Defense Health Agency

PROCEDURES MANUAL

NUMBER 6025.13, Volume 2
August 29, 2019

Medical Affairs

SUBJECT: Clinical Quality Management in the Military Health System, Volume 2: Patient Safety

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedures Manual (DHA-PM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (ad), establishes the Defense Health Agency's (DHA's) procedures to assign responsibilities and establish procedures for managing Clinical Quality Management (CQM) in the Military Health System (MHS). This DHA-PM replaces, in full, the contents of the DoD Manual 6025.13 (Reference (e)), which is targeted for cancellation. This DHA-PM, replaces, in Volume 2, the full contents, unless otherwise stated, of the following memorandums, which are targeted for cancellation: Assistant Secretary of Defense for Health Affairs Memorandum, "Policy on Reporting Joint Commission on Accreditation of Healthcare Organizations-Reviewable Sentinel Events in the Military Health System," July 13, 2004 (Reference (h)); Assistant Secretary of Defense for Health Affairs Memorandum, "Amplifying Guidance Relating to the Reporting of Sentinel Events and Personally Identifiable Information Breaches to the Office of the Assistant Secretary of Defense (Health Affairs)," February 13, 2012 (Reference (i)) [as related to the reporting of sentinel events only]; and Assistant Secretary of Defense for Health Affairs Memorandum, "Medical Quality Assurance and Clinical Quality Management in the Military Health System Sentinel Event and Root Cause Analysis Process Improvements," March 12, 2015 (Reference (j)).

2. APPLICABILITY. This DHA-PM applies to:

a. OSD, Military Departments, Office of the Chairman of the Joint Staff and the Joint Staff, Combatant Commands, Office of the Inspector General of the DoD, Defense Agencies, DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this DHA-PM as the "DoD Components");

b. The entire MHS, including each DoD Military Medical Treatment Facility (MTF) and all other healthcare provided by the MHS;

c. Uniformed services personnel of the active and reserve components (including National Guard personnel in a Federal duty status), civilian, contract, volunteer, and other medical or dental healthcare providers who are assigned to and deliver healthcare; and

(1) Credentialed healthcare providers who are members of the Army National Guard or the Air National Guard, while working in a non-federal status (Reference (k) are subject to the procedures, policies, and authorities, as prescribed by their respective Army Regulation Reference (l)) and Air Force Instruction (Reference (m)), or as defined in the policies, rules, procedures, and laws of the State, territory, or District of Columbia in which they are credentialed and/or privileged;

(2) Trainees who have been granted clinical privileges outside the training program when patient safety concerns arise;

d. Managed care support contractors (MCSCs), designated providers, and overseas contractors, consistent with their respective contracts awarded by the DoD.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to authority delegated in Reference (b) and based on authorities in Reference (a) through (ad), that:

a. Establishes CQM procedures in the MHS to provide an organized structure for an integrated framework of programs to objectively define, measure, assure, and improve the quality of care received by MHS beneficiaries.

b. Strengthens MHS CQM accountability, transparency, and standardization in the MHS.

c. Affirms the MHS's unwavering commitment to quality healthcare for our beneficiaries, joint healthcare teams, and Combatant Commands across the globe, through CQM.

4. CANCELLED DOCUMENTS. This DHA-PM replaces, in Volume 2, the full contents of DHA-Procedural Instruction (DHA-PI) 6200.01, "Comprehensive Infection Prevention and Control (IPC) Program," April 24, 2017 (Reference (n)), which is being cancelled.

5. RESPONSIBILITIES. See Enclosure 2 of Volume 1.

6. PROCEDURES. Procedures specific to each program within the MHS CQM are addressed in Volumes 2–7 of this DHA-PM.

7. INFORMATION REQUIREMENTS. CQM uses several data capture, analysis, reporting, and decision support tools for patient safety, clinical quality assurance, and improvement to

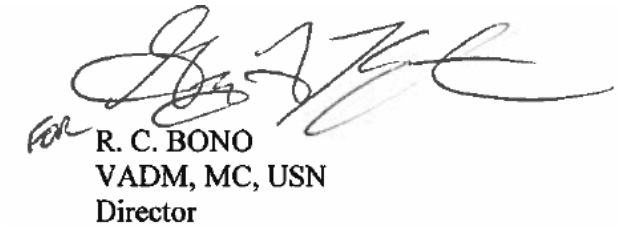
include the electronic medical record, databases such as the Joint Centralized Credentials Quality Assurance System (JCCQAS), and the Joint Patient Safety Reporting (JPSR), data visualization and report tools on CarePoint (a SharePoint platform), and more.

8. RELEASABILITY. **Cleared for public release**. This DHA-PM is available on the Internet from the Health.mil site at: http://www.health.mil/dhapublications.

9. EFFECTIVE DATE. This DHA-PM:

a. Is effective on October 01, 2019.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date, in accordance with Reference (c).



for R. C. BONO
VADM, MC, USN
Director

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REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011, as amended
(e) DoD Manual 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," October 29, 2013
(f) National Defense Authorization Act for Fiscal Year 2017, Sections 702
(g) National Defense Authorization Act for Fiscal Year 2019, Sections 711 and 712
(h) Assistant Secretary of Defense for Health Affairs Memorandum, "Policy on Reporting Joint Commission on Accreditation of Healthcare Organizations-Reviewable Sentinel Events in the Military Health System," July 13, 2004
(i) Assistant Secretary of Defense for Health Affairs Memorandum, "Amplifying Guidance Relating to the Reporting of Sentinel Events and Personally Identifiable Information Breaches to the Office of the Assistant Secretary of Defense (Health Affairs)," February 13, 2012
(j) Assistant Secretary of Defense for Health Affairs Memorandum, "Medical Quality Assurance and Clinical Quality Management in the Military Health System Sentinel Event and Root Cause Analysis Process Improvements," March 12, 2015
(k) United States Code, Title 32, Sections 502 – 505
(l) Army Regulation 40–68, "Clinical Quality Management," February 26, 2004, as amended
(m) Air Force Instruction 44–119, "Medical Quality Operations," August 16, 2011
(n) DHA-Procedural Instruction 6200.01, "Comprehensive Infection Prevention and Control (IPC) Program," April 24, 2017, hereby cancelled
(o) National Defense Authorization Act for Fiscal Year 2001, Sections 742 and 654
(p) National Quality Forum, "NQF Patient Safety Terms and Definitions, Safety Definitions," February 18, 2010[1]
(q) Agency for Healthcare Research and Quality's Patient Safety Organization Program, "Common Formats for Event Reporting – Hospital Version 2.0," May 2017[2]
(r) The Joint Commission, "Sentinel Event Policy," June 29, 2017[3]
(s) National Patient Safety Foundation, "RCA[2]: Improving Root Cause Analyses and Actions to Prevent Harm," 2015[4]

[1] Available on the Internet at https://www.qualityforum.org/Topics/Safety_Definitions.aspx
[2] Available on the Internet at https://www.pso.ahrq.gov/common/scope
[3] Available on the Internet at https://www.jointcommission.org/sentinel_event.aspx
[4] Available on the Internet at http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx

(t) DoD Instruction 6000.11, "Patient Movement," June 22, 2018
(u) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017
(v) "DHA MEDLOG Division HAR Guidance," October 31, 2017[1]
(w) Defense Logistics Agency, "DLA Troop Support, Medical Supply Chain-DMMonline"[2]
(x) United States Code, Title 10, Section 1102
(y) Agency for Healthcare Research and Quality, "TeamSTEPPS™ Teamwork Perceptions Questionnaire (T-TPQ)," March 2014[3]
(z) The Joint Commission, "Root Cause Analysis in Health Care: Tools and Techniques, 6th Edition," October 2017
(aa) DoD Patient Safety Learning Center, "Military Health System Leadership Engagement Toolkit," December 2017[4]
(ab) Agency for Healthcare Research and Quality's Patient Safety Network, "Patient Safety Primer: Culture of Safety," January 2019[5]
(ac) Agency for Healthcare Research and Quality, "Comprehensive Unit-based Safety Program (CUSP) Unit Level Cultural Assessments," March 2018[6]
(ad) The High Reliability Organization Task Force Report. A Resource Guide for Achieving High Reliability in the MHS," September 15, 2015[7]

[1] Please contact DHA MEDLOG Chief of Quality and Safety Optimization at (301) 619-9851 for this document.
[2] Available on the Internet at https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx
[3] Available on the Internet at https://www.ahrq.gov/teamstepps/instructor/printver/index.html
[4] Available on the Internet at https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/leadership.aspx
[5] Available on the Internet at https://psnet.ahrq.gov/primers/primer/5/safety-culture
[6] Available on the Internet at https://www.ahrq.gov/professionals/education/curriculum-tools/cusptoolkit/index.html
[7] Available on the Internet at https://info.health.mil/coi/mhshro/Documents/Deliverables

ENCLOSURE 2

PATIENT SAFETY

1. GENERAL OVERVIEW. This enclosure outlines procedures for the implementation and sustainment of the DoD Patient Safety Program (PSP) within the MHS.

a. Purpose. The DoD PSP is a comprehensive program providing products, services, and educational and training resources to promote safety and prevent harm, as mandated in accordance with Reference (o). The DoD PSP contributes to the MHS's focus to achieve the Quadruple Aim, aligned with DoD, MHS, and DHA strategic objectives, centered on Readiness—Ready Medical Force and Medically Ready Force—across all environments. Supporting the objective is the goal to achieve zero preventable harm and provide patient-centered, evidence-based care to improve patient outcomes. The DoD PSP provides products, services, and support to enable frontline healthcare personnel to eliminate harm and promote a culture of safety.

b. Functions. The primary functions of the DoD PSP are to promote a strong culture of safety to eliminate preventable patient harm by engaging, educating, and equipping patient care teams to institutionalize evidence-based, safe practices.

(1) Manage Patient Safety (PS) Events. Eliminate harm through identification, investigation, and mitigation of PS events.

(2) Support a Learning Organization. Strengthen systems through the implementation of robust mitigations and providing education and training to all staff to promote concepts of high reliability in healthcare.

(3) Foster a Culture of Safety. Foster a culture in which mistakes are acknowledged and lead to sustainable, positive change; respectful and inclusive behaviors are instinctive and serve as behavioral norms for the organization; and the physical and psychological safety of patients and the workforce are both highly valued and ardently protected.

2. KEY OPERATIONAL DEFINITIONS. Knowledge of these terms is essential to understanding the scope, core responsibilities, and procedures of the DoD PSP. A full list of definitions for this manual is included in the Glossary.

a. Patient Safety (PS) Event. A PS event is an incident or condition that could have resulted, or did result, in harm to a patient. A PS event can be but is not necessarily the result of a defective system or process design, a system or process breakdown, equipment failure or malfunction, or human error. PS events include adverse events, no-harm events, near miss events, and unsafe/hazardous conditions as defined below:

(1) Adverse Event. PS event that resulted in harm to the patient. The event may occur by the omission or commission of medical care.

(2) No-harm Event. PS event that reached the patient but did not cause harm.

(3) Near Miss Event. PS event that did not reach the patient (also known as "close call" or "good catch").

(4) Unsafe/Hazardous Condition. A condition or a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

b. Event Reporting. The DoD Patient Safety Program (PSP) captures the full range of patient safety (PS) events listed in Paragraph 2.a. and all such events must be reported into the Joint Patient Safety Reporting (JPSR) system to be used as opportunities to prevent harm. Any PS event that reaches the patient (i.e., adverse events and no-harm events) must be reported to the appropriate Healthcare Risk Management (HRM) Program for assessment. (See Paragraph 2.c.(1) for potentially compensable event (PCE) definition.) DoD Reportable Events (DoD REs) also have reporting, notification, and analysis requirements beyond JPSR. (See Paragraph 2.e. for DoD RE definition.)

c. Other Event Types

(1) Potentially Compensable Event (PCE). Any patient safety (PS) event that both a) reaches the patient (i.e., adverse event and no-harm event) and b) has a Healthcare Risk Management assessment that determines that the event is likely to present a possible financial loss to the Federal Government. All DoD Reportable Events (DoD REs) are PCEs. All events that trigger a PCE will also be referred to the Patient Safety Manager to ensure capture in the Joint Patient Safety Reporting (JPSR) system and investigation/analysis as defined in this volume.

(2) Intentional Unsafe Act. Any alleged or suspected act or omission of a healthcare provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves a criminal act, a purposefully unsafe act, patient abuse, or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, disciplinary system, or administrative investigation.

d. Harm and Assigning Harm to Adverse Events

(1) The assignment of a harm category allows a better understanding of the nature of harm when an adverse event occurs and facilitates trending and analysis for learning.

(2) Harm is any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury. (Reference (p)).

(3) The MHS has adopted the Agency for Healthcare Research and Quality's (AHRQ) Harm Scale to assign harm to PS events recorded in each of the JPSR system, the Global Trigger

Tool (GTT), and JCCQAS. The AHRQ Harm Scale can be found in the AHRQ Common Formats – Hospital Version 2.0 (Reference (q)), and includes the following assignment categories:

(a) No-Harm: Event reached the patient, but no harm was evident.

(b) Mild Harm: Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

(c) Moderate Harm: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

(d) Severe Harm: Bodily or psychological injury (including pain or disfigurement) that interferes substantially with functional ability or quality of life.

(e) Death.

(4) The harm scale defined by AHRQ Common Formats – Hospital Version 2.0, further delineates harm as:

(a) Temporary Harm. Expected to revert to approximately normal (i.e., patient's baseline).

(b) Permanent Harm. Not expected to revert to approximately normal (i.e., patient's baseline).

(5) It is important to note that harm scales can vary. To promote high reliability and MHS-wide learning, the MHS seeks to align and standardize its use of harm scales across all its electronic data systems, as well as to maintain the most prudent current version.

(6) Different tasks require different tools. In the context of events known as DoD REs, it is important to be cognizant of The Joint Commission's (TJC) classification of harm. (See Paragraph 2.e.(3) for further guidance.)

(7) While all PS events that both reach the patient (i.e., adverse events and no-harm events) and don't reach the patient (i.e., near miss events and unsafe/hazardous conditions) must be reported in JPSR, DoD REs have additional reporting and notification requirements. (See Paragraph 2.e. for further guidance.)

e. <u>DoD Reportable Events (DoD REs)</u>

(1) A DoD RE is any patient safety (PS) event resulting in death, permanent harm, or severe temporary harm, as per the AHRQ Harm Scale; or meeting The Joint Commission's

(TJC) sentinel event (SE) (Reference (r)) or the National Quality Forum's (NQF) serious reportable event (SRE) (Reference (p)) definitions. DoD REs require a Comprehensive Systematic Analysis (CSA) and follow on Corrective Action Implementation (CAI) Plan Report.

(2) DoD REs are events not primarily related to the natural course of the patient's illness or underlying condition and could include events identified by the Office of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) or DHA leadership in alignment with MHS strategic initiatives.

(3) As stated in Paragraph 2.e.(1), DoD REs include TJC's SE (Reference (r)) and the NQF's SRE (Reference (p)) definitions. It is important to note TJC's SE definition includes severe temporary harm: critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. Recognize that TJC categorizes some event types as SEs regardless of the magnitude of the outcome and must be reported as DoD REs.

(4) All DoD REs require mandatory reporting to ASD(HA)/DHA leadership through the DoD PSP. See Appendix for a list of DoD REs. Note that this list may change based upon organizational focus.

(5) All DoD REs are PCEs and require referral and collaboration with HRM.

f. Comprehensive Systematic Analysis (CSA). CSA is a thorough, credible, and acceptable analysis following a patient safety (PS) event that seeks to identify system vulnerabilities so that they can be eliminated or mitigated in a sustainable manner to prevent reoccurrence. A root cause analysis (RCA) is one type of CSA. CSAs can also be conducted for performance improvement purposes for those events that have the potential to be catastrophic (Reference (s)). The following guidelines support the identification of casual factors in CSAs:

(1) Clearly show cause and effect relationships.

(2) Use specifics and accurate descriptions of events.

(3) Human errors must have a preceding cause.

(4) Violations in procedure must have a proceeding cause.

(5) Failure to act is only causal when there is a pre-existing duty to act.

g. Corrective Action Implementation (CAI) Plan Report. The CAI Plan Report describes the effectiveness of the corrective action after implementation. The CAI Plan Report should include identified solutions, corrective actions implemented, and measures of effectiveness and sustainment to show that a corrective action has been implemented and is reducing or eliminating the risk of reoccurrence in a lasting way.

h. Proactive Risk Assessment (PRA). Process used to identify, rate, and prioritize risks and/or hazards. Based on a risk assessment, policies, procedures and controls may be put into place to manage the risk as appropriate to the organization, with the intent of reducing risk to the lowest possible level. A form of PRA is Failure Mode Effect Analysis (FMEA): a systematic, proactive method for evaluating a process to identify where and how it might fail, to assess the relative impact of different failures, and to identify the parts of the process that are most in need of change.

3. GOVERNANCE STRUCTURE. The DoD PSP is managed out of the CQM Branch in the Clinical Support Division under the Deputy Assistant Director for Medical Affairs (DAD MA) within the DHA. The Chief of the DoD PSP manages program operations in collaboration with the Patient Safety Improvement Collaborative (PSIC) and Infection Prevention and Control Working Group (IPCWG).

a. The PSIC is chaired by the Chief of the DoD PSP and may include representatives from the Services, DHA Markets, the TRICARE Health Plan, and United States Transportation Command (USTRANSCOM). The purpose of the PSIC is to develop, promote, and support a comprehensively aligned DoD PSP.

b. The IPCWG is administratively aligned under the DoD PSP. In addition to providing direction and guidance, it monitors and evaluates compliance and clinical quality improvement of MHS infection prevention and control activities.

4. SCOPE AND CORE RESPONSIBILITIES

a. The DoD PSP is a comprehensive program to eliminate patient harm and promote a PS culture across the MHS continuum of care and various healthcare settings. This is accomplished through a collaborative, multidisciplinary, and systems-based approach emphasizing data-driven, continual improvement. The DoD PSP includes Infection Prevention and Control (IPC), and shares educational and training information through the Patient Safety Learning Center (PSLC).

b. The DoD PSP will be implemented in every MTF as a dedicated program to reduce harm due to medical errors and improve PS that is focused on prevention by improving medical systems and processes to mitigate preventable errors. The administration of the PSP at the MTF must be through an MTF PS or MTF CQM program. The MTF PSP, with its emphasis on process and system design, must be an integral part of the risk reduction and performance improvement efforts of the MTF, and must function as an integral part of the CQM of the MTF.

c. Within CQM, the DoD PSP collaborates with the Healthcare Risk Management (HRM), Credentialing and Privileging (CP), Accreditation and Compliance (AC), Clinical Measurement (CM), and Clinical Quality Improvement (CQI) programs to improve care for beneficiaries. The PSP collaborates with the MHS Clinical Communities and other divisions and offices within the DHA by providing PS and process improvement data and analysis, lessons learned, and updates regarding nationally recognized PS and quality organizations. The DoD PSP also collaborates

with the Deputy Assistant Director for Healthcare Operations/TRICARE Health Plan Division, the Military Departments, and other federal and non-federal agencies to ensure alignment with the MHS strategic goals and values of the Quadruple Aim, to include:

(1) USTRANSCOM. The DoD PSP collaborates with the DoD Patient Movement Program in support of PS and quality of care for the movement of patients across the MHS continuum and enterprise healthcare settings. The operational patient movement safety program executes Reference (t), and USTRANSCOM standard operating procedures. The regulating TRANSCOM Patient Movement Requirements Center is available as a resource for patient preparation concerns (Reference (t)).

(2) DHA Assistant Director for Combat Support (AD CS)/Medical Logistics Division (MEDLOG). The DoD PSP collaborates with the Logistics community participating in the Hazards, Alerts, and Recalls Notice System (HAR-NESS) to ensure medical product, tissue, and device safety (Reference (u), Reference (v), and Reference (w)).

(3) Uniformed Services University (USU). The Patient Safety Quality Academic Collaborative (PSQAC) at USU is responsible for the development, execution, and ongoing supervision of rigorous scientific research and integration into medical education and graduate-level activities in direct support of the DoD PSP and other CQM objectives.

(4) U.S. Department of Veterans Affairs (VA). The DoD PSP collaborates with the VA National Center for Patient Safety to share trending safety information, alerts, and advisories, and develop action plans and other tools and systems designed to reduce patient harm due to medical errors and enhance PS.

d. Core Responsibilities

(1) DHA Headquarters PSP (DoD PSP) will:

(a) Provide direction and guidance, and monitor and evaluate compliance, and CQI of DoD PSP activities.

(b) Address potential PS concerns and inform senior leadership.

(c) Maintain centralized reporting structures, tools, and processes, to include reporting to the Office of the ASD(HA).

(d) Manage event investigation process.

(e) Measure PS to improve patient outcomes.

(f) Utilize data to guide and drive change.

(g) Build PS workforce capabilities.

(h) Equip teams for safe care practices.

(i) Support MHS-wide improvements.

(j) Serve as PS advisors and consultants for the MHS.

(k) Serve as enabling expertise for Clinical Communities and work groups.

(l) Provide PS consultation on Health Information Technology (HIT)-related safety events.

(m) Support, facilitate, and enhance continuous performance improvement in IPC.

(n) Design, develop, and disseminate PS resources.

(2) DHA Market/Intermediate Headquarters PSPs, in support of MTFs/subordinate organizations, will:

(a) Participate fully in the DoD PSP including initiatives to promote the objectives of the program.

(b) Monitor for appropriate/inappropriate use of information in accordance with Reference (x).

(c) Provide interpretation of this manual, and implementation guidance to the field.

(d) Make recommendations for improvement efforts for safe care practices.

(e) Serve as a resource by providing consultation on all PS matters and training opportunities.

(f) Receive, review, monitor, and manage performance for reporting requirements to the DoD PSP of JPSR, DoD RE Notifications, CSA and CAI Plan Reports, PRAs, and Annual PS Plans.

(g) Consolidate reports and submit regularly to centralized DoD PSP repositories.

(h) Provide consultation on performance management for all deliverables.

(i) Abstract, analyze, and trend data to identify system issues, and provide feedback on system issues identified and recommendations for changes.

(j) Regularly meet with the PS community for informed dissemination of PS-related information.

(k) Communicate findings to the field through data visualization tools and publications on a routine basis.

(3) MTF Director/Military Department Designee will:

(a) Establish and implement a PSP consistent with this manual.

(b) Designate an individual as the Patient Safety Manager (PSM) to implement this program who meets DHA competency requirements and is an integral part of the executive administrative team. There is no limitation on titles used for the PS professional; examples of terms include: PSM, patient safety specialist, patient safety coordinator, patient safety analyst, and patient safety officer. Where resources permit, the PSM and Healthcare Risk Manager should not be the same person to preclude organizational conflicts of interest.

(c) Report, investigate, and forward all DoD REs to the DoD PSP through respective DHA Market/Intermediate Headquarters.

(4) PSM will:

(a) Develop, implement, and assess the organization's PS plan by collaborating with leadership and staff to ensure PS initiatives effectively address identified risks within the organization. This includes devising strategies to enlist medical staff, employee, and patient/family input into the PS plan annually approved by leadership.

(b) Support a culture of safety fostering trust, transparency, teamwork, and communication through reporting PS events; focusing on process improvement rather than individual blame and encouraging a systems approach to improve healthcare processes.

(c) Coordinate and collaborate with the executive leadership, the HRM Program, IPC, and others as necessary.

(d) Serve as the organizational liaison for PS to the DHA Market/Intermediate Headquarters. Ensure compliance with required PS events, DoD REs, and events reportable to accrediting organizations (AOs). This includes ensuring appropriate investigations; CSAs, including development and implementation of corrective action plans; CAI Plan Reports; and PRAs.

(e) Take necessary action as a result of any PS event to ensure staff and patients are safe.

(f) Provide key members of local executive leadership of the facts and recommendations of the result of the investigation of DoD REs and PS events, and provide updates through closure of the investigation of each event.

(g) Serve as a consultant and advisor to the local executive leadership on PS issues and concerns.

(h) Prepare trend analysis reports of local PS outcomes.

(i) Facilitate the utilization of JPSR and other PS data in performance improvement initiatives.

(j) Prepare and present briefings on PS and outcomes improvement to all levels of organizational personnel.

(k) Support integrating team-based practices into daily work, to include training, implementation, and evaluation of Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™) (Reference (y)), which may be supplemented by other tools that advance reliable, safe care.

(l) Facilitate development of PS/CQI projects to continuously improve healthcare delivery and outcomes for beneficiaries.

(m) Conduct an annual assessment of the adequacy of organization-wide PS activities, policies, and procedures to ensure program effectiveness and compliance.

(n) Provide expertise, training, and guidance to staff members in the areas of PS principles, PRA, DoD RE reporting, CSA using RCA methodology (Reference (s)), and data analysis review.

(o) Monitor and ensure compliance with National Patient Safety Goals and all applicable regulatory patient safety standards.

5. PROCEDURES

a. Managing PS Events. By using data, knowledge management tools, and established resources, the DoD PSP can develop actionable improvement steps that support the goal of achieving zero preventable harm. PS event reports are collected through various methods to include: 1) anonymous, self-reported PS events through JPSR, and 2) harm surveillance data using the GTT methodology, and 3) administrative data related to patient harms collected through other programs. In addition, various tools are utilized to extract risk factors contributing to errors and to develop strategies to mitigate the risks. These tools include: 1) CSA reports, 2) CAI Plan Reports, 3) PRAs, and 4) other focused efforts directed toward specific types of events. Collection of data allows for the identification, investigation, analyses, reporting, and learning from PS events and is instrumental in ensuring the sustainment of a safe patient environment. This information, along with culture survey results, is used for establishing strategies to address process failures and mitigate risks in the system.

(1) Identification, Documentation, and Management of PS Events

(a) MHS Event Reporting System (currently JPSR). JPSR is the DoD electronic system used to capture data for all types of PS events in MTFs and other applicable healthcare

environments, as well as PS events identified in other quality data programs to promote a comprehensive and accurate view of PS events across the MHS. The PSM is responsible for JPSR data management, the review of facts associated with the PS event, and for ensuring an appropriate evaluation is performed as required per this manual. JPSR usage is the only authorized method for the reporting of adverse events, no-harm events, near miss events, and unsafe/hazardous conditions. Individual MTF/organizational developed applications are not authorized.

1. All PS events (adverse events, no-harm events, near miss events, or unsafe/hazardous conditions) must be reported to JPSR as soon as practicable.

2. Immediate action must be taken to make sure all affected, or potentially affected patients and staff are protected from additional injury and to minimize the effects of the event.

(b) JPSR consists of three major processes and forms: PS event reporting form, investigation and analysis form, and aggregation and reports design/development.

1. All Common Access Card (CAC) authenticated users can access and are expected to report PS events in JPSR. JPSR allows the reporter to self-identify or report anonymously. The staff member who identified the event will complete the electronic PS event reporting form. This form must be completed and submitted in one sitting due to system requirements associated with the anonymous reporting capability.

2. The investigation and analysis form will be completed by the PSM or assigned staff. This form allows the PSM to assess the event, assign a handler and investigators if needed, and complete an analysis of the PS event.

3. The roles of handler and investigator and the development of aggregation and trending reports are controlled by role-based security authorized by the PSM.

4. JPSR allows a reporter to report multiple occurrences of the identical PS event using the information from one JPSR event report (e.g., medication error where the same medication was administered three times before error identification). The Number of Times Occurred (NOTO) field in JPSR supports this capability.

a. The NOTO field must not be used to report multiple events reaching multiple patients.

b. An individual JPSR report must be prepared for each occurrence of the event.

c. To use the NOTO functionality, the reporter of the multiple occurrences of the identical PS event fills out the report and indicates the number of occurrences observed in the

NOTO field. Then, during the PS investigation of the event the PSM must use the copy functionality for each occurrence so that the magnitude (number) of the event is accurately captured in JPSR.

d. Likewise, if the NOTO field is used to report multiple occurrences of the identical PS event involving the same patient, the PSM must use the copy functionality for each occurrence so the magnitude (number) of the event is accurately captured in JPSR.

(2) Review and Classification of a PS Event (Adverse Event, No-Harm Event, Near Miss Event, or Unsafe/Hazardous Condition)

(a) Documentation. JPSR is the electronic system used to capture data for all types of PS events which occur in the DoD (where practicable), as well as safety events tracked and trended in other programs such as those in designated national data bases.

1. The specific type of event will determine the additional documentation that is required and the responsible point of contact (POC) for follow-up action. For example, the initial event may require action and/or documentation by PS, HRM, CP or be referred to criminal investigation services. A combination may be required.

2. A DHA approved alternative hard copy documentation method may be used only if JPSR is not available for documenting the PS event. (See the PSLC Portal for the JPSR Offline Report Form: https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/Home.aspx.) This written document provides concise, factual, objective, and complete details about the event. The hard copy documentation method will not be included in patient medical or dental records; it will not be duplicated or maintained at the department or service level. The alternate hard copy document shall be marked with the 10 U.S.C. 1102 Medical Quality Assurance Program (MQAP) information marker. (See Paragraph 5.c.(5) for further guidance.)

3. If the JPSR Offline Report Form is used, the data collected will be entered into JPSR within 72 hours; thereafter, the hard copy may be destroyed, or it may be uploaded to JPSR as a PDF document and the original destroyed.

4. JPSR events must not be printed and held within user files.

(b) PS Event Review. Submission into the JPSR serves as the initial report of an event that requires investigation, detailed documentation, tracking, and trending.

1. Immediate action must be taken to make sure patients are protected from additional injury, or potential for injury, and to minimize the effects of the event.

2. The PSM routes PS event reports to the Chief of the Medical Staff and other appropriate individuals within the organization for further action. The PSM notifies the Healthcare Risk Manager for assessment of all PS events that reach the patient (adverse events and no-harm events). PS event reports include review of associated facts, evaluation as required

by this manual, and assignment of harm based upon the DHA approved harm scale and the Probability/Severity Matrix for all PS events. Information on the event should be finalized in at least 80 percent of patient safety reports (PSRs) within 30 calendar days of the event report date.

3. All PS events require assessment and action. The PSM will actively and regularly review all events reported within JPSR to identify risks or potential problem areas for focus. The ultimate goal of reporting is to prevent harm.

4. If the event meets DoD RE criteria, a CSA is required.

5. For adverse events that do not meet DoD RE criteria, further action may be considered according to their Risk Assessment Grade (RAG) as determined by the Probability/Severity matrix in JPSR. The Probability/Severity Matrix is a useful way to assign priority to events based upon their risk (Reference (s)). The Probability/Severity Matrix must be used for all PS events. CSAs are strongly encouraged, along with implementation of a corrective action plan, for events with a RAG scored as high.

6. PSMs are encouraged, but not required, to conduct CSAs on other adverse, no-harm, and near miss events. PSMs are required to conduct CSAs as directed by leadership.

7. All CSAs are to be submitted in the DHA approved format to DHA Market/Intermediate Headquarters personnel for review and organizational learning.

8. An aggregate review and analysis may be performed quarterly for more common non-DoD RE event types that do not result in a RAG scored as high. The outcome should drive further action, if warranted. Aggregate review products should be shared with the DHA Market/Intermediate Headquarters and the DoD PSP for MHS-wide learning.

9. Similarly, for PS events that do not reach the patient (near miss events or unsafe/hazardous conditions), the decision may be to track, trend and complete an aggregate review and analysis. The outcome should drive further action, if warranted.

10. If the event involves physical safety issues, hazardous environment of care conditions or staff, the event response will be coordinated with the Senior Administrator and the Facility Manager for a multidisciplinary response.

11. Closure of PSRs will be monitored with the goal of 80 percent for closure within 30 calendar days of the PS event reported date. PSRs more than 30 calendar days old will be monitored weekly by the PSM.

12. Timely closure of PSRs will be tracked by the PSM and DHA Market/Intermediate Headquarters personnel.

(c) Adverse Drug Reactions. PS events caused by an adverse drug reaction will be reported using JPSR. These events require investigation by pharmacy personnel to determine if the event should be reported to the Food and Drug Administration (FDA). Adverse drug

reactions that are determined to be significant by the local Pharmacy and Therapeutic Committee will be reported to the FDA. Adverse drug reactions will be centrally monitored to generate complete statistical data necessary to make effective recommendations.

(d) PCE. A PCE is any PS event that both a) reaches the patient (i.e., adverse event and no-harm event), and b) has a Healthcare Risk Management assessment that determines that the event is likely to present a possible financial loss to the Federal Government (to include but not limited to a medical tort claim, an active duty disability payment, or an active duty death payment). All DoD Reportable Events (DoD REs) are PCEs. All events that trigger a PCE will also be referred to the PSM to ensure capture in JPSR and investigation/analysis as defined in this volume, to include PCEs that do not meet the definition of a DoD RE. PCEs referred to PS must include identification as to whether or not the PCE is also a DoD RE, and the harm scale category and type of event (using the taxonomy established in Reference (q)). PS event investigations and their products are protected in accordance with Reference (x) are not utilized for administrative or punitive purposes. While information cannot be shared between ongoing HRM and PS investigations, following completion of both investigations, system and process findings will be shared for organizational learning.

(e) Intentional Unsafe Acts. If, in the course of the activities of the DoD PSP, information about intentional unsafe acts is revealed, the original report shall be referred to the appropriate command authority and MTF Director. The investigation and consideration of intentional unsafe acts are under the authority, direction, and control of the command authority for purposes of personnel standards and conduct, while the investigation and consideration of the intentional unsafe act for purposes of assessing the impact on healthcare is under the authority, direction, and control of the MTF Director (Commander where appropriate). The PSM will proceed with a review of facility systems and processes implicated in the actual or potential intentional unsafe act but defers to the separate investigation consideration with respect to any matter of culpability of any person involved in the act. The PSM will notify the Healthcare Risk Manager of any concern for intentional unsafe acts by a healthcare provider, for possible reporting requirements. (See Volume 3 of this manual for further guidance.)

(f) Information Concerning Clinical Competence. If professional competency is questioned or the PS event is identified as a PCE, the team leader will forward the PS event to HRM for the PCE review. (See Volume 3 of this manual for further guidance.) If, during the course of a CSA, the competence of an individual involved in the PS event is in question, the team will also determine if the healthcare system provided every opportunity for the individual to succeed. It is crucial to identify process or system obstacles that may have affected a patient outcome.

(g) Criminal Investigative Service (CIS) and Command Investigations. Allegations involving professional misconduct may also arise during the investigation of a PS event. Allegations of professional misconduct will become the subject of a CIS or command criminal investigation. The PS investigation should not conflict or interfere with these investigations; this may result in the PS investigation being delayed pending the completion of the CIS or command criminal investigation. The Privileging Authority, or Investigating Office (IO), should

coordinate through the servicing healthcare legal counsel with the assigned CIS agent or command IO to determine when the criminal investigation is completed, and the PS investigation can resume.

(h) Peer Support Program. Leaders recognize that conscientious healthcare workers who are involved in DoD REs are themselves victims and require support. To that end, the Healthcare Resolutions Program, as described in Volume 1 of this manual, shall be made available to the staff involved along with any additional help and resources as needed.

(i) Disclosure. All factual medical data related to a PS event that reaches the patient (i.e., adverse event or no-harm event) will be entered in the patient's electronic medical or dental record. The entry should describe in detail exactly what occurred, any evidence of injury and the immediate action(s) initiated in response to the event. In addition, all the facts surrounding the adverse event or no-harm event must be fully disclosed to the patient/family member without attribution of blame or fault and must be at a time and in a language and terms that are readily understood by the patient and family. The annotation in the medical/dental record will neither conclude that an adverse event or no harm event occurred (use those specific terms), nor will it indicate that a PSR (which is protected in accordance with Reference (x)) was completed.

b. Management of DoD REs

(1) Knowledge gained from reporting and managing DoD REs helps in learning from those events and improve safety across the MHS through knowledge sharing.

(2) A DoD RE is any PS event resulting in death, permanent harm, or severe temporary harm, as per the AHRQ Harm Scale; or meeting The Joint Commission's (TJC) sentinel event (SE) (Reference (r)) or the National Quality Forum's (NQF) serious reportable event (SRE) (Reference (p)) definitions. DoD REs require a Comprehensive Systematic Analysis (CSA) and follow on Corrective Action Implementation (CAI) Plan Report.

(3) All DoD REs require mandatory reporting to ASD(HA)/DHA leadership through the DoD PSP. See Appendix for a list of DoD REs. Note that this list may change based upon organizational focus.

(4) As stated in Paragraph 2.e.(1), DoD REs include TJC's SE (Reference (r)) and the NQF's SRE (Reference (p)) definitions. It is important to note TJC's SE definition includes severe temporary harm: critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. Recognize that TJC categorizes some event types as SEs regardless of outcome and must be reported as DoD REs.

(5) All DoD REs are PCEs and require referral and collaboration with HRM.

c. CSA

(1) Overview. For PS events, a CSA is used to identify the root cause(s), causal and contributing factors that underlie variation in process or system performance including the occurrence or possible occurrence of a DoD RE. The CSA process provides a way to identify breakdowns in processes and systems that contributed to the event and how to prevent future events. The intention of the investigation is to find out what happened, why it happened, and determine what changes need to be made to improve performance.

(a) The product of a CSA is a corrective action plan to implement and sustain corrective measures to prevent or eliminate future harm. The corrective action plan should include the following elements (References (s) and (z)):

1. Corrective actions to eliminate or control system hazards or vulnerabilities related to causal and contributing factors

2. Identify who is responsible for implementation

3. Identify wherever possible at least one strong or intermediate strength corrective action

4. Timeline for completion

5. Strategies for evaluating the measurable effectiveness of actions and sustaining change

(b) As part of the CSA, the corrective action plan should be developed in anticipation of measuring improvement/sustainment in the required 4-month CAI Plan Report. Effectiveness/sustainment measures are quantifiable metrics, typically with a numerator and a denominator that identify whether a planned corrective action was effective at controlling or eliminating system vulnerabilities and that its effectiveness was sustained over time. Sentinel Event Measures of Success (SE MOS) are identical to the measures expected in corrective action plans and CAI Plan Reports and may be used in a CAI Plan Report whenever SE MOS are required for AO reporting. If the AO does not require SE MOS, a report identifying the status of all identified corrective actions, including an evaluation of effectiveness and sustainment, is still due to DoD PSP within the reporting period. This assessment forms the basis for further actions taken with improvement efforts.

(c) All DoD REs will have a thorough and structured CSA conducted to ensure quality healthcare is consistently delivered across the MHS for all its beneficiaries. RCA is one type of CSA (Reference (s)).

(d) The focus of these investigations is on breakdowns in systems and processes, not individual performance. The process should seek underlying system vulnerabilities that were manifest in personnel-related performance issues. This is done in a non-punitive interdisciplinary environment (Reference (s)).

(2) Required Performance of a CSA. CSAs will be completed on all DoD REs. Additionally, CSAs are encouraged for any adverse event that does not meet DoD RE criteria, but results in a RAG of high, based upon the Severity/Probability Matrix in JPSR. CSAs may also be appropriate for adverse events of lesser severity, no-harm and near miss events, or when there is a potential for a future catastrophic event. Where policy guidance does not exist, the decision to complete a CSA will be at the discretion of the MTF Director/Commander with guidance from their DHA Market/Intermediate Headquarters. All CSAs must be submitted to the DoD PSP for organizational learning.

(3) Actions

(a) DHA Market/Intermediate Headquarters will:

1. Create and send notification using the DHA approved standardized DoD RE form. (See the Patient Safety Learning Center (PSLC) Portal for the DoD RE Form: https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/Home.aspx.) The DHA Market/Intermediate Headquarters will forward this DoD RE form to the DoD PSP within 24 hours of being notified of the event, or the next business day. DoD REs must also be reported to AOs as appropriate.

2. Provide additional CSA references and tools as needed.

3. Provide the PSM with recommendations that will improve the CSA overall clinical and administrative quality.

4. Collect and analyze CSA data to include leading practices and current trends. Communicate findings to the field and the DoD PSP on a routine basis.

5. Before submitting to the DoD PSP, ensure that all documentation and information associated with the CSA is identified as protected Medical Quality Assurance Program (MQAP) information in accordance with Reference (x). Additionally, make certain that all identifiable information (protected health information, personally identifiable information, and provider information) is redacted from the documentation.

6. Review all CSAs to ensure they are thorough and credible, that corrective actions are measurable and appropriate, that at least one strong or intermediate strength corrective action is identified (Reference (s)), and that CSAs are in the designated proper format.

7. Review all CAI Plan Reports to ensure that corrective actions were effective and sustained.

8. Review all CSAs that are ready for submittal to the approved AO that do not have any causal factors found prior to submission to the approved AO.

9. Provide consultation for the CSA process.

10. Notify the DoD PSP of extension(s) and revised due dates for CSAs.

(b) MTF Directors/Commanders and the PSM will report, investigate, and submit all DoD REs to their respective DHA Market/Intermediate Headquarters.

(4) Maintenance of CSA Proficiency. MTF Directors/Commanders are encouraged to ensure at least one CSA is completed in every 12-month period for maintenance of knowledge and skill proficiency in completing CSAs.

(5) Use of PS CSA Data. The DOD internally uses PS CSA data to improve healthcare systems and processes that impact quality and PS. The goal of the DoD PSP is to prevent injuries to patients, visitors, and personnel and to minimize the negative consequences of injuries that do occur. This is accomplished through the identification, reporting, and intensive analysis of PS events for use in CQI. In cases where possible administrative or disciplinary action could result, leadership should conduct two separate and independent investigations. CSA information is confidential and protected in accordance with Reference (x). Except as specifically authorized by instruction, DoD PSP records or information shall not be disclosed unless authorized by Reference (x), required by applicable authority, or authorized by ASD(HA). CSA information is NOT releasable to patients or patients' legally authorized representatives. CSA information is NOT to be included in patients' medical records. All CSA information shall be designated as such using the following wording placed in the footer of the documents:

Medical Quality Assurance Program document, protected pursuant to 10 U.S.C. 1102. Copies of this document, enclosures thereto and information therefrom will only be released in accordance with the law.

(6) Reporting, Deliverables, and Timeline

(a) MTF Directors/Commanders will ensure notification of DHA Market/ Intermediate Headquarters personnel of a DoD RE within 24 hours of determining that a PS event is a DoD RE. In turn, the DHA Market/Intermediate Headquarters will notify the DoD PSP within 24 hours of receiving notification of a DoD RE, or the next business day.

(b) All DoD REs require that a completed CSA be submitted to the DoD PSP within 90 calendar days of the date of the PSM determination that a PS event is a DoD RE. All CSAs and CAI Plan Reports will be forwarded by the DHA Market/Intermediate Headquarters to the DoD PSP for MHS-wide learning.

(c) Extensions for submitting the CSA may be granted in rare exceptions by the DHA Market/Intermediate Headquarters.

(d) Following implementation of corrective actions, a CAI Plan Report will be submitted to the respective DHA Market/Intermediate Headquarters to ensure that implemented

corrective actions were effective and that mitigations are sustained. CAI Plan Reports may be equivalent to the AO required follow-up reports. CAI Plan Reports must then be forwarded by the DHA Market/Intermediate Headquarters to the DoD PSP following all CSAs.

(e) For DoD REs which involve care received at other MTFs/organizations, regardless of DHA Market/Intermediate Headquarters, the leadership and PSMs at the involved facilities will participate in and ensure a credible and thorough CSA is conducted through mutual cooperation and shared findings.

(7) AO Reporting, Deliverables and Timeline. In addition to reporting DoD REs to MHS leadership through respective DHA Market/Intermediate Headquarters and the DoD PSP, all DoD REs that meet AO definitions as reportable and occurring in MTFs accredited by the AO, must be reported by the MTF Director/Commander or PSM to the AO.

(a) All AO accredited MTFs will notify the respective DHA Market/Intermediate Headquarters and the AO of the DoD RE within 24 hours of determining that a PS event is a DoD RE. The completed CSA, consistent with AO policy and time limits, shall be made available to the AO with a copy simultaneously forwarded to the respective DHA Market/Intermediate Headquarters and the DoD PSP for MHS-wide learning.

(b) MTFs accredited by the AO will complete CSAs on all AO reviewable DoD REs, within 45 business days of the MTF becoming aware of the DoD RE.

(c) Extensions for submitting CSAs to the AO may be granted by the AO in coordination with the DHA Market/Intermediate Headquarters but will not ordinarily exceed 90 calendar days. The DHA Market/Intermediate Headquarters will inform the DoD PSP when an extension has been granted.

(d) A follow-up report (e.g., SE MOS) to the AO in response to the intervention(s) listed in the CSA may be required by the AO to indicate whether a planned action was effective or sustained. This report would meet the MTF's requirement for a CAI Plan Report to the DHA Market/Intermediate Headquarters. Lack of an AO requirement for follow up effectiveness reporting for any given CSA does not negate the DoD requirement for CAI Plan Reporting. MTFs must follow their AO's policy.

(8) CSA Process

(a) The CSA Team. The CSA team will be comprised of clinical leaders and subject matter experts (SMEs) to review the processes and systems surrounding the event. The team membership will vary according to the type of event analyzed with the team's goal to complete a thorough and credible interdisciplinary corrective action plan. It is generally recommended to keep the core team to a small number (three or five) with additional ad hoc members as needed. The patients, patients' family members, or patients' legally authorized representatives are not appropriate members of the CSA team.

(b) MTF/Leadership CSA Briefing. The team shall formally brief the MTF Director/Commander and senior leadership upon completion and obtain written approval of the CSA. This briefing provides the MTF Director/Commander and other leadership the opportunity to interact with the CSA team for clarification and necessary changes.

(c) CSA Documentation. The completed CSA must be submitted in the DHA designated format to the DHA Market/Intermediate Headquarters. A completed CSA will include the following:

1. A signed cover letter by the MTF Director/Commander to the DHA Market/Intermediate Headquarters, or the names of the AOs to include: The AO identifier for the event, the type of event, the MTF Director's/Commander's POC with e-mail and phone number, and MTF Director's/Commander's signature. The letter will be marked as MQAP information with prohibition against re-disclosure.

2. Description of the DoD RE

3. Description of the investigation

4. Corrective Actions Overview – Utilize the VA Action Hierarchy to develop strong corrective actions (Reference (s)).

5. Corrective Actions by Causal Factor

6. Corrective Action Plan – Identify factors of a CSA that may have caused or contributed to a PS event. Within the CSA, the action plan should result in identifying solutions and corrective action recommendations that will be implemented by the facility in order to reduce the risk of reoccurrence. Corrective actions should be measurable and appropriate, and each report should identify at least one strong or intermediate strength corrective action.

(9) CSA/CAI Plan Report Submission

(a) The completed CSA will be submitted to the DHA Market/Intermediate Headquarters within 45 business days of initial notification to the DHA Market/Intermediate Headquarters of the DoD RE, unless extension has been approved. In addition, the CAI Plan Report on the effectiveness and sustainment of actions taken following a 4-month CAI period, will be forwarded to the DHA Market/Intermediate Headquarters within 30 calendar days following closure of the CAI period.

(b) Redacted and de-identified CSAs, as per Volume 1, will be submitted to the DoD PSP within 90 calendar days of the initial notification of the DoD RE to the DHA Market/Intermediate Headquarters. The DHA Markets/Intermediate Headquarters will forward the CAI Plan Report to the DoD PSP within 14 calendar days from receiving the report, as well as any subsequent corrective action monitoring. The data provided must not contain any

identifying information related to the patient(s) or the individual healthcare provider(s). The DoD RE identification will be included on the submitted CSA. These copies must be maintained as protected MQAR in accordance with Reference (x).

(c) Copies of additional updates or changes to the CSA (such as those required by the AO or DHA Markets/Intermediate Headquarters) will be forwarded to the DoD PSP within 90 calendar days of the initial notification of the DoD RE.

(d) The DoD PSP will conduct a review of all CSAs and provide timely feedback to the DHA Market/Intermediate Headquarters within 14 business days for improvement.

(e) The DoD PSP develops and maintains tools for the administrative tracking and performance management of reporting requirements. The CSA Progress Tracker tool allows tracking of DoD RE notifications, CSA packages, CAI Plan Reports, as well as PRAs and clinical improvement CSAs. The tool allows data validations between the DoD PSP and the DHA Market/Intermediate Headquarters. The DHA Market/Intermediate Headquarters will:

1. Monitor submission of DoD RE notifications and other DoD policy compliance with respect to timely submission of CSA packages and CAI Plan Report via the CSA Progress Tracker tool.

2. Confirm, at least on a monthly basis, that all required elements of data submitted (e.g., MTF name, DoD RE type, date of occurrence, date of discovery, date of reporting, patient demographics) are correctly reflected in the CSA Progress Tracker tool and to monitor and track of other PS reports/data submitted (e.g., PRAs and clinical improvement CSAs).

3. Verify that the DoD RE notifications submitted were appropriately received by the DoD PSP since the last reconciliation.

4. Verify pending CSAs and their associated due dates.

5. Verify pending CAI Plan Report and their associated due dates.

6. Confirm the correct JPSR numbers associated with DoD RE notifications.

7. Confirm open or closed status of JPSR events.

8. Send updates and corrections to DoD PSP.

(10) Notification. All DoD REs will be reported to the DoD PSP.

(a) Notification of a DoD RE must include the MTF/organization's name, the event type, date of occurrence, date of discovery, patient demographics (i.e., gender, age, beneficiary category, current clinical status of patient), and a brief event-facts synopsis. The notification

report must not include personal health information, personally identifiable information, or Health Insurance Portability and Accountability Act (HIPAA) information. Names or other identifying information on healthcare providers shall not be included.

(b) MTF Directors/Commanders will have five calendar days in which to determine if an event meets the requirements of the DoD RE. Once the event has been determined (discovered) a DoD RE, DHA Market/Intermediate Headquarters will be notified within 24 hours. All MTFs, regardless of accreditation status, will subsequently notify the AO and include: MTF name, DoD RE event type, date of occurrence, date of discovery, patient demographics (i.e., gender, age, beneficiary category, current clinical status of patient), and a brief event-facts synopsis). The MTF Director/Commander, or designee, will notify the DHA Market/Intermediate Headquarters of the AO due date for the CSA, including the DoD RE identification.

(c) DHA Market/Intermediate Headquarters will then notify DoD PSP within the next 24 hours or the next business day that a DoD RE has occurred. Within five business days of initial notification to the DoD PSP, the DHA Market/Intermediate Headquarters will submit the DoD RE report to include the JPSR and the CSA reference number.

(d) All DoD REs are to be considered potential PCEs, therefore the HRM Program will be notified of all DoD REs for an assessment. Notification must include the DoD RE report number/identifier, and the harm scale category and type of event using the established taxonomy.

d. External Patient Safety Investigation Teams

(1) External Patient Safety Investigation Teams execute rapid response investigations conducted to study DoD PS events worldwide. These investigations are non-punitive and intended to reveal systems-level vulnerabilities, identify strong actions to mitigate future risk, and inform MHS-wide PS improvements.

(2) The DoD PSP manages and administers the External Patient Safety Investigation process.

(a) External Patient Safety Investigations are DAD MA/Service Headquarters directed and may be conducted in response to triggers such as DoD REs or other PS events that align with strategic initiatives, actual or anticipated media attention, unanticipated death, or in response to event patterns and trends with consideration for systemic issues. Investigations may also be requested in coordination with the DHA Market/Intermediate Headquarters.

(b) In response to a qualifying trigger and after a determination by DAD MA/Service Headquarters leadership, a team will be identified and engage with the MTF Director/ Commander for any pre-work, on-site work and post-investigation work. Teams are deployed as directed by DAD MA/Service Headquarters leadership, usually within one week to 30 calendar days after deciding that an investigation is required and remain onsite for a short duration (typically two days to three weeks). Teams are to be supported and a primary POC will be identified to coordinate with the External Patient Safety Investigation Team lead.

(c) External Patient Safety Investigation Team composition includes expertise in investigation methodology, patient safety, human factors analysis, incident specific clinical subject matter expertise as well as DAD MA/Service Headquarters directed subject matter expertise. Local subject matter experts should participate in the investigation whenever feasible. Investigations will be conducted using DHA/Service Headquarters approved methodologies and tools.

(d) Investigative analysis includes reconstruction of an incident sequence, granular understanding of clinical process failures and latent vulnerabilities, human factors contributions, and corrective actions to mitigate future risk and inform future policy development. Following the completion of the investigation:

1. Findings will be briefed to the MTF Director/Commander prior to team departure and documented in a report, which incorporates system and process level findings, clinical lessons learned, recommended solutions, and actions to mitigate future risk, prevent errors and plans for sustainment.

2. Report findings will be briefed to DoD PSP and DHA Market/Intermediate Headquarters, and incident specific strategic communications will be utilized for sharing across the MHS to include relevant Clinical Communities and promote MHS-wide learning.

3. The MTF Director/Commander is responsible for implementation of corrective actions and will send a 4-month CAI Plan Report to respective DHA Market/Intermediate Headquarters, and Clinical Communities as appropriate.

4. Final reports will be securely archived in the Patient Safety Learning Center portal to enhance MHS knowledge sharing efforts.

e. Proactive Risk Assessment (PRA)

(1) Purpose. To proactively identify and reduce risk to the safety of patients by selecting a high-risk process to be analyzed on at least an 18-month basis (or as per the AO requirements). This PRA process is used to identify, rate, and prioritize risks and/or hazards. Based on this risk assessment, policies, procedures, and controls may be put into place to manage the risks as appropriate to the organization, with the intent of reducing them to the lowest possible level.

(2) Goal. The goal of performing risk assessments is to reduce the likelihood of or mitigate the impact of incidents or other negative experiences that have the potential to result in injury, accident, or other loss to patients, visitors, staff, or assets.

(3) Responsibilities

(a) DHA Market/Intermediate Headquarters will:

1. Send out notices with instructions for initiating the PRA project.

2. Provide consultation for topic selection, and answer questions as the process and gap analysis proceed.

3. Follow up with sites for late submissions.

4. Redact final PRA reports for submission to the DoD PSP.

(b) The MTF Director/Military Department Designee will provide direction for topic selection.

(c) PSM will facilitate the PRA process and provide current DoD PRA tools.

(4) Use of PRA Data. PRA data is used internally by the DoD for improving healthcare system and processes that impact quality and PS. In cases where possible administrative or disciplinary action could result, two separate and independent investigations will be conducted. PRA materials are confidential and protected in accordance with Reference (x).

(5) Requirement to Complete a PRA. PRAs will be completed on high-risk processes in accordance with requirements established by their AO and/or DHA Market/Intermediate Headquarters guidance. With regard to MTFs, this manual requires all MTFs to complete a PRA at a minimum of every 18 months or as required by the AO; if no accreditation requirement, MTFs follow the DHA minimum of every 18 months. Results of the PRA will be forwarded to DHA/Service Headquarters for review and evaluation.

(6) PRA Submission

(a) PRA topic selection with rationale and supporting baseline data must be submitted to the respective DHA Market/Intermediate Headquarters one third of the way into the PRA cycle. Submissions must be in the DHA designated format. Strong topics include those related to new or modified clinical or support services or processes, National Patient Safety Goals, recent AO findings, local/national event reporting data, local studies, customer complaints.

(b) Completed PRA analysis with corrective actions identified and scheduled for implementation will be submitted to the respective DHA Market/Intermediate Headquarters within 30 calendar days of completion. Submissions must be in the DHA designated format. This includes documentation of a developed process flow identifying and ranking potential failures. Corrective actions must have quantifiable measures for potential failures deemed most at risk.

(c) The PRA documentation must be finalized, to include follow-up evaluation of actions implemented and measures. The DHA Market/Intermediate Headquarters must forward all completed PRAs to the DoD PSP within 45 calendar days of receipt. The reporting MTF/organization will be fully identified and included on the PRA. Any requests for additional or clarifying information required from the MTF/organization by the DoD PSP will be coordinated through the DHA Market/Intermediate Headquarters staff.

(7) PRA Documentation. The PRA will include:

(a) Assessment of the intended and actual implementation of the process to identify the steps where there is, or may be, undesirable variation;

(b) Identification of the possible effects on patients and the seriousness of the possible effects for each identified variation;

(c) A risk assessment conducted for most critical variations that could or do occur with selected process;

(d) Redesign of the process and/or underlying system(s) to minimize the risk of the variation (failure mode) or to protect patients from the effects of the variation;

(e) Testing and implementation of the redesigned process;

(f) Identification and implementation of measures of the effectiveness of the redesigned process; and

(g) Implementation of strategy for maintaining effectiveness of the redesigned process over time.

f. Global Trigger Tool (GTT). The GTT is a standardized process for identifying harm that addresses concerns with the under-reporting of events inherent in self-reporting systems to more effectively target those clinical processes requiring improvement. In contrast to the JPSR, GTT identifies harm through retrospective chart review of events identified by triggers. GTT is utilized to augment self-reporting of safety events and allows a harm rate to be calculated for improvement monitoring. All designated MTFs will participate in the GTT program according to the prescribed methodology.

(1) DHA will provide central GTT abstraction, analysis, adjudication, and reporting.

(2) DHA Market/Intermediate Headquarters will:

(a) Review the reporting findings and trends;

(b) Hold assigned MTFs accountable for addressing identified findings and trends; and

(c) Notify higher headquarters of findings and trends within the respective DHA Market/Intermediate Headquarters.

(3) MTFs will:

(a) Ensure remote access to medical records identified for review;

(b) Identify a physician champion; and

(c) Report all confirmed adverse events identified by GTT into JPSR and to HRM for the PCE review process for appropriate investigation and analysis procedures identified in both Volume 2 and Volume 3.

(4) Physician champions will:

(a) Attend and participate in teleconferences as scheduled;

(b) Discuss findings with the appropriate MTF staff;

(c) Assist MTF leadership and PS in the implementation of harm reduction; and

(d) Review the reported findings and trends and report the findings to the appropriate Clinical Communities, leadership, and patient care areas identified within their MTF.

g. Alerts and Advisories. Alerts and advisories are targeted PS guidance documents published and shared by the DoD PSP to bring focused attention to emerging risks and hazards related to healthcare quality and PS. Guidance material is used as a communication tool that outlines precautionary measures to be taken by quality and safety professionals.

(1) The DoD PSP will:

(a) Monitor internal and external sources for emerging trends and patterns of concern;

(b) Develop guidance in collaboration with subject matter experts; and

(c) Disseminate publications through DHA Market/Intermediate Headquarters and post to PSLC.

(2) DHA Market/Intermediate Headquarters will:

(a) Monitor internal and external sources for emerging trends and forward to the DoD PSP for consideration and validation; and

(b) Provide consultation and subject matter expertise for product development. Disseminate publications to respective subordinate organizations.

(3) MTF Directors/Commanders, or their designees, will receive publications, implement recommended practices and precautions, and share with staff.

h. HAR-NESS. The DoD PSP collaborates with the DHA AD CS/MEDLOG by participating in the HAR-NESS process to ensure medical product, tissue, commodities and device safety. This is an interdisciplinary collaborative process to ensure closed loop

communication for critical level notices regarding product safety. The DoD PSP takes action in this process when patients have been or may have been exposed to identified materiel. Strategies are developed for patients impacted by the recall to mitigate additional harm, including: notification, clinical evaluation and intervention if necessary; documentation of all actions taken by involved staff; and communication to appropriate levels of MHS leadership of the efforts undertaken, patients potentially impacted and any harmful outcomes.

(1) DAD MA will:

(a) Coordinate with MEDLOG for management and administration all hazards, alerts and recall notices where patients have been affected and ensure all notices are handled appropriately.

(b) Require MHS-wide action be taken, depending on the number of patients affected or potentially affected in a recall. The DHA Office of General Counsel shall be consulted for advice regarding such notifications and/or mass mailings to patients.

(2) DoD PSP will:

(a) Collect, consolidate and report information on the recall from the DHA Market/Intermediate Headquarters to DAD MA and the Office of ASD(HA).

(b) Develop DoD PSP-specific alerts, reports or updates based on FDA Class I and critical PS recall data and submit to MEDLOG for dissemination through the approved alert tracker.

(3) DHA Market/Intermediate Headquarters will collect, consolidate, and report information on the recall and actions taken by the MTF Director/Commander, and applicable involved staff, to DoD PSP.

(4) MTF Director/Commander will:

(a) Ensure handling of the event by the PSM/designee and applicable clinical department/unit.

(b) Collect, consolidate, review, and approve the consolidated report and forward to the DHA Market/Intermediate Headquarters.

(5) PSM/Designee will:

(a) Subscribe to FDA Class I and approved tracker critical alerts.

(b) Coordinate with the Medical Unit Logistics Officer and Medical Unit Hazards, Alerts, and Recalls (HAR) Coordinator to obtain information regarding usage of the FDA Class I and critical priority-alerted product within the MTF/organization.

(c) Analyze impact to patient(s) and risk in cooperation with the clinical department/unit.

(d) Document potential effect to patient(s), the actions taken and report, as required, to the MTF Director/Commander in coordination with the clinical department/unit.

(6) The clinical department/unit where the materiel was used will:

(a) Assess impact of the exposure to patients, and to the clinical department/unit, caused by the hazardous materiel.

(b) Submit a JPSR documenting the PS event.

(c) When classifying an event in JPSR that involves an FDA-Class I or approved critical priority alerts, staff will use the event type, sub-type, and event detail that best describes the event.

1. If the event reached the patient, classify as adverse event or no-harm event, as appropriate.

2. In the event description, the staff must clearly write "INVOLVED A CRITICAL OR CLASS I RECALLED PRODUCT, DEVICE, or MEDICATION," and must include the approved alert tracker accession number.

(d) Provide a report to the PSM/designee outlining number of products in active inventory, documented action plan, and patients affected or potentially affected; number of affected/potentially affected patients contacted and not contacted if warranted; JPSR number, if applicable; and Work Order number obtained from Medical Maintenance, if applicable.

(e) Report, as required, to the MTF Director/Commander in coordination with the PSM/designee.

i. Health Information Technology (HIT)-related PS Events. The DoD PSP collaborates with the DHA Informatics and IT communities to ensure that MHS HIT is safe, implemented safely, used safely and ultimately used to improve PS. The DoD PSP provides enabling expertise and works to establish processes to provide actionable HIT-related PS data trends and analysis to stakeholders.

(1) DoD PSP will:

(a) Develop a strategy and plan for safe and effective use of HIT and apply established HIT PS leading practices and standards.

(b) Manage and execute a monitoring strategy for PS in MHS GENESIS implementation and the maintenance and sunsetting of legacy HIT electronic health record systems.

(c) Serve as DoD PSP liaison and POC to the DHA Office of the Chief Health Information Officer, and the Office of the Functional Champion for the DoD electronic medical record, to support safe use of HIT in both new and legacy systems.

(d) Serve as subject matter expert for HIT PS providing consultation and guidance to stakeholders. Develop briefs, presentations and standardized reports for information sharing and knowledge building based upon HIT-related PS event data and trends.

(e) Provide MHS-level reporting of related content for stakeholders.

(f) Monitor, trend and analyze data to identify critical HIT risks to PS.

(g) Develop and implement a standardized process for issuance of HIT PS-related alerts and advisories.

(h) Maintain internal collaborations with stakeholders (e.g., IT, Program Offices, functional communities), and with external federal and commercial partners.

(2) DHA Market/Intermediate Headquarters will:

(a) Provide consultation and process support and ensure execution.

(b) Monitor, track, and trend reported concerns of MTFs/organizations for which they are accountable.

(c) Collect, trend, and analyze data for reporting to the DoD PSP.

(d) Identify critical HIT risks for consideration of an MHS-wide alert/notification.

(e) Participate in the defined DoD PSP HIT PS alert/advisory process.

(3) PSMs will:

(a) Monitor JPSR daily and identify potential HIT-related PS events.

(b) Utilize the Probability/Severity Matrix for all PS events.

(c) Execute defined process steps in collaboration with local Informatics staff to capture and generate information and knowledge to be used locally, regionally, and as an organization.

(d) Share data through regular informatics meetings.

(e) Collect, trend, and analyze data for reporting to the MTF Director/Commander and DHA Market/ Intermediate Headquarters.

j. Supporting a Learning Organization. The DoD PSP sustains the healthcare learning organization by sharing safety-related information through numerous venues. Formal competency-based training in PS principles and high reliability plays a key role, but the DoD PSP offers many other types of learning resources. These include learning action network webinars offering continuing medical education credits, toolkits and resource guides outlining leading practices, face-to-face and virtual coaching sessions for sharing successes and lessons learned, web-based courseware, and just-in-time access to documentation and data through the PSLC portal.

(1) User Directed Data and Analytic Tools. The Safety Event Root Cause Analysis (SERCA) tool is a data visualization application, designed to allow for interactive, self-directed trend analysis of a variety of PS data. In addition to trend analysis, this tool facilitates sharing of lessons learned and strengthening of corrective actions across the MHS.

(a) DHA CQM will support ongoing development, maintenance, distribution, and improvement to data visualization tools for informing strategic decision making.

(b) DHA Market/Intermediate Headquarters will facilitate access to the visualization tools for designated organizational leadership and provide DHA CQM feedback on tool value with recommendations for improvement.

(c) MTF Directors/Commanders, and designees, will use visualization tools to identify areas of focus and positive trends and provide DHA Markets/Intermediate Headquarters and DoD PSP feedback on tool value with recommendations for improvement.

(2) PS Resources. The DoD PSP publishes various PS resources based on analyses and trending of PS data. These publications and resources are generally available for distribution. However, some are limited if they are protected in accordance with Reference (x). They are housed on the PSLC portal.

(a) The DHA ensures the resources are evidence-based and current.

(b) PS professionals must remain current with DoD PSP guidance, recommendations and reports, and are strongly encouraged to utilize these resources for improvement and share knowledge with their teams and facilities. Such resources and publications include but are not limited to the PS Annual Summary, PS Spotlight, PS Data Snapshot, and Focused Reviews.

(3) PSLC Portal. The PSLC is a shared, online portal designed for MHS collaboration. It is a repository of available products, tools, and solutions designed to engage, educate, and equip the MHS leaders, commanders, healthcare and PS professionals. The DoD PSP ensures the PSLC is evidence-based and current. The link for the PSLC is: https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/home.aspx.

(4) PS Annual Summary. The purpose of the DoD PS Annual Summary is to provide MHS leaders and frontline safety professionals an overview of the MHS performance in the areas of safety for the calendar year beginning January 1st and ending on December 31st. It aims

to feature areas that have shown improvements and examines areas where more attention is needed based on data along with historical PS trends and milestones. Additionally, the PS Annual Summary serves to meet regulatory requirements to maintain MTF accreditation status.

(a) DoD PSP will:

1. Maintain centralized MHS-level databases for content.

2. Validate content with DHA Market/Intermediate Headquarters.

3. Analyze, trend, and develop visualizations for reporting.

4. Receive clinical content from DHA Market/Intermediate Headquarters.

5. Generate, coordinate, distribute, and post to PSLC.

(b) DHA Market/Intermediate Headquarters PSPs, in support of MTFs/subordinate organizations, will:

1. Reconcile data accountable to their respective organizations.

2. Receive and appropriately protect clinical information.

3. Coordinate, distribute, and review final summary.

4. Perform deep dives for knowledge generation.

5. Provide consultation for understanding.

(c) MTFs/subordinate organizations will:

1. Report event data per policy and ensure data integrity.

2. Share clinically relevant content with DHA Market/Intermediate Headquarters.

3. Review and share the PS Annual Summary to drive discussion on improvements, or necessary areas of focus, encourage reporting of all safety events and celebrate successes.

4. Explore the DoD PSP analytic and visualization tools for deeper dives into performance trends and patterns at MTF/organizations and within specific units and services.

(5) Clinical Community Support. With the DoD's Clinical Communities and the High Reliability Operating Model (HROM), healthcare providers have access to PS expertise, consultant, and analytic support to enable their targeted improvement progress which may focus on a high-risk, high-volume area. PS experts serve as enablers. The DoD PSP will:

(a) Provide data measurement analyses, such as deep dives into safety events in specific areas of interest and ad hoc reports to support safety goals and performance improvement targets.

(b) Apply advanced techniques to improve clinical performance.

(c) Expand knowledge sharing by working with Clinical Community leadership to identify and support evidence-based solution development.

(d) Build PS capabilities with Clinical Communities.

(e) Support Clinical Communities to eliminate harm and foster a culture of safety across care settings.

(6) Sharing of Lessons Learned. To enhance learning and decrease variation in systems and processes related to quality and PS, MTF Directors/Commanders should ensure leverage of available mechanisms designed to share lessons learned and leading practices. These include the following Learning Circles and Webinars:

(a) Annual Advancement toward High Reliability in Healthcare Awards Program: Recognizes teams who have shown initiative and commitment to the development of systems and processes that will lead the MHS toward a better, safer, and nationally recognized healthcare system. Award winners share and discuss initiatives during webinars. DHA Market/Intermediate Headquarters will encourage participation in the program to share PS initiatives and practices to help the MHS advance toward high reliability.

(b) Annual TeamSTEPPS™ Conference: DoD teamwork experts share lessons and leading practices, relative to implementation, sustainment and spread of TeamSTEPPS™ with their DoD colleagues, and national and international audiences (Reference (y)).

(7) Fostering a Culture of Safety

(a) Purpose. For the MHS to advance high reliability across the organization, a culture of safety, leadership commitment to achieving zero preventable harm, and continuous process improvement are critical elements. Additionally, two other domains for change for high reliability, teamwork and patient-centeredness, are pillars to enable organization change.

(b) A culture of safety is demonstrated by an organizational commitment to provide safe, high quality and reliable patient care via a focus on collaborative teamwork, communication, and effective processes. This commitment must be shared by leadership and staff members at all levels. Organizations with a culture of safety acknowledge that medical errors can and will occur and strive to identify and reduce risk before it results in harm.

(c) A strong safety culture within the MHS is critical to achieving zero preventable patient harm, supporting the healthcare workforce, and must occur across the MHS through leadership engagement. Learning from reporting and investigating PS events, engaging staff

through activities such as sharing PS event findings and process improvements, promoting internal transparency through communication, coordination, and teamwork fosters a strong safety culture. This should include conducting leadership rounds, establishing recognition programs, and embracing national initiatives deemed beneficial to the MHS.

(d) In order to foster a culture of safety, deliberate attention on the following key components is essential.

1. Trust. Leaders foster trust and psychological safety by modeling behavior derived from publicly available principles and enable staff at all levels to excel through coaching and by removing barriers.

2. Accountability. The influence of peers is exercised through a culture of accountability, where peer checking, and coaching is the norm. However, none of the above overshadows individual accountability. Individual accountability is not about blame and punishment, but about learning and growing. A comprehensive accountability system recognizes the collective influence of each source of accountability in providing positive reinforcement to engrain safety and improvement behaviors aligned to high reliability principles. Remedial action is generally sufficient to address these concerns. Punitive action is reserved for the extreme cases where standardized processes are not followed and there is a conscious disregard for safety, intentionally putting patients at risk.

3. Identifying, reporting, analyzing, and learning from PS events and performing comprehensive analyses results in enhancing safe healthcare systems.

4. Strengthening systems through the implementation of robust mitigations and providing education and training to all staff to promote the concepts of high reliability in healthcare.

(e) At every level of the MHS, from frontline providers to senior executives, the DoD PSP seeks to promote and sustain this commitment to safety culture. As a responsibility, every member of the MHS strives to create a non-punitive, learning culture by focusing on improved communication and cooperation, teamwork, systems, and processes rather than blame, and prevention rather than punishment.

1. MHS leadership at all levels will:

a. Create a psychologically safe atmosphere of trust and confidence that encourages all staff to report PS events in order to protect patients, to learn from the situations identified, and, wherever possible, to prevent future recurrences.

b. Perform regular evaluations of the culture of safety, using valid and reliable tools such as surveys that measure staff perceptions about the safety culture.

c. Prioritize results of culture of safety evaluations and implement appropriate changes to address the results.

d. Take a systems-based approach to advance a culture of safety, reduce vulnerability, and promote competent patient-centered care. These concepts are anchored in the organization's mission, vision, prioritization plan, guidance, and policies.

e. Establish the infrastructure, policies, programs, and staff training necessary to implement and sustain the essential elements of a highly reliable and safe MHS.

2. The MTFs/subordinate organizations will:

a. Commit to develop, communicate, and execute on an organizational vision of zero harm to patients, families and the workforce.

b. Establish organizational behaviors that lead to trust in leadership and respect and inclusion throughout the organization regardless of rank, role, or discipline.

c. Select and develop an executive board to create clear competencies, focus, and accountability regarding safety culture.

d. Educate and develop leaders at all levels who embody organizational principles and values of safety culture.

e. Build a culture in which all leaders and the workforce understand basic principles of PS science and recognize one set of defined and enforced behavioral standards for all individuals in the organization.

f. Create one set of behavior expectations that apply to every individual in the organization and encompass the mission, vision, and values of the organization.

g. Incorporate leadership engagement strategies including but not limited to daily safety briefings, safety leadership rounds, and physician involvement in leadership huddles, as referenced in the Leadership Engagement Toolkit (Reference (aa)), which contains a set of evidence-based tools that have been used successfully in healthcare settings across the nation for both executive and physician leaders.

(8) Assessing and Learning from Culture Surveys of Safety

(a) The MHS PS Culture Survey captures staff perceptions about PS culture, which provides a PS culture assessment for each MTF. Developed by the AHRQ, this survey serves to assist MTFs and the DHA Market/Intermediate Headquarters to compare the current state of PS culture to that of the past (Reference (ab)). The anonymous survey encourages all staff to communicate their perceptions so that leaders can identify strengths and opportunities for improvement in areas essential to a culture of safety, including communication, empowerment of frontline staff, collaboration among staff, and units and event reporting.

(b) DoD PSP will, approximately every 3 years, conduct the PS Culture Survey at all MTFs within the MHS.

1. Administer the MHS PS Culture Survey.

2. Compare the current state of PS culture to that of the past.

3. Provide tools and information to MTF leadership to interpret survey results and develop and implement an effective action plan to improve PS culture.

(c) DHA Market/Intermediate Headquarters will:

1. Hold MTFs accountable to interpret survey results and develop and implement an effective action plan to improve PS culture at a local level.

2. Serve as a resource to the MTFs for interpretation survey results and development of effective action plans.

(d) MTFs will:

1. Participate in MHS PS Culture Survey on the prescribed schedule.

2. Utilize the MHS PS Culture Survey Reference Guide to interpret their results and develop and implement an effective action plan to improve PS culture at the local level.

(9) Additional Culture of Safety Evaluation Tools.

(a) TeamSTEPPS™ tools: TeamSTEPPS™ Teamwork Perceptions Questionnaire (T-TPQ) measures staff perceptions of PS based on the implementation of team-based practices (Reference (y)).

(b) Comprehensive Unit-based Safety Program (CUSP) Unit Level Cultural Assessments (Reference (ac)): Developed by the AHRQ and noted as a leadership strategy found in the Leadership Engagement Toolkit (Reference (aa)), CUSP Cultural Assessments target a result for improvement shortly after the culture assessment, and every 36 months or as needed to promote culture conversations, evaluate cultural issues (between survey administrations), and monitor the progress of culture change (Reference (ac)).

(c) Related assessment tools: Within the High Reliability Task Force Guide: A Resource Guide for Achieving High Reliability in the MHS are methods to assess culture (References (ad)).

(10) Effective Communication: TeamSTEPPS™

(a) Ineffective communication is a leading cause of preventable patient harm. The MHS is focused on culture of safety initiatives that enhance safety behaviors, teamwork, and improved communication. TeamSTEPPS™ is an evidence-based system aimed at optimizing

patient outcomes by improving communication and other teamwork skills (Reference (y)). Its consistent use is essential for improving not only communication but coordination and cooperation.

(b) DoD PSP Team-Based Practice Program Manager will:

1. Coordinate with the DHA Market/Intermediate Headquarters coordinator for MTF TeamSTEPPS™ POC to provide ongoing consultation, coaching, and follow-up evaluation of the initiative.

2. Coordinate annual TeamSTEPPS™ Team Training National Conference and host DoD-specific conference with the American Hospital Association to include funding approval process and conferences specifics, where lessons learned and leading practices on sustaining high-performing teams are shared.

(c) MTF Directors/Commanders will:

1. Establish TeamSTEPPS™ as the foundation to local PSPs (Reference (y)) and as the standard for maximally integrating teamwork principles into practice.

2. Set expectations for TeamSTEPPS™ implementation in daily operations.

3. Ensure their executive leaders will review and implement "Teamwork Training and Skill Building" from the Leadership Engagement Toolkit (Reference (aa)).

4. Align TeamSTEPPS™ learning and implementation to their goals, PS events and other applicable data sources (e.g., PS Culture Survey, patient and staff satisfaction surveys).

5. Sustain a cadre of instructors and coaches, to put learning into practice through feedback, to equip staff with the knowledge and skills for implementation, sustainment, and spread of leading practice behaviors.

6. Ensure new staff and multidisciplinary teams are trained in TeamSTEPPS™ as per this manual, incorporating simulation and scenario-based learning. Staff new to a unit or department will receive an orientation that includes use of TeamSTEPPS™ tools specific to that unit or department. Initial training for staff new to the facility is at least a two-hour introduction to TeamSTEPPS™ tools and strategies.

7. Ensure training opportunities for their staff to learn and practice tools, that the Online Registration Center for initial course registrations, continuing education, and summary reports is used. All tools expected to be taught in initial training as the core tools should be included. Other tools for implementation based on unit PS data should be identified, for example: Two-Challenge Rule and/or CUS Assertive Statement.

8. Identify and use PS coaches from all levels of the MHS, as appropriate, to provide guidance, feedback and direction during learning, implementation and sustainment. Monitor implementation of those tools and strategies identified for use. This may be done by observations, checklists or other appropriate mechanisms.

9. Monitor the impact of the TeamSTEPPS™ system with a focus on behaviors and organizational results. Examples include:

a. Behavior: Team Performance Observation Tool; T-TPQ; and the PS Culture Survey.

b. Organizational Results: Patient outcome measures (complication rates, infection rates, measurable medication errors, patient perceptions of care); clinical process measures (length of patient wait time, time to intubate, medication administration delays, compliance with preventive screenings, number of misdiagnoses, number of structured handoffs used); PS Culture Survey.

(11) Training

(a) All PS professionals will play a critical role in establishing and sustaining a culture of safety. In order to prepare PS professionals for their role, all PS professionals will complete the Patient Safety Professional Course (PSPC) within their first year in the role. In addition, they should participate in coaching calls 3, 6, and 12 months post-instruction.

(b) PS professionals learn to:

1. Recognize the elements of a successful PSP.

2. Develop a PS plan for their facility.

3. Examine data to identify potential risks within their facility and evaluate improvement efforts.

4. Engage healthcare providers, patients, and leadership in PS.

(12) Coaching

(a) Coaching is one of many strategies to facilitate change. Coaching can ensure the successful execution, sustainment and improvement of the improvement activities. Evidence shows coaches are essential to the mission of executing transformational healthcare strategies.

(b) In order to provide guidance, feedback, and direction toward success, internal (peer-to peer) coaching resources should be identified and developed. Coaching should be available to frontline change teams, leadership teams, and PS champions. Those PSMs identifying a need for external coaching support should contact the DHA Market/Intermediate Headquarters, or the DoD PSP, as appropriate.

(c) DHA Market/Intermediate Headquarters will:

1. Provide external coaching support or strategies to develop a coaching plan, address conflicts, professional conduct, contact the DoD PSP Program Manager as needed.

2. Facilitate group coaching of leaders seeking assistance for establishing leadership engagement strategies into daily practice.

APPENDIX

DOD REPORTABLE EVENT DEFINITIONS MATRIX

A DoD Reportable Event (DoD RE) is any patient safety (PS) event resulting in death, permanent harm, or severe temporary harm, as per the AHRQ Harm Scale; or meeting The Joint Commission's (TJC) sentinel event (SE) or the National Quality Forum's (NQF) serious reportable event (SRE) definitions. DoD REs require a Comprehensive Systematic Analysis (CSA) and follow on Corrective Action Implementation (CAI) Plan Report.

TJC defined a SE in 2015 as a patient safety event (not related to the natural course of illness or underlying condition) that reaches the patient and results in death, permanent harm or severe temporary harm. Severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care/monitoring, additional surgery, procedure or treatment to resolve (The Joint Commission Accreditation, 2018). If an event is submitted and approved by TJC, a CSA must be submitted to TJC within 45 days. DoD REs require a CSA and follow on CAI Plan Report. A list of the NQF's SREs can be found at (National Quality Forum, 2011): http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx."

The table below provides a listing of types of DoD RE as they align with TJC's SE and NQF's SRE definitions.

References:

National Quality Forum. (2011). *Serious Reportable Events.* Washington DC: National Quality Forum. Retrieved from www.qualityforum.org

The Joint Commission Accreditation (2018). Sentinel Events. In *Comprehensive Accreditation Manual: CAMH for hospitals effective January 1, 2018* (pp: SE1-SE20). Oakbrook, Illinois: Joint Commission.

Category	Event Categories	TJC SE	NQF SRE	TJC Reportable	DoD Reportable	Additional Information
Surgical or Invasive Procedure	Wrong Site Surgery (WSS)	Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure	(1) Surgery or other invasive procedure performed on the wrong site. (2) Surgery or other invasive procedure performed on the wrong patient. (3) Wrong surgical or other invasive procedure performed on a patient **(3 events combined)**	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.
Surgical or Invasive Procedure	Unintended Retained Foreign Object (URFO)	Unintended retention of a foreign object in a patient after an invasive procedure, including surgery	Unintended retention of a foreign object in a patient after surgery or other invasive procedure	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	"After surgery" is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. If a foreign object is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the facility shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
Surgical or Invasive Procedure	Death- Post Operative Healthy Patient		Intraoperative or immediate postoperative/post procedure death in an ASA Class 1 patient	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Product or Device	Contamination		Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Product or Device	Malfunction		Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.

Product or Device	Air Embolism		Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Discharge	Discharge	Discharge of infant to the wrong family		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
		Discharge or release of a patient/ resident of any age, who is unable to make decisions, to other than an authorized person			Meets TJC (2018) or National Quality Forum (2011)	
Patient Protection	Elopement	Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient	Patient death or serious injury associated with patient elopement (disappearance)	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Patient Protection	Suicide	Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)	Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
General (Care Management)	GENERAL (Care Management)	Any patient safety event not related to the natural course of illness or underlying condition that results in death, permanent harm, or severe temporary harm		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Medication Error		Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.

Care Management	Blood Transfusion	Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)	Patient death or serious injury associated with unsafe administration of blood products	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Maternal Event	Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm	Maternal death or serious injury associated with labor or delivery in a **low-risk** pregnancy while being cared for in a health care setting	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	Severe maternal morbidity is defined as a patient safety event that occurs from the intrapartum through the immediate postpartum period (24 hours), requiring the transfusion of four or more units of packed red blood cells (PRBC) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.
Care Management	Maternal Event	Any intrapartum (related to birth process) maternal death		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Neonatal Event	Unanticipated death of a full-term infant (37 wks.)	Death or serious injury of a neonate associated with labor or delivery in a **low-risk** pregnancy	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Neonatal Hyperbilirubinemia	Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)		Meets TJC (2018) or National Quality Forum (2011))	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Fall		Patient death or serious injury associated with a fall while being cared for in a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.

Care Management	Pressure Ulcers		Any stage 3 or 4 and unstageable pressure ulcer acquired after admission/ presentation to a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	Severe temporary harm is critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care / monitoring, additional major surgery, procedure or treatment to resolve (The Joint Commission Accreditation, 2018). General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Care Management	Loss of Specimen		Death or serious injury resulting from irretrievable loss of an irreplaceable biological specimen	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Care Management	Wrong Procedure			Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Care Management	Delay in Treatment		Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Environmental	Electrical		Patient or **staff** death or serious injury associated with an electric shock in the course of a patient care process in a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Environmental	Oxygen/Gas		Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances		Meets TJC (2018) or National Quality Forum (2011)	

Environmental	Burn		Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Environmental	Fire	Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in a smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association. NFJJA 901: Standard Classifications for Incident Reporting and Fire Protection Data. Quincy, MA: NFPA, 2011.
Environmental	Restraints		Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Radiologic	MRI Magnet		Death or serious injury of a patient or **staff** associated with the introduction of a metallic object into MRI area	Meets TJC General Definition	Meets TJC (2018) or National Quality Forum (2011)	General TJC definition incudes a patient safety event not related to the natural course of illness or underlying condition that reaches the patient and results in death, permanent harm or severe temporary harm.
Radiologic	Radiation Exposure	Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to wrong body region or > 25% above the planned radiotherapy dose		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
Potential Criminal	Impersonation		Any instance of care ordered/provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider		Meets TJC (2018) or National Quality Forum (2011)	
Potential Criminal	Abduction	Abduction of any patient receiving care, treatment and services	Abduction of a patient/resident of any age	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011))	

Potential Criminal	**Rape/Assault**	Rape, assault (leading to death, permanent harm or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the practice (includes sexual assault)	Rape, assault (leading to death, permanent harm or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the practice (includes sexual assault)	Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event: • Any staff-witnessed sexual contact as described above; • Admission by the perpetrator that sexual contact, as described above, occurred on the premises; and • Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact (The Joint Commission Accreditation, 2018).
		Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting	Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting			
Potential Criminal	Assault/Physical	Rape, assault (leading to death, permanent harm or severe temporary harm) or homicide of a **staff member, licensed independent practitioner, visitor, or vendor** while on site at the practice		Meets TJC (2018) or National Quality Forum (2011)	Meets TJC (2018) or National Quality Forum (2011)	
		Death or serious injury of a **staff** resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting	Death or serious injury of a **staff** resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting			

ENCLOSURE 3

INFECTION PREVENTION AND CONTROL

1. GENERAL OVERVIEW

a. Purpose. This manual provides guidance in preventing healthcare-associated infections (HAIs) and sustaining leading infection prevention and control (IPC) practices across the MHS.

b. Functions

(1) Strengthen and enhance continuous performance improvement in IPC.

(2) Review and improve compliance with leading IPC practices.

(3) Facilitate IPC-related educational programs, training, and consultation regarding complex IPC issues.

2. GOVERNANCE STRUCTURE

a. DHA IPC is aligned to the DoD Patient Safety Program (PSP) which is under the CQM Branch, Clinical Support Division under the DAD MA within DHA. The DoD PSP manages IPC operations in collaboration with the Infection Prevention and Control Working Group (IPCWG). The IPCWG provides direction and guidance supporting a comprehensive MHS-wide activity that mitigates or prevents infection risks within the MHS. The IPCWG reports to the DoD PSP.

b. IPC staff provide reports through DHA Market/Intermediate Headquarters staff to the DoD PSP IPC. DoD PSP staff collaborate with DHA Market/Intermediate Headquarters staff, who in turn are responsible for supporting and holding accountable their respective subordinate organizations.

3. SCOPE AND CORE RESPONSIBILITIES

a. Scope Statement. The core responsibilities of the program are to protect patients, personnel, and visitors in the healthcare environment and reduce the risk and occurrence of HAIs across the continuum of care in the MHS's various healthcare settings. This is accomplished through a collaborative, multidisciplinary, and systems-based approach emphasizing sound epidemiological principles; incorporating evidence-based leading practices, current standards, and guidelines; and applicable local, state, and federal regulations and AO standards.

b. Collaborative Relationships. The DoD PSP IPC maintains important collaborative relationships with the following entities:

(1) Clinical Communities

(2) Navy EpiData Center

(3) Public Health Center

(4) Pharmocoviligence Center

(5) Armed Forces Health Surveillance Branch

(6) National healthcare databases

(7) Antibiotic Stewardship Program

(8) AO(s)

c. The DAD MA will:

(1) Ensure the implementation of the responsibilities outlined in this manual to maintain consistent application across the MHS.

(2) Provide ongoing guidance and support to DHA Market/Intermediate Headquarters to ensure successful implementation of the IPC plan by understanding, developing, disseminating, and/or communicating resources/resource needs.

(3) Initiate and facilitate setting annual priorities and identify any new initiative(s).

(4) Ensure IPC activities are monitored and that a comprehensive IPC plan is managed across the MHS.

d. The DoD PSP IPC, leveraging the IPCWG, will:

(1) Determine annual surveillance and reporting requirements based on current trends and risks to the MHS.

(2) Provide information and guidance to DHA Market/Intermediate Headquarters staff to ensure that standards and protocols are implemented and followed.

(3) Facilitate educational programs, training, and consultation regarding complex issues as the leading infection prevention expert.

(4) Identify high- and low-performing organizations by leadership-identified national benchmarking standards and share updates, alerts, trends, and/or findings in collaboration with the DoD PSP. Monitor and analyze device-associated data quarterly or semiannually as appropriate. Conduct program evaluation plans for HAIs.

(5) Monitor and analyze available IPC data and information for patterns and trends. Develop recommendations as indicated to continually improve care in the MHS.

(6) Review, provide guidance, and direction for emerging pathogens, antibiotic stewardship, emerging infectious diseases, and trends in HAIs through collaboration with the following: a) EpiData Center, b) Multidrug-Resistant Organism Repository and Surveillance Network of the Walter Reed Army Institute of Research, c) MHS Pharmacovigilance Center, d) National healthcare registries, and e) appropriate DHA working groups.

(7) Monitor progress/gaps in compliance based on lessons learned from AO survey findings, media-related concerns, and JPSR data.

(8) Provide subject matter expertise for electronic health records modifications related to IPC.

(9) Use educational materials from professional societies to help develop Infection Preventionists; encourage Infection Prevention Program Managers to maintain national certifications and advanced level competencies; disseminate current relevant tools to the field quarterly or on an as needed basis; and use IPCWG community of practice sessions, webinars, and other training venues to educate and improve IPC practices.

(10) Develop a process ensuring updates and current trends are disseminated across the MHS.

(11) Identify funding requirements for IPC training to national- or state-sponsored education in IPC.

e. The DHA Market/Intermediate Headquarters staff will:

(1) Identify an IPC Subject Matter Expert (SME) within the DHA Market/Intermediate Headquarters who is encouraged to maintain certification in IPC and advanced-level competency by national certifying standards. This DHA Market/Intermediate Headquarters IPC SME will serve as the DHA Market/Intermediate Headquarters lead for planning, coordinating, and conducting IPC reviews. This SME may also represent their DHA Market/Intermediate Headquarters in DHA and other inter-agency meetings involving matters relating to IPC.

(2) Collaborate with interdisciplinary experts to optimize the effectiveness of this manual and the MHS-wide goal to reduce HAIs and improve infection prevention measures.

(3) Provide the IPCWG leading practices and lessons learned from implementation of improvement activities on a quarterly basis.

(4) Be actively involved in helping to set annual priorities and identifying any new initiative(s).

(5) Communicate and work collaboratively with the individual Infection Preventionists/IPC Managers.

(6) Manage measurable metrics and prepare reports to include analysis of MHS data from national registries, as well as identify trends and prioritize risk(s).

(7) Support review of proposed regulations and guidelines and assist facilities in preparing for accreditation and regulatory compliance.

(8) Develop a DHA Market/Intermediate Headquarters community of practice to provide training and disseminate information.

(9) Analyze any special studies or reviews (e.g., Government Accountability Office audits) of MHS IPC policies and practices and develop standard procedures and informational material to address any concerns.

(10) Provide expert consultation regarding HAI data.

(11) Maintain certification(s) as appropriate and remain aware of new evidence-based practice developments and trends published in professional literature.

(12) Support the development of data-driven action plans and recommendations for improvement for their respective organizations to be shared with the IPCWG on a quarterly basis.

(13) Provide guidance to organizations concerning their action plans to sustain improvement. Mentor and guide low-performing facilities in the development of corrective action plans as needed.

(14) Share lessons learned from focused improvement activities at IPCWG meetings and teleconferences and disseminate lessons learned. The DoD PSP IPC will share lessons learned from high-performing organizations to sustain and spread leading practices.

f. MTF Directors/Military Department Designees have overall accountability and responsibility for their organization's IPC. They will allocate needed resources, including providing access to information, laboratory resources, equipment, and supplies. Resources will be provided to support all training requirements to equip the Infection Preventionist/IPC Manager to successfully manage quality IPC.

g. The MTF/subordinate organizations Infection Preventionist/IPC Manager will:

(1) Provide management and execution of IPC.

(2) Serve as the SME for all IPC activities. Certification in Infection Control is encouraged for all practitioners and is indicative of a high level of expertise in the field.

(3) Collaborate with interdisciplinary experts to optimize the effectiveness of this manual and the MHS-wide goal to reduce HAIs and improve IPC measures.

(4) Provide educational programs, consultation, surveillance, implementation science, PS, clinical process improvement, and research regarding the complex issues surrounding IPC and the safe provision of healthcare for patients, visitors, and environmental safety for healthcare workers.

(5) Be actively involved in helping to set annual priorities and identifying any new initiative(s).

(6) Manage measurable metrics and prepare reports to include analysis of their organization's data from national registries, as well as identify trends and prioritize risk(s).

(7) Support review of proposed regulations and guidelines and assist facilities in preparing for accreditation and regulatory readiness.

(8) Analyze any special studies or reviews (e.g., Government Accountability Office audits) of MHS IPC policies and practices and develop standard procedures and informational material to address any concerns.

(9) Provide expert consultation support to healthcare staff regarding HAI data.

(10) Conduct, reassess, and update a risk assessment and annual IPC plan.

(11) Report infection data to the subscribed national registry as directed by the DoD PSP IPC.

(12) Communicate/report pertinent IPC information to the executive leadership and DHA Market/Intermediate Headquarters on a routine basis.

(13) Provide relevant IPC education and training to healthcare professions, patients, and nonmedical caregivers to include ancillary staff (e.g., environmental services, maintenance workers).

(14) Serve as SME for the infection prevention committee/functional management team.

4. MANAGEMENT OF IPC EVENTS

a. In coordination with other programs within CQM and other disciplines within the facility and DHA Market/Intermediate Headquarters, collaborate for an appropriate response and management of IPC events.

b. Support management of outbreaks of communicable diseases and infection.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

Unless otherwise noted, these abbreviations and acronyms are for the purpose of this DHA-PM

AABB	AABB (formerly known as American Association of Blood Banks)
AAMFT	American Association of Marriage and Family Therapy
AAO	American Academy of Optometry
ABA	American Board of Audiology
ABCMO	American Board of Certification in Medical Optometry
ABMS	American Board of Medical Specialties
ABO	American Board of Optometry
AC	accreditation and compliance
ACS	American College of Surgeons
ACGME	Accreditation Council for Graduate Medical Education
ACLS	Advanced Cardiac Life Support
ACPE	Accreditation Council for Pharmacy Education
AD CS	Assistant Director for Combat Support
ADA	American Dental Association
ADA	American with Disabilities Act
ADN	Associate's Degree in Nursing
AHRQ	Agency for Healthcare Research and Quality
ALS	Advanced Life Support
AMA	American Medical Association
ANCC	American Nurses Credentialing Center
AO	accrediting organization
AOA	American Osteopathic Association
APA	American Psychological Association
APMA	American Podiatric Medical Association
APN	advance practice nurse
APTA	American Physical Therapy Association
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASHA	American Speech-Language-Hearing Association
Au.D.	Doctor of Audiology
BAA	business associate agreement
BLS	Basic Life Support
BSN	Bachelor of Science in Nursing
CAC	Common Access Card
CADE	Commission on Accreditation for Dietetics Education
CAI	Corrective Action Implementation
CAP	College of American Pathologists
CCE	Council on Chiropractic Education
CDR	Commission on Dietetic Registration

CE	continuing education
CFR	Code of Federal Regulations
CGFNS	Commission on Graduates of Foreign Nursing Schools
CHBC	Criminal History Background Check
CIS	Criminal Investigative Service
CLIP	Clinical Laboratory Improvement Program
CM	clinical measurement
CMO	Chief Medical Officer
CMS	Centers for Medicare & Medicaid Services
CNM	certified nurse midwife
CNS	certified nurse specialist
COAMFTE	Commission on Accreditation for Marriage and Family Therapy Education
COMLEX	Comprehensive Osteopathic Medical Licensing Examination
COR	Contracting Officer's Representative
CP	credentialing and privileging
CPME	Council on Podiatric Medical Education
CQI	clinical quality improvement
CQIS	Clinical Quality Improvement Studies
CQM	clinical quality management
CRNA	certified registered nurse anesthetist
CSA	Comprehensive Systematic Analysis
CUSP	Comprehensive Unit-based Safety Program
CVO	Centralized Credentials Verification Office
DAD MA	Deputy Assistant Director for Medical Affairs
DEA	Drug Enforcement Agency
DES	Disability Evaluation System
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DHA-PM	Defense Health Agency-Procedures Manual
DHHS	Department of Health and Human Services
DMAT	Disaster Medical Assistance Team
D.O.	Doctor of Osteopathic Medicine
DoD RE	DoD Reportable Event
DSA	data sharing agreement
DSAA	data sharing agreement application
DLA	Defense Logistics Agency
EDIS	Educational and Developmental Intervention Services
EHR	electronic health record
ECFMG	Educational Commission for Foreign Medical Graduates
EIDS	Enterprise Intelligence and Data Solutions
eMSM	Enhanced Multi-Service Market
ER	emergency room
ERM	enterprise risk management

FAAO	Fellowship in the American Academy of Optometry
FDA	Food and Drug Administration
FHPQA	Force Health Protection Quality Assurance
FMEA	Failure Mode Effect Analysis
FNLH	Foreign National Local Hire
FNP	family nurse practitioner
FOIA	Freedom of Information Act
FPGEC	Foreign Pharmacy Graduation Examination Committee
FPPE	focused professional practice evaluation
GME	Graduate Medical Education
GS	General Schedule
GTT	Global Trigger Tool
HAI	healthcare-associated infection
HAR	Hazards, Alerts, and Recalls
HAR-NESS	Hazards, Alerts, and Recalls Notice System
HEDIS®	Healthcare Effectiveness Data and Information Set
HIPDB	Health Integrity Protection Data Bank
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIT	health information technology
HPSP	Health Professions Scholarship Program
HRM	healthcare risk management
HRO	high reliability organization
HROM	High Reliability Operating Model
ICTB	Inter-facility Credentials Transfer Brief
IDES	Integrated Disability Evaluation System
IHPP	Impaired Healthcare Provider Program
IMA	Individual Mobilization Augmentee
IO	Investigating Office
IOM	Institute of Medicine
IPC	infection prevention and control
IPCWG	Infection Prevention and Control Working Group
JCCQAS	Joint Centralized Credentials Quality Assurance System
JOES	Joint Outpatient Experience Survey
JPSR	Joint Patient Safety Reporting
LEIE	List of Excluded Individuals and Entities
LIP	licensed independent practitioner
LPN	licensed practical nurse
LVN	licensed vocational nurse
MC	Medical Corps
MCSC	Managed Care Support Contractor

M.D.	Doctor of Medicine
MEB	medical evaluation board
MEDLOG	Medical Logistics Division
MHS	Military Health System
MHSPHP	Military Health System Population Health Portal
MOU	memorandum of understanding
MPL	Master Privilege List
MQA	medical quality assurance
MQAP	medical quality assurance program
MQAR	medical quality assurance record
MQSA	Mammography Quality Standards Act
MSM	medical staff manager
MSP	medical staff professional
MSW	Master of Social Work
MTF	military medical treatment facility
NBDHE	National Board Dental Hygiene Examination
NCC	National Certification Corporation
NCQA	National Committee of Quality Assurance
NCCPA	National Commission on Certification of Physician Assistants
NDAA	National Defense Authorization Act
NGO	non-governmental organization
NHSN	National Healthcare Safety Network
NOTO	Number of Times Occurred
NPDB	National Practitioner Data Bank
NPI	National Provider Identifier
NPIC	National Perinatal Information Center
NQF	National Quality Forum
NSQIP®	National Surgical Quality Improvement Program
OCONUS	outside the continental United States
ODE	off-duty employment
OHU	operational healthcare unit
OPM	Office of Personnel Management
OPPE	ongoing professional practice evaluation
OSD	Office of the Secretary of Defense
PA	physician assistant
PA-C	Physician Assistant-Certified
PAF	Provider Activity File
PALS	Pediatric Advanced Life Support
PCE	potentially compensable event
PCMH	Patient Centered Medical Home
PCS	permanent change of station
PDCA	Plan-Do-Check-Act
PDSA	Plan-Do-Study-Act

PEB	physical evaluation board
PEBLO	Physical Evaluation Board Liaison Officer
PECOS	Provider Enrollment, Chain and Ownership System
PG	Postgraduate
Pharm.D.	Doctor of Pharmacy
Ph.D.	Doctor of Philosophy
PHI	protected health information
PHM	Population Health Management
PII	personally identifiable information
PIV	Personal Identity Verification Card
P/MHNP	psychiatric/mental health nurse practitioner
POAM	Plans of Action and Milestones
POC	point of contact
PNCB	Pediatric Nursing Certification Board
PNP	pediatric nurse practitioner
PQDR	Product Quality Deficiency Report
PQI	Prevention Quality Indicator
PRA	proactive risk assessment
PS	patient safety
PSC	personal services contract
PSI	Patient Safety Indicator
PSIC	Patient Safety Improvement Collaborative
PSLC	Patient Safety Learning Center
PSM	patient safety manager
PSP	Patient Safety Program
PSPC	Patient Safety Professional Course
PSQAC	Patient Safety Quality Academic Collaborative
PSR	patient safety report
PSV	primary source verification
Psy.D.	Doctor of Psychology
QA	quality assurance
QAI	Quality Assurance Investigation
QAIO	Quality Assurance Investigating Officer
RAG	Risk Assessment Grade
RCA	root cause analysis
RDH	registered dental hygienist
RD	registered dietitian
RDN	registered dietician nutritionist
RMWG	Risk Management Working Group
RN	registered nurse
SAFE	Sexual Assault Forensic Exam
SAMFE	Sexual Assault Medical Forensic Examiner
SANE-A®	Sexual Assault Nurse Examiner – Adult/Adolescent

SDD	Solution Delivery Division
SE	sentinel event
SE MOS	Sentinel Event Measures of Success
SERCA	Safety Event Root Cause Analysis
SERE	survival, evasion, resistance and escape
SG	Surgeon General
SHEA	Society for Healthcare Epidemiology of America
SIP	significantly involved provider
SMDR	senior medical department representative
SME	subject matter expert
SOC	standard of care
SRE	serious reportable event
STEEEP	safe, timely, effective, efficient, equitable, patient–centered
T-TPQ	TeamSTEPPS™ Teamwork Perceptions Questionnaire
TAA	training affiliation agreement
TDY	temporary duty
TeamSTEPPS™	Team Strategies and Tools to Enhance Performance and Patient Safety
TJC	The Joint Commission
TRISS	TRICARE Inpatient Satisfaction Survey
U.S.C.	United States Code
UCMJ	Uniform Code of Military Justice
UMO	Undersea Medical Officer
USMLE	United States Medical Licensing Exam
USN	United States Navy
USTRANSCOM	United States Transportation Command
USU	Uniformed Services University of the Health Sciences
VA	Department of Veterans Affairs
VADM	Vice Admiral
VMC	virtual medical center
VTC	video teleconferencing
WHNP	women's health nurse practitioner

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this DHA-PM.

accreditation. Process of review that allows healthcare organizations to demonstrate their ability to meet regulatory requirements and standards established by a recognized accrediting organization (AO).

adverse event. See definition for patient safety (PS) event.

adverse practice action. Restriction, reduction, or revocation of the clinical practice of a non-privileged provider as a result of a due process professional review action, based upon evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

adverse privileging action. Denial, restriction, reduction, or revocation of clinical privileges as a result of a due process professional review action, based upon evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

Agency for Healthcare Research and Quality (AHRQ) Harm Scale. The AHRQ Harm Scale can be found in the AHRQ Common Formats – Hospital Version 2.0, and includes the following assignment categories:

No-Harm: Event reached the patient, but no harm was evident.

Mild Harm: Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay.

Moderate Harm: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

Severe Harm: Bodily or psychological injury (including pain or disfigurement) that interferes substantially with functional ability or quality of life.

Death

The harm scale defined by AHRQ Common Formats – Hospital Version 2.0, further delineates harm as:

Temporary Harm. Expected to revert to approximately normal (i.e., patient's baseline)

Permanent Harm. Not expected to revert to approximately normal (i.e., patient's baseline)

approved postgraduate training. Postgraduate training program accredited by the Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic Association (AOA), or other similar entities regulating healthcare provider training programs.

auditing. A process used by health professionals to assess, evaluate, and improve care in a systematic way; used by clinical governance to safeguard high quality of clinical care for patients.

certification. A process by which a nationally recognized organization confirms that an individual healthcare organization has met certain predetermined standards or procedures required for certification.

clinical adverse action. Action invoked against a healthcare provider, privileged or not, with the result that the authority to practice clinically is adversely affected. Adversely affected privilege(s)/practice are the result of a due process professional review action based on evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient, and that leads to the inability of a provider to exercise their privilege(s)/practice with their own independent judgment. This is the collective term used in this manual that encompasses both an adverse practice action and an adverse privileging action.

clinical data evaluation. Analysis of collected, compiled, and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be justified or unjustified; and problems or opportunities to improve care are identified.

clinical measurement (CM). CM uses tools to help evaluate and track the quality of healthcare services provided to beneficiaries in the Military Health System (MHS). Analyzing CM data and acting on identified trends for improvement helps ensure the MHS delivers safe, timely, effective, efficient, equitable, and patient-centered care.

clinical privileges. Permission granted by the Privileging Authority to provide medical and other patient care services. Clinical privileges define the scope and limits of practice for privileged providers and are based on the capability of the healthcare facility, licensure, relevant training and experience, current competence, health status, judgment, and peer and department head recommendations.

clinical privileging. The granting of permission and responsibility of a healthcare provider to provide specified or delineated healthcare within the scope of the provider's license, certification, or registration.

clinical quality improvement (CQI). CQI consists of systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups. Focuses on the application of several widely accepted process improvement methodologies to improve clinical performance and desired outcomes.

clinical quality management (CQM). The integrated processes, both clinical and administrative, that provide the framework to objectively define, measure, assure, and improve the quality and safety of care received by beneficiaries. The CQM functional capability includes the following programs: Patient Safety, Healthcare Risk Management, Credentialing and Privileging, Accreditation and Compliance, Clinical Measurement, and Clinical Quality Improvement.

competency assessment. Assessment of a healthcare provider's knowledge, skills, and ability to deliver high quality, safe patient care. The Military Health System (MHS) assesses providers

using standards from the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS), recognizing six areas of "General Competencies" including: patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice. These may serve as the basis for healthcare provider care evaluation and privileging decisions.

compliance. The ongoing process of meeting the legal, ethical, and professional standards applicable to a particular healthcare organization or provider.

Comprehensive Systematic Analysis (CSA). CSA is a thorough, credible, and acceptable analysis following a patient safety (PS) event that seeks to identify system vulnerabilities so that they can be eliminated or mitigated in a sustainable manner to prevent reoccurrence. A root cause analysis (RCA) is one type of CSA. CSAs can also be conducted for performance improvement purposes for those events that have the potential to be catastrophic. The following guidelines support the identification of causal factors in CSAs:

Clearly show cause and effect relationships.

Use specifics and accurate descriptions of events.

Human errors must have a preceding cause.

Violations in procedure must have a proceeding cause.

Failure to act is only causal when there is a pre-existing duty to act.

continuing education. Education beyond initial academic or professional preparation approved by an appropriate certifying professional organization that is relevant to the type of care or service delivered in an organization.

Corrective Action Implementation (CAI) Plan Report. The CAI Plan Report describes the effectiveness of the corrective action after implementation. The CAI Plan Report should include identified solutions, corrective actions implemented, and measures of effectiveness and sustainment to show that a corrective action has been implemented and is reducing or eliminating the risk of reoccurrence in a lasting way.

credentialing. The process of obtaining, verifying, and assessing the qualifications of both privileged and non-privileged providers to provide safe patient care services. This assessment serves as the basis for decisions regarding delineation of clinical privileges, as well as appointments and reappointments to the medical staff. The required information should include qualification data such as relevant education, training, and experience; current licensure; and specialty certification (if applicable) as well as performance data, such as current competency, and the ability to perform the selected privileges. This data is collected, verified, and assessed initially and on an ongoing basis.

credentials. The documents that constitute evidence of appropriate education, training, licensure, experience, and expertise of a healthcare provider.

credentials file. A file containing pertinent information regarding an individual privileged provider to include credentialing and privileging documents, permanent performance data, medical practice reviews, continuing health education documentation, and information related to permanent adverse privileging actions.

credentials review. The credentials inspection and verification process conducted for healthcare providers before selection for military service, employment, and procurement. The credentials review process is also conducted for healthcare providers before medical staff appointment and granting of clinical privileges and is repeated at the time of reappointment and renewal of privileges.

current competence. The state of having adequate ability and up-to-date knowledge to perform the functions of a healthcare provider in a particular discipline, as measured by meeting these criteria:

The provider has actively pursued the practice of their discipline within the past two years by having encountered a sufficient number of clinical cases to represent a broad spectrum of the privileges requested and that the individual has satisfactorily practiced the discipline as determined by the results of ongoing professional practice evaluation (OPPE).

The provider possesses documented evidence of appropriate continued medical education to maintain the currency of skills and knowledge.

data monitoring. The systematic and ongoing collection, compilation, and organization of data pertaining to indicators for the quality and appropriateness of important aspects of care in order that problems or opportunities to improve care can be identified.

denial of clinical privilege(s). Refusal to grant requested privileges to a healthcare provider at the time of initial application or renewal. Denials that result from a professional review action following appropriate due process proceedings, and relating to evidence of the provider's misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient are reported to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies. Denials that occur solely because a provider does not meet a healthcare institution's established threshold criteria for that particular privilege, should not be reported to the NPDB - these are considered decisions based on eligibility and are not deemed to be a result of a professional review action.

denominator. The part of a fraction that is below the line and that functions as the divisor of the numerator; the population at risk in the calculation of a rate or ratio.

department/clinical unit. The department, unit, or area utilized for patient care (e.g., pharmacy, surgical area, emergency department, procedural area, nursing unit).

deviation. The action of departing from an established course or accepted standard; the amount by which a single measurement differs from a fixed value such as the mean.

direct care system. Healthcare facilities and medical support organizations managed by the DoD through the Defense Health Agency (DHA) or Service Surgeons General in accordance with applicable federal laws and regulations.

DoD Reportable Event (DoD RE). Any patient safety (PS) event resulting in death, permanent harm, or severe temporary harm, as per the AHRQ Harm Scale; or meeting The Joint Commission's (TJC) sentinel event (SE) or the National Quality Forum's (NQF) serious reportable event (SRE) definitions. DoD REs require a Comprehensive Systematic Analysis (CSA) and follow on Corrective Action Implementation (CAI) Plan Report.

enterprise risk management (ERM). ERM provides a comprehensive framework for making risk management decisions to promote safe and reliable healthcare and to mitigate risks across the organization. Effective ERM practices are continuous in nature and support the journey to high reliability.

event reporting. The DoD Patient Safety Program (PSP) captures the full range of patient safety (PS) events listed in Volume 2 and all such events must be reported into the Joint Patient Safety Reporting (JPSR) system to be used as opportunities to prevent harm. Any PS event that reaches the patient (i.e., adverse events and no-harm events) must be reported to the appropriate Healthcare Risk Management (HRM) Program for assessment. DoD Reportable Events (DoD REs) also have reporting, notification, and analysis requirements beyond JPSR.

focused review. A review that concentrates on a perceived problem area that involves a specific standard, procedure, policy or any other limited scope healthcare delivery matter.

focused professional practice evaluation (FPPE). A process whereby the organization evaluates the privilege/practice of the healthcare provider who does not have documented evidence of competently performing the requested privilege, or of demonstrated practice competency, at the organization. This process may also be used when a question arises regarding a healthcare provider's ability to provide safe, high quality patient care. Focused professional practice evaluation is a time-limited period during which the organization evaluates and determines the healthcare provider's professional performance.

harm. Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.

healthcare provider. Any member of the uniformed services, civilian employee of the DoD, or contract employee authorized by the DoD to perform healthcare services.

healthcare risk management (HRM). Includes clinical and administrative activities, processes, and policies to identify, monitor, assess, mitigate, and prevent risks to the healthcare organization, patients, and staff. By employing risk management, the healthcare organization

proactively and systemically safeguards patient safety and the organization's resources, accreditations, legal/regulatory compliance, assets, and customer confidence (integrity).

intentional unsafe act. Any alleged or suspected act or omission of a healthcare provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves a criminal act, a purposefully unsafe act, patient abuse, or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, disciplinary system, or administrative investigation.

Joint Centralized Credentials Quality Assurance System (JCCQAS). A secure, worldwide healthcare provider credentialing, privileging, adverse actions, and risk management web-based application mandated by the Military Health System (MHS) used in the provider credentialing and privileging process. Portions of the information contained in JCCQAS are confidential, privileged and protected from disclosure in accordance with Section 1102 of Title 10, United States Code. JCCQAS is the official file for healthcare providers credentialed and privileged within the MHS.

Joint Patient Safety Reporting (JPSR) system. DoD electronic system used to capture data for all types of patient safety (PS) events in Military Medical Treatment Facilities (MTF) and other applicable healthcare environments, as well as PS events tracked and trended in other programs. The MTF Patient Safety Manager (PSM) is responsible for JPSR data management, the review of facts associated with the PS event, and for ensuring an appropriate evaluation is performed as required by DHA guidance. JPSR usage is the only authorized method for the reporting of adverse events, no harm events, near misses, and unsafe conditions.

lean. A process of continuous cycle improvement to maximize value by improving efficiencies and decreasing waste.

licensed independent practitioner (LIP). Any individual permitted by law and by the organization to provide care, treatment and services, without direction or supervision, and within the scope of the individual's license and consistent with individually granted clinical privileges.

measure sets. Sets of measures that focus on different aspects of healthcare delivery and are used to improve healthcare quality and help drive improvement through a consistent approach.

medical quality assurance program (MQAP). Any peer review activity carried out before, on, or after November 14, 1986 by or for the DoD to assess the quality of medical care, including activities conducted by individuals, military medical or dental treatment facility committees, or other review bodies responsible for quality assurance, credentials, infection control, patient care assessment (including treatment procedures, blood, drugs, and therapeutics), medical records, health resources management review and identification and prevention of medical or dental incidents and risks as defined in Section 1102 of Title 10, United States Code.

medical quality assurance record (MQAR). The proceedings, records, minutes, and reports that emanate from quality assurance program activities and are produced or compiled by the DoD as part of a medical quality assurance program as defined in Section 1102 of Title 10, United States Code.

Military Health System (MHS). DoD medical and dental programs, personnel, facilities, and other assets operating pursuant to Chapter 55 of DoD Directive 5136.01, by which the DoD provides:

Healthcare services and support to the Military Services during the range of military operations.

Healthcare services and support to members of the Military Services, their family members, and others entitled to DoD medical care.

monitoring and evaluation. A well-defined, time-limited, well documented plan of focused professional practice evaluation (FPPE) to confirm a healthcare provider possesses the knowledge, skills, and ability to render safe and effective healthcare. It must include a documented plan with delineation of clear expectations and measures of success. It requires a preceptor who provides full written evaluation of the monitoring period, with regular interval feedback, to both the provider and the Credentials Committee/Function. Privileges/practice remain intact during the period of monitoring and evaluation.

National Practitioner Data Bank (NPDB). The NPDB is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to healthcare practitioners, providers, and suppliers. The NPDB is managed by the Department of Health and Human Services in accordance with Section 11101 of Title 42, United States Code.

near miss event. See definition of patient safety (PS) event.

no–harm event. See definition of patient safety (PS) event.

non-privileged provider. An individual who possesses a license, certification, or registration by a state, commonwealth, territory, or possession of the United States, and is only permitted to engage in the delivery of healthcare as defined in their granted scope of practice. Examples include registered nurse (RN), licensed vocational nurse (LVN), registered dental hygienist (RDH), and medical technician.

ongoing professional practice evaluation (OPPE). A documented summary of ongoing data collected for the purpose of assessing a healthcare provider's clinical competence and professional behavior. The information gathered during this process allows for identification of practice trends that may adversely affect, or could adversely affect, the health or welfare of a patient. It is the responsibility of the organization to determine the criteria used in the ongoing professional practice evaluation.

other authorizing document. A mechanism, such as registration and certification, by which a State, the District of Columbia, a Commonwealth, territory, or possession of the United States, grants authority to provide healthcare in a specified discipline. In specialties not licensed and where the requirements of the granting authority for registration or certification are highly variable, the validation by a national organization that an individual is professionally qualified to provide healthcare in a specified discipline. Special considerations apply in the case where healthcare is provided in a foreign country by any person who is not a national of the United States.

outcomes. The result of performance (or nonperformance) of a function, process, or series of processes. States or conditions of individuals and populations attributed or attributable to antecedent healthcare. They can include adverse or beneficial results of care, short- or long-term results of care, complications, or occurrences, and are the product of the performance (or nonperformance) of one or more functions or processes.

patient safety (PS) event. A PS event is an incident or condition that could have resulted, or did result, in harm to a patient. A PS event can be but is not necessarily the result of a defective system or process design, a system or process breakdown, equipment failure or malfunction, or human error. PS events include adverse events, no-harm events, near miss events, and unsafe/hazardous conditions as defined below:

adverse event. PS event that resulted in harm to the patient. The event may occur by the omission or commission of medical care.

no-harm event. PS event that reached the patient but did not cause harm.

near miss event. PS event that did not reach the patient (also known as "close call" or "good catch").

unsafe/hazardous condition. A condition or a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

peer. A healthcare provider with generally similar privileges, practice, clinical specialty and level of training.

peer review. Any assessment of the quality of medical care carried out by a healthcare provider, including any such assessment of professional performance, any patient safety program Comprehensive Systematic Analysis (CSA) or report, or any other such assessment carried out by a healthcare provider under provisions of this manual.

performance improvement. Continuous study and improvement of processes with the intent to achieve better services or outcomes, and prevent or decrease the likelihood of problems, by identifying areas of opportunity and testing new approaches to fix underlying causes of persistent/systemic problems or barriers to improvement.

plan-do-check-act/plan-do-study-act (PDCA/PDSA). A management method for the control and continuous improvement of processes and products. This four-step model includes assessing the current process; enacting the plan; evaluating and comparing data to expected outcomes; and developing corrective actions based on outcomes.

potentially compensable event (PCE). Any patient safety (PS) event that both a) reaches the patient (i.e., adverse event and no-harm event) and b) has a Healthcare Risk Management assessment that determines that the event is likely to present a possible financial loss to the Federal Government. All DoD Reportable Events (DoD REs) are PCEs. All events that trigger a PCE will also be referred to the Patient Safety Manager to ensure capture in the Joint Patient Safety Reporting (JPSR) system and investigation/analysis as defined in Volume 2, Patient Safety of this manual.

preceptor. A clinical peer who has been appointed in writing to evaluate a healthcare provider's clinical practice. The preceptor is designated for consultation, clinical feedback, and general oversight of the clinical activities of the provider. A preceptor may review medical records, and conduct direct observation of a provider's practice, however they are not required to be present for or approve the provider's procedures or clinical decisions since the provider's clinical privilege(s)/practice is not restricted in any manner. [Contrast with the definition for "proctor".]

primary source verification. Validation that a document is true and valid through contact with the issuing institution or its authorized agent.

privileged provider. An individual who possesses appropriate credentials and is granted authorized clinical privileges to diagnose, initiate, alter, or terminate regimens of healthcare with defined scope of practice.

Privileging Authority. The Privileging Authority is a designated official who grants permission to individuals to provide specific care, treatment, or services within well-defined limits. The Privileging Authority also initiates and makes determinations on clinical adverse actions.

proactive risk assessment (PRA). Process used to identify, rate, and prioritize risks and/or hazards. Based on a risk assessment, policies, procedures and controls may be put into place to manage the risk as appropriate to the organization, with the intent of reducing risk to the lowest possible level. A form of PRA is Failure Mode Effect Analysis (FMEA): a systematic, proactive method for evaluating a process to identify where and how it might fail, to assess the relative impact of different failures, and to identify the parts of the process that are most in need of change.

process. A goal-directed, interrelated series of actions, events, mechanisms, or steps. Processes should always be designed with flexibility in mind and the ability to periodically introduce controlled, measurable changes.

proctor. A clinical peer who has been appointed in writing to supervise all or some of a healthcare provider's clinical practice. The proctor is required in order for the provider to proceed in exercising designated clinical privilege(s)/practice. The proctor provides direct

oversight of designated clinical activities and must co-sign all such documentation conducted by the provider. Certain procedures may require proctor approval prior to performing. All designated procedures will require some period of direct observation by the proctor. Proctors are required for providers with supervised privileges, and for those who have had a clinical adverse action taken against them with subsequent restriction in privilege(s)/practice. [Contrast with the definition for "preceptor".]

purchased care system. A component of the uniform program of medical and dental care for members and certain former members of the Services, and for their dependents where services are provided to beneficiaries by TRICARE-authorized civilian network and non-network healthcare providers and facilities.

quality healthcare. The degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Care that is evidence-based and provided in a technically and culturally competent manner with good communication and shared decision making as defined in the Institute of Medicine's (IOM) Crossing the Quality Chasm: A New Health System for the 21st Century.

rapid process improvement or just do it. A fast and effective approach to improve a process that usually takes a week or less completed by the members of the process or value stream.

reduction of clinical privilege(s)/practice. A portion of a healthcare provider's clinical privilege(s)/practice that is permanently removed as a result of a professional review action following appropriate due process proceedings. It may be based on evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Reductions in privilege(s)/practice are reportable to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies.

reinstatement of clinical privilege(s)/practice. The return of regular clinical privilege(s)/practice as a result of a professional review action following appropriate due process proceedings that may or may not include a period of monitoring and evaluation. Reinstatement after a clinical adverse action that was previously reported to the National Practitioner Data Bank (NPDB) is documented in the Revision-to-Action Report to the NPDB. Reinstatement is also reported to state(s) of licensure, and other applicable certifying/regulatory agencies.

Report Authority. The official with responsibility to report to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies following appropriate due process proceedings. The Report Authority is:

(1) The Director of the DHA with respect to matters arising from acts or omissions of healthcare providers privileged by a Privileging Authority under the responsibility of the DHA.

(2) The Surgeon General of the Army, Navy, or Air Force, respectively, with respect to matters arising from acts or omissions of healthcare providers privileged by a Privileging Authority under the responsibility of the Army, Navy, or Air Force, respectively.

(3) In cases in which the healthcare provider is privileged by more than one of the Report Authorities listed in subparagraphs (1) and (2), the one whose responsibility applies to the Privileging Authority most responsible for the matters under review. In cases of uncertainty, the DHA Director will designate the Report Authority. The designated Report Authority will ensure there is a comprehensive review of the entire matter.

restriction of clinical privilege(s)/practice. A temporary or permanent limit placed on a portion of a healthcare provider's clinical privilege(s)/practice that results from a professional review action following appropriate due process proceedings. It may be based on evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Restricted privilege(s)/practice require supervision by a proctor. Restrictions are reportable to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies.

revocation of clinical privileges/practice. The permanent removal of all of a healthcare provider's clinical privileges/practice as a result of a professional review action following appropriate due process proceedings. It may be based on evidence of misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Revocations of privileges/practice are reportable to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies.

significantly involved provider (SIP). A SIP is one who actively delivered care (based on clinical record entries) in either primary or consultative roles during the episodes of care that gave rise to the allegation, regardless of standard of care (SOC) determination. Additional defining characteristics include providers that: have the authority to start, stop or alter a course of treatment; have the authority to recommend to start, stop, or alter a course of treatment; or have the responsibility to implement a plan of evaluation or treatment. Authority to recommend means that input was solicited and legitimate (i.e., the individual making the recommendation was acknowledged to have special expertise or other specific standing in the clinical issues). This term is not meant to include the providers who had only peripheral, yet appropriate, patient interaction, nor those providers whose patient involvement was not reasonably related to the specific indications or allegations of sub-standard care and injury.

Six Sigma. The focus is a data-driven approach and methodology for eliminating defects and reducing variability. The goal is to achieve measurable and quantifiable returns by developing processes to achieve stable and predictable results and identifying procedures that can be defined, measured, analyzed, improved upon, and controlled. A commitment from the entire organization, especially high-level management, is essential to achieve sustainment in quality management.

standard of care (SOC). Healthcare judgments and actions of a healthcare provider generally accepted in the discipline or specialty involved as reasonable and appropriate.

summary suspension of clinical privilege(s)/practice. The temporary removal of all or a portion of a healthcare provider's privilege(s)/practice, taken prior to the completion of due process

procedures, based on determination by the Privileging Authority for concerns regarding suspected misconduct, impairment, or incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient. A summary suspension continues until due process proceedings are complete. All summary suspensions of privileged providers that last longer than 30 calendar days must be reported to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying/regulatory agencies.

telemedicine. Telemedicine, also known as telehealth or virtual health, is the use of telecommunications and information technologies to provide health assessment, treatment, diagnosis, intervention, consultation, clinical supervision, education, and information across distances.

> distant site. The distant site is where the healthcare provider providing the medical service is located at the time the service is provided via telemedicine. The DoD virtual medical center (VMC) may function as a distant site for purposes of this manual.
>
> originating site. The originating site is the location of a patient at the time the service is provided via telemedicine. The DoD virtual medical center (VMC) may be considered an originating site for purposes of this manual.

trainee. Any resident, intern, or other healthcare provider in a formal healthcare training status.

unsafe/hazardous condition. See definition for patient safety (PS) event.

variation. An undesirable deviation from expected outcomes.

virtual medical center (VMC). A VMC is an organization which serves as a coordination body overseeing the delivery of healthcare via telemedicine. The DoD VMC must operate in affiliation with an accredited MTF or be independently accredited. If the DoD VMC does not have its own Privileging Authority, it should use the Privileging Authority of an accredited MTF with which it is affiliated. The DoD VMC, acting as a distant site, must have a process in place to accept quality and safety feedback on the care provided, and take action as appropriate.