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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion

CHIP Report | 22-04112-125 | April 4, 2024

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Figure 1. *Marion VA Medical Center of the VA Northern Indiana Health Care System.*

Source: https://www.va.gov/northern-indiana-health-care/locations/ (*accessed November 16, 2023)*.

Abbreviations

ADPCS	Associate Director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
CLC	community living center
FPPE	Focused Professional Practice Evaluation
FY	fiscal year
LIP	licensed independent practitioner
OIG	Office of Inspector General
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 VA Northern Indiana Health Care System, which includes the Fort Wayne and Marion VA Medical Centers, multiple outpatient clinics in Indiana, and an outpatient clinic in Ohio. 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 the nation's veterans receive high-quality and timely VA healthcare services. The OIG inspects each facility approximately every three years and selects and evaluates specific areas of focus each year. At the time of this inspection, the OIG focused on core processes in the following five areas of clinical and administrative operations:

1. Leadership and organizational risks
2. Quality, safety, and value
3. Medical staff privileging
4. Environment of care
5. Mental health (focusing on suicide prevention initiatives)

The OIG initiated an unannounced inspection of the VA Northern Indiana Health Care System during the week of January 9, 2023. 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 the healthcare system's performance within the identified focus areas at the time of the OIG inspection and may help leaders identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Results Summary

The OIG noted opportunities for improvement and issued 10 recommendations to the Director, Chief of Staff, Associate Director for Patient Care Services, and Associate Director in the following areas of review: Medical Staff Privileging, Environment of Care, and Mental Health. The number of recommendations should not be used as a gauge for the overall quality of care provided at this system. The intent is for leaders to use recommendations as a road map to help improve operations and clinical care moving forward. Recommendations are based on retrospective findings of deficiencies in adherence to Veterans Health Administration national policy and require action plans that can effectively address systems issues that may have

contributed to the deficiencies or interfered with the delivery of quality health care. The results are detailed throughout the report, and the recommendations are summarized in appendix A on page 26.

VA Comments

The Veterans Integrated Service Network Director and interim Medical Center Director agreed with the comprehensive healthcare inspection findings and recommendations and provided acceptable improvement plans (see appendixes C and D, pages 28–29, and the responses within the body of the report for the full text of the directors' comments). The OIG considers recommendations 3 through 9 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities that provide healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the VA Northern Indiana Health Care System 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 healthcare system leaders so they can make informed decisions 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]

To examine risks to patients and the organization, the OIG focused on core processes in the following five areas of clinical and administrative operations:[4]

1. Leadership and organizational risks
2. Quality, safety, and value
3. Medical staff privileging
4. Environment of care
5. Mental health (focusing on suicide prevention initiatives)

[1] VA administers healthcare services through a nationwide network of 18 regional systems referred to as Veterans Integrated Service Networks.

[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): 13, https://doi.org/10.1136/bmjopen-2014-005055.

[3] Danae F. Sfantou et al., "Importance of Leadership Style towards Quality of Care Measures in Healthcare Settings: A Systematic Review," *Healthcare (Basel)* 5, no. 4 (October 14, 2017): 73, https://doi.org/10.3390/healthcare5040073.

[4] CHIP site visits addressed these processes during fiscal year (FY) 2023 (October 1, 2022, through September 30, 2023); they may differ from prior years' focus areas.

Methodology

The VA Northern Indiana Health Care System includes the Fort Wayne and Marion VA Medical Centers, multiple outpatient clinics in Indiana, and an outpatient clinic in Ohio. General information about the healthcare system can be found in appendix B.

The inspection team conducted an on-site review during the week of January 9, 2023.[5] During the site visit, the OIG did not receive any complaints beyond the scope of this inspection that required referral to the OIG hotline.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.[6] 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 healthcare system leaders complete corrective actions. The interim Medical Center Director's responses to the report recommendations appear within each topic area. The OIG accepted the action plans that 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.

[5] The OIG's last comprehensive healthcare inspection of the VA Northern Indiana Health Care System occurred in July 2020. The Joint Commission performed hospital, behavioral health care and human services, and home care accreditation reviews in June 2021.

[6] Inspector General (IG) Act of 1978, as amended, 5 U.S.C. §§ 401–424.

Results and Recommendations

Leadership and Organizational Risks

Healthcare leaders must focus their efforts to achieve results for the populations they serve.[7] High-impact leaders should be person-centered and transparent, engage front-line staff members, have a "relentless focus" on their organization's vision and strategy, and "practice systems thinking and collaboration across boundaries."[8] When leaders fully engage and inspire employees, create psychological safety, develop trust, and apply organizational values to all decisions, they lay the foundation for a culture and system focused on clinical and patient safety.[9]

To assess this healthcare system's leadership and risks, the OIG considered the following indicators:

1. Executive leadership position stability and engagement
2. Budget and operations
3. Employee satisfaction
4. Patient experience
5. Identified factors related to possible lapses in care and healthcare system leaders' responses

Executive Leadership Position Stability and Engagement

Each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves. The healthcare system had a leadership team consisting of the Director, Chief of Staff, Associate Director for Patient Care Services (ADPCS), Associate Director, and Assistant Director. The Chief of Staff and ADPCS oversaw patient care, which included managing service directors and program chiefs.

At the time of the OIG inspection, the Associate Director had served as the interim Director for approximately four months, the Assistant Director was serving as acting Associate Director, and another staff member was serving as acting Assistant Director. The Chief of Staff had the longest tenure. The executive team had worked together since the ADPCS started, approximately 10 days earlier.

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[7] Stephen Swensen et al., *High-Impact Leadership: Improve Care, Improve the Health of Populations, and Reduce Costs*, Institute for Healthcare Improvement White Paper, 2013.

[8] Swensen et al., *High-Impact Leadership: Improve Care, Improve the Health of Populations, and Reduce Costs*.

[9] Allan Frankel et al., *A Framework for Safe, Reliable, and Effective Care,* Institute for Healthcare Improvement White Paper, 2017.

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

Budget and Operations

The OIG noted that the healthcare system's fiscal year (FY) 2022 annual medical care budget of $561,194,595 had increased by approximately 10 percent compared to the previous year's budget of $511,179,454.[10] The interim Director expressed concern that while the budget was sufficient to sustain operations, shortages for administrative support staff and long-term care, mental health, and substance abuse nurses would require additional funds going forward. The ADPCS added that the nursing shortages were improving.

When asked what change the leaders might implement with unlimited resources, the interim Director and ADPCS focused on increasing nursing staff salaries to compete with the local market and advancing the system's plan for a new community living center (CLC).[11] The Chief of Staff highlighted the need for a comprehensive system for communication among employees and veterans, replacing the current approach which employs multiple systems.

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential."[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 facility leaders.

The OIG reviewed results from VA's All Employee Survey from FYs 2020 through 2022 regarding employees' perceived ability to disclose a suspected violation without fear of reprisal.[13] Table 1 provides relevant survey results for Veterans Health Administration (VHA) and the healthcare system over time.

The system's scores for the selected question were slightly lower than VHA averages for all three years. The Chief of Staff attributed the scores to decreased communication between staff and senior leaders and added that leaders were working to optimize communication throughout

[10] Veterans Health Administration (VHA) Support Service Center.

[11] VHA Handbook 1142.01, *Criteria and Standards for VA Community Living Centers (CLC)*, August 13, 2008. (VHA rescinded and replaced this handbook with VHA Directive 1142(1), *Standards for Community Living Centers*, October 5, 2023, amended January 29, 2024.)

[12] "AES Survey History, Understanding Workplace Experiences in VA," VHA Support Service Center.

[13] The OIG makes no comment on the adequacy of the VHA average. The VHA average is used for comparison purposes only.

the healthcare system. The interim Director further described implementing weekly town halls and having executive leaders visit staff workspaces to improve communication.

Table 1. All Employee Survey Question: Ability to Disclose a Suspected Violation (FYs 2020 through 2022)

All Employee Survey Group	FY 2020	FY 2021	FY 2022
VHA	3.8	3.9	3.9
VA Northern Indiana Health Care System	3.7	3.7	3.7

Source: VA All Employee Survey (accessed October 13, 2022).

Note: Respondents scored this survey item from 1 (Strongly disagree) through 6 (Do not know).

Patient Experience

VHA uses surveys from the Consumer Assessment of Healthcare Providers and Systems program to assess patients' healthcare experiences and compare them to the private sector. VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home (primary care), and Specialty Care surveys.[14] The OIG reviewed responses to three relevant survey questions that reflect patient experiences with the healthcare system from FYs 2020 through 2022. Table 2 provides survey results for VHA and the healthcare system over time.

Survey scores indicate patients' satisfaction with their inpatient care decreased over all three years. The interim Director attributed the decrease in inpatient scores to staff turnover and recruitment and nurse supervision challenges. The interim Director reported believing the recent hire of the ADPCS would help improve the quality of supervision in the inpatient nursing department.

[14] "Patient Experiences Survey Results," VHA Support Service Center.

Table 2. Survey of Healthcare Experiences of Patients (FYs 2020 through 2022)

Questions	FY 2020		FY 2021		FY 2022	
	VHA	Healthcare System	VHA	Healthcare System	VHA	Healthcare System
Inpatient: *Would you recommend this hospital to your friends and family?**	69.5	70.6	69.7	67.8	68.9	67.1
Patient-Centered Medical Home: *Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?*†	82.5	82.0	81.9	79.2	81.7	84.0
Specialty Care: *Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?*†	84.8	79.2	83.3	85.3	83.1	83.3

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed December 8 and 14, 2022).

**The response average is the percent of "Definitely yes" responses.*
†*The response average is the percent of "Very satisfied" and "Satisfied" responses.*

Identified Factors Related to Possible Lapses in Care and Healthcare System Leaders' Responses

Leaders must ensure patients receive high-quality health care that is safe, effective, timely, and patient-centered because any preventable harm episode is one too many.[15] According to The Joint Commission's standards for leadership, a culture of safety and continual process improvements lead to safe, quality care for patients.[16] A VA medical facility's culture of safety and learning enables leaders to identify and correct systems issues. If leaders do not respond

[15] Frankel et al., *A Framework for Safe, Reliable, and Effective Care*; "Quality and Patient Safety (QPS)," Department of Veterans Affairs, accessed October 13, 2021, https://www.va.gov/QUALITYANDPATIENTSAFETY/.

[16] The Joint Commission, *Standards Manual,* E-dition, July 1, 2022. A culture of safety is "the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management." "Hospital Survey on Patient Safety Culture: User's Guide," Agency for Healthcare Research and Quality, July 2018, https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/hospital/userguide/hospcult.pdf.

when adverse events occur, they may miss opportunities to learn and improve from those events and risk losing trust from patients and staff.[17]

"A sentinel event is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm)."[18] Additionally, an institutional disclosure is "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."[19] Lastly, a large-scale disclosure is "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."[20] To this end, VHA implemented standardized processes to guide leaders in measuring, assessing, and reacting to possible lapses in care to improve patient safety.[21]

The OIG requested a list of sentinel events and institutional and large-scale disclosures that occurred during FY 2022. The Quality Management Program Analyst reported there were six sentinel events and two institutional disclosures. According to the Chief of Staff, staff conducted root cause analyses for all sentinel events to determine their cause and identify corrective actions.[22] The OIG found that leaders conducted institutional disclosures for two sentinel events that resulted in an elbow and a hip fracture. At the time of the OIG inspection and in a subsequent follow-up, facility managers indicated they were still trying to contact the family to complete an institutional disclosure for the only sentinel event that resulted in a death.

Leadership and Organizational Risks Findings and Recommendations

The OIG made no recommendations.

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[17] Jim Conway et al., *Respectful Management of Serious Clinical Adverse Events (2nd ed.)*, Institute for Healthcare Improvement White Paper, 2011.

[18] The Joint Commission, *Comprehensive Accreditation Manual for Hospitals*, Sentinel Event Policy (SE), July 2023. VHA incorporates The Joint Commission's definition of a sentinel event in VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[19] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

[20] VHA Directive 1004.08.

[21] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. (VHA rescinded and replaced this handbook with VHA Directive 1050.01(1), *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024. The new directive contains similar language regarding patient safety as the rescinded handbook.)

[22] A root cause analysis "is a comprehensive team-based, systems-level investigation with a formal charter for review of health care adverse events and close calls." VHA Directive 1050.01(1).

Quality, Safety, and Value

VHA is committed to providing exceptional health care to veterans.[23] To achieve this goal, VHA requires that its medical facility leaders implement programs to monitor the quality of patient care and performance improvement activities and maintain Joint Commission accreditation.[24] Many quality-related activities are informed and required by VHA directives and nationally recognized accreditation standards.[25]

VHA implemented the National Center for Patient Safety program to develop a range of patient safety methodologies and practices. VHA's Patient Safety program includes staff assessing system vulnerabilities that may result in patient harm, reporting adverse patient safety events, and focusing on prevention.[26] According to The Joint Commission's standards for performance improvement, staff must analyze data to monitor performance and identify trends and improvement opportunities, then implement actions to enhance patient safety.[27]

The OIG assessed the healthcare system's processes for conducting peer reviews of clinical care.[28] 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."[29] Peer reviews are "intended to promote confidential and non-punitive assessments of care" that consistently contribute to quality management efforts at the individual provider level.[30]

The OIG team interviewed key managers and staff and evaluated peer reviews and patient safety reports. The team also reviewed one unanticipated death that occurred within 24 hours of inpatient admission. The team found that no suicides had occurred within seven days of discharge from the inpatient mental health unit during FY 2022.

Quality, Safety, and Value Findings and Recommendations

The OIG made no recommendations.

[23] Department of Veterans Affairs, *Veterans Health Administration Blueprint for Excellence*, September 21, 2014.

[24] VHA Directive 1100.16, *Health Care Accreditation of VHA Facilities and Programs*, July 19, 2022.

[25] VHA Directive 1100.16.

[26] VHA Handbook 1050.01; VHA Directive 1050.01(1).

[27] The Joint Commission, *Standards Manual*, E-dition, PI.03.01.01, PI.04.01.01, January 1, 2022.

[28] 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. VHA Directive 1190.

[29] VHA Directive 1190.

[30] VHA Directive 1190.

Medical Staff Privileging

VHA has defined procedures for the clinical privileging of "all health care professionals who are permitted by law and the facility to practice independently."[31] These healthcare professionals are known as licensed independent practitioners (LIPs) and provide care "without supervision or direction, within the scope of the individual's license, and in accordance with individually-granted clinical privileges."[32]

Privileges need to be specific and based on the individual practitioner's clinical competence. Privileges are requested by the LIP and reviewed by the responsible service chief, who then makes a recommendation to approve, deny, or amend the request. An executive committee of the medical staff evaluates the LIP's credentials and service chief's recommendation to determine whether "clinical competence is adequately demonstrated to support the granting of the requested privileges," and submits the final recommendation to the facility director.[33] LIPs are granted clinical privileges for a limited time and must be reprivileged prior to their expiration.[34]

VHA states the Focused Professional Practice Evaluation (FPPE) is a defined period during which service chiefs assess LIPs' professional performance. The FPPE process occurs when an LIP is hired at the facility and granted initial or additional privileges. Facility leaders must also monitor the LIP's performance by regularly conducting an Ongoing Professional Practice Evaluation to ensure the continuous delivery of quality care.[35]

VHA's credentialing process involves the assessment and verification of healthcare practitioners' qualifications to provide care and is the first step in ensuring patient safety.[36] Historically, many VHA facilities had portions of their credentialing processes aligned under different leaders, which led to inconsistent program oversight, position descriptions, and reporting structures. VHA implemented credentialing and privileging modernization efforts to increase standardization and now requires all credentialing and privileging functions to be merged into one office under the chief of staff. VHA also requires facilities to have credentialing and

[31] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (VHA rescinded and replaced this handbook with VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. VHA previously replaced the credentialing portion of this handbook with VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021.)

[32] VHA Handbook 1100.19.

[33] VHA Handbook 1100.19.

[34] VHA Handbook 1100.19.

[35] VHA Handbook 1100.19.

[36] VHA Directive 1100.20.

privileging managers and specialists with job duties that align under standard position descriptions.[37]

The OIG interviewed key managers and selected and reviewed the privileging folders of 27 medical staff members who underwent initial privileging or reprivileging during FY 2022.

Medical Staff Privileging Findings and Recommendations

VHA states the FPPE is a defined period during which service chiefs assess LIPs' professional performance.[38] The OIG found all six FPPEs reviewed had start dates but lacked end dates to define the time frame. When service chiefs do not define the time frame, LIPs may not understand FPPE expectations. The Credentialing and Privileging Manager reported believing that FPPEs completed within 90 days of the start date, without clear documentation of this time-limited period, met the requirement.

Recommendation 1

1. The Chief of Staff ensures service chiefs define the time frames for Focused Professional Practice Evaluations.

[37] Assistant Under Secretary for Health for Operations/Chief Human Capital Management memo, "Credentialing and Privileging Staffing Modernization Efforts—Required Modernization Actions and Implementation of Approved Positions Fiscal Year 2020," December 16, 2020.

[38] VHA Handbook 1100.19; VHA Directive 1100.21(1).

Healthcare system concurred.

Target date for completion: September 30, 2024

Healthcare system response: The Chief of Staff evaluates reasons for noncompliance and ensures that Service Chiefs include defined time frames for Focused Professional Practice Evaluations. The facility service chiefs utilize standardized facility focused professional practice evaluation forms which the providers review and acknowledge. In February 2023, the Medical Executive Board implemented new processes to ensure the focused professional evaluation has the appropriate time frames defined by the service chiefs. The data has been tracked by the number of providers reviewed in committee demonstrating the above compliance divided by the number of focused professional evaluations completed. This is then reviewed by the committee with the compliance tracked until 90 percent or greater compliance is established for a minimum of six consecutive months.

Compliance Monitor: The numerator equals the number of focused professional practice evaluations reviewed with the defined time frame. The denominator equals the number of total focused professional practice evaluations reviewed by the Medical Executive Board.

Compliance Goal: 90 percent compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through Medical Executive Board.

VHA requires service chiefs to recommend continued privileges based, in part, on Ongoing Professional Practice Evaluation activities such as direct observation, chart reviews, and clinical discussions with other members of the care team.[39] The OIG found that for 4 of 21 LIPs reprivileged during FY 2022, service chiefs did not review all Ongoing Professional Practice Evaluation activities in determining whether to recommend continued privileges, which may result in missed evidence of LIPs' poor quality of care and jeopardize patient safety. The Chief of Staff attributed noncompliance to competing priorities and staffing changes, including transition between two associate chiefs of staff in the medicine service.

Recommendation 2

2. The Chief of Staff ensures service chiefs recommend reprivileging based, in part, on Ongoing Professional Practice Evaluation activities.

[39] VHA Handbook 1100.19; VHA Directive 1100.21(1).

Healthcare system concurred.

Target date for completion: September 30, 2024

Healthcare system response: The Chief of Staff evaluates reasons for noncompliance and ensures that the Service Chiefs determine to continue privileges based, in part, on results of ongoing professional practice evaluation activities. The Service Chief reviews and includes the results of ongoing professional practice evaluation activities in their determination to recommend the continuation of clinical privileges.

Compliance Monitor: The numerator equals the number of those providers reviewed that have evidence that the results of the ongoing professional practice evaluation activities were used in the determination to recommend the renewal of privileges. The denominator equals the number of total reprivileging requests approved by the Medical Executive Board.

Compliance Goal: 90 percent compliance for six consecutive months.

Responsibility: The Chief of Staff will ensure compliance. The results will be reported through Medical Executive Board.

Environment of Care

Any facility, regardless of its size or location, faces vulnerabilities in the healthcare environment. VHA requires staff to conduct environment of care inspections and track issues until they are resolved.[40] The goal of VHA's environment of care program is to ensure "a safe, clean health care environment that provides the highest standards in the health care setting."[41] The environment of care program includes elements such as infection control, patient and employee safety, privacy, and supply chain management.[42]

The purpose of this inspection was to determine whether staff at VA medical facilities maintained a clean and safe healthcare environment in accordance with applicable standards. The OIG inspected selected areas that are often associated with higher risks of harm to patients. These areas may include inpatient mental health units, where patients with active suicidal ideations or attempts are treated, and CLCs, where vulnerable populations reside in a home-like environment and receive assistance in achieving their highest level of function and well-being.[43]

During the OIG's review of the environment of care, the inspection team examined relevant documents, interviewed managers and staff, and inspected 10 patient care areas:

- Fort Wayne VA Medical Center
    - 4 Medical unit
    - Emergency Department
    - Intensive Care Unit
    - Patient-Aligned Care Team (PACT) clinic (primary care)
- Marion VA Medical Center
    - CLCs (1B Eagle's Wing, 1C Heroes' Haven, and 1E Eagle's Landing)
    - Inpatient Mental Health unit
    - PACT clinic (primary care)
    - Urgent Care Center

[40] VHA Directive 1608, *Comprehensive Environment of Care Program*, June 21, 2021. (This directive was in effect at the time of the inspection. VHA amended it September 7, 2023.)

[41] VHA Directive 1608.

[42] VHA Directive 1608. The supply chain management system must meet the needs of its customers, which involves ensuring availability of the right product in the right place and at the right time. VHA Directive 1761, *Supply Chain Management Operations*, December 30, 2020.

[43] VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013. (VHA rescinded and replaced this handbook with VHA Directive 1160.06, *Inpatient Mental Health Services,* September 27, 2023.) VHA Directive 1142(1).

Environment of Care Findings and Recommendations

Joint Commission standards state that hospital staff must implement infection prevention practices when storing medical supplies.[44] Corrugated containers may harbor infection-causing organisms and are considered contaminated.[45] The OIG found corrugated containers in 4 of 10 patient care areas inspected. The Chief Nurse of Operations cited a lack of communication between Environmental Management Services and nursing staff at the Fort Wayne VA Medical Center regarding removal of corrugated containers in the 4 Medical unit. Additionally, the Chief Nurse of Extended Care cited insufficient storage at CLC 1B Eagle's Wing, and the Chief of Environmental Management Services reported that new staff assigned to maintain the PACT clinic and CLC 1E Eagle's Landing at the Marion VA Medical Center were unaware of storage requirements.

Recommendation 3

3. The Director ensures staff remove corrugated containers from patient care areas.[46]

[44] The Joint Commission, *Standards Manual,* E-dition, IC 02.02.01, August 27, 2023.

[45] "What is The Joint Commission's Position on Managing Cardboard or Corrugated Boxes and Shipping Containers?," The Joint Commission, accessed August 2, 2023, https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/infection-prevention-and-control-ic.

[46] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. The identified corrugated containers were removed during the inspection. EOC [environment of care] rounds were completed per VHA Directive 1608 Comprehensive Environment of Care Program. Additionally, inspections were conducted monthly in patient care areas. In the event corrugated boxes are found, boxes would be immediately removed, and managers are notified. General education was also provided to entire staff about the importance of proper storage of corrugated containers.

Compliance Monitor: The numerator is the number of EOC inspections where no corrugated boxes were found in Patient Care areas. The denominator is the total number of EOC areas inspected.

Compliance Goal: 90 percent or greater for a minimum of six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

VHA requires staff to keep storerooms clean, with no visible dust or soiling on surface areas.[47] The OIG noted clean supply storerooms had dirty bottom shelves in 5 of the 10 patient care areas inspected.[48] This constituted a failure to maintain a generally clean environment and increased the potential spread of infection. The Chief Logistics Officer attributed the dirty bottom shelves to an oversight by logistics staff and the environment of care team.

Recommendation 4

4. The Director ensures staff keep storerooms clean and free of visible dust and soiling.[49]

[47] VHA Directive 1761.

[48] The OIG found deficiencies in the Emergency Department and 4 Medical unit at the Fort Wayne VA Medical Center, and the Urgent Care Center and CLCs 1B Eagle's Wing and 1C Heroes' Haven at the Marion VA Medical Center.

[49] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. In January 2023, responsibilities were added to the Lead Supply Technician to verify storerooms were clean and free of visible dust and soiling of all 54 supply closets within the Supply Management Service.

Compliance Monitor: The numerator is the number of inspections that were clean and free of visible dust and soiling for 6 consecutive months. The denominator is the total number of Supply Chain closets inspected.

Compliance Goal: 90 percent or greater for a minimum of six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

VHA requires Environmental Management Services staff to ensure patient care areas are clean.[50] The OIG found stained floors in 3 of the 10 patient care areas inspected.[51] Lack of cleanliness increases the potential spread of infection. The Chief of Environmental Management Services said staff did not submit work orders to repair previously leaking ice machines, which resulted in the stained floors.

Recommendation 5

5. The Director ensures Environmental Management Services staff keep patient care areas clean.[52]

[50] VHA Directive 1850, *Environmental Programs Service*, March 31, 2017. (VHA rescinded and replaced this directive with VHA Directive 1850, *Environmental Programs Service*, January 30, 2023.)

[51] The OIG identified deficiencies in the Emergency Department at the Fort Wayne VA Medical Center and CLC 1C Heroes' Haven and Urgent Care Center at the Marion VA Medical Center.

[52] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. The Engineering service staff completed the work order related to the stained floor tiles in the Emergency Department at the Fort Wayne VA Medical Center in January 2023. However, the floor tiles located at the Community Living Center Unit 1C Heroes' Haven, and the Urgent Care Center at the Marion VA Medical Center did not need replacement. The Environmental Management Service staff were able to clean the stained areas. A QM [Quality Management] Coordinator completed rounds monthly to ensure these areas remained clean and stain free for six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

VHA requires staff to monitor expiration dates on commercial products and remove them from supply when outdated.[53] The OIG found expired medical supplies and outdated handwashing solution in 2 of the 10 patient care areas inspected.[54] Using expired supplies poses infection risks to those seeking healthcare services. The Chief Logistics Officer reported that due to an oversight, logistics staff did not remove two expired commercial packages of sterile supplies. Additionally, the Chief of Environmental Management Services said new supervisors and staff were unaware of proper processes for checking expiration dates.

Recommendation 6

6. The Associate Director for Patient Care Services ensures staff remove expired commercial products from patient care areas.[55]

[53] VHA Directive 1116(2), *Sterile Processing Services (SPS)*, March 23, 2016. (VHA rescinded and replaced this directive with VHA Directive 1116, *Management of Critical and Semi-Critical Reusable Medical Devices*, July 17, 2023.)

[54] The OIG found two expired Arrow Peripherally Inserted Central Catheter Line Kits in the Intensive Care Unit and expired handwashing solution in the 4 Medical unit at Fort Wayne VA Medical Center.

[55] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Associate Director for Patient Care Services reviewed the recommendation and did not identify any additional reasons for noncompliance. The expired commercial products were immediately removed from the area during the site visit. The Lead Supply Technician inspects the storage supply closets weekly for expired products and completes a checklist. In addition, VA NIHCS [Northern Indiana Health Care System] completes EOC rounds per Directive 1608 Comprehensive Environment of Care Program, dated June 21, 2021, to review for expired products.

Compliance Monitor: The numerator is the number of weekly inspections where no expired products were found. The denominator is the total number of inspections.

Compliance Goal: 90 percent or greater for a minimum of six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

The Joint Commission requires hospital staff to minimize the possibility of transmitting infections by storing dirty and used equipment separately from clean equipment.[56] The OIG found dirty equipment stored with clean equipment and supplies in 3 of the 10 areas inspected.[57] Storing contaminated items with clean equipment and supplies may create an infection risk. The Chiefs of Engineering and Environmental Management Services reported that some staff were unaware of proper storage requirements. In addition, the Chief Nurse of Operations cited a lack of oversight by nursing staff and environment of care team.

Recommendation 7

7. The Director ensures staff store clean and dirty equipment separately.[58]

[56] The Joint Commission, *Standards Manual*, E-dition, IC.02.02.01, EP 4, January 1, 2020.

[57] The OIG noted deficiencies in the 4 Medical unit at the Fort Wayne VA Medical Center and the PACT clinic and Urgent Care Center at the Marion VA Medical Center.

[58] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. The items identified as clean and dirty were removed and separated during the inspection. Monthly inspections are conducted in patient care areas to assess for clean and dirty equipment being stored separately. In addition, EOC rounds are completed per Directive 1608 Comprehensive Environment of Care Program, dated June 21, 2021; VA NIHCS demonstrated 90 percent attendance compliance. In the event soiled equipment is found, it would be immediately removed, and managers are notified.

Compliance Monitor: The numerator is the number of inspections where patient care areas were compliant with clean and dirty equipment being stored separately. The denominator is the total number of areas inspected.

Compliance Goal: 90 percent or greater for a minimum of six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

The Joint Commission requires hospital staff to maintain a safe environment, making sure "interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided."[59] The OIG found holes, punctures, and incomplete repairs in the walls of multiple patient care areas on 5 of the 10 units inspected.[60] Walls that are not intact cannot be properly cleaned, which may promote the spread of disease. The Chief of Engineering stated lack of work orders from staff and insufficient coordination between departments resulted in engineering staff being unaware of needed repairs to the walls.

Recommendation 8

8. The Director ensures staff maintain walls to allow for thorough cleaning.[61]

[59] The Joint Commission, *Standards Manual*, E-dition, EC.02.06.01, EP 1, January 1, 2020.

[60] The OIG identified the deficiencies in the Emergency Department at the Fort Wayne VA Medical Center and the Urgent Care Center and all three CLCs at the Marion VA Medical Center.

[61] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. Work orders were placed during the inspection into the VA based software application, used to report and track work orders until completion. The holes in the walls have been repaired and/or corrected.

In addition, EOC rounds are completed per Directive 1608 Comprehensive Environment of Care Program, dated June 21, 2021, with 90 percent attendance compliance demonstrated. Upon discovery, all repair needs are addressed immediately.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

VHA requires staff to test over-the-door alarms per manufacturers' recommendations.[62] The OIG found that Inpatient Mental Health unit staff did not follow the manufacturer's recommendations for monthly testing of over-the-door alarms and instead tested annually. Lack of adequate testing may result in staff being unaware of potential malfunctioning alarms, which could pose a safety risk in the event of an emergency. The Chief of Engineering reported being aware of the testing requirement but unaware of the manufacturer's frequency recommendations.

Recommendation 9

9. The Associate Director ensures staff test over-the-door alarms in the Inpatient Mental Health unit per the manufacturer's recommendations.[63]

[62] VHA Directive 1167, *Mental Health Environment of Care Checklist for Mental Health Units Treating Suicidal Patients*, May 12, 2017; VHA National Center for Patient Safety, "Mental Health Environment of Care Checklist," October 18, 2022.

[63] The OIG reviewed evidence sufficient to demonstrate that leaders completed improvement actions and therefore closed the recommendation as implemented before publication of the report.

Healthcare system concurred.

Target date for completion: Completed

Healthcare system response: The Associate Director reviewed the recommendation and did not identify any additional reasons for noncompliance. The monthly testing frequency has been established in the VA based software application used to report and track work orders until completion, per the manufacturers recommendations for testing the over-the-door alarm systems.

Compliance Monitor: The numerator is the number of inspections that were compliant with the over-the-door alarms requirements in the Inpatient Mental Health area, within six consecutive months. The denominator is the total number of inspections.

Compliance Goal: 90 percent or greater for a minimum of six consecutive months.

We would like to request closure for this recommendation prior to publication based on supporting evidence provided to the OIG.

Mental Health: Suicide Prevention Initiatives

Suicide prevention is the top clinical priority for VA.[64] Suicide is a significant health problem in the United States, with over 45,000 lives lost in 2020.[65] The suicide rate for veterans was higher than for nonveteran adults during 2020.[66] "Congress, VA, and stakeholders continue to express concern over seemingly limited progress made…to reduce veteran suicide."[67]

Due to the prevalence of suicide among at-risk veterans, VHA implemented a two-phase process to screen and assess for suicide risk in clinical settings. The phases include the Columbia-Suicide Severity Rating Scale Screener and subsequent completion of the Comprehensive Suicide Risk Evaluation when the screen is positive.[68] VHA states that providers should complete the Comprehensive Suicide Risk Evaluation on the same calendar day as the positive screen and notify the suicide prevention team if a patient reports suicidal behaviors during the evaluation.[69]

VHA requires each medical center and very large community-based outpatient clinic to have a full-time suicide prevention coordinator to track and follow up with high-risk veterans, conduct community outreach activities, and inform leaders of suicide-related events.[70]

To determine whether staff complied with selected suicide prevention requirements, the OIG interviewed key employees and reviewed relevant documents and the electronic health records of 47 randomly selected patients who had a positive suicide screen in FY 2022 and received primary care services.

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[64] VA Secretary memo, "Agency-Wide Required Suicide Prevention Training," October 15, 2020.

[65] "Suicide Prevention: Facts about Suicide," Centers for Disease Control and Prevention, accessed January 20, 2023.

[66] VA Office of Mental Health and Suicide Prevention, *2022 National Veteran Suicide Prevention Annual Report*, September 2022.

[67] Congressional Research Service, "Veteran Suicide Prevention," IF11886 version 2, July 29, 2021.

[68] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," November 13, 2020. (This memo was superseded by the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation Update (Risk ID Strategy)," November 23, 2022.)

[69] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation Update (Risk ID Strategy);" Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Suicide Behavior and Overdose Reporting," July 20, 2021. (This memo was superseded by the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Update to Suicide Behavior and Overdose Reporting," May 9, 2023.)

[70] VHA Directive 1160.07, *Suicide Prevention Program*, May 24, 2021. "Very large CBOCs [community-based outpatient clinics] are those that serve more than 10,000 unique veterans each year." VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. (VHA rescinded and replaced this handbook with VHA Directive 1160.01, *Uniform Mental Health Services in VHA Medical Points of Service*, April 27, 2023.)

Mental Health Findings and Recommendations

VHA requires providers to complete the Comprehensive Suicide Risk Evaluation following a patient's positive suicide risk screen.[71] The OIG estimated that of the 47 patients with a positive screen, providers did not evaluate 28 (95% CI: 15 to 41) percent of them using the Comprehensive Suicide Risk Evaluation, which is statistically significantly above the OIG's 10 percent deficiency benchmark.[72] Providers' failure to complete the Comprehensive Suicide Risk Evaluation could result in missed opportunities to identify patients who are at imminent risk of suicide and intervene. The Chief of Mental Health attributed the noncompliance to providers not understanding evaluation requirements, not using the correct template to evaluate patients, or not transferring patients to a mental health professional after a positive screen.

Recommendation 10

10. The Director ensures providers complete the Comprehensive Suicide Risk Evaluation following a patient's positive suicide risk screen.

[71] Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy);" Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer memo, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation Update (Risk ID Strategy)."

[72] A confidence interval (CI) is a range of estimates, computed based on a statistical sample, for an unknown true value. The 95% confidence level indicates that among confidence intervals computed from all possible samples with the same sample size and the study design, the true value would have been covered by the confidence intervals 95 percent of the time.

Healthcare system concurred.

Target date for completion: September 30, 2024

Healthcare system response: The Director reviewed the recommendation and did not identify any additional reasons for noncompliance. All direct care clinical staff received additional training to reinforce the mandatory completion of the Comprehensive Suicide Risk Evaluation (CSRE) on the same calendar day that a positive Columbia Suicide Severity Rating Screen (CSSRS) is identified. Additionally, the Suicide Prevention Program team provides scheduled education regarding suicide risk screening to all staff during new employee orientation and to clinical staff throughout the year.

The VANIHCS Suicide Prevention Program team receives real-time alerts for positive CSSRS assessments through the Electronic Health Record System and ensures daily review of the Corporate Data Composite report for all positive CSSRS assessments, including those documented during off-tours.

When a CSRE is not completed following a positive CSSRS, the Suicide Prevention Program team provides additional education to the involved clinical staff, working together to develop a plan of action for CSRE completion.

Compliance Monitor: The numerator is the number of Veterans with a CSRE completed timely. The denominator is the number of positive CSSRS.

Compliance Goal: VANIHCS will demonstrate 90 percent adherence for six consecutive months.

Report Conclusion

To assist leaders in evaluating the quality of care at their healthcare system, the OIG conducted a detailed inspection of five clinical and administrative areas and provided 10 recommendations on systemic issues that may adversely affect patient care. The total number of recommendations does not necessarily reflect the overall quality of all services delivered within this healthcare system. However, the OIG's findings highlight areas of concern, and the recommendations are intended to help guide improvement efforts. The OIG appreciates the participation and cooperation of VHA staff during this inspection process. A summary of the recommendations is presented in appendix A.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

The table below outlines 10 OIG recommendations aimed at reducing vulnerabilities that may lead to adverse patient safety events. The recommendations are attributable to the Director, Chief of Staff, ADPCS, and Associate Director. The intent is for leaders to use recommendations as a road map to help improve operations and clinical care.

Table A.1. Summary Table of Recommendations

Review Areas	Recommendations for Improvement
Leadership and Organizational Risks	• None
Quality, Safety, and Value	• None
Medical Staff Privileging	• Service chiefs define the time frames for Focused Professional Practice Evaluations. • Service chiefs recommend reprivileging based, in part, on Ongoing Professional Practice Evaluation activities.
Environment of Care	• Staff remove corrugated containers from patient care areas. • Staff keep storerooms clean and free of visible dust and soiling. • Environmental Management Services staff keep patient care areas clean. • Staff remove expired commercial products from patient care areas. • Staff store clean and dirty equipment separately. • Staff maintain walls to allow for thorough cleaning. • Staff test over-the-door alarms in the Inpatient Mental Health unit per the manufacturer's recommendations.
Mental Health: Suicide Prevention Initiatives	• Providers complete the Comprehensive Suicide Risk Evaluation following a patient's positive suicide risk screen.

Appendix B: Healthcare System Profile

The table below provides general background information for this medium complexity (2) healthcare system reporting to VISN 10.[1]

Table B.1. Profile for VA Northern Indiana Health Care System (610) (October 1, 2019, through September 30, 2022)

Profile Element	Healthcare System Data FY 2020*	Healthcare System Data FY 2021†	Healthcare System Data FY 2022‡
Total medical care budget	$425,566,569	$511,179,454	$561,194,595
Number of:			
• Unique patients	43,501	43,731	45,108
• Outpatient visits	434,400	476,084	449,687
• Unique employees§	1,540	1,536	1,438
Type and number of operating beds:			
• Community living center	180	104	104
• Domiciliary	30	30	0
• Medicine	26	26	20
• Mental health	65	65	65
Average daily census:			
• Community living center	97	66	62
• Domiciliary	16	5	–
• Medicine	12	14	11
• Mental health	19	11	10
• Surgery	–	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.

**October 1, 2019, through September 30, 2020.*

†*October 1, 2020, through September 30, 2021.*

‡*October 1, 2021, through September 30, 2022.*

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

[1] VHA medical facilities are classified according to a complexity model; a designation of "2" indicates a facility with "medium volume, low-risk patients, few complex clinical programs, and small or no research and teaching programs." VHA Office of Productivity, Efficiency & Staffing (OPES), "VHA Facility Complexity Model Fact Sheet," October 1, 2020.

Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: December 22, 2023

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

Subj: Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion

To: Director, Office of Healthcare Inspections (54CH01)

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

1. I have reviewed and concur with OIG's recommendations and the action plans submitted by the VA Northern Indiana Healthcare System for the report – Comprehensive Healthcare Inspection of the of VA Northern Indiana Healthcare System in Marion.
2. Thank you for the opportunity to review and comment.

(Original signed by:)

Ronald E. Stertzbach, P.E.
Deputy Network Director for
Laura E. Ruzick, FACHE
Network Director

Appendix D: Healthcare System Director Comments

Department of Veterans Affairs Memorandum

Date: December 21, 2023

From: Director, VA Northern Indiana Health Care System (610)

Subj: Comprehensive Healthcare Inspection of the VA Northern Indiana Health Care System in Marion

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

1. Attached is a status update as a result of the VA Northern Indiana's Health Care System's OIG Comprehensive Healthcare Inspection (Report Number 54CH01-HI-1321) that was conducted during the week of January 09, 2023.
2. We have provided narrative responses and our recommendation for consideration of closure for seven of the ten open recommendations.
3. Thank you for allowing us the opportunity to submit the status updates, which denotes improvements we have made based upon the OIG CHIP review.

(Original signed by:)

Anthony L. Colón, FACHE
Interim Medical Center Director

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