# Defense Health Agency

# PROCEDURES MANUAL

**NUMBER** 6025.13, Volume 1
August 29, 2019

Medical Affairs

SUBJECT: Clinical Quality Management in the Military Health System, Volume 1: General Clinical Quality Management

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 (ab), 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 (ab), 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

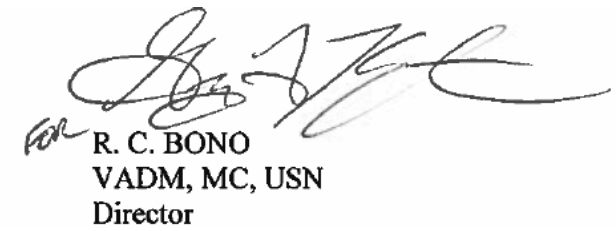
include the electronic medical record, databases such as the Joint Centralized Credentials Quality Assurance System (JCCQAS), and the Joint Patient Safety Reporting (JPSR), data visualization and report tools on CarePoint (a SharePoint platform), and more.

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 1, 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, Section 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) Office of the Under Secretary of Defense, Personnel and Readiness Memorandum, "Strengthening Clinical Quality Management in the Military Health System," April 1, 2019
(p) United States Code, Title 10
(q) Office of Management and Budget, Statistical Policy Working Paper 22, December 2005[1]
(r) The High Reliability Organization Task Force Report, "A Resource Guide for Achieving High Reliability in the Military Health System," September 15, 2015[2]
(s) Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press, 2001
(t) DHA-Procedural Instruction 6025.17, "Healthcare Resolutions, Disclosure, Clinical Conflict Management and Healthcare Provider Resiliency and Support in the Military Health System (MHS)," June 18, 2019

[1] This reference can be found at: https //www.hhs.gov/sites/default/files/spwp22.pdf
[2] This reference is available internally through a CAC–enabled website at: https://info.health.mil/coi/mhshro/Documents/Deliverables

(u) Deputy Secretary of Defense Memorandum, "Implementing Congressional Direction for Reform of the Military Health System," September 28, 2018
(v) DoD Manual 5400.07, "DoD Freedom of Information Act (FOIA) Program," January 25, 2017
(w) Code of Federal Regulations, Title 45, Parts 160 and 164
(x) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019
(y) DoD 5400.11-R, "DoD Privacy Program," May 14, 2007
(z) Office of the Deputy Chief Management Officer Administrative Instruction 15, "OSD Records and Information Management Program," May 3, 2013, as amended
(aa) Public Law 101-629, "Safe Medical Devices Act of 1990," November 28, 1990
(ab) DoD Instruction 8580.02, "Security of Individually Identifiable Health Information in DoD Health Care Programs," August 12, 2015

# ENCLOSURE 2

# RESPONSIBILITIES

1. MILITARY DEPARTMENTS. The Military Departments will establish, direct implementation of, and ensure compliance with standards and procedures in this DHA-PM.

2. DIRECTOR, DHA. The Director, DHA will:

a. Establish, direct implementation of, and ensure compliance with standards and procedures in this DHA-PM.

b. Ensure that contracts for all MCSCs, designated providers, personal services contractors and non-personal services contractors, overseas contractors, and civilian authorized provider agreements throughout the MHS reflect the applicable guidance set forth in this DHA-PM through contract language.

c. Approve exceptions to policy contained in this manual, consistent with law and applicable DoD policy. Exceptions to policy may be requested by the Military Departments, acting through the Surgeon General or Military Department Secretariat.

(1) During the period of transition to full operational capability of the DHA under Section 1073c of Reference (p), consideration of potential exceptions to policy will take into account practical circumstances of the transition, pursuant to Reference (o).

(2) Although this manual is applicable to the entire MHS, consideration of potential exceptions will take into account practical circumstances of MHS functions and activities that are under the primary responsibility of the Military Departments. However, exceptions to policy shall maintain comparable clinical quality standards.

3. ASSISTANT DIRECTOR, HEALTHCARE ADMINISTRATION, DHA/MILITARY DEPARTMENT DESIGNEE. The Assistant Director, Healthcare Administration, DHA/Military Department Designee will:

a. Establish, direct implementation of, and ensure compliance with standards and procedures in this DHA-PM.

b. Ensure that contracts for all MCSCs, designated providers, personal services contractors and non-personal services contractors, overseas contractors, and civilian authorized provider agreements throughout the MHS reflect the applicable guidance set forth in this DHA-PM through contract language.

4. DEPUTY ASSISTANT DIRECTOR MEDICAL AFFAIRS (DAD MA), DHA/MILITARY DEPARTMENT DESIGNEE. The DAD MA, DHA/Military Department Designee will:

a. Be responsible for the execution of CQM in the MHS.

b. Monitor and evaluate execution of CQM in the MHS. Align CQM reporting with associated DHA and MHS committees.

c. Prepare correspondence of waivers, requests for release of data, data sharing agreements (DSA), and registry participation requests for the Assistant Secretary of Defense for Health Affairs (ASD(HA)) or DHA Director/Military Department Designee, as appropriate.

d. Standardize CQM activities, to include the DHA DAD MA established core competencies of CQM personnel.

e. Develop implementing guidance for data use, data transparency, release of aggregated statistical data, and protection of Medical Quality Assurance Program (MQAP) data.

f. Ensure CQM review or coordination of appropriate DHA clinical issuances.

5. DHA MARKET DIRECTOR/INTERMEDIATE HEADQUARTERS. The DHA Market Director/Intermediate Headquarters will:

a. Be responsible for the execution of CQM in the DHA Market/Intermediate Headquarters organizations, as per DHA guidance.

b. Support Clinical Community clinical quality improvement (CQI) priorities, as per DHA guidance.

c. Support coordination of CQM activities with clinical service delivery operations to implement highly reliable, high value, patient-centered experiences and outcomes.

d. Ensure requests for the release of CQM aggregated statistical data are in accordance with Section 1102 of Reference (p) and Reference (q). Ensure requests are sent to DHA DAD MA (or designee).

6. MTF DIRECTOR/MILITARY DEPARTMENT DESIGNEE. The MTF Director/Military Department Designee will:

a. Be responsible for the execution of CQM in their organization.

b. Ensure the protection of Medical Quality Assurance Records (MQAR). Ensure that release violations of MQAP data are reported, as well as violations of the Health Insurance Portability and Accountability Act (HIPAA).

c. Ensure requests for the release of CQM aggregated statistical data are in accordance with Section 1102 of Reference (p) and Reference (q). Ensure requests are sent through the respective DHA Market/Intermediate Headquarters CQM personnel prior to sending requests to DHA DAD MA (or designee).

d. Communicate concerns or barriers to compliance with policy or regulatory standards to DHA DAD MA through appropriate higher headquarters.

# ENCLOSURE 3

# GENERAL CLINICAL QUALITY MANAGEMENT

1. GENERAL OVERVIEW. This overview and each of the subsequent volumes outline the CQM activities that occur to assure and improve the quality and safety of healthcare services delivered. Through competent and committed staff, a robust foundation for the provision of high-quality care and the highest levels of MHS leadership advocacy, the MHS strives to promote health, prevent harm, and provide high-quality, evidence-based care with each encounter.

a. Purpose. The purpose of CQM in the MHS is 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. The framework is guided by CQM strategy elements and supported by CQM functions and programs. Through CQM, the MHS affirms its unwavering commitment to quality healthcare for beneficiaries, joint healthcare teams, and Combatant Commands across the globe.

b. Functions. Subsequent volumes of this DHA-PM outline programs and specific procedures through which the MHS defines, measures, assures, and improves the quality of care received by the beneficiaries. These volumes provide accountability, transparency, and standardization throughout the MHS. The CQM programs include:

(1) Patient Safety (PS). MHS program to promote safety and prevent harm.

(2) Healthcare Risk Management (HRM). MHS program to mitigate risk in the clinical aspects of healthcare delivery.

(3) Credentialing and Privileging (CP). MHS program to ensure qualified and competent staff.

(4) Accreditation and Compliance (AC). MHS program to ensure compliance with standards.

(5) Clinical Measurement (CM). MHS program to objectively define, measure, assess, and report the quality of care delivered.

(6) Clinical Quality Improvement (CQI). MHS program to improve the quality of care and services delivered.

c. CQM Strategy Elements. The elements are foundational aims and principles that guide CQM in the MHS. They include:

(1) MHS Quadruple Aim. The MHS Quadruple Aim, the MHS's goal, represents leadership's commitment to delivering value to all they serve. The Quadruple Aim is aligned with the MHS strategic goals. Elements of the Quadruple Aim include:

(a) Increased Readiness. Ensuring the entire military force is medically ready to deploy and the medical force is ready to deliver healthcare anytime, anywhere, in support of the full range of military operations.

(b) Better Care. Providing a care experience that is patient and family centered, compassionate, convenient, equitable, safe, and always of the highest quality.

(c) Better Health. Improving the health of a population by encouraging healthy behaviors and reducing the likelihood of illness through focused prevention and increased resilience.

(d) Lower Cost. Creating value by focusing on quality, eliminating waste, and reducing unwarranted variation. Considering the total cost of care over time, not just the cost of an individual healthcare activity.

(2) MHS High Reliability Organization (HRO) Principles. Through application of HRO principles, MHS staff affirm and express a single-minded focus on identifying potential problems and high-risk situations before they lead to a PS event that reaches the patient. The MHS aims for harm prevention and process improvement to become second nature for everyone. HRO principles provide a common knowledge base for healthcare personnel and provide information on how all staff and leadership can demonstrate behaviors necessary for HRO maturity. Taken individually, each principle may improve elements of the healthcare delivery system; however, collectively, they form the foundation for an HRO and are critical enablers for the MHS to achieve its strategic goals of the Quadruple Aim. MHS HRO principles include (Reference (r)):

(a) First, Do No Harm (changed to "Preoccupation with Failure" per the Medical Operations Group approval March 13, 2017)

1. By eliminating harm and maximizing benefits, leaders and staff enable better care and better health, improve the efficiency of the MHS, and improve readiness to execute missions.

2. Evidenced by commitment from all members of the healthcare team at every level to first consider the risks and potential benefits of any clinical decision or action.

(b) Sensitivity to Operations

1. High-performing healthcare organizations have leaders and staff who are constantly aware of the state of systems and processes that affect patient care.

2. Evidenced by the use of standards and standard work to mitigate errors, reduce undesired variability, and identify opportunities for improvement.

3. Leaders support the use of regular staff huddles to share information and engage in walk rounds to learn more about how they can help frontline staff improve care and eliminate harm.

(c) Deference to Expertise

1. When confronted by a new threat, HROs have mechanisms in place to identify the individuals with the greatest expertise relevant to managing the new situation and to place decision-making authority in the hands of that person or group.

2. Evidenced by seeking out, listening to, and valuing the input of those with the most knowledge and expertise on an issue, rather than relying on top-down direction to solve problems.

(d) Reluctance to Simplify

1. Staff are reluctant to simplify, avoiding simple or easy explanations for mishaps.

2. Evidenced by seeking to understand how complex, interdependent policies and processes can better support safe healthcare delivery.

3. Leaders and staff recognize that healthcare delivery is highly complex with inherent patient risks that must be explored, mitigated, and overcome.

(e) Commitment to Resilience

1. Leaders and staff recognize that, despite safeguards and a shared commitment at every level of eliminating harm, systems can still fail in unexpected ways.

2. Evidenced by ensuring all staff are trained, supported, and prepared to learn from failures to minimize the risk of recurrence.

3. Leaders incorporate appropriate redundancies or safeguards to mitigate the effects of system failures before they lead to harm.

4. Commitment to resilience enables staff to continue to deliver high-quality care even after a major mishap.

(f) Constancy of Purpose

1. Leaders evidence constancy of purpose by agreeing on a clear commitment to eliminating harm and setting organizational goals based on a shared vision of safety.

2. Staff evidence constancy of purpose by aligning actions with the organization's highest priority to eliminate harm.

3. Over time, with a focus on constancy of purpose to eliminate harm, there is a collective mindfulness, which fosters a culture of safety.

(g) Respect for People

1. Healthcare organizations that deliver the safest and most effective care also uniformly endorse the principle of respect for people as the foundation for improving healthcare delivery.

2. Evidenced by striving to create a just culture in which staff and patients are trusted, valued, and relied on to initiate improvement and innovations at the frontlines.

3. Every member of the healthcare team demonstrates respect for the patients and the families they serve, as well as their professional colleagues.

(h) Fostering a Culture of Safety

1. Staff in high-performing organizations rely on leadership commitment to create a culture focused on safe care, continuous learning, innovation, and improvement.

2. Evidenced by staff with openness to change, seeking knowledge and making application of process improvement tools.

3. Evidenced by proactive vigilance for any deviations from leading practices and speaking up at any opportunity to improve the safety of the care they provide or the environment in which they work.

4. Evidenced by staff members who view themselves as leaders committed to: influencing others to strive for zero harm in the MHS; learning from feedback; engaging in effective teamwork; and anticipating the unexpected (Reference (r)).

(3) MHS Aims for Healthcare Quality. The MHS strives to adopt the six aims of healthcare put forth by the Institute of Medicine (IOM) (now known as the National Academy of Medicine). According to the IOM, quality healthcare should be safe, timely, effective, efficient, equitable, and patient-centered (STEEEP) (Reference (s)).

(a) Safe. Avoiding harm to patients from the care intended to help them. In addition to the DoD Patient Safety Program (PSP), staff safety is also an MHS priority for safe patient care.

(b) Timely. Reducing wait times and sometimes harmful delays for both those who receive and give care.

(c) Effective. Providing services based on scientific knowledge, to all who could benefit and refraining from providing services to those not likely to benefit (e.g., avoiding underuse and misuse, respectively).

(d) Efficient. Avoiding waste of equipment, supplies, ideas, and energy.

(e) Equitable. Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, socioeconomic status, or any other demographic detail.

(f) Patient-centered and provider-centered. Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring patient values guide all clinical decisions.

d. Healthcare Resolutions and a Patient's Right to Be Heard. In addition to many patient-centered advocacies and activities throughout the MHS, the Healthcare Resolutions Program uniquely focuses on disclosures for PS events that reach the patient, complex clinical issues requiring assistance with resolution, and peer support for involved providers. Healthcare Resolutions Specialists are neutral and must serve the needs of patients, providers and the involved organization. Healthcare Resolutions is separate and distinct from Legal, CQM (to include PS and HRM), and patient experience programs, such as Patient Advocacy or Patient Relations. Furthermore, any patient, including any uniformed Service member, who believes they have suffered personal harm due to a perceived failure to provide quality medical care, has the right to submit their concerns in writing as part of an MQAP review of the care provided. The requirement that a patient's concerns be written will ensure inclusion of the patient's input throughout the MQAP review procedures; this includes, but is not limited to, those described in Volume 2 and Volume 3 of this manual. This written requirement does not include the complaint and grievance procedures handled by Healthcare Resolutions and Patient Experience staff (e.g., Patient Advocacy or Patient Relations). For further guidance on Healthcare Resolutions and a Patient's Right to Be Heard, please see Reference (t).

2. KEY OPERATIONAL DEFINITIONS. The quality of healthcare in the MHS is defined as the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Knowledge of this term is essential to understanding the scope, core responsibilities, and procedures of CQM. A full list of definitions for this manual is included in the Glossary.

3. GOVERNANCE. The DHA Director/Service Surgeon General (SG) supports the ASD(HA) by executing effective CQM in the MHS in accordance with References (d) and (u), and aligns CQM reporting with associated MHS committees for ASD(HA) oversight.

4. MEDICAL QUALITY ASSURANCE PROGRAM (MQAP). The term "Medical Quality Assurance Program (MQAP)" (per the law) means any peer review 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. The term "Medical Quality Assurance Record (MQAR)" means the proceedings, records, minutes, and reports that emanate from quality assurance program activities described under MQAP and are produced or compiled by the DoD as part of an MQAP. The term "peer review" means any assessment of the quality of medical care carried out by a healthcare provider, including any such assessment of professional performance, any PS program Comprehensive Systematic Analysis (CSA) or report, or any assessment carried out by a healthcare provider under the provisions of this manual. Each of the six CQM programs may potentially create an MQAR from peer review and care must be taken to protect such records, in accordance with Section 1102 of Reference (p).

a. Confidentiality of Records

(1) MQARs created by or for the DoD as part of an MQAP are confidential and privileged. MQARs may not be disclosed to any person or entity, except as provided in Section 1102 of Reference (p).

(2) In accordance with Section 1102 of Reference (p), these records are exempt from the disclosure requirements in Reference (v).

(3) Except for the subject of an MQAP action, the identity of any person receiving healthcare services from the DoD or the identity of any other person associated with the DoD for purposes of an MQAP that is disclosed in an MQAR must be redacted in accordance with Section 164.514(a) and (b) of Reference (w) before any disclosure is made outside of the DoD.

(4) Information in an MQAR may also contain protected health information (PHI) relating to a patient. The use of this PHI is authorized in accordance with References (w) and (x). PHI contained in an MQAR may also be released, pursuant to Section 4.4.d. of Reference (x), to other government agencies and outside entities that have been designated as part of the DoD MQAP. To be so designated, Reference (x) requires:

(a) A written business associate agreement (BAA) between the DoD Component and the other entity.

(b) A DSA restricting further dissemination of the information.

(5) Release of personally identifiable information (PII) and PHI to entities engaged in MQAP activities, but that have not been incorporated into part of an MQAR, is not authorized. Nothing in this enclosure limits access to information:

(a) In a record created and maintained outside an MQAP, including a patient's medical records, because the information was presented during meetings of a review body and that review body is part of an MQAP.

(b) That is part of an organization's policies or procedures because the information was considered in an MQAR.

(c) That is not part of a peer review under an MQAP.

(6) If an actual or possible compromise of PII or PHI occurs, as defined in References (x) and (y), the event must be treated as a breach and required breach response activities must be initiated. Such requirements have been established by References (x) and (y). Among other requirements, a cyber-related breach must be reported to www.us-cert.gov within one hour of a discovery of a potential compromise and must be reported to the DHA Privacy Office within 24 hours via email at DHA.PrivacyOfficer@mail.mil, or Service Privacy Office, where appropriate (within the same timeframe).

b. Prohibition on Disclosure and Testimony

(1) No part of an MQAR may be subject to discovery or admitted into evidence in any judicial or administrative proceeding, except as provided in Section 1102 of Reference (p).

(2) A person who reviews or creates an MQAR by or for the DoD as part of an MQAP or who participates in any proceeding that reviews or creates such records may not be permitted or required to testify in any judicial or administrative proceeding with respect to such records or with respect to any finding, recommendation, evaluation, opinion, or action taken by such person or body in connection with such record, except as provided in Section 1102 of Reference (p).

(3) A person or entity having possession of or access to an MQAR or testimony may not disclose the contents of such record or testimony in any manner or for any purpose, except in accordance with Section 1102 of Reference (p).

(4) An unauthorized willful disclosure must be reported as a breach to the DHA Privacy and Civil Liberties Office as per Paragraph 4.a.(6) of this enclosure. Any person who willfully discloses an MQAR, except in accordance with Section 1102 of Reference (p), knowing that such record is an MQAR, will be subject to adverse personnel action (to include, in appropriate cases, dismissal or separation). He or she shall be fined not more than $3,000 in the case of a first offense and not more than $20,000 in the case of a subsequent offense.

(5) As provided in Paragraph (g) of Section 1102 of Reference (p), a person who participates in or provides information to a person or body that reviews or creates an MQAR shall not be civilly liable for such participation or for providing such information if the participation or provision of information was in good faith, based on prevailing professional standards at the time the MQAP activity took place.

(6) MQARs are protected from disclosure, except as described in this enclosure. For additional guidance regarding the disclosure of an MQAR, local, DHA Market, DHA Headquarters, or other appropriate servicing healthcare legal counsel should be consulted. Regarding the disposition of an MQAR, refer to Reference (z), which includes procedures for the management and disposition of OSD records.

(7) Subject to Paragraph (c) of Section 1102 of Reference (p), an MQAR or testimony may be disclosed for the following authorized purposes:

(a) To a federal executive agency or private organization, if the MQAR or testimony is needed by the agency or organization to perform licensing or accreditation functions related to DoD healthcare facilities or to perform monitoring, required by law, of DoD healthcare facilities. An example of an authorized disclosure is the mandatory requirement, in accordance with Reference (aa), to report to the Food and Drug Administration (FDA) the details of fatal or serious adverse events relating to the use of a medical device.

(b) To an administrative or judicial proceeding commenced by a present or former DoD healthcare provider concerning the termination, suspension, or limitation of clinical privileges of the healthcare provider.

(c) To a governmental board or agency or a professional healthcare society or organization, if an MQAR or testimony is needed by such board, agency, society, or organization to perform licensing, credentialing, or the monitoring of professional standards with respect to any healthcare provider who is or was a member or an employee of the DoD. This includes reports to the National Practitioner Data Bank (NPDB), in accordance with this manual.

(d) To a hospital, medical center, or other institution that provides healthcare services, if an MQAR or testimony is needed by the institution to assess the professional qualifications of any healthcare provider who is or was a member or employee of the DoD and who has applied for or been granted authority or employment to provide healthcare services in or on behalf of the institution.

(e) To an officer, employee, or contractor of the DoD who has need for a record or testimony to perform official duties. Such official duties are not limited to MQAP activities and should protected health information as defined in References (w) and (x) be included, information may not be disclosed to any party without an authorization or exception.

(f) To a criminal or civil law enforcement agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of the agency or instrumentality makes a written request that the record or testimony be provided for a purpose authorized by law.

(g) To an administrative or judicial proceeding commenced by a criminal or civil law enforcement agency or instrumentality referred to in this enclosure, but only with respect to the subject of the proceeding.

(8) This enclosure must not be construed as an authority to withhold any MQARs from a committee of Congress or any joint committee of Congress or the Comptroller General, if the record pertains to any matter within their respective jurisdictions.

5. TRANSPARENCY FOR LEARNING AND IMPROVEMENT. The MHS aims to promote transparency where disclosure of data does not conflict or is not protected by law or other guidance. Transparency promotes internal visibility of performance across the MHS by identifying leading practices over a sustained period of time; by providing important information about MHS PS, clinical quality outcomes, access, and patient experience that can help patients with their own healthcare decisions while improving the health literacy of the patient population; and by clearly establishing the MHS as accountable to its mission and the people it serves.

a. Transparency is a core characteristic of HROs and sets the course for a culture that embraces open and honest communication.

b. The MHS adopted the National Patient Safety Foundation's four domains of transparency in its Transparency Framework:

(1) Transparency between Clinicians and Patients;

(2) Transparency between Clinicians Themselves;

(3) Transparency between Healthcare Organizations; and

(4) Transparency between Clinicians and Healthcare Organizations with the Public.

c. Transparency with the Public

(1) This enclosure must not be misconstrued as authorizing or requiring the withholding from any person or entity aggregate statistical information regarding the results of the MQAP.

(2) The MHS will promote transparency where disclosure of data does not conflict or is not protected by law or other guidance. To ensure MHS CQM data transparency while protecting the patients and providers, all MHS personnel must take adequate precautions to protect the identity and privacy of the individual patients and providers involved.

(3) The MHS is committed to providing patient-centered and quality healthcare by providing CQM and MQAP aggregated statistical data in order to improve the services provided to all beneficiaries.

(4) The MHS will maintain readily available, transparent, and relevant CQM data, including MQAP aggregated statistical data, to provide its beneficiaries, enrollees, and providers in an understandable manner.

(5) MHS CQM and MQAP aggregated statistical data may be released publicly outside of the DoD, consistent with the requirements for release of aggregated statistical information. This includes response to written requests, however received, or as directed by the ASD(HA).

(a) Written requests for CQM or MQAP aggregated statistical data must be processed by the respective DHA Headquarters/Service SG CQM personnel as the primary point of contact, in close coordination with their respective legal counsel. CQM personnel support CQM and MQAP data collection, analysis, report writing, publication, and distribution. Local Privileging Authorities do not have public release authority of CQM or MQAP aggregated statistical data without prior authorization from the DHA Director or ASD(HA).

(b) Freedom of Information Act (FOIA) requests are directed to the DHA Headquarters Privacy and Civil Liberties Office or Service Privacy Office, where appropriate.

(c) Requests received by MCSC staff shall be directed in accordance with the TRICARE MCSC and reported to the MCSC Privacy Office. The MCSC's Privacy Office staff will direct the request to the DHA Headquarters Privacy and Civil Liberties Office or Service Privacy Office, where appropriate.

(6) Requirements and Standards for Release of Aggregated Statistical Data, and for Ensuring Record Privacy

(a) In accordance with Section 1102 of Reference (p) and Reference (q), CQM and MQAP aggregated statistical data may only be released outside of the DoD if adequate precautions, including but not limited to the de-identification requirements of Reference (w) and (x), are taken to protect the identity and privacy of the individual patients and providers involved. The measures must minimize the risk that a third party could use the information, along or in combination with other reasonably available information, to identify an individual who is the subject of the information released.

(b) Although CQM and MQAP data and information from individual medical records may not be released, the data may be released publicly when stated as part of aggregated statistical data, in accordance with the requirements and standards set forth in Section 1102 of Reference (p), and this manual. Statistical measures used to ensure the sufficient aggregation of data for purposes of release must be approved by the DHA Director, or ASD(HA) in the case of Service SG authority (unless delegated to the DHA Director).

(c) Requirements for release of CQM and MQAP data, including standards for the sufficient aggregation of data, have been developed to ensure the privacy of the individual's health and treatment records, as well as to prevent the inadvertent release of information that would allow identification of the individuals involved when the released information is combined with other publicly available data. DoD has adopted a threshold rule (Reference (q)), which helps ensure data are appropriately aggregated to protect health information prior to release. Compliance with aggregation standards alone may not be sufficient to comply with the fundamental requirement that CQM and MQAP aggregated statistical data derived from medical records may only be released outside of the DoD if adequate precautions are taken to protect the

identity and privacy of the individual patients and providers involved per the requirements of References (w) and (x). In all cases, measures must minimize the risk that a third party could use the information alone, or in combination with, other reasonably available information, to identify an individual who is the subject of the information released.

(d) These requirements recognize that there may be instances when a third party possesses insider information or knowledge about a patient or individual provider based on a personal relationship (e.g., family member, neighbor, close friend) with that patient or individual provider and that these persons may be able to add their insider knowledge to the information released by the DoD to the public, thereby identifying that individual as a member of the demographic grouping. However, absent this insider information, the requirements outlined in this section provide protections against others being able to positively identify a member of a demographic grouping.

(e) The ASD(HA) shall establish guidance regarding other releases of individual organizational (e.g., MTF, other) CQM data. Generally, CQM aggregated statistical data may be released outside of the DoD when adequate precautions have been taken to protect the identity and privacy of the individual patients and providers involved.

(f) The MHS shall utilize a threshold rule of four, as described in Chapter II, Section D.2.b. of Reference (q), pertaining to the release of aggregated statistical data, to protect the identity and privacy of the individual patients and providers involved. With the threshold rule, a cell in a table of frequencies is defined as sensitive if the number of respondents, or non-zero observations or events, is less than four. The choice of the minimum number was made in accordance with Reference (q) in consideration of: (1) the sensitivity of the information that the MHS is considering publishing and (2) the amount of protection the MHS determines to be necessary given the degree of precision required to achieve disclosure. The threshold rule of four provides the standard "minimum" level of protection against statistical disclosure by essentially masking numbers below the threshold. By withholding data with numerical values below "4" (essentially, withholding 1's, 2's and 3's), the DHA introduces a level of ambiguity so that reviewers of this data cannot single out specific individuals.

1. In some instances, information may be of a nature that when combined with other relevant publicly-available data may lead to the reasonable identification of the individual. On a case-by-case basis in consultation with legal counsel, information may be withheld from release even though the data complies with the threshold rule, where a determination has been made that the identity and privacy of the individual patients and providers involved is subject to identification.

2. Limiting disclosure to a threshold rule of four is not mandatory in every instance where the information presented is sufficiently broad and lacks meaningful identifying demographic groupings. On a case-by-case basis in consultation with legal counsel, sufficiently broad information may be released, where a determination has been made that the identity and privacy of the individual patients and providers involved is not likely subject to identification.

Such a determination must include consideration of compliance with the HIPAA Privacy Rule, to include situations where the data includes geographic subdivisions smaller than a state (e.g., MTF-specific data).

d. DSAs

(1) A DSA is required for release of patient-related information. In addition to maintaining the confidentiality of PII of MHS providers and other DoD personnel involved in an MQAP, the DoD is also required to establish safeguards to protect the privacy of beneficiaries' PHI, in accordance with References (x), (y), and (ab). Among the required safeguards are DSAs. DSAs must be executed by outside parties who request access to DoD beneficiary data. DSAs obligate outside parties to maintain the confidentiality of patient-related data they receive. This is not intended to require a DSA when releasing patient-related information to Congressional committees or to individuals involved in accreditation, state licensing boards, and the like.

(2) Prior to requesting access to MHS CQM or DoD beneficiary data, the requestor should obtain an approved DSA. To do so, the requestor should submit a DSA application (DSAA) to the DHA Headquarters Privacy and Civil Liberties Office. The DHA Headquarters Privacy and Civil Liberties Office will review the DSAA for compliance to determine whether the intended data use complies with all applicable requirements. If the DSAA is approved, the DHA Headquarters Privacy and Civil Liberties Office will provide a DSA for execution. Once the DSA is executed, the requestor may apply for data access to the DHA Program Office.

# 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.