DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky

CHIP REPORT | **REPORT #21-03309-23** | **DECEMBER 6, 2022**

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Figure 1. *Rex Robley VA Medical Center in Kentucky. This is locally referred to as the Louisville VA Medical Center. Source: https://www.va.gov/louisville-health-care/locations/.*

Abbreviations

ADPCS	Associate Director for Patient Care Services
CHIP	Comprehensive Healthcare Inspection Program
FPPE	Focused Professional Practice Evaluation
FY	fiscal year
LIP	licensed independent practitioner
OIG	Office of Inspector General
TJC	The Joint Commission
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 Louisville VA Medical Center and associated outpatient clinics in Indiana and Kentucky. The inspection covers key clinical and administrative processes that are associated with promoting quality care.

Comprehensive healthcare inspections are one element of the OIG's overall efforts to ensure that the nation's veterans receive high-quality and timely VA healthcare services. The OIG performs the inspections approximately every three years for each facility 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 emergency department and urgent care center suicide prevention initiatives)

The OIG conducted an unannounced inspection of the Louisville VA Medical Center from November 29 through December 3, 2021. 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 medical center's performance within the identified focus areas at the time of the OIG inspection. Although it is difficult to quantify the risk of patient harm, the findings may help leaders at this medical center and other Veterans Health Administration (VHA) facilities identify vulnerable areas or conditions that, if properly addressed, could improve patient safety and healthcare quality.

Inspection Results

The OIG noted opportunities for improvement in several areas reviewed and issued five recommendations to the Medical Center Director, Chief of Staff, and Associate Director for Operations. These opportunities for improvement are briefly described below.

Quality, Safety, and Value

The OIG identified weaknesses with the oversight of the governing committees and peer review processes.[1]

Medical Staff Privileging

The OIG identified improvement opportunities with Focused Professional Practice Evaluations.[2]

Environment of Care

The OIG noted a concern with heavily soiled floors in multiple inpatient and outpatient areas.

Conclusion

The OIG conducted a detailed inspection across five key areas and subsequently issued five recommendations for improvement to the Medical Center Director, Chief of Staff, and Associate Director for Operations. The number of recommendations should not be used as a gauge for the overall quality of care provided at this medical center. The intent is for these leaders to use the recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues that may eventually interfere with the delivery of quality health care.

[1] 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, *Peer Review for Quality Management*, November 21, 2018.

[2] A Focused Professional Practice Evaluation is "a time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance." VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (The credentialing portion of this handbook was replaced by VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021.)

VA Comments

The Veterans Integrated Service Network Director and Medical Center Director agreed with the comprehensive healthcare inspection findings and recommendations and provided acceptable improvement plans (see appendixes C and D, pages 26–27, and the responses within the body of the report for the full text of the directors' comments). The OIG considers recommendations 2 and 3 closed. The OIG will follow up on the planned actions for the open recommendations until they are completed.

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

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Purpose and Scope

The purpose of the Office of Inspector General (OIG) Comprehensive Healthcare Inspection Program (CHIP) is to conduct routine oversight of VA medical facilities that provide healthcare services to veterans. This report's evaluation of the quality of care delivered in the inpatient and outpatient settings of the Louisville VA Medical Center examines a broad range of key clinical and administrative processes associated with positive patient outcomes. The OIG reports its findings to Veterans Integrated Service Network (VISN) and medical center leaders so 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 emergency department and urgent care center suicide prevention initiatives)

[1] VA administers healthcare services through a nationwide network of 18 regional systems called 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), https://doi.org/10.1136/bmjopen-2014-005055.

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

[4] CHIP site visits address these processes during fiscal year 2022 (October 1, 2021, through September 30, 2022); they may differ from prior years' focus areas.

Methodology

The Louisville VA Medical Center also provides care through associated outpatient clinics in Indiana and Kentucky. General information about the medical center can be found in appendix B.

The inspection team examined operations from August 27, 2018, through December 3, 2021, the last day of the unannounced multiday evaluation.[5] Following the site visit, the OIG referred concerns that were beyond the scope of this inspection to the OIG's hotline management team for further review.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978.[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 medical center leaders complete corrective actions. The Medical Center Director's responses to the report recommendations appear within each topic area. The OIG accepted the action plans that medical center leaders developed based on the reasons for noncompliance.

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

[5] The OIG's last comprehensive healthcare inspection of the Louisville VA Medical Center occurred in August 2018. The Joint Commission performed hospital, behavioral health care, and home care accreditation reviews in February 2019.

[6] Pub. L. No. 95-452, 92 Stat 1101, as amended (codified at 5 U.S.C. App. 3).

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 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 medical center's leadership and risks, the OIG considered several 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 medical center leaders' responses

Executive Leadership Position Stability and Engagement

Because each VA facility organizes its leadership structure to address the needs and expectations of the local veteran population it serves, organizational charts may differ across facilities. Figure 2 illustrates this medical center's reported organizational structure. The medical center had a leadership team consisting of the Medical Center Director, Associate Director for Operations, Associate Director for Patient Care Services (ADPCS), and Chief of Staff. 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 executive team had worked together for about one month. The Medical Center Director and Chief of Staff, both assigned in October 2021, were the newest executive leaders. The Associate Director for Operations and ADPCS had been in their positions for over three and five years, respectively.

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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, *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 the executive leaders' engagement, the OIG interviewed the Medical Center Director, Chief of Staff, acting ADPCS, and Associate Director for Operations regarding their knowledge, involvement, and support of actions to improve or sustain performance.[10]

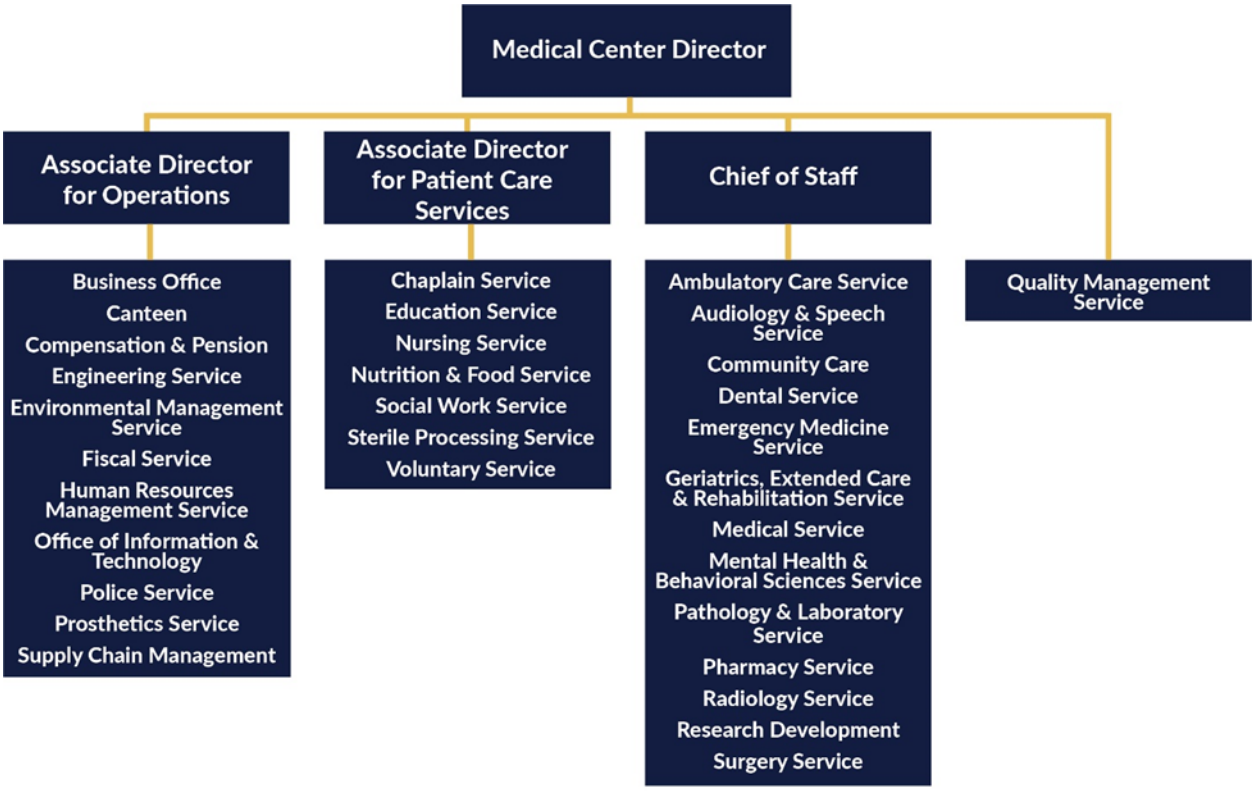

Figure 2. *Medical center organizational chart.*
Source: Louisville VA Medical Center (received December 13, 2021).

Budget and Operations

The OIG noted that the medical center's fiscal year (FY) 2021 annual medical care budget of $515,703,535 had increased approximately 13 percent compared to the previous year's budget of $458,375,083.[11] When asked about the effect of this change on the medical center's operations, the Medical Center Director stated that the increased funds helped leaders purchase additional care in the community and hire more staff to support pandemic response efforts. The Associate Director for Operations stated the extra funds helped cover increased drug costs and supported pandemic efforts by paying for a hangar (temporary structure) for the drive-through testing and vaccination clinic.

[10] At the time of the inspection, the ADPCS was on leave. The Chief Nurse, Specialty Care, who had been in the position since May 2018, was the delegated authority for the ADPCS from November 29 to December 3, 2021.
[11] VHA Support Service Center (VSSC).

The Associate Director for Operations indicated that an additional increase in the FY 2022 budget had allowed recruitment for critical positions and a salary increase for registered nurses, pharmacists, pharmacy technicians, engineers, and biomedical engineers.

Employee Satisfaction

The All Employee Survey is an "annual, voluntary, census survey of VA workforce experiences. The data are anonymous and confidential."[12] The instrument has been refined several times in response to VA leaders' inquiries on VA culture and organizational health. Although the OIG recognizes that employee satisfaction survey data are subjective, they can be a starting point for discussions, indicate areas for further inquiry, and be considered along with other information on medical center leaders.

To assess employee attitudes toward medical center leaders and the workplace, the OIG reviewed results from VHA's All Employee Survey from FYs 2019 to 2021 regarding employees' perceived ability to disclose a suspected violation without fear of reprisal.[13] Although the scores were mostly similar to VHA averages, the scores for the ADPCS were lower than VHA and medical center averages but had improved over time. The acting ADPCS attributed the improvement to more frequent communication with staff.

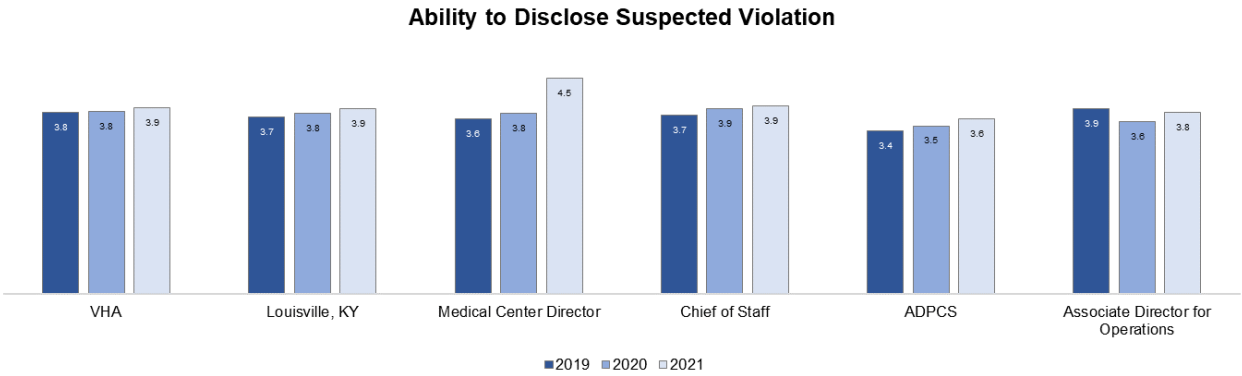

Figure 3. *All Employee Survey Results: I can disclose a suspected violation of any law, rule, or regulation without fear of reprisal.*

Source: VA All Employee Survey (accessed October 25, 2021).

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

[12] "AES Survey History, Understanding Workplace Experiences in VA," VSSC website.

[13] 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. The FY 2019 through 2021 All Employee Survey results are not reflective of employee satisfaction with the current Medical Center Director and Chief of Staff, who assumed their roles after the survey was administered.

Patient Experience

VHA uses industry standard surveys from the Consumer Assessment of Healthcare Providers and Systems program to evaluate patients' experiences with their health care and benchmark performance against the private sector. VHA's Patient Experiences Survey Reports provide results from the Survey of Healthcare Experiences of Patients program.

VHA also collects Survey of Healthcare Experiences of Patients data from Inpatient, Patient-Centered Medical Home (primary care), and Specialty Care surveys. The OIG reviewed responses to three relevant survey questions that reflect patient experiences with the medical center from October 1, 2017 (FY 2018), through June 30, 2021. Figures 4–6 provide survey results for VHA and the medical center over time.[14]

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

The medical center's inpatient satisfaction survey results consistently reflected lower scores than the VHA averages. The acting ADPCS attributed the lower scores to the COVID-19 pandemic and families not being allowed to visit with patients. The acting ADPCS also stated that nurses visited patient rooms more often to ensure timely responses to calls and better understand patient needs. Although new in the position, the Medical Center Director reported providing inpatients with iPads to improve communication with family members during the visitation restrictions. The Medical Center Director added that leaders have reduced visitation restrictions and implemented the Red Coat Ambassador program (assigning staff to escort patients to find their way around the hospital) to help improve patient experiences.[15] The Chief of Staff stated that with decreasing numbers of COVID-19 cases and reduced reassignment of staff from their primary work areas, the scores may improve.

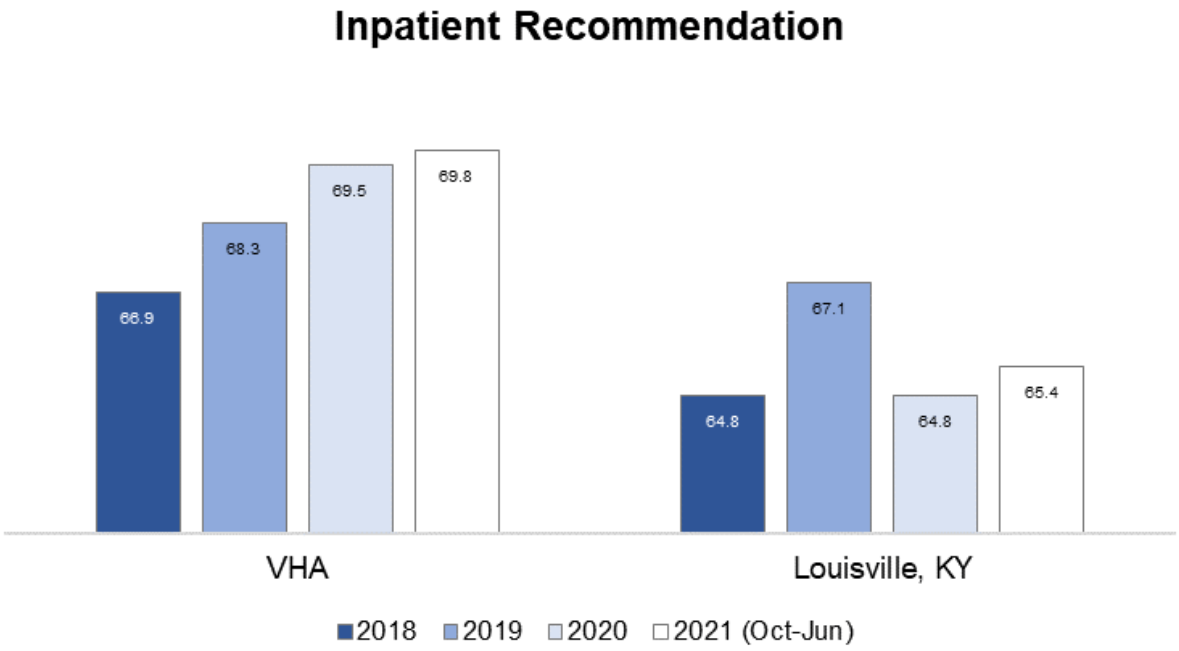

Figure 4. *Survey of Healthcare Experiences of Patients Results (Inpatient): Would you recommend this hospital to your friends and family?*

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed September 21, 2021).

Note: The score is the percent of "Definitely Yes" responses.

[15] "Journey Maps: Plotting the Moments That Matter to Veterans and Their Families," Veterans Experience Office (VEO), March 5, 2020, https://www.va.gov/VE/pressreleases/2020030501.asp.

The medical center's patient satisfaction survey results for primary care reflected higher scores than the VHA averages, beginning in FY 2019. The Chief of Staff attributed the improved scores to a more efficient workflow in primary care, better communication between community care and ambulatory care teams, and new clinics in Louisville and Fort Knox, Kentucky. The Chief of Staff also discussed working to improve relationships with the University of Louisville to increase staff recruitment. The Medical Center Director reported adding staff to home-based primary care to improve patient satisfaction.

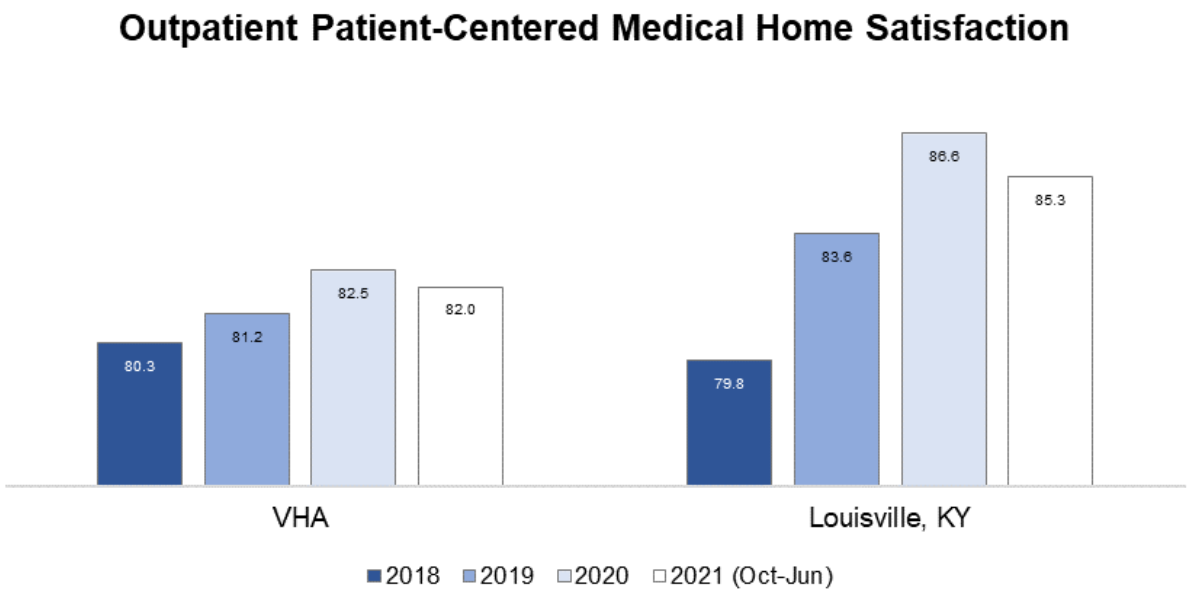

Figure 5. *A Survey of Healthcare Experiences of Patients Results (Outpatient Patient-Centered Medical Home): Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?*

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed September 21, 2021).

Note: The score is the percent of "Very satisfied" and "Satisfied" responses.

The medical center's patient satisfaction survey scores for outpatient specialty care were consistently higher than the VHA averages. The Chief of Staff shared actions taken to continuously improve patients' specialty care experiences, which included increasing recruitment efforts for specialty providers and hiring additional staff to decrease wait times.

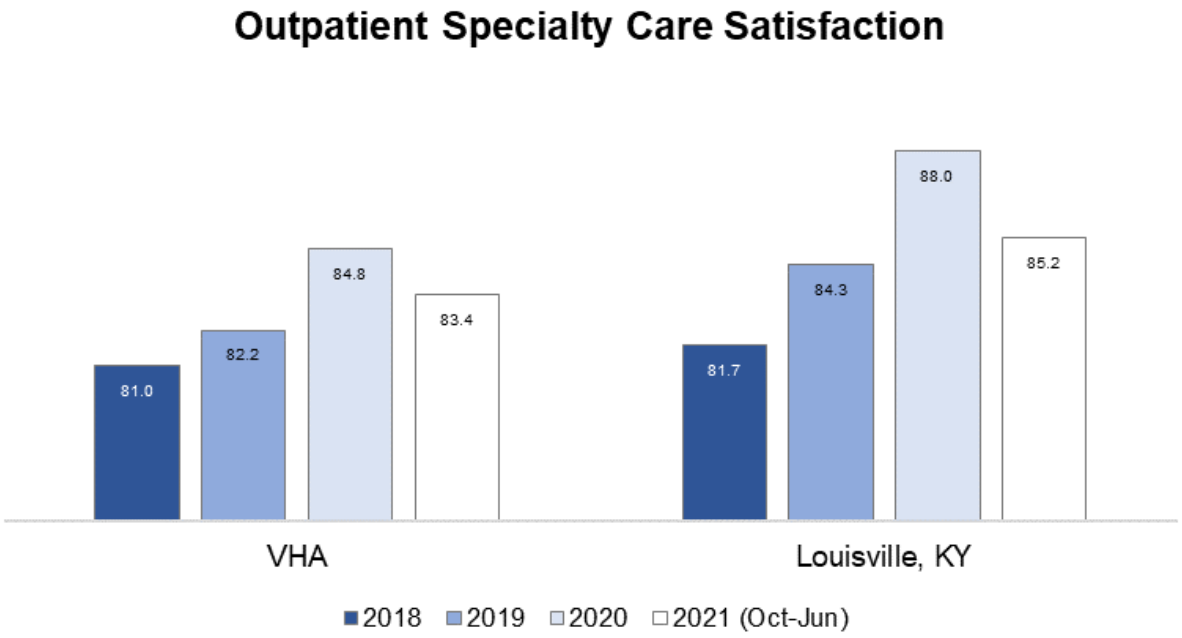

Figure 6. *A Survey of Healthcare Experiences of Patients Results (Outpatient Specialty Care): Overall, how satisfied are you with the health care you have received at your VA facility during the last 6 months?*

Source: VHA Office of Quality and Patient Safety, Analytics and Performance Integration, Performance Measurement (accessed September 21, 2021).

Note: The score is the percent of "Very satisfied" and "Satisfied" responses.

Identified Factors Related to Possible Lapses in Care and Medical Center Leaders' Responses

Leaders must ensure that patients receive high-quality health care that is safe, effective, timely, and patient-centered because any preventable harm episode is one too many.[16] VHA defines a sentinel event as an incident or condition that "results in death, permanent harm, or severe temporary harm and [where] intervention [is] required to sustain life."[17] 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

[16] Frankel, *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/.

[17] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse."[18] 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."[19] To this end, VHA implemented standardized processes to guide leaders in measuring, assessing, and reacting to possible lapses in care to improve patient safety.

Table 1 lists the reported patient safety events from August 27, 2018 (the prior OIG CHIP site visit), through November 30, 2021.

Table 1. Summary of Selected Organizational Risk Factors (August 27, 2018, through November 30, 2021)

Factor	Number of Occurrences
Sentinel Events	0*
Institutional Disclosures	12
Large-Scale Disclosures	0

Source: Louisville VA Medical Center's Patient Safety Manager, Risk Manager, and Chief of QSV (initially received December 1, 2021; updated March 8, 2022).

**The Patient Safety Manager reported no sentinel events since the previous OIG CHIP site visit; however, medical center leaders reviewed the disclosed cases and determined that certain adverse events met the criteria for sentinel events.*

Although the Medical Center Director spoke knowledgeably about the adverse event reporting process, the OIG noted concerns related to leaders identifying sentinel events. Failure to identify adverse events as sentinel events may lead to missed opportunities for staff to recognize safety trends and report patient harm and could cause delays in mitigating risks of future events. The Medical Center Director reported taking steps to make certain that leaders accurately identify adverse events as sentinel events when criteria are met.

Leadership and Organizational Risks Findings and Recommendations

The OIG made no recommendations.

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

[19] VHA Directive 1004.08.

Quality, Safety, and Value

VHA strives to provide healthcare services that compare "favorably to the best of [the] private sector in measured outcomes, value, access, and patient experience."[20] To meet this goal, VHA requires that its facilities implement programs to monitor the quality of patient care and performance improvement activities and maintain The Joint Commission (TJC) accreditation.[21] Many quality-related activities are informed and required by VHA directives and nationally recognized accreditation standards (such as those from TJC).[22]

To determine whether VHA facilities have implemented OIG-identified key processes for quality and safety and incorporated them into local activities, the inspection team evaluated the medical center's committee responsible for oversight of healthcare operations and its ability to review data and ensure that key executive leadership functions are discussed and integrated on a regular basis.

Next, the OIG assessed the medical center's processes for conducting peer reviews of clinical care.[23] 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."[24] Peer reviews are "intended to promote confidential and non-punitive" processes that consistently contribute to quality management efforts at the individual provider level.[25]

Finally, the OIG assessed the medical center's culture of safety.[26] VA implemented the National Center for Patient Safety program in 1999, which involved staff from across VHA developing a range of patient safety methodologies and practices.

The OIG reviewers interviewed managers and key employees and evaluated meeting minutes, peer reviews, patient safety reports, and other relevant information.

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

[21] VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017. (This directive was rescinded and replaced by VHA Directive 1100.16, *Health Care Accreditation of VHA Facilities and Programs*, July 19, 2022.)

[22] VHA Directive 1100.16.

[23] 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.

[24] VHA Directive 1190.

[25] VHA Directive 1190.

[26] 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, accessed October 3, 2022, https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patientsafetyculture/hospital/userguide/hospcult.pdf.

Quality, Safety, and Value Findings and Recommendations

The OIG identified deficiencies with the governing body responsible for oversight of medical center operations and peer reviews.

According to TJC, the governing body provides "internal structures and resources, including staff that support safety and quality."[27] TJC requires hospitals to measure and analyze performance, identify trends, establish corrective actions, and monitor outcomes for effectiveness and sustainability to improve safety and quality of care.[28]

The medical center's governance structure was composed of four governing committees responsible for reporting to the Executive Leadership Council, which oversaw medical center operations and reviewed quality data to ensure information and key quality components were discussed and monitored. The OIG reviewed Executive Leadership Council meeting minutes from December 2020 through October 2021 and determined that governing committees did not report to the council during any of the 11 months. Lack of reporting may have prevented quality of care and patient safety process improvements at the medical center. The Medical Center Director attributed the noncompliance to a lack of effective oversight, competing priorities during the pandemic, and a new Chief, Quality Management Service who had no prior VA experience.

Recommendation 1

1. The Medical Center Director evaluates and determines any additional reasons for noncompliance and ensures governing committees report to the Executive Leadership Council.

[27] TJC, *Standards Manual*, E-dition, January 1, 2020, Rationale for Leadership standard LD.01.03.01.

[28] TJC, *Standards Manual*, E-dition. Rationale for Leadership standard LD.01.03.01, Rationale for Leadership standard LD.03.05.01, Leadership Introduction to Operations standards LD.03.07.01 through LD.04.03.11, and Performance Improvement standard PI.01.01.01.

Medical center concurred.

Target date for completion: February 28, 2023

Medical center response: The Medical Center Director evaluated the reasons for non-compliance and determined there were no additional reasons for non-compliance. The Medical Center Director will ensure that the governing committees report to the Executive Leadership Council (ELC). In February 2022, the Quality Manager gathered best-practice models for Organizational Governance Structure to improve information flow across committees to executive leaders. A temporary model was implemented while review of all committee structures and reporting processes could be done. Use of the consent agenda was eliminated. A reporting template was implemented in June 2022 to include action items, current data, action plan moving forward, and target completion dates. The Organizational Governance Structure is being revised to improve the information flow through the governing committees. Medical Center Policy 603-22-00QM-36 is being revised to reflect changes to the Organizational Governance Structure. The charters for the Executive Leadership Council and the four governing committees: Healthcare Operations; Healthcare Delivery; Quality, Safety, and Value; and Organizational Health are being updated and revised to reflect the changes in information flow and include the appropriate quality reporting metrics. A quality data reporting grid is being developed to identify monthly, quarterly, and annual data reports required for ELC monitoring based on VHA directives and The Joint Commission (TJC). Quality data reports are expected to include analysis, identification of trends, corrective actions, and outcomes. The Quality Management Administrative Officer will audit the ELC minutes for required quality data reporting until a 90 percent or greater compliance is sustained for six consecutive months. Compliance will be reported to the ELC monthly.

The numerator equals the number of quality data reporting requirements completed monthly, quarterly, and annually, as required.

The denominator equals the total number of quality data reporting requirements.

VHA requires peer reviewers to use at least one of the nine aspects of care to evaluate Level 3 peer review findings to support the level of care assigned, as well as any other information that supports the rationale for their decision.[29] The OIG found that two of five Level 3 peer reviews lacked evidence that reviewers used at least one of the nine aspects of care. Failure to use any of the aspects of care may affect reviewers' ability to determine whether appropriate care was provided. The Chief, Quality Management Service stated the Peer Review Committee advised peer reviewers to complete the aspects of care section but acknowledged the lack of oversight by the committee to ensure compliance.

[29] VHA Directive 1190.

Recommendation 2

2. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures peer reviewers consistently use at least one of the nine aspects of care when conducting peer reviews.[30]

Medical center concurred.

Target date for completion: Completed

Medical center response: The Chief of Staff evaluated the reasons for non-compliance and determined there were no additional reasons for non-compliance. The Chief of Staff will ensure that all peer review cases assigned a level 2 or 3 will have an aspect of care identified. In January 2022, the Risk Manager implemented a process to return all peer reviews to the reviewer if an aspect of care has not been identified. The aspect of care identified was discussed at the Peer Review Subcommittee meeting when the case is presented, as evidenced by the February 2022 through July 2022 Peer Review Subcommittee minutes. The Risk Manager audited the Peer Review Subcommittee minutes from February 2022 through July 2022 and verified an aspect of care has been documented for all level 2 or 3 cases at 100% compliance for six consecutive months. The Peer Review Subcommittee is chaired by the Chief of Staff.

The numerator equals the times an aspect of care is identified for a level 2 or 3 peer review case.

The denominator equals the total number of level 2 or 3 peer review cases.

The medical center requested closure based on evidence of sustained compliance.

VHA also requires clinical managers to implement improvement actions recommended by the Peer Review Committee.[31] The OIG did not find evidence that clinical managers implemented recommended actions for four of five Level 3 peer reviews. Failure to implement improvement actions likely prevented improvements in patient care practices. The Risk Manager acknowledged failure to follow up with clinical managers to ensure they implemented recommended actions.

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

[31] VHA Directive 1190.

Recommendation 3

3. The Chief of Staff evaluates and determines any additional reasons for noncompliance and ensures clinical managers implement improvement actions recommended by the Peer Review Committee.[32]

Medical center concurred.

Target date for completion: Completed

Medical center response: The Chief of Staff evaluated the reasons for non-compliance and determined there were no additional reasons for non-compliance. The Chief of Staff will ensure that all peer review cases assigned a level 2 or 3 have evidence of improvement actions and monitors for sustainability. In January 2022, a template was created, entitled "Level 2 and 3 Peer Review Quality Improvement" Template. The Risk Manager sends this document to the supervisor, manager, and/or Service Chief for the clinical area(s) to review. Improvement actions that were identified were reviewed and tracked by the Peer Review Subcommittee, chaired by the Chief of Staff. The Risk Manager audited the Peer Review Committee minutes from February 2022 through July 2022 and verified that improvement actions are identified and tracked to completion for six consecutive months. The Peer Review Subcommittee is chaired by the Chief of Staff.

The numerator equals the number of improvement actions identified and tracked.

The denominator equals the number of improvement actions identified for a level 2 or 3 peer review case.

The medical center requested closure based on evidence of sustained compliance.

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

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."[33] 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."[34]

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.[35] LIPs are granted clinical privileges for no more than two years and must be reprivileged prior to their expiration.[36]

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."[37] The FPPE process occurs when a practitioner is hired at the facility and granted initial or additional privileges.[38] 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.[39]

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.[40] 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 and aligned under the Chief of Staff. VHA also requires facilities to have credentialing

[33] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. (The credentialing portion of this handbook was replaced by VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021.)
[34] VHA Handbook 1100.19.
[35] VHA Handbook 1100.19.
[36] VHA Handbook 1100.19.
[37] VHA Handbook 1100.19.
[38] VHA Handbook 1100.19.
[39] VHA Handbook 1100.19.
[40] VHA Directive 1100.20.

and privileging managers and specialists with job duties that align under standard position descriptions.[41]

The OIG interviewed key managers and selected and reviewed the privileging folders of several medical staff members:

- Three solo/few practitioners who underwent clinical privileging in the previous 12 months[42]
- Ten LIPs who had an FPPE completed in the previous 12 months
- Twenty LIPs who were reprivileged in the previous 12 months

Medical Staff Privileging Findings and Recommendations

The OIG identified opportunities for improvement with FPPEs. VHA requires an FPPE to be completed within a defined time frame, during which the medical staff leaders evaluate and determine the practitioner's professional performance.[43] The OIG found that 3 of 10 practitioners' FPPEs lacked documentation of a time frame for evaluation. This could have resulted in LIPs delivering care without a thorough evaluation of their practices. The Credentialing and Privileging Manager attributed the noncompliance to a lack of oversight when administrative staff were reassigned to other areas to help with the influx of COVID-19 patients.

Recommendation 4

4. The Chief of Staff evaluates and determines any additional reasons for noncompliance and makes certain that service chiefs complete Focused Professional Practice Evaluations within clearly defined time frames.

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

[42] VHA refers to a solo practitioner as being one provider in the facility who is privileged in a particular specialty. VHA Acting Deputy Under Secretary for Health for Operations and Management memo, "Requirements for Peer Review of Solo Practitioners," August 29, 2016. (This memo was rescinded and replaced by the Assistant Under Secretary for Health for Clinical Services memo, "Implementation of Enterprise-Wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-Specific Clinical Indicators" on December 18, 2020. The December 18, 2020, memo was rescinded and replaced by the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer's Revision memo, "Implementation of Enterprise-Wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-Specific Clinical Indicators" on May 18, 2021.) The OIG considers a few practitioners as being two providers in the facility who are privileged in a particular specialty.

[43] VHA Handbook 1100.19.

Medical center concurred.

Target date for completion: February 28, 2023

Medical center response: The Chief of Staff evaluated the reasons for non-compliance and determined there were no additional reasons for non-compliance. The Chief of Staff will ensure the completion of Focused Professional Practice Evaluations (FPPE) within defined time frames. Digital signatures are required for all FPPEs, if the service chief has the digital signature capability. A tracking sheet was developed to ensure all FPPEs are dated and signed. Education was provided on the new tracking sheet. The Credentialing and Privileging (C&P) Program Analyst will review all received FPPE forms for defined timeframes and return to services if not completed. The C&P Program Analyst will audit 100% of FPPEs to ensure compliance until 90 percent or greater compliance is sustained for six consecutive months. This will be monitored monthly in the C&P Subcommittee and forwarded monthly to the Healthcare Delivery Committee (HDC), chaired by the Chief of Staff.

The numerator equals the number of FPPE completed within the defined time frame.

The denominator equals the total number of FPPE.

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. 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.[44] The physical environment of a healthcare organization must not only be functional but should also promote healing.

The purpose of this inspection was to determine whether VA medical facilities maintained a clean and safe healthcare environment in accordance with applicable standards. The OIG assessed compliance in 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 community living centers, where vulnerable populations reside in a home-like environment and receive assistance in achieving their highest level of function and well-being.[45]

An estimated 75,673 of 100,306 drug overdose deaths that occurred in the United States from April 2020 to April 2021 were opioid-related. This was an increase from 56,064 in the previous 12 months.[46] VA implemented the Rapid Naloxone Initiative to reduce the risk of opioid-related deaths. This initiative involves stocking the reversal agent naloxone in Automated External Defibrillator cabinets in nontraditional patient care areas to enable fast response times in emergencies and contribute to a safe healthcare environment.[47]

During the OIG's review of the environment of care, the inspection team examined relevant documents, interviewed managers and staff, and inspected 11 patient care areas:

- Ambulatory surgery unit

[44] VHA Directive 1608, *Comprehensive Environment of Care (CEOC) Program*, February 1, 2016. (This directive was rescinded and replaced with VHA Directive 1608, *Comprehensive Environment of Care Program*, June 21, 2021.)

[45] Community living centers were previously known as nursing home care units. VHA Handbook 1142.01, *Criteria and Standards for VA Community Living Centers (CLC),* August 13, 2008.

[46] Centers for Disease Control and Prevention – National Center for Health Statistics, "Drug Overdose Deaths in the U.S. Top 100,000 Annually," accessed December 6, 2021, https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm.

[47] Opioids are medications that are "effective at reducing pain" but "when taken in excess, can lead to respiratory arrest." Naloxone is a highly effective treatment for reversing an opioid overdose. "Automated External Defibrillator (AED) Cabinet Naloxone Program: Implementation Toolkit," VHA. AEDs are devices used to treat sudden cardiac arrest. Food and Drug Administration, "Automated External Defibrillators (AEDs)," accessed December 16, 2021, https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds. "Pharmacy Benefits Management Services," Department of Veterans Affairs, accessed October 6, 2021, https://www.pbm.va.gov/PBM/academicdetailingservice/Opioid_Overdose_Education_and_Naloxone_Distribution.asp.

- Dermatology clinic
- Emergency department
- Intensive care unit
- Inpatient medical surgical unit (4-North)
- Inpatient medical surgical/hospice unit (5-North)
- Inpatient medical surgical unit (6-South)
- Mental health inpatient unit (7-North)
- Optometry clinic
- Post-anesthesia care unit
- Primary care clinic

Environment of Care Findings and Recommendations

The OIG noted a concern with environmental cleanliness. Specifically, VHA requires that all VA medical facilities provide a safe, clean, functional, and high-quality environment for patients, staff, and visitors.[48] In 8 of 11 clinical areas inspected, the OIG found heavily soiled floors in multiple inpatient, supply, and outpatient clinic examination rooms; one medication room; and a restroom.[49] This presented a potential risk of infection to patients, staff, and visitors. The Chief, Environmental Management Service attributed the deficiencies to limited access to inpatient rooms due to the high patient census and frequent staff reassignment from routine housekeeping duties to intensive pandemic-related sanitation tasks.

Recommendation 5

5. The Associate Director for Operations evaluates and determines any additional reasons for noncompliance and makes certain that managers maintain a safe and clean environment.

[48] VHA Directive 1608, *Comprehensive Environment of Care Program*, June 21, 2021.

[49] The OIG found deficiencies in the emergency department; intensive care unit; inpatient medical/surgical units (4-North, 5-North, and 6-South); and dermatology, optometry, and primary care clinic.

Medical center concurred.

Target date for completion: February 28, 2023

Medical center response: The Associate Director for Operations evaluated the reasons for non-compliance and determined there were no additional reasons for non-compliance. The Associate Director for Operations, in collaboration with the Associate Director for Patient Care Services (ADPCS), will ensure managers maintain a safe and clean environment. It was determined that routine and terminal cleaning were being done but that the soiled areas on the floor (especially transitions and under doors) could be attributed to excess waxy residue. A facility-wide floor maintenance and refinishing plan has been developed and implemented to strip and wax all floors throughout the facility including areas with > 80% occupancy due to COVID-19. Nursing Services (NS) and Environmental Management Services (EMS) have enhanced coordination and cooperation in addressing flooring issues in patient wards. Nursing staff will report floor cleanliness concerns at the daily Tier 1 Huddle. Identified rooms will be noted and NS will facilitate patient movement to allow deep cleaning. EMS will be informed promptly when rooms are identified and available to clean. To maintain this standard, scrubbing, stripping, and waxing of floors will be done for all clinical areas on a cyclical basis not to exceed semi-annually. Continual progress towards cleanliness standards will be assessed via weekly audits by an EMS, Nursing, and Quality Management representative. Monitoring will continue until 90% compliance for 6 consecutive months is achieved. Audit results will be communicated to the Associate Director for Operations until six consecutive months at 90% compliance are met. These audit results will be reported to the Environment of Care (EOC) Subcommittee monthly.

The numerator equals the number of rooms, in the specific clinical area, audited that meet cleanliness standards.

The denominator equals the total number of rooms available in the randomly selected clinical area.

Mental Health: Emergency Department and Urgent Care Center Suicide Prevention Initiatives

Suicide prevention remains a top priority for VA. In 2019, the suicide rate for veterans was higher than for nonveterans and estimated to represent "13.7 [percent] of suicides."[50] Additionally, "among the average 17.2 Veteran suicides per day, an estimated 6.8 suicides per day were among those with VHA encounters in 2018 or 2019, whereas 10.4 per day were among Veterans with no VHA encounter in 2018 or 2019."[51]

VHA implemented various evidence-based approaches to reduce veteran suicides, including a two-phase process to screen and assess for suicide risk in clinical settings. The phases include the Columbia-Suicide Severity Rating Scale and subsequent completion of the Comprehensive Suicide Risk Evaluation when the screening is positive.[52] The OIG assessed whether staff completed the Comprehensive Suicide Risk Evaluation for veterans who were seen in emergency departments or urgent care centers and determined to be at risk for suicide.

Additionally, VHA requires intermediate, high-acute, or chronic risk-for-suicide patients to have a suicide safety plan completed or updated prior to discharge from emergency departments or urgent care centers and receive "structured post-discharge follow-up to facilitate engagement in outpatient mental health care."[53] The OIG assessed the medical center for its adherence to staff completion of suicide safety plans prior to patient discharge from emergency departments or urgent care centers and follow-up within seven days of discharge.

To determine whether VHA facilities complied with selected requirements for suicide risk evaluation, the OIG interviewed managers and reviewed the electronic health records of 50 randomly selected patients who were seen in the emergency department or urgent care center from December 31, 2020, through August 1, 2021.

Mental Health Findings and Recommendations

The OIG made no recommendations.

[50] Office of Mental Health and Suicide Prevention, *2021 National Veteran Suicide Prevention Annual Report*, September 2021.

[51] Office of Mental Health and Suicide Prevention, *2021 National Veteran Suicide Prevention Annual Report.*

[52] 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.

[53] Deputy Under Secretary for Health for Operations and Management memo, "Eliminating Veteran Suicide: Implementation Update on Suicide Risk Screening and Evaluation (Risk ID Strategy) and the Safety Planning for Emergency Department (SPED) Initiatives," October 17, 2019.

Report Conclusion

The OIG acknowledges the inherent challenges of operating VA medical facilities, especially during times of unprecedented stress on the US healthcare system. To assist leaders in evaluating the quality of care at their medical center, the OIG conducted a detailed inspection of five clinical and administrative areas and provided five recommendations on systemic issues that may adversely affect patients. The number of recommendations does not reflect the overall caliber of services delivered within this medical center. However, the OIG's findings illuminate areas of concern, and the recommendations may help guide improvement efforts. A summary of recommendations is presented in appendix A.

Appendix A: Comprehensive Healthcare Inspection Program Recommendations

The table below outlines five OIG recommendations aimed at reducing vulnerabilities that may lead to patient safety issues or adverse events. The recommendations are attributable to the Medical Center Director, Chief of Staff, and Associate Director for Operations. The intent is for these leaders to use the recommendations as a road map to help improve operations and clinical care. The recommendations address systems issues that, if left unattended, may potentially interfere with the delivery of quality health care.

Table A.1. Summary Table of Recommendations

Healthcare Processes	Recommendations for Improvement
Leadership and Organizational Risks	• None
Quality, Safety, and Value	• Governing committees report to the Executive Leadership Council. • Peer reviewers consistently use at least one of the nine aspects of care when conducting peer reviews. • Clinical managers implement improvement actions recommended by the Peer Review Committee.
Medical Staff Privileging	• Service chiefs complete Focused Professional Practice Evaluations within clearly defined time frames.
Environment of Care	• Managers maintain a safe and clean environment.
Mental Health: Emergency Department and Urgent Care Center Suicide Prevention Initiatives	• None

Appendix B: Medical Center Profile

The table below provides general background information for this high complexity (1b) affiliated medical center reporting to VISN 9.[1]

Table B.1. Profile for Louisville VA Medical Center (603)
(October 1, 2018, through September 30, 2021)

Profile Element	Medical Center Data FY 2019*	Medical Center Data FY 2020†	Medical Center Data FY 2021‡
Total medical care budget	$385,053,440	$458,375,083	$515,703,535
Number of:			
• Unique patients	45,173	43,607	48,415
• Outpatient visits	612,922	554,074	639,056
• Unique employees§	1,856	1,920	2,038
Type and number of operating beds:			
• Domiciliary	16	16	16
• Medicine	56	56	56
• Mental health	22	19	19
• Surgery	23	23	23
Average daily census:			
• Domiciliary	12	8	8
• Medicine	48	45	56
• Mental health	12	8	10
• Surgery	7	6	4

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, 2018, through September 30, 2019.*
†October 1, 2019, through September 30, 2020.*
‡October 1, 2020, through September 30, 2021.*
§Unique employees involved in direct medical care (cost center 8200).*

[1] VHA medical facilities are classified according to a complexity model; a designation of "1b" indicates a facility with "medium-high volume, high risk patients, many complex clinical programs, and medium-large research and teaching programs." Facility Complexity Level Model Fact Sheet," VHA Office of Productivity, Efficiency & Staffing (OPES). An affiliated healthcare system is associated with a medical residency program. VHA Handbook 1400.03, *Veterans Health Administration Educational Relationships*, February 16, 2016.

Appendix C: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: August 15, 2022

From: Director, VA MidSouth Healthcare Network (10N9)

Subj: Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky

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

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

1. I have reviewed the findings and recommendations in the OIG report entitled, Draft Report: Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky. I concur with the action plans submitted by the Louisville VA Medical Center Director.

2. We thank the OIG for the opportunity to review and respond to the Draft Report: Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky.

3. If you have any questions or require additional information, please contact the Quality Management Officer.

(Original signed by:)

Gregory Goins, FACHE
Network Director, VISN 9

Appendix D: Medical Center Director Comments

Department of Veterans Affairs Memorandum

Date: August 8, 2022

From: Director, Louisville VA Medical Center (603/00)

Subj: Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky

To: Director, VA MidSouth Healthcare Network (10N9)

1. This memorandum is in response to the Office of Inspector General's draft report entitled Comprehensive Healthcare Inspection of the Louisville VA Medical Center in Kentucky.

2. I have reviewed the draft report for the Louisville VA Medical Center and concur with the findings and recommendations.

3. Attached are the facility responses to the recommendations, including actions that have been completed, or are in progress, to correct the identified opportunities for improvement.

4. The medical center also requests that Recommendations 2 and 3 be closed.

5. This supportive documentation is evidence that the recommendations made during the OIG Comprehensive Healthcare Inspection of Louisville VA Medical Center were put forward into action and measures put in place to ensure sustained improvement.

6. If additional information or assistance is needed, please do not hesitate to contact me.

(Original signed by:)

Jo-Ann Ginsberg, RN, MSN
Medical Center Director
Louisville VAMC

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Inspection Team	Sheeba Keneth, MSN/CNL, RN, Team Leader Daisy Arugay-Rittenberg, MT Bruce Barnes Myra J. Brazell, MSW, LCSW Rose C. Griggs, MSW, LCSW Miquita Hill-McCree, MSN, RN Frank Keslof, MHA, EMT Barbara Miller, BSN, RN Jennifer Reed, MSHI, RN Sandra Vassell, MBA, RN
Other Contributors	Melinda Alegria, AuD, CCC-A Limin Clegg, PhD Kaitlyn Delgadillo, BSPH Jennifer Frisch, MSN, RN Justin Hanlon, BAS LaFonda Henry, MSN, RN Cynthia Hickel, MSN, CRNA Adam Hummel, MPPA Ping Luo, PhD, MS Amy McCarthy, JD Scott McGrath, BS Joan Redding, MA Larry Ross, Jr., MS Krista Stephenson, MSN, RN Caitlin Sweany-Mendez, MPH Erika Terrazas, MS Elizabeth Whidden, MS, APRN Thomas Wong, DO Jarvis Yu, MS

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