DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the VA Manila Outpatient Clinic

Pasay City, Philippines

CHIP REPORT | **REPORT #19-00024-39** | **DECEMBER 11, 2019**

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Figure 1. *VA Manila Outpatient Clinic, Pasay City, Philippines (Source: https://vaww.va.gov/directory/guide/, accessed on September 20, 2019)*

Abbreviations

CHIP	Comprehensive Healthcare Inspection Program
FPPE	focused professional practice evaluation
FY	fiscal year
LIP	licensed independent practitioner
MST	military sexual trauma
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
QSV	quality, safety, and value
TJC	The Joint Commission
UCC	urgent care center
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Report Overview

This Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) provides a focused evaluation of the quality of care delivered at the VA Manila Outpatient Clinic (the facility). The inspection covers key clinical and administrative processes that are associated with promoting quality care.

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

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

This unannounced visit was conducted during the week of April 1, 2019. The OIG held interviews and reviewed clinical and administrative processes related to areas of focus that affect patient care outcomes. Although the OIG reviewed a broad spectrum of clinical and administrative processes, the sheer complexity of VA medical facilities limits inspectors' ability to assess all areas of clinical risk. The findings presented in this report are a snapshot of this

[1] This review was not performed at the VA Manila Outpatient Clinic because of an insufficient number of veterans identified during the study period.

[2] The OIG's review of the emergency department and urgent care center (UCC) operations and management focused on the clinical risks of the emergency department/UCC areas. This review was not performed at the VA Manila Outpatient Clinic because the facility did not have an emergency department or UCC.

facility's performance within the identified focus areas at the time of the OIG visit. Although it is difficult to quantify the risk of patient harm, the findings in this report may help this facility and other Veterans Health Administration (VHA) facilities to identify areas of vulnerability or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results and Inspection Impact

Leadership and Organizational Risks

At the time of the OIG's site visit, the facility was under the leadership of a clinic manager, (director) who reported directly to Veterans Integrated Service Network (VISN) 21 deputy director and the chief medical officer. The facility, located in the Republic of the Philippines on U.S. Embassy property, is the only VA healthcare facility located in a foreign country.

The facility's leadership team had been working together for two years, although the director had served in the position for many years. The director was permanently assigned July 15, 2012, and a new director was anticipated to assume the role one week after the OIG's on-site visit. The chief medical officer was permanently assigned March 22, 2015, and the recruitment for a new assistant clinic manager (assistant director) was ongoing.

The OIG noted that selected employee satisfaction survey results, except that for the director regarding servant leadership, indicated that facility leaders were engaged and promoted a culture of safety where employees feel safe bringing forward issues and concerns. The selected patient experience survey scores for facility leaders were better than the VHA average, and facility leaders appeared actively engaged with patients.

Additionally, the OIG reviewed accreditation agency findings, sentinel events,[3] and disclosures of adverse patient events and did not identify any substantial organizational risk factors. However, the impact of political unrest in the Philippines may affect access to care and safety of veterans and staff.

The OIG noted deficiencies in four of the six clinical areas reviewed and issued seven recommendations that are attributable to the director and chief medical officer. These are briefly described below.

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

Medical Staff Privileging

The facility generally complied with requirements for privileging. However, the OIG identified concerns with focused and ongoing professional practice evaluations.[4]

Medication Management

Overall, the facility complied with requirements for most of the performance indicators evaluated for medication management, including the controlled substances coordinator reports and requirements for controlled substances inspectors. The OIG team noted that the staff who review the monthly balance adjustments were also able to conduct the balance adjustments, which was corrected during the OIG site visit. However, the OIG identified noncompliance with pharmacy inspection inventory counts.

Mental Health

The OIG team also found the facility complied with many of the mental health performance indicators, including the designation of a military sexual trauma (MST) coordinator, establishing and monitoring MST-related staff training and informational outreach, and providers completing MST mandatory training. The OIG identified noncompliance with communicating the status of MST services and initiatives with facility leaders, tracking MST-related data, and providers' timely completion of diagnostic treatment evaluations.

Geriatric Care

For geriatric patients, providers documented the reasons for prescribing medications. However, the OIG identified inadequate patient and/or caregiver education related to newly prescribed medications and medication reconciliation to minimize duplicative medications and adverse interactions.

Summary

In reviewing key healthcare processes, the OIG issued seven recommendations for improvement directed to the facility director/clinic manager and chief medical officer. The number of

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

recommendations should not be used, however, as a gauge for the overall quality provided at this facility. The intent is for facility leaders to use these recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues as well as other less-critical findings that, if left unattended, may eventually interfere with the delivery of quality health care.

Comments

The VISN director and facility director agreed with the CHIP inspection findings and recommendations and provided acceptable improvement plans. (See Appendixes C and D, pages 41–42, and the responses within the body of the report for the full text of the directors' comments.) The OIG considers recommendation 2 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Contents

Purpose and Scope

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

Effective leaders manage organizational risks by establishing goals, strategies, and priorities to improve care; setting the quality agenda; and promoting a culture to sustain positive change.[5] Investments in a culture of safety and quality improvement with robust communications and leadership significantly contribute to positive patient outcomes in healthcare organizations.[6] Figure 2 shows the direct relationships between leadership and organizational risks and the processes used to deliver health care to veterans.

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

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

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

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

9. High-risk processes (specifically the emergency department and urgent care center operations and management).[7]

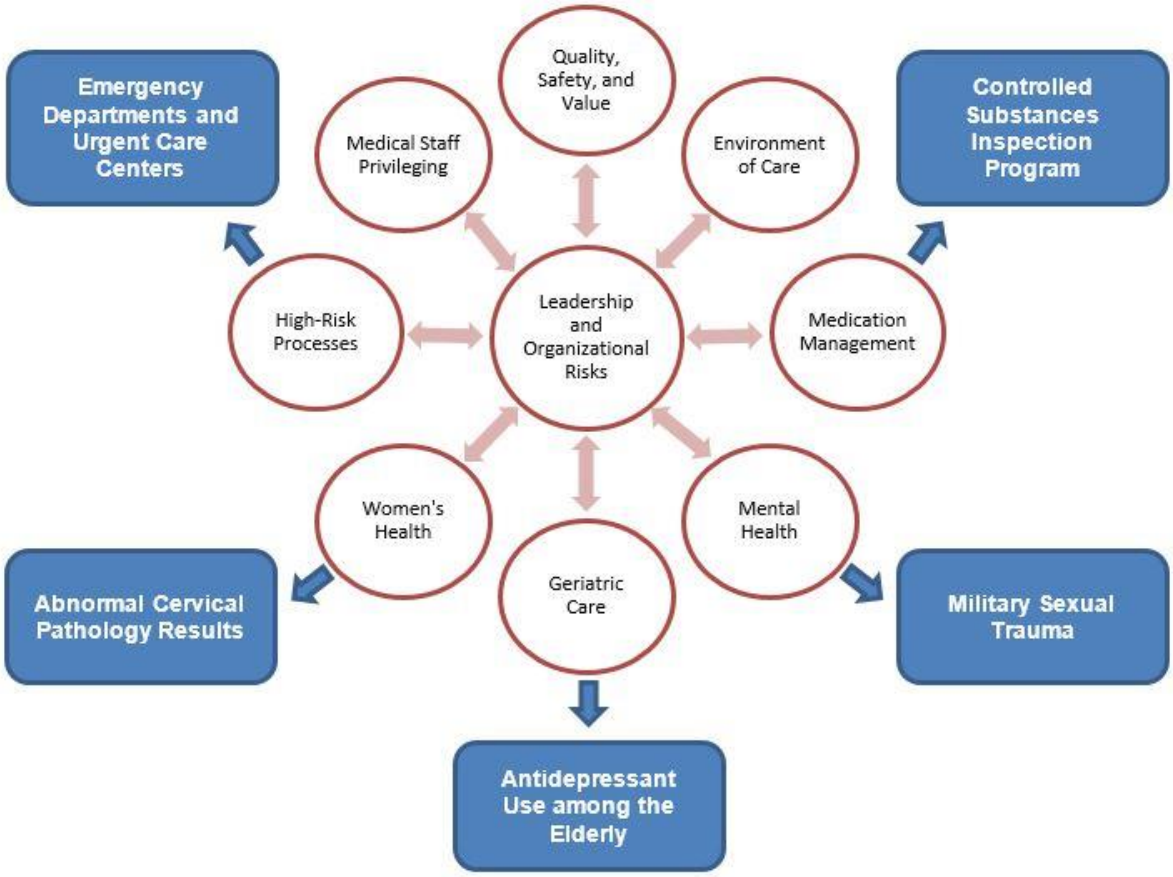

Figure 2. *Fiscal Year (FY) 2019 Comprehensive Healthcare Inspection of Operations and Services*
Source: VA OIG

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

Methodology

To determine compliance with the Veterans Health Administration (VHA) requirements related to patient care quality, clinical functions, and the environment of care, the inspection team reviewed OIG-selected clinical records, administrative documents, and accreditation survey reports;[8] physically inspected OIG-selected areas; and discussed processes and validated findings with managers and employees. The OIG also interviewed members of the facility and VISN leadership team.

The inspection period examined operations from January 29, 2016, through April 5, 2019, the last day of the unannounced week-long site visit.[9] While on site, the OIG did not receive any complaints beyond the scope of the CHIP inspection.

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

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

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

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

Results and Recommendations

Leadership and Organizational Risks

Stable and effective leadership is critical to improving care and sustaining meaningful change within a VA healthcare facility. Leadership and organizational risks can impact the facility's ability to provide care in all of the selected clinical areas of focus.[10] To assess the facility's risks, the OIG considered the following indicators:

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

Leadership Position Stability and Engagement

The VA Manila Outpatient Clinic provides outpatient care to veterans residing in or visiting the Republic of the Philippines. The care provided is limited to the scope of services and the capacity of the clinic. Eligible veterans requiring care not available at the clinic can obtain services through the Foreign Medical Program—a VA health care benefits program for veterans residing or traveling outside the U.S. and having VA-rated, service-connected disabilities.[11] The clinic is located on U.S. Embassy property and is the only VA healthcare facility in a foreign country.

At the time of the OIG's visit, the facility was under the leadership of a clinic manager (director), who reports to Veterans Integrated System Network (VISN) 21 deputy director and the chief medical officer. The facility had 62 staff of various healthcare disciplines, such as physicians, nurses, pharmacists, technologists, and administrative. The director was the only clinic staff member with U.S. citizenship; the rest of the workforce were Philippine nationals (Filipinos). The recruitment for a new assistant clinic manager (assistant director) with U.S. citizenship was ongoing.

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

[11] VHA Directive 1521, *Outpatient Health Care for United States Veterans Residing In or Visiting the Philippines at the Department of Veterans Affairs (VA) Clinic in Manila*, February 5, 2018.

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 3 illustrates this facility's reported organizational structure. The chief medical officer oversees patient care, which requires managing clinical operations and outpatient treatment services.

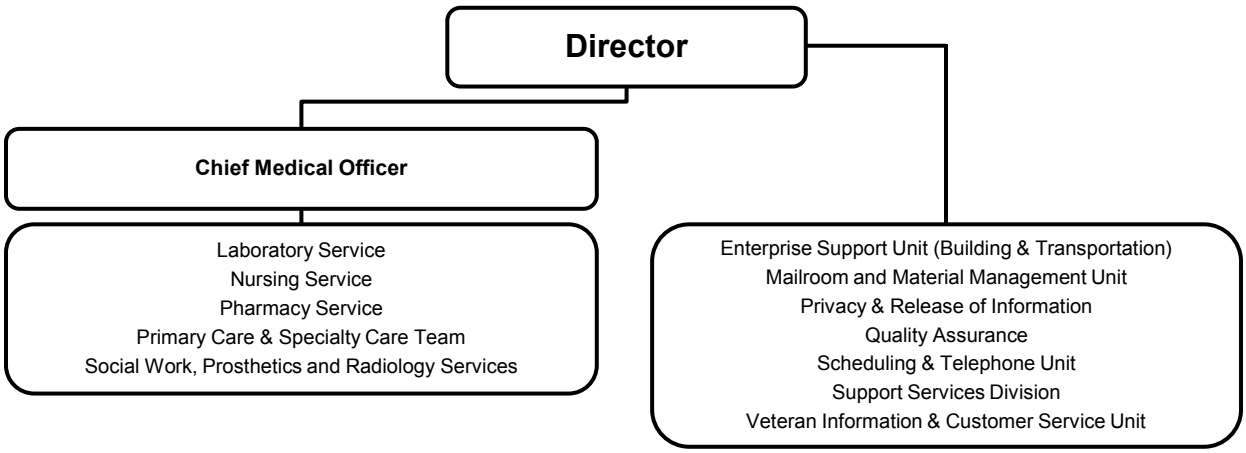

Figure 3. *Facility Organizational Chart*[12]
Source: VA Manila Outpatient Clinic (received April 2, 2019)

At the time of the OIG site visit, the leadership team had been working together for over two years, although the director had been in the position for many years (see Table 1). It is important to note that a new director was anticipated to assume the role on April 14, 2019.

Table 1. Leader Assignments

Leadership Position	Assignment Date
Director	July 15, 2012
Chief medical officer	March 22, 2015

Source: VA Manila Outpatient Clinic VISN 21 deputy quality management officer (received April 2, 2019)

To help assess facility executive leaders' engagement, the OIG interviewed the director and chief medical officer regarding their knowledge of employee satisfaction and patient experience data and their involvement and support of actions to improve or sustain performance. The OIG also interviewed the VISN 21 deputy director to understand the supervision provided to the facility and the director. The VISN deputy director inspects the facility twice a year and seemed aware of facility activities and challenges.

[12] At this facility, the director is responsible for Enterprise Support Unit (Building & Transportation), Mailroom and Material Management Unit, Privacy & Release of Information, Quality Assurance, Scheduling & Telephone Unit, Support Services Division, and Veteran Information & Customer Service Unit.

In individual interviews, the director, chief medical officer, and VISN deputy director were able to speak knowledgeably about actions taken during the previous 12 months in order to maintain or improve performance as well as employee and patient survey results.

The director serves as the chairperson of the Joint Executive Board, with the authority and responsibility for establishing policy, maintaining quality care standards, and performing organizational management and strategic planning. The Joint Executive Board oversees the Medical Executive, Clinic Operations, Disruptive Behavior, and Resource Management Committees.

The leaders are also engaged in monitoring patient safety and care through the Clinic Operations Committee, which the director chairs. The Clinic Operations Committee is responsible for tracking and identifying trends and monitoring quality of care and patient outcomes. See Figure 4.

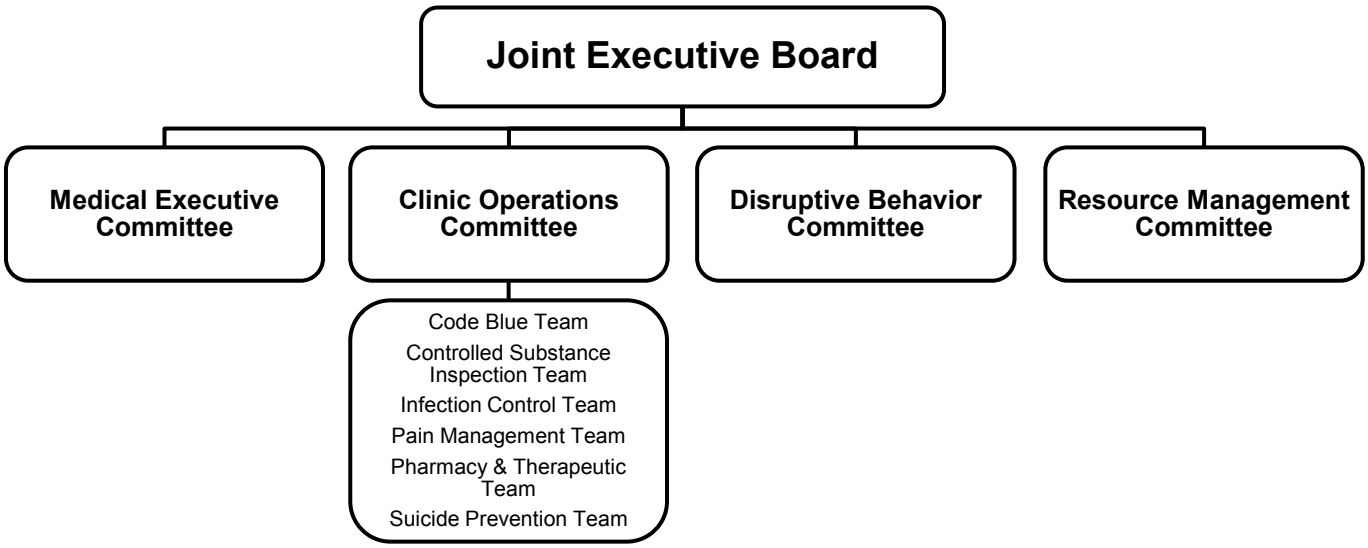

Figure 4. *Facility Committee Reporting Structure*
Source: VA Manila Outpatient Clinic (*received April 3, 2019*)

Employee Satisfaction

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

To assess employee attitudes toward facility leaders, the OIG reviewed employee satisfaction survey results from VHA's All Employee Survey that relate to the period of October 1, 2017,

through September 30, 2018.[13] Table 2 provides relevant survey results for VHA, the facility, and selected facility leaders. It summarizes employee attitudes toward these leaders as expressed in VHA's All Employee Survey. The OIG found the facility average for several selected survey leadership questions was higher than the VHA average.[14] The same trend was generally noted for the members of the leadership team; however, the director was unable to explain the lower rating for the servant leadership survey result. In all, employees appear generally satisfied with facility leaders.

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

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Facility Director	Chief Medical Officer–Outpatient Treatment Services Average
All Employee Survey: *Servant Leader Index Composite*[15]	0–100 where HIGHER scores are more favorable	71.7	72.8	63.3	77.5
All Employee Survey: *In my organization, senior leaders generate high levels of motivation and commitment in the workforce.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.3	3.9	3.6	3.8
All Employee Survey: *My organization's senior leaders maintain high standards of honesty and integrity.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.5	3.9	3.6	4.0
All Employee Survey: *I have a high level of respect for my organization's senior leaders.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.6	4.1	4.1	3.9

Source: VA All Employee Survey (accessed March 8, 2019)

[13] Ratings are based on responses by employees who report to or are aligned under the clinic manager/director and chief medical officer (clinical services).

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

Table 3 summarizes employee attitudes toward the workplace as expressed in VHA's All Employee Survey. Note that the facility and leadership team averages for the selected survey questions were generally similar to the VHA average, except for the question related to moral distress at work. The director believed that the low scores reflected employees' wishes to expand the clinic's services for veterans with non-service connected conditions.

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

Questions/ Survey Items	Scoring	VHA Average	Facility Average	Director Average	Chief Medical Officer–Outpatient Treatment Services Average
All Employee Survey: *I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.8	3.7	3.6	3.7
All Employee Survey: *Employees in my workgroup do what is right even if they feel it puts them at risk (e.g., risk to reputation or promotion, shift reassignment, peer relationships, poor performance review, or risk of termination).*	1 (Strongly Disagree) – 5 (Strongly Agree)	3.7	3.7	3.6	3.8
All Employee Survey: *In the past year, how often did you experience moral distress at work (i.e., you were unsure about the right thing to do or could not carry out what you believed to be the right thing)?*	0 (Never) – 6 (Every Day)	1.5	2.0	2.4	1.4

Source: VA All Employee Survey (*accessed March 8, 2019*)

Patient Experience

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

relevant survey results for facility leadership and compares the results to the overall VHA averages.[16]

VHA also collects SHEP survey data from Patient-Centered Medical Home, Specialty Care, and Inpatient Surveys. The OIG reviewed responses to two relevant survey questions that reflect patients' attitudes toward facility leaders (see Table 4). For this facility, both survey results reflected higher care ratings than the VHA average. Facility leaders appeared to be actively engaged with patients; for example, the director had daily interactions with patients in the waiting room.

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

Questions	Scoring	VHA Average	Facility Average
Survey of Healthcare Experiences of Patients (inpatient): *Would you recommend this hospital to your friends and family?*	The response average is the percent of "Definitely Yes" responses.	66.9	n/a[17]
Survey of Healthcare Experiences of Patients (inpatient): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	84.2	n/a
Survey of Healthcare Experiences of Patients (outpatient Patient-Centered Medical Home): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.3	89.5
Survey of Healthcare Experiences of Patients (outpatient specialty care): *I felt like a valued customer.*	The response average is the percent of "Agree" and "Strongly Agree" responses.	76.5	79.1

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

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

[17] The facility does not provide inpatient care; therefore, the facility average for the two inpatient survey questions is not applicable (n/a).

Accreditation Surveys and Oversight Inspections

To further assess leadership and organizational risks, the OIG reviewed recommendations from previous inspections and surveys, including those conducted for cause, by oversight and accrediting agencies to gauge how well leaders respond to identified problems.[18] The facility is not accredited by The Joint Commission (TJC).[19] Table 5 summarizes the relevant facility inspection most recently performed by the OIG. Indicative of effective leadership, the facility has closed all recommendations for improvement.[20] At the time of the site visit, the OIG also noted the facility laboratory's current accreditation status with the College of American Pathologists.[21]

Table 5. Office of Inspector General Inspections

Accreditation or Inspecting Agency	Date of Visit	Number of Recommendations Issued	Number of Recommendations Remaining Open
OIG (*Combined Assessment Program Review of the VA Manila Outpatient Clinic, Manila, Philippines,* Report No. 16-00103-160, March 9, 2016)	January 2016	6	0

Source: OIG (*Inspection/survey results verified with the clinic manager on April 3, 2019*)

Factors Related to Possible Lapses in Care

Within the healthcare field, the primary organizational risk is the potential for patient harm. Many factors affect the risk for patient harm within a system, including hazardous environmental conditions; poor infection control practices; and patient, staff, and public safety. Leaders must be

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

[19] According to VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017, TJC provides an "internationally accepted external validation that an organization has systems and processes in place to provide safe and quality-oriented health care." TJC "has been accrediting VA medical facilities for over 35 years." Compliance with TJC standards "facilitates risk reduction and performance improvement." TJC accreditation did not apply to the facility. VHA has not pursued TJC accreditation since the facility does not provide the full compliment of care typical of accredited facilities.

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

[21] According to the College of American Pathologists, for 70 years it has "fostered excellence in laboratories and advanced the practice of pathology and laboratory science." College of American Pathologists. https://www.cap.org/about-the-cap. (The website was accessed on February 20, 2019.); In accordance with VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016, VHA laboratories must meet the requirements of the College of American Pathologists.

able to understand and implement plans to minimize patient risk through consistent and reliable data and reporting mechanisms. Table 6 lists the reported patient safety events from January 29, 2016 (the prior comprehensive OIG inspection), through April 5, 2019.[22]

Table 6. Summary of Selected Organizational Risk Factors (January 29, 2016, through April 5, 2019)

Factor	Number of Occurrences
Sentinel Events[23]	0
Institutional Disclosures[24]	0
Large-Scale Disclosures[25]	0

Source: VA Manila Outpatient Clinic's chief of Quality Management (*received April 2, 2019*)

The OIG also reviewed patient safety indicators developed by the Agency for Healthcare Research and Quality within the U.S. Department of Health and Human Services. These provide information on potential in-hospital complications and adverse events following surgeries and procedures.[26] These data are not applicable since inpatient care is not provided at the facility.

As the only VA healthcare facility in a foreign country, one of the facility's external risks stems from the country's political unrest. Staff cited frequent political protests or demonstrations which may affect access to care and safety.

[22] It is difficult to quantify an acceptable number of adverse events affecting patients because even one is too many. Efforts should focus on prevention. Events resulting in death or harm and those that lead to disclosure can occur in either inpatient or outpatient settings and should be viewed within the context of the complexity of the facility. (Note that the VA Manila Outpatient Clinic is excluded from complexity level model per Complexity Model Workgroup Recommendation.)

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

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

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

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

Leadership and Organizational Risks Conclusion

The facility's leadership team appeared relatively stable; however, a new clinic manager (director) was scheduled to assume duties one week after the OIG's on-site visit. Selected survey scores related to employees' satisfaction with the facility executive leaders were generally better than VHA averages. Outpatient experience survey data revealed that scores related to satisfaction with the facility were above VHA averages. The facility leaders appeared actively engaged with employees and patients and were working to sustain and further improve employee and patient engagement and satisfaction. The leaders appeared to support efforts to improve and maintain patient safety, quality care, and other positive outcomes (such as initiating plans to maintain positive perceptions of the facility through active stakeholder engagement). The OIG's review of the facility's accreditation findings, sentinel events, and disclosures did not identify any substantial organizational risk factors. However, as the only VA healthcare facility in a foreign country, political unrest in the Philippines can pose a risk to patients and staff.

Quality, Safety, and Value

VHA's goal is to serve as the nation's leader in delivering high-quality, safe, reliable, and veteran-centered care that involves coordinating care among members of the healthcare team. To meet this goal, VHA must foster a culture of integrity and accountability in which personnel are vigilant and mindful, proactively risk-aware, and committed to consistently providing quality care, while seeking continuous improvement.[27] VHA also strives to provide healthcare services that compare favorably to the best of the private sector in measured outcomes, value, and efficiency.[28] VHA requires that its facilities operate a quality, safety, and value (QSV) program to monitor the quality of patient care and performance improvement activities.[29]

In determining whether the facility implemented and incorporated several OIG-selected key functions of VHA's enterprise framework for QSV into local activities, the inspection team evaluated protected peer reviews of clinical care,[30] utilization management (UM) reviews,[31] patient safety incident reporting with related root cause analyses,[32] and cardiopulmonary resuscitation (CPR) episode reviews.[33]

When conducted systematically and credibly, protected peer reviews reveal areas for improvement (involving one or more providers' practices) and can result in both immediate and long-term improvements in patient care. Peer reviews are intended to promote confidential and nonpunitive processes that consistently contribute to quality management efforts at the individual provider level.[34]

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

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

[29] VHA Directive 1026.

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

[31] According to VHA Directive 1117(2), *Utilization Management Program*, July 9, 2014 (amended April 30, 2019), UM reviews include evaluating the "appropriateness, medical need, and efficiency of health care services according to evidence-based criteria." This directive expired July 31, 2019.

[32] The definition of a root cause analysis can be found within VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. (This VHA Handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.) A root cause analysis is "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls."

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

[34] VHA Directive 1190.

The UM program, a key component of VHA's framework for quality, safety, and value, provides vital tools for managing the quality and the efficient use of resources. It strives to ensure that the right care occurs in the right setting, at the right time, and for the right reason using evidence-based practices and continuous measurement to guide improvements.[35]

Among VHA's approaches for improving patient safety is the mandated reporting of patient safety incidents to its National Center for Patient Safety. Incident reporting helps VHA learn about system vulnerabilities and how to address them. Required root cause analyses help to more accurately identify and rapidly communicate potential and actual causes of harm to patients throughout the facility.[36]

VHA has also issued guidance to support its strategic priority of providing personalized, proactive, patient-driven care and to ensure that the provision of life-sustaining treatments, including CPR, is aligned with patients' values, goals, and preferences. VHA requires that each facility establishes a CPR Committee or equivalent that fully reviews each episode of care in which resuscitation was attempted. The ongoing review and analysis of high-risk healthcare processes is essential for ensuring patient safety and the provision of high-quality care. VHA also has established requirements for basic life support and advanced cardiac life support training and certification for clinicians responsible for administering life-sustaining treatments.[37]

The OIG interviewed senior managers and key QSV employees and evaluated meeting minutes, protected peer reviews, root cause analyses, the annual patient safety report, and other relevant documents. Specifically, OIG inspectors evaluated the following performance indicators:[38]

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

[35] VHA Directive 1117(2).

[36] VHA Handbook 1050.01.

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

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

  - Peer review of all applicable deaths within 24 hours of admission to the hospital[39]
  - Peer review of all completed suicides within seven days after discharge from an inpatient mental health unit[40]
- UM[41]
  - Completion of at least 75 percent of all required inpatient reviews
  - Documentation of at least 75 percent of physician UM advisors' decisions in the National UM Integration database
  - Interdisciplinary review of UM data
- Patient safety
  - Annual completion of a minimum of eight root cause analyses[42]
  - Inclusion of required content in root cause analyses (generally)
  - Submission of completed root cause analyses to the National Center for Patient Safety within 45 days
  - Provision of feedback about root cause analysis actions to reporting employees
  - Submission of annual patient safety report to facility leaders
- Resuscitation episode review[43]
  - Evidence of a committee responsible for reviewing resuscitation episodes
  - Confirmation of actions taken during resuscitative events being consistent with patients' wishes
  - Evidence of basic or advanced cardiac life support certification for code team responders
  - Evaluation of each resuscitation episode by the CPR Committee or equivalent

[39] The facility does not provide inpatient care; therefore, review of deaths within 24 hours of admission was excluded from this review.

[40] The facility does not provide inpatient care; therefore, review of completed suicides within seven days after discharge from an inpatient mental health unit was excluded from this review.

[41] The facility does not provide inpatient care.

[42] According to VHA Handbook 1050.01, "the requirement for a total of eight [root cause analyses] and Aggregated Reviews is a minimum number, as the total number of [root cause analyses] is driven by the events that occur and the [Safety Assessment Code] SAC score assigned to them. At least four analyses per fiscal year must be individual [root cause analyses], with the balance being Aggregated Reviews or additional individual [root cause analyses]." This portion of the review is not applicable since the facility had no events that would trigger an RCA.

[43] This portion of the review is not applicable since the facility had no resuscitation events.

Quality, Safety, Value Conclusion

Generally, the facility met requirements as reflected by the performance indicators above. The OIG made no recommendations.

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).[44]

Clinical privileges need to be specific, based on the individual's clinical competence. They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the director. Clinical privileges are granted for a period not to exceed two years, and LIPs must undergo re-privileging prior to their expiration.[45]

VHA defines the focused professional practice evaluation (FPPE) as "a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance. The FPPE typically occurs at the time of initial appointment to the medical staff or the granting of new, additional privileges." "The on-going monitoring of privileged practitioners, Ongoing Professional Practice Evaluation (OPPE), is essential to confirm the quality of care delivered."[46]

According to TJC, the "FPPE for Cause" should be used when a question arises regarding a privileged provider's ability to deliver safe, high-quality patient care. The "FPPE for Cause" is limited to a particular time frame and customized to the specific provider and related clinical concerns.[47] Federal law requires VA facilities to report to the National Practitioner Data Bank when facilities take adverse clinical privileging actions, accept the surrender of clinical privileges, or restrict clinical privileges when the action is related to professional competence or professional conduct of LIPs.[48]

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

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

[45] VHA Handbook 1100.19.

[46] VHA Handbook 1100.19.

[47] 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).

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

- One solo or few (less than two in a specialty) practitioners hired within 18 months before the site visit or was privileged within the prior 12 months.[49]
- One LIP hired within 18 months before the site visit
- Three LIPs re-privileged within 12 months before the visit
- No providers underwent a FPPE for cause within 12 months prior to the visit

The OIG evaluated the following performance indicators:

- Privileging
  - Privileges requested by the provider
    - Facility-specific
    - Service-specific
    - Provider-specific[50]
  - Approval of privileges for a period of less than, or equal to, two years
- Focused professional practice evaluations
  - Criteria defined in advance
  - Use of required criteria in FPPEs for selected specialty LIPs
  - Results and time frames clearly documented
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's consideration of FPPE results in its decision to recommend continuing the initially granted privileges
- Ongoing professional practice evaluations
  - Criteria specific to the service or section
  - Use of required criteria in OPPEs for selected specialty LIPs

[49] The 18-month period was from October 1, 2017, through March 31, 2019. The 12-month review period covered April 1, 2018, through March 31, 2019. VHA Memorandum, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016, refers to a solo practitioner as being one provider in the facility that is privileged in a particular specialty. The OIG considers "few practitioners" as being fewer than three providers in the facility that are privileged in a particular specialty.

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

  - Service chief's determination to recommend continuation of current privileges was based in part on the results of OPPE activities
  - Evaluation by another provider with similar training and privileges
  - Executive Committee of the Medical Staff's decision to recommend continuing privileges based on OPPE results
- Focused professional practice evaluations for cause
  - Clearly defined expectations/outcomes
  - Time-limited
  - Provider's ability to practice independently not limited for more than 30 days
  - Shared with the provider in advance
- Reporting of privileging actions to National Practitioner Data Bank

Medical Staff Privileging Conclusion

The OIG found general compliance with requirements for privileging. However, the OIG identified noncompliance in the professional practice evaluation processes.

For focused and ongoing professional practice evaluations (FPPEs and OPPEs), VHA requires providers with "similar training and privileges evaluate the privilege-specific competence of the practitioner."[51] For all five provider profiles reviewed, one of which was a solo provider, the OIG found that the chief medical officer, who did not have similar training and privileges, conducted the evaluations. As a result, providers continued to deliver care without a thorough evaluation of their practice. Facility managers attributed the noncompliance to misinterpretation of the Deputy Under Secretary for Health Operations and Management memorandum and Medical Staff Bylaw and believed that facility efforts met requirements.

Recommendation 1

1. The chief medical officer ensures that focused and ongoing professional practice evaluations are completed by providers with similar training and privileges and monitors compliance.

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

Facility concurred.

Target date for completion: March 2020

Facility response: In August 2019, charts for focused professional practice evaluation (FPPE) and ongoing professional practice evaluation (OPPE) of specialty providers were sent to assigned facilities in the VA Sierra Pacific Network (VISN 21) to be reviewed by a provider with the same specialty/discipline. Likewise, FPPE forms and OPPE forms were revised to include the same provider's signature block and date to document review of relevant service-specific data.

The Chief Medical Officer and Quality Manager will ensure that all charts for OPPE/FPPEs of specialty providers will be reviewed by a provider with the same specialty. This will be monitored by the Quality Manager for a minimum of six consecutive months for 90 percent compliance rate. Monitoring data will be reported to the Medical Executive Committee.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires managers to conduct environment of care inspection rounds and resolve issues in a timely manner. The goal of the environment of care program is to reduce and control environmental hazards and risks; prevent accidents and injuries; and maintain safe conditions for patients, visitors, and staff. The physical environment of a healthcare organization must not only be functional, but should also promote healing.[52]

The purpose of this facet of the OIG inspection was to determine whether the facility maintained a clean and safe healthcare environment in accordance with applicable requirements. The OIG examined whether the facility met requirements in selected areas that are often associated with higher risks of harm to patients, such as in the locked inpatient mental health unit. The inspection team also looked at facility compliance with emergency management processes.[53]

VHA requires its facilities to have the "capacity for [providing] mental health services for veterans with acute and severe emotional and/or behavioral symptoms causing a safety risk to self or others, and/or resulting in severely compromised functional status. This level of care is typically provided in an inpatient setting;" however, for facilities that do not have inpatient mental health services, that "capacity" could mean facilitating care at a nearby VA or non-VA facility.[54]

VHA requires managers to establish a comprehensive emergency management program to ensure the continuity of patient care and hospital operations in the event of a natural disaster or other emergency. This includes conducting a hazard vulnerability analysis and developing an emergency operations plan. These requirements are meant to support facilities' efforts to identify and minimize harm from potential hazards, threats, incidents, and events related to healthcare and other essential services.[55] Managers must also develop utility management plans to increase reliability and reduce failures of electrical power distribution systems in accordance with TJC,[56]

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

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

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

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

[56] VHA Directive 1028, *Electrical Power Distribution Systems*, July 25, 2014. (This VHA Directive was scheduled for recertification on or before the last working date of July 2019 and has not been recertified.)

Occupational Safety and Health Administration,[57] and National Fire Protection Association standards.[58] The provision of sustained electrical power during disasters or emergencies is critical to healthcare facility operations.[59]

The inspection team inspected the clinic and reviewed relevant documents and interviewed key employees and managers. The OIG evaluated the following location-specific performance indicators:

- Community based outpatient clinic
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies

The following performance indicators did not apply.[60]

- Parent Facility
  - General safety
  - Environmental cleanliness and infection prevention
  - General privacy
  - Women veterans program
  - Availability of medical equipment and supplies
- Locked inpatient mental health unit
  - Mental health environment of care rounds
  - Nursing station security

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

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

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

[60] The facility operations are similar to a community based outpatient clinic and no inpatient mental health unit. The Department of State, not VA, had oversight of the emergency management activities for the entire U.S. Embassy compound where the clinic is located.

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

Environment of Care Conclusion

Generally, the facility met applicable requirements as reflected by performance indicators above. The OIG did not note any issues with the availability of medical supplies. The OIG made no recommendations.

Medication Management: Controlled Substances Inspections

The Controlled Substances Act divides controlled drugs into five categories based on whether they have an accepted medical treatment use in the United States, their relative potential for abuse, and the likelihood of causing dependence if abused.[61] Diversion of controlled substances by healthcare workers—the transfer of legally prescribed controlled substances from the prescribed individual to others for illicit use—remains a serious problem that can increase patient safety issues and elevate the liability risk to healthcare facilities.[62]

VHA requires that facility managers implement and maintain a controlled substances inspection program to minimize the risk for loss and diversion and to enhance patient safety. Requirements include the appointment of controlled substances coordinator(s) and controlled substances inspectors, implementation of procedures for inventory control, and inspections of the pharmacy and clinical areas with controlled substances.[63]

To determine whether the facility complied with requirements related to controlled substances security and inspections, the OIG team interviewed key managers and reviewed inspection reports; monthly summaries of findings, including discrepancies, provided to the facility director; inspection quarterly trend reports for the prior two completed quarters;[64] and other relevant documents. The OIG evaluated the following performance indicators:

- Controlled substances coordinator reports
  - Monthly summary of findings to the director
  - Quarterly trend reports to the director
  - Quality Management Committee's review of monthly and quarterly trend reports
  - Actions taken to resolve identified problems
- Pharmacy operations
  - Staff restrictions for monthly review of balance adjustments[65]

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

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

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

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

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

- Requirements for controlled substances inspectors
  - No conflicts of interest
  - Appointed in writing by the director for a term not to exceed three years
  - Hiatus of one year between any reappointment
  - Completion of required annual competency assessment
- Controlled substances area inspections[66]
  - Completion of monthly inspections
  - Rotations of controlled substances inspectors
  - Patterns of inspections
  - Completion of inspections on day initiated
  - Reconciliation of dispensing between pharmacy and each dispensing area
  - Verification of controlled substances orders
  - Performance of routine controlled substances inspections
- Pharmacy inspections
  - Monthly physical counts of the controlled substances in the pharmacy
  - Completion of inspections on day initiated
  - Security and verification of drugs held for destruction[67]
  - Accountability for all prescription pads in pharmacy
  - Verification of hard copy controlled substances prescriptions
  - Verification of twice a week (three days apart) inventories of the main vault[68]
  - Quarterly inspections of emergency drugs
  - Monthly checks of locks and verification of lock numbers

[66] These performance indicators did not apply as controlled substances were stored in the pharmacy.

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

[68] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010. (This handbook was rescinded on May 1, 2019, and replaced by VHA Directive 1108.01, *Controlled Substances Management*.)

- Facility review of override reports[69,70]

Medication Management Conclusion

The OIG found general compliance with requirements for most of the performance indicators evaluated, including the controlled substances coordinator reports and requirements for controlled substances inspectors. The OIG team noted that staff who review the monthly balance adjustments also had a security key to perform changes to pharmacy vault inventory; this was corrected during the OIG site visit and will not be a recommendation in this report. However, the OIG identified noncompliance with pharmacy inspection inventory counts that warranted a recommendation for improvement.

VHA requires controlled substances inspectors, in the presence of the Pharmacy chief or designee, to perform a complete physical count of the pharmacy inventory during the first month of the quarter and 50 line items (all if less than 50) of the inventory during the other two months when conducting monthly inspections.[71] For the review period, the facility had 41 line items in its inventory; therefore, a complete (100 percent) count was required monthly. The OIG found that inspectors completed 100 percent (41 line items) physical count during the first month of each quarter (July and October 2018); however, for the other two months of the two quarters reviewed (August, September, November, and December 2018), inspectors completed only 10 line items for each month. Inspectors' failure to perform a complete count of the pharmacy inventory can result in missed opportunities to identify potential drug diversion activities and discrepancies related to controlled substances. Program staff cited misinterpretation of the requirement as the reason for noncompliance.

Recommendation 2

2. The facility director makes certain that controlled substances inspectors perform a complete count of the pharmacy's controlled substances physical inventory during monthly inspections and monitors inspectors' compliance.[72]

[69] When automated dispensing cabinets are used, nursing staff can override and remove medications prior to the pharmacists' review of medications ordered by the providers. This requirement did not apply since the facility had no automated dispensing devices outside pharmacy.

[70] This performance indicator did not apply as there were no automated dispensing cabinets in the facility.

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

[72] The OIG reviewed evidence sufficient to demonstrate that the facility had completed improvement actions and therefore closed the recommendation before the report's release.

Facility concurred.

Target date for completion: October 2019

Facility Response: The controlled substance inspection team started conducting a (100%) physical count of the pharmacy's controlled substances inventory in April 2019 and the facility has been 100 percent compliant since that time.

We request closure of this recommendation based on the evidence provided.

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

The Department of Veterans Affairs uses the term "military sexual trauma" (MST) to refer to a "psychological trauma, which in the judgment of a mental health professional employed by the Department [of Veterans Affairs], resulted from a physical assault of a sexual nature, battery of a sexual nature, or sexual harassment which occurred while the Veteran was serving on active duty, active duty for training, or inactive duty training."[73] MST is an experience, not a diagnosis or a mental health condition. Although posttraumatic stress disorder is commonly associated with MST, other frequently associated diagnoses include depression and substance use disorders.[74]

VHA requires that the facility director designates an MST coordinator to support national and VISN-level policies related to MST-related care and serve as a source of information; establish and monitor MST-related staff training and informational outreach; and communicate MST-related issues, services, and initiatives with leadership.[75] Additionally, the facility director is responsible for ensuring that MST-related data are tracked and monitored.[76]

VHA requires that all veterans and potentially eligible individuals seen in VHA facilities be screened for experiences of MST with the required MST clinical reminder in the computerized patient record system.[77] Those who screen positive must have access to appropriate MST-related care.[78] VHA also requires that evidence-based mental health care be available to all veterans with mental health conditions related to MST. Patients requesting or referred for mental health services must receive an initial evaluation within 24 hours of the referral to identify urgent care needs and a more comprehensive diagnostic evaluation within 30 days.[79]

The MST coordinator may provide clinical care to individuals experiencing MST and is thus subject to the same mandatory training requirements as mental health and primary care providers.[80] All mental health and primary care providers must complete MST mandatory

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

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

[75] VHA Directive 1115.

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

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

[78] VHA Directive 1115.

[79] VHA Handbook 1160.01.

[80] VHA Directive 1115.

training; for those hired after July 1, 2012, this training must be completed no later than 90 days after assuming their position.[81]

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

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

Mental Health Conclusion

Generally, the OIG found compliance with the designation of an MST coordinator, establishing and monitoring MST-related staff training and informational outreach, and providers completing MST mandatory training. The OIG noted concerns, however, with communicating MST-related issues with facility leaders, tracking MST-related data, and completing diagnostic evaluations within the required time frame that warranted recommendations for improvement.

Specifically, VHA requires MST coordinators to communicate the status of MST services and initiatives with local leaders.[82] The OIG team determined that the MST coordinator did not communicate MST services and initiatives with leadership. This may hinder accomplishment of

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

[82] VHA Directive 1115.

project goals and hamper leadership's ability to identify and address improvement opportunities. The physician MST coordinator reported being appointed in January 2019 and cited a lack of oversight by the previous coordinator as the reason for noncompliance.

Recommendation 3

3. The chief medical officer ensures the military sexual trauma coordinator communicates the status of military sexual trauma services and initiatives with facility leaders and monitors coordinator's compliance.

Facility concurred.

Target date for completion: January 2020

Facility Response: The Military Sexual Trauma (MST) coordinator began reporting status of available MST services in the clinic in the June 2019 Medical Executive Committee meeting. The report included tracking and discussion of MST-related data. Starting November 2019, The Military Sexual Trauma (MST) coordinator or Chief Medical Officer will provide a report to the Joint Executive Board every quarter.

The clinic Quality Manager will monitor documentation of the discussion in the Medical Executive Committee and/or Joint Executive Board meeting minutes for a minimum of six consecutive months with a goal of 90 percent compliance.

VHA also requires that MST-related data are tracked, including monitoring, screening, referral, and treatment services provided to veterans.[83] The OIG found that the facility did not have a process to track and monitor MST-related data. This may result in ineffective program evaluation and missed opportunities for improvement. The MST coordinator attributed the noncompliance to the lack of oversight by the previous coordinator.

Recommendation 4

4. The chief medical officer makes certain that the military sexual trauma coordinator tracks and monitors military sexual trauma-related data.

[83] VHA Handbook 1160.01.

Facility concurred.

Target date for completion: January 2020

Facility Response: The Military Sexual Trauma (MST) coordinator began reporting status of available MST services in the clinic in June 2019 Medical Executive Committee meeting. This will include the MST Dashboard information, which includes compliance of MST screenings, MST related care and provider training. Starting November 2019, The Military Sexual Trauma (MST) coordinator or Chief Medical Officer will provide a report to the Joint Executive Board every quarter.

The clinic Quality Manager will monitor documentation of the discussion in the Medical Executive Committee and/or Joint Executive Board meeting minutes for a minimum of six consecutive months with a goal of 90 percent compliance.

VHA requires that providers complete an initial evaluation for all new patients referred for mental health services within 24 hours of referral and a comprehensive diagnostic evaluation within 30 days of referral.[84] Of the nine electronic health records reviewed, the OIG found that two patients were referred for mental health services. Clinicians did not complete diagnostic and treatment planning evaluations within 30 days of referral.[85] Failure to provide consistent and timely evaluations can result in missed opportunities to identify potential patient risks and to offer appropriate follow-up. The MST coordinator cited an inadequate number of mental health providers as the reason for noncompliance.

Recommendation 5

5. The chief medical officer ensures providers complete comprehensive diagnostic evaluations within the required time frame for all new patients referred for mental health services for military sexual trauma and monitors providers' compliance.

[84] VHA Handbook 1160.01.

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

Facility concurred.

Target date for completion: May 2020

Facility Response: In July 2019, the Clinic Applications Coordinator implemented a process to send a list of patients from the MST dashboard to assigned providers for reminder and completion thru email in July 2019. Starting November 2019, a review of 20 referrals will be completed monthly (if less than 20 referrals are identified, all referrals will be reviewed). This recommendation will be considered compliant when 90 percent or greater of MST referrals have been reviewed to find providers completing diagnostic and treatment planning evaluations within the required time frame for 6 consecutive months. Monitoring of this recommendation will be reported monthly to the Medical Executive Committee meeting.

Geriatric Care: Antidepressant Use among the Elderly

VA's National Registry for Depression reported that "11 [percent] of veterans aged 65 years and older have a diagnosis of major depressive disorder."[86] The VA/DoD Clinical Practice Guideline (CPG) describes depression as "a common mental disorder that presents with depressed mood, loss of interest or pleasure in regular activities, decreased energy, feelings of guilt or low self-worth, disturbed sleep or appetite, and poor concentration." This can lead to poor quality of life, decreased productivity, and increased mortality from suicide.[87]

According to the Centers for Disease Control and Prevention, older adults are at increased risk for experiencing depression because "80 [percent] of older adults have at least one chronic health condition and 50 [percent] have two or more." Further, "most older adults see an improvement in [their] symptoms when treated with antidepression drugs, psychotherapy, or a combination of both."[88]

The American Geriatrics Society revised the Beers Criteria in 2015 to include lists of potentially inappropriate medications to be avoided. Potentially inappropriate medication use in older adults continues to be associated with confusion, falls, and mortality.[89] The criteria provide guidelines that help to improve the safety of prescribing certain medications including antidepressants for older adults.

TJC requires clinicians to educate patients and families about the "safe and effective use of medications."[90] In 2015, VHA outlined essential medical information "necessary for review, management, and communication of medication information" with patients, caregivers, and their healthcare teams.[91] Further, TJC requires clinicians to perform medication reconciliation by comparing the medication a patient is actually taking to the new medications that are ordered for the patient and resolving any discrepancies.[92] The CPG recommends that clinicians monitor patients monthly after therapy initiation or a change in treatment until the patient achieves

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

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

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

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

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

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

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

remission. Monitoring includes assessment of symptoms, adherence to medication and psychotherapy, and any adverse effects. The CPG also recommends that treatment planning includes patient education about treatment options, including risks and benefits.[93]

To determine whether the facility complied with requirements concerning use of antidepressants among the elderly, the OIG inspection team interviewed key employees and managers. The team also reviewed the electronic health records of 8 selected patients, ages 65 and older, who were newly prescribed one of seven selected antidepressant medications from July 1, 2017, through June 30, 2018.[94] The OIG evaluated the following performance indicators:

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

Geriatric Care Conclusion

The OIG found compliance with providers justifying the reason for medication initiation. However, the OIG identified concerns with inadequate patient/caregiver's education about the newly prescribed medications and with reconciling medications that warranted recommendations for improvement.

TJC requires that clinicians educate patients and families about safe and effective use of medications.[95] The OIG determined that clinicians provided this education to 13 percent of the patients at the facility, based on the electronic health records reviewed.[96] Providing medication education is critical to ensuring that patients or their caregivers have the information they need to manage their own health at home. The chief medical officer acknowledged inconsistent documentation practices and cited the lack of administrative time for providers to complete all required documentation as the reason for noncompliance.

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

[94] The seven selected antidepressant medications are Amitriptyline, Clomipramine, Desipramine, Doxepin (>6mg/day), Imipramine, Nortriptyline, and Paroxetine.

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

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

Recommendation 6

6. The chief medical officer makes certain that clinicians provide and document patient and/or caregiver education about the safe and effective use of newly prescribed medications and monitors clinicians' compliance.

Facility concurred.

Target date for completion: May 2020

Facility Response: The Chief Medical Officer discussed the documentation requirements when prescribing new antidepressants and completion of medication reconciliation with members of the Medical Staff at the April 24, 2019 Clinic Operations Committee (COC) meeting. Also, in April 2019, the psychiatry outpatient consult and follow-up note templates were revised to include a line item to document education to the patient and/or caregiver about the potential interactions and side effects of newly prescribed medications.

Starting November 2019, a monthly review of 10 clinician notes (if less than 10 notes are identified, all notes will be reviewed) will be conducted to monitor compliance with the use of the template. This will continue to be assessed until 90 percent compliance is achieved for six consecutive months. The results of the monitoring will be reported monthly to the Medical Executive Committee (MEC) by the Quality Manager.

According to TJC, the required process of medication reconciliation is when "a clinician compares the medications a patient should be using (and is actually using) to the new medications that are ordered for the patient and resolves any discrepancies."[97] Additionally, VHA requires that clinicians review and reconcile medications relevant to the episode of care.[98]

The OIG determined that clinicians performed medication reconciliation for 63 percent of the patients at the facility, based on electronic health records reviewed.[99] Failure to maintain and communicate accurate patient medication information and reconcile medications increases the risk that there may be duplications, omissions, and interactions in the patient's actual drug regimen. The chief medical officer cited the lack of administrative time for providers to complete all required documentation and inconsistent documentation practices as the reasons for noncompliance.

Recommendation 7

7. The chief medical officer ensures clinicians review and reconcile medications and monitors clinicians' compliance.

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

[98] VHA Directive 1164.

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

Facility concurred.

Target date for completion: May 2020

Facility Response: During a meeting, all providers were reminded of the need to conduct medication reconciliation. Starting November 2019, a monthly review of 10 clinician notes (if less than 10 notes are identified, all notes will be reviewed) will be conducted to ensure clinicians complete medication reconciliation of newly prescribed medications. This will continue to be assessed until 90 percent compliance is achieved for six consecutive months. The results of the monitoring will be reported monthly to the Medical Executive Committee (MEC) by the Quality Manager.

Appendix A: Summary Table of Comprehensive Healthcare Inspection Findings

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

Healthcare Processes	Performance Indicators	Conclusion
Leadership and Organizational Risks	• Executive leadership position stability and engagement • Employee satisfaction • Patient experience • Accreditation and/or for-cause surveys and oversight inspections • Factors related to possible lapses in care	Seven 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 and chief medical officer. See details below.

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Quality, Safety, and Value	• Protected peer reviews • UM reviews • Patient safety • Resuscitation episode review	• None	• None
Medical Staff Privileging	• Privileging • FPPEs • OPPEs • FPPEs for cause • Reporting of privileging actions to National Practitioner Data Bank	• FPPEs and OPPEs are completed by providers with similar training and privileges.	• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement

Environment of Care	• Parent facility
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
	• Community based outpatient clinic
	  ○ General safety
	  ○ Environmental cleanliness and infection prevention
	  ○ General privacy
	  ○ Women veterans program
	  ○ Availability of medical equipment and supplies
		• None	• None

Healthcare Processes	Performance Indicators	Critical Recommendations for Improvement	Recommendations for Improvement
Medication Management: Controlled Substances Inspections	• Controlled substances coordinator reports • Pharmacy operations • Controlled substances inspector requirements • Controlled substances area inspections • Pharmacy inspections • Facility review of override reports	• None	• Controlled substances inspectors perform a complete count of the pharmacy's controlled substances physical inventory during monthly inspections.
Mental Health: Military Sexual Trauma (MST) Follow-Up and Staff Training	• Designated facility MST coordinator • Evidence of tracking MST-related data • Provision of clinical care • Completion of MST mandatory training requirement for mental health and primary care providers	• Providers complete comprehensive diagnostic evaluations within the required time frame for all new patients referred for mental health services for MST.	• MST coordinator communicates the status of MST services and initiatives with facility leaders. • The MST coordinator tracks and monitors MST-related data.
Geriatric Care: Antidepressant Use among the Elderly	• Justification for medication initiation • Evidence of patient and/or caregiver education specific to the medication prescribed • Clinician evaluation of patient and/or caregiver understanding of the education provided • Medication reconciliation	• Clinicians provide and document patient/caregiver education about the safe and effective use of newly prescribed medications. • Clinicians review and reconcile medications.	• None

Appendix B: Facility Profile

The table below provides general background information for this facility reporting to VISN 21.[100]

**Table B.1. Facility Profile for VA Manila Outpatient Clinic (358)
(October 1, 2015, through September 30, 2018)**

Profile Element	Facility Data FY 2016[101]	Facility Data FY 2017[102]	Facility Data FY 2018[103]
Total medical care budget in dollars	$13,758,340	$16,030,258	$7,452,010
Number of:			
• Unique patients	6,340	6,074	6,109
• Outpatient visits	18,180	19,427	21,382
• Unique employees[104]	35	34	35
Number of operating beds:	0	0	0

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

[100] According to VHA, Manila, PI is excluded from complexity level model per Complexity Model Workgroup Recommendation. http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx. (The website was accessed on August 30, 2019.)

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

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

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

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

Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: November 20, 2019

From: Director, VA Sierra Pacific Network (10N21)

Subj: Comprehensive Healthcare Inspection of the VA Manila Outpatient Clinic, Pasay City, Philippines

Director, Los Angeles Office of Healthcare Inspections (54CH01)

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

1. Thank you for the opportunity to review the draft report. I concur with the findings and the action plan from the facility in response to those findings.
2. Should you have any questions, please contact my Deputy Quality Manager.

(Original signed by:)

John A. Brandecker

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

Appendix D: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: November 20, 2019

From: Director, VA Manila Outpatient Clinic (358/002)

Subj: Comprehensive Healthcare Inspection of the VA Manila Outpatient Clinic, Pasay City, Philippines

To: Network Director, VA Sierra Pacific Network (10N21)

1. I have reviewed the VA Office of Inspector General's Comprehensive Healthcare Inspection Program report of the VA Manila Outpatient Clinic and concur with its assessment and findings. I appreciate the review team's thoroughness and dedication to quality improvement across VA.
2. A corrective action plan remedying identified deficiencies is provided. VA Manila will continue to monitor performance to ensure all recommendations are addressed and action plans successfully implemented.

(Original signed by:)

Daniel P. Gutkoski, MHA

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

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