

DOD INSTRUCTION 6025.13

MEDICAL QUALITY ASSURANCE AND CLINICAL QUALITY MANAGEMENT IN THE MILITARY HEALTH SYSTEM

Originating Component: Office of the Under Secretary of Defense for Personnel and Readiness

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Reissues and Cancels: DoD Instruction 6025.13, "Medical Quality Assurance and Clinical

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as amended

Cancels: See Paragraph 1.3.

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Purpose: In accordance with the authority of DoD Directive 5124.02, this issuance:

- Establishes policy, assigns responsibilities, and provides procedures for medical quality assurance and clinical quality management (CQM), consistent with the requirements of section 744 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021.
- Authorizes the Defense Health Agency (DHA) to issue further guidance involving medical quality assurance, CQM programs, activities for all military medical treatment facilities (MTFs), and all operational clinical services to the extent practicable, in the Military Health System (MHS).
- Supersedes the February 13, 2012 Assistant Secretary of Defense for Health Affairs Memorandum but only with respect to the reporting of sentinel events.

TABLE OF CONTENTS

SECTION 1: GENERAL ISSUANCE INFORMATION	3
1.1. Applicability.	3
1.2. Policy	3
1.3. Cancelled Documents.	4
1.4. Summary of Change 1.	5
Section 2: Responsibilities	6
2.1. ASD(HA)	6
2.2. Director, DHA	6
2.3. Secretaries of the MILDEPS	9
SECTION 3: MILDEP SG SUPPORT OF MHS CQM	11
3.1. Establishing CQM Capability.	11
3.2. Establishing Off-Duty Employment Procedures.	12
3.3. Exercising Privileging Authority.	12
SECTION 4: CQM PROGRAMS	13
4.1. CQM	13
4.2. PS	17
4.3. HRM	18
4.4. CP	22
4.5. AC	25
4.6. CM	26
4.7. CQI	27
SECTION 5: MHS HRM WORKING GROUP	29
5.1. Mission	29
5.2. Organization	29
5.3. Reporting	29
GLOSSARY	31
G.1. Acronyms.	31
G.2. Definitions.	32
REFERENCES	38

SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

This issuance applies to:

- a. OSD, the Military Departments (MILDEPs), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the "DoD Components").
 - b. All MTFs.
 - c. Operational clinical services.
- d. Service members of the Active and Reserve Components (including National Guard personnel in a Title 10 or Title 32 duty status), civilian, contract, volunteer, and other medical or dental health care providers who deliver health care or operational clinical services in the DoD.
- e. Managed care support contractors, designated providers, and overseas contractors, consistent with their respective contracts awarded by the DoD.

1.2. POLICY.

- a. DoD ensures safety and quality in all aspects of the MHS under a comprehensive Military Health System Clinical Quality Management Program pursuant to Section 744 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021.
- b. MHS CQM programs are implemented with a focus on accountability, transparency, and standardization throughout the MHS; and include, but are not limited to:
 - (1) Patient safety (PS).
 - (2) Health care risk management (HRM).
 - (3) Credentialing and privileging (CP).
 - (4) Accreditation and compliance (AC).
 - (5) Clinical measurement (CM).
 - (6) Clinical quality improvement (CQI).
- c. DoD develops and implements those organizational structures, education and training requirements, policies, and means to engage external stakeholders to ensure the MHS adheres to

high reliability organization (HRO) principles when delivering health care and operational clinical services.

- d. DoD implements a full range of procedures for productive communication between patients and health care providers regarding actual or perceived adverse clinical events.
- (1) Procedures for full disclosure of such events (respecting the confidentiality of medical quality assurance (MQA) records).
- (2) Procedures to resolve patient concerns by independent, neutral health care resolutions specialists under Defense Health Agency Procedural Instruction 6025.17.
- (3) Patients and their families, including Service members and their dependents, have a right to have their thoughts, opinions, and complaints heard regarding care provided by the MHS. If any patient believes they have suffered personal harm due to a perceived failure to provide quality medical care, they have the right to submit their concerns in writing as part of the MQA review of the care provided. The requirement for written concerns will ensure inclusion of these submissions throughout the MQA review procedures. This written requirement does not extend to complaints, concerns, or grievances presented to health care resolutions and patient experience staff (e.g., patient advocacy or patient relations) when not associated with an MQA review.
- e. MQA records and information created by or for the DoD as part of the MQA program are confidential and privileged in accordance with Section 1102 of Title 10, United States Code (U.S.C.). Disclosures of such records and information, other than aggregate statistical information, will occur only as authorized by Section 1102 of Title 10, U.S.C.
- f. DoD implements medical management procedures in accordance with DoD Instruction 6025.20 to ensure that health care services provided in MTFs or by non-DoD providers at DoD expense are necessary and appropriate.

1.3. CANCELLED DOCUMENTS.

This issuance cancels the following documents:

- a. Assistant Secretary of Defense for Health Affairs (ASD(HA) Memorandums:
- (1) "Medical Quality Assurance and Clinical Quality Management in the Military Health System Sentinel Event and Root Cause Analysis Process Improvements," March 12, 2015
 - (2) "Military Health System Definition of Quality in Health Care," May 9, 2002
- (3) "Policy Memorandum for Military Health System Health Care Quality Assurance Data Transparency," October 20, 2010
- (4) "Policy on Reporting Joint Commission on Accreditation of Healthcare Organizations-Reviewable Sentinel Events in the Military Health System," July 13, 2004

- (5) "Reporting Sentinel Events to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)," September 24, 1998
- b. DoD Manual 6025.13, "Medical Quality Assurance and Clinical Quality Management in the Military Health System," October 29, 2013
- c. Under Secretary of Defense for Personnel and Readiness Memorandum, "Strengthening Clinical Quality Management in the Military Health System," April 1, 2019

1.4. SUMMARY OF CHANGE 1.

The change to this issuance is administrative and updates language to comply with Executive Order 14173.

SECTION 2: RESPONSIBILITIES

2.1. ASD(HA).

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, and in accordance with DoD Directive 5136.01, the ASD(HA):

- a. Is accountable for the success of CQM in the MHS.
- b. Oversees the implementation of this issuance, ensuring consistent application across the MHS.
 - c. Develops supporting guidance, as necessary, to implement this issuance.
 - d. Exercises any authority:
- (1) Of the Secretary of a MILDEP, a MILDEP Surgeon General (SG), or the Director, DHA, including authority pertaining to clinical adverse actions and reports to the National Practitioner Data Bank (NPDB) pursuant to this issuance, to the extent the ASD(HA) determines necessary in the implementation of this issuance.
- (2) To approve MHS participation in systematic measurement of indicators of health care quality and comparison of such indicators with benchmarks from other health care systems and promotion of transparency regarding MHS CQM. The participation of DoD Components in such compilations for disclosure is subject to ASD(HA) approval.
- (3) To grant waivers or exceptions to this issuance in exceptional circumstances, in accordance with law.
 - e. Develops measures for appropriate oversight of MHS CQM programs.

2.2. DIRECTOR, DHA.

Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, through the ASD(HA), the Director, DHA:

- a. Is accountable for the success of CQM in the DHA.
 - (1) Provides a CQM strategy and plan to the ASD(HA), or designee, annually.
 - (2) Establishes in TRICARE:
 - (a) Regulations, contracts, and regulatory guidance to implement this instruction.
- (b) Appropriate standards for quality assurance and PS in TRICARE provider networks and other TRICARE-authorized providers.

- b. Develops procedures to satisfy the requirements of each of the six CQM programs outlined in this issuance, and implements them within all MTFs under the authority, direction, and control of the DHA. Ensures quality programs are in place for health care in private sector care purchased through managed care support contracts.
- (1) Includes procedures pertaining to standard of care (SOC) determinations and the reporting of those determinations to:
 - (a) The ASD(HA).
- (b) The respective MILDEP SG when the determination involves a provider who is a Service member.
- (c) The NPDB, State(s) of licensure, and applicable certifying or regulatory agencies as appropriate.
 - (2) Includes procedures to:
 - (a) Assess potentially compensable events (PCE).
 - (b) Identify significantly involved providers (SIPs).
 - (c) Determine whether or not SOC was met.
 - (d) Learn from system and human factors issues causing or contributing to PCEs.
 - (e) Provide for appropriate accountability for SIPs in PCEs.
- (f) Develop and implement process improvement activities with follow-up reassessment for effectiveness of risk mitigation and harm prevention.
- (3) Includes procedures to establish support within the MHS for all activities under this issuance, including support for such activities for operational clinical services. At the installation level, on installations where there is an MTF, such support may take the form of integrating some or all CQM and related activities of MTFs and operational clinical services under arrangements agreed to by the MTF Director and MILDEP Medical Commander.

c. Exercises authority:

- (1) To report those providers, suppliers, and practitioners under the Director's privileging authority to the NPDB, State(s) of licensure, and applicable certifying or regulatory agencies, as appropriate. The Director, DHA:
- (a) Will not delegate this report authority below the Assistant Director for Health Care Administration, DHA, except for reports where there is no discretion on filing the report.
- (b) For action involving individuals under administrative control of a MILDEP, will notify the respective MILDEP SG within 24 hours of the report.

- (2) In cases in which a health care provider is practicing or privileged under more than one report authority (among any combination of the DHA Director or MILDEP SGs), and it is uncertain whose responsibility applies to the privileging authority most responsible for the matters under review, to designate the report authority responsible for a comprehensive review of the entire matter.
- (3) To establish procedures for off-duty employment of health care personnel under their administrative control. For health care providers, notifies any privileging authority, military or civilian, under whose authority the individual is practicing, or has been granted privileges, the nature of any off-duty employment and any noncompliance with these procedures. The privileging authority may disallow or limit any off-duty employment the privileging authority determines would interfere with delivery of health care services for which the privileging authority is responsible.
- d. Manages the ASD(HA)-approved repository for provider credential and privileging records and HRM activities (e.g., NPDB reports, status and outcome of QAIs, PCE procedures, and clinical adverse actions). Management of this repository includes management and administration of all unit identification codes and controlling access appropriately.
- (1) Coordinates with the MILDEP SGs for management of this repository and its associated functions for operational clinical services, to include authorizing MILDEP management of unit identification codes within the database in compliance with DHA procedures.
 - (2) Maintains records within this repository to at least 50 years post record inactivity.
- (3) Manages any such repository that creates, ingests, exports, or stores records in accordance with DoDI 5015.02.
- e. Requests and sustains access to Under Secretary of Defense for Personnel and Readiness casualty reports for the HRM Program within the Office of the Deputy Assistant Director for Medical Affairs (DAD MA), DHA.
 - f. Develops and implements telemedicine initiatives, including privileging by proxy.
 - g. Develops appropriate metrics to monitor, evaluate, and improve DHA CQM programs.
- h. Reports to ASD(HA) any non-concurrence with external peer review, through the MHS HRM Working Group:
- (1) Any paid medical tort or active duty claim in which the DHA Director non-concurs with the external peer review determination of SOC not met, regardless of determination of causation.
- (2) Any active duty death or disability payment, or imminent payment as in active duty health care, other adjudicated action, or decision, in which the DHA Director non-concurs with the external peer review determination of SOC not met, and the care delivered by the SIP caused or contributed to the patient harm.

2.3. SECRETARIES OF THE MILDEPS.

The Secretaries of the MILDEPs:

- a. Designate their respective SGs to serve as chief medical advisor to the Director, DHA.
- b. Hold the SG appropriately accountable for the success of CQM in accordance with this issuance in their respective Department, with respect to all health care provided under the authority of the Department.
- c. Ensure Departmental legal offices conducting adjudication of medical tort and active duty claims (including claims under Section 2733a of Title 10, U.S.C., and Part 45 of Title 32, Code of Federal Regulations (CFR)) promptly notify the HRM program in the respective MTF and the HRM program in the Office of the DHA DAD MA concerning the amount of a medical tort or active duty claim filing, settlement, judgment, or any other change in status. Data fields will include any factual information discovered during the claims process that bore on the decision to deny or settle or was relevant for any judgment, and at least:
 - (1) Unique claim identification number.
 - (2) Claimant last and first names and middle initial.
 - (3) Incident date.
 - (4) Claim filing date.
 - (5) Type of claim (Federal Tort Claims Act, Military Claims Act, active duty claim).
 - (6) Base of origin (MTF) of claim (and incident location if different than base of origin).
 - (7) Claim status (open or closed).
 - (8) Claim allegation.
 - (9) Claim amount.
 - (10) Date claim closed.
- (11) Disposition of claim when closed (e.g., was appeal filed with Department of Justice).
 - (12) Other data fields as determined appropriate by the ASD(HA).
- d. Through their respective military criminal investigative or personnel organizations, ensure completed DoD health care provider criminal, disciplinary, and government administrative actions be forwarded to privileging authorities, or designees, and the HRM Program in the office of the DHA DAD MA or respective Service HRM representative, as appropriate, for action and reporting purposes as required. Actions to be forwarded might include judicial or non-judicial

punishment, disability retirement or separation from Service, and reprimands or terminations for civilian health care providers.

- e. Ensure Departmental personnel facilitate the exchange of information needed by the DHA Director for clinical reviews of active duty death and disability cases.
- f. Ensure their respective SG reports to ASD(HA) any non-concurrence with external peer review, through the MHS HRM Working Group:
- (1) Any paid medical tort or active duty claim in which the MILEP SG non-concurs with the external peer review determination of SOC not met, regardless of determination of causation.
- (2) Any active duty death or disability payment, or imminent payment as in active duty health care other adjudicated action or decision, in which the MILDEP non-concurs with the external peer review determination of SOC not met and the care delivered by the SIP caused or contributed to the patient harm.

SECTION 3: MILDEP SG SUPPORT OF MHS CQM

3.1. ESTABLISHING CQM CAPABILITY.

Each SG:

- a. Is accountable for the success of CQM in accordance with this issuance in their respective Department with respect to all health care provided under the authority of the Department.
- b. Establishes, consistent with this issuance, in relation to operational clinical services provided under the authority of the MILDEP, CQM capability within their respective MILDEP to satisfy the requirements of each of the six CQM programs outlined in this issuance, all volumes of the Defense Health Agency-Procedures Manual (DHA-PM) 6025.13, and other activities under this issuance. Such capability may include support from DHA and may, at the installation level where an MTF is located, rely on integrated implementation of some or all such programs and activities under arrangements agreed to by the MTF Director and MILDEP Medical Commander.
 - c. Will establish guidance for operational clinical services:
- (1) Consistent with DHA-PM 6025.13, for SOC determinations and all reportable actions and resulting reporting of determinations to ASD(HA), the NPDB, State(s) of licensure, and applicable certifying or regulatory agencies.
 - (2) Consistent with DHA-PM 6025.13, to:
 - (a) Assess PCEs.
 - (b) Identify SIPs.
 - (c) Determine whether or not SOC was met.
 - (d) Learn from system and human factors issues causing or contributing to PCEs.
 - (e) Provide for appropriate accountability for SIPs in PCEs.
- (f) Develop and implement process improvement activities with follow-up reassessment for effectiveness of risk mitigation and harm prevention.
- (3) Consistent with DHA Procedural Instruction 6025.17 for health care resolutions and peer support programs, and DHA-PM 6025.13 for impaired health care provider programs.
 - (4) Consistent with DHA-PM 6025.13 for CP, to include:
 - (a) Supervision and competency review of health care providers.
 - (b) Maintenance of active privileges for members of the Reserve forces.

- (c) Standards for health care provider competencies commensurate with duty assignment and required operational clinical skills.
- (d) Standards to ensure health care provider new accessions' competencies are commensurate with duty assignment and required operational clinical skills.
 - (5) Consistent with this issuance and DHA-PM 6025.13, for AC.
- (6) Consistent with DHA-PM 6025.13, for the continuous monitoring, evaluating, and improvement of CQM programs. Guidance must incorporate MHS HRO guiding principles, with emphasis on promoting a strong culture of safety, eliminate preventable patient harm, and improve patient outcomes and experience.
- d. Will provide a CQM strategy and plan, consistent with this issuance, to the ASD(HA), or designee, annually.

3.2. ESTABLISHING OFF-DUTY EMPLOYMENT PROCEDURES.

Each SG establishes procedures for off-duty employment of health care personnel under their administrative control. For health care providers, notifies any privileging authority, military or civilian, under whose authority the individual is practicing or has been granted privileges, the nature of any off-duty employment, and any noncompliance with these procedures. The privileging authority may disallow or limit any off-duty employment the privileging authority determines would interfere with delivery of health care services for which the privileging authority is responsible.

3.3. EXERCISING PRIVILEGING AUTHORITY.

Each SG exercises authority for the following in relation to operational clinical services provided under the privileging authority of the MILDEP, and will notify the Director, DHA, or designee, in the case of any action or decision involving a health care provider:

- a. Report providers under their privileging authority to the NPDB, State(s) of licensure, and applicable certifying or regulatory agencies, as appropriate.
 - b. For clinical adverse actions under their privileging authority.
- c. For any criminal convictions or for other adjudicated actions or decisions related to the delivery of health care reported under their privileging authority.

SECTION 4: CQM PROGRAMS

4.1. CQM.

- a. Clinical quality strategy and plans will be developed, communicated, and implemented at the MHS, MILDEP SG, DHA, DHA market, and MTF leadership levels, and in operational clinical services, to ensure:
- (1) Support of the MHS mission, vision, core values, strategy, and the MHS quadruple aim.
- (2) Delivery of safe, timely, effective, efficient, outcomes-focused, and patient-centered health care across all DHA markets and their MTFs, in the MILDEPS and their operational clinical services, and in the TRICARE Health Plan network.
- (3) Consideration of social determinants, community factors, and care coordination factors that impact health outcomes.
 - (4) Incorporation of the MHS HRO guiding principles:
 - (a) Preoccupation with failure.
 - (b) Sensitivity to operations.
 - (c) Deference to expertise.
 - (d) Reluctance to simplify.
 - (e) Commitment to resilience.
 - (f) Constancy of purpose.
 - (g) Respect for people.
- b. Clinical quality planning to implement the MHS clinical quality strategy will set clear priorities for clinical quality control and assurance, and CQI. It requires leadership engagement and a learning system with standardized approaches to control, assurance, improvement, and transparency. It also requires engaging those requiring and receiving the services provided, as well as those front line staff who provide those services.
 - (1) Leadership engagement for effective CQM must be demonstrated through:
- (a) Established committee infrastructure in support of all CQM programs to define accountability and support improvement over time.
 - 1. The MHS HRM Working Group in accordance with Section 5 of this issuance.

- <u>2</u>. Additional infrastructure will be established, as appropriate, to support CQM at all levels throughout the MHS.
- (b) Established organizational expectations and training for leadership behaviors, and a structured means to identify, prioritize, and address daily management concerns and barriers impacting clinical operations (e.g., visual management, leader standard work at all levels, and accountability).
- <u>1</u>. Relationships inherent in such a system require trust, respect, and inclusion. MHS leadership at all levels must strive for a just culture that rewards reporting actual or potential harm, yet addresses reckless or malicious behavior appropriately.
- <u>2</u>. Contextual excellence (e.g., how well a service helps someone or performs) in daily management of clinical operations should be sought and encouraged over simply compliance excellence (e.g., whether or not a service was performed). MHS leadership must actively promote and encourage health care workforce development in CQM skills, and support sustainment of CQM capability and capacity.
 - (2) Transparency for effective CQM will be demonstrated in four domains:
 - (a) Transparency Between Clinicians and Patients.

Clinicians will practice honesty with patients and their families about all aspects of care, provide disclosure for adverse outcomes, and continue to strive to improve care to prevent future adverse outcomes.

(b) Transparency Between Clinicians Themselves.

Clinicians will communicate with other clinicians about the care delivered to improve coordination and consistency of care and to prevent errors.

(c) Transparency Between Health Care Organizations.

As a learning organization, each health care organization will continue to strive to improve patient care by sharing information among organizations and learning from their peers.

(d) Transparency Between Health Care Organizations, Clinicians, and the Public.

Health care organizations and their clinicians will be committed to sharing timely, accurate information about the care provided, in a way that is useful to patients.

- (3) Standardized approaches for effective CQM will be established for each MHS HRO domain of change:
 - (a) Leadership Commitment.

Leaders will engage at every level, committed to and fostering MHS HRO guiding principles.

(b) Culture of Safety.

Leaders will encourage a system-wide culture of advancing toward zero harm.

(c) Continuous Process Improvement.

Leaders will promote an integrated system in which every member is a problem solver capable of leveraging improvement science to include at least:

- $\underline{1}$. Identification, communication, and management of priorities for both clinical quality control and improvement, with clear depiction of drivers, associated measures, metrics, and respective data sources.
- <u>2</u>. Daily management of concerns with, barriers to, or sustainment of success in priorities, leveraging a health care workforce trained on CQM and MHS-wide standard processes and tools.

(d) Patient-centeredness.

Leaders will establish partnerships with empowered patients and families in communities to optimize safety, quality, and the care experience. Patient-centeredness should involve:

- $\underline{1}$. Co-design of health care and health outcomes with patients as equal partners in defining and creating value.
- <u>2</u>. Co-production with frontline health care staff for those health care services that directly impact patient health care experience and health outcomes (e.g., using the MHS HRO model involving clinical communities, clinical support services, and enabling expertise, integrating both co-design with patients and clinical decision support into care pathways and PS processes).
- c. MQA records and information created by or for the DoD as part of an MQA program are confidential and privileged in accordance with Section 1102 of Title 10, U.S.C. Disclosures of such records and information (other than aggregate statistical information) will occur only as authorized by Section 1102 of Title 10, U.S.C.
 - (1) DHA will use electronic databases to collect, track, and report:
 - (a) PS surveillance and reporting.
 - (b) HRM documentation.
- (c) Required health care provider data for credentials, clinical performance, and granting of clinical privileges.
 - (d) AC findings.

- (e) Clinical measures and metrics reported internally to the MHS or reported transparently to the public (e.g., as part of a Federal, commercial, or professional organization quality improvement effort), and relationship of such metrics and measures to MHS strategic objectives and initiatives.
- (f) CQI priorities, plans, and progress, as well as leading practices for sharing and learning.
 - (g) Strategy, plans, and performance of CQM itself.
 - (h) Additional information as needed.
- (2) All required data will be promptly documented and available in respective databases for review by the ASD(HA) or designee.
- d. The DHA and each MILDEP will ensure their respective clinical standards issuances will be reviewed or coordinated through their respective CQM programs.
- e. The DHA and each MILDEP will provide their respective CQM strategy and plan to the ASD(HA), or designee, annually.
- (1) The DHA CQM strategy and plan will be coordinated across the direct care and TRICARE Health Plan CQM programs, through regular meetings throughout the year, for an integrated approach across the system that is under DHA authority.
- (2) DHA and MILDEP submitted CQM strategies and plans will address each of the six CQM programs and will be accompanied by an annual assessment of the respective Component's previous year strategy and plan.
- (a) The DHA will provide an annual assessment of the CQM programs and program outcomes for both direct care and the TRICARE health plan to the ASD(HA) or designee; this requirement may be met through the annual TRICARE program evaluation report to Congress.
- (b) Each MILDEP will provide an annual assessment to the ASD(HA), or designee, of their respective CQM program and program outcomes.
- (c) DHA and MILDEP annual CQM strategies, plans, and assessments should be submitted to ASD(HA), or designee, no later than the publication date of the DHA annual TRICARE program evaluation report to Congress.
- f. Operational clinical services are delivered under the authority, direction and control of a MILDEP Medical Commander designated by the SG concerned.
- (1) The MILDEP Medical Commander is responsible for implementing CQM programs in relation to operational clinical services with standards and procedures comparable, to the extent practicable, to those in MTFs. This requirement applies to all provisions of this issuance and all CQM-related issuances of DHA. The MILDEP Medical Commander will maintain

written documentation of any deviations in standards and procedures determined to be not practicable.

(2) On a military installation in or outside the United States where there is an MTF, the MTF Service Commander, who is under DoD Directive 5136.13 dual-hatted as the MTF Director (unless dual hatting was waived by ASD(HA)), is deemed to be the MILDEP Medical Commander unless a different MILDEP Medical Commander is designated by the SG concerned. The MILDEP Medical Commander may provide for integrated implementation of some or all CQM programs for MTF services and operational clinical services on the installation, either through action of the dual-hatted MTF Director/Commander or other arrangements agreed to by the MTF Director.

4.2. PS.

- a. MHS PS programs incorporate the MHS HRO guiding principles, with emphasis on promoting a strong culture of safety to eliminate preventable patient harm MHS-wide.
- (1) MHS PS programs support elimination of harm through identification, investigation, mitigation, and analysis of PS events.
- (2) MHS PS programs support learning through a focus on systems, procedures, and teamwork. They integrate and complement other CQM activities, as appropriate, for local or MHS-wide standardized safe practices.
 - (3) MHS PS programs foster a culture of safety in which:
 - (a) Mistakes are acknowledged and lead to sustainable, positive change.
- (b) Respectful and inclusive behaviors serve as behavioral norms for the organization.
- (c) The physical and psychological safety of patients and the workforce are both highly valued and ardently protected.
- (d) Reporting of near miss and no harm patient safety events is encouraged to correct systems and process failures before they cause a reportable event.
- (4) As required by Section 744(b)(1) of the William M. Thornberry National Defense Authorization Act for Fiscal Year 2021, MHS PS programs include the implementation of systematic procedures to eliminate, to the extent feasible, risk of harm to patients at MTFs, including through identification, investigation, and analysis of events indicating a risk of patient harm and corrective action plans to mitigate such risks.
- b. PS event reporting to the ASD(HA) will be through the DHA Patient Safety Program (DHA PSP) pursuant to DHA-PM 6025.13.

- (1) DoD Reportable Events (REs) occurring in MTFs will be reported to the ASD(HA), or designee, and to the Director and DAD MA, DHA, through the DHA PSP.
- (2) DoD REs occurring in operational clinical services will be reported to the ASD(HA), or designee, by the respective MILDEP SG, through the DHA PSP.

4.3. HRM.

- a. HRM programs incorporate the MHS HRO guiding principles, with emphasis on promoting safe patient care and health care environments, and to identify, assess, and mitigate risks contributing to harm and financial loss to the Federal Government.
- (1) HRM programs support development, implementation, and assessment of effectiveness of prioritized, systematic risk reduction strategies, and process improvement activities to mitigate risk of harm to patients, family members or caregivers, facility visitors, and health care staff.
- (2) HRM programs work in collaboration with the rest of the organization's CQM team, its organizational leadership, and other relevant process owners throughout the organization.
- b. The MHS provides safe and effective health care by requiring that its health care providers are properly qualified, trained, and competent to perform their clinical duties, and by taking appropriate action when there are allegations or concerns for misconduct, incompetence, or any conduct which adversely affects, or could adversely affect, the health or welfare of a patient or staff member.
- (1) The MHS electronic database for HRM data is managed by the DHA. MTF and operational clinical services HRM data, to include reports to the NPDB, State(s) of licensure, or other applicable certifying or regulatory agencies, will be promptly documented in the MHS electronic database designated by the ASD(HA), reported to the MHS HRM Working Group; and available for review by the ASD(HA) or designee.
- (2) Paid medical tort claims may require a report to the NPDB. In accordance with Sections 11131 through 11152 and Sections 1320a-7 through 1320a-7e of Title 42, U.S.C., the September 1987 Memorandum of Understanding between the Department of Health and Human Services and the DoD, and the November 9, 1992 follow-up letter from ASD(HA) to the Assistant Secretary for Health for the Department of Health and Human Services, reports to the NPDB will be made in the name of a health care provider each time a medical tort claim payment is made, and for which a determination of SOC not met for that SIP is made, after a thorough peer review of the facts of the health care provided.
- (a) A report to the NPDB for each SIP will be made unless, within 180 days after receipt of notice of such payment, the report authority makes a final determination, following external peer review of the case, that SOC was met. The external peer review will consider all relevant information available to the HRM program regarding the patient care involved, including in paid malpractice cases input from DoD legal counsel involved in adjudication or litigation of the claim regarding factual information developed in the process pertinent to the

final settlement or judgment. Special emphasis is given to the results of external peer reviews, which are accepted by the report authority unless the report authority makes a specific, non-delegable determination that the results are contradicted by clear and convincing evidence.

- (b) If no final decision has been made by the report authority by the end of this 180-day period, all SIPs identified for the medical tort claim payment must be reported to the NPDB immediately. A report by the report authority is not discretionary. A voidance or modification of such a report, consistent with NPDB procedures, will be made if appropriate based on subsequent decisions (e.g., reduction in the number of SIPs, narrative notation regarding a determination of SOC met). The ASD(HA) has waiver approval authority in exceptional circumstances for any exceptions to this 180-day limit.
- (c) Except for any NPDB report of an "active duty health care adjudicated action or decision" under this section, SOC determinations for purposes of medical tort claim NPDB reports are not adverse actions and thus are not subject to due process procedures.
- (d) If a claim is filed and adjudicated against the United States or Department of Defense for medical malpractice affecting a member of the uniformed services under Section 2733a of Title 10, U.S.C., and Part 45 of Title 32, CFR, follow the processes, procedures, and reporting criteria for medical tort claims.
- (3) Payments made for active duty death or disability arising from PS events may require a report to the NPDB. This is independent of whether a claim was filed under Section 2733a of Title 10, U.S.C., and Part 45 of Title 32, CFR. For active duty death or disability benefits arising from PS events, HRM programs support their respective organizations with assessments for potential risk of liability, done in consultation with appropriate servicing health care legal counsel.
- (a) Every case in which a medical evaluation board makes a referral to a physical evaluation board, the medical evaluation board approving official will identify and report to the respective HRM programs (operational clinical services, DHA, or both) every instance in which the condition that is the subject of the referral may have been incurred or aggravated as a result of MHS-provided medical care.
- (b) Every active duty death or disability payment for which the delivery of health care within the MHS may have been the cause or a contributing factor will have an objective peer review. The peer review will make a determination for each SIP as to whether or not a deviation in the SOC occurred, and if the deviation caused or contributed to the active duty death or disability.
- (c) All SIPs in active duty death and disability payments with a SOC determination of "not met" and that the deviation in SOC caused or contributed to the death or disability will be reported to the NPDB, State(s) of licensure, or other applicable certifying or regulatory agencies. In any case in which peer review determines with respect to a SIP that SOC was met or that a deviation from SOC did not cause or contribute to the death or disability, the case will receive external peer review under the same procedures applicable to paid medical tort claims.

- 1. This includes the 180-day review period process described in Paragraph 4.3.b(2)(b), with the 180-day period beginning on the day the medical evaluation board approving official reports that the condition that is the subject of the referral may have been incurred or aggravated as a result of MHS-provided medical care.
- 2. In any case in which a SOC review of care provided to a member of the uniformed services is triggered by both a report from the medical evaluation board approving official and the adjudication of a claim under Section 2733a of Title 10, U.S.C., and Part 45 of Title 32, CFR, the SOC reviews will be merged to produce a final outcome properly accounting for all evidence relating to the care provided.
- (d) For any DoD RE or PCE involving a patient who is an active duty Service member that is at high risk for becoming a disability or death payment, but there is expected to be a significant time lapse prior to such payment being made, due process with appeal rights must be afforded prior to an NPDB report of an "active duty health care adjudicated action or decision."
- <u>1</u>. A SIP determined in the PCE review process to have deviated from SOC, and the deviation caused or contributed to the Service member's harm, will be afforded due process with appeal rights.
- <u>2</u>. The SIP will also be afforded a timely resolution in the deliberation by the report authority for a potential report to the NPDB, State(s) of licensure, or other applicable certifying or regulatory agencies.
- $\underline{3}$. These reports are submitted to the NPDB under "active duty health care adjudicated actions or decisions."
- (4) A legal sufficiency review is required prior to completing SOC reviews for potential NPDB reporting under Paragraphs 4.3.b.(2) and 4.3.b.(3) in the following cases:
 - (a) Any case of a paid malpractice claim in which no SIP will be reported.
- (b) Any case in which the report authority decides not to report a SIP for whom external peer review determined the criteria for reporting was met.
 - (5) Every PCE in MTFs or those associated with operational clinical services will be:
- (a) Reviewed and promptly documented in the MHS electronic database designated by the ASD(HA).
 - (b) Reported to the MHS HRM Working Group.
 - (c) Available for review by the ASD(HA) or designee.
- (6) Professional review activities are indicated when there are allegations or concerns for misconduct, incompetence, or any conduct which adversely affects, or could adversely affect, the health or welfare of a patient. Criminal convictions, civil judgments, or government

administrative actions related to conduct in, or conduct that could adversely affect the delivery of health care, are subject to professional review activities. Also subject to professional review activities is improper conduct in interactions with other staff when such conduct could adversely affect the delivery of health care. Professional review activities will be conducted in accordance with Section 11112 of Title 42, U.S.C.

- (a) Professional review activities have the potential for a health care provider to be reported to the NPDB, State(s) of licensure, and other applicable certifying or regulatory agencies. Final adverse actions are reportable to these entities.
- (b) Due process with appeal rights as well as procedures to require a timely resolution will be included in MHS professional review activities for potential clinical adverse actions.
- (c) Summary suspensions of privileged providers that last longer than 30 calendar days, clinical adverse actions, and criminal convictions related to health care are reported to the NPDB, State(s) of licensure, and other applicable certifying or regulatory agencies.
- (7) Impaired health provider programs (IHPP) are designed to provide support, assistance, and coordination or advocacy for wellness of health care providers who suffer from a condition that adversely affects, or could adversely affect, the safety or welfare of a patient.
- (a) Notwithstanding the emphasis on wellness, clinical adverse action due process may need to be initiated in cases in which a health care provider who is, or may be, impaired does not self-refer, lacks insight or willingness to address their condition or be compliant with treatment, fails to complete a treatment program, or relapses after treatment.
- (b) If a clinical adverse action is taken against a provider for misconduct or incompetence related to impaired health, it must be reported to the NPDB, State(s) of licensure, or other applicable certifying or regulatory agencies as appropriate.
- (c) Reports to State(s) of licensure or other applicable certifying or regulatory agencies should be considered as appropriate, e.g., ending affiliation with the MHS while in continued monitoring by the IHPP, separation from Service as a result of the disability evaluation system decision, State(s) licensing board, or other applicable certifying or regulatory agency requiring a notification of enrollment in the IHPP, or failure to successfully complete the IHPP.
- (d) Privileging authorities without the resources to have an IHPP of their own, will require affiliation with such a program to support their providers, consistent with applicable laws, regulations and contract provisions.
- (8) DoD also reports to the NPDB, State(s) of licensure, and other applicable certifying or regulatory agencies health care practitioners, providers, or suppliers who engage in certain criminal or adverse administrative actions related to the delivery of health care items or services. Reportable actions include:

- (a) Uniform Code of Military Justice (UCMJ) Actions. Convictions under chapter 47 of Title 10, United States Code, also known and referred to as "the UCMJ," as approved contained in the entry of judgment, or final non-judicial punishment under the UCMJ, regardless of whether the conviction or punishment is the subject of a pending appeal.
- (b) Other Adjudicated Actions or Decisions. The following actions are reportable if they are against a health care provider, supplier, or provider based on acts or omissions that affect the payment, provision, or delivery of a health care item or service:
- <u>1</u>. Adverse Personnel Actions Affecting Uniformed Services Members. Any administrative action resulting in separation, reduction in grade, involuntary military occupational specialty reclassification, ending affiliation with the MHS while in continued monitoring by the IHPP, or other adverse administrative action.
- <u>2</u>. Adverse Civilian Personnel Actions. Any adverse personnel action as described in chapter 75 (Sections 7501 through 7543) of Title 5, U.S.C., as well as actions under chapter 43 of Title 5, U.S.C., when there is a due process proceeding.
- <u>3</u>. Contract Termination for Default. A contract termination for default taken by an MTF or medical command against a personal services or non-personal services contractor.

4.4. CP.

- a. CP programs incorporate the MHS HRO guiding principles, with emphasis on full evaluation of individual health care provider credentials and qualifications before allowing involvement in patient care.
- (1) All MHS health care providers who are licensed, certified, or registered will be entered and tracked in the MHS electronic database designated by the ASD(HA), and available for review by the ASD(HA) or designee.
- (2) All CP data and information will be promptly documented in the MHS electronic database designated by the ASD(HA), and available for review by the ASD(HA) or designee.
- (3) CP processes will be standardized in DHA-PM 6025.13 and streamlined across the MHS to require that health care providers are fully functional as quickly as possible with limited downtime. Standardized CP processes will be implemented to the extent practicable in operational clinical services per Service guidance.
 - (4) CP will be performed on initial appointments, renewals, and modifications.
- (a) The inter-facility credentials transfer brief (ICTB) documents a health care provider's credentials and is the means by which information is shared between privileging authorities. The expiration date of the professional privileges on which it is based results in expiration of the ICTB on the same day.

- $\underline{1}$. ICTB documentation will be accurate, complete, primary source verified, include documentation of expiration of time-limited credentials, and for privileged providers it will include a complete list a provider's privileges.
- <u>2</u>. Privileges granted using an ICTB that are used to support a complete privileging application request, require at least primary source verification of time-limited credentials and query of the NPDB.
- (b) Privileging by proxy is a process which may be used when privileges and the credentials supporting those privileges are not altered in a provider's transfer to new clinical duties. The ICTB used for privileging by proxy does not require repeat primary source verification, and query of the NPDB is optional.
- (5) For MTFs, privileging authority resides with the Director, DHA and may be delegated. At the MTF level, MTF directors may delegate privileging authority to the MTF deputy director or similarly appropriate senior leadership member. The delegation is made and maintained in writing. Further redelegation is not authorized.
- (6) For operational clinical services, privileging authority is delegated from the Secretary concerned to the respective SG. SGs may further delegate privileging authority to appropriate medical unit commanders or other appropriate medical command level entities (e.g., SGs of MILDEP subordinate commands).
- (7) For telemedicine, MHS providers who are authorized and providing virtual health care within the scope of their assigned duties pursuant to licensure portability under Section 1094(d) of Title 10, U.S.C., are authorized to provide this virtual health care (telephonic or video) from any U.S. location, to any U.S. location. (Licensure portability does not extend to non-personal services contract health care providers.) Clinical concerns for the health care provided at the originating site will be reported to the distant site, to include a portion of patient health care records to be incorporated in the distant site peer review process. The distant site will also provide to the originating site privileging authority any identified clinical concerns for the health care provided. In the case of health care in foreign countries, such virtual services are authorized from any U.S. location to any location on a U.S. installation or U.S. operational location with the approval of the responsible medical authority at the originating site, who is responsible for confirming that no local requirements preclude the arrangement. That authority is the MTF Director, if applicable, or if no MTF, the senior medical officer or command surgeon responsible.
- b. Pursuant to requirements in Section 1094 of Title 10, U.S.C., health care providers in the MHS must have and maintain an active, current, valid, and unrestricted license or other authorizing documents to practice independently within the defined scope of practice for their specialties. Additional licenses held by a provider must be in good standing whether they are inactive, expired, or limit the provider's practice to a military setting. Providers in the MHS may not have one active license and another currently suspended or probationary license. For example, if a provider is licensed in both Texas and Tennessee, and the provider's Texas license is active, but the provider's Tennessee license is on probation, restricted, or is temporarily suspended, the provider would not meet requirements for clinical practice in the MHS.

- (1) Section 1094(d) of Title 10, U.S.C. provides portability of State licensure for DoD health care providers as long as their practice is within the scope of authorized Federal duties.
- (2) For health care providers in the MHS, an unrestricted license is one that is not subject to any limitation on the scope of practice and would allow the health care provider to fully practice within the State of issuance.
- (a) Maintenance of an unrestricted license requires the military health care provider to fulfill all licensure requirements necessary to allow unabridged permission to practice in any civilian community in the jurisdiction of licensure without having to take any additional action on the license.
- (b) An unrestricted license does not waive the standard license fee solely on the basis of the member being in the military. For those instances in which a state may waive standard license fees solely on the basis that the licensee is in the military, the DHA DAD MA must make a determination as to whether that fee waiver would have the appearance of a license not fully comparable in all respects to a full fee license.
- (3) Authority to waive the license requirement is vested with the ASD(HA) and will be used only to address extraordinary circumstances and in accordance with Section 1094 of Title 10, U.S.C. Such extraordinary circumstances include circumstances in which a state of licensure establishes a requirement or takes an action the ASD(HA) determines would have the effect of interfering with the effective implementation of MHS policy or accomplishment of an MHS mission. This authority is not delegable.
- c. Clinical quality of health care delivery is the responsibility of the medical staff, and will be reflected as such in respective medical staff bylaws.
- (1) Peer review is required to ensure individual health care providers deliver safe and effective health care and practice within the scope of their clinical privileges or clinical practice, and will be implemented in both MTFs and operational clinical services to require the ongoing capability and competency of health care providers.
- (2) Peer review processes will incorporate ongoing professional practice evaluation and focused professional practice evaluation. Ongoing professional practice evaluations and focused professional practice evaluations (with accompanying monitoring and evaluation plans), and any other clinical performance assessments, will be documented in the respective provider's provider activity file, securely maintained training records (e.g., graduate medical education programs), or competency or training record (e.g., enlisted training programs), as appropriate.
- d. Health care providers approved for and participating in off-duty employment will submit reports to MTF directors and their MILDEP chain of command on the number of patients seen and the case mix of care provided.
- e. Foreign national local hires (FNLH) health care providers will meet the same credentialing and privileging requirements of U.S. health care providers within the same specialty, with the exception of U.S. licensure. This applies only to DoD care delivered in foreign countries by foreign nationals that are hired to work in accordance with the Status of

Forces Agreement and the DHA-PM 6025.13. FNLH physicians employed within the DoD before January 1, 2017 that were previously granted an Educational Commission for Foreign Medical Graduates waiver are exempt from the Educational Commission for Foreign Medical Graduates requirement.

- (1) FNLH non-privileged providers may be credentialed on a case-by-case basis contingent upon MHS requirements and validated clinical competency for the scope of practice assigned. They will meet the same credentials requirements of other providers within the same specialty with the exception of U.S. licensure. This applies only to DoD care delivered in foreign countries.
- (2) FNLH health care providers from jurisdictions other than the United States and its territories who care for DoD beneficiaries are required to have documented proof of comprehension and proficiency in oral and written use of the English language provided by an external agency and current clinical skills.

4.5. AC.

- a. AC programs incorporate the MHS HRO guiding principles, with emphasis on requiring adherence to nationally recognized, evidence-based standards for quality and PS.
- b. MTFs must maintain accreditation through an accreditation source recognized by the Centers for Medicare and Medicaid Services or approved by the ASD(HA). On a military installation in or outside the United States, if operational clinical services are provided in a fixed facility, the facility is subject to accreditation unless a waiver is granted by ASD(HA).
- (1) ASD(HA) will consider accreditation waivers on a case-by-case basis. All accreditation waivers must be reviewed annually and renewed at least every 3 years.
- (2) Waived facilities must demonstrate use of the same evidence-based standards for quality and PS as required for accredited MTFs, and implement them to the extent practicable.
- (3) Waived facilities will undergo a comprehensive on-site assessment at a minimum of every 3 years. This assessment will be led by DHA or by another authority designated by DHA for this purpose.
- c. Managed care support contractors, designated providers, and overseas contractors, maintain accreditation, or manage accreditation requirements within their respective networks, in compliance with Section 199.6(b)(3)(i) of Title 32, Code of Federal Regulations, and their respective contracts awarded by the DoD.
- d. Operational clinical services, while under separate rules with respect to accreditation, are provided under standards and procedures comparable to the extent practicable to those applicable to clinical services provided in accredited MTFs.
- (1) On a military installation in or outside the United States where there is an MTF, operational clinical services are delivered under the authority, direction and control of a

MILDEP Medical Commander. With respect to operational clinical services provided in a fixed facility on the installation, unless the accreditation requirement is waived by ASD(HA), the MILDEP Medical Commander is responsible for either including those operational clinical services under the MTF's accreditation, by agreement with the MTF Director, or for advising the DHA Director and their respective MILDEP SG of the separate accreditation obtained.

- (2) With respect to operational clinical services provided in fixed facilities other than on a military installation where there is an MTF, the applicable privileging authority is responsible for obtaining accreditation, unless waived by the ASD(HA).
- (3) Operational clinical services are documented in the ASD(HA) approved electronic medical record, or uploaded when practicable and in accordance with Military Service guidance.
- (4) Operational clinical services not associated with an MTF AC program will undergo comprehensive Military Service-led assessments of CQM every 3 years for issues in implementation of applicable standards (i.e., DHA PM 6025.13 standards to the extent practicable), with special attention to:
- (a) Assessment of PCEs, identification of SIPs, and determinations of whether or not SOC was met.
- (b) Assessment of learning from system and human factors issues causing or contributing to PCEs.
- (c) Assessment of development and implementation of process improvement activities with follow-up reassessment for effectiveness of risk mitigation and harm prevention.
- e. DHA or MILDEP comprehensive on-site assessments waived from accreditation requirements will be submitted to ASD(HA), or designee, within 30 days of completion of the assessment visit.

4.6. CM.

- a. CM programs incorporate the MHS HRO guiding principles, with emphasis on assessment of quality of care delivered and alignment of CQI efforts with clinical quality strategy and plans, identification of trends, and facilitate transparency strategy (particularly transparency with the public).
- (1) They help participation in local, State, and national quality programs and incorporate comparative analysis of benchmarks from these organizations in MHS quality assessments.
- (2) They advance the use of electronic measurement for increased efficiency and availability of data and information needed to assess clinical quality processes, outcomes, experience, and organizational structure and systems.

- (3) CM must be incorporated in every level of performance management to objectively measure the quality of health care delivered; confirm effectiveness of quality control; and identify opportunities for improvement.
- (4) Clinical quality metrics will be defined by clinical leadership, be evidence-based to the extent possible, and focus on quality outcomes.
- b. The MHS participates with, and monitors quality assessment activities in, local, State, and Federal programs and in external CQM and improvement organizations. MTF's participation in such programs should be aligned with MHS and DHA strategy. All MTF participation in these programs must be approved by the Director, DHA. CM programs will monitor and evaluate participation in these programs, to include protection of MQA records and information created by or for the DoD as part of an MQA program. Disclosures of these records and information (other than aggregate statistical information) will occur only as authorized by Section 1102 of Title 10, U.S.C.
- c. The force health protection quality assurance program provides another aspect of clinical quality performance measurement for DoD readiness health care issues, and is conducted in accordance with DoD Instruction 6200.05.

4.7. CQI.

- a. CQI programs incorporate the MHS HRO guiding principles, with emphasis on frontline staff driving MHS-wide CQI. CQI produces measurable and sustained improvement in the processes and outcomes of care through elimination of unwarranted variance, increased system-wide efficiency, improved patient-centered care and experience, and may decrease the cost of health care delivery.
- (1) CQI takes place across all environments of health care delivery, and demonstrates leadership commitment to zero harm, a culture of safety, and leading practice standardized tools and approaches for data driven improvement of patient-centered care.
- (2) The MHS demonstrates CQI primarily through the MHS HRO model which depends on clinical communities to assess key clinical processes, identify priorities for improvement that align with strategy, and create conditions for high reliability at the point of care (processes, standards, and metrics). The MHS HRO model is a formalized mechanism to defer to expertise for:
 - (a) Innovation in improving patient-centered outcomes.
 - (b) Eliminating preventable harm and waste.
 - (c) Maximizing value.
 - (d) Establishing evidence-based MHS clinical process standards.
 - (e) Reducing unnecessary variability.

- (f) Embedding learning and safety culture across all care sites.
- (3) CQI programs recommend (based on gaps in clinical performance measurement), help prioritize, and facilitate specific opportunities for improvement.
- (4) CQI programs support advancement of CQM capability through coordination of the development of standardized CQM training and education.
- b. Mechanisms for the reporting, sharing and sustainment of lessons learned from process improvement projects across the MHS will be developed.

SECTION 5: MHS HRM WORKING GROUP

5.1. MISSION.

The MHS HRM Working Group supports the ASD(HA) in oversight of HRM programs in all DoD Components. Responsibilities include:

- a. Review of the management, processing, and reporting of providers (as appropriate) to the NPDB, states(s) of licensure, and other applicable regulatory or certifying organizations, of medical tort claims, active duty death or disability cases associated with the delivery of health care, PCE, adverse privileging actions, or other adjudicated actions.
- b. Review of reporting of providers (as appropriate) to the NPDB, States(s) of licensure, and other applicable regulatory or certifying organizations, of judgments and convictions, or government administrative actions.
- c. Review and analysis of cases when there is nonconcurrence by the report authority with an external SOC review.
- d. Monitoring and analysis of trends in payments associated with the delivery of health care in the MHS, of trends in clinical adverse actions, and of trends in judgments and convictions, or government administrative actions.
- e. Monitoring and analysis of trends in the types of compensated events, contributing factors and human factors involved, and what risk mitigation and CQI activities resulted from event analysis.

5.2. ORGANIZATION.

- a. The MHS HRM Working Group is chaired by the Deputy Assistant Secretary of Defense for Health Services Policy and Oversight.
- b. Principal members will be representatives from the HRM programs, and their respective supporting legal counsel, of the Military Services and the DHA. Others attend as designated by the Chair or principal members, e.g., the DHA TRICARE Health Plan Medical Director, or PS or CP program leads or subject matter experts.

5.3. REPORTING.

The MHS HRM Working Group provides to the Deputy Assistant Secretary of Defense for Health Services Policy and Oversight:

a. HRM data, trends, and analysis.

b. Review and analysis of cases when there is nonconcurrence by the report authority with an external SOC review. Report memoranda, format as determined by the MHS HRM Working Group, must explain the findings and the rationale for variance in SOC determinations.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
AC ASD(HA)	accreditation and compliance Assistant Secretary of Defense for Health Affairs
CFR CM CP CQI CQM	Code of Federal Regulations clinical measurement credentialing and privileging clinical quality improvement clinical quality management
DAD MA DHA DHA-PM DHA PSP DoD RE	Deputy Assistant Director for Medical Affairs Defense Health Agency Defense Health Agency procedures manual Defense Health Agency Patient Safety Program Department of Defense Reportable Event
FNLH	foreign national local hires
HRM HRO	health care risk management high reliability organization
ICTB IHPP	inter-facility credentials transfer brief impaired health provider programs
MILDEP MHS MQA MTF	Military Department military health system medical quality assurance military medical treatment facility
NPDB	National Practitioner Data Bank
PCE PS	potentially compensable events patient safety
RE	reportable event
SG SIP SOC	surgeon general significantly involved provider standard of care
U.S.C.	United States Code

G.2. DEFINITIONS.

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

TERM	DEFINITION
Accreditation	Process of review that allows health care organizations to demonstrate their ability to meet regulatory requirements and standards established by a recognized accrediting organization.
adverse event	See definition for PS event.
aggregate statistical information	Statistical information relating to medical quality assurance records under Section 1102 of Title 10, U.S.C., that are at a sufficient level of aggregation, under criteria established by the Director, DHA, as to avoid disclosure of particular patients, events, or circumstances relating to such records.
clinical adverse action	Action invoked against a health care provider, privileged or not, with the result that the authority to practice clinically is adversely affected. Adversely affected privilege(s) or practice are the result of a due process professional review action based on evidence of misconduct, 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) or 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 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 health care 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 health care provider to provide specified or delineated health care within the scope of the provider's license, certification, or registration.
clinical quality assurance	A program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met. Clinical quality assurance's main purpose is to verify that clinical quality control is being maintained.

TERM

DEFINITION

clinical quality control

Monitoring clinical services for stability, detecting emerging process problems (special causes), and taking steps to address them. Clinical quality control is about ensuring that a process remains stable ("in control") over time, that its performance remains within the upper and lower control limits. It is usually performed by those closest to the process.

CM

CM uses tools to help evaluate and track the quality of health care services provided to beneficiaries in the MHS. Analyzing CM data and acting on identified trends for improvement helps ensure the MHS delivers safe, timely, effective, efficient, outcomes-focused, and patient-centered care.

compliance

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

CQI

CQI consists of systematic and continuous actions that lead to measurable improvement in health care 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.

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: PS; HRM; CP; AC; CM; and CQI.

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.

TERM **DEFINITION**

credentials The documents that constitute evidence of appropriate education,

training, licensure, experience, and expertise of a health care

provider.

Any PS event resulting in death, permanent harm, or severe **DoD** reportable event

> temporary harm, as per the Agency for Healthcare Research and Quality Harm Scale; or meeting The Joint Commission's sentinel event or the National Quality Forum's serious reportable event definitions. DoD REs require a comprehensive systematic analysis and follow-up corrective action implementation plan report. This term encompasses sentinel events referred to in Section 744 of the William M. (Mac) Thornberry National Defense Authorization Act

for Fiscal Year 2021.

health care provider Any Service member, civilian employee of the DoD, or contract

employee authorized by the DoD to perform health care services.

health care risk Includes clinical and administrative activities, processes, and policies to identify, monitor, assess, mitigate, and prevent risks to the health management

> care organization, patients, and staff. By employing risk management, the health care organization proactively and systemically safeguards PS and the organization's resources, accreditations, legal or regulatory compliance, assets, and customer

confidence (integrity).

legal sufficiency A determination by the Office of General Counsel, Staff Judge

Advocate or other servicing legal office providing legal services to a

deciding official that a proposed action meets applicable legal

requirements.

Defined in DoD Directive 5136.01 **MHS**

review

MOA Consistent with Section 1102 of Title 10, U.S.C., 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.

TERM DEFINITION

MQA records The proceedings, records, minutes, and reports that emanate from

quality assurance program activities and are produced or compiled by the DoD as part of MQA as defined in Section 1102 of Title 10,

U.S.C..

MTF Consistent with 10 U.S.C. 1073c and DoD Directive 5136.13, any

fixed facility of the Department of Defense that is outside of a deployed environment and used primarily for health care, including dental care; and any other location used for purposes of providing health care services as designated by the Secretary of Defense or

USD(P&R).

NPDB The NPDB is a web-based repository of reports containing

information on medical malpractice payments and certain adverse actions related to health care practitioners, providers, and suppliers. The NPDB is managed by the Department of Health and Human Services in accordance with Section 11101 of Title 42, U.S.C.

near-miss event See definition for PS event.

no-harm event See definition for PS event.

operational clinical services

Clinical and clinical support services on ships and planes, in deployed settings, and in all other circumstances outside an MTF.

peer review Any assessment of the quality of medical care carried out by a health

care provider, including any such assessment of professional performance, any PS program comprehensive systematic analysis or report, or any other such assessment carried out by a health care

provider under the provisions of this issuance.

potentially compensable event

Any PS event that both reaches the patient (i.e., adverse events and no-harm events) and has an HRM assessment that determines that the event is likely to present a possible financial loss to the Federal Government. All DoD RE are PCEs. All events that trigger a PCE will also be referred to the PS manager to ensure capture in the joint PS reporting system and investigation or analysis as defined in

Volume 2 of DHA-PM 6025.13.

TERM

DEFINITION

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.

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 or hazardous conditions defined as:

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

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

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

quality health care

The degree to which health care 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.

report authority

The official with the responsibility to report to the NPDB, State(s) of licensure, and other applicable certifying or regulatory agencies following appropriate due process proceedings. The report authority is: the Director, DHA with respect to matters arising from acts or omissions of health care providers practicing under or privileged by a privileging authority under the responsibility of the DHA; or the SG of the Army, Navy, or Air Force, respectively, with respect to matters arising from acts or omissions of health care providers practicing under or privileged by a privileging authority under the responsibility of the Departments of the Army, Navy, or Air Force, respectively. Designated report authorities ensure there is a comprehensive review of the entirety of such matters.

TERM

DEFINITION

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.

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. This term includes:

Distant site. The distant site is where the health care provider providing the medical service is located at the time the service is provided via telemedicine.

Originating site. The originating site is the location of a patient at the time the service is provided via telemedicine.

unsafe or hazardous conditions

See definition for PS event.

REFERENCES

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- Defense Health Agency Procedures Manual 6025.13, "Clinical Quality Management in the Military Health System," August 29, 2019
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- DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
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- DoD Manual 8910.01, Volume 2, "DoD Information Collections Manual: Procedures for DoD Public Information Collections," June 30, 2014, as amended
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- Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) Research Regulatory Oversight Office Guidance, GD-20-003, "Research Determinations for Process Improvement, Quality Improvement, and Evidence-Based Practice Projects," March 2, 2020
- Public Law 116-57, Section 744, "William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021," January 1, 2021

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