organizational Risks Conclusion

Three out of four members of the medical center’s executive leadership team were serving in an acting capacity at the time of the OIG’s review. Selected survey items revealed opportunities for the ADPCS to improve employee satisfaction. Similarly, patient experience survey data highlighted various opportunities to improve satisfaction. The OIG’s review of the medical center’s accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. In individual interviews, the executive leaders were able to speak in depth about actions taken during the previous 12 months to maintain or improve employee satisfaction and patient experiences. In addition, the executive leaders were knowledgeable within their scope of responsibilities and tenure about selected SAIL and CLC SAIL data and performance opportunities. However, leaders should continue to take actions to sustain and improve performance of the measures.

COVID-19 Pandemic Readiness and Response

On March 11, 2020, due to the “alarming levels of spread and severity” of COVID-19, the World Health Organization declared a pandemic.²⁹ VHA subsequently issued its *COVID-19 Response Plan* on March 23, 2020, which presents strategic guidance on prevention of viral transmission among veterans and staff and appropriate care for sick patients.³⁰

During this time, VA continued providing for veterans’ healthcare needs and engaged its fourth mission, “the provision of hospital care and medical services during certain disasters and emergencies” to persons “who would otherwise not have eligibility to receive such care and services.”³¹ “In effect, VHA facilities provide a safety net for the nation’s hospitals should they become overwhelmed—for veterans (whether previously eligible or not) and non-veterans.”³²

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

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

The OIG also surveyed medical center staff to solicit their feedback and potentially identify any problematic trends and/or issues that may require follow-up. The results of the OIG’s evaluation of the medical center’s COVID-19 pandemic readiness and response were compiled and reported with other facilities in a separate publication to provide stakeholders with a more comprehensive picture of regional VHA challenges and ongoing efforts.³³

²⁹ “WHO Director-General’s Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020,” World Health Organization, accessed March 23, 2020, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

³⁰ VHA Office of Emergency Management, *COVID-19 Response Plan*, March 23, 2020.

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

³² 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.

³³ VA OIG, *Comprehensive Healthcare Inspection of Facilities’ COVID-19 Pandemic Readiness and Response in Veterans Integrated Service Networks 10 and 20*, Report No. 21-01116-98, March 16, 2021.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care.³⁴ To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation.³⁵ 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."³⁶

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.³⁷ 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."³⁸ Peer reviews are "intended to promote confidential and non-punitive" processes that consistently contribute to quality management efforts at the individual provider level.³⁹ The OIG team examined the completion of the following elements:

³⁴ Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 21, 2014.

³⁵ VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017.

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

³⁷ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A peer review is a "critical review of care, performed by a peer," to evaluate care provided by a clinician for a specific episode of care, identify learning opportunities for improvement, provide confidential communication of the results back to the clinician, and identify potential system or process improvements. In the context of protected peer reviews, "protected" refers to the designation of review as a confidential quality management activity under 38 U.S.C. § 5705 as "a Department systematic health-care review activity designated by the Secretary to be carried out by or for the Department for improving the quality of medical care or the utilization of health-care resources in VA facilities."

³⁸ VHA Directive 1190.

³⁹ VHA Directive 1190.

- Evaluation of aspects of care (for example, choice and timely ordering of diagnostic tests, prompt treatment, and appropriate documentation)
- Peer review of all applicable deaths within 24 hours of admission to the hospital
- Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit⁴⁰
- Completion of final reviews within 120 calendar days
- Implementation of improvement actions recommended by the Peer Review Committee
- Quarterly review of the Peer Review Committee's summary analysis by the Executive Committee of the Medical Staff

Next, the inspection team assessed the 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.⁴¹ 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.⁴² 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.⁴³ Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root

⁴⁰ VHA Directive 1190.

⁴¹ 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." (This directive was rescinded and replaced with VHA Directive 1117, *Utilization Management Program*, October 8, 2020.)

⁴² VHA Directive 1117(2).

⁴³ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the medical center.⁴⁴ The medical center was assessed for its performance on several dimensions:

- Annual completion of a minimum of eight root cause analyses⁴⁵
- Inclusion of required content in root cause analyses
- Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
- Provision of feedback about root cause analysis actions to reporting employees
- Submission of an annual patient safety report to 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.⁴⁶

Quality, Safety, and Value Findings and Recommendations

The medical center complied with requirements for a committee responsible for QSV oversight functions, protected peer reviews, and most patient safety elements reviewed. However, the OIG identified weaknesses in the recommendation of action items in response to opportunities for improvement and the review of utilization management data.

TJC standards specify that the medical center’s governing body provides structure and resources to support quality and safety. TJC also requires facilities to measure and analyze performance using data so that improvement “effectiveness can be sustained, assessed, and measured” and ensure that improvement actions are recommended, fully implemented, and monitored.⁴⁷ The OIG reviewed Executive Leadership Quality Board (this medical center’s governing body) meeting minutes from January 16, 2019, through December 18, 2019, and noted that problems and opportunities for improvement were identified. However, the OIG did not find evidence that improvement actions were recommended, implemented, or monitored. This may have prevented quality of care and patient safety process improvements. The Chief of Quality Resource Services

⁴⁴ VHA Handbook 1050.01.

⁴⁵ VHA Handbook 1050.01, “The requirement for a total of eight RCAs [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of RCAs is driven by the events that occur and the SAC [Safety Assessment Code] score assigned to them...At least four analysis per fiscal year must be individual RCAs, with the balance being Aggregated Reviews or additional individual RCAs.”

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

⁴⁷ The Joint Commission, *Standards Manual*, LD.01.03.01, 03.02.01, 03.05.01, 03.07.01–03.10.01, PI.03.01.01, September 2020.

acknowledged opportunities to improve quality process documentation in meeting minutes but did not provide a reason for noncompliance.

Recommendation 1

1. The Medical Center Director determines the reasons for noncompliance and ensures specific action items are recommended, implemented, and monitored when problems and opportunities for improvement are identified.

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. A routine reporting schedule for each board and special program was developed and implemented, 2. The reporting function of each board was clarified to include incorporation of minutes, follow-up to previous Executive Leadership Quality Board issues, updates on current activities/issues of concern and items for discussion, recommendation or action, 3. Executive Decisions Memorandums initiated by the Veterans Integrated Service Network that affects the facility will be presented in Executive Leadership Quality Board and disseminated to Boards and Committees, 4. Chief, Quality Resource Service will conduct audits of the Executive Leadership Quality Board meeting minutes to ensure all action items have appropriate follow-up. Compliance will be monitored until a 90% compliance rate is sustained for six consecutive months. The numerator is the number of action items completed. The denominator is the number of action items in each month.

VHA requires that medical center directors ensure an interdisciplinary committee reviews UM data at least quarterly.⁴⁸ The OIG found that between January 1, 2019, through December 31, 2019, the UM Committee convened only once—in April 2019. The OIG did not find evidence that the committee reviewed UM data as required. As a result, the committee missed opportunities to improve efficiency. The Chief of Quality Resource Services stated that members had responsibilities on other committees, and the UM Committee did not meet regularly because of the lack of quorum.

⁴⁸ VHA Directive 1117(2), *Utilization Management Program*. (This directive was in place for the time frame covered for the utilization management review. It was rescinded and replaced with VHA Directive 1117 on October 8, 2020. Both directives contain the same or similar language regarding review of utilization management data by the multidisciplinary team.)

Recommendation 2

2. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that an interdisciplinary committee reviews utilization management data as required.

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The Utilization Management Committee was dissolved, 2. Utilization Management Quarterly Review has been added as a standing agenda item to the multidisciplinary Clinical Executive Board, 3. The Chief, Quality Resource Service will monitor until two consecutive quarters of 90% or greater reporting to the Clinical Executive Board (CEB) has been attained. The numerator is the number of times the utilization management data is reported to CEB per quarter. The denominator is the number of times the utilization management data is required to report to CEB per quarter.

Medical Staff Privileging

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

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

VHA defines the focused professional practice evaluation (FPPE) as “a time-limited period during which the medical staff leadership evaluates and determines the practitioner’s professional performance.” The FPPE process occurs when a provider is hired at the facility and granted initial privileges and before any new clinical privileges are granted. 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.”⁵¹ The OIG examined various requirements for FPPEs and OPPEs:

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

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

⁵⁰ VHA Handbook 1100.19.

⁵¹ VHA Handbook 1100.19.

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

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

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

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

- Eight solo/few practitioners who underwent initial or reprivileging during calendar year 2019⁵⁶
- Seven LIPs who completed an FPPE in calendar year 2019
- Ten LIPs privileged during calendar year 2019
- Twenty LIPs who left the medical center in calendar year 2019

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

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

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

Medical Staff Privileging Findings and Recommendations

The medical center complied with requirements for FPPE and OPPE performance indicators. However, the OIG identified a deficiency in the provider exit review process.

At the time of the OIG visit, VHA required provider exit review forms, which document the review of a provider’s clinical practice, to “be completed within 7 calendar days of the departure of a licensed health care professional from a VA facility.”⁵⁷ Of the 20 providers who departed the medical center from January 1, 2019, through December 31, 2019, the OIG found that service chiefs did not complete five exit review forms within the required time frame. However, as of January 28, 2021, VHA requires the medical center director to ensure provider exit review forms are completed within 7 business days.⁵⁸ Based on the updated requirement, four exit review forms were not completed within the new time frame. Failure to complete forms on time could have resulted in delayed reporting of potential substandard care to SLBs. The Chief of Staff attributed noncompliance to vacancies in two service chief positions.

Recommendation 3

3. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that service chiefs complete provider exit review forms within seven business days of licensed healthcare professionals’ departure from the medical center.

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility’s process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. An e-fillable form was created which includes a, “SUBMIT” button that goes directly to the Credentialing Office, 2. The Credentialing Office was added to the facility Clearance Form, 3. The Service Chief will submit the Exit [form] within seven business days as required, 4. The Chief of Staff will monitor until two consecutive quarters of 90% or greater compliance of timely Exit [form] submissions has been attained. The numerator will be the number of exit reviews completed within seven business days of the staff departure. The denominator will be the number of staff that have left Medical Center employment. 5. Data will be reviewed by the Clinical Executive Board.

⁵⁷ VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018. (VHA Handbook 1100.18 was rescinded on January 28, 2021, and replaced with VHA Directive 1100.18.)

⁵⁸ VHA Directive 1100.18.

Medication Management: Long-Term Opioid Therapy for Pain

Opioid medications are known to cause dependence, tolerance, abuse, and accidental overdose.⁵⁹ The opioid crisis is a national public health emergency with, on average, 130 Americans dying every day from an opioid overdose.⁶⁰ 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.⁶¹ These disorders coupled with high-dose opioid use can potentially lead to an increased risk of overdose compared to the general population.⁶²

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.⁶³ Healthcare providers are required to conduct initial and random ongoing urine drug testing during opioid therapy.⁶⁴ 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.⁶⁵ 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.⁶⁶

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

⁵⁹ "Information Sheet on Opioid Overdose," World Health Organization, accessed November 6, 2019, https://www.who.int/substance_abuse/information-sheet/en/.

⁶⁰ "Opioid Overdose, Understanding the Epidemic," Centers for Disease Control and Prevention, accessed November 6, 2019, <https://www.cdc.gov/drugoverdose/epidemic>.

⁶¹ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*, Version 3.0. February 2017.

⁶² *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁶³ "Benzodiazepines, Street Names: Benzos, Downers, Nerve Pills, Tranks," U.S. Drug Enforcement Administration, accessed December 1, 2019, https://www.deadiversion.usdoj.gov/drug_chem_info/benzo.pdf. Benzodiazepines "are a class of drugs that produce central nervous system (CNS) depression and that are most commonly used to treat insomnia and anxiety."

⁶⁴ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁶⁵ VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 13, 2020.

⁶⁶ *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

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

VHA also requires facilities to establish a multidisciplinary pain management committee “to provide oversight, coordination, and monitoring of pain management activities and processes.” Monitoring measures include, but are not limited to, “adherence to published clinical practice guidelines, timeliness of pain treatment, adequacy of pain control, medication safety, appropriate use of stepped care treatment...patient satisfaction, physical and psychosocial functioning, and quality of life.”⁶⁷ The OIG examined indicators for program oversight and evaluation:

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

The OIG interviewed key employees and managers and reviewed relevant documents and the electronic health records of 17 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 medical center addressed some of the indicators of expected performance, including pain screening and justification for concurrent therapy with benzodiazepines. However, the OIG identified weaknesses in aberrant behavior risk assessments, urine drug testing, informed consent, patient follow-up, and pain management oversight and evaluation.

VA/Department of Defense (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.⁶⁸ The OIG determined that providers’ aberrant behavior risk assessments did not include a history of substance abuse for 18 percent of the patients reviewed and aberrant drug-related behaviors for 12 percent of the patients reviewed.⁶⁹ This may have resulted in providers prescribing opioids for patients at high risk for misuse. The Associate Chief of Staff for Specialty Services reported

⁶⁷ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

⁶⁸ *Pain Management, Opioid Safety, VA Educational Guide (2014)*, July 2014. Examples of aberrant drug related behaviors include “lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, and frequent accidents.” *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain*.

⁶⁹ Confidence intervals are not included because the data represents every patient in the study population.

believing the assessments completed by the Patient Aligned Care Team nurse met the requirement.

VA/DoD clinical practice guidelines also recommend that providers conduct “UDT [urine drug test] prior to initiating or continuing LOT [long-term opioid therapy] and periodically thereafter.”⁷⁰ The OIG determined that providers did not conduct initial urine drug testing for 12 percent of the patients reviewed.⁷¹ This resulted in providers’ inability to identify patients who had substance use disorders, determine potential diversion, or ensure patients adhered to the prescribed medication regimen. According to the Chief of Pharmacy, providers did not repeat urine drug tests for patients previously prescribed short-term opioid therapy.

VHA requires providers to obtain and document informed consent prior to initiating long-term opioid therapy. VHA also recommends that informed consent conversations cover the risks and benefits of opioid therapy, as well as alternative therapies.⁷² The OIG determined that providers did not document informed consent prior to initiating long-term opioid therapy for 12 percent of the patients reviewed.⁷³ As a result, these patients may have received treatment without knowledge of the risks associated with long-term opioid therapy, including dependence, tolerance, addiction, and fatal overdose. For one patient, the Associate Chief of Staff for Specialty Services stated that the complexity of health problems and multiple ancillary services’ involvement caused the provider to overlook completing the informed consent. For the remaining patient, the Associate Chief of Staff for Specialty Services could not provide a reason for noncompliance.

VA/DoD clinical practice guidelines recommend that providers follow up with patients within three months after initiating long-term opioid therapy.⁷⁴ The OIG determined that providers did not follow up in the recommended time frame with 29 percent of patients, based on the electronic health records reviewed. Providers’ failure to conduct timely follow-up with patients could have resulted in missed opportunities to evaluate the benefits of continued opioid therapy. The Associate Chief of Staff for Specialty Services stated that providers completed a monthly note and that they believed this represented documentation for timely follow-up with patients.

The OIG made no recommendations due to the small sample of patients identified for these review elements.

⁷⁰ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

⁷¹ Confidence intervals are not included because the data represents every patient in the study population.

⁷² VHA Directive 1005(1), *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014, amended November 13, 2018. (This directive was in place for the time frame covered by the electronic health record reviews. It was rescinded and replaced by VHA Directive 1005 on May 13, 2020. Both directives contain the same or similar language regarding informed consent.)

⁷³ Confidence intervals are not included because the data represents every patient in the study population.

⁷⁴ VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain.

VHA requires that “the quality of pain assessment and the effectiveness of pain management interventions must be monitored” by a multidisciplinary pain management committee.⁷⁵ The OIG requested Pain Management Committee meeting minutes from July through December 2019, but only received minutes for January 28, 2020. Based on the lack of committee minutes available for review, the OIG did not have sufficient evidence to determine if pain assessment quality or pain management intervention effectiveness were monitored. This may have resulted in lack of “oversight, coordination, and monitoring of pain management activities.”⁷⁶ The Associate Chief of Staff for Specialty Services stated that the restructuring of the medical service line and the onset of the COVID-19 pandemic response contributed to noncompliance.

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures the Pain Management Committee monitors the quality of pain assessments and effectiveness of pain management interventions.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility’s process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The Pain Management Committee charter has been updated, 2. The reporting structure for Pain Management Committee was revised to report to the Specialty Care Integrated Clinical Community Subcommittee which reports to Clinical Executive Board, 3. Pain Management reporting includes pain metrics and quality indicators, 4. The Opioid Safety workgroup reports data to the Pain Management Committee bi-monthly, 5. The Associate Chief of Staff for Specialty Services will monitor Pain Management Committee meeting minutes to ensure pain metrics and quality indicators are reported each meeting for six months. The numerator will be the number of times pain metrics and indicators are reviewed by the Pain Management Committee. The denominator will be the number of Pain Management Committee meetings, 6. Compliance will be demonstrated at 90% or greater.

⁷⁵ VHA Directive 2009-053.

⁷⁶ VHA Directive 2009-053.

Mental Health: Suicide Prevention Program

Suicide prevention remains a top priority for VHA. Suicide is the 10th leading cause of death, with over 47,000 lives lost across the United States in 2019.⁷⁷ The suicide rate for veterans was 1.5 times greater than for nonveteran adults and estimated to represent approximately 13.8 percent of all suicide deaths in the United States during 2018. However, suicide rates among veterans who recently used VHA services decreased by 2.4 percent between 2017 and 2018.⁷⁸

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.⁷⁹

VHA requires that each medical center and very large community-based outpatient clinic have a full-time suicide prevention coordinator (SPC) to track and follow up with high-risk veterans, develop a process for responding to referrals from hotlines such as the Veteran Crisis Line, and conduct community outreach activities.⁸⁰ 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

⁷⁷ "Preventing Suicide," Centers for Disease Control and Prevention, accessed December 9, 2020, <https://www.cdc.gov/violenceprevention/suicide/fastfact.html>.

⁷⁸ VA Office of Mental Health and Suicide Prevention, *2020 National Veteran Suicide Prevention Annual Report*, November 2020.

⁷⁹ VA Office of Mental Health and Suicide Prevention, *VA Office of Mental Health and Suicide Prevention Guidebook*, June 2018.

⁸⁰ VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. "Very large CBOCs [community-based outpatient clinics] are those that serve more than 10,000 unique veterans each year." The Veterans Crisis Line connects veterans with qualified responders through a confidential toll-free hotline, online chat, and text-messaging service to receive confidential support 24 hours a day. Community outreach activities are described in VHA Handbook 1160.01.

in his or her electronic health record “as soon as possible but no later than 1 business day after such determination by the SPC.”⁸¹ 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.”⁸² The HRS PRF is reviewed at least every 90 days and depending on changes to the suicide risk status, will remain active or be removed.⁸³ 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.⁸⁴

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.”⁸⁵ 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.”⁸⁶ 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.”⁸⁷

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

⁸¹ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*, January 16, 2020.

⁸² VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008.

⁸³ *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.

⁸⁴ VA Manual, *Safety Plan Treatment Manual to Reduce Suicide Risk: Veteran Version*, August 20, 2008. A safety plan is a “written list of coping strategies and sources of support that patients can use during or preceding suicidal crises.” Face-to-face visits may be performed as telephone visits if requested by the patient. The requirement for four face-to-face visits within 30 days of designation can be found in *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care, Suicide Prevention Coordinator Guide*.

⁸⁵ VHA DUSHOM Memorandum, *High Risk for Suicide Patient Record Flag Changes*, October 3, 2017.

⁸⁶ VHA DUSHOM Memorandum, *Update to High Risk for Suicide Patient Record Flag Changes*.

⁸⁷ VHA, response to questions by VA OIG Office of Healthcare Inspections from February 12, 2020, received February 19, 2020.

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

On March 27, 2020, VHA also updated existing policy requirements to allow the review of an HRS PRF to “occur no earlier than 10 days before and no later than 10 days after the 90-day due date.”⁸⁸

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.⁸⁹ VHA also requires that all staff receive annual refresher training.⁹⁰ In addition, SPCs are required to provide in-person Operation S.A.V.E. training as part of orientation for nonclinical employees.⁹¹

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

- Relevant documents;

⁸⁸ VHA Notice 2020-13, *Inactivation Process for Category I High Risk for Suicide Patient Record Flags*, March 27, 2020.

⁸⁹ Operation S.A.V.E. is a VA gatekeeper training program provided by suicide prevention coordinators to veterans and those who serve veterans. The acronym “S.A.V.E” summarizes the steps needed to take in recognizing and responding to a veteran in suicidal crisis. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

⁹⁰ VHA Directive 1071, *Mandatory Suicide Risk and Intervention Training for VHA Employees*, December 22, 2017.

⁹¹ VHA DUSHOM Memorandum, *Suicide Awareness Training*, April 11, 2017. The training was designed for nonclinical employees and includes food service workers, registration clerks, volunteers, and police. It should also be viewed by ancillary/support staff or any other category not covered by the clinical training.

- The electronic health records of 36 outpatients 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, monthly outreach activities, and suicide prevention training.

The OIG noted a concern with the review of HRS PRFs within the required time frame. VHA required that the SPC be responsible for “establishing a system of reviewing these flags at least every 90 days.”⁹² The OIG estimated that 8 percent of patients with an HRS PRF were reevaluated at least every 90 days.⁹³ Based on the updated requirement that the SPC ensures HRS PRFs are reviewed up to 10 days prior to or after the due date for reevaluation, the OIG found that clinical staff did not review three patients within the new time frame (observed range was 3-132 days).⁹⁴ The OIG made no recommendations but remains concerned about this update.

The OIG identified an additional concern with mental health appointment completion. VHA requires a patient to have four outpatient follow-up visits with a qualified provider within 30 days of HRS PRF placement.⁹⁵ The follow-up visits should be face-to-face unless the patient requests a telephonic visit, and include documentation identifying the patient’s preference for a telephone call.⁹⁶ The OIG estimated that 44 percent of the patients reviewed did not receive the required four mental health visits.⁹⁷ Failure to complete the visits could have prevented staff from providing optimal treatment to patients with suicidal ideation. The Associate Chief of Staff for Mental Health and the SPCs stated that visits occurred by telephone; however, they did not provide a reason for the lack of documentation identifying the patients’ preference for telephonic visits.

⁹² VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2018.

⁹³ The OIG estimated that 95 percent of the time, the true compliance rate is between 0.0 and 18.6 percent, which is statistically significantly below the 90 percent benchmark.

⁹⁴ VHA Notice 2020-13, *Inactivation Process for Category 1 High Risk For Suicide Patient Record Flags*, March 27, 2020.

⁹⁵ *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*, January 5, 2018.

⁹⁶ *VA’s Integrated Approach to Suicide Prevention: Ready Access to Quality Care Suicide Prevention Coordinator Guide*.

⁹⁷ The OIG estimated that 95 percent of the time, the true compliance rate is between 38.9 and 71.4 percent, which is statistically significantly below the 90 percent benchmark.

Recommendation 5

5. The Chief of Staff determines the reasons for noncompliance and makes certain that providers conduct four follow-up visits, either face-to-face or telephonic with documented patient preference, within the required time frame.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The Associate Chief of Staff Mental health and Suicide Prevention Team have informed the Mental Health Program Managers of the need to document the Veteran's preference for telephone visits within their note, 2. The Suicide Prevention Team has encouraged clinicians to use the Suicide Risk Management Follow Up Note which includes the Veteran's stated preference for a telephone visit within the template, 3. The Suicide Prevention Team will monitor clinical notes after flag placement to ensure four appointments occur within 30 days and ensure that patient preference of a face-to-face or telephonic appointment is documented, 4. The Suicide Prevention Team will provide feedback to the Mental Health Program Managers until 90 percent compliance is maintained for six consecutive months, 5. Data will be monitored by the Mental Health Integrated Clinical Community Committee.

Care Coordination: Life-Sustaining Treatment Decisions

Life-sustaining treatments (LSTs) are intended to extend the life of a patient expected to die soon without medical intervention. LSTs may include artificial nutrition, hydration, and mechanical ventilation. VHA issued the life-sustaining treatment decision (LSTD) handbook to standardize practices related to discussing and documenting goals of care and LSTDs. Per VHA, the goal is to encourage personalized, proactive, patient-driven treatment plans for veterans with serious illness by “eliciting, documenting, and honoring patients’ values, goals, and preferences.”⁹⁸

VA healthcare facilities were expected to fully implement new procedures outlined in the LSTD handbook by July 12, 2018.⁹⁹ 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.¹⁰⁰ 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.¹⁰¹

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.

⁹⁸ 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.

⁹⁹ VHA Handbook 1004.03(1). The medical facility must fully implement handbook requirements within 18 months of publication.

¹⁰⁰ 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.

¹⁰¹ VHA Directive 1139, *Palliative Care Consult Teams (PCCT) And VISN Leads*, June 14, 2017. Hospice patients are defined as individuals diagnosed with a terminal condition with a life expectancy of six months or less if the disease runs its projected course. VHA Handbook 1004.03(1). Triggering events requiring goals of care conversations include those “prior to referral or following admission (e.g., within 24 hours) to VA or non-VA hospice.”

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

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

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

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

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

VHA also requires facilities to appoint a multidisciplinary committee that reviews proposed LST plans for patients who lack both decision-making ability and a surrogate. The committee must be composed of three or more diverse disciplines (for example, social workers, nurses, and physicians) and include one or more members of the facility's Ethics Consultation Service.¹⁰² Inspectors examined if the medical center established an LSTD committee that was comprised of a multidisciplinary membership, which included representation from the Ethics Consultation Service, and reviewed proposed LST plans.

To determine whether the 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 26 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.

¹⁰² VHA Handbook 1004.03(1).

Women’s Health: Comprehensive Care

Women represented 9.4 percent of the veteran population as of September 30, 2017.¹⁰³ 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.¹⁰⁴ To help the VA better understand the needs of the growing women veterans population, efforts have been made by VHA to identify and address the urgent needs “by examining health care use, preferences, and the barriers Women Veterans face in access to VA care.”¹⁰⁵ 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.”¹⁰⁶

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.¹⁰⁷ VHA also requires delivery of quality care to all women veterans accessing VA emergency services. In addition, VHA requires facilities to establish a multidisciplinary women veterans health committee “that develops and implements a Women’s Health Program strategic plan to guide the program and assist with carrying out improvements for providing high-quality equitable care for women Veterans.”¹⁰⁸

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

¹⁰³ “Veteran Population,” Table 1L: VetPop2016 Living Veterans by Age Group, Gender, 2015–2045, National Center for Veterans Analysis and Statistics, accessed November 14, 2019, https://www.va.gov/vetdata/Veteran_Population.asp.

¹⁰⁴ “Veteran Population,” National Center for Veterans Analysis and Statistics, accessed on September 16, 2019, https://www.va.gov/vetdata/docs/Demographics/VetPop_Infographic_2019.pdf.

¹⁰⁵ Department of Veterans Affairs, *Study of Barriers for Women Veterans to VA Health Care, Final Report*, April 2015.

¹⁰⁶ Claire Hoffmire, “Concerning Trends in Suicide Among Women Veterans Point to Need for More Research on Tailored Interventions,” *Suicide Prevention, Forum*, Spring 2018, <https://www.hsrd.research.va.gov/publications/forum/spring18/default.cfm?ForumMenu=Spring18-5>.

¹⁰⁷ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020.

¹⁰⁸ VHA Directive 1330.01(3).

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

Women's Health Findings and Recommendations

The medical center complied with requirements for the provision of care indicators reviewed. However, the OIG identified concerns with the Women Veterans Health Advisory Committee, Women Veterans Program Manager duties, and a designated maternity care coordinator.

VHA requires that the Women Veterans Health Committee meets quarterly, reports to executive leaders, and has a core membership. 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."¹⁰⁹

While the Women's Health Advisory Committee met quarterly and reported to executive leaders, it did not include all required members. The OIG found that the Women's Health Medical Director, as well as representatives from pharmacy, radiology, and laboratory, were not assigned

¹⁰⁹ VHA Directive 1330.01(2), *Health Care Services for Women Veterans*, February 15, 2017, amended July 24, 2018. (This directive was in place for the time frame of the minutes reviewed in this report. It was amended on June 29, 2020 (1330.01(3)), and again on January 8, 2021 (1330.01(4)). All three directives contain the same or similar language regarding the Women Veterans Health Committee.

as required members. Additionally, the OIG reviewed Women’s Health Advisory Committee meeting minutes from July 2019 through December 2019 and found no representation from quality management or business office/non-VA medical care. This resulted in a lack of expertise and oversight in the review and analysis of data as the committee planned and carried out care improvements. The Women Veterans Program Manager reported being unaware of the requirement for core members. Also, the Chief of Quality Resource Services stated that representatives were unaware of their responsibility to attend the meetings.

Recommendation 6

6. The Medical Center Director evaluates and determines any additional reasons for noncompliance and makes certain that required members are assigned and consistently attend Women’s Health Advisory Committee meetings.

Medical center concurred.

Target date for completion: December 31, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility’s process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The charter for the Women’s Health Advisory Committee has been rewritten to reflect mandatory committee members, 2. Meetings will be held quarterly and as needed, 3. Members will be asked to send an alternate if they are unable to attend the meeting, 4. Women’s Veteran Program Manager will monitor attendance until 90% of required committee members have attended the meeting for two consecutive quarters, 5. The numerator is the number of required committee members who attended the Women’s Health Advisory Committee per meeting. The denominator is the number of required committee members, 6. Data will be monitored by the Clinical Executive Board.

VHA requires each facility to have a women veterans program manager who is full-time and free of collateral duties.¹¹⁰ The OIG found the medical center’s Women Veterans Program Manager was also acting as the Maternity Care Coordinator and Papanicolaou (Pap) Coordinator.¹¹¹ This could have negatively affected the coordination and oversight of women’s healthcare services. The Women Veterans Program Manager attributed the noncompliance to a vacancy in the maternity care coordinator position.

¹¹⁰ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020. (This directive was in place at the time of the site visit. It was amended on January 8, 2021, (1330.01(4)). The two versions contain similar language related to women veterans program manager duties.)

¹¹¹ American Cancer Society, “The Pap (Papanicolaou) Test,” accessed July 31, 2020, <https://www.cancer.org/cancer/cervical-cancer/detection-diagnosis-staging/screening-tests/pap-test.html>.” A Pap “test is a procedure that collects cells from the cervix so that they can be looked at closely in the lab to find cancer and pre-cancer.”

Recommendation 7

7. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures the Women Veterans Program Manager is full-time and free of collateral duties.¹¹²

Medical center concurred.

Target date for completion: Completed

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. A Maternity Care Coordinator and Papanicolaou Coordinator has been hired, 2. The Women Veterans Program Manager is free of collateral duties, 3. The facility requests closure of this recommendation.

VHA requires each facility to have a designated maternity care coordinator.¹¹³ The OIG interviewed the Associate Chief of Staff for Medical Service and the Women Veterans Program Manager and found that the medical center did not have the required position; this may have negatively affected the coordination of maternity care and tracking of maternity purchased care outcomes. The Associate Chief of Staff for Medical Service and the Women Veterans Program Manager stated that the Chief of Staff denied the maternity care coordinator position because the associated responsibilities were determined to be the responsibility of the Patient Aligned Care Team and Care in the Community team.

Recommendation 8

8. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures the medical center has a designated maternity care coordinator.¹¹⁴

¹¹² The OIG reviewed evidence sufficient to demonstrate that the medical center had completed improvement actions and therefore closed the recommendation before publication of the report.

¹¹³ VHA Directive 1330.01(3), *Health Care Services for Women Veterans*, February 15, 2017, amended June 29, 2020. (This directive was in place at the time of the site visit. It was amended on January 8, 2021, (1330.01(4)). The two versions contain similar language related to a maternity care coordinator.)

¹¹⁴ The OIG reviewed evidence sufficient to demonstrate 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 Medical Center Director evaluated reasons for noncompliance and implemented the following action to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. A Maternity Care Coordinator has been hired as required. The facility requests closure of this recommendation.

High-Risk Processes: Reusable Medical Equipment

Reusable medical equipment (RME) includes devices or items designed by the manufacturer to be used for multiple patients after proper decontamination, sterilization, and other processing between uses. VHA requires that facilities have Sterile Processing Services (SPS) “to ensure proper reprocessing and maintenance of critical and semi-critical reusable medical equipment.”¹¹⁵ The goal of SPS is to “provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare-associated infections.”¹¹⁶ 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 manufacturers’ guidelines and reviewed at least triennially
- Use CensiTrac[®] Instrument Tracking System for tracking reprocessed instruments¹¹⁷
- 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 inspections¹¹⁸

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.¹¹⁹ The required documentation includes high-level disinfectant solution testing, eyewash station maintenance records, and quality assurance records for RME reprocessing and sterilization.¹²⁰

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.¹²¹

¹¹⁵ VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

¹¹⁶ Julie Jefferson, Martha Young. *APIC Text of Infection Control and Epidemiology*. Association for Professionals in Infection Control and Epidemiology, 2019. “Chapter 108: Sterile Processing.”

¹¹⁷ VHA DUSHOM Memorandum, *Instrument Tracking Systems for Sterile Processing Services*, January 1, 2019.

¹¹⁸ VHA Directive 1116(2).

¹¹⁹ 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.

¹²⁰ VHA Directive 7704(1), *Location, Selection, Installation, Maintenance, and Testing of Emergency Eyewash and Shower Equipment*, February 16, 2016.

¹²¹ 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.¹²²

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

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

¹²² VHA Directive 1116(2).

High-Risk Processes Findings and Recommendations

The medical center complied with some elements of expected performance for reprocessing RME. However, the OIG identified deficiencies with SOPs, staff training, and competency assessments.

VHA requires that facilities “must have standard operating procedures (SOPs) based on manufacturer’s guidelines that establishes a documented and systematic approach to critical and semi-critical RME processes.”¹²³ The OIG found that the SOPs for the selected endoscope, transducer, and dilator did not align with the manufacturers’ guidelines and instructions for use.¹²⁴ Failure to follow the manufacturers’ instructions could have resulted in inadequate reprocessing, damage to the equipment, and/or significant safety risks for patients. The Chief of SPS acknowledged failure to review the SOPs as the reason for noncompliance.

Recommendation 9

9. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that standard operating procedures align with the manufacturers’ guidelines and instructions for use.

¹²³ VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016.

¹²⁴ Philips, “Ultrasound Probes & Transducers: High-resolution ultrasound transducers enable swift and precise imaging,” accessed April 8, 2021, <https://www.usa.philips.com/healthcare/solutions/ultrasound/ultrasound-transducer>. Cook Medical, “Savary-Gillard Dilator,” accessed April 8, 2021, https://www.cookmedical.com/products/esc_sgd_webds/. Savary-Gillard Dilators are used for esophageal dilation.

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The Phillips Transducer has been replaced with the BK Transducer. The Standard Operating Procedure was reviewed and is in alignment with manufacturer's guidelines and instructions for use, 2. Endoscope 190 series Standard Operating Procedure was reviewed and is in alignment with Manufacturer's guidelines and instructions for use, 3. The Savary Gillard Dilators Standard Operating Procedure was reviewed and is in alignment with the Manufacturer's guides and instruction for use, 4. The Chief, Sterile Processing Services reviews fifteen Standard Operating Procedures per quarter to ensure Standard Operating Procedures match the Manufacturer's guidelines and instructions for use, 5. This will be completed on a quarterly basis until 90% compliance is demonstrated for two consecutive quarters. The numerator will be the number of Standard Operating Procedures reviewed and in alignment with manufacturer's guidance and instruction for use. The denominator will be the number of Standard Operating Procedures reviewed quarterly. 6. Audit results will be reported to the Reusable Medical Equipment Committee.

Since March 23, 2016, VHA has required that "all new SPS employees must complete the SPS Level 1 training program within 90 days of hire."¹²⁵ The OIG identified that two SPS employees hired after March 23, 2016, did not complete the training within the required time frame. Lack of adequate training could have resulted in improper reprocessing, handling, and use of medical equipment. The Chief of SPS reported being hired in 2019 and assumed that staff hired in 2016 would have completed training in accordance with VHA policy.

Recommendation 10

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

¹²⁵ VHA Directive 1116(2).

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. All current Sterile Processing Service employees have completed all 12 volumes of SPS Level 1 Training, 2. One job vacancy currently exists. The Chief of Sterile Processing Service and/or designee will ensure the plan of action is taken after the employee completes New Employee Orientation and during the employees first week of orientation to SPS. An audit will be completed during and after the employee completes all twelve modules of the Level 1 training in the first week, which will be well within the 90 days of hire; audits will be ongoing thereafter will [track] all new hires in their first week of orientation to SPS and within 90 days of hire. No new hire will be allowed to work in any restricted areas of SPS (i.e., Clean/Prep, Decontamination, etc.) until completion of the required 12 modules of the Level one Training. This will be monitored for six months and completed on a quarterly basis until a 90% or greater compliance is demonstrated for two consecutive quarters. The numerator will be the number of new hires that complete Level 1 Training within 90 days of working in SPS. The denominator will be the number of new hires in SPS. 3. All results will be shared with the Reusable Medical Equipment Committee.

VHA requires the Chief of SPS to ensure employees complete competency assessments prior to performing reprocessing duties.¹²⁶ The OIG identified that as applicable, employees completed assessments for the three SOPs reviewed; however, the assessments were invalid due to lack of congruency between the manufacturers' instructions for use and SOPs. The Chief of SPS agreed that the competency assessments were invalid and reported lack of supervisory oversight as a reason for noncompliance.

Recommendation 11

11. The Associate Director for Patient Care Services evaluates and determines any additional reasons for noncompliance and ensures that Sterile Processing Services employees complete valid competency assessments prior to reprocessing reusable medical equipment.

¹²⁶ VHA Directive 1116(2).

Medical center concurred.

Target date for completion: September 30, 2021

Medical center response: The Medical Center Director evaluated reasons for noncompliance and implemented the following actions to improve the facility's process in identifying opportunities for improvement and implementing and monitoring corrective actions. 1. The Phillips Transducer has been replaced with the BK Transducer. The Standard Operating Procedure was reviewed in and is in alignment with manufacturer's guidelines and instructions for use, 2. Endoscope 190 series Standard Operating Procedure was reviewed and is in alignment with Manufacturer's guidelines and instructions for use, 3. The Savary Gillard Dilators Standard Operating Procedure was reviewed and is in alignment with the Manufacturer's guidelines and instruction for use. 4. Staff competencies are congruent with the SOP and were completed on February 3, 2021, 5. The Chief Sterile Processing Services will review fifteen Standard Operating Procedures per quarter at which time staff competencies will also be reviewed to ensure they align and are congruent with the Manufacturer's instruction for use and the Standard Operating Procedure. The numerator will be the number of staff completing competencies that are congruent with Standing Operating Procedure and the Manufacturer's instruction for use. The denominator will be the number of staff [who] needed competencies. 6. This will be completed on a quarterly basis until 90% compliance is demonstrated for two consecutive quarters, 7. Audit results will be reported to the Reusable Medical Equipment Committee.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

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

Table A.1. Summary Table of Recommendations

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

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	<ul style="list-style-type: none"> • QSV Committee • Protected peer reviews • UM reviews • Patient safety 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Action items are recommended, implemented, and monitored when problems and opportunities for improvement are identified. • An interdisciplinary committee reviews UM data as required.
Medical Staff Privileging	<ul style="list-style-type: none"> • FPPEs • OPPEs • Provider exit reviews and reporting to state licensing boards 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Service chiefs complete provider exit review forms within seven business days of licensed healthcare professionals' departure from the medical center.
Medication Management: Long-Term Opioid Therapy	<ul style="list-style-type: none"> • Provision of pain management using long-term opioid therapy • Program oversight and evaluation 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • The Pain Management Committee monitors the quality of pain assessments and effectiveness of pain management interventions.
Mental Health: Suicide Prevention Program	<ul style="list-style-type: none"> • Designated facility suicide prevention coordinator • Tracking and follow-up of high-risk veterans • Provision of suicide prevention care • Completion of suicide prevention training requirements 	<ul style="list-style-type: none"> • Providers conduct four follow-up visits, either face-to-face or telephonic with documented patient preference, within the required time frame. 	<ul style="list-style-type: none"> • None
Care Coordination: Life-Sustaining Treatment Decisions	<ul style="list-style-type: none"> • LSTD multidisciplinary committee • LSTD progress note documentation • LSTD note/orders completed by an authorized provider or delegated 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • None

Healthcare Processes	Requirements	Critical Recommendations for Improvement	Recommendations for Improvement
Women's Health: Comprehensive Care	<ul style="list-style-type: none"> • Provision of care • Program oversight and performance improvement data monitoring • Staffing requirements 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Required members are assigned and consistently attend Women's Health Advisory Committee meetings. • The Women Veterans Program Manager is full-time and free of collateral duties. • The medical center has a designated maternity care coordinator.
High-Risk Processes: Reusable Medical Equipment	<ul style="list-style-type: none"> • Administrative processes • Quality assurance • Staff training 	<ul style="list-style-type: none"> • Standard operating procedures align with manufacturers' guidelines and instructions for use. 	<ul style="list-style-type: none"> • Sterile Processing Services employees complete Level 1 training within 90 days of hire. • Sterile Processing Services employees complete valid competency assessments prior to reprocessing reusable medical equipment.

Appendix B: Medical Center Profile

The table below provides general background information for this low complexity (3) medical center reporting to VISN 10.¹

**Table B.1. Profile for Battle Creek VA Medical Center (515)
(October 1, 2016, through September 30, 2019)**

Profile Element	Medical Center Data FY 2017*	Medical Center Data FY 2018	Medical Center Data FY 2019‡
Total medical care budget	\$287,920,439	\$290,418,663	\$302,310,981
Number of:			
• Unique patients	44,209	43,714	43,790
• Outpatient visits	560,089	525,882	519,713
• Unique employees	1,359	1,375	1,369
Type and number of operating beds:			
• Community living center	109	109	109
• Domiciliary	92	92	92
• Medicine	11	11	11
• Mental health	55	55	55
• Residential rehabilitation	9	9	9
Average daily census:			
• Community living center	77	71	73
• Domiciliary	69	65	65
• Medicine	3	3	3
• Mental health	42	36	42
• Residential rehabilitation	6	8	7

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

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

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

October 1, 2017, through September 30, 2018.

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

¹ The VHA medical centers are classified according to a facility complexity model; a designation of “3” indicates a facility with “low volume, low-risk patients, few or no complex clinical programs, and small or no research and teaching programs.”

Appendix C: VA Outpatient Clinic Profiles

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

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

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Wyoming, MI	515BY	36,195	15,458	Anesthesia Cardiology Dermatology Endocrinology Eye Gastroenterology General surgery GYN Hematology/ Oncology Infectious disease	EKG EMG Laboratory & pathology Nuclear Med Radiology	Dental Nutrition Pharmacy Prosthetics Social work Weight management

¹ Includes outpatient clinics in the community that were in operation as of August 27, 2019. The OIG omitted Lansing, MI (515QA) and Grand Rapids, MI (515QB) as no workload/encounters or services were reported. VHA Directive 1230(3), *Outpatient Scheduling Processes And Procedures*, July 15, 2016, amended January 7, 2021. An encounter is a “professional contact between a patient and a provider vested with responsibility for diagnosing, evaluating, and treating the patient’s condition.” Specialty care services refer to non-primary care and non-mental health services provided by a physician. Diagnostic services include electrocardiogram (EKG), electromyography (EMG), laboratory & pathology, nuclear medicine, and radiology. Ancillary services include dental, nutrition, pharmacy, prosthetics, social work, and weight management.

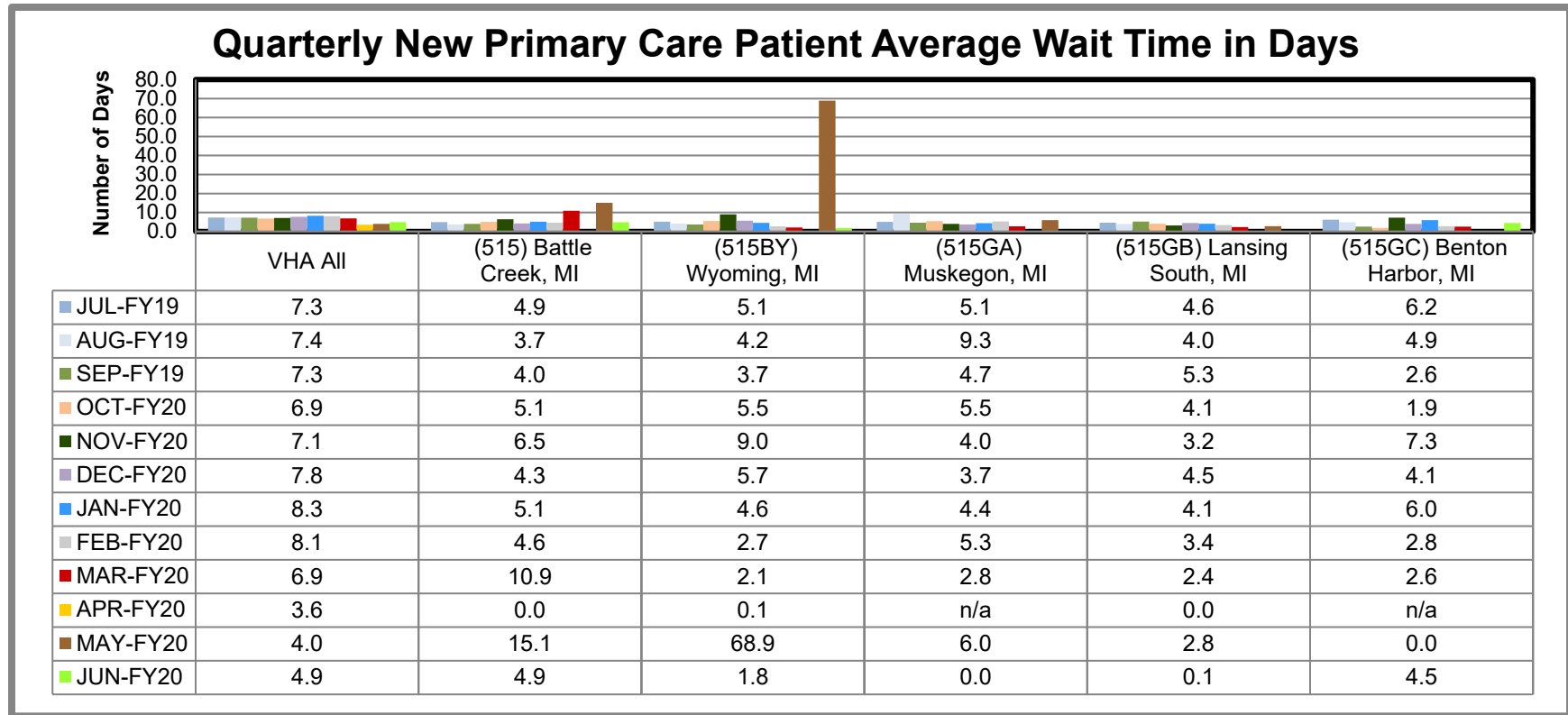
Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Wyoming, MI cont.				Nephrology Neurology Neurosurgery Orthopedics Otolaryngology Podiatry Pulmonary/ Respiratory disease Rehab physician Rheumatology Spinal cord injury Urology Vascular		
Muskegon, MI	515GA	12,785	4,025	Cardiology Dermatology Endocrinology Gastroenterology General surgery GYN Hematology/ Oncology Neurosurgery Orthopedics Otolaryngology Pulmonary/ Respiratory disease Rheumatology Urology	EKG Nuclear Med	Nutrition Pharmacy Weight management

Location	Station No.	Primary Care Workload/ Encounters	Mental Health Workload/ Encounters	Specialty Care Services Provided	Diagnostic Services Provided	Ancillary Services Provided
Lansing, MI	515GB	11,990	4,580	Cardiology Dermatology Endocrinology Gastroenterology General surgery GYN Infectious disease Orthopedics Otolaryngology Poly-Trauma Rheumatology Urology	EKG Nuclear Med	Nutrition Pharmacy Social work Weight management
Benton Harbor, MI	515GC	5,204	3,267	Cardiology Dermatology Endocrinology Gastroenterology General surgery GYN Infectious disease Nephrology Neurosurgery Orthopedics Otolaryngology Rheumatology Urology Vascular	EKG Nuclear Med	Nutrition Pharmacy Weight management

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

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

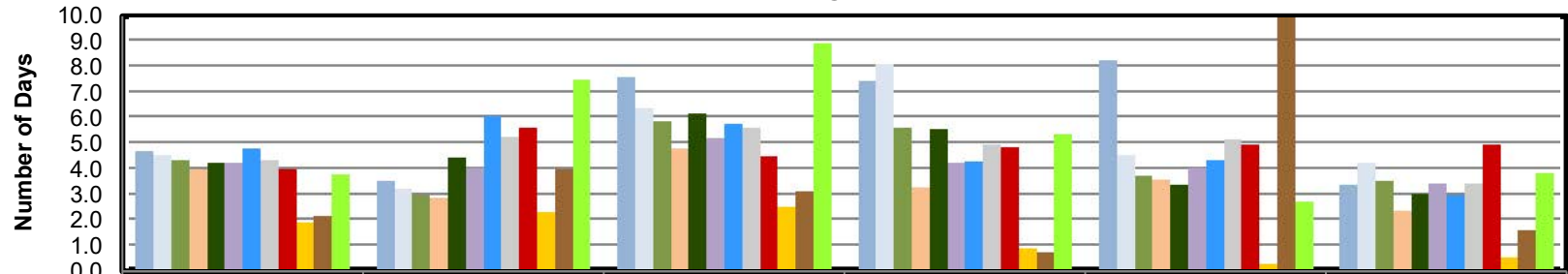
Appendix D: Patient Aligned Care Team Compass Metrics



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

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG has on file the medical center’s explanation for the increased wait times for Wyoming, MI. The OIG omitted (515QA) Lansing, MI and (515QB) Century Avenue, MI as no data was reported. “The average number of calendar days between a New Patient’s Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL)), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date.” Prior to FY 2015, this metric was calculated using the earliest possible create date. The absence of reported data is indicated by “n/a.”

Quarterly Established Primary Care Patient Average Wait Time in Days



	VHA All	(515) Battle Creek, MI	(515BY) Wyoming, MI	(515GA) Muskegon, MI	(515GB) Lansing South, MI	(515GC) Benton Harbor, MI
JUL-FY19	4.6	3.5	7.5	7.4	8.2	3.3
AUG-FY19	4.5	3.2	6.3	8.0	4.5	4.2
SEP-FY19	4.3	3.0	5.8	5.6	3.7	3.5
OCT-FY20	3.9	2.8	4.8	3.2	3.5	2.4
NOV-FY20	4.2	4.4	6.1	5.5	3.3	3.0
DEC-FY20	4.2	4.0	5.2	4.2	4.0	3.4
JAN-FY20	4.8	6.0	5.7	4.2	4.3	3.0
FEB-FY20	4.3	5.2	5.6	4.9	5.1	3.4
MAR-FY20	3.9	5.6	4.5	4.8	4.9	4.9
APR-FY20	1.9	2.3	2.5	0.9	0.2	0.5
MAY-FY20	2.1	3.9	3.1	0.7	17.3	1.5
JUN-FY20	3.7	7.4	8.9	5.3	2.7	3.8

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

Note: The OIG did not assess VA’s data for accuracy or completeness. The OIG omitted (515QA) Lansing, MI and (515QB) Century Avenue, MI as no data was reported. “The average number of calendar days between an Established Patient’s Primary Care completed appointment (clinic stops 322, 323, and 350, excluding [Compensation and Pension] appointments) and the earliest of [three] possible preferred (desired) dates (Electronic Wait List (EWL), Cancelled by Clinic Appointment, Completed Appointment) from the completed appointment date.”

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

Measure	Definition	Desired Direction
Adjusted LOS	Acute care risk adjusted length of stay	A lower value is better than a higher value
AES Data Use	Composite measure based on three individual All Employee Survey (AES) data use and sharing questions	A higher value is better than a lower value
Care transition	Care transition (inpatient)	A higher value is better than a lower value
CMS MORT	Centers for Medicare and Medicaid Services (CMS) risk standardized mortality rate	A lower value is better than a higher value
ED Throughput	Composite measure for timeliness of care in the emergency department	A lower value is better than a higher value
HC assoc infections	Health care associated infections	A lower value is better than a higher value
HEDIS like – HED90_1	Healthcare Effectiveness Data and Information Set (HEDIS) composite score related to outpatient behavioral health screening, prevention, immunization, and tobacco	A higher value is better than a lower value
HEDIS like – HED90_ec	HEDIS composite score related to outpatient care for diabetes and ischemic heart disease	A higher value is better than a lower value
MH continuity care	Mental health continuity of care (FY14Q3 and later)	A higher value is better than a lower value
MH exp of care	Mental health experience of care (FY14Q3 and later)	A higher value is better than a lower value
MH popu coverage	Mental health population coverage (FY14Q3 and later)	A higher value is better than a lower value
Oryx – GM90_1	ORYX inpatient composite of global measures	A higher value is better than a lower value

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

Source: VHA Support Service Center.

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

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

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

Source: VHA Support Service Center.

Appendix G: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: April 30, 2021

From: Network Director, Veterans Integrated Service Network (10N10)

Subj: Comprehensive Healthcare Inspection of the Battle Creek VA Medical Center in Michigan

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

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

1. I have reviewed and concur with the response for the draft report of our Comprehensive Healthcare Inspection of the Battle Creek VA Medical Center in Battle Creek, Michigan.
2. I concur with the responses and action plans submitted by the Battle Creek VA Medical Center Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson

Appendix H: Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: April 21, 2021

From: Director, Battle Creek VA Medical Center (515)

Subj: Comprehensive Healthcare Inspection of the Battle Creek VA Medical Center in Michigan

To: Director, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

1. I have reviewed the draft report – Comprehensive Healthcare Program Review of the Battle Creek VA Medical Center, Battle Creek, Michigan. We concur with all the findings and recommendations.
2. I appreciate the opportunity for this review as a continuing process to improve the care to our Veterans. Thank you

(Original signed by:)

Michelle A Martin

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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Inspection Team	Rose Griggs, MSW, LCSW, Team Leader Sheila Cooley, MSN, GNP Sheeba Keneth, MSN/CNL, RN Barbara Miller, BSN, RN Renay Montalbano, MSN, RN Jennifer Reed, MSHI, RN
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Other Contributors	Elizabeth Bullock Limin Clegg, PhD Kaitlyn Delgadillo, BSPH Ashley Fahle Gonzalez, MPH, BS Jennifer Frisch, MSN, RN Justin Hanlon, BS LaFonda Henry, MSN, RN-BC Cynthia Hickel, MSN, CRNA Scott McGrath, BS Larry Ross, Jr., MS Krista Stephenson, MSN, RN Caitlin Sweany-Mendez, MPH, BS Robert Wallace, ScD, MPH
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Director, Battle Creek VA Medical Center (515/00)

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House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
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