Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 AMENDED March 5, 2024

VHA QUALITY AND PATIENT SAFETY PROGRAMS

1. SUMMARY OF MAJOR CHANGES:

Amendment dated March 5, 2024, adds paragraph 1.b.(1).(c). in Appendix A.

As of March 24, 2023, this Veterans Health Administration (VHA) directive:

a. Describes alignment of the VHA Office of Quality and Patient Safety (QPS) with quality and patient safety infrastructure and processes at VHA program offices, Veterans Integrated Services Networks (VISNs) and Department of Veterans Affairs (VA) medical facilities.

b. Recognizes the following governance infrastructure for VHA quality and patient safety programs: VHA Quality, Safety and Value Council; VISN Quality and Patient Safety Committee (QPSC); and the VA medical facility QPSC. See Appendix B.

c. Sets forth a new requirement directing the Executive Directors of the Office of Quality Management and the National Center for Patient Safety to establish, administer and manage proactive, recurring VISN quality and patient safety programs engagements. These engagements include reviewing quality and patient safety data and related process improvement activities at the national, regional and local levels. See paragraphs 2.e. and 2.f.

2. RELATED ISSUES: VHA Directive 1002, Bed Management Solution (BMS) for Tracking Beds and Patient Movement Within and Across VHA Facilities, dated November 28, 2017; VHA Directive 1004.08, Disclosure of Adverse Events to Patients, dated October 31, 2018; VHA Directive 1026.01, Systems Redesign and Improvement Program, dated December 12, 2019; VHA Directive 1039(3), Ensuring Correct Surgery and Invasive Procedures In and Out of the Operating Room, dated November 28, 2018; VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020; VHA Directive 1070, Adverse Drug Event Reporting and Monitoring, dated May 15, 2020; VHA Directive 1083, Notification of Medical Malpractice (Tort) Claims to Involved Staff and Notice of Employment Status to Office of General Counsel, dated February 9, 2023; VHA Directive 1100.16, Health Care Accreditation of VHA Facilities and Programs, dated July 19, 2022; VHA Handbook 1100.17, National Practitioner Data Bank (NPDM) Reports, dated December 28, 2009; VHA Directive 1100.18, Reporting and Responding to State Licensing Boards, dated January 28, 2021; VHA Directive 1100.20, Credentialing of Health Care Providers, dated September 15, 2021; VHA Directive 1100.21, Privileging, dated March 2, 2023; VHA Directive 1103(1), Prevention of Retained Surgical Items, dated March 5, 2016; VHA Directive 1117, Utilization Management Program, dated October 8, 2020; VHA Directive 1167, Mental Health Environment of Care Checklist for Mental Health Units Treating Suicidal Patients, dated May 12, 2017; VHA Directive 1170.01,

Accreditation of VHA Rehabilitation Programs, dated September 23, 2022; VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018; VHA Directive 1320, Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents, dated July 10, 2020.

3. POLICY OWNER: The VHA Office of Quality and Patient Safety (17) is responsible for the contents of this directive. Questions may be referred to QPS at <u>VHA17QPSAction@va.gov</u>.

4. RESCISSIONS: VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011; VHA Memorandum 2022-04-31, Annual Minimum Requirements for Facilities to Perform Patient Safety Analyses, dated April 25, 2022; and VHA Memorandum 2022-09-43, Joint Patient Safety Reporting 14-days to Finalize an Event, dated September 8, 2022, are rescinded.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working date of March 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Gerard R. Cox, MD, MHA Assistant Under Secretary for Health for Quality and Patient Safety

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on March 27, 2023.



CONTENTS

VHA QUALITY AND PATIENT SAFETY PROGRAMS

1. POLICY	1
2. RESPONSIBILITIES	1
3. NATIONAL CENTER FOR PATIENT SAFETY ADVISORIES, ALERTS AND NOTICES	13
4. NATIONAL CENTER FOR PATIENT SAFETY REPORTS	13
5. OVERSIGHT, ACCOUNTABILITY AND ENGAGEMENT	14
6. QUALITY AND PATIENT SAFETY EDUCATIONAL PROGRAMS	14
7. TRAINING	15
8. RECORDS MANAGEMENT	15
9. BACKGROUND	15
10. DEFINITIONS	17
11. REFERENCES	20
APPENDIX A	
MINIMUM PATIENT SAFETY ANALYSES REQUIREMENTS, DOCUMENTS AND LINKS	
APPENDIX B	
GOVERNANCE	B-1

VHA QUALITY AND PATIENT SAFETY PROGRAMS

1. POLICY

It is Veteran Health Administration (VHA) policy that the Office of Quality Management (OQM) and National Center for Patient Safety (NCPS) establish and provide operational oversight of VHA quality programs and VHA patient safety programs (collectively referred to as VHA quality and patient safety programs), including the monitoring of quality and patient safety data and related process improvement activities at the national, regional and local levels. VHA quality and patient safety programs must be aligned under the VISN Director or VA medical facility Director. **AUTHORITY:** 38 U.S.C. §§ 7301(b), 7311(a).

2. RESPONSIBILITIES

a. Under Secretary for Health. The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Establishing the expectation that organizational leadership throughout VHA will make accountability determinations consistent with the principles of a just culture to promote the delivery of highly reliable, high-quality and safe patient care.

b. **Deputy Under Secretary for Health.** The Deputy Under Secretary for Health is responsible for:

(1) Supporting the Under Secretary for Health in promoting the delivery of highquality and safe patient health care across VHA.

(2) Ensuring that VHA program offices engage in quality and patient safety activities and priorities.

(3) Ensuring the Office of Quality and Patient Safety (QPS) is included in strategic discussions that affect quality and patient safety activities across VHA.

c. <u>Assistant Under Secretary for Health for Quality and Patient Safety.</u> The Assistant Under Secretary for Health for Quality and Patient Safety is responsible for:

(1) Providing oversight of OQM and NCPS.

(2) Supporting OQM and NCPS with implementation and oversight of this directive.

(3) Ensuring OQM and NCPS are appropriately resourced to perform duties and responsibilities assigned in this directive.

(4) Ensuring collaboration across QPS to achieve success in the goals and intent of this directive.

(5) Collaborating with other Assistant Under Secretaries for Health overseeing other

program offices to promote highly reliable, high-quality and safe patient care throughout VHA.

(6) Serving as a co-chair of the VHA Quality, Safety and Value (QSV) Council as outlined in Appendix B, which reports to the VHA Governance Board, and providing governance leadership and management for the proactive, recurring VHA quality and patient safety programs review processes.

(7) Communicating enterprise-wide initiatives that address quality and patient safety programs, processes and practices.

d. <u>Assistant Under Secretary for Health for Operations.</u> The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all Department of Veterans Affairs (VA) medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure effective implementation of and compliance with this directive.

e. <u>Executive Director, Office of Quality Management.</u> The Executive Director, OQM is responsible for:

(1) Serving as a principal advisor to the Assistant Under Secretary for Health for Quality and Patient Safety on operational management, policy and improvement pertaining to quality management (QM).

(2) Providing leadership and management of OQM and the VHA quality program.

(3) Managing the OQM operational program office budget.

(4) Ensuring that quality management subject matter experts (SMEs) are available to provide consultation to stakeholders, as applicable, on matters involving quality management.

(5) Providing leadership, administration and curriculum for quality management training and related educational programs, including but not limited to the National Organization of Leadership and Analytics University (NOLA U), professional pathways orientation and competencies.

(6) Ensuring the development and dissemination of quality of care and quality management information concerning accreditation-related activities, medical-legal risk management, credentialing and privileging, quality and systems improvement and Evidence-Based Practice (EBP) and the organization's high reliability journey.

(7) Providing guidance to VISNs, quality professionals and other VHA staff to support quality improvement (QI) and OQM.

(8) Conducting regular meetings, at least quarterly, with VISN Quality Management Officers (QMOs) to support alignment of efforts and the sharing of information across VHA.

(9) Sharing quality data with VHA leadership and program offices, VISNs and VA medical facilities to support VHA's mission and VA's public reporting of data.

(10) Ensuring regular meetings of the Quality Professionals Community of Practice (CoP) occur.

(11) Collaborating with the Executive Director, NCPS to provide the process for and the administration and management of the proactive, recurring VHA quality and patient safety programs review processes.

(12) Requesting the VISN QMO conduct QI activities when necessary.

(13) Ensuring the collection of aggregate data from all VISNs in order to identify, review and monitor quality data and related process improvement activities at all levels of VHA.

(14) Ensuring the maintenance of an accurate list of VISN QMOs. The list can be accessed at: https://dvagov.sharepoint.com/sites/VHAQPS/qm/cop/Lists/QMO%20POC%20List/AllIte ms.aspx. **NOTE:** This is an internal VA website that is not available to the public.

f. <u>Executive Director, National Center for Patient Safety.</u> The Executive Director, NCPS is responsible for:

(1) Serving as a principal advisor to the Assistant Under Secretary for Health for Quality and Patient Safety on operational management, policy and improvement pertaining to patient safety.

(2) Providing leadership and management of the VHA patient safety program and collaborating with other VHA program offices, national SMEs and other Federal agencies and business associates in all matters requiring patient safety expertise.

(3) Managing the NCPS operational program office budget.

(4) Ensuring an accurate list of VISN Patient Safety Officers (PSOs) and VA medical facility Patient Safety Managers (PSMs). The list can be accessed at: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSM-%26-PSO-Facility-</u> <u>Directory.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

(5) Ensuring that a patient safety SME is available to provide consultation to stakeholders, as applicable, on matters involving patient safety.

(6) Identifying a VISN PSO to participate in VHA patient safety program initiatives.

(7) Providing guidance to VISNs PSOs, VA medical facility PSMs and other VHA staff to support the performance of patient safety analyses, including but not limited to submission and investigation of events entered into Joint Patient Safety Reporting (JPSR), Root Cause Analysis (RCA), Proactive Risk Assessment (PRA) and Patient Safety Assessment Tool (PSAT). For further details regarding patient safety analyses, see Appendix A.

(8) Providing oversight, administration and curriculum (in conjunction with the Office of Academic Affiliations), for educational programs that support patient safety and high reliability through training of Health Professions Trainees.

(9) Providing leadership and administration of core patient safety curriculum for use by, and in collaboration with, the VISN PSOs to teach VA medical facility patient safety professionals. This includes, but is not limited to orientation, coaching and mentoring and development of professional pathways.

(10) Overseeing the process for the selection and funding of Patient Safety Centers of Inquiry (PSCIs). See paragraph 2 in Appendix A.

(11) Ensuring the NCPS administration and business ownership of JPSR, Root Cause Analysis System and PSAT and their subsequent data repositories for VHA users.

(12) Overseeing the management of the VHA Alerts and Recalls Application. **NOTE:** For more information, see VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.

(13) Ensuring the development and dissemination of patient safety information to VISNs, VA medical facilities and external agencies as appropriate, including, but not limited to Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices, in collaboration with the Assistant Under Secretary for Health for Operations.

(14) Ensuring a Patient Safety Culture Survey (included in the All-Employee Survey) is updated annually.

(15) Ensuring regular meetings of the Patient Safety CoP occur.

(16) Ensuring a routine national call is facilitated by NCPS staff for VISN PSO participation.

(17) Collaborating with the Executive Director, OQM to provide the process for and administration and management of the proactive, recurring VHA quality and patient safety programs review processes.

(18) Ensuring the collection of aggregate data from all VISNs on patient safety metrics and activities in order to review, identify and monitor patient safety data and

related process improvement activities at the national, regional and local levels.

(19) Monitoring, generating and publishing documentation of VA medical facility compliance with patient safety analyses requirements in the NCPS Quarterly Report using annual evaluation reports to provide a standardized set of relevant information to support the VHA patient safety program. See paragraph 4 in Appendix A.

g. <u>Veterans Integrated Services Network Director</u>. The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Promoting quality and patient safety through:

(a) Planning and ensuring that resources are available for quality and patient safety initiatives, and

(b) Celebrating successes of initiatives.

(3) Ensuring VISN quality and patient safety programs are aligned under the VISN Director.

(4) Ensuring the selection and appointment of a minimum of 1.0 full-time equivalent (FTE) VISN QMO and a minimum of 1.0 FTE VISN PSO.

(5) Ensuring both the VISN QMO and VISN PSO have direct access to and participate in executive conversations, such as huddles, where a quality and patient safety perspective is necessary. **NOTE:** Regularly occurring one-on-one meetings are encouraged to foster communication, maintain clear awareness of emerging or concerning issues and identify opportunities for improvement.

(6) Ensuring both quality and patient safety are represented throughout governance structures.

(7) Establishing, maintaining and overseeing the fulfillment of duties for the VISN Quality and Patient Safety Committee (QPSC). **NOTE:** See Appendix B for VISN QPSC duties and responsibilities.

(8) Ensuring Patient Safety Alert actions and Patient Safety Advisory recommendations are assigned and completed by VISN PSO as defined by the Patient Safety Alert or Advisory documents in cases where VISN-level actions are required.

(9) Ensuring Patient Safety Notices and any provided recommendations are acknowledged by the VISN within timeframes provided within the Patient Safety Notice document, in cases where VISN-level issues are identified or VISN-level recommendations are provided. *NOTE:* See the Patient Safety Notice document at: <u>https://dvagov.sharepoint.com/sites/vhancps/Lists/AlertsAdvisoriesandNoticesTracker/A</u>

<u>Illtems.aspx</u>. This is an internal VA website that is not available to the public.

(10) Ensuring the Executive Director of NCPS is notified when a safety vulnerability is identified that affects multiple VA medical facilities.

(11) Receiving notification from the VISN QMO and subsequently ensuring the VISN QMO notifies the Executive Director of OQM and respective program office when a vulnerability is identified that may result in an adverse accreditation decision or opportunity to validate quality management practices across VHA.

(12) Reviewing and approving VA medical facility requests for OQM or NCPS Consultative Site Visits and ensuring resolution of actions required as a result of any Level of Concern Site Visit pursuant to paragraph 5 (Oversight, Accountability and Engagement).

(13) Ensuring the VISN PSO and each VA medical facility within the VISN actively participate in the VHA patient safety programs review processes. See Appendix A.

(14) Ensuring the VISN QMO and each VA medical facility within the VISN actively participate in the VHA quality programs review processes.

h. <u>Veterans Integrated Services Network Quality Management Officer.</u> The VISN QMO is responsible for:

(1) Serving as the principal advisor for each VA medical facility in the VISN and facility leadership on operational management, policy and improvement pertaining to quality management.

(2) Communicating and disseminating quality management best practices and quality management-related policy to VA medical facilities in the VISN.

(3) Providing guidance to VA medical facility Quality Managers within their VISN on implementation of their respective quality program.

(4) Conducting program assessments of the structure, work and support systems at each VA medical facility in the VISN to determine if additional resources are needed.

(5) Notifying the VISN Director and Executive Director, OQM when a VA medical facility Quality Manager reports a quality management vulnerability that could affect other VA medical facilities.

(6) Promoting and participating in quality management training and related educational programs as offered by OQM.

(7) Promoting and facilitating QI activities in each VA medical facility in the VISN as opportunities arise or by request from OQM.

(8) Promoting and facilitating implementation of evidence-based clinical practice

guidelines (CPGs) within the VISN as offered by OQM.

(9) Promoting and supporting the implementation of high-reliability practices and processes. **NOTE:** For more information on High Reliability Organization (HRO) see <u>https://dvagov.sharepoint.com/sites/OHT-PMO/high-reliability/Pages/Home-Page.aspx</u>. This is an internal VA website that is not available to the public.

(10) Actively participating in VA medical facility Level of Concern or Consultative Site Visits under the provisions of paragraph 5 (Oversight, Accountability and Engagement), and providing reports upon request to the Executive Director, OQM.

(11) Disseminating information, actions and recommendations related to quality of care and quality management initiatives and plans.

(12) Actively participating in the VHA quality and patient safety programs review processes.

i. <u>Veterans Integrated Services Network Patient Safety Officer.</u> The VISN PSO is responsible for:

(1) Serving as the principal advisor for each VA medical facility in the VISN and facility leadership on operational management, policy and improvement pertaining to patient safety.

(2) Communicating and disseminating leading practices and patient safety-related policy to VA medical facilities in the VISN.

(3) Advising VISN leadership on appropriate course of action related to sentinel events reported by VA medical facilities.

(4) Providing guidance as needed to VA medical facility PSMs within their VISN on implementation of their respective patient safety program.

(5) Reviewing all sentinel events and a sample of patient safety events, RCAs and patient safety risk analyses (including PSAT) for content, recommendations and required actions, and providing consultation and guidance to the VA medical facility PSM as needed. See Appendix A.

(6) Conducting program assessments of the structure, work and support systems at each VA medical facility in the VISN to determine if additional resources are needed.

(7) Ensuring actions are taken to review, address and correct deficiencies, when identified (e.g., from quarterly reports, issue briefs, dashboards, trend reports).

(8) Serving as the point of contact for the VISN for Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices.

(9) Notifying the VISN Director and Executive Director, NCPS when a VA medical

facility PSM reports a safety vulnerability that could affect other VA medical facilities and may require the development of a Patient Safety Alert, Patient Safety Advisory or Patient Safety Notice.

(10) Promoting and participating in patient safety training and educational programs.

(11) Promoting and supporting the implementation of high-reliability practices and processes. **NOTE:** For more information on HRO see <u>https://dvagov.sharepoint.com/sites/OHT-PMO/high-reliability/Pages/Home-Page.aspx</u>. This is an internal VA website that is not available to the public.

(12) Actively participating in the NCPS patient safety program review process and VA medical facility Level of Concern or Consultative Site Visits under the provisions of paragraph 5 (Oversight, Accountability and Engagement) and providing reports upon request from the Executive Director, NCPS.

j. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring VA medical facility compliance with this directive and related OQM and NCPS policy and ensuring corrective action is taken if non-compliance is identified.

(2) Ensuring effective VA medical facility quality and patient safety programs are maintained as outlined in this directive.

(3) Ensuring the VA medical facility quality and patient safety programs are aligned under the VA medical facility Director.

(4) Ensuring the VA medical facility Quality Manager and PSM both have direct access to and participate in executive conversations, such as huddles where a quality and patient safety perspective is necessary. **NOTE:** Regularly occurring one-on-one meetings are encouraged to foster communication and maintain clear awareness of emerging or concerning issues, as well as opportunities for improvement.

(5) Ensuring the selection and appointment of a minimum of 1.0 FTE for the VA medical facility Quality Manager and a minimum of 1.0 FTE for the VA medical facility PSM.

(6) Reviewing quality and patient safety program assessments required by paragraphs 5.b., 2.h.(4) and 2.l.(6) and addressing resource needs.

(7) Designating the VA medical facility PSM as the point of contact for the distribution and tracking of Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices within the VA medical facility, including any associated Community-Based Outpatient Clinic, domiciliary and community care facility providing care to Veterans.

(8) Ensuring the VA medical facility Quality Manager and PSM actively participate in the quality and patient safety programs review processes.

(9) Encouraging and supporting bi-directional communication and collaboration between VISN and VA medical facility quality and patient safety staff.

(10) Promoting quality and patient safety through:

(a) Planning and ensuring that resources are available for quality and patient safety initiatives, and

(b) Celebrating successes of initiatives.

(11) Establishing, maintaining and overseeing the fulfillment of duties of the VA medical facility QPSC. See Appendix B.

(12) Ensuring Patient Safety Alert actions and Patient Safety Advisory recommendations are assigned and completed within the timeframes required in cases where VA medical facility-level actions are needed.

(13) Ensuring Patient Safety Notices and any provided recommendations are acknowledged by the VA medical facility as defined and within timeframes required in the Patient Safety Notices. *NOTE:* See Patient Safety Notices at: <u>https://dvagov.sharepoint.com/sites/vhancps/Lists/AlertsAdvisoriesandNoticesTracker/A</u> *Illtems.aspx.This is an internal VA website that is not available to the public.*

(14) Ensuring the Executive Director, NCPS and the VISN PSO are notified when a safety vulnerability is detected that could affect other VA medical facilities and may require the development of a Patient Safety Alert, Patient Safety Advisory or Patient Safety Notice.

(15) Promoting and encouraging VA medical facility staff to enter patient safety adverse events and close calls into JPSR.

(16) Ensuring VA medical facility staff enter sentinel events into JPSR within 24 hours of event awareness.

(17) Ensuring JPSR entries are investigated and closed within 14 days of the date of entry.

(18) Ensuring individual RCAs are chartered, performed and completed within 45 calendar days from date aware of events identified in Appendix A.

(19) Ensuring if an RCA is halted for an intentionally unsafe act, a separate process, formal investigation or other administrative action is initiated in accordance with applicable policy and regulations such as VA Directive 0700, Administrative Investigation Boards and Factfindings, dated August 10, 2021, and VA Handbook 0700, Administrative Investigation Boards and Factfindings, dated August 17, 2021. **NOTE:** *Unlike RCAs, formal investigations can result in individually directed action in addition to systems improvement. An RCA can use information gleaned from an investigation, but due to confidentiality constraints of RCAs, a formal investigation cannot use information*

from an RCA. If there is an intention to perform both types of reviews on the same incident, the RCA is routinely performed after the completion of the investigation. If an investigation is performed after an RCA is started, members of the RCA team are not to serve on the formal investigation team or review group to ensure that the confidentiality of the RCA process is maintained and that the perception of the integrity of the RCA process is preserved.

(20) Reviewing the end of fiscal year Patient Safety Annual Report and ensuring the VA medical facility completes at least eight patient safety analyses every year and addresses any noted vulnerabilities. See Appendix A.

k. **VA Medical Facility Quality Manager.** The VA medical facility Quality Manager is responsible for:

(1) Managing and overseeing the quality program in the VA medical facility.

(2) Serving as the SME on quality management matters in the VA medical facility.

(3) Serving as the quality management representative on the VA medical facility QPSC. See Appendix B.

(4) Recommending actions to the VA medical facility Director related to quality management based on the review of reports included in Appendix B.

(5) Participating in the VISN QPSC, when requested.

(6) Advising the VA medical facility Director on the development of the VA medical facility and VISN quality management strategic plan to align with VISN and OQM priorities.

(7) Implementing and monitoring quality management and performance improvement activities.

(8) Participating in VA medical facility quality forums and related educational events.

(9) Participating in the Quality Professionals' CoP meeting.

(10) Promoting the use of evidence-based CPGs.

(11) Ensuring VA medical facility quality data is collected when required to be manually submitted as directed by OQM.

(12) Promoting the use of JPSR as the system for the initial assessment of patient safety event reports.

(13) Notifying the VISN QMO and VA medical facility Director of issues that might adversely impact quality outcomes, related to but not limited to the following areas:

(a) QI activities.

(b) Medical-Legal risk management.

(c) Accreditation.

(d) Credentialing and privileging matters, in collaboration with VISN Chief Medical Officer (CMO) and VISN Credentialing and Privileging Officer.

(14) Disseminating to VA medical facility staff information, actions and recommendations related to quality management and plans.

(15) Facilitating and supporting QI and other quality management related educational activities at the VA medical facility. Supporting a culture that recognizes that quality management is the responsibility of all employees.

(16) Developing VA medical facility level strategies and plans based on quality metrics that support QI initiatives to promote highly reliable, high-quality, safe patient care throughout the organization.

(17) Actively participating in the VHA quality and patient safety programs review processes as described in paragraph 5.a.

I. <u>VA Medical Facility Patient Safety Manager.</u> The VA medical facility PSM is responsible for:

(1) Managing and overseeing the patient safety program at the VA medical facility.

(2) Serving as the SME on patient safety and representing patient safety in relevant patient safety forums and discussions and on appropriate committees.

(3) Serving as the patient safety representative on the VA medical facility QPSC. See Appendix B.

(4) Recommending actions to the VA medical facility Director related to patient safety based on the review of reports included in paragraph 4 (NCPS Reports).

(5) Providing patient safety input to the VISN PSO to inform VISN QPSC discussions.

(6) Implementing and monitoring patient safety performance improvement activities. See Appendix A.

(7) Participating in VA medical facility patient safety forums and related educational events.

(8) Ensuring JPSR is used for the initial assessment of patient safety event reports.

(9) Sharing identified RCA lessons learned with appropriate committees, teams and/or other staff venues for use in system improvement.

(10) Validating that immediate actions are taken following a patient safety event that protect other patients from harm and preserve relevant information that assists in fully understanding the event.

(11) Reviewing patient safety event reports in JPSR to determine the level of harm associated with the event, assigning the appropriate safety assessment code (SAC) and determining required action. **NOTE:** Business rules and educational material for JPSR, RCA and PRA are available on the NCPS website at: <u>https://dvagov.sharepoint.com/sites/VHANCPS/SitePages/Analytics-and-Reporting.aspx</u>. This is an internal VA website and not available to the public.

(12) Preparing team charters for RCAs, aggregate RCAs and PRAs for the VA medical facility Director's review and signature. For more information on RCAs, aggregate RCAs and PRAs see Appendix A.

(13) Notifying the VISN PSO, NCPS and VA medical facility Director of patient safety issues that might result in a Patient Safety Alert, Patient Safety Advisory or Patient Safety Notice.

(14) Serving as the point of contact for Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices at the VA medical facility.

(15) Disseminating Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices to the individuals identified in each document and ensuring documentation that actions and recommendations within Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices have been acknowledged and completed.

(16) Documenting completion of the Patient Safety Alerts, Patient Safety Advisories and Patient Safety Notices on the VHA Alerts and Recalls application within the timeframes specified in the documents. This includes uploading information on how the actions were completed and when they were completed. **NOTE:** Access to the VHA Alerts and Recalls application is available for use on VHA desktops through the Software Center.

(17) Facilitating patient safety educational activities at the VA medical facility (e.g., new employee orientation, RCA training).

(18) Actively participating in the VHA quality and patient safety programs review processes as described in paragraph 5.a.

(19) Advising the VA medical facility Director on the development of the VISN and VA medical facility patient safety strategic plan to align with VISN and NCPS priorities.

(20) Submitting an end of fiscal year Patient Safety Annual Report to the VA medical facility Director that provides an overview of the VA medical facility's patient safety program status. Information may include, but is not limited to, program successes, areas for improvement, reports of RCAs, Aggregate RCAs, Sentinel Events, alerts, and advisories.

3. NATIONAL CENTER FOR PATIENT SAFETY ADVISORIES, ALERTS AND NOTICES

a. <u>Patient Safety Advisory.</u> A Patient Safety Advisory is prepared by NCPS to provide awareness of patient safety vulnerabilities. The advisory is a mandate for specific action to address issues such as equipment design, product failure, procedures or training and may recommend clinical action.

b. <u>Patient Safety Alert.</u> A Patient Safety Alert is prepared by NCPS to provide awareness of patient safety vulnerabilities. The alert is a mandate for specific action to address actual or potential threats to life or health and often will require one or more clinical actions. VA medical facility staff affected by the alert are required to complete the specific actions outlined in the alert.

c. <u>Patient Safety Notice.</u> A Patient Safety Notice is prepared by NCPS to provide awareness of patient safety vulnerabilities even where no solutions are immediately evident. Patient Safety Notices may or may not provide recommendations. VA medical facility staff must acknowledge that they have received and reviewed each Patient Safety Notice.

4. NATIONAL CENTER FOR PATIENT SAFETY REPORTS

a. NCPS reports provide a foundation to support regular and ongoing improvement in the delivery of high-quality and safe patient care for VHA-enrolled Veterans. These reports support ongoing and continuous patient safety improvement by providing validated data for the VA medical facility with VISN and national comparisons. **NOTE:** In addition to NCPS data sources (e.g., JPSR, Root Cause Analysis System), the NCPS reports integrate relevant patient safety data from other VHA data sources. Reports include VISN and VA medical facility data with comparison to VHA national statistics for patient safety activities.

(1) The NCPS Annual Report is a single national compilation of patient safety data available to all VHA personnel.

(2) The NCPS Quarterly Report is a VISN-level report with VA medical facilityspecific information distributed to VISN and VA medical facility leaders and CoPs. This report is protected under 38 U.S.C. § 5705.

b. NCPS report data elements include but are not limited to the following:

- (1) Patient safety events.
- (2) Sentinel events.
- (3) RCAs and aggregate RCAs.
- (4) Patient Safety Culture Survey.

- (5) Compliance with mandated PSAT surveys.
- (6) Compliance with Patient Safety Alerts and Patient Safety Advisories.
- (7) Compliance with Product Recall postings.

5. OVERSIGHT, ACCOUNTABILITY AND ENGAGEMENT

a. OQM and NCPS sponsor VHA quality and patient safety programs review on a recurring and as needed basis. The VHA quality and patient safety programs review is the interactive engagement between VHA QPS and VISN PSO and QMO to cooperatively and proactively review and monitor aggregate data, process and outcomes to identify areas for improvement, as well as reliable and strong practices to support future directions and priorities of those programs.

b. OQM and NCPS Site Visits are conducted to facilitate QI and patient safety improvement activities and to improve reliability in the provision of safe patient care. Conducted under the purview of OQM or NCPS, all documents gathered under this activity are protected under 38 U.S.C. § 5705 and its implementing regulations.

(1) Field Initiated Consultative Site Visit. A VISN, or a VA medical facility with VISN concurrence, may request a field initiated Consultative Site Visit to obtain subject matter expertise from OQM or NCPS. Under the direction of their respective Executive Directors, OQM or NCPS will (with the VISN Director, VISN QMO and PSO awareness) assemble an appropriate team to conduct an outside review of the VA medical facility quality of care and quality management or patient safety program/processes. The team will be comprised of OQM or NCPS staff, the VISN QMO or PSO and other clinical and non-clinical SMEs as deemed appropriate. The VISN CMO and Chief Nursing Officer (CNO) will be invited to participate in the Site Visit as needed.

(2) VHA Central Office Initiated Consultative Site Visit. A VHA Central Office initiated-Site Visit may be initiated by either OQM or NCPS for reasons related to quality management practices or quality outcomes, patient safety events or outcomes. If a VHA Central Office-initiated Site Visit is initiated by either OQM or NCPS, under the direction of their respective Executive Directors, OQM or NCPS must (with VISN Director, VISN QMO and PSO awareness) assemble an appropriate team to conduct a review of the VA medical facility quality of care and quality management or patient safety program/processes related to the identified concern. The team will be comprised of OQM or NCPS staff, VISN QMO or PSO and other clinical and non-clinical program offices as deemed appropriate by the office initiating the visit. The VISN CMO and CNO will be invited to participate in the VHA Central Office-initiated Site Visit as needed.

6. QUALITY AND PATIENT SAFETY EDUCATIONAL PROGRAMS

a. <u>Quality Professional Pathway.</u> The Quality Professional Pathway is a program provided to quality professionals throughout VHA designed to provide in-depth knowledge of the fundamentals and principles of analytics, QI, leadership, HROs and related courses. These are provided through the National Organization for Leadership

and Analytics University (NOLA U). Additional information regarding courses included in the Quality Professional Pathway can be found at: https://dvagov.sharepoint.com/sites/VHAOQMNOLAU/. **NOTE:** This is an internal VA website that is not available to the public.

b. <u>Education and Training of Patient Safety Professionals.</u> Education and training for patient safety professionals consists of a variety of offerings for all levels of staff and leadership providing knowledge about patient safety culture and the fundamental principles and activities required for successful oversight and management of the VA medical facility Patient Safety Program. The administrative functions of these opportunities are overseen by NCPS.

c. <u>Healthcare Professions Trainee Training Programs</u>. In collaboration with other National VHA Offices, NCPS acts as a coordinating center for Health Professions Trainees (HPTs) training programs. These programs offer quality improvement, patient safety, and high reliability training to HPTs.

7. TRAINING

There are no formal training requirements associated with this directive.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

9. BACKGROUND

a. VHA has been actively engaged in QI activities since 1990. These activities have been implemented on a system-wide and VA medical facility-specific basis. QI efforts have been targeted to both specific clinical services and overall processes of providing patient care. VHA affirms its unwavering commitment to quality health care and patient safety for Veterans, Veterans' families and health care teams serving across the enterprise. Continuous Quality Management and Process Improvement sciences provide an organized framework of programs to objectively define, measure, assess and improve to assure that quality of care is realized. Continuous quality management strengthens high reliability practices to build accountability, transparency, inclusion and standardization to prevent harm, promote continuous learning and improve the quality of care and services delivered.

b. OQM was established as part of the 2020 VA Central Office reorganization to support the ongoing assessment and improvement of VHA clinical outcomes and health care delivery processes. OQM foundational principles include:

(1) Promoting principles of high reliability, in order to ensure the provision of high-

quality health care that is patient-centered, effective, timely, efficient, equitable and safe.

(2) Acknowledging that front line employees have detailed knowledge of QI opportunities in the operational environment.

(3) Supporting the use of an improvement framework in QI activities.

(4) Supporting the use of a change management framework in quality-related activities.

(5) Supporting the use of quality metrics for QI.

(6) Fostering a culture of continuous improvement.

(7) Supporting the use of EBP and CPGs.

(8) Building capacity and capability for high reliability in quality and QI across VHA.

(9) Promoting responsibility for quality and QI at all levels of VHA.

c. NCPS was established in 1999 and subsequently implemented the VHA patient safety program with the following foundational principles:

(1) Promoting a culture that recognizes that the responsibility for improving patient safety and promoting just culture resides at all levels of VHA.

(2) Anticipating and taking action to reduce risk of harm and examining patient harm when it occurs.

(3) Reporting adverse events and close calls through the JPSR System. This is the primary mechanism through which NCPS learns about health care system vulnerabilities. These reports provide the foundation for investigating and analyzing root causes and to identifying the contributing factors which require action to prevent future events.

(4) Acknowledging that front-line employees have detailed knowledge of patient safety risks in the operational environment.

(5) Promoting responsibility for employee reporting of patient safety risks when adverse events and close calls occur.

(6) Utilizing just culture principles in response to actual or potential patient safety events or harm; Examining systems and processes that may increase the likelihood of harm or contribute to an adverse event when it occurs.

(7) Acknowledging that the level of accountability is not based on the degree of harm or outcome. Creating an understanding of behaviors and activities that move an organization towards zero harm.

(8) Applying knowledge-based actions that can be formulated, tested and implemented at the local, regional and national levels, to effectively address system vulnerabilities that can lead to patient harm.

10. DEFINITIONS

a. <u>Adverse Events.</u> For the purpose of this directive, adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm directly associated with care or services delivered by VA providers.

b. <u>Aggregate Root Cause Analysis.</u> Aggregate RCA is a method to analyze a collection of similar patient safety events (usually in a high-volume category such as medication and fall events) to determine prominent themes and risks worthy of a formal, focused review. The Aggregate RCA review process is a method to analyze a group of similar patient safety or quality events to determine common causes and identify actions to prevent recurrences. Aggregate RCAs are formally chartered and adhere to the same process and protections as the individual RCA. *NOTE: See Appendix A for additional resources.*

c. <u>Aggregate Review.</u> An aggregate review is a process outlined by NCPS to assess organization risks which can include the completion of an Aggregate RCA, PSAT or some other methodology.

d. <u>Clinical Practice Guidelines.</u> For the purpose of this directive, CPGs include evidence-based recommendations for care that are intended to optimize patient care and are informed by both a systematic review of current evidence as well as consideration of the benefits and harms of different treatment options.

e. <u>Close Call.</u> For the purpose of this directive, a close call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention.

f. <u>Evidence-Based Practice.</u> EBP is the objective, balanced and responsible use of current research, gathered by a systematic and critical review of published literature. EBP utilizes the best available data, along with practitioner skill and experience, to guide policy and practice decisions.

g. <u>Intentionally Unsafe Act.</u> An intentionally unsafe act is an action that involves reckless behavior done with the knowledge that it poses risk to patient safety. Intentionally unsafe acts in health care include, but are not limited to, criminal acts, acts related to alcohol or substance abuse by an impaired provider or staff member and acts involving patient abuse.

h. Joint Patient Safety Reporting System. JPSR system is a mandated web-based system used by VHA employees to report patient safety events. The JPSR system is accessible through the following link: <u>https://patientsafety.csd.disa.mil/</u>. **NOTE:** This is an internal VA website that is not available to the public.

i. <u>Just Culture.</u> For the purpose of this directive, a just culture is an atmosphere of trust in which people are expected to provide essential safety related information. Individuals trust they will not be held accountable for system failures; however, the individual is also clear on where the line must be drawn between acceptable and unacceptable behavior.

j. <u>Patient Safety.</u> Patient safety is freedom from accidental or preventable harm resulting from medical care and treatment.

k. <u>Patient Safety Assessment Tool.</u> PSAT is a web-based tool used to conduct self-assessments, referred to as "surveys," on topics related to patient safety. PSAT comprises questions related to patient safety based on regulations, guidelines, evidence in the literature and accepted best practices. *NOTE: See PSAT resources at:* <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSAT.aspx</u>. This is an internal VA website that is not available to the public.

I. <u>Patient Safety Event.</u> A patient safety event is an event, incident or condition, directly associated with care or services provided to a patient, that could have resulted or did result in unintentional harm. Patient safety events include but are not limited to adverse events and close calls.

m. <u>Proactive Risk Assessment.</u> A PRA is a method of evaluating a product or process to identify systems vulnerabilities and their associated corrective actions before an adverse event occurs. The method of PRA most used is the VHA Healthcare Failure Mode and Effect Analysis (HFMEA), although other strategies (e.g., The Joint Commission FMEA process, Bowtie, Fault Tree) may be employed. *NOTE:* Additional guidance about PRAs can be found at:

https://dvagov.sharepoint.com/sites/vhancps/SitePages/Proactive-Risk-Assessment.aspx. This is an internal VA website that is not available to the public.

n. <u>Product Recall.</u> A product recall is a method for removing products from use that are in violation of laws administered by the Food and Drug Administration (FDA) or otherwise deemed defective or potentially harmful to patients. Product recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority.

o. <u>Quality.</u> For the purpose of this directive, quality is the provision of highly reliable health care services that are safe, timely, effective, efficient, equitable and patient-centered.

p. **Quality Improvement.** QI is a structured approach to evaluating the performance of systems, processes, products and services that leads to incremental and

breakthrough improvements.

q. **Quality Management.** Quality management is a systematic process to oversee a desired outcome that includes quality planning, assurance, control and improvement.

r. <u>Quality and Patient Safety Measure Set.</u> The Quality and Patient Safety Measure Set is a defined set of metrics that derive from other primary reporting systems and may allow for comparisons using both internal and external health care systems.

s. <u>Quality and Patient Safety Programs Review.</u> For the purpose of this directive, the VHA quality and patient safety programs review is the interactive engagement between VHA QPS and VISN patient safety and quality management professionals to cooperate and proactively review and monitor aggregate data, process and outcomes to identify areas for improvement, as well as reliable and strong practices to support future directions and priorities of those programs.

t. <u>Root Cause Analysis.</u> RCA is a comprehensive team-based, systems-level investigation with a formal charter for review of health care adverse events and close calls. *NOTE:* For further information, see <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Root-Cause-Analysis.aspx</u>. This is an internal VA website that is not available to the public.

u. <u>Safety Assessment Code.</u> A SAC is a score assigned to a patient safety event utilizing a matrix that takes into account both the severity and probability of harm. The matrix is used to generate a risk score of 1, 2, or 3 (1=Lowest Risk; 2=Intermediate Risk; 3=Highest Risk).

v. <u>Sentinel Event.</u> A sentinel event is any patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that results in death, permanent harm or severe temporary harm. VHA defines harm events utilizing SAC outlined in Appendix A.

w. <u>Patient Safety Centers of Inquiry.</u> PSCIs are research centers located at VA medical facilities for investigating error-reducing strategies to mitigate risk and improve patient safety like those used in aviation and nuclear power industries. Established in 1999, the PSCIs are supported by specific purpose Veterans Equitable Resource Allocation funds. *NOTE:* Additional information about PSCIs can be found at: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSCI.aspx</u>. This is an internal VA website that is not available to the public.

x. <u>Wild Card Aggregate Root Cause Analysis.</u> A Wild Card Aggregate RCA is completed on patient safety events that do not require an individual RCA but represent either the most often reported type of event in JPSR, or a type of event that is trending upward in report frequency. A Wild Card Aggregate RCA is an addition to the aggregate review and applies to categories other than those mandated for specific categories outlined in Appendix A. The Wild Card Aggregate RCA is accomplished using JPSR event reports receiving an actual or potential SAC score of 2 or less.

11. REFERENCES

a. 38 U.S.C. §§ 5705, 7301(b), 7311(a).

b. VA Directive 0700, Administrative Investigation Boards and Factfindings, dated August 10, 2021.

c. VA Handbook 0700, Administrative Investigation Boards and Factfindings, dated August 17, 2021.

d. VHA Directive 1068, Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities, dated June 19, 2020.

e. JPSR System. <u>https://patientsafety.csd.disa.mil/</u>. **NOTE:** This is an internal VA website that is not available to the public and contains Department of Defense (DoD) restrictions.

f. JPSR Guidance.

<u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/JPSR.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

g. VHA NCPS Patient Safety Notice.

https://dvagov.sharepoint.com/sites/vhancps/Lists/AlertsAdvisoriesandNoticesTracker/A Illtems.aspx. **NOTE:** This is an internal VA website that is not available to the public.

h. VHA HRO. <u>https://dvagov.sharepoint.com/sites/OHT-PMO/high-</u> <u>reliability/Pages/Home-Page.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

VHA NCPS Analytics and Reporting.

https://dvagov.sharepoint.com/sites/VHANCPS/SitePages/Analytics-and-Reporting.aspx. **NOTE:** This is an internal VA website that is not available to the public.

j. VHA NCPS PRAs.

<u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Proactive-Risk-</u> <u>Assessment.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

k. VHA NCPS PSOs and PSMs.

<u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSM-%26-PSO-Facility-</u> <u>Directory.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

I. VHA NCPS PSAT.

<u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSAT.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

m. VHA NCPS PSCI.

https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSCI.aspx. NOTE: This is an

internal VA website that is not available to the public.

n. VHA NCPS RCA. <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Root-</u> <u>Cause-Analysis.aspx</u>. **NOTE:** This is an internal VA website that is not available to the public.

o. VHA NCPS SAC Scoring Guidance. https://dvagov.sharepoint.com/sites/vhancps/SitePages/Safety-Assessment-Coding-Resources.aspx. **NOTE:** This is an internal VA website that is not available to the public.

p. VHA Governance Board QSV Council. <u>https://dvagov.sharepoint.com/sites/VHAGovBoard/QSV/Pages/default.aspx</u>. *NOTE: This is an internal VA website that is not available to the public.*

q. VISN QMO Point of Contact List. https://dvagov.sharepoint.com/sites/VHAQPS/qm/cop/Lists/QMO%20POC%20List/AllIte ms.aspx. **NOTE:** This is an internal VA website that is not available to the public.

r. NOLA U Courses. <u>https://dvagov.sharepoint.com/sites/VHAOQMNOLAU/</u>. **NOTE:** This is an internal VA website that is not available to the public.

MINIMUM PATIENT SAFETY ANALYSES REQUIREMENTS, DOCUMENTS AND LINKS

1. PATIENT SAFETY REQUIREMENTS

The Department of Veterans Affairs (VA) medical facility Director ensures the VA medical facility performs at least eight patient safety analyses annually including: Root Cause Analysis (RCA), Aggregate RCAs, Wild Card Aggregate RCA, Proactive Risk Assessment (PRA) and Patient Safety Assessment Tool (PSAT) evaluations. The patient safety analyses help detect patient safety vulnerabilities that affect Veterans Health Administration (VHA). Therefore, it is recommended that dedicated time be allotted for staff to complete patient safety analyses.

a. Individual RCAs are performed based on the Safety Assessment Code (SAC) matrix and include any event receiving an actual or potential SAC score of 3 in the Joint Patient Safety Reporting (JPSR) system. Additional detail regarding RCA requirements can be accessed at: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Root-Cause-Analysis.aspx</u>. *NOTE: This is an internal VA website that is not available to the public.*

b. Aggregate RCAs.

(1) Are used for the following:

- (a) Medication events that do not require an individual RCA.
- (b) Fall events that do not require an individual RCA.
- (c) Home oxygen fire events that do not result in harm.

(2) The log of cases, used for review of Aggregate RCAs include cases that:

(a) Are in the category of Medication, Fall Events, or Electronic Health Record Modernization (EHRM) as noted below;

(b) Have an Actual SAC score of 2 or less. **NOTE:** Exceptions are subject to the most current Joint Commission and VHA guidance.

(c) Have a Potential SAC score of 3 or less;

(d) Represent a full year of data.

(3) Require a review process where all cases are reviewed for risk themes. Once all cases in the log are reviewed, the VA medical facility Patient Safety Manager identifies the highest risk subset, regardless of SAC score, for the focus of the Aggregate RCA.

(4) The Wild Card Aggregate RCA on patient safety events that do not require an individual RCA but represent either the most often reported type of event in the JPSR or represent a type of event that is trending upward in report frequency. Wildcard RCAs must:

(a) Be in a category other than medication, fall and wandering and missing patient events.

(b) Include events with an actual and/or potential SAC score of 2 or less.

c. PSAT is used for the following:

(1) Annual Wandering and Missing Patients.

(2) Semiannual Mental Health Environment of Care Checklist if the VA medical facility has an Inpatient Mental Health Unit or a Mental Health treatment room in the Emergency Department or Urgent Care Clinic.

(3) EHRM PSAT prior to EHRM implementation.

(4) Other PSATs based on emerging requirements/priorities.

d. PRA such as Health Care Failure Mode and Effect Analysis or one of the methods outlined in the PRA guidebook. Additional guidance about PRA can be found at: https://dvagov.sharepoint.com/sites/vhancps/SitePages/Proactive-Risk-Assessment.aspx. **NOTE:** This is an internal VA website that is not available to the public.

e. For VA medical facilities completing EHRM go-live, the following modifications are applicable to the annual requirements:

(1) In lieu of performing an individual RCA for each potential SAC-3 event, facilities may compete an aggregate RCA of EHRM associated potential SAC-3 events reported in JPSR for one year post go-live.

(2) An Aggregate RCA for EHRM associated events one year post go-live may be used to satisfy the annual requirement for a Wild Card RCA.

(3) Completion of the EHRM PSAT may be used to satisfy the annual requirement for a PRA for one year post go-live.

2. RESOURCES

a. <u>Patient Safety Analysis.</u> This link provides information on patient safety analysis resources available: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSAT.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

b. Joint Patient Safety Reporting System, VHA National Center for Patient Safety Joint Patient Safety Reporting Guidebook. The use of and reference to this guidance is required. This link provides specific information regarding the use of the JPSR system: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/JPSR.aspx</u>. *NOTE: This is an internal VA website that is not available to the public.*

c. <u>Patient Safety Assessment Tool.</u> This link provides information on how-to complete a PRA utilizing the PSAT and how to use the PSAT tool: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSAT.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

d. <u>Patient Safety Centers of Inquiry (PSCI)</u>. This link provides information about the PSCIs: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/PSCI.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

e. <u>Proactive Risk Assessment.</u> This link provides resources and guidance on how to perform various PRAs to include Healthcare Failure Mode and Effect Analysis Fault Tree, Event Tree, Bowtie Diagram, Hazard Assessment, and Medication Safety Self Assessments: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Proactive-Risk-Assessment.aspx</u>. *NOTE: This is an internal VA website that is not available to the public.*

f. <u>Root Cause Analysis</u>. The following link provides guidance and further information on the RCA process: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Root-</u> <u>Cause-Analysis.aspx</u></u>. *NOTE: This is an internal VA website that is not available to the public*

g. <u>Safety Assessment Code Scoring.</u> The following link contains SAC guidebooks: <u>https://dvagov.sharepoint.com/sites/vhancps/SitePages/Safety-Assessment-Coding-</u> <u>Resources.aspx</u>. *NOTE:* This is an internal VA website that is not available to the public.

GOVERNANCE

1. VHA QUALITY AND PATIENT SAFETY GOVERNANCE

The Veterans Health Administration (VHA) Quality, Safety and Value (QSV) Council acts at the direction of the Assistant Under Secretary for Health for Quality and Patient Safety and respective co-chair as outlined in the QSV Council Charter. QSV Council membership and responsibilities are set forth in this formal charter, available at: https://dvagov.sharepoint.com/sites/VHAGovBoard/QSV/Pages/default.aspx. **NOTE:** This is an internal Department of Veterans Affairs (VA) website that is not available to the public.

2. VISN QUALITY AND PATIENT SAFETY COMMITTEE

a. The Veterans Integrated Services Networks (VISN) Quality and Patient Safety Committee (QPSC) may replace the current VISN QSV Council or other entity that has historically provided monitoring and oversight within the VISN governance structure. **NOTE:** The VISN or VA medical facility may maintain the term council, committee or workgroup to fit within their governance structure.

b. Membership should include, but is not limited to:

(1) VISN Quality Management Officers (QMO).

- (2) VISN Patient Safety Officers (PSO).
- (3) VISN High Reliability Organizations (HRO) lead.

(4) VISN Chief Medical Officer/Deputy or VA medical facility Chief of Staff (COS).

(5) VISN Chief Nursing Officer/Deputy or VA medical facility Associate Director for Patient Care Services (Nurse Executive).

(6) VA medical facility Director.

(7) VA medical facility Patient Safety Manager (PSM).

(8) VA medical facility Quality Manager.

(9) Ad hoc VISN leads, for example: Risk Management, Accreditation, Systems Redesign, Community Care, Dental, Emergency Medicine, Health Informatics, Mental Health, Nursing, Perioperative Services, Pharmacy, Primary Care, Specialty Care Medicine and Utilization Management.

c. The VISN QPSC meets at least six times a year and supports the following:

(1) The development of the VISN quality management and patient safety strategic

plan, to include long-term goals to improve the delivery of high-quality and safe patient care in alignment with this directive, Office of Quality Management (OQM) and National Center for Patient Safety (NCPS).

(2) Monitoring of Evidence-Based Practice, quality of care, quality management and patient safety performance improvement activities within the VISN to ensure system issues are addressed.

(3) Sharing best practices across the VISN.

(4) Identifying gaps in performance and recommending actions and opportunities for improvement.

d. The VISN QPSC reviews multiple sources for quality of care, quality management and patient safety data for the purpose of assessing impact and effectiveness of the VISN quality and patient safety programs as well as to inform the prioritization of improvement work. Sources of data that may be reviewed include, but are not limited to:

(1) Quality and Patient Safety Measure Set.

(2) NCPS reports and other relevant patient safety information, such as aggregate reviews, Proactive Risk Assessments (PRAs), alerts, advisories, notices and recalls.

(3) Quality outcomes data including Inpatient Evaluation Center, Strategic Analytics for Improvement and Learning (SAIL) and Care Compare, Nursing Sensitive Indicators and staffing and data related to the Integrated Clinical Communities, such as National Surgery Office (NSO) reports, mental health outcomes and others.

(4) Trend reports from other high-risk areas, such as credentialing and privileging report cards, Sterile Processing Services (SPS), controlled substances and code-blue committees.

(5) Clinical documentation integrity and improvement reports.

(6) Reports and results from regulatory and oversight bodies.

(7) Risk management reports, such as peer review, tort claims and institutional disclosures of adverse events.

(8) Customer satisfaction and engagement data, such as Learner's Perception Survey, Patient Safety Culture Survey, patient satisfaction sources, employee satisfaction sources and patient advocate reports.

3. VA MEDICAL FACILITY QUALITY AND PATIENT SAFETY COMMITTEE

a. The VA medical facility QPSC may replace the current VA medical facility QSV Council or other entity that meets the intent of monitoring and oversight. b. Membership should include, but is not limited to:

(1) VA medical facility Quality Manager.

(2) VA medical facility PSM.

(3) VA medical facility HRO lead.

(4) VA medical facility COS.

(5) VA medical facility Associate Director for Patient Care Services (Nurse Executive).

(6) Non-clinical Service Chief (such as Health Information Management Services, Engineering, Environmental Management Service, business office) on a rotational basis.

(7) Designee identified by each Integrated Clinical Community.

(8) Front-line nursing representative.

(9) Ad Hoc VA medical facility Leads, for example: other non-clinical service chiefs, Risk Manager, Systems Redesign Lead, Accreditation Specialist, Community Care, Dental, Emergency Medicine, Health Informatics, Mental Health, Perioperative Services, Pharmacy, Primary Care, Specialty Care Medicine and Utilization Management.

c. The VA medical facility QPSC meets at least six times a year or more frequently as necessary.

d. The VA medical facility QPSC reviews multiple sources for quality of care, quality management and patient safety data for the purpose of assessing impact and effectiveness of the VA medical facility quality and patient safety program as well as to inform the prioritization of improvement work. Sources of data that may be reviewed include, but are not limited to:

(1) Quality and Patient Safety Measure Set.

(2) NCPS reports and other relevant patient safety information, such as aggregate reviews, PRAs, alerts, advisories, notices and recalls.

(3) Quality outcomes data including VHA Inpatient Evaluation Center, SAIL and Care Compare, Nursing Sensitive Indicators and staffing and data related to the Integrated Clinical Communities, such as NSO reports, Mental Health outcomes and others.

(4) Trend reports from other high-risk areas, such as credentialing and privileging report cards, SPS, controlled substances and code-blue committees.

(5) Clinical documentation integrity and improvement reports.

(6) Reports and results from regulatory and oversight bodies.

(7) Risk Management reports, such as peer review, tort claims and institutional disclosures.

(8) Customer satisfaction and engagement data, such as Learner's Perception Survey, patient safety culture, patient satisfaction sources, employee satisfaction sources and patient advocate reports.