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VETERANS HEALTH ADMINISTRATION

Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama

HEALTHCARE INSPECTION | REPORT #22-00031-67 | FEBRUARY 27, 2023

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Tuscaloosa VA Medical Center (facility) in Alabama to assess concerns specific to the Patient Safety Program and the programmatic oversight provided by facility and Veterans Integrated Service Network (VISN) 7 leaders.[1]

In September 2021, while conducting a separate healthcare inspection at the facility, the OIG received a Veterans Health Administration (VHA) Issue Brief indicating that during the time of the extended leave and abrupt retirement of the former patient safety manager (PSM), the facility identified "Patient Safety Management Program Concerns."[2] The Issue Brief outlined programmatic deficiencies that included a failure (1) to complete patient safety incident reports in the Joint Patient Safety Reporting (JPSR) system within the required time frame; (2) to complete the required number of root cause analyses (RCAs); (3) to identify a 2021 proactive risk assessment topic applicable to the facility and implement the assessment process; and (4) of the facility's former PSM to attend facility or VISN committee meetings related to patient safety.[3] The OIG team thus conducted this inspection that identified additional concerns regarding oversight of the Patient Safety Program and the facility's culture of safety. Specifically, and described in more detail below, the OIG found that the former PSM was derelict in the performance of duties, and that both facility and VISN leaders performed inadequate oversight of the Patient Safety Program. This inadequate oversight was particularly troubling as the facility was on notice from prior OIG inspections, which identified issues in the facility's Patient Safety Program that had not been corrected.

The goal of VHA's Patient Safety Program is to "prevent harm to patients" through prevention of adverse events and development of a safety culture.[4] The PSM "oversees, coordinates, and manages all patient safety related activities at the facility level," including determining the severity of an event and the type of follow-up needed, if any.[5]

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[1] "VA Southeast Network (VISN 7)," U.S. Department of Veterans Affairs, accessed March 08, 2022, https://www.southeast.va.gov/about/index.asp. VISN 7 is the regional office for eight VA medical facilities and 50 Community Based Outpatient Clinics located in Alabama, Georgia, and South Carolina. VA, *2020 Functional Organization Manual Version 6*, September 1, 2020, Each VISN is "a shared system of care working together to better meet local health care needs and provide Veterans greater access to care."

[2] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[3] VA National Center for Patient Safety (NCPS), *Joint Patient Safety Reporting (JPSR) System Business Rules*, May 1, 2018. The JPSR system is an electronic event reporting application used by the VA to capture real time incident data throughout the healthcare system. VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. An RCA is defined as a process to analyze basic or contributing factors that is associated with a respective patient safety incident.

[4] VHA Handbook 1050.01.

[5] NCPS, *Quick Reference Guide for PSOs and PSMs*, July 2005.

VHA's 2011 VHA National Patient Safety Improvement Handbook (Patient Safety Handbook) states that once aware of a patient safety event, staff must inform the PSM.[6] Staff may use the JPSR system to submit information regarding the event. Reporting patient safety events provides a foundation for VHA to identify potential contributing factors that compromise patient safety and "take action to prevent future events."[7]

Within 14 days of a staff member entering an event into the JPSR system, the PSM is tasked with reviewing the information and determining whether the event should be accepted or rejected and, if accepted, ensuring the event is investigated and follow-up completed prior to finalizing the event.[8] The OIG reviewed facility patient safety events entered into the JPSR system from July 9, 2019, through July 19, 2021. The data showed the majority of the determinations made to either reject or accept and finalize a reported event occurred on or after the 14-day due date.[9] The OIG found the distribution of the data suggests that the former PSM's handling of rejected events was driven by the date the events were to be finalized rather than managing events as they were submitted by reporters in real time. The failure to manage JPSR events timely introduces unnecessary risks of not identifying, and potentially compromising a thorough evaluation of, a patient safety event.

To determine if the former PSM managed JPSR events in accordance with guidance, the OIG reviewed a sample of JPSR events and found inconsistent management of reports, including the failure to appropriately flag some events for further analysis, properly determine which events to accept, and categorize similar events in the same manner. Missed opportunities at this critical stage of event reporting weaken the facility's Patient Safety Program and most importantly, the care provided to veterans.

When applicable, investigations to gather additional details related to accepted JPSR events provide facility staff with opportunities to learn about process gaps that if addressed, may prevent a recurrence of an event. Since July 2020, JPSR Business Rules have required the PSM to provide feedback to the individual who reported the event in order to engage staff, and doing so reminds them of their roles in ensuring the safety of every veteran at every interaction.[10] The

[6] VHA Handbook 1050.01. The OIG found the Patient Safety Handbook to be outdated and lacking inclusion of the expectations outlined in the 2018 *Joint Patient Safety Reporting (JPSR) System Business Rules,* the 2020 *JPSR Business Rules and Guidebook* (JPSR Business Rules), and VHA memorandums. The OIG learned from the Assistant Under Secretary for Health, Office of Quality and Patient Safety, of a draft VHA Directive intended to define VHA's Quality and Patient Safety Program organizational structure and programmatic requirements. The VHA Directive will replace VHA Handbook 1050.01.

[7] NCPS, *2020 JPSR Business Rules and Guidebook.*

[8] NCPS, *2020 JPSR Business Rules and Guidebook.* The PSM determines if the event meets VHA's definition of a patient safety event or close call. Events are rejected if the PSM determines they are not a patient safety event or a close call.

[9] NCPS, *2020 JPSR Business Rules and Guidebook.* A report is finalized once the PSM has reviewed the final information in a report to ensure its accuracy.

[10] NCPS, *2020 JPSR Business Rules and Guidebook*.

OIG reviewed completed JPSR event reports and found the former PSM did not ensure investigation results were documented as required to complete each event report, or that feedback was provided to all reporters.

The former PSM refused to cooperate with the OIG inspection process. The OIG was required to use its testimonial subpoena authority to compel the former PSM to be interviewed. In interviews with the OIG, the former PSM described a strong history of facility staff reporting events in the JPSR system, but went on to say that facility leaders did not provide the requested staffing resources to fully manage the Patient Safety Program as intended by the VA National Center for Patient Safety (NCPS). The former PSM acknowledged that there were events in the JPSR system that were incomplete and that some may not have been finalized timely. The former PSM described a large number of JPSR events to manage. Additionally, the former PSM discussed difficulty engaging front-line managers in the investigation process, which led to prioritizing resolution of patient safety issues over completion of the corresponding documentation in the JPSR system. The former PSM said that reported incidents were looked at each morning and communicated to facility staff and leaders attending the daily safety call. The former PSM said that all reported incidents were addressed. However, this statement is not supported by required documentation. Moreover, the sample reviewed by the OIG pointed to issues with the accuracy and quality of the completed portions of the JPSR event reports.

VHA policy requires that facility directors ensure "a minimum of eight patient safety analyses" made up of RCAs, proactive risk assessments, and Patient Safety Assessment Tool (PSAT)are completed annually.[11] RCAs focus on finding system failures and providing solutions that can prevent similar adverse patient safety events. Facility directors are responsible for ensuring that individual RCAs are performed by an interdisciplinary team for any identified serious safety event. A medication aggregate review must be completed for medication events that do not require an individual RCA, such as an incorrect or missed dose of a medication, along with a Wild Card Aggregate Review for events that represent a trend or the "most often" event type reported in the JPSR system. The Patient Safety Handbook states that RCA teams must use WebSPOT, a national application used to guide, document, and report the RCA process through completion.[12]

The OIG published a Comprehensive Healthcare Inspection Program (CHIP) report in 2019 (2019 CHIP report) about the facility and made four recommendations related to the completion of RCAs, the implementation of improvement actions specific to the RCA findings, and provision of feedback to staff members who submitted patient safety concerns that resulted in

[11] VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements for Facilities to Perform Patient Safety Analyses," March 17, 2020.

[12] VHA Handbook 1050.01.

RCAs.[13] The OIG published another CHIP report in 2020 (2020 CHIP report) documenting that the OIG found no evidence that the facility had resolved the prior four RCA related recommendations.[14]

The OIG was unable to determine the specifics of why the recommendations made in the 2019 CHIP report had not been addressed. During an OIG interview, the Facility Director described realizing, with the repeat findings in the 2020 CHIP report, that the previously identified RCA deficiencies in the 2019 CHIP report had not been addressed. The Facility Director explained that in response to the unresolved findings with RCAs, the chief of quality management took action to address these issues with the former PSM, including meetings with the former PSM to monitor the status of RCAs over six months to ensure completion. In an interview with the OIG, the former PSM confirmed attendance at the meetings and shared the view that reporting the workload status at these meetings ensured accountability. However, the chief of quality management reported to the OIG of having requested, but not receiving access to the official RCA tracking database and was therefore unable to confirm reports given by the former PSM.

In August 2021, while the former PSM was on leave, the facility and VISN Quality Management staff identified the programmatic deficiencies, updated facility leaders, and outlined the concerns in the Issue Brief sent to the VISN.

Following identification of the RCA-related programmatic deficiencies, the Facility Director recalled that, as was routinely done upon completion of draft RCAs, the former PSM had provided briefings. However, the Facility Director could not locate documentation showing receipt of any final RCAs ready for signature. In interviews with the OIG, the former PSM acknowledged the time frame in which RCAs were to be done and the expectation for RCA information to be entered into WebSPOT. The former PSM reported that challenges with completing RCAs on time included putting RCA teams together and delays in getting RCAs back from the Facility Director. In discussing the closure of recommendations made by RCA teams, the former PSM shared that at times, the recommendations were not addressed due to those tasked with addressing issues determining that the proposed solution was not possible, staff assigned to the task being unwilling to accept responsibility, or budgetary restraints.

The chief of quality management stated that the review conducted after the former PSM retired found that RCA reports submitted by the former PSM to facility leaders did not accurately represent the actual progress of the RCAs as documented in the official RCA database and did not correspond with the information reported to facility leaders. In late fall 2021, facility staff provided the OIG with four individual and three aggregate review RCA charters for patient

[13] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center, Alabama,* Report No.19-00057-238, September 27, 2019.

[14] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center in Alabama,* Report No.20-00130-194, September 2, 2020. The last of the four recommendations specific to the completion of RCAs was formally closed on September 1, 2020.

safety analyses identified within the fiscal year.[15] In early 2022, the OIG was provided evidence that all seven RCAs were completed.

VHA requires each facility to annually complete at least one proactive risk assessment to evaluate system vulnerabilities and identify corrective actions before a patient safety event occurs.[16] For example, a facility may study the steps used to manage lab samples to ensure there are no gaps in the process that could contribute to misidentification of the sample or delays in processing and reporting of the results. As of September 2021, a proactive risk assessment topic applicable to the facility and implementation of the assessment process had not been initiated. However, the OIG determined that following the retirement of the former PSM, the facility completed a proactive risk assessment within the 2021 calendar year.

The OIG also determined that supervision of the former PSM was ineffective, in part due to the former PSM's supervisors lacking access to applications that would permit them to review JPSR and RCA entries made by the former PSM. Supervisors applied a trust-and-not-verify approach to performance management. The OIG learned from the Facility Director that the Facility Associate Director (Associate Director) and chief of quality management, who were the former PSM's supervisors, lacked access to the JPSR system and WebSPOT.[17] When discussing the lack of access to the JPSR system and WebSPOT, the chief of quality management acknowledged not knowing of the need to have access to the JPSR system; "trusted that my patient safety manager was…accurately reporting information;" and relied on information reported in committee meetings to monitor the completion of work by the former PSM.

An OIG review of performance appraisals found that the former PSM's supervisors were aware, to some degree, of performance issues and discussed them in supervisory meetings with the former PSM. However, there was no formal improvement plan with objective performance outcomes outlined by which to measure the former PSM's performance. In addition, the Associate Director told the OIG of being aware of the former PSMs requests for more staff due to workload demands. This failure to take sufficient action became evident when the programmatic deficiencies were identified at the time of the former PSM's retirement.

The OIG learned the former PSM held a State Licensing Board (SLB) issued nursing license that was no longer active due to an SLB action taken against it. At the time of this SLB action, the former PSM was not required to have a valid license for the position occupied at the facility.

[15] "Budget of the US Government," accessed November 8, 2022, https://www.usa.gov/budget#:~:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%20the%20next. The budget office of the US Government defines a fiscal year as October 1 of one calendar year through September 30 of the next.

[16] VHA Handbook 1050.01, VA NCPS, *Healthcare Failure Modes and Affects Analysis (HFMEA) Guidebook*, January 2021. VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements."

[17] The Associate Director was the former chief of quality management and, while in that role, supervised the former PSM.

However, the respective SLB informed the OIG that licensees are responsible for informing and providing their healthcare employer(s) with a copy of the action taken by the respective SLB. During an OIG interview, the former PSM shared an understanding that the SLB reported the action to someone at the facility and denied having any conversations with supervisors regarding the issue.

The OIG determined that the facility's organizational structure permitted multiple pathways for oversight of the Patient Safety Program, however, as operationalized, they were insufficient. The Performance Measure Oversight Committee, later changed to the High Reliability Organization Committee, had oversight responsibilities related to the Patient Safety Program such as review of the Patient Safety Executive Quarterly Report.[18] The former PSM was not originally a member of the Performance Measure Oversight Committee and only was required to electronically submit a report for inclusion in the meeting agenda. An OIG review of meeting minutes found the reports were submitted as scheduled. Records show the former PSM was listed as a member once the committee converted to the High Reliability Organization Committee in 2020, however, the former PSM reported not learning of this membership until 2021. Facility Patient Safety Program reports provided to the committee identified information about the patient safety events, such as the number of JPSR events reported or RCAs conducted, but an OIG review of meeting minutes from the High Reliability Organization Committee found that minutes lacked documentation of oversight activities of key metrics or improvement opportunities to address identified deficiencies. Therefore, the OIG found that the structural oversight in place was not fully operational and as a result opportunities to identify or mitigate gaps in the Patient Safety Program were missed.

The OIG found that the VISN Patient Safety Officer (PSO) was not aware of the extent that the facility Patient Safety Program was out of compliance with VHA requirements. The VISN Director, in the position since July 2021, told the OIG that the VISN had both a support and oversight function. The PSO told the OIG that as a result of a leadership change at the VISN Director level in the summer of 2021, the PSO's understanding of the role transitioned from a consultative approach to one of oversight of the patient safety programs at all facilities within the VISN. The PSO had structures in place to meet with facility PSMs across the VISN that included weekly calls and the VISN-level Patient Safety/Risk Management Subcommittee. PSMs within that VISN were encouraged, but not required, to attend either meeting. The former PSM attended these meetings inconsistently. While speaking with the former PSM, the OIG learned of a scheduling conflict that prevented regular attendance at this VISN meeting and finding coverage for the call was challenging. However, the former PSM described a strong and trusting relationship with the PSO, reporting access to call the PSO "at any time, day or night."

Guidance provided to the field in the JPSR Business Rules suggests a VISN PSO ensures adherence to VHA patient safety policies by monitoring JPSR events and reviewing a subset of

[18] The facility's Performance Measure Oversight Committee was in place until March 2020.

event reports to evaluate compliance, accuracy, trends, and risks at the facility.[19] Using access to the JPSR system, the PSO reported awareness that facility JPSR events were overdue from time-to-time and contacting the former PSM to prompt completion of pending reports. The PSO told the OIG of accessing WebSPOT to review RCAs and of providing feedback to PSMs. The 2019 CHIP report identified deficiencies that had not been identified through reviews of WebSPOT conducted by the PSO including completion of RCAs, the implementation of improvement actions specific to the RCA findings, and provision of feedback to those submitting patient safety concerns that resulted in RCAs.[20]

VHA's organizational structure for patient safety programs is decentralized. The influence of NCPS at the field level relates more to policy and the provision of tools rather than programmatic oversight of field-level operations.[21] Facility-level oversight by NCPS would allow for further evaluation and monitoring of VA patient safety programs and may have identified the facility program-level deficiencies.

The OIG concluded that the multi-level missed opportunities to recognize deficiencies in the Patient Safety Program were in part due to lack of action by facility and VISN leaders. Facility leaders failed to fully engage with the Patient Safety Program and did not sufficiently utilize available tools to assess and evaluate programmatic performance. In doing so, the framework in place at the facility to support a culture of safety and ensure the safety of every patient was fractured and could not comprehensively address vulnerabilities that can lead to patient harm. The PSO had the tools and structure necessary to provide oversight of Patient Safety Program performance at each facility. However, the OIG determined that the VISN oversight of the facility's Patient Safety Program was ineffective as evidenced by the failure to proactively identify programmatic deficiencies during the tenure of the former PSM.

The OIG made four recommendations to the Under Secretary for Health related to granting specific positions access to Patient Safety Program data bases, reporting SLB actions to supervisors, oversight of the Patient Safety Program, and publishing of updated policies reflecting required practices.

The OIG made two recommendations to the VISN Director related to determining which patient safety event reports the VISN PSO will review and the role of the Patient Safety/Risk Management Subcommittee in the oversight of facility-level performance with patient safety activities.

The OIG made five recommendations to the Facility Director related to the timely completion and investigation of JPSR events; provision of feedback to patient safety event reporters;

[19] NCPS, *2020 JPSR Business Rules and Guidebook*.

[20] VHA Handbook 1050.01.

[21] NCPS is responsible for preparing and disseminating patient safety related policies, reports, alerts, and advisories across VHA.

determining the need for a review of facility JPSR event reports managed by the former PSM; ensuring structure and processes are in place for programmatic oversight; and ensuring that oversight committee meeting minutes document discussion, analysis, and needed follow-up of Patient Safety Program data for review and action.

Comments

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A, B, and C). Based on information provided, the OIG considers recommendation 5 closed. For the remaining open recommendations, the OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

HFMEA	Healthcare Failure Mode Effects Analysis
JPSR	Joint Patient Safety Reporting
OIG	Office of Inspector General
PSM	patient safety manager
PSO	patient safety officer
RCA	root cause analysis
SAC	safety assessment code
NCPS	VA National Center for Patient Safety
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Tuscaloosa VA Medical Center (facility) in Alabama to assess concerns specific to the Patient Safety Program and the programmatic oversight provided by facility and Veterans Integrated Service Network (VISN) 7 leaders.[1]

Background

The facility, part of VISN 7, is located on a 125-acre campus and provides 317 operating beds consisting of 43 inpatient mental health, 134 community living center, 128 domiciliary, and 12 compensated work therapy transitional residence beds. The facility is designated as level 3, low complexity, and provides primary care, mental health, and long-term and rehabilitative care.[2] From October 1, 2019, through September 30, 2020, the facility served 15,451 patients.

Culture of Safety

The Joint Commission describes culture within a facility as a reflection of all staff "beliefs, attitudes, and priorities." In a culture of safety, facility staff share responsibility in minimizing harm to patients as a result of patient care.[3] VA's National Center for Patient Safety (NCPS) notes that a necessary component of a culture of safety is a just culture. Just culture refers to an environment where employees are able to report medical errors without fear that the default response will be one of blame or punishment. In a just culture, employees assume accountability for reporting issues they feel may be unsafe. [4]

VHA Patient Safety Program

VHA facility leaders are responsible for creating a culture of safety and just culture and for ensuring that patient safety is made a priority at each facility.[5] The goal of VHA's Patient Safety

[1] "VA Southeast Network (VISN 7)," U.S. Department of Veterans Affairs, accessed March 08, 2022, https://www.southeast.va.gov/about/index.asp. VISN 7 is the regional office for eight VA medical facilities and 50 community-based outpatient clinics located in Alabama, Georgia, and South Carolina. VA, *2020 Functional Organization Manual Version 6*, September 1, 2020. Each VISN is "a shared system of care working together to better meet local health care needs and provide Veterans greater access to care."

[2] VHA Office of Productivity, Efficiency, and Staffing. The Facility Complexity Model "classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex." A level 3 facility has "low volume, low risk patients, few or no complex clinical programs, and small or no research and teaching programs."

[3] The Joint Commission, *Standards Manual,* LD.03.06.01, March 14, 2021. "Those who work in the hospital are focused on improving safety and quality."

[4] "Culture of Safety and Just Culture," NCPS, accessed January 20, 2022, https://www.patientsafety.va.gov/docs/joe/just_culture_2013_tagged.pdf.

[5] "Culture of Safety and Just Culture," NCPS website.

Program is to "prevent harm to patients" through prevention of adverse events and development of a safety culture. VHA's Patient Safety Program utilizes a three-step approach to improving patient safety, including (1) the exploration of "system vulnerabilities that can result in patient harm;" (2) the "reporting of adverse events and close calls;" and (3) emphasis on "prevention rather than punishment" as the "preferred method to mitigate system vulnerabilities and reduce adverse events."[6] VHA puts this guidance into practice by requiring facility patient safety programs to identify and report events, determine cause, disseminate safety alert information, conduct risk assessments, implement effective practices, and submit an end-of-fiscal-year Patient Safety Annual Report to facility leaders.[7]

VHA provides guidance for patient safety programs and the management of patient safety events through the 2011 *VHA National Patient Safety Improvement Handbook* (Patient Safety Handbook), the 2018 *Joint Patient Safety Reporting (JPSR) System Business Rules*, the *2020 JPSR Business Rules and Guidebook* (JPSR Business Rules), and VHA memorandums that provide clarifications and updates of prior guidance for the field.[8]

VHA established the NCPS in 1999 to provide guidance about VHA's approach to patient safety and a "culture of safety." NCPS has one primary goal, which is to reduce and prevent injury to VA patients throughout the course of their care. In addition, NCPS provides "policies and strategies to measure and mitigate harm to the Veteran and those who support their care."[9] NCPS also provides guidance to the field through an intranet site, the distribution of patient safety alerts, and a newsletter.[10]

Since 2018, VHA has utilized an electronic event reporting system known as JPSR system to capture real-time incident data throughout the healthcare system.[11] The reporting system is managed by and allows NCPS to learn of system vulnerabilities through the reporting of patient

[6] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

[7] VHA Handbook 1050.01. "Budget of the US Government," accessed November 8, 2022, https://www.usa.gov/budget#:~:text=The%20federal%20government%27s%20fiscal%20year,September%2030%20of%20the%20next.The budget office of the US Government defines a fiscal year as October 1 of one calendar year through September 30 of the next.

[8] VHA Handbook 1050.01, NCPS, *Joint Patient Safety Reporting (JPSR) System Business Rules*, May 1, 2018. This document was in effect at the time of events discussed in this report until it was replaced by NCPS*, 2020 JPSR Business Rules and Guidebook*, July 2020. Unless otherwise noted, the July 2020 version is the version referenced throughout this report. The NCPS, *Guidebook for JPSR Business Rules and Guidance*, November 2021 does not apply to the time frame covered by this report or alter report recommendations. VHA memorandums referenced in this report include: VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements for Facilities to Perform Patient Safety Analyses," March 17, 2020; VHA Assistant Under Secretary for Health for Quality and Patient Safety memorandum, "Annual Requirement to Perform a Falls Aggregated Review," February 6, 2021; VHA Principal Deputy Under Secretary for Health, "Joint Patient Safety Reporting System (JPSR)," January 30, 2018.

[9] "VHA National Center for Patient Safety," NCPS website.

[10] VHA Handbook 1050.01.

[11] NCPS, *Joint Patient Safety Reporting (JPSR) System Business Rules*.

safety events and close calls. Patient safety managers are responsible for ensuring that reports entered into the system by staff are reviewed and tasked for action, as warranted. In doing so, the JPSR system provides a foundation for VHA to identify potential contributing factors and "take action to prevent future events."[12]

Other methods to identify vulnerabilities within the patient safety program include root cause analysis (RCA) and proactive risk assessment. An RCA is defined as a process to analyze basic or contributing factors associated with a respective patient safety incident.[13] An RCA is a focused review conducted by an interdisciplinary team that places an emphasis on systems and processes. Through a charter, an RCA team is tasked with identifying areas within a system or process that could be changed to prevent the reoccurrence of an incident in the future.[14]

A proactive risk assessment allows for the review and analysis of potential areas of weakness before an incident occurs. VHA utilizes the Healthcare Failure Mode and Effect Analysis (HFMEA) model in its approach for a proactive risk assessment.[15]

Prior OIG Reports

In the Comprehensive Healthcare Inspection Program (CHIP) report for the facility, published on September 27, 2019, the OIG made four recommendations related to the completion of RCAs, the implementation of improvement actions specific to the RCA findings, and provision of feedback to those submitting patient safety concerns that resulted in RCAs.[16]

The OIG published another CHIP report on September 2, 2020, and found no evidence that the facility had resolved the four 2019 RCA related recommendations. With the 2019 recommendations remaining open at the time of the second site visit in February 2020, the OIG did not make any new recommendations in the 2020 report.[17]

The last of the four recommendations specific to the completion of RCAs was formally closed on September 1, 2020.

[12] NCPS, *Joint Patient Safety Reporting (JPSR) System Business Rules*, NCPS, *2020 JPSR Business Rules and Guidebook*, July 2020. The two versions contain similar language related to the basic role of the patient safety manager.

[13] VHA Handbook 1050.01.

[14] VHA Handbook 1050.01.

[15] VHA Handbook 1050.01.

[16] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center, Alabama*, Report No.19-00057-238, September 27, 2019.

[17] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center in Alabama*, Report No.20-00130-194, September 2, 2020.

Concerns

In September 2021, while conducting a separate healthcare inspection at the facility, the OIG received a Veterans Health Administration (VHA) Issue Brief indicating facility "Patient Safety Management Program Concerns." The Issue Brief, dated September 20, 2021, was sent by facility leaders to VISN 7 leaders, and outlined deficiencies within the facility's Patient Safety Program that included failure

- to complete "approximately" 160 JPSR incidents within the required 14-day time frame,
- to complete the required number of individual or aggregate RCAs,
- to identify an HFMEA topic applicable to the facility for 2021 and implement the assessment process, and
- of the facility's former patient safety manager (PSM) to attend facility or VISN committee meetings related to patient safety.

During this inspection, the team identified additional concerns specific to leaders oversight of the Patient Safety Program and the facility's culture of safety.

Scope and Methodology

The OIG initiated a healthcare inspection on October 7, 2021, and conducted a virtual site visit the week of November 15, 2021. Inspection related interviews were concluded by March 16, 2022, with the exception of an additional interviewee whose interviews, were completed in September and October of 2022.

The OIG reviewed VHA and facility policies and documents related to the Patient Safety Program, which included documents from July 2015 through September 2021, as well as VISN and facility committee meeting minutes and reports related to patient safety. Additionally, the facility's former PSM's performance appraisals from October 2017 through September 2021, and the VISN's patient safety staff's performance appraisals from October 2017 through September 2020 were reviewed.

The OIG interviewed facility leaders, Quality Management leader and staff, the VISN Director, former and current VISN Quality Management leaders, the VISN Patient Safety Officer (PSO), and staff from NCPS. The former PSM refused to cooperate with the OIG inspection process. The OIG was required to use its testimonial subpoena authority to compel the former PSM to be interviewed.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, Pub. L. 117-286 § 3(b) (to be codified at 5 U.S.C. § 401, *et seq.*). 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.

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

Inspection Results

1. Deficiencies in the Patient Safety Program

The OIG found deficiencies in the facility's Patient Safety Program and that a lack of programmatic oversight by facility and VISN leaders resulted in the failure to comply with VHA mandated standards for patient safety including managing and completing JPSR events, RCAs, and a proactive risk assessment. Following the identification of these deficiencies, facility leaders ensured the completion of all required patient safety analyses for the most recent 12-month cycle.[18]

In 2011, the Patient Safety Handbook established requirements for patient safety programs with the goal of preventing harm to patients.[19] Patient safety program requirements included identification of patient safety events, incident reporting, completion of four RCAs based on individual incidents reported, three aggregated reviews plus one more individual or aggregate review, and completion of an annual proactive risk assessment.[20]

A Deputy Under Secretary for Health for Organizational Excellence memorandum to VISN Directors, dated March 17, 2020, states that facility directors are responsible for ensuring annual compliance with the completion of "a minimum of eight patient safety analyses including the following: Root Cause Analysis (RCA), Aggregated Review, Wild Card Aggregated Review, Proactive Risk Assessment, and Patient Safety Assessment Tool (PSAT) evaluation."[21] Facility policy states that the Chief of Staff and Associate Director for Nursing and Patient Care Services are responsible for "facilitating implementation of the requirements" of the Patient Safety

[18] The facility reported the 12-month cycle timeline to be January 1 to December 31 of the calendar year.

[19] VHA Handbook 1050.01.

[20] VHA Handbook 1050.01.

[21] VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements for Facilities to Perform Patient Safety Analyses," March 17, 2020. The memorandum allowed PSATs as a permitted alternative tool for falls and missing patients aggregate reviews.

Improvement Program.[22] All facility employees play a role in patient safety and are encouraged to report patient safety events and concerns.[23]

A facility's PSM "oversees, coordinates, and manages all patient safety related activities at the facility level."[24] Based on criteria set by VHA, PSMs determine the severity of an event, which then determines the type of follow-up needed, if any.

Facility Patient Safety

Through interviews with the Facility Director, Facility Associate Director (Associate Director), and chief of quality management, the OIG learned that the PSM reports to the chief of quality management. The chief of quality management is responsible for oversight of the Patient Safety Program including monitoring of the "timeliness and adequacy" of JPSR event reports, as well as the completion of RCAs, and the annual proactive risk assessment.[25] The facility chief of quality management reports to the Facility Director. The chief of quality management informed the OIG that in January 2020, the chief of quality management was in an acting role and was later appointed to the permanent position.[26]

Facility documentation shows that in summer 2021, the former PSM went on leave, and abruptly retired approximately five weeks later. When the former PSM went on leave, the position was assigned to another Quality Management staff member who served as the facility's PSM in an acting capacity. Less than a week later, the interim facility chief of quality management notified the VISN 7 PSO of this change and requested a point of contact to serve as a resource for the acting PSM. A month after the former PSM initiated leave, the PSO alerted the facility acting PSM that the facility had 143 JPSR event reports that were overdue. Seventeen days later, the facility submitted an Issue Brief informing VISN 7 leaders of concerns related to the facility's Patient Safety Program.

Joint Patient Safety Reports

The Issue Brief stated that the facility had "approximately 160 Joint Patient Safety Reporting (JPSR) incidents" that were not closed out within the 14-day time frame.[27] The chief of quality

[22] Facility Policy 11-58, *Patient Safety Improvement Program,* June 12, 2020. The Associate Director for Nursing and Patient Care Services is also referred to within the facility as the Associate Director, Patient Care Services.

[23] NCPS, *Quick Reference Guide for PSOs and PSMs*, July 2005.

[24] NCPS, *Quick Reference Guide for PSOs and PSMs*.

[25] Functional Statement, "Registered Nurse - Chief, Quality Management Service, Nurse IV."

[26] The chief of quality management started serving in an acting capacity in January 2020 and officially received the permanent position in September 2021.

[27] NCPS, *2020 JPSR Business Rules and Guidebook*. The JPSR system labels events that are not closed within 14 days of submission as "overdue." For this report, the OIG defined overdue JPSR events as those events that were not closed out within the 14-day time frame and remained in either a "still being reviewed" or a "awaiting final approval status."

management told the OIG that the facility reviewed JPSR events that were reported from June through September 2021 and identified 230 reported JPSR events that were overdue.

VHA requires that once aware, facility staff must inform the PSM of any patient safety event, even if the condition has not resulted in an adverse event, close call, or unsafe condition.[28] The JPSR system may be used to report the event.[29] When a JPSR system entry is made, the event goes into *Awaiting Review* status, notifying the PSM to review the report to determine if the concern is specific to patient safety or needs to be redirected to another department.[30] If the event is specific to patient safety, the PSM assigns a Safety Assessment Code (SAC) score, a method used to determine whether any further action, such as an RCA, is required based on severity of the incident and its probability of occurrence. A SAC score ranges from 1 to 3 with 3 being the most severe. [31]Once a SAC score is determined, the PSM assigns an investigator, changing the event status to *Event Still Being Reviewed*.[32] The investigator has seven days to complete a review of the event and enter details about the investigation outcome and any actions taken into the JPSR system. After the investigation is completed, the investigator returns the JPSR event report to the PSM, changing the event into an *Event Awaiting Final Approval* status that indicates that the investigation is completed for the PSM to review the final information and ensure its accuracy. Once the PSM finishes the final review and closes the report, the status changes to *Events with Final Approval.* The facility's PSM is responsible for completing a review of all JPSR event reports for "timeliness and accuracy and appropriate follow-up" prior to finalizing the event and saving the report in the system. The PSM must close JPSR event reports within 14 days of the reported date or the JPSR system will automatically mark the event overdue. The PSM may refer to the JPSR event report status to track event reports from submission through report closure.[33] In interviews with the OIG, the former PSM described a strong history of facility staff reporting events and acknowledged awareness of the process and timelines for managing and finalizing these JPSR entries.

The OIG reviewed events that were entered into the JPSR system from July 9, 2019, through July 19, 2021, to determine whether reports were assessed and finalized within the required

[28] VHA Handbook 1050.01. Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher-level of care.

[29] NCPS, *2020 JPSR Business Rules and Guidebook*.

[30] NCPS*, 2020 JPSR Business Rules and Guidebook*. Events are rejected if the PSM determines they are not a patient safety event or a close call.

[31] VHA Handbook 1050.01. NCPS, *2020 JPSR Business Rules and Guidebook*. SAC is assigned by the PSM; the severity category in the SAC matrix should match the degree of harm field in the "details" section of the JPSR system.

[32] NCPS, *2020 JPSR Business Rules and Guidebook*. Investigators are facility staff that have more "familiarity or expertise" with a specific JPSR event report and assist PSMs with the review, investigation, and documentation of event details in the JPSR system. Department of Defense/VA, *Joint Patient Safety Reporting* (*JPSR)Train the Trainer Course Instructor Guide*, version 1.1, January 7, 2017.

[33] NCPS, *2020 JPSR Business Rules and Guidebook*.

14 days. To evaluate the facility's compliance with timely review of JPSR entries, the OIG reviewed the number of days that passed until an event was rejected by the former PSM (see figure 1). The data showed the majority of determinations to reject an event occurred on or after the 14-day due date. The distribution of the data suggests that the PSM's handling of rejected events was driven by the date that the events needed to be finalized rather than managing events as they were submitted by reporters in real time.

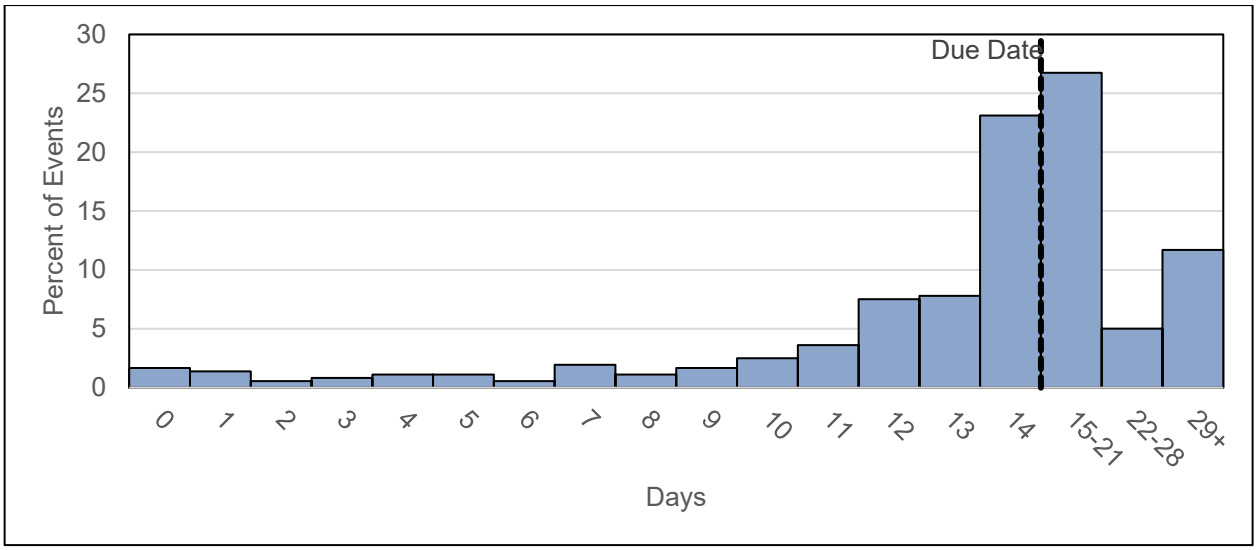

Figure 1. *JPSR Events: Distribution of Days Until Rejection July 9,2019 – July 19, 2021.*
Source: VA OIG Analysis of JPSR Event Report Data from July 9, 2019, to July 19, 2021.

Additionally, the OIG reviewed the number of days until an accepted event was finalized (see figure 2). The data shows the majority of the accepted events were finalized after the required 14-day due date.

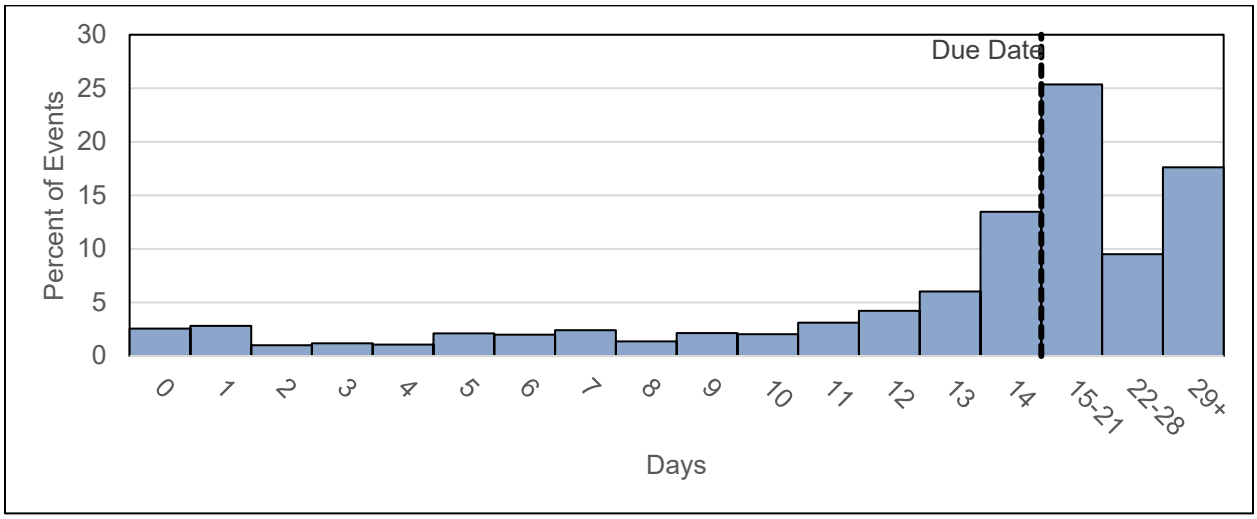

Figure 2. *JPSR Events: Distribution of Days Until Finalized July 9, 2019 – July 19, 2021.*
Source: VA OIG Analysis of JPSR Event Report Data from July 9, 2019, to July 19, 2021.

To determine whether the former PSM managed JPSR events in accordance with guidance, the OIG conducted a review of a statistical sample of 100 finalized JPSR events and 100 rejected JPSR events reported from January 1, 2017, through July 19, 2021.[34] In reviewing events that were rejected, the OIG estimated that the PSM correctly rejected events 75 percent of the time (95 percent CI: between 66 and 83 percent). The OIG estimated with 95 percent confidence that if an event was related to a fall, medication, or missing patient, the event was being appropriately flagged for an individual or aggregate RCA between 33 and 56 percent of the time. [35] Furthermore, the OIG determined that there were inconsistencies in the former PSM's management of JPSR events including the categorization with which similar events were grouped. For example, a delay in pharmacy filling a medication request because the order was not signed by a medical provider was categorized as "medication/biological/nutritional error," a similar event was categorized as "clinical administration, process or procedure" event. Similarly, the OIG found that events that presented potential delays in care that would warrant further investigation, were rejected by the former PSM. The OIG was unable to determine the rationale for the differences or the rejections when reviewing the reports in the JPSR system.

[34] An NCPS health systems specialist reported that VHA began national implementation of the JPSR system in a phased approach, with some facilities using the system as early as 2017. Therefore, the OIG's review of facility JPSR event entries included a statistical sample of all rejected JPSR entries and a statistical sample of all finalized entries reported between January 1, 2017, and July 19, 2021, and completed before the former PSM went on extended leave on August 2, 2021. Elements of review included rejection status and reason, assessment of degree-duration of harm, determination of sentinel event criteria being met and if so whether The Joint Commission was notified, classification of the event and assignment of the SAC score. Five of the rejected JPSR entries were events entered as "test" events or "duplicates" and therefore, excluded from the review.

[35] The 95 percent confidence interval indicates that among all possible samples of the same size and design that could have been selected, the true rate would have been included in the computed intervals 95 percent of the time.

The OIG acknowledges that the failure to manage JPSR events timely introduces the unnecessary risk of not identifying patient safety events in need of evaluation and compromises the quality of the review given that, as time passes, the opportunity to properly evaluate and disposition the individual reports becomes more difficult. Missed opportunities at this critical stage of event reporting ultimately weaken the facility's Patient Safety Program and most importantly, the care provided to veterans.

The investigation phase of the JPSR process is key to understanding the circumstances specific to an event and gives facility staff an opportunity to learn about process gaps that if addressed, may prevent a recurrence of the event. Timely investigations increase the likelihood of credible findings as staff are more likely to accurately recall the details of an event and to be available for consultation. The OIG reviewed completed JPSR event reports from July 9, 2019, through July 19, 2021, to determine whether investigation results were documented in the system and found 100 percent of finalized events lacked the documentation required to be considered a complete investigation The absence of investigation results limited the facility's ability to educate and share lessons learned. More importantly, the lack of documentation suggests that investigations were not completed, potentially leaving significant system risks unaddressed.

The JPSR Business Rules introduced a requirement for the PSM to provide feedback to the original reporter of the event to reinforce that all staff have a role in patient safety and encourage future reporting.[36] After reviewing completed JPSR entries from July 9, 2020, through July 19, 2021, the OIG noted the former PSM did not enter information in the feedback to reporter field for 99.8 percent of the entries.

In interviews with the OIG, the former PSM acknowledged that there were events in the JPSR system that were incomplete and that some entries may not have been finalized timely. The former PSM described a large number of JPSR event reports to manage. Additionally, the former PSM discussed difficulty engaging front-line managers in investigations, which led to prioritizing resolution of patient safety issues over completion of the corresponding documentation in the JPSR system. The former PSM also said that all reported incidents were looked at and conveyed to facility staff and leaders attending the daily safety call. The former PSM reported that all reported incidents were addressed; however; due to the lack of documentation to indicate that JPSR events were managed and investigated, the OIG was concerned that reported events may not have been thoroughly reviewed. Further, the sample reviewed by the OIG points to issues with the accuracy and quality of the completed portions of the JPSR event reports. Therefore, the risk that prior events in need of an RCA, disclosure, or process change may have been missed remains, warranting a review of the records.

[36] NCPS*, 2020 JPSR Business Rules and Guidebook*.

Facility Leaders Response to Overdue JPSR Event Reports

Through interviews with the acting PSM and Facility Director, the OIG is optimistic that there is a better understanding of the JPSR process and steps are underway to improve compliance with JPSR event report completion.

During interviews with the acting PSM, the OIG learned that facility leaders, managers, and the acting PSM were unaware that an individual was to be assigned to investigate the reported event as part of the JPSR process. The acting PSM reported serving as the "back-up" to the former PSM for the previous three years. The acting PSM described being unaware of the need to send JPSR event reports to investigators for further review while serving as back-up and attributed this lack of knowledge to an absence of training by the former PSM. The Facility Director stated that JPSR event reports were discussed daily but noted now understanding that the "actual important part of it, having the area investigate, look in [look into circumstances related to the event], see what we can learn from them [the events] was not being done."

During an OIG interview, the VISN 7 Director reported notifying NCPS of the overdue JPSR event reports and noted that NCPS staff were available to ensure facility staff had a "comfort level with how they're managing [JPSR events]." As part of the process to close out overdue JPSR event reports, the Facility Director and acting PSM reported that a manager from the location where the event occurred was assigned to conduct an investigation of the event. The managers were given a seven-day turnaround time to complete an investigation and submit the information back to the acting PSM. During an interview with the OIG in mid-November 2021, the acting PSM reported that all overdue JPSR event reports were addressed. Following completion of the overdue JPSR event reports, the Facility Director reported tasking the chief of quality management to complete a review of the JPSR event reports closed by the acting PSM to ensure opportunities for further review of events were not missed.

Root Cause Analysis

The Issue Brief reported that the facility did not have any individual or aggregate RCAs completed for the 12-month cycle as of September 17, 2021.[37]

An RCA is a retrospective review used to identify factors that cause or contribute to adverse events or close calls. RCAs focus on finding system failures and providing solutions that can prevent future similar adverse patient safety events. Facility directors are responsible for ensuring that RCAs are performed annually for any identified sentinel or serious safety events. A medication aggregate review must be completed for medication events, such as an incorrect or missed dose of a medication, not requiring an individual RCA. A Wild Card Aggregate Review

[37] Facility staff reported the 12-month cycle timeline to be January 1 to December 31 of the calendar year.

for events that represent a trend or the "most often" event type reported in the JPSR system is also required.[38]

An RCA may be warranted based on the severity of a reported event.[39] RCAs must be chartered, signed by the facility director, and completed within 45 calendar days.[40] VHA states that staff must use WebSPOT, the national system used for reporting and managing patient safety events and RCAs, to document the RCA progress through completion.[41] Once RCAs are completed, leaders evaluate the recommended actions and if the facility director concurs, the actions and outcomes must be monitored for completion and sustainment, and ideally through a system of reporting, such as implementing a regular agenda item within a patient safety meeting.[42] PSMs track implementation and follow-up.

A patient safety event report can provide the facility with valuable information that can potentially prevent future similar events. Minimizing both delays or inadequate evaluations for JPSR event reports and any resulting RCAs can provide patients and staff with assurance that the facility is aware of identified risks and is taking measures to ensure patient safety.

The OIG found that the facility had RCAs that had not been done or were not fully implemented despite prior OIG reviews dating back to 2019 identifying these failures and making four recommendations to the Facility Director to ensure completion of RCA requirements.[43] In response to the OIG's recommendations, facility leaders developed action plans to correct the deficiencies.[44] However, a subsequent 2020 OIG CHIP report found that facility leaders had failed to correct the deficiencies identified in the 2019 CHIP report and that "the medical center had no evidence of improvement or movement toward resolution for the four open recommendations related to RCAs from the previous inspection."[45]

The OIG was unable to determine the specifics of why the recommendations were not addressed. In an interview with the Associate Director, the OIG learned that the Associate Director, who at the time was the former PSM's supervisor, was detailed to another position shortly after the

[38] VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements." Serious safety events are defined as either sentinel events or adverse events that are unrelated to the patient's natural course of illness or underlying condition and result in "permanent lessening of bodily function (sensory, motor, physiologic, or intellectual)."

[39] VHA Handbook 1050.01.

[40] VHA Handbook 1050.01.

[41] VHA Handbook 1050.01.

[42] VHA Handbook 1050.01. "Guide to Performing a Root Cause Analysis," NCPS.

[43] The Facility Director is the same Facility Director at the time of the 2019 findings. VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center, Alabama*.

[44] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center, Alabama.*

[45] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center, Alabama.*

publication of the 2019 CHIP report.[46] During interviews with the OIG, the Facility Director described realizing, with the repeat findings in the 2020 CHIP report, that deficiencies previously identified with RCAs in the 2019 CHIP report had not been addressed.

In response to the unresolved findings with RCAs, the chief of quality management took action to address these issues with the former PSM, including monitoring the status of RCAs for six months to ensure completion. The chief of quality management reported monitoring RCA completion in 2021 that included weekly follow-up meetings with the former PSM to discuss the status of each RCA and inclusion of RCA status updates at monthly Executive Leadership Council meetings. In an interview with the OIG, the former PSM confirmed attendance at the follow-up meetings and shared that reporting workload status at these meetings ensured accountability. The chief of quality management also described developing an RCA tracking tool for the former PSM to use in the management of RCAs. This tracking tool was saved in a location on the facility's computer system that allowed the chief of quality management to see the status and topic of each RCA, stage of completion, and any documented outcomes. However, the chief of quality management expressed concerns that the former PSM did not consistently update the tracking tool and may have saved RCA information in a separate location that was inaccessible to the chief of quality management.

In interviews with the OIG, the former PSM acknowledged the time frame in which RCAs were to be done and the expectation for RCA information to be entered into WebSPOT. The former PSM shared challenges with completing on-time RCAs included putting RCA teams together and delays in getting the RCAs back from the Facility Director. In explaining the process used to track RCAs, the former PSM said "all of those are tracked in WebSPOT, but I tracked them in the RCA tracker first. And then I could update it to WebSPOT…if I got around to it because, like I said, putting out fires is more important than updating a database. Databases don't take care of veterans." In discussing the closure of recommendations made by RCA teams, the former PSM shared that at times, the recommendations were not addressed due to those tasked with addressing an issue determining that a proposed solution was not possible, staff assigned to the task being unwilling to accept that responsibility, or budgetary restraints.

During interviews, the chief of quality management reported that in mid-August 2021, becoming aware of recurring issues with RCAs and that two RCAs for the year were chartered and in progress, but that no RCAs were completed. The Facility Director recalled that the former PSM had provided briefings about three RCAs; however, documentation showing receipt of any final RCA reports ready for signature could not be located.[47] The chief of quality management stated that a review conducted after the former PSM retired found that RCA reports submitted by the

[46] The 2019 report was published on September 27, 2019. The former PSM's supervisor was detailed to another position in October 2019.

[47] The Facility Director explained that the former PSM routinely provided briefings upon completion of the draft RCAs, before formal completion and signature.

former PSM to facility leaders did not accurately represent the actual progress of the RCAs as documented in WebSPOT and did not correspond with the information reported to facility leaders.

Facility Leaders Response to Incomplete RCAs

The OIG determined that, although completed in February 2022, the facility individual and aggregate RCAs were completed for events identified during the 12-month fiscal year 2021 cycle.[48] In late fall 2021, the OIG was provided with four individual RCA charters and three aggregate review charters for patient safety analyses that were identified within the fiscal year. In early 2022, to ensure completion of the chartered RCAs, the OIG requested and was provided evidence that all seven RCAs were completed.[49]

Proactive Risk Assessments

The September 2021 facility Issue Brief reported that the 2021 proactive risk assessment topic that had been approved by facility leaders had not been completed, and that the topic was going to be changed by facility leaders to one that would be more applicable to the facility.

VHA requires each facility to annually complete at least one proactive risk assessment, such as an HFMEA, to evaluate system vulnerabilities and identify corrective actions before a patient safety event occurs.[50] For example, a facility may study the steps used to manage lab samples to ensure there are no gaps in the process that could contribute to misidentification of the sample or delays in processing and reporting of the results. Similar to completed RCAs, when issues are identified through an HFMEA, findings and actions are assigned to individuals and tracked for effectiveness. [51] Timeliness in completing HFMEAs allows for prompt attention to potential areas of identified risk and the implementation of corrective actions resulting in improved patient care.[52]

The PSM typically serves as the team adviser and is responsible for providing a clear definition of the scope of the project, assembling the team, and documenting concurrence from the facility director with a signed charter.[53] No more than three months after completion of the analysis the

[48] Fiscal year 2021 included October 1, 2020, through September 30, 2021.

[49] The patient safety analyses that were completed and provided to the OIG were four individual RCAs; three aggregate reviews: Falls Aggregate, Medication Aggregate, and Wild Card Aggregate; and two PSATs: Wandering-Missing Patient, and Mental Health Environment of Care Checklist.

[50] VHA Handbook 1050.01; VA NCPS, Healthcare Failure Modes and Affects Analysis (HFMEA) Guidebook, January 2021. VHA Deputy Under Secretary for Health for Organizational Excellence memorandum, "Annual Minimal Requirements."

[51] "HFMEA Guidebook," NCPS website.

[52] "HFMEA Guidebook," NCPS website.

[53] "HFMEA Guidebook," NCPS website.

proactive risk assessment topic and report summary are to be entered into the NCPS website.[54]

During interviews with the Facility Director and chief of quality management, and through a review of the executive leadership committee (ELC) meeting minutes, the OIG learned that prior to the former PSM's departure, a topic for the 2021 proactive risk assessment was selected but no other status updates on the project were provided to the ELC. The OIG reviewed ELC meeting minutes from January 11, 2021, through September 13, 2021, and noted lack of progress regarding the 2021 proactive risk assessment.

The former PSM told the OIG about the process for selecting an HFMEA topic and for completion of the assessment, and described the competing demands of the job as a barrier to timely completion of these risk assessments.

Facility Response to the Incomplete Proactive Risk Assessment

The OIG determined that the facility completed a proactive risk assessment within the 2021 calendar year. The Issue Brief to the VISN acknowledged that the topic that had been voted on in 2021 would be changed, and that a new 2021 topic would be brought forward for voting during the October 2021 ELC meeting. The OIG found that on October 21, 2021, the proactive risk assessment topic was changed to one entitled *Workplace Violence Prevention in the Healthcare Setting* and introduced to the ELC by the acting PSM. The charter was subsequently signed by the Facility Director on October 26, 2021. The team notified the Facility Director that the proactive risk assessment was completed and provided the results of their work on December 30, 2021.

2. Deficiencies in Oversight of the Patient Safety Program

The OIG found that the former PSM was derelict in the performance of duties and determined that supervision of the former PSM was ineffective in part due to the former PSM's supervisors lacking access to applications that would allow them to review JPSR and RCA entries made by the former PSM and instead applying a trust-and-not-verify approach to performance management. The OIG determined that the facility's organizational structure permitted multiple pathways for oversight of the Patient Safety Program. However, the structural oversight in place was not fully operational and failed to identify or mitigate gaps in the Patient Safety Program.

Facility-Level Oversight of Patient Safety Program

To determine who had awareness of the Patient Safety Program failures, the OIG team assessed the supervision of the former PSM as well as the Patient Safety Program's reporting structure; a structure that exists to provide program oversight and guidance.

[54] "HFMEA Guidebook," NCPS website.

PSM Supervision

The PSM position description states that the PSM position is considered a leadership role with duties that include providing support, advice, and assistance to the Facility Director, Chief of Staff, and Associate Director, with supervisory oversight provided by the chief of quality management.[55] The Associate Director, who was the former chief of quality management, was the sole supervisor for the former PSM from October 2016 until the end of September 2019. In an interview with the OIG, the chief of quality management reported supervising the former PSM, beginning in January 2020. The chief of quality management reports to the Facility Director.

The OIG team interviewed the Associate Director, chief of quality management, and the Facility Director to better understand their awareness of the work done by the former PSM. The Associate Director reported that the PSM's performance was evaluated using a combination of approaches such as verbally verifying RCA timelines and reviewing RCA calendar invites, attending briefings related to RCAs, and meetings where the PSM presented. The Associate Director acknowledged that the former PSM had a prior challenge with timeliness of an aggregate RCA review in 2018, but that the individual RCAs were completed; it was not until the 2019 OIG CHIP inspection that an ongoing issue with RCAs became evident.

The OIG learned that the chief of quality management relied on information reported in committee meetings to monitor the completion of work by the former PSM. Information reported during these meetings included RCAs that were chartered, in progress, and closed out; the progress of aggregate reviews; any sentinel events that may have occurred; and concerns reported through daily safety calls.

During OIG interviews, the chief of quality management shared that the former PSM was responsible for reporting on daily safety calls and at medical staff meetings, Associate Director for Nursing and Patient Care Services Council, Clinical Executive Board, the High Reliability Organization Committee, and ultimately the ELC. The OIG learned from the Facility Director that the Associate Director and chief of quality management lacked access to the JPSR system and WebSPOT. The chief of quality management acknowledged not knowing of the need to have access to the JPSR system. While the chief of quality management told the OIG of requesting access to WebSPOT, both the Associate Director and chief of quality management confirmed that they did not have access to WebSPOT during the tenure of the former PSM.

The chief of quality management reported requesting WebSPOT access from the PSO in January 2020, but had not heard back, and after the 2020 OIG report, created an RCA tracking system to review RCA activity and outcomes. The Patient Safety Handbook does not provide specifics related to who needs, or would benefit from, access to WebSPOT for supervision and oversight of RCAs, and predates the JPSR system. The JPSR Business Rules includes information on user

[55] Position Description, "Program Specialist GS-0301-12."

roles but does not specify who needs or would benefit from access to the JPSR system for purposes of supervision or oversight.[56] When discussing the lack of access to the JPSR system and WebSPOT, the chief of quality management told the OIG about "trust[ing] that my patient safety manager was…accurately reporting information."

In an interview with the OIG, the Facility Director explained the former PSM held a State Licensing Board (SLB) issued nursing license that was no longer active.[57] An OIG review of the SLB's website confirmed the former PSM's license was no longer active due to a Board action taken against it. At the time of this SLB action, the former PSM was not required to have a valid license for the position occupied at the facility. The OIG learned from the respective SLB that licensees are responsible for informing and providing their healthcare employer(s) with a copy of any action(s) taken by the respective SLB. In correspondence with the OIG, the Associate Director, who was the chief of quality at the time of the action, confirmed being made aware of the subject nursing board action from a facility employee, not from the former PSM. Reportedly, details specific to the action were not provided to this facility leader (or any other interviewed facility leaders) by the former PSM, despite an SLB order mandate stating the licensee (former PSM) "shall provide all health care employers…with a copy" of the action. In an interview with the OIG, the former PSM shared an understanding that the State of Alabama Nursing Board reported the action to someone at the facility and denied having any conversations with supervisors regarding the issue.

The Associate Director reported consulting with Human Resources department upon learning of the SLB action. The Human Resources department confirmed a license was not required for the position. In an OIG interview, the facility chief of human resources explained the former PSM's job series was more than likely classified as one of limited risk that did not require suitability reviews beyond the time of hire. The Associate Director acknowledged being "uncertain as to the reasoning" for the SLB action, and that no further actions were taken because of no known issues with the former PSM at that time.

Given the clear instructions the SLB provided and the former PSM's obligation to report the SLB action and outcome to the healthcare employer (VHA), a failure to disclose an SLB action to the facility, which was the case with the former PSM, raises a question about whether this conduct was consistent with VA core values, including integrity. In addition, the facility may have missed an opportunity to gather details about the matter underlying the SLB action to consider whether the reason for it gave rise to concern about the former PSM's compliance with VA core values, and warranted action.

[56] NCPS, *2020 JPSR Business Rules and Guidebook*.

[57] The former PSM held a nursing license in the State of Alabama from March 1994, through September 2015. The former PSM's tenure, in the PSM role, commenced in August 2009 until retirement in late summer 2021. When asked by the OIG, the Facility Director denied knowledge of the former PSM's SLB action prior to early fall 2021.

In discussions with the OIG, the former PSM shared a lack of confidence in the level of knowledge the most recent supervisor had about the former PSMs role. The former PSM stated, "I don't think [the chief of quality management] had much any idea how any of the stuff, the intricate inside mechanisms of the databases related to patient safety, I don't think [chief of quality management] had any idea about those things nor do I think [chief of quality management] had any real interest in it because [chief of quality management] would trust me in doing it." The former PSM reported alerting the Facility Director and quality management supervisors of the heavy workload and that at one point in time, an employee at NCPS made a recommendation for additional staff to assist with the work of patient safety.

Regarding access to the JPSR system, the former PSM reported that only the PSM and back-up PSM had patient safety administrator level access that included keys to run reports. Front-line managers, the former PSM's supervisor, as well as the Facility Director could view entries related to an incident up until the report was finalized. The former PSM recalled believing at one time that the chief of quality management had access to WebSPOT but later learned that was not the case and that no other facility employee(s) had access. The former PSM thought that, as a result of this discovery, access was granted to two staff on the quality management team.

The former PSM reported performance ratings of outstanding up until the time of the OIG report identifying problems with the facility's RCAs. After that, the former PSM described having supervisory performance meetings every two weeks that eventually just stopped. When speaking of performance ratings for the last few years of employment, the former PSM described an "uphill climb" because "every tiny detail [of the former PSMs work] was scrutinized."

The OIG reviewed the former PSM's performance ratings at midpoint and end of the rating year from October 2017 to September 2021. Documentation of the performance appraisal in 2018 indicated the former PSM was performing at or above expectations at both points in time. Midway through the 2019 rating period, the Associate Director documented a need for improvement by the former PSM, sharing with the OIG that this rating was based upon Patient Safety Program deficiencies identified in the 2019 OIG CHIP report. The Associate Director told the OIG that upon learning of the issues with RCA numbers, the former PSM was reminded of prior discussions they had, dating back to 2018, about report submitting and timeliness.

The final rating of record for 2019 indicated that the former PSM was meeting all elements of performance. In 2020, the chief of quality management documented that the former PSM's performance was below expectations at both the midpoint progress review and annual rating, and included four planned actions that the chief of quality management would expect of the former PSM. In the final year of employment at the facility, 2021, the former PSM's midpoint progress review indicated that performance expectations were being met. The annual rating for the same year was completed to close the rating period following the former PSM's retirement and was documented as unacceptable.

The OIG found the supervision of the former PSM was ineffective in part due to the former PSM's supervisors lacking access to applications that would allow them to review JPSR and RCA entries made by the former PSM and instead applying a trust-and-not-verify approach to performance management. In addition, a review of the performance appraisals found that the former PSM's supervisors had awareness of performance issues and discussed them in supervisory meetings with the PSM but there was no formal improvement plan with objective performance outcomes outlined in order to measure the former PSM's performance. This failure to take sufficient action became evident when the programmatic deficiencies were identified at the time of the former PSM's retirement.

Reporting of Patient Safety Program Activities

The OIG found that the structural oversight in place was not fully operational and missed opportunities to identify or mitigate gaps in the Patient Safety Program.

The facility's Patient Safety Program policy (Patient Safety policy) provides a framework for integrating patient safety into facility activities. The Facility Director is responsible for ensuring facility compliance with the Patient Safety policy. The facility Patient Safety policy states, "the Quality Manager is responsible for program oversight and coordination of activities" and the PSM is responsible for ensuring that data is tracked, trended and reported to "appropriate individuals and/or oversight committees for review and action."[58]

The most basic level of reporting of patient safety events by the PSM takes place during daily safety calls. Multiple facility leaders told the OIG that the former PSM reported JPSR events that had been entered in the prior 24 hours during the morning week-day safety calls but did not provide ongoing status reports during the calls. However, the Associate Director reported that the former PSM kept a log to track items that could not be addressed right away and that "everything is followed up on and maintained until it is resolved."

The facility Performance Measure Oversight Committee had responsibility for establishing a "planned, systematic, organization-wide approach to process design and performance measurement, analysis and improvement." The chief of quality management told the OIG that the name of the committee was changed in March 2020 to the High Reliability Organization Committee (HRO Committee) but operationally remained the same.[59] The committee was chaired by the chief of quality management and co-chaired by the Chief of Staff. Per the Performance Measure Oversight Committee charter, the former PSM was not a member of the

[58] Facility Policy 11-58, *Patient Safety Improvement Program*, June 12, 2020. The facility chief of quality management holds the role of Quality Manager. Facility Policy 11-58, *Patient Safety Improvement Program*, July 31, 2015, was in effect during the OIG's inspection period. The policy was rescinded and replaced by Facility Policy 11-58*, Patient Safety Improvement Program*, June 12, 2020. Unless otherwise specified, the requirement in the 2020 policy contain the same or similar language as the rescinded July 2015 document.

[59] Charter 679-11Q-001, *Tuscaloosa VA Medical Center High Reliability Organization Committee*, March 1, 2020.

committee nor listed on the attendance roster despite the Patient Safety Executive Quarterly Report was a recurring topic in meeting minutes. The quarterly report, presented by a committee chair or designee, highlighted the importance of patient safety event analyses to identify underlying causes and implement changes to prevent recurrence.[60] The OIG reviewed meeting minutes from October 2018 through February 2020, which showed the Patient Safety Executive Quarterly Report was a recurring topic at the February, May, August, and November meetings; however discussion of the report was not reflected in the minutes and the former PSM was not in attendance at these meetings.

In an interview with the OIG, the former PSM described being "excluded from attending" the Performance Measure Oversight Committee but was still required to electronically submit a report to an administrative assistant who ensured the report was on the agenda and also provided it to the chief of quality management. When asked if the former PSM knew about how the reports were reviewed or if they were shared with facility leaders, the former PSM shared awareness of the report being distributed in the meeting minutes and that the Performance Measure Oversight Committee reported to the ELC. However, the former PSM stated having "no idea what happened in those meetings [Performance Measure Oversight Committee]…until I started attending." In not having the former PSM attend these meetings to present the quarterly report, committee members lost the opportunity to include the subject matter expert for patient safety in the review of data, discussions, and potential action planning.

As noted earlier, the HRO Committee chartered in March 2020 took the place of the Performance Measure Oversight Committee. The HRO Committee is responsible for "receiving, reviewing and evaluating performance improvement reports," reviewing Patient Safety Program activities, "ensuring a robust Root Cause Analysis (RCA) program," and identifying opportunities for improvement.[61] The chief of quality management is the chair of the HRO Committee and explained that in the committee charter, the former PSM was made a voting member. Despite being a voting member during this time frame, the OIG determined that the former PSM was not in attendance for any of the meetings held in 2020 but did attend five of the six meetings held prior to taking extended leave in 2021. In speaking with the OIG, the former PSM reported not learning of membership on this committee until 2021, shortly before going on extended leave. The HRO Committee charter carried over the functions of the Performance Measure Oversight Committee and added reporting, including some that were patient safety specific. Reports that were incorporated consisted of "key metrics" related to patient safety such as adverse event reports, close call event reports, and RCA reporting and scoring.[62] The OIG reviewed the HRO Committee minutes from March 2020 through July 2021, which showed

[60] NCPS, *2020 JPSR Business Rules and Guidebook*.

[61] Facility Charter 679-11Q-001, *Tuscaloosa VA Medical Center High Reliability Organization Committee*, March 1, 2020.

[62] Facility Charter 679-11Q-001.

Patient Safety Executive Quarterly Report as a recurring quarterly agenda item for meetings and that the report was provided in the May 2020, August 2020, November 2020, February 2021, and May 2021 meetings. The OIG found that the quarterly reports identified the volume of patient safety events, such as the number of JPSR event reports or RCAs conducted but lacked documentation of key metrics or improvement opportunities to address identified deficiencies.

The ELC is responsible for providing oversight of all performance improvement plans and activities within the facility.[63] The Facility Director serves as the chair and the Associate Director as the co-chair. Members of the ELC include the Chief of Staff, Associate Director for Nursing and Patient Care Services, as well as service chiefs and associate chiefs.[64] The OIG reviewed the October 15, 2018, through November 17, 2021, ELC meeting minutes, which showed patient safety reports as a recurring agenda item. The OIG found that the ELC meeting minutes lacked detailed information to support evidence of oversight related to the Patient Safety Program.

Facility Leaders Response to Oversight Failures

The OIG found that despite having supervisory controls and a committee structure in place to provide oversight, facility leaders only became aware of the Patient Safety Program deficits as they were revealed during a 2019 OIG CHIP inspection. The OIG found the facility responded with a corrective action plan that was ineffective and resulted in repeat findings in the 2020 OIG CHIP report. [65] Likewise, the actions taken in response to the repeat findings were insufficient as evidenced by the RCA failures outlined in the 2021 Issue Brief.

In response to the findings in the 2019 CHIP report, the Associate Director, who was the chief of quality management at the time, told the OIG that the findings were unexpected, stating "I had never had an issue" with the Patient Safety Program in previous years. The Associate Director also told the OIG of conducting informal coaching with the former PSM specific to timeliness of work assignments. Additionally, the PSO reported that, upon learning of the challenges identified with the RCAs in the 2019 CHIP report, the Facility Director requested that the PSO provide RCA training to facility leaders and Quality Management staff. The PSO told the OIG that this RCA training occurred in January 2020.

Following the 2020 CHIP report, the chief of quality management met with the former PSM to provide performance-specific verbal and written counseling. The discussion resulted in action agreed upon and signed by both parties to include regular meetings, use of an RCA tracking tool, and clarification of the PSM's roles and responsibilities.

[63] Facility Memorandum NO. 00-03, *Organizational Performance Improvement Plan*, December 1, 2017.

[64] Facility Memorandum NO. 00-03.

[65] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center in Alabama*.

In early August 2021, due to the extended leave of the former PSM, the facility designated an acting PSM, and in an effort to support this change, the chief of quality management contacted the VISN Quality Management Officer (QMO) and PSO seeking their recommendation for an experienced PSM point of contact within the VISN, to connect with the facility acting PSM. From mid-August through mid-September 2021, facility and VISN Quality Management staff identified significant programmatic concerns and updated facility leaders on September 17, 2021. On September 20, 2021, the Facility Director submitted a VHA Issue Brief outlining programmatic concerns and action items to address deficiencies.

Other than the facility PSM and VISN PSO, VHA does not identify specific positions that are required to have access to patient safety applications like the JPSR system and WebSPOT.[66] The Facility Director told the OIG that the Associate Director and chief of quality management did not have access to WebSPOT and JPSR systems at the time the programmatic deficiencies were identified. Upon reflection on the Patient Safety Program failures, facility leaders attributed the inability to effectively track RCA status to the lack of access to WebSPOT. The Facility Director told the OIG that without access to WebSPOT, the chief of quality management did not have a way to validate the status of each RCA. Additionally, upon taking on the role, the chief of quality management reported lacking awareness that access to the JPSR system was needed to provide oversight of the former PSM's management of patient safety events, including those that may lead to RCAs.[67] In November 2021, the chief of quality management reported having access to WebSPOT and the ability to see information being reported in the JPSR system.

In an interview with the OIG, the Facility Director reported not having regularly scheduled meetings with the former PSM, however, started one-on-one weekly meetings with the acting PSM by November 2021. In addition, the OIG learned that the patient safety events reported at the daily safety calls now include the number of JPSR event reports submitted as well as a status update of those in progress. The OIG learned through interviews with the Facility Director, chief of quality management, and acting PSM that to monitor the timely completion and closeout of the patient safety events, the acting PSM now reports to the chief of quality management regarding JPSR event reports that are within the seven-day investigation period as well as overdue JPSR event reports.

Facility leaders not only acknowledged the deficiencies in the Patient Safety Program, but also recognized that a lack of supervision and programmatic oversight resulted in the failure to identify deficiencies. In retrospect, the Facility Director shared they did not have a good tracking system to verify information provided by the former PSM and acknowledged that "you can't

[66] NCPS, *2020 JPSR Business Rules and Guidebook.* The facility PSM and VISN PSO has access to view or edit all records submitted to the JPSR system.

[67] NCPS, *JPSR Business Rules and Guidebook.* The facility PSM and VISN PSO has access to view or edit all records submitted to the JPSR system.

have a system that just depends on people's integrity and commitment for their job, you gotta [*sic*] have a system of stronger checks and balances than that."

VISN Level Oversight of Facility Patient Safety Program

The OIG found that the PSO was aware of periodic delays in the management of the facility's JPSR event reports and the OIG CHIP findings specific to RCAs; however, was not aware of the facility Patient Safety Program's level of noncompliance with VHA requirements prior to the departure of the former PSM.

According to the VISN 7 PSO position description, the PSO "has primary responsibility for all areas related to patient safety in the [Southeast] Network (VISN 7), including developing, monitoring, administering and planning patient safety programs and activities." The PSO is to analyze data, note discrepancies and, when issues are identified, recommend corrective actions.[68] A review of the PSO's performance plan for the fiscal year 2020 rating period included the expectation of tracking, trending, and analyzing VISN patient safety data and the identification of patient safety program gaps.[69] Although not required, an NCPS reference guide states, most VISNs have a network level patient safety related committee or subcommittee that consists of both the VISN PSO and the facility PSMs. Agenda items generally include trends, best practices, lessons learned, and findings stemming from the various required patient safety program analyses.[70] Guidance provided to the field in the JPSR Business Rules, suggests a VISN PSO ensures adherence to VHA patient safety policies by monitoring JPSR events and reviewing a subset of event reports to evaluate compliance, accuracy, trends, and risks at the facility.[71]

The OIG interviewed VISN 7 leaders, and reviewed the VA Functional Organization Manual and a VISN 7 organizational chart to gain a better understanding of how the VISN interfaces with facility patient safety programs.[72] The VISN Director, in the position since July 2021, reported during an interview that the VISN has both a support and oversight function, and expects the PSO to interact regularly with facility staff. The PSO told the OIG that as a result of leadership changes at the VISN in the summer of 2021, the PSO's understanding of the role transitioned from a consultative approach to one of oversight of patient safety programs at all facilities within VISN 7.

The PSO described different ways of interacting with facility PSMs to discuss the various patient safety program requirements. The PSO acknowledged facilities' annual proactive risk assessment requirement and said, "I keep track of where they are," adding that if facilities have

[68] PD# 0127, VISN 7, Patient Safety Officer, Health System Specialist GS-671-14.

[69] Fiscal year 2020 included October 1, 2019, through September 30, 2020.

[70] NCPS, *Quick Reference Guide*.

[71] NCPS, *2020 JPSR Business Rules and Guidebook*.

[72] VA Functional Organization Manual, "Description of Organization Structure, Missions, Functions, Tasks, and Authorities," 2020.

problems, the problems would be revealed through conversations with the PSMs. Using access to the JPSR system, the PSO reported awareness of overdue JPSR event reports at the facility from time-to-time, and contacting the former PSM to prompt completion of pending reports.

The PSO told the OIG that PSMs are responsible for entering RCAs into WebSPOT and that the PSO accessed WebSPOT to review RCAs and provide feedback to the PSMs. The PSO stated that any feedback related to JPSR event reports or RCAs was communicated to the PSMs throughout VISN 7 via email or phone calls. Yet, as previously mentioned, the 2019 OIG CHIP report identified deficiencies related to the completion of RCAs, the implementation of improvement actions specific to the RCA findings and provision of feedback to those submitting patient safety concerns that resulted in RCAs that had not been identified through reviews of WebSPOT conducted by the PSO.[73]

The OIG learned that the VISN has a Patient Safety/Risk Management Subcommittee (subcommittee) co-chaired by a VISN 7 facility's Chief of Staff and VISN PSO.[74] The subcommittee is tasked with reviewing JPSR event report trends, "patient safety analyses and implementation of actions, aggregated reviews, [HFMEA], and annual patient safety reports."[75] The PSO told the OIG that the subcommittee reports to the VISN Quality, Safety, and Value Committee. The facility's Associate Director for Nursing and Patient Care Services and former PSM were members of the VISN subcommittee. The PSO reported that attendance at the committee was encouraged, but not required. The facility's Associate Director for Nursing and Patient Care Services attended one meeting and the former PSM attended inconsistently.[76] In speaking with the former PSM, the OIG learned of a scheduling conflict that prevented regular attendance at this VISN meeting and that finding coverage for the call was challenging. However, the former PSM described a strong and trusting relationship with the VISN PSO, reporting access to call the PSO "at any time, day or night." The OIG reviewed the VISN subcommittee meeting minutes from December 2018 through August 2021 and determined that while not specifically required to, the meeting minutes lacked evidence of regular discussions related to facility-level compliance with required patient safety processes.[77] In addition, the OIG determined that documentation of follow-up actions for any Patient Safety Program analyses not meeting programmatic expectations were not included in the meeting minutes.

The OIG learned that in March 2020, in response to new guidelines issued by NCPS specific to RCAs, the PSO offered optional weekly calls with the PSMs throughout the VISN. The PSO

[73] VA OIG, *Comprehensive Healthcare Inspection of the Tuscaloosa VA Medical Center Alabama*, Report No.19-00057-238, September 27, 2019.

[74] VHA VA Southeast Network (VISN 7) Charter, *Patient Safety/Risk Management Subcommittee Charter* March 9, 2021.

[75] VHA VA Southeast Network (VISN 7) Charter.

[76] VHA VA Southeast Network (VISN 7) Charter.

[77] VHA VA Southeast Network (VISN 7) Charter.

shared with the OIG that the purpose of the calls was to provide training to the PSMs as well as an opportunity for discussion of RCA challenges and other topics with their colleagues, along with any feedback related to RCAs from the NCPS. Attendance on the calls was voluntary, and the information shared during the meeting was distributed by email to all PSMs. The PSO reported that the former PSM or a back-up attended the weekly calls periodically.

The OIG transmits healthcare inspection reports to the VISN and Facility Directors associated with the location of the specific report. Additional sharing of the report by the Director is limited to individuals needed to officially review and comment. Following review of the report, the directors are responsible for returning the report, with their concurrence or non-concurrence of the findings and action plans for each recommendation to the OIG. As previously noted, two OIG CHIP facility reports outlined concerns with the completion of RCAs. In an interview with the OIG, the PSO reported that the VISN QMO and another VISN staff member prepare the VISN response to OIG healthcare inspection reports from facilities within the VISN. The OIG was told that the PSO did not have a consistent role in the preparation of the response but was included periodically to review appropriateness and adequacy of a response. The OIG was informed that the PSO did not assist with the VISN response to the 2019 OIG CHIP report and learned of the findings from the former PSM and the facility risk manager after the conclusion of the OIG's on-site visit.

The PSO had the tools necessary to provide oversight of patient safety program performance at each facility. In addition, the PSO had meeting structures in place with the PSMs through weekly calls and subcommittee. However, the OIG determined that the VISN oversight of the facility's Patient Safety Program was ineffective as evidenced by the failure to proactively identify programmatic deficiencies during the tenure of the former PSM.

VISN Response to Oversight Failures

Embedded in the report from a VISN 7 review of the facility Patient Safety Program, the OIG found email communication between the VISN 7 PSO and the facility chief of quality management showing that in the midst of the extended absence of the former facility PSM, the chief of quality management reached out to the PSO requesting a referral for an experienced PSM to "connect" with the acting PSM. On August 10, 2021, the PSO met with the acting PSM to provide assistance in completing an RCA. In addition, this communication reflected that the PSO met with the acting PSM on two separate occasions and included the acting PSM in the weekly VISN PSM calls.

The same report from the VISN 7 review documents showed that in response to the concerns identified in the Issue Brief, the VISN Director met with the Assistant Under Secretary for Health, Office of Quality and Patient Safety, and staff from the NCPS to develop immediate

action plans to address deficiencies of the Patient Safety Program at the facility.[78] In addition, the VISN QMO was tasked to conduct a review of the facility's Quality Management program including the Patient Safety Program. The VISN QMO and PSO conducted a site visit and completed the review of the Patient Safety Program on October 8, 2021. At the conclusion of the review, the VISN made several recommendations including "continued collaboration, oversight, and tracking" of the Patient Safety Program to include follow-up by the VISN QMO and PSO.

Role of NCPS

The OIG spoke with the Acting Executive Director and Acting Deputy Executive Director of the NCPS to gain an understanding of the role of NCPS. The OIG was informed that the overall responsibility of the NCPS Executive Director is to inform and advise the Assistant Under Secretary for Health, Office of Quality and Patient Safety, on patient safety policies and procedures. The NCPS is responsible for preparing and disseminating patient safety related policies, quarterly NCPS reports, Patient Safety Alerts, and Patient Safety Advisories across VHA, as well as the provision of education to the field.[79]

The Acting Executive Director of NCPS reported that there is no standardized position description for PSOs and PSMs across VHA and that the positions are hired and managed locally as determined by VISN and Facility Directors. The Acting Deputy Executive Director of NCPS reported the variability continues with the reporting structure of PSOs and PSMs in the field and that in some VISNs and facilities, access to the directors is filtered through the supervisory chain of the Quality Management service. Additionally, the Acting Executive Director of NCPS shared that some PSOs and PSMs have ancillary duties outside of patient safety. As the organizational structure for patient safety programs is decentralized, the influence of NCPS at the field level relates more to policy and the provision of tools such as the JPSR system and WebSPOT than the programmatic oversight of field level operations. The OIG concluded that facility-level oversight by NCPS would allow for independent and impartial evaluation and monitoring of VA patient safety programs, and may have identified the facility program-level deficiencies.

The NCPS is the office responsible for the contents of the Patient Safety Handbook issued in 2011.[80] The OIG identified changes to patient safety program processes that are not in the current Patient Safety Handbook including the 2018 implementation of the JPSR system and the 2020 update to the number of required RCAs. When speaking with the OIG, the Acting Executive Director of NCPS noted that revisions to the Patient Safety Handbook were underway. This was confirmed by VHA's Assistant Under Secretary for Health, Office of Quality and Patient Safety,

[78] VISN 7 Facility Review, *Tuscaloosa Patient Safety Program*, October 13, 2021.

[79] VHA Handbook 1050.01.

[80] VHA Handbook 1050.01.

who provided evidence of a draft VHA Directive intended to define the organizational structure and programmatic requirements for VHA's Quality and Patient Safety Program.[81]

3. Leaders Failure in the Promotion of a Culture of Safety

The OIG found, that by not ensuring an operational Patient Safety Program, facility leaders missed a critical opportunity to promote a culture of safety within the facility. In promoting a culture of safety, leaders must make patient safety an organizational priority and ensure programmatic integrity.[82]

In an interview with the OIG, the VISN Director described assessing what led to programmatic failures at the facility stating, "you have a facility that has a Patient Safety Program on paper…but it's not operational." The VISN Director shared that facility leaders considered programmatic failures discovered after the resignation of the former PSM to be a "person problem." The VISN Director shared the view that addressing issues at an individual level results in a failure to adequately address what is inevitability a larger system issue.

As noted earlier in the report, the OIG confirmed that the Associate Director and chief of quality management were aware to some degree of the former PSM's performance issues. However, both supervisors failed to adequately assess the extent of the issues and initiate effective corrective action. In addition, the Associate Director reported to the OIG having awareness of the former PSM's requests for more staff due to workload demands. The OIG determined that the lack of discussion and analysis of patient safety reports in committee meeting minutes suggested that facility leaders and committee members were not actively engaged in supporting a culture of safety.

The OIG concluded that multi-level failures to recognize deficiencies of the Patient Safety Program were in part due to lack of action by facility leaders. Facility leaders failed to fully engage with the Patient Safety Program and did not sufficiently utilize available tools to assess and evaluate programmatic performance. In doing so, the framework in place to support a culture of safety and ensure the safety of every patient was fractured and could not comprehensively address vulnerabilities that can lead to patient harm.

Conclusion

The OIG found deficiencies in the facility's Patient Safety Program resulting in the failure to comply with VHA's patient safety standards including managing and completing JPSR event reports, RCAs, and a proactive risk assessment.

[81] The VHA Directive will replace the VHA Handbook 1050.01.

[82] *Hearing on Lessons Learned? Building a Culture of Patient Safety within the Veterans Health Administration*, U.S. House of Representatives Committee on Veterans' Affairs (October 27, 2021) (statement of Julie Kroviak, M.D. Deputy Assistant Inspector General, Office of Healthcare Inspections, VA Office of Inspector General).

The OIG reviewed events entered into the JPSR system prior to the departure of the former PSM and found that the majority of determinations to reject or accept and finalize an event occurred on or after the 14-day due date. Analysis of additional record reviews found that between 33 and 56 percent of the accepted and finalized events related to a fall, medication, or missing patient were not appropriately flagged for further patient safety analyses; 75 percent of the time the PSM appropriately rejected events, and there were inconsistencies in the former PSM's management of JPSR event reports. The OIG determined that none of the entries had documentation required to be considered a complete investigation and nearly all lacked evidence of feedback to the reporter. Although the former PSM reported that all reported incidents were addressed, the absence of investigation results limits the facility's ability to educate and share lessons learned. More importantly, the lack of documentation suggests that investigations were not completed, potentially leaving reported events without a thorough review. In addition, the sample reviewed by the OIG points to issues with the accuracy and quality of the completed portions of the JPSR event reports. Therefore, the risk that prior events in need of an RCA, disclosure, or process change may have been missed remains, warranting a review of the records.

In interviews with the OIG, the former PSM acknowledged the time frame in which RCAs were to be completed and that the entry of RCA data into WebSPOT was required. Challenges to getting RCAs completed and closing out the subsequent recommendations were also shared with the OIG by the former PSM. The OIG determined that, although not completed until February 2022, RCAs for events identified during the 12-month fiscal year 2021 cycle were completed. During an interview, the chief of quality management reported becoming aware, in late summer 2021, of recurring issues with completion of the two RCAs for the year that were chartered and in progress, but that no RCAs had been completed for the annual cycle. In late fall 2021, the OIG was provided with four individual and three aggregate review RCA charters for patient safety analyses, that were identified within fiscal year 2021. In early 2022, the OIG was provided evidence of completion for all seven reviews. In addition, the OIG determined that, after changing the original topic to a new one, the facility completed a proactive risk assessment within the 2021 calendar year.

The OIG determined that supervision of the former PSM was ineffective in part due to the former PSM's supervisors lacking access to applications that would permit oversight of the former PSM's work. Records show that the former PSM's supervisors had awareness of the former PSM's performance issues but did not implement any formal performance improvement plans. Rather, the supervisors described taking an approach of trusting what the former PSM reported to them directly or in meetings.

The former PSM described a strong history of facility staff reporting events in the JPSR system. However, went on to say that facility leaders did not provide the requested resources to fully manage the Patient Safety Program as intended by NCPS. In addition, the former PSM shared that it was challenging to engage front-line managers in response to incidents and RCAs. As a

result, the former PSM reported spending "most of my time doing, is tracking down the little things that could cause harm for people in the long run" and being aware that in doing so, administrative tasks may have been incomplete or delayed. The former PSM reported believing that supervisors did not fully understand the demands of the Patient Safety Program and lacked supervisory access to the databases related to the program. As a result, the former PSM described a lack of support for and engagement with the program.

The OIG learned the former PSM held an SLB-issued nursing license while in the role of PSM that was no longer active due to an SLB action. Additionally, the former PSM's supervisor was made aware of the subject nursing board action from a facility employee, not from the former PSM. Given the instruction from the SLB that the former PSM was obligated to report the loss of the professional license to the healthcare employer (VHA), a failure to disclose an SLB action to the facility, which was the case with the former PSM, raises a question about whether this conduct was consistent with VA core values, including integrity. In addition, the facility may have missed an opportunity to gather details about the matter underlying the SLB action to consider whether the reason for the action gave rise to concern about the former PSM's compliance with VA core values and warranted action.

The OIG determined that the facility's organizational structure permitted multiple pathways for oversight of the Patient Safety Program and that patient safety was routinely included as a topic in meeting minutes for a committee with oversight responsibilities. The OIG found that the reports identified the volume of patient safety events, such as the number of JPSR event reports or RCAs conducted, but the minutes lacked documentation of review and evaluation of the key metrics or improvement opportunities to address identified deficiencies. Therefore, the OIG found that structural oversight in place was not fully effective and missed opportunities to identify or mitigate gaps in the Patient Safety Program.

The OIG found the PSO was not aware of the degree the facility Patient Safety Program was out of compliance with VHA requirements prior to the departure of the former PSM. According to the VISN 7 PSO position description, the PSO "has primary responsibility for all areas related to patient safety in the Southeast Network (VISN 7), including developing, monitoring, administering and planning patient safety programs and activities." The PSO told the OIG that as a result of VISN leadership changes in the summer of 2021, the PSO's understanding of the role has transitioned from a consultative approach to one of oversight of the patient safety programs at all facilities within the VISN. The PSO had structures in place to meet with facility PSMs that included weekly calls and a VISN level Patient Safety/Risk Management Subcommittee. VISN PSMs were encouraged, but not required, to attend; the former PSM attended inconsistently. Using access to the JPSR system, the PSO reported awareness of overdue JPSR event reports at the facility from time-to-time and contacting the former PSM to prompt completion of the pending reports. The PSO told the OIG of accessing WebSPOT to review RCAs and providing feedback to the former PSM. Yet, the 2019 OIG CHIP report identified deficiencies related to

the completion of RCAs, the implementation of improvement actions specific to the RCA findings, and provision of feedback to those submitting patient safety concerns resulting in RCAs that had not been identified through reviews of WebSPOT conducted by the VISN PSO. The OIG determined that the VISN oversight of the facility's Patient Safety Program was ineffective as evidenced by the failure to evaluate patient safety events and analysis to proactively identify programmatic deficiencies during the tenure of the former PSM.

VHA's organizational structure for patient safety programs is decentralized. NCPS's influence at the field level relates more to policy and the provision of tools rather than organizational oversight of field level operations. The OIG concluded that facility-level oversight by NCPS would allow for independent and impartial evaluation and monitoring of VA Patient Safety Programs, and may have identified the facility program-level deficiencies.

The OIG found that by not ensuring an operational Patient Safety Program, facility leaders missed a critical opportunity to promote a culture of safety within the facility. The OIG concluded that the multi-level failures to recognize deficiencies of the Patient Safety Program were in part due to lack of action by facility leaders. Facility leaders failed to fully engage with the Patient Safety Program and did not sufficiently utilize available tools to assess and evaluate programmatic performance. In doing so, the framework in place to support a culture of safety and ensure the safety of every patient was fractured and could not comprehensively address vulnerabilities that can lead to patient harm.

Recommendations 1–11

1. The Tuscaloosa VA Medical Center Director confirms that a process is in place to review all Joint Patient Safety Reporting event reports for completion within 14 days of submission and monitor progress.

2. The Tuscaloosa VA Medical Center Director ensures event report investigation and feedback documentation has been fully completed in the Joint Patient Safety Reporting system.

3. The Tuscaloosa VA Medical Center Director reviews the risk associated with the Joint Patient Safety Reporting event reports managed by the former Patient Safety Manager, including those that were rejected and those without completed investigations, to determine whether they warrant further review and if so, ensures the review is completed and actions required resulting from the review are completed.

4. The Tuscaloosa VA Medical Center Director reviews the organizational structure and process for oversight of the eight annually required patient safety analyses to ensure they are completed and validated moving forward in accordance with Veterans Health Administration requirements.

5. The Under Secretary for Health reviews the current process for providing access to the Joint Patient Safety Reporting system and WebSPOT to determine whether any specific staff positions would benefit from automatic access upon hire into the position.

6. The Under Secretary for Health conducts an evaluation to determine whether Veterans Health Administration employees with active clinical licenses regardless of licensure requirement for their current position must report State Licensing Board actions against their clinical license to their supervisor.

7. The Tuscaloosa VA Medical Center Director conducts a review of current fiscal year High Reliability Organization Committee and Executive Leadership Council meeting minutes to confirm that they reflect discussion, analysis, and needed follow-up of Patient Safety Program data for review and action.

8. The Veterans Integrated Service Network Director reviews the *JPSR Business Rules and Guidebook* and determines which, if any, subset of patient safety event reports for each facility the Patient Safety Officer will review.

9. The Veterans Integrated Service Network Director evaluates the role of the Patient Safety/ Risk Management Subcommittee to determine the degree to which the subcommittee will address facility level performance with Patient Safety Program activities and tracking of action plans when a deficiency is identified, and updates the subcommittee charter as warranted.

10. The Under Secretary for Health ensures that policies related to patient safety are updated to reflect current required practice, publishes, and disseminates the updated policy (ies).

11. The Under Secretary for Health evaluates the process for programmatic oversight by VA's National Center for Patient Safety over Veterans Integrated Service Networks' and facilities' patient safety programs.

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: February 1, 2023

From: Under Secretary for Health (10)

Subj: OIG Draft Report, Deficiencies in the Patient Safety Program and the Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VAMC (Project 2022-00031-HI-0011) (VIEWS 09291826)

To: Program Director, Office of Healthcare Inspections (54HL05)

1. Thank you for the opportunity to review and comment on the draft report regarding the patient safety concerns identified during a healthcare inspection of the Tuscaloosa VA Medical Center in Alabama. The Veterans Health Administration (VHA) is committed to providing world-class healthcare to Veterans. This includes building a Just Culture that supports the prevention of patient harm as a High-Reliability Organization.
2. I am pleased to report that after receiving the VA OIG's draft report and reviewing the recommendations, our dedicated team of subject matter experts worked quickly to develop specific, measurable, attainable, relevant, and time-based action plans. The medical facility Director's memo and action plan address recommendations 1, 2, 3, 4 and 7. The VISN Director's memo and action plan address recommendations 8 and 9. In addition, VHA's response to recommendations 5, 6, 10, and 11 is attached.
3. VHA is committed to hiring high-quality healthcare professionals. This includes maintaining a process to recruit high-performing patient safety managers. This also includes ensuring all healthcare facilities have a patient safety program that actively investigates, documents, and mitigates harm to Veterans. The VA OIG's draft report highlighted opportunities to improve not only the patient safety program at the Tuscaloosa VA Medical Center but also at the national level.
4. VHA concurs with recommendation 6 regarding an evaluation to determine whether VHA employees, with active clinical licenses regardless of licensure requirement for their current position, must report State Licensing Board actions against their clinical license to their supervisor. Existing VHA oversight processes and requirements ensure staff are fully credentialed for positions requiring licensure (VHA Directive 1100.20). Licensure actions taken on staff requiring an active, full, and unrestricted license may ultimately impact employment with VHA. When employees occupy positions that do not require licenses, actions taken against unrelated licenses would not impact the employee's VA employment. Where licensing issues have an association with performance in a position, those types of positions would most properly be aligned to a Title 38 (or Hybrid Title 38) occupation to ensure positions requiring an active, full, and unrestricted license are staffed by licensed clinical staff.

5. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VACOVHA10BGOALOIG@va.gov. Thank you again for partnering with VHA to ensure our Veterans receive the high-quality healthcare they deserve.

(Original signed by:)

Shereef Elnahal. M.D., MBA.

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Deficiencies in The Patient Safety Program and Oversight Provided By Facility and VISN Leaders At The Tuscaloosa VA Medical Center
2022-00031-HI-0011

Recommendation 5. The Under Secretary for Health reviews the current process for providing access to the Joint Patient Safety Reporting system and SPOT to determine whether any specific staff positions would benefit from automatic access upon hire into the position.

VHA Comments: Concur

The National Center for Patient Safety (NCPS) reviewed the current process for Joint Patient Safety Report and SPOT access. The process in place for access to the Joint Patient Safety Reporting System includes user roles that provide various levels of access to modify the system. In the same manner, SPOT provides users with the ability to view and search confidential 5705-protected patient safety information. Access to these systems relies on timely communication and the relationship between the Patient Safety Manager, the Medical Center Director, and other personnel with a need- to-know justification. The benefit of maintaining the current process outweighs the risks incurred by expanding access to a 38 U.S.C. 5705 protected patient safety database. The National Center for Patient Safety determined that providing automatic access upon hire for specific positions could compromise data integrity. VHA has completed the actions on this recommendation and requests closure.

Status: Complete Completion Date: December 15, 2022

OIG Comment

The Under Secretary for Health provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 6. The Under Secretary for Health conducts an evaluation to determine whether VHA employees, with active clinical licenses regardless of licensure requirement for their current position, must report State Licensing Board actions against their clinical license to their supervisor.

VHA Comments: Concur

The Office of Human Capital Management reviewed the policy regarding the requirement to report licensing board actions. VHA's policy is clear and appropriate with respect to the reporting requirements for VHA employees with an active clinical

license. Existing VHA oversight processes and requirements ensure staff are fully credentialed for positions requiring licensure (VHA Directive 1100.20). VHA's credentialing professionals monitor the licensure of these staff members. Licensure actions taken on staff requiring an active, full, and unrestricted license may ultimately impact employment with VHA. State Licensing Boards (SLB) require licensees to provide their healthcare employer(s) with a copy of any action(s) taken by the SLB. Employees that are required to report SLB actions are aligned to a Title 38 (or Hybrid Title 38) occupation. Employees that are not in a Title 38 (or Hybrid Title 38) position are performing functions that are not applicable to their state license. When employees occupy positions that do not require licenses, actions taken against unrelated licensure are not required to be reported to their supervisor because it does not impact their employment. VHA has therefore completed its action on this recommendation and requests closure.

Status: Complete Completion Date: December 30, 2022

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 10. The Under Secretary for Health ensures that policies related to patient safety are updated to reflect current required practice, publishes and disseminates the updated policy (ies).

VHA Comments: Concur

The Patient Safety Handbook 1050.01 is being updated to a Quality and Patient Safety Directive. This draft policy is in the final stages of review and comment resolution. This updated draft directive reflects current patient safety practices.

Status: In Progress Target Completion Date: October 2023

Recommendation 11. The Under Secretary for Health evaluates the process for programmatic oversight by VA's National Center for Patient Safety over Veterans Integrated Service Networks' and facilities' patient safety programs.

VHA Comments: Concur

NCPS uses a comprehensive approach to provide programmatic oversight of Veterans Integrated Service Networks (VISNs) and facility-level patient safety programs. The following are a few examples:

a) Highlighting compliance through the review of quarterly and annual patient safety metrics reports;
b) Discussing compliance and trends during Quality and Patient Safety/ VISN engagements;
c) Reviewing patient safety culture data and trends with the VISNs and facilities;

d) Providing VISNs and facilities with Root Cause Analysis (RCA) quality review results;
e) Reviewing performance indicators on monthly Patient Safety Officer Calls, and NCPS Office Hours Calls with Patient Safety Officers, Managers, Specialists, and Professionals;
f) Conducting VISN patient safety program evaluations/consultative visits and/or facility reviews on a recurring and as-needed basis;
g) Providing VISN Patient Safety Officers with operational tools to use to conduct patient safety program evaluations.

To further NCPS oversight efforts of patient safety programs, NCPS will establish a workgroup to develop an enhanced oversight process. This workgroup will also evaluate patient safety data and processes for the dissemination of best practices across VISNs and facilities.

Status: In Progress Target Completion Date: September 2023

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 16, 2022

From: Director, VA Southeast Network (10N7)

Subj: Healthcare Inspection— Deficiencies in the Patient Safety Program and the Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama

To: Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections (54HL05)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have completed a full review of the Healthcare Inspection— Deficiencies in the Patient Safety Program and the Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama.
2. I concur with the VISN 7 and Tuscaloosa's VA Medical Center's action plan and ongoing implementation for recommends 1-4, and 7-9.
3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.
4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

(*Original signed by:*)

Benita Miller
Deputy Network Director
For
David M. Walker, MD, MBA, FACHE
Network Director
VA Southeast Network (VISN 7) (10N7)

VISN Director Response

Recommendation 8

The Veterans Integrated Service Network Director reviews the Joint Patient Safety Report Business Rules and determines which, if any, subset of patient safety event reports for each facility the Patient Safety Officer will review.

Concur.

Target date for completion: March 31, 2023

Director Comments

The Veterans Integrated Service Network Director has determined that the Patient Safety Officer will review, according to the requirements from the Joint Patient Safety Report Business Rules, the following:

- JPSR timeliness
- Reviews and investigations by subject matter experts and feedback to the reporter
- Key patient safety analysis timelines and content,
- Examples of action implementation and sustainment from patient safety analyses and/or culture survey results.

This information will be tracked by a monthly dashboard. The dashboard and any needed actions will be monitored and tracked by the Patient Safety Subcommittee and reported to Quality Safety Value Council.

Recommendation 9

The Veterans Integrated Service Network Director evaluates the role of the Patient Safety/ Risk Management Subcommittee to determine the degree to which the subcommittee will address facility level performance with Patient Safety Program activities and tracking of action plans when a deficiency is identified and updates the subcommittee charter as warranted.

Concur.

Target date for completion: March 31, 2023

Director Comments

The Veterans Integrated Service Network Director has determined the role of the Patient Safety/ Risk Management Subcommittee will be to track facility-level performance by monitoring the monthly dashboard and tracking any OIG/Joint Commission/VISN-related open patient safety-

related action plans across the VISN. The subcommittee charter will be reviewed and/or updated as warranted.

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: December 15, 2022

From: Director, Tuscaloosa VA Medical Center (679)

Subj: Healthcare Inspection—Deficiencies in the Patient Safety Program and the Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama

To: Director, VA Southeast Network (10N7)

I have completed a full review of our facility's response to Healthcare Inspection— Deficiencies in the Patient Safety Program and the Oversight Provided by Facility and VISN Leaders at the Tuscaloosa VA Medical Center in Alabama and concur with the report in full.

If you have any questions or require further information, please contact Mr. John F. Merkle, Director.

(*Original signed by*:)

John F. Merkle, FACE, VHA-CM
Director

Facility Director Response

Recommendation 1

The Tuscaloosa VA Medical Center Director confirms that a process is in place to review all Joint Patient Safety Reporting event reports for completion within 14 days of submission and monitor progress.

Concur.

Target date for completion: February 1, 2022

Director Comments

The Tuscaloosa VA Medical Center has a process in place to review all Joint Patient Safety Reporting (JPSR) events. The process includes ensuring completion within 14 days of submission and monitoring the progress of all reported patient safety events. At the beginning of each business day, the Patient Safety Manager (PSM) or designee reviews all JPSR events that were entered into the database over the previous 24 hours. Events are reviewed for appropriateness and whether they need to be rejected. Each event is assigned an investigator through the email method within the JPSR database. Investigators have access to go directly into the database and enter investigative data. In addition, feedback is provided to the reporter utilizing the email method within the database. All events are discussed on the daily safety call, which is open for all staff in the facility to attend via Microsoft Teams. The daily safety call includes the following information: the number of JPSR event reports that require investigative feedback after having been open for 7-day days, JPSR event reports that are beyond the 14-day timeframe of completion, the opportunity to verbally report safety concerns and added to the patient safety issue log, and follow-up/progress on additional items that may have been verbally reported during the daily safety call. The progress of reported safety events is also monitored each morning for feedback from the assigned investigator(s). The feedback is reviewed by the PSM for accuracy and thoroughness prior to closing the event in the JPSR database. A de-identified list of open JPSR event reports is provided to the Executive Leadership on a weekly basis for their situational awareness. The PSM meets with the medical center director bi-weekly to discuss JPSR event reports, sentinel events, RCAs and an opportunity for open discussion. The Chief of Quality Management received JPSR access on October 22, 2021 for review and oversight. In addition, appropriate Quality Management staff have also obtained a higher level of JPSR access to serve as backup/review.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 2

The Tuscaloosa VA Medical Center Director ensures event report investigation and feedback documentation has been fully completed in the Joint Patient Safety Reporting system.

Concur.

Target date for completion: April 1, 2022

Director Comments

The Tuscaloosa VA Medical Center has a process in place to ensure event report investigation and feedback documentation has been fully completed in the Joint Patient Safety Reporting system. After the new Patient Safety Manager attended the Patient Safety Bootcamp training conducted by National Center for Patient Safety (NCPS), improvements were made to the event report investigation and feedback documentation in JPSR. At the beginning of each business day, the Patient Safety Manager (PSM) or designee reviews all JPSR events that were entered into the database over the previous 24 hours. The progress of previously reported safety events is also monitored each morning for feedback from the assigned investigator(s). The feedback is reviewed by the PSM for accuracy and thoroughness prior to closing the event in the JPSR database. If there are any areas of the report that are incomplete, the PSM or designee will return the report to the investigator(s) outlining the deficient areas. When all areas are complete and returned to the PSM, it is then the JPSR event is finalized in the database. Event report investigation and feedback documentation is included in the quarterly Patient Safety report, which is reported to ELC. The Chief of Quality Management received JPSR access on October 22, 2021 for review and oversight. In addition, appropriate Quality Management staff have also obtained a higher level of JPSR access to serve as backup/review. Also, the PSM meets with the MCD bi-weekly to discuss JPSR event reports, sentinel events, RCAs and an opportunity for open discussion.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 3

The Tuscaloosa VA Medical Center Director reviews the risk associated with the Joint Patient Safety Reporting event reports managed by the former Patient Safety Manager, including those that were rejected and those without completed investigations, to determine whether they warrant further review and if so, ensures the review is completed and actions required resulting from the review are completed.

Concur.

Target date for completion: December 14, 2022

Director Comments

A review of JPSR event reports open greater than 14 days with event dates between the timeframe of July 2020 until September 12, 2021 were reviewed. All JPSR incident reports, which was extracted from the JPSR database, were sent to the nurse managers of the areas where the incident occurred, and feedback was provided to then acting Chief of Quality Management. Data was sent to the Quad for review and to all nurse managers with responsibility. All responses were submitted to and reviewed by the acting Chief of Quality Management and the acting Patient Safety Manager with emphasis on events with an actual SAC score of 3, sentinel events and also events which required further follow-up, i.e., fact finding, AIB, Peer Review or RCA. From this review, there were 3 Root Cause Analyses (RCAs), 1 Peer Review and 1 fact finding conducted. RCA JH0001 completed on 2/23/2022' RCA # JH0002 completed on 2/23/2022; JH0007 completed on 3/03/2022.

A review of rejected JPSR event reports was completed by Quality Management on December 14, 2022, for the timeframe of July 2020 until September 2021, resulting in 601 rejected events. Of the 601 events, 24 warranted further review, 24 additional reviews were completed, with no actions required from the review.

Falls and medications were erroneously listed as duplicate reports. Additional processes in place (i.e., falls documentation and pharmacy mitigations) prevented these events from requiring additional review.

Veterans admitted to the Residential Rehabilitation Treatment Program (RRTP) marked as absent without leave (AWOL) and employee events were either labeled as duplicates (which were incorrectly labeled) or the appropriate label "outside patient safety responsibilities"—these did not require further review.

Numerous events were reported from the Call Center regarding medications not being filled timely in Primary Care: these events were not labeled correctly and would have been an opportunity to review system issues during this time period. The records reviewed all indicated medications were received, filled and or updated as of this date. It is hard to determine at this late date how these system processes could have been improved/mitigated.

24 events required further chart review:

- 10-Labs orders during WHEN [weekend, holiday, evening, and night] hours–there is a weekend, holiday, evening, and night hour policy for lab collection- all of these labs were collected with no harm to the Veteran
- 13- consult and/or medications follow-up called to the Call Center- after review these have all had the appropriate follow-up in Primary Care.

- 1-Suicidal Ideation event called to the Call Center- the JPSR was labeled as "no identified system errors" and rejected. This was inappropriately rejected and labeled. The care needed for the Veteran was completed.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 4

The Tuscaloosa VA Medical Center Director reviews the organizational structure and process for oversight of the eight annually required patient safety analyses to ensure they are completed and validated moving forward in accordance with Veterans Health Administration requirements.

Concur.

Target date for completion: February 2022

Director Comments

The Tuscaloosa VA Medical Center has reviewed the organizational structure and process for oversight of the eight annually required patient safety analyses. The PSM reports the status of required patient safety analyses to the Executive Leadership Council (monthly), Clinical Executive Board (quarterly) and High Reliability Organization Committee (quarterly). The status of required analyses is provided to all committees; however, updates are provided more frequently to the Executive Leadership Council. The PSM also meets with the Medical Center Director bi-weekly where updates are provided on the Patient Safety Program. The VISN 7 PSO has disseminated a standardized schedule to all PSMs outlining when each analysis is due for completion. To verify completion, the Chief of Quality Management, Executive Leadership Team members/designee and appropriate stakeholders attend all out-briefings for patient safety analyses.

Action items related to patient safety analyses is monitored monthly by the PSM. A report is pulled from JPSR database to identify actions that remain open. Communication is sent to all points of contact to provide updates on their respective action items. Action item closure is then documented in the JPSR database. A pending actions and outcomes report is included in the PSM's reports to the Executive Leadership Council (monthly), Clinical Executive Board (quarterly) and High Reliability Organization Committee (quarterly). In addition, the Chief of Quality Management received access to the WebSpot database on December 14, 2021.

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 7

The Tuscaloosa VA Medical Center Director conducts a review of current fiscal year High Reliability Organization Committee and Executive Leadership Council meeting minutes to confirm that they reflect discussion, analysis, and needed follow up of Patient Safety Program data for review and action.

Concur.

Target date for completion: February 2022

Director Comments

A review of the FY22 High Reliability Organization Committee and Executive Leadership Council meeting minutes was conducted in the February 2022 timeframe to confirm they reflect discussion, analysis and needed follow up of the Patient Safety Program data for review and action. Through collaboration with the Medical Center Director, PSM and Chief of Quality Management, some improvements have been implemented to ensure a more robust discussion, analysis and follow up occur. After receiving the draft report in December 2022, the facility re-evaluated the information reported by the PSM in FY22 (current fiscal year) in the High Reliability Organization Committee and Executive Leadership Council meeting minutes. From this December 12, 2022 review, beginning with the December 12, 2022 ELC meeting, the Patient Safety Program reporting template now includes the date of completion and topic of patient safety analyses and the inclusion of quarterly JPSR lesson learned (which is covered in the Daily Safety Call).

OIG Comments

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Glossary

To go back, press "alt" and "left arrow" keys.

adverse event. An untoward incident directly associated with a patient's care or provided under the jurisdiction of a facility. Examples of adverse events include patient falls, complications or errors from a procedure, and missing patients.[1]

aggregated review. A method used to analyze "a group of similar incidents or event types to determine common causes" and facilitate corrective actions to prevent recurrence.[2]

close call. Also called a "near miss," a close call is an incident "that could have resulted in an adverse event, but did not, either by chance or through timely intervention."[3]

Issue Brief. A tool used to provide information to leadership within the organization, regarding a situation, event, or issue.[4]

patient safety assessment tool. A VHA tool to provides "patient safety managers with a cognitive aid to assist them in improving their patient safety program. The questions contained in this aid are meant to act as a road map to help individual facilities identify program strengths and potential weaknesses."[5]

proactive risk assessment. "A method of evaluating a product or process to identify systems vulnerabilities, and their associated corrective actions, before an adverse event occurs." Healthcare Failure Mode and Effect Analysis (HFMEA) is one type of proactive risk assessment.[6]

sentinel event. A type of adverse event that is unexpected and may involve death, serious physical or psychological injury such that if there was a recurrence, could result in a serious adverse outcome.[7]

WebSPOT. An application "used to guide teams through the RCA process, document the RCA, and provide information to NCPS" and the PSO.[8]

wild card aggregated review. A type of aggregate review "completed on a category of adverse event other than one of the three required Aggregated Review categories" of falls, adverse drug

[1] VHA Handbook 1050.01.

[2] VHA Handbook 1050.01.

[3] VHA Handbook 1050.01.

[4] Deputy Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, March 29, 2018.

[5] VHA NCPS Intranet Site, Tools & Products.

[6] VHA Handbook 1050.01.

[7] VHA Handbook 1050.01.

[8] VHA Handbook 1050.01.

events and missing patients. The wild card aggregated reviews "may be done on a category of adverse event of the facility's choosing."[9]

[9] VHA Handbook 1050.01.

OIG Contact and Staff Acknowledgments

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