



Defense Health Agency

PROCEDURES MANUAL

NUMBER 6025.13, Volume 3
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Medical Affairs

SUBJECT: Clinical Quality Management in the Military Health System, Volume 3:
Healthcare Risk 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 (ac), 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 (ac), 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 of this DHA-PM.

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, data visualization and report tools on CarePoint (a SharePoint platform), and more.

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

9. **EFFECTIVE DATE.** This DHA-PM:

a. Is effective on October 01, 2019.

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


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

Enclosures

1. References
2. Healthcare Risk Management Overview
3. Clinical Adverse Actions, Criminal Convictions Related to Healthcare, and Other Adjudicated Actions or Decisions
4. Impaired Healthcare Provider Program
5. Potentially Compensable Events, Active Duty Disability, Active Duty Death, and Medical Tort Claims

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ENCLOSURE 1

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 and Clinical Quality Management in the Military Health System," October 29, 2013
- (f) National Defense Authorization Act for Fiscal Year 2017, Sections 702
- (g) National Defense Authorization Act for Fiscal Year 2019, Sections 711 and 712
- (h) Assistant Secretary of Defense for Health Affairs Memorandum, "Policy on Reporting Joint Commission on Accreditation of Healthcare Organizations-Reviewable Sentinel Events in the Military Health System," July 13, 2004
- (i) Assistant Secretary of Defense for Health Affairs Memorandum, "Amplifying Guidance Relating to the Reporting of Sentinel Events and Personally Identifiable Information Breaches to the Office of the Assistant Secretary of Defense (Health Affairs)," February 13, 2012
- (j) Assistant Secretary of Defense for Health Affairs Memorandum, "Medical Quality Assurance and Clinical Quality Management in the Military Health System Sentinel Event and Root Cause Analysis Process Improvements," March 12, 2015
- (k) United States Code, Title 32, Sections 502 – 505
- (l) Army Regulation 40–68, "Clinical Quality Management," February 26, 2004, as amended
- (m) Air Force Instruction 44–119, "Medical Quality Operations," August 16, 2011
- (n) DHA-Procedural Instruction 6200.01, "Comprehensive Infection Prevention and Control (IPC) Program," April 24, 2017, hereby cancelled
- (o) United States Code, Title 42, Section 11101
- (p) Code of Federal Regulations, Title 45, Part 60
- (q) U.S. Department of Health and Human Services, Health Resources and Services Administration. NPDB Guidebook. Rockville, Maryland: U.S. Department of Health and Human Services, 2018
- (r) Memorandum of Understanding between the Department of Health and Human Services and the Department of Defense of September 1987, Participation of the DoD in the national reporting system established under Part B of The Health Care Quality Improvement Act of 1986 (the Act)¹
- (s) Assistant Secretary of Defense for Health Affairs Letter of November 9, 1992, Participation in the National Practitioner Data Bank²

¹ This reference is available internally through a CAC-enabled website at:
<https://info.health.mil/hco/clinicsup/quality/SitePages/Home.aspx>

² This reference is available internally through a CAC-enabled website at:
<https://info.health.mil/hco/clinicsup/quality/SitePages/Home.aspx>

- (t) United States Code, Title 10
- (u) Public Law 104-191, "Health Insurance Portability and Accountability Act of 1996," August 21, 1996, as amended
- (v) United States Code, Title 5, Section 552a, as amended
- (w) United States Code, Title 5, Chapter 75
- (x) DoD Instruction 6490.04, "Mental Health Evaluations of Members of the Military Services," March 4, 2013
- (y) United States Code, Title 29, Section 701
- (z) Code of Federal Regulations, Title 29, Part 1630
- (aa) Code of Federal Regulations, Title 5, Part 339
- (ab) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019
- (ac) 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

ENCLOSURE 2

HEALTHCARE RISK MANAGEMENT OVERVIEW

1. GENERAL OVERVIEW

a. Enterprise Risk Management (ERM). ERM provides the framework for the Healthcare Risk Management (HRM) Program to mitigate risk in the clinical aspects of healthcare delivery. This includes achieving safe and reliable healthcare through activities to identify and manage risk holistically by considering all forms of risk across the organization. ERM integrates the concepts and programs of operational risk management, HRM, patient safety (PS), high reliability, and process improvement. It provides a process for identifying explicit risks relevant to the MHS's mission and objectives, assessing the potential frequency and magnitude of those risks, determining a response strategy, and monitoring process improvement and sustainment. ERM includes analyzing risk from a broader, cross-functional and enterprise-wide perspective, defining roles and responsibilities, and creating a strategy matrix to address specific risk areas. These risks can include clinical, operational, financial, human capital, strategic, legal and regulatory, and technological risks. Risks do not exist in isolation or silos and should be viewed across the organization. A robust ERM Program incorporates the concepts of risk identification, risk assessment, risk control and risk mitigation. Risk identification includes tracking, trending, and reporting of adverse and no-harm events, trends, and other relevant risk data. Risk assessment includes the use of tools aimed at both proactive and reactive evaluation of the sources (common causes) of risks within the organization. Risk control and risk mitigation encompass activities to prevent or reduce risk, improve processes, and sustain or enhance performance. ERM creates organizational value through improved clinical outcomes, reduction of adverse and no-harm events, improved satisfaction for patients, family, and staff, and reduced financial loss to the government. Healthcare Risk Managers at all levels of the MHS manage ERM activities, in accordance with the requirements outlined in this manual, applicable federal and state laws, and accrediting organization's (AO) standards.

b. HRM Program.

(1) The overarching goal of the HRM Program is to protect PS, mitigate risks and harm within our healthcare delivery system, and improve the reliability of MHS healthcare. The HRM Program supports risk identification and assessment, and the development of prioritized, systematic risk reduction strategies and process improvement activities to provide safe, high-quality patient care. This is a collaborative effort within the organization's CQM team, with leadership, and with other relevant process owners throughout the organization.

(2) This volume, in all of its enclosures, addresses HRM procedures in the management of medical tort claims, active duty death, active duty disability, potentially compensable events, and the required due process for clinical adverse actions taken against privileged and non-privileged healthcare providers, in accordance with References (o), (p), (q), (r), and (s). Hereinafter, the term "clinical adverse action" will be used to describe the due process procedures for both privileged providers and non-privileged providers. In addition, the term

“individual” may be used to describe both the privileged and non-privileged provider. All documents generated through professional review activities are protected as Medical Quality Assurance Program (MQAP) documents, in accordance with Section 1102 of Reference (t). These documents must not be released without proper authority.

(3) HRM Guiding Principles

- (a) Advance safe, trusted, and effective healthcare
- (b) Promote a fair and just culture
- (c) Use risk data/trends to prioritize risks and strategic responses to those risks
- (d) Manage risks effectively
- (e) Use strategies to reduce financial losses to the government
- (f) Encourage organization and individual accountability
- (g) Optimize organizational preparedness and performance

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

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

b. 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, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

c. 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, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient.

d. 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, 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.

e. 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.

f. 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.

g. denial of clinical privilege(s). Refusal to grant requested privilege(s) 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, 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.

h. 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.

i. 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. (See Volume 2 of this manual for additional information.)

j. 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.

k. 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.

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

m. 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).

n. 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 Reference (t). JCCQAS is the official file for healthcare providers credentialed and privileged within the MHS.

o. 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.

p. 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 Reference (o).

q. near miss event. See definition for patient safety (PS) event.

r. no-harm event. See definition for patient safety (PS) event.

s. 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.

t. 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.

u. patient safety (PS) event. A PS event is an incident or condition that could have resulted, or did result, in harm to a patient. A PS event can be but is not necessarily the result of a

defective system or process design, a system or process breakdown, equipment failure or malfunction, or human error. PS events include adverse events, no-harm events, near miss events, and unsafe/hazardous conditions as defined below:

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

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

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

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

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

w. 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 the provisions of this manual.

x. 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 of this manual.

y. 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”.]

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

aa. 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.

ab. 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".]

ac. 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, 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.

ad. 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.

ae. Report Authority. The official with responsibility to report to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other 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.

af. 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, 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.

ag. 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, 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.

ah. 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.

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

aj. 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, 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.

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

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

3. GOVERNANCE STRUCTURE. The HRM Program develops, promotes, and supports a comprehensive mission that mitigates and/or prevents risk within the healthcare delivery system, applying principles and practices of a high reliability organization (HRO). The HRM Program shares risk data/trends to contribute to organizational learning and to support an integrated response to risk prevention, mitigation, and management, as appropriate. The DHA HRM Program is managed out of the CQM Branch under the Clinical Support Division within the Directorate of the Deputy Assistant Director for Medical Affairs (DAD MA). Service Surgeon General (SG) HRM Programs are respective to Service structures.

a. The DHA HRM Program Lead manages operations in collaboration with the DoD Risk Management Working Group (DoD RMWG), DoD Joint Credentials Working Group; DoD and DHA Office of General Counsel; DHA Office of Strategic Communications; the DoD Patient Safety Program (PSP); the DHA Office of the Chief Informatics Officer; and other DHA, Service and Office of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) working groups and offices impacting HRM functions.

b. The DoD RMWG is co-chaired by the Deputy ASD(HA) Health Services Policy and Oversight designee, and the DHA DAD MA representative. Membership includes representatives from the DHA Clinical Support Division to include the DoD PSP, the DHA Medical Legal Office within the DHA HRM Program, the Services HRM Program representation, the DHA Office of General Counsel, and subject matter experts (SMEs), as needed. The purpose of the DoD RMWG is to develop, promote, and support a comprehensive, MHS-wide HRM Program that mitigates and/or prevents risk and loss (financial, human injury, human capital) within the healthcare delivery system. The DoD RMWG:

- (1) Defines HRM for the DoD;
- (2) Facilitates just culture supportive of DoD HRM;
- (3) Supports principles and practices of an HRO;
- (4) Establishes the HRM structure for the DoD;
- (5) Approves the HRM plan for the DoD (e.g., communications, reporting plans); and
- (6) Provides oversight for the DHA/Services HRM Programs, specifically:
 - (a) Monitors HRM Program compliance with Federal, DoD, and DHA regulations and policies;
 - (b) Reviews and reports DoD compliance with reporting to the National Practitioner Data Bank (NPDB) as mandated by References (o), (p) and (q), (r), and (s); and
 - (c) Reviews current DoD and DHA policies related to HRM to ensure they support current standards and that policies are congruent.

4. SCOPE AND CORE RESPONSIBILITIES. DHA Headquarters/Military Departments, DHA Markets/Intermediate Headquarters, and MTF and other military leadership will interpret DoD policies and provide direction for the implementation of the HRM Program requirements within their scope of their authority, direction, and control. Each echelon of leadership will provide appropriate oversight to their Healthcare Risk Managers who will plan and manage the processes and procedures in accordance to this manual. Three roles in particular bear specific mention.

a. MTF Chief of the Medical Staff or Military Department Chief of the Medical Staff designee (descriptive term, role may also be known as Chief Medical Officer, Medical Executive Committee Chair, or other titles for similar responsibilities):

- (1) Must be a privileged physician with an active appointment to the medical staff.
- (2) Is the principal executive staff advisor to the Privileging Authority concerning matters of medical quality assurance and CQM, to include the scope of medical care under the respective Privileging Authority and clinical adverse actions.
- (3) Is accountable for the HRM Program, to include clinical adverse action procedures.
- (4) Initiates Quality Assurance Investigations (QAI) in coordination with the Healthcare Risk Manager, and in consultation with the servicing healthcare legal counsel.
- (5) Chairs the Credentials Committee/Function, or ensures an appropriate alternate (physician appointed to the medical staff and in good standing).
- (6) Is authorized to intervene on behalf of the Privileging Authority to immediately summarily suspend a healthcare provider's privileges/practice if the provider's conduct adversely affects or could adversely affect the health or welfare of a patient, employee or other individual, until the matter is investigated and resolved in accordance with this manual.
- (7) Collaborates with the Healthcare Risk Manager to communicate summary suspension, and/or hearing notifications on behalf of the Privileging Authority.
- (8) Ensures with the Healthcare Risk Manager that providers are informed of their due process rights.

b. Healthcare Risk Managers are responsible for providing HRM consultation and educational support to their areas of responsibility, specifically they:

- (1) Manage HRM activities according to this manual and in consultation with the appropriate servicing healthcare legal counsel, and in coordination with the Chief of the Medical Staff, the Chief Nurse, and the Chair of the Credentials Committee/Function.
- (2) Are a member of the local committee that performs and reviews HRM functions.

(3) Develop, implement and report HRM activities and related topics as required not only to their local leadership but also to the DHA Headquarters/Military Departments HRM Program through their respective DHA Market/Intermediate Headquarters.

(4) Collaborate with the Chief of the Medical Staff, Chair of the Credentials Committee/Function (if it is a different person), Chief Nurse, Senior Enlisted Advisor, Chief Administrator, and PS program and other CQM program leads on HRM activities and on all other CQM activities as appropriate, to identify, analyze, trend, mitigate risk, and to recommend corrective actions for processes/procedures needing improvement.

(5) Evaluate CQM activities for real and potential risks for provision of clinical care.

(6) Direct actions to preserve, protect, secure evidence and equipment involved in PS events that reach the patient (adverse and no harm events).

(7) Facilitate clinical adverse action due process, and procedures for other HRM activities as per this manual.

(8) Forward information to respective higher headquarters in support of reports to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

(9) Disseminate lessons learned, advisories, alerts and other formal communications as needed pertaining to ERM/HRM.

c. Healthcare Professional Appropriate Panel

(1) The DHA Headquarters/Military Departments healthcare professional appropriate panel is a panel of senior clinician executives on behalf of the Report Authority. The panel reviews full and complete Medical Quality Assurance Records (MQAR) for concerns with procedures and due process, and standard of care (SOC) determination variance between DoD and the external peer review (as designated by the ASD(HA)), for active duty disability, active duty death, paid medical tort claims, and for clinical adverse actions. The healthcare professional appropriate panel will include:

(a) The Chair: this is a senior quality physician, e.g., DHA Headquarters/Military Departments HRM Program Lead or CQM Functional Capability Lead or deputy. This person is responsible for ensuring a complete and appropriate composition for every healthcare professional appropriate panel, and for ensuring relevant clinical consultants (or designees) are available to provide expert review of the case.

(b) Voting Members, assigned by the Chair and issued an appointment letter from the DAD MA:

1. Senior Physician Executive: must have Chief of the Medical Staff experience.
2. Senior Nurse Executive: must have Chief Nurse experience.

3. Senior Enlisted Advisor: must have Senior Enlisted Advisor experience, e.g., be the Senior Enlisted Advisor for an MHS medical center or large hospital, or regional or major command, or higher.

(c) Ad Hoc Voting Members, as appropriate for SIP under review:

1. Senior Dental Executive
2. Senior Advanced Practice Registered Nurse or Physician Assistant
3. Senior Allied Health Provider

(d) Non-voting Member: appropriate servicing healthcare legal counsel

(e) One of the voting members is recommended to be a civilian if the SIP under review is a civilian.

(2) The healthcare professional appropriate panel members may neither have provided care, nor acted as Quality Assurance Investigating Officer (QAIO) or peer reviewer, in the case under review.

(3) Healthcare professional appropriate panel functions:

(a) Will consider a full and complete MQAR, to include external peer SOC reviews. The Chair will ensure each SIP has an appropriate clinical peer reviewer provide a report to the panel upon review of the full and complete MQAR. The healthcare professional appropriate panel Chair will ensure these clinical peer reviewers are available for questions during the panel's deliberations.

(b) Recommend final action to the Report Authority on adverse privileging/practice actions, paid medical tort claims, and active duty death and disability events. Verify and make recommendations to change the status of providers as "significantly involved" or remove provider as "not significantly involved" as appropriate.

(c) Provide in writing, signed by the panel Chair, a reporting recommendation to the Report Authority for report to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. Written recommendations will include review and analysis of any appeals to clinical adverse actions, or of any provider statements to the standard of care determinations made by senior peer reviewers, as appropriate to the case under review. Written recommendations in active duty death or disability events will include review of the SOC determinations for each SIP and analysis of whether that care was related to the active duty death or disability. See Enclosure 5 for further guidance.

(d) Identify clinical lessons learned and opportunities to improve healthcare management and clinical processes.

(e) Identify clinical policy/procedure changes as appropriate based on analysis of malpractice claims, active duty cases, and adverse privileging/practice actions using relevant clinical consultants within the clinical communities and other subject matter experts.

ENCLOSURE 3

CLINICAL ADVERSE ACTIONS, CRIMINAL CONVICTIONS RELATED TO
HEALTHCARE, AND OTHER ADJUDICATED ACTIONS OR DECISIONS

1. GENERAL OVERVIEW. Clinical adverse actions, criminal convictions related to healthcare, and other adjudicated actions or decisions are managed in accordance with Reference (o), applicable accreditation standards, and this enclosure. The MHS provides safe and effective healthcare by ensuring its healthcare providers are properly qualified, trained, and competent to perform their clinical duties. When there are concerns for suspected misconduct, impairment, incompetence, or any conduct which adversely affects, or could adversely affect, the health or welfare of a patient, or staff member, a Quality Assurance Investigation (QAI) for a clinical adverse action may be indicated with potential report to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies. Additionally, criminal convictions of, civil judgments against, or administrative actions taken against healthcare providers, which are related to, or could adversely affect, the delivery of healthcare items or services, are subject to review for potential reporting of the healthcare provider to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies.

2. CLINICAL ADVERSE ACTIONS

a. Purpose. The purpose of the clinical adverse action process is to protect PS, preserve the quality and safety of healthcare, protect the integrity of the MHS, protect the rights of the involved healthcare provider, ensure timely resolution of the issues, and ensure timely reporting to regulatory entities, when required.

b. Basic Principles and Guidance

(1) Clinical adverse action basic principles:

(a) Clinical adverse action procedures are Medical Quality Assurance Program (MQAP) activities. The primary goal is to assure and advance the delivery of safe, trusted, and effective healthcare items or services.

(b) The clinical adverse action process is not a disciplinary tool. Concerns for suspected misconduct, impairment, incompetence, or any conduct related to the delivery of healthcare and services that adversely affect, or could adversely affect, the health or welfare of a patient, or staff member, are the basis for a clinical adverse action. Routine and regular evaluation of clinical privileges/practice is required and provides an opportunity for continuous learning and practice improvement in addition to a means to validate clinical proficiency. Non-adverse procedures for routine and regular evaluations include ongoing professional practice evaluations (OPPE), focused professional practice evaluations (FPPE) with monitoring and evaluation, and regular training and education. A robust peer review system for privilege/practice evaluation is an important risk mitigation strategy for preventing harm, and for

increasing the reliability of safe, high quality clinical outcomes. However, a period of FPPE with monitoring and evaluation may be indicated for concerns of substandard care, or incompetence, when there is not sufficient information to warrant immediate removal from practice through summary suspension and initiation of a QAI. (See Volume 4 in this manual for more information on OPPE, FPPE and associated monitoring and evaluation plans.)

(c) Conduct that violates local, state, or federal law, the Uniform Code of Military Justice (UCMJ) or other military regulations, or those civil judgments against a healthcare provider, when related to the delivery of healthcare items or services, may be the basis for reporting to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. A separate report could be required for any clinical adverse action needing to take place concurrently or following final disposition of these circumstances. Similarly, military leadership, in consultation with appropriate servicing legal counsel, may determine a personnel administrative action against a provider is required concurrent with, during, or following clinical adverse action due process. Such “other adjudicated action or decision” may be the basis for reporting, separate from the clinical adverse action. Consultation with servicing Staff Judge Advocate or servicing healthcare legal counsel is required to ensure proper military and/or civilian procedures are followed. See “Criminal Convictions Related to Healthcare and Other Adjudicated Actions or Decisions” in Paragraph 3. of this enclosure for further guidance.

(2) Clinical adverse action guidance:

(a) Privileging Authorities or designees will consult with the appropriate servicing healthcare legal counsel when initiating the clinical adverse action and ensure notification issuances to the healthcare provider are reviewed by such legal counsel prior to release.

(b) All decisions must be warranted by the findings of fact and comply with the due process procedures in this enclosure.

(c) Severing the employment relationship with the MHS (e.g., separation, resignation, termination, or retirement), a permanent change of station (PCS), or negotiating a contractual or employment settlement in lieu of the Privileging Authority taking a clinical adverse action is not permitted.

(d) An individual may not voluntarily surrender or self-relinquish clinical privileges/practice in lieu of investigation for concerns for suspected misconduct, impairment, incompetence or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient. Any voluntary surrender of clinical privileges or failure to renew clinical privileges, while under investigation, is reportable to the NPDB.

(e) Individuals who separate from or end affiliation with the MHS while in summary suspension or follow-on clinical adverse action due process procedures, have the right to request continued due process to include a hearing. The request must be submitted in writing by the individual to the Privileging Authority, or designee, within five calendar days following their knowledge of the change in affiliation status. If the individual fails to submit the request for this right, it is considered waived.

(f) If the individual waives the right to further due process, the following actions will be taken:

1. The QAI will be completed and the report of investigation forwarded to the respective Credentials Committee/Function for review. The Credentials Committee/Function will then recommend a final action to the Privileging Authority.

2. The Privileging Authority will give written notice to the individual of their decision on clinical privileges/practice.

3. Clinical adverse action decisions are reported in accordance with this enclosure.

(g) If a Service SG is considering initiating clinical adverse action due process under their Privileging Authority, the MTF at which the provider also is privileged/practices shall assist, as needed, due to operational resource constraints. With regard to the MTF, the MTF Privileging Authority, as evidence is provided from the Service, may need to consider evaluation of the privileges/practice within the MTF for a separate clinical adverse action.

(h) When a deployed Reserve Component individual is returned to the Reserve Component unit from the theater of operations, the Reserve Component command and MTF (as appropriate) Credentials Committee/Function Chairperson will coordinate with the respective Reserve Component Service SG to conduct the clinical adverse action due process.

(i) To ensure compliance with required due process and the procedures in this manual, the healthcare provider under review will be notified in writing, delivered in person when possible; otherwise, by certified return receipt requested mail, or secure electronic system with confirmation of receipt.

c. Disposition of Clinical Adverse Action Case Files When MTFs Close. When an MTF is closed to any future delivery of healthcare items or services, clinical adverse action case files are not destroyed. The DHA Headquarters HRM Program will ensure respective JCCQAS adverse action modules are completed and accurate, and that completed action files are maintained by the DHA Headquarters HRM Program (Medical Legal Office).

d. Protection of the Identity of Personnel Who Provide Implicating Information. All reasonable efforts will be taken to protect the identity of persons who offer information that may result in a clinical adverse action taken against another individual. For example, the name of the person providing information will be protected unless (according to the servicing healthcare legal counsel) the due process rights of the individual who is the subject of the action requires disclosure, or if disclosure is deemed appropriate pursuant to a request under the Freedom of Information Act or Privacy Act. No disciplinary action, punishment, or any form of retaliatory action will be taken against a person who submits information concerning an individual unless it is later determined the person engaged in misconduct or that the person knew the information was false.

e. Release of Clinical Adverse Action Information to State and Other Regulatory Agencies. Report Authorities ensure appropriate and timely responses to official requests for information in accordance with applicable laws and regulations (References (u), Section 1102 of Reference (t), and Reference (v)), to comply with requests from State licensing boards and other applicable certifying/regulatory agencies for their official review of the action. If such requests for information are received by the local Privileging Authority, that request will be forwarded to the DHA Market/Intermediate Headquarters, who in turn coordinates responses with DHA/Service Headquarters as necessary.

f. Clinical Adverse Action Process of a Clinically-Practicing Privileging Authority. When there are concerns regarding a clinically-practicing Privileging Authority for suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient, or staff member, or could threaten the integrity of the MHS, the respective Credentials Committee/Function Chairperson will notify the appropriate higher headquarters (e.g., with regard to MTFs, the DHA Market/Intermediate Headquarters for MTFs, or DHA Headquarters' HRM Program for a clinically-practicing DHA Market Director). The respective higher headquarters will designate an appropriate Privileging Authority to initiate the clinical adverse action due process and be responsible for the due process procedures and appropriate notifications.

g. Retraining. Comprehensive retraining of individuals is not permitted after the initiation of a clinical adverse action (e.g., repeating a year of residency or conducting a period of restriction in a residency program).

h. Notifications and Consultations

(1) Prior to proceeding with any clinical adverse action and continuing throughout the clinical adverse action process, consultation with the servicing healthcare legal counsel is required to ensure that appropriate due process proceedings, adequate notice, and fair peer review hearing procedures are afforded to the involved individual.

(2) A Service chain of command, in consultation with appropriate servicing legal counsel, may determine that personnel administrative action is required concurrent with, during, or following the clinical adverse action investigation or decision (e.g., the appropriateness of a promotion delay action, unfavorable performance report, and/or approval for special pay for a military individual who is facing a clinical adverse action).

(3) Privileging Authorities must notify DHA/Service Headquarters' HRM Programs through respective DHA Market/Intermediate Headquarters when a clinical adverse action process is initiated and must provide monthly updates throughout the process.

(4) Privileging Authorities will ensure notification of initiation of clinical adverse action due process to all Privileging Authorities, DoD and civilian, under whom the healthcare provider holds privilege(s)/practices. Privileging Authorities will also ensure that the appropriate chain of command is notified when the clinical adverse action due process is initiated on a uniformed Service member. Similarly, the appropriate person in a Service chain of command will notify all

DoD Privileging Authorities under whom a uniformed Service member holds privilege(s)/practices, of any healthcare-related UCMJ action and any other adjudicated action or decision (typically personnel administrative actions).

(5) DHA/Service Headquarters' HRM Program notifies the applicable Privileging Authority for a Reserve Component individual. If the individual was released from assignment in which they held privilege(s)/practiced prior to the discovery of concerns for suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient, the Privileging Authority for the discovered concerns retains the authority and responsibility to conduct the necessary QAI and to take appropriate action. Upon conclusion of the clinical adverse action due process, the appropriate Reserve Component office will be notified.

(6) Privileging Authorities will coordinate with the appropriate servicing civilian personnel office when initiating a clinical adverse action against a civilian employee, and throughout the process. This coordination is mandatory to ensure civilian employee guidelines are met.

(7) When Privileging Authorities initiate clinical adverse actions due process procedures against a contract healthcare provider, the Contracting Officer will be provided a copy of the summary suspension letter. Action on the contract, if any, is a matter separate from the healthcare provider clinical adverse action process. Strict adherence to the terms of the contract is essential. The Contracting Officer will provide to the contractor only as much information as is necessary to address any obligations under the contract. In all matters of contract administration, it is vital that the Contracting Officer be the one to interact with the contractor. For contract healthcare providers who no longer work under the Privileging Authority, refer to Paragraph 2.m. for further guidance.

(8) Host nation healthcare providers may hold privileges/practice under a Privileging Authority. If there is potential for a clinical adverse action to be taken against a host nation contract employee, consult with the Contracting Officer, servicing healthcare legal counsel, and Contract Officer Representative (COR) as the due process proceedings are initiated, in accordance with the provisions of the contract. If the host nation individual in question is a civilian employee, contact the servicing civilian personnel office. Regardless of whether NPDB reporting may be applicable in either case (host nation civilian or contract employee), a report of any clinical adverse action taken must be entered into JCCQAS in the adverse action module. For both situations, all due process procedures herein apply.

(9) Privileging Authorities will notify all Privileging Authorities, DoD and civilian, under whom the individual holds privileges/practices, and the respective Service for uniformed Service members, pursuant to a training agreement, resource sharing agreement, or other similar arrangement, when the clinical adverse action due process is initiated. Privileging Authorities will ensure any agreements (e.g., training agreements, resource sharing agreements, other) entered into with civilian medical facilities include notification to the (DoD) Privileging Authority by the civilian medical facility of any clinical adverse action due process initiated or action taken and the reason why the action is being taken.

i. Roles

(1) Healthcare Risk Manager/Medical Staff Manager/Medical Staff Professional:

(a) Shall be the primary point of contact to ensure due process policy and procedures for clinical adverse actions are followed.

(b) Manages the clinical adverse action process in consultation with the Privileging Authority's servicing healthcare legal counsel, and in coordination with the Chief of the Medical Staff, Chief Nurse, Senior Enlisted Advisor, and the Credentials Committee/Function Chair. Any correspondence related to the clinical adverse action process must be reviewed by the servicing healthcare legal counsel.

(c) Assists appointed Quality Assurance Investigating Officers (QAIO) in the collection of records or documents required for review and inclusion in the QAI report.

(d) Provides copies of documents under review to the individual and other reviewing authorities, as per servicing healthcare legal counsel.

(e) Assists appointed representatives in the preparation of materials for the formal peer review hearing process (e.g., recorders).

(f) Ensures delivery and receipt of all notification letters to the individual.

(g) Notifies DHA Market/Intermediate Headquarters' HRM Program, with subsequent notification to DHA/Service Headquarters' HRM Program, of clinical adverse action due process documentation (e.g., notification letters, investigations, reports, transcripts, exhibits, attorney communications, decision letters).

(2) Servicing Healthcare Legal Counsel:

(a) Provides ongoing legal advice to the Privileging Authority, and all relevant leadership and staff, to ensure due process procedures are followed.

(b) Provides guidance to QAIOs assigned to conduct peer review QAIs, and may review reports of QAIs for legal sufficiency.

(c) Ensures legal requirements and timelines are met regarding due process procedures.

(d) Reviews healthcare provider notifications and other documents related to the due process prior to signature by the Privileging Authority taking action.

(3) Local Privileging Authority (e.g., MTF Director or Commander, a Service unit Commander with delegated Privilege Authority from the Service SG):

(a) When delegated from higher Privileging Authority, serves as the Privileging Authority for the individuals assigned. With respect to the MTF, taking a clinical adverse action against a healthcare provider is not delegable below the MTF Privileging Authority. It is strongly recommended that only in circumstances in which the local Privileging Authority is absent and immediate action (e.g., for PS) is required, that the acting Director/Commander initiate due process for clinical adverse actions. Every effort should be made to notify and consult with an absent Privileging Authority prior to initiating action.

(b) Takes action, including summarily suspending, denying, restricting, reducing, or revoking clinical privileges/practice. In the event of information indicating a significant risk of harm to patient, staff, or other individuals, a Privileging Authority may immediately invoke summary suspension of a healthcare provider's privileges/practice. All summary suspensions of privileged providers lasting greater than 30 calendar days are reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. Action taken by a Privileging Authority follows review of the respective Credentials Committee/Function's deliberation of evidence, to include the QAI, and recommendation for action. Appropriate clinical and leadership SMEs are consulted with as circumstances indicate.

(c) Inquires into or investigates, without delay, concerns regarding suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient or staff member. Prompt action is necessary to safeguard patient care, to protect individual rights, to preserve the effectiveness and integrity of military medicine, and to initiate judicial, non-judicial, clinical adverse action, or other administrative action, as appropriate.

(d) Ensures that due process, notification procedures, and clinical adverse action decisions comply with this manual.

(e) Ensures that DHA Market/Intermediate Headquarters is notified, with subsequent notification of DHA/Service Headquarters' HRM Program, of an initiation of clinical adverse action due process, and is provided monthly status updates.

(f) Forwards results of completed clinical adverse or administrative actions involving healthcare providers to the DHA/Service Headquarters' HRM Program via the DHA Market/Intermediate Headquarters with recommendation for reporting, as appropriate.

(g) Immediately notifies the DHA/Service Headquarters' HRM Program via the DHA Market/Intermediate Headquarters of any egregious situation of a sensitive or a potentially notorious nature, any incident of gross negligence, and any act of incompetence or negligence causing death or serious bodily injury (e.g., a DoD RE), or allegations thereof.

(4) Intermediate Headquarters (DHA Markets, Service Intermediate Commands or Agencies, or Other Similar Management Entities):

(a) Provides policy support, personnel resources, and technical assistance regarding clinical adverse action due process and related procedures.

(b) Notifies DHA Headquarters/Service HRM Program, as appropriate, of initiation of summary suspension and a QAI, and of any clinical adverse action taken against healthcare providers. Reviews and forwards monthly status updates.

(c) Ensures all decisions to invoke a clinical adverse action have their final action packages reviewed by the appropriate servicing healthcare counsel for both due process requirements and legal sufficiency before submission to DHA Headquarters/Service HRM Program, as appropriate.

(5) Report Authority:

(a) Ensures notification of the respective Service SG of a decision to report a uniformed Service healthcare provider, when the decision authority for the report is not the uniformed Service member's respective Service SG.

(b) Decides in cases in which there is discretion as to whether a report will be made and directs all reporting to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

(c) Directs the release of information related to clinical adverse actions to official requests for information, as appropriate and with appropriate servicing healthcare legal counsel.

(d) Directs the release of information related to criminal and administrative actions to official requests for information, as appropriate and with appropriate servicing legal counsel.

j. Procedures for Medical Conditions that May Affect Healthcare. See Enclosure 4 of this volume for management of healthcare providers with impairments.

k. Special Pay/Other Administrative Considerations

(1) Uniformed Service members who are the subject of an adverse action decision must have their special pays re-evaluated consistent with current DoD policy.

(2) Follow-on administrative action may be required for healthcare providers whose privileges/practice have been restricted or reduced to the extent that they can no longer perform the full range of assigned duties in their specialty practice, or who can no longer fully practice. For civilian employees, this may warrant separation, as per civilian personnel regulations.

(3) For contracted individuals who are the subject of a clinical adverse action decision, the Privileging Authorities must ensure the decision is reported to the responsible Contracting Officer.

l. Due Process Timelines

(1) Specify all due process procedure timelines in calendar days. If the final day for any specified timeline falls on a weekend or federal holiday, the timeline is extended to the next business day. Privileging Authorities may grant timeline extensions on the individual's behalf for good cause throughout the process and then document the extension and rationale for such.

(2) Timelines are designed to allow the individual in question adequate time to prepare for and sufficiently participate in the proceedings and to facilitate timely resolution of the clinical adverse action. While it is important that timelines reflected in this manual are met, no rights will accrue to the benefit of an affected individual, in an otherwise proper action, based solely on the organization's failure to meet such time limits. Privileging Authorities will make every effort to meet the timelines outlined in this enclosure and will notify the individual, in writing, of the delay and the reason for such delay. There is no remedy for a breach of these timelines that does not deny the individual the meaningful opportunity to be heard. The established timelines may be extended by the appropriate Privileging Authority or Report Authority for good cause. If the individual fails to meet established timelines, absent good cause, the respective Credentials Committee/Function will continue the clinical adverse action due process procedures. At the written request of the individual, the Privileging Authorities will determine the existence of good cause.

(3) Privileging Authorities must notify DHA/Service Headquarters' HRM Programs through DHA Market/Intermediate Headquarters when a clinical adverse action process is initiated, and must provide monthly status updates.

m. Clinical Adverse Actions for Healthcare Providers No Longer Affiliated with the Local Privileging Authority or No Longer Affiliated with the Federal Government

(1) Any concerns regarding suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient (or staff member), reported to have occurred prior to a healthcare provider's separation from federal service or termination of affiliation under a Privileging Authority must be investigated, as described below.

(2) For allegations involving individuals who are still affiliated with the Federal Government, but who have ended their affiliation under a specific Privileging Authority (e.g., PCS or moved to another location, but still practicing within the MHS):

(a) The gaining Privileging Authority will determine what clinical reviews into the individual's practice under their Authority, if any, are warranted under the circumstances.

(b) The losing Privileging Authority, initiates the clinical adverse action due process to include the QAI. The individual is notified in writing by certified return receipt requested mail or secure electronic delivery with confirmation of receipt, with a copy sent to the gaining Privileging Authority.

(c) The losing Privileging Authority, will send notification of initiation of the clinical adverse action process to, and coordinate related due process procedures with the DHA/Service Headquarters' HRM Program, through the DHA Market/Intermediate Headquarters to include communication of proposed decisions, peer review hearings, decisions, and appeals.

(d) DHA/Service Headquarters' HRM Programs, with appropriate servicing healthcare legal counsel, will assist DHA Market/Intermediate Headquarters with ensuring due process procedures, and any subsequent reporting procedures, are followed.

(3) For individuals who have left federal service:

(a) The Privileging Authority under whose authority an individual held privilege(s)/practiced and clinical concerns arose, will initiate the clinical adverse action process and notify the individual in writing by certified return receipt requested mail or secure electronic delivery with confirmation of receipt. The individual will be notified, in writing, regarding the procedures to be followed.

(b) If the Privileging Authority proposes a clinical adverse action decision based on the evidence, all due process procedures apply. If the Privileging Authority determines that a clinical adverse action would not be appropriate, based on the evidence, they will notify the individual, in writing, by certified return receipt requested mail or secure electronic delivery with confirmation of receipt.

(c) There is no time limit restricting initiation of a clinical adverse action process; however, only in exceptional circumstances should one be initiated more than 24 months after a healthcare provider's privilege(s)/practice ceased under the respective Privileging Authority, or any concerns regarding suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient became known.

n. Expiration of Privileges During Adverse Action Process. If the healthcare provider's privileges are due to expire during the clinical adverse action due process, no renewal action is taken on the affected privileges. The affected privileges will remain summarily suspended during the entire due process. Unaffected privileges may be renewed, if appropriate.

o. Concurrent Clinical Adverse Action and Criminal Investigation

(1) Criminal investigations (e.g., narcotics pilfering, physical or sexual abuse of a patient or staff member) may need to be initiated concurrently with initiation of the clinical adverse action due process. In these situations, the servicing healthcare legal counsel and appropriate criminal investigative agency will be notified. Concurrent action by the criminal investigative agency and the Privileging Authority is encouraged and will facilitate timely notification to outside agencies of those individuals for whom such notice is warranted. Likewise, investigations for administrative actions or other adjudicated actions may also need to be conducted concurrently with clinical adverse action due process.

(2) Although such actions can proceed concurrently, Privileging Authorities may need to extend clinical adverse action due process timeline(s) until the law enforcement investigation is complete and the criminal matter is resolved. If there is a conflict between the Privileging Authority and other investigating agencies regarding the continuation of a clinical adverse action due process, the Privileging Authority will consult with the servicing healthcare legal counsel to determine whether the clinical adverse action timeline(s) should be extended.

(3) When the clinical adverse action due process timeline is extended:

(a) The healthcare provider's privileges/practice remain in summary suspension. The Privileging Authority notifies the individual, in writing, by certified return receipt requested mail or secure electronic delivery with confirmation of receipt, that the clinical adverse action timeline(s) is extended until the law enforcement investigation is complete and the criminal matter is resolved. The clinical adverse action due process timeline should not be extended to accommodate an appeal of the criminal action.

(b) If the clinical adverse action due process timeline(s) is extended, this does not prevent the Privileging Authority from taking other appropriate action to protect PS and the quality of healthcare within the MHS (e.g., conducting an initial records review to ensure safe care, and/or removing the individual's access to electronic databases/electronic health record).

(4) When the basis of a clinical adverse action is professional misconduct from a criminal conviction, the individual is not permitted to use the clinical adverse action due process to challenge the finding of guilt. However, if a clinical adverse action is completed and reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies, based on a court-martial conviction or non-judicial punishment per Chapter 47 of Reference (t), and that conviction or non-judicial punishment is successfully appealed, the respective Privileging Authority must still determine whether the underlying facts still warranted the clinical adverse action. In consultation with the servicing legal healthcare counsel, the Privileging Authority may need to forward a request to the respective Report Authority, via the DHA/Service Headquarters' HRM Program and the DHA Market/Intermediate Headquarters, for a Revision-to-Action Report or a Void Report, as appropriate.

(5) Members serving on a panel for the criminal investigation will not be appointed to be a QAIO or be involved in the clinical adverse action due process. This will ensure objectivity in the due process.

p. Initiation of Clinical Adverse Action Due Process

(1) Summary Suspension

(a) A Privileging Authority may put all or a portion of an individual's privilege(s)/practice into summary suspension on the basis of concerns regarding suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient or staff member. Summary suspension is the temporary action that remains in effect while a thorough and impartial QAI is conducted, but must be

reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies if it lasts longer than 30 calendar days. The Privileging Authority promptly notifies DHA Market/Intermediate Headquarters, with subsequent notification to DHA/Service Headquarters' HRM Program as appropriate, to coordinate the appointment of the QAIO, the scope of the QAI, and to confirm respective leadership support for the QAIO's time away from their regular duties. Summary suspension may be invoked by a Privileging Authority or designee, but privileged providers must be reported if it exceeds 30 calendar days.

1. Summary suspension and initiation of clinical adverse action due process procedures will be considered with the initiation of every potentially compensable event (PCE) SOC review. Documentation by the Privileging Authority regarding the decision for or against summary suspension will be kept with the full and complete PCE case file.

2. When available information indicates there is no significant risk that allowing the individual's privileges/practice to remain in effect would adversely affect the health or welfare of a patient or staff member, a period of FPPE with monitoring and evaluation may be indicated. FPPE is non-adverse and is not a QAI. If during the FPPE, it is revealed that a QAI for clinical adverse action due process procedures is warranted, the Privileging Authority will initiate due process procedures with summary suspension. (See Volume 4 in this manual for more information on OPPE, FPPE and associated monitoring and evaluation plans.)

(b) The individual will be notified in writing on the day clinical privilege(s)/practice were placed in summary suspension. Servicing healthcare legal counsel will review notification letters. The notification letter will state the basis for the summary suspension, the privilege(s)/practice affected, that a QAI will be conducted, and that the QAI will be reviewed by the respective Credentials Committee/Function who then will provide a recommendation for the proposed decision to the Privileging Authority; the notification letter must also include the duty and supervision requirements during the clinical adverse action process (the individual should be able to continue to provide healthcare with those privilege(s)/practice not affected by the summary suspension; however, the individual is not to practice, even under supervision, any clinical privilege(s)/practice that are under summary suspension). The notification letter will be delivered in person when possible, by certified return receipt requested mail, and/or secure electronic system with confirmation of receipt. The QAI and all related documents produced from the summary suspension will be maintained in a secure file with the Medical Staff Professional (MSP)/Medical Staff Manager (MSM), Healthcare Risk Manager, or other designee, for 2 years, after which it will then be forwarded to and maintained by the DHA/Service Headquarters' HRM Program.

(c) The notification letter must also inform individuals of the consequences of separating from or ending affiliation with the MHS, while under summary suspension. The letter must afford the individual with information about the implications of the individual's actions and their right to request that due process procedures be continued following the end of their affiliation with the MHS. If the individual chooses to have the due process continued, they must send a written request to the Privileging Authority initiating the clinical adverse action process within five calendar days following their knowledge of the change in their employment affiliation status. If the individual chooses to not continue with the due process, the QAI is still

completed and forwarded to the Credentials Committee/Function who then provides a recommendation for the action to be taken to the Privileging Authority. If the Privileging Authority's decision is to take a clinical adverse action, it is reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

(d) The individual will acknowledge receipt of this notification by signed memorandum. If the individual refuses to sign the memorandum, a witness may indicate "refused to sign" where the signature would normally appear.

(e) The Privileging Authority (or designee) initiating the clinical adverse action due process must request the appropriate Service chain-of-command to withdraw any permission for the individual to practice in off-duty employment, from the initiation of a summary suspension until all due process procedures are completed.

(f) The Privileging Authority initiating the clinical adverse action process must also notify any other Privileging Authority, military or civilian, where the individual (military or civilian) is practicing under an agreement or where the individual has been granted permission for off-duty employment. Coordination with the DHA/Service Headquarters' HRM Program through the DHA Market/Intermediate Headquarters will be done for appropriate notifications involving telemedicine care delivery. Coordination will also be done with the servicing healthcare legal office to ensure the Privacy Act rights of the individual are not violated in the notification of off-duty employers.

(g) While under summary suspension and during the clinical adverse action due process, the individual shall not be assigned to any clinical duties involving the privilege(s)/practice under QAI (e.g., shall not be assigned to another clinic), reassigned to another MTF, PCS to another MTF, deploy, or engage in off-duty employment. Additionally, the Privileging Authority needs to consider whether it is appropriate for the individual to continue to have electronic healthcare records systems access during the clinical adverse action process.

(h) Written notification will be forwarded to DHA Market/Intermediate Headquarters within 10 calendar days, who subsequently notifies the DHA/Service Headquarters' HRM Program, who in turn notifies the respective Report Authority. Summary suspension notification will be entered into the DHA approved clinical adverse action database. If the individual is a uniformed Service member, a copy will be provided to the respective Service Headquarters' HRM Program. If the individual is a federal civilian employee, the servicing civilian personnel office will be provided a copy. If the healthcare provider is a contract employee, a copy of the summary suspension letter will be provided to the Contracting Officer and COR. The Contracting Officer will notify the contractor if the individual is unable to fulfill contract requirements.

(i) Summary suspension of privileged providers is a reportable action when it exceeds 30 calendar days at which time it will be reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. Should the summary suspension last less than 30

calendar days with no clinical adverse action taken, the individual may still need to disclose that they were under investigation depending on the wording of questions on official documents. The summary suspension with QAI may be mentioned in clinical performance assessments.

(2) QAI Procedures for Clinical Adverse Action Due Process

(a) A QAI is initiated at the discretion of the Privileging Authority to examine any suspected misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect, the health or welfare of a patient or a staff member. The Privileging Authority, or designee, initiates the QAI and appoints a QAIO in writing. The purpose and scope of the QAI will be explicit to the QAIO in the written appointment letter. **The QAIO must be an appropriate clinical peer to the individual under review.** If no such individual is on staff under the Privileging Authority, they will reach to DHA Market/Intermediate Headquarters, with subsequent reach to DHA/Service Headquarters' HRM Program, to coordinate or obtain the services of an appropriate peer QAIO to conduct the QAI.

(b) If the individual holds privilege(s)/practices under more than one Privileging Authority, the Privileging Authority initiating the clinical adverse action process consults the DHA Market/Intermediate Headquarters (who in turn notifies DHA/Service Headquarters' HRM Program), who will consult with the servicing healthcare legal counsel for determining the QAIO, the scope of the QAI, and for identification of the appropriate Privileging Authority responsible for conducting the QAI.

(c) Conducting the QAI is the QAIO's sole duty, and that is included in the appointment letter. The appointment letter will provide the QAIO with the date by which the QAI must be completed. The Privileging Authority, or designee, may grant a timeline extension if needed. The QAI completion date should take into consideration whether the individual is under a summary suspension to allow an opportunity to evaluate the case and afford an ability to reinstate privileges, if warranted, within 30 calendar days.

(c) The QAIO must be disinterested and have no personal or professional conflict of interest related to the investigation. No one in the office of the Chief of the Medical Staff, and neither the individual's Supervisor nor the unit's Senior Corps Representative can serve as the QAIO; for example, with respect to MTFs, the MTF Senior Corps Representative will not serve as the QAIO. If the individual is a member of the Credentials Committee/Function, they are disqualified from any formal committee vote on this matter.

(d) At the discretion of the Privileging Authority, and in coordination with DHA Market/Intermediate Headquarters, with subsequent coordination with DHA/Service Headquarters' HRM Program as appropriate, the QAIO may be requested from another MTF or a Reserve Component, or may be a DoD federal service employee, as long as the QAIO is an appropriate clinical peer.

(e) The QAIO may be asked to provide clarifying information, respond to questions from the respective Credentials Committee/Function or testify at a peer review hearing, but may not vote on the action recommendation. Requests for the QAIO to provide additional

information or investigation will be submitted in writing to the Privileging Authority who initiated the QAI, and, along with any responses from the QAIO, will be made an addendum to the QAI.

(f) The servicing healthcare legal counsel must review the appointment letter before it is given to the QAIO.

(g) Before beginning the QAI, the QAIO will consult with the servicing healthcare legal office to receive instruction on conducting the QAI. The QAIO should also consult with the Healthcare Risk Manager/MSP/MSM to receive guidance/assistance in obtaining documents relevant to the QAI. The Healthcare Risk Manager/MSP/MSM will also be able to assist the QAIO in assembling the investigative report. The QAIO may be asked to consider the individual's privilege(s)/practice under other DoD Privileging Authorities.

(h) The QAIO must collect relevant facts, review, and preserve documentation and other evidence, and make findings as to whether the allegations are substantiated.

(i) The content of the QAI report must contain the following:

1. A preliminary statement describing the education, training, clinical specialty, and experience of the QAIO; the scope of the investigation (e.g., what allegations and subsequent evidence was reviewed); and any difficulties in completing the investigation or obtaining information.

2. A summary of the education, training, clinical specialty, and experience of the individual under investigation. Specific detail should include when the individual began working in the current assignment, results of performance evaluations, and origin of the allegation(s) under investigation.

3. A separate statement for each allegation with a recitation of relevant facts and an analysis of the evidence related to that allegation. Based on the evidence discovered during the investigation, a QAIO may amend, or add to, the allegations investigated but clearly document so in the investigation report.

4. All relevant documents. If documents or other exhibits are not appended to the QAI report, a complete list of those items and their location must be stated. Documents or other exhibits not appended to the QAI report must be safeguarded to ensure their availability during the peer review hearing process. Of note, in cases of suspected misconduct, the legal investigation results (e.g., investigative reports from law enforcement or court martial documents) are required for the QAIO to review in order to make a complete/accurate QAI report.

5. Witness statements and other interviews summarized by the QAIO and attached to the QAI report. In addition, a list of the names and contact information for all witnesses must be included.

6. Conclusions for each allegation as to whether the allegation is substantiated. The standard for reaching these conclusions is preponderance of the evidence; that is, based upon the evidence, it is more likely than not the allegation is true or untrue.

7. An action recommendation, based on the findings, which should include one of the following, as applicable:

- a. Reinstatement of Clinical Privilege(s)/Practice.
- b. Reinstatement of Clinical Privilege(s)/Practice with Monitoring and Evaluation (FPPE with a monitoring and evaluation plan).
- c. Restriction of Clinical Privilege(s)/Practice.
- d. Reduction in Clinical Privilege(s)/Practice.
- e. Revocation of Clinical Privileges/Practice.
- f. Denial of Clinical Privilege(s).

8. The following statement must be at the bottom of every page of the report: “Medical Quality Assurance Program document, protected pursuant to 10 U.S.C. 1102. Copies of this document, enclosures thereto, and information therefrom will only be released in accordance with the law.”

9. The QAIO will have the draft QAI report reviewed by the servicing healthcare legal counsel to ensure the requirements stated in this manual have been met and that the evidence in the report supports the QAIO’s findings and recommendations.

10. The QAIO will submit the written QAI report with findings and conclusions to the Healthcare Risk Manager/MSP/MSM who will redact the report presented to the healthcare provider (e.g., witness names, patient privacy information). The redacted QAI report will be delivered in person when possible, by certified return receipt requested mail, and/or secure electronic system with confirmation of receipt. After receipt of the redacted QAI report, the individual will have 15 calendar days to submit a written statement, if desired, to the Credentials Committee/Function. If the statement is not received within this allotted time and the individual did not request an extension, then the right to submit a statement is waived.

(3) Credentials Committee/Function

(a) Professional clinical review activities, including clinical and administrative adverse actions involving individuals, are performed by Credentials Committees/Functions. Impartial representatives with appropriate peer composition are required below. Credentials Committees/Functions will make recommendations to the respective Privileging Authorities regarding the individual’s ability to safely execute their clinical privilege(s)/practice.

(b) After the Credentials Committee/Function receives a QAI report and individual's statement, if submitted, they will meet to review the information and make a recommendation to the Privileging Authority.

(c) When a privileged provider is under review, the Credentials Committee/Function includes a minimum of three privileged providers. At least one peer, a healthcare provider with similar privileges and clinical specialty, level of training and experience, must be in attendance. For the non-privileged provider, three non-privileged providers, at least one of which is a peer with similar practice, must be in attendance. At the discretion of the Privileging Authority, and with coordination with DHA Market/Intermediate Headquarters, with subsequent coordination with DHA/Service Headquarters' HRM Program as appropriate, a member of the Credentials Committee/Function may be from another MTF, a Reserve Component, or may be a DoD federal service employee, as long as there is an appropriate peer as described, and the majority are from the Privileging Authority's medical staff.

(d) The following personnel will not participate:

1. The direct Supervisor or a subordinate of the individual under review;
2. Any QAIO(s) involving the individual and associated clinical adverse action under review;
3. Any person whose testimony is relevant to the case;
4. Any person who is or has participated in other proceedings (courts-martial or administrative review boards) involving the individual under review; and
5. Any person who is reviewing, or has reviewed, the individual's actions under consideration.
6. To the extent practicable, the same representatives should be used each time the Credentials Committee/Function is convened to review the case.

(e) The individual under review does not have the right to attend the Credentials Committee/Function meeting.

(f) The Credentials Committee/Function will submit a written action recommendation, based on the findings, to the Privileging Authority no later than 10 calendar days following completion of the Credentials Committee/Function. The recommendation should include one of the following:

1. Reinstatement of Clinical Privilege(s)/Practice.
2. Reinstatement of Clinical Privilege(s)/Practice with Monitoring and Evaluation (FPPE with a monitoring and evaluation plan).

3. Restriction of Clinical Privilege(s)/Practice.
4. Reduction in Clinical Privilege(s)/Practice.
5. Revocation of Clinical Privileges/Practice.
6. Denial of Clinical Privilege(s).

(4) Privileging Authority Proposed Action Decision

(a) The Privileging Authority will give written notification to the individual of their proposed decision and basis for the action no later than 10 calendar days of receipt following the Credentials Committee/Function's recommendation.

1. Before the Privileging Authority's proposed decision memorandum is issued, a legal sufficiency review of the case and memorandum is required.

2. In cases where the proposed decision is restriction, the proposed decision memorandum will include the conditions and requirements (including any specified time duration of the restriction) that must be met prior to the individual returning to clinical practice.

3. In cases where the decision is to reinstate clinical privilege(s)/practice, with or without an FPPE monitoring and evaluation plan, the decision is final, and no further due process is required. The Privileging Authority decision memorandum shall provide information regarding the FPPE monitoring and evaluation plan. In cases in which the Credentials Committee/Function's recommendation is reinstatement with an FPPE monitoring and evaluation plan, but the individual has separated from or ended affiliation with the MHS, the Privileging Authority will issue a decision memorandum reinstating privileges and include any findings of clinical deficiency that was discovered in the due process. The decision letter will also state that these findings will be included in the individual's close out or detachment clinical evaluation and relied upon in responding to future queries regarding the individual. In instances in which an individual separates or ends affiliation with the MHS while under an FPPE monitoring and evaluation plan, the Privileging Authority will need to determine if the facts in the particular instance warrant a determination in the individual's credentials file/competency folder that the individual satisfactorily completed the period of the FPPE monitoring and evaluation plan. (See Volume 4 of this manual for FPPE with a monitoring and evaluation plan.)

(b) The Privileging Authority is not bound by the recommendations of the Credentials Committee/Function. Action different from the Credentials Committee/Function's recommendations requires written justification and must be included in the proposed action decision memorandum.

(c) If the proposed action decision is to deny (in the case of a privileged provider), restrict, reduce, or revoke the individual's clinical privilege(s)/practice, then the Privileging Authority must advise the individual in writing of the individual's right to a peer review hearing and appeal rights. The written notification of appeal rights must include notification that the

individual's appeal request must be received within 30 calendar days. Notification of the proposed action decision will be delivered to the individual either in person, by certified return receipt requested mail, and/or secure electronic system with confirmation of receipt. If the individual refuses to sign the memorandum, a witness may indicate "refused to sign" where the signature would normally appear.

(d) The individual must be given a copy of the redacted QAI report, including the findings and recommendation and excluding the enclosures, and a copy of the Credentials Committee/Function recommendation memorandum. Meeting minutes and other documents that reflect the deliberative process are not provided to the individual under review.

(e) The Healthcare Risk Manager/MSP/MSM will notify DHA/Service Headquarters' HRM Program through the respective DHA Market/Intermediate Headquarters, within five calendar days of the written proposed action decision. If the individual is a federal civilian employee, a copy of the proposed action decision memorandum will also be provided to the servicing civilian personnel office. If the healthcare provider is a contract employee, a copy of the proposed action decision memorandum will also be provided to the Contracting Officer. The Contracting Officer will ensure a letter documenting these actions is provided to the contractor at the address of record.

(5) Peer Review Hearing Request

(a) The individual has 30 calendar days after receipt of the Privileging Authority's proposed action decision memorandum to request a peer review hearing. The Privileging Authority may extend this time period if appropriate.

(b) If the individual waives their right to a peer review hearing, the right to appeal is also waived.

(c) If no written peer review hearing request is received within the allotted time, the peer review hearing and appeal rights are waived.

(d) If the individual requested a peer review hearing but fails to appear for the scheduled peer review hearing, the Privileging Authority may choose to proceed with the peer review hearing or act on the individual's privileges/practice as in the written notice of the proposed action decision.

(e) If the individual was re-assigned during the clinical adverse action due process (e.g., a PCS for unusual or special circumstances occurred, or the individual separated from or ended affiliation with the MHS), VTC or telephone conferencing will be provided and is sufficient for the due process. The individual may attend the peer review hearing in person, but the Privileging Authority is not responsible for funding travel, temporary duty, or other arrangements save for the VTC or telephone conferencing.

(6) Peer Review Hearing Notifications

(a) If the individual requests a peer review hearing, the individual must be given at least 30 calendar days after receipt of the Privileging Authority's proposed action decision before the peer review hearing is held. However, there must be agreement between the individual and the Privileging Authority as to the date of the peer review hearing within 15 calendar days of the individual receiving the proposed action decision. Additionally, the Privileging Authority will ensure the individual receives written notification of the peer review hearing with the information contained in Paragraph 2.p.(6)(b) of this enclosure as soon as possible, but no later than 20 calendar days before the agreed-upon hearing date. The servicing healthcare legal counsel must review the letter prior to it being given to the individual.

(b) Written notice for the peer review hearing must include:

1. The date, time, and location of the peer review hearing.
2. A statement of the individual's right to be represented by counsel at the individual's expense or to have another representative present. For uniformed Service members, they may be able to receive assistance from military counsel, consistent with Service regulations. The legal or other representative may actively participate in the peer review hearing, address the peer review hearing panel, and question witnesses.
3. A statement of the individual's right to be present, to present evidence, to call witnesses, to make a statement (sworn or unsworn), and cross-examine witnesses. If the individual cannot be physically present, VTC or teleconference may be used.
4. The names of the witnesses to be called to testify at the peer review hearing. Witnesses may testify in person, by teleconferencing, or via a written statement. The Federal Government is not required to support witness travel costs. Contract employees cannot be compelled to testify at the peer review hearing.

(c) The individual will disclose the names and contact information for all witnesses testifying on the individual's behalf no later than 15 calendar days before the scheduled peer review hearing. Witnesses may testify in person, by teleconferencing, or via a written statement. The individual should be advised that the failure of such witnesses to appear will not constitute a procedural error or basis for delay of the proceedings.

(d) The individual may request, in writing, a delay of the peer review hearing for good reason. The Privileging Authority may grant a request for a delay. However, no postponement should be granted by the Privileging Authority if the delay request is made less than five calendar days prior to the scheduled peer review hearing unless there are extenuating circumstances.

(e) Prior to the peer review hearing, the individual will have access to all information that will be presented at the peer review hearing to include the disclosure of witnesses in the QAI report.

(7) Composition of Peer Review Hearing Panel

(a) The peer review hearing panel will be fair and impartial.

1. For the privileged provider, the peer review hearing panel will include a minimum of three voting privileged providers. A majority of the members will be a peer of the healthcare provider under review, with similar awarded privilege(s), clinical specialty and practice, and level of training and experience.

2. For the non-privileged provider, the peer review hearing panel will include a minimum of three voting non-privileged providers. A majority of the members will be a peer of the healthcare provider under review, with similar practice, level of training and experience.

3. To facilitate a fair peer review hearing panel, the following personnel will not be peer review hearing panel members:

a. The direct Supervisor or subordinates of the individual under review;

b. Any QAIOS of the individual under review;

c. Any person who is or has participated in other proceedings (for instance, the Credentials Committee/Function, courts-martial, or administrative review boards) involving the individual under review;

d. Any person who has reviewed or given an opinion of the individual under review; or

e. Any potential witnesses.

4. For civilian healthcare providers under review, at least one member should be a civilian, if available.

5. For active duty healthcare providers under review who belong to a different Military Service, at least one member should be from that Military Service, if available.

6. If the Privileging Authority is the individual being evaluated, or is disqualified from acting in the case, the DHA Market/Intermediate Headquarters (or, if the Privileging Authority is of this level then the DHA/Service Headquarters' HRM Program) is involved in helping to convene the peer review hearing panel.

7. The individual under review may challenge any voting peer review hearing panel member for cause; that is, by showing a member cannot render a fair, impartial decision. Cause for removal of a member exists if a member has a predisposed attitude toward the outcome of the peer review hearing. Mere knowledge of the facts of a case is not sufficient cause for removal. The Chairperson of the peer review hearing panel rules on a challenge to a peer review hearing member; the Privileging Authority rules on a challenge to the Chairperson.

8. The peer review hearing panel will be fully informed of the facts to allow an intelligent, reasonable, good faith judgment. The panel may question witnesses and examine documents, as necessary, to collect pertinent information.

(b) The peer review hearing panel Chairperson will be one of the three voting peer review hearing panel members. The Chairperson and other peer review hearing members will be identified by a letter of appointment from the Privileging Authority. The Chairperson consults with the appointed legal advisor to ensure compliance with conducting the peer review hearing. All objections will be noted in the record of the hearing. The Chairperson, in consultation with the legal advisor, arranges for the orderly presentation of evidence and rules on the relevance and admissibility of substantive clinical matters.

(c) The peer review hearing panel has a non-voting legal advisor, who facilitates due process procedures and ensures the individual is given adequate notice and an opportunity to be heard. This legal advisor shall not be one that is on assignment to provide regular and routine support to the Privileging Authority (e.g., with respect to MTFs, the legal advisor assigned to support the MTF directly); however, the legal advisor will be a federal employee (military or civilian). Once appointed in writing, the legal advisor may rule on any procedural and evidentiary issues that are raised during the peer review hearing. At the discretion of the Privileging Authority, the legal advisor may participate in person or via VTC or telephone. The legal advisor supports the Chairperson, and any consultations are permitted to be off the record and outside the presence of the individual, the individual's representative(s), and the Privileging Authority's representative(s). The legal advisor would advise the Privileging Authority on ruling on any challenges made to the peer review hearing panel Chairperson. The legal advisor may administer oaths to the peer review hearing panel members and witnesses.

(d) The Privileging Authority may appoint additional non-voting representative(s), which may include an attorney, to present evidence as appropriate; the Privileging Authority appointed non-voting representative(s) will be a federal employee(s) (military or civilian). The Healthcare Risk Manager/MSP/MSM will assist these representatives in preparing evidentiary packets and exhibits for the peer review hearing panel and the individual's counsel. These representatives assist the peer review hearing panel in obtaining factual information related to the allegations under review. As such, these representative may address the peer review hearing panel, respond to comments made by healthcare provider's counsel, and question witnesses.

(8) Transcript of the Peer Review Hearing

(a) The Healthcare Risk Manager/MSP/MSM will arrange for a verbatim record of the peer review hearing proceedings, with exhibit items listed and numbered as they are presented. Court reporters may be used from the base legal office, if available, to document the peer review hearing process and results. Obtaining court reporting services is at the cost of the DHA Headquarters/Service SG. If a non-DoD court reporter is retained, a business associate agreement is necessary in accordance Reference (u). The contract for the court reporter must also contain Section 1102 of Reference (t) and Reference (v) citations.

(b) Regardless of the source of the court reporter, the Privileging Authority or designee ensures that the peer review hearing record transcript (paper or electronic) be completed no later than 30 calendar days from peer review hearing completion, to the extent practicable. The Privileging Authority and the individual must be notified regarding any delays in completing the transcript.

(c) The peer review hearing transcript is protected, in accordance with Section 1102 of Reference (t). One original and one copy of the transcript are prepared. The court reporter may provide the peer review hearing transcript and exhibits in electronic medium.

(9) Peer Review Hearing

(a) The peer review hearing is a closed and confidential peer review proceeding.

(b) The peer review hearing is an administrative proceeding, and the rules of evidence for courts-martial and other judicial proceedings do not apply. **The burden of proof is preponderance of the evidence.** The term “preponderance of the evidence” means the greater weight of credible evidence or that the factual allegation is more likely than not true. There is no requirement to prove any allegation beyond a reasonable doubt. Oral and written matter that is not admissible in a court of law may be considered by the peer review hearing panel subject only to reasonable restrictions on relevance, materiality, competence, and cumulativeness.

(c) The peer review hearing panel may call and question witnesses and request and examine documents. **However, information that relates to new allegations (i.e., that were not included in the Privileging Authority proposed action decision memorandum) may not be presented at the peer review hearing.** The results of concurrent or previous administrative or legal proceedings may not be presented at the peer review hearing, unless they are relevant to the individual’s privilege(s)/practice and were part of the allegations being investigated by the Credentials Committee/Function and the Privileging Authority.

(10) Witnesses

(a) Any witness with knowledge relevant to the specific allegations under consideration at the peer review hearing, reasonably available, and whose testimony will add materially to the issues before the peer review hearing committee, may be invited to appear in person before the peer review hearing panel. This includes the QAIO and the individual’s supervisors.

(b) Witnesses not within the immediate geographic area of the site of the peer review hearing are not considered to be reasonably available. Alternative means of testimony, such as written statements, telephonic testimony, or videoconferencing, may be used in the alternative.

(c) Witnesses whose appearance at the peer review hearing is considered material to the proceedings may be requested, at the discretion of the Privileging Authority, from another MTF or a Reserve Component, or may be a DoD federal service employee. Requests will be in coordination with DHA Market/Intermediate Headquarters, with subsequent coordination with

DHA/Service Headquarters as appropriate. The witness's leadership determines whether the witness will be permitted to attend the peer review hearing in person or will need to testify via some other fashion, such as secure VTC.

(d) Witnesses not on active duty or not employed by the DoD (i.e., contract employees) appear voluntarily; they cannot be directed to appear.

(e) The peer review hearing panel is charged with making an objective and independent action recommendation to the Privileging Authority.

(11) Peer Review Hearing Panel Findings and Recommendations

(a) At the close of the presentation of all the evidence and closing statements, the peer review hearing concludes, and the peer review hearing panel deliberates off the record. The peer review hearing panel makes findings as to each allegation outlined in the notification letter and makes a recommendation to the Privileging Authority. They cannot deviate from the wording of the stated allegations or propose additional allegations with findings. However, they are not restricted by the Privileging Authority's proposed action decision memorandum; they are permitted to make any action recommendation to the Privileging Authority based on their review of the evidence.

(b) The peer review hearing panel provides a written report that includes rationale for all substantiated allegations. Substantiated allegations must be supported by sufficient credible evidence. The report will reference any pertinent section of the peer review hearing record or exhibits, as needed, to support the findings. The peer review hearing panel will also provide their rationale for unsubstantiated allegations.

(c) The peer review hearing panel's recommended action(s) requires a majority vote and is based upon prevailing professional standards and on the findings and conclusions from the evidence. Members of the peer review hearing panel will cast a vote either "yes" or "no." No abstentions are permitted.

(d) The recommendation(s) are limited to one or more of the following:

1. Reinstatement of Clinical Privilege(s)/Practice.
2. Reinstatement of Clinical Privilege(s)/Practice with Monitoring and Evaluation (FPPE with a monitoring and evaluation plan).
3. Restriction of Clinical Privilege(s)/Practice.
4. Reduction in Clinical Privilege(s)/Practice.
5. Revocation of Clinical Privileges/Practice.
6. Denial of Clinical Privilege(s).

(e) The peer review hearing panel report of findings and recommendations shall be signed by all peer review hearing panel members. Any peer review hearing panel member may accomplish a minority report. If submitted, the minority report will be attached to the peer review hearing panel's report.

(12) Peer Review Hearing Panel Record

(a) The peer review hearing record is comprised of: A verbatim transcript of the peer review hearing, the Credentials Committee/Function findings and recommendations, input from the individual, medical records, QAI report, and other relevant attachments. The Chairperson of the peer review hearing panel will review the verbatim record of the peer review hearing and make the necessary corrections or edits. The peer review hearing panel will provide a report of their findings on each allegation and their recommendation(s) for action to the Privileging Authority. A copy of this record will be given to the individual within 30 calendar days of peer review hearing completion.

(b) After the individual has received the peer review hearing record, the individual has 10 calendar days to submit a written statement of exceptions and corrections to the Privileging Authority. The individual may request an extension of time to submit a statement of exceptions and corrections. Extensions may be granted by the Privileging Authority or designee for good cause.

(13) Privileging Authority Decision

(a) After legal review, the Privileging Authority will make a decision within 10 calendar days of receipt of the peer review hearing panel record to include the individual's statement of exceptions and corrections.

(b) The Privileging Authority is limited to the peer review hearing record and individual-submitted statement of exceptions or corrections in decision deliberation.

(c) Although not bound by the peer review hearing panel recommendation(s), the Privileging Authority must provide rationale for taking a different action. The Privileging Authority will provide written notification to the individual of their decision and the basis (allegation findings) for such action.

(d) If the Privileging Authority's decision is for a clinical adverse action, notification to the individual will include that the action may be reportable to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies, and will include the individual's appeal rights to the Report Authority.

(e) With regard to non-privileged providers, clinical adverse actions are reported to state(s) of licensure and other applicable certifying/regulatory agencies (e.g., the National Council of State Boards of Nursing for clinical nurses), and to the NPDB as appropriate.

(f) The Privileging Authority's decision is effective immediately, and the adversely affected privilege(s)/practice is modified according to the Privileging Authority's decision.

(g) Written notice of the Privileging Authority's decision will be furnished to the individual either in person, certified return receipt requested mail, and/or secure electronic system with confirmation of receipt. The appropriate department, service, unit, or clinic chiefs will also be advised of the decision. If the individual refuses to sign the memorandum, a witness may indicate "refused to sign" where the signature would normally appear. A copy of this notice will be placed in JCCQAS in both the provider credential record in a Section 1102 of Reference (t) protected document folder and in the adverse action module. For providers not registered in JCCQAS, a JCCQAS credentials record must be established. Annotation will be made in the provider's activity file/competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review/competency assessments.

(h) If the individual is a federal civilian employee, a copy of the decision letter will also be provided to the servicing civilian personnel office. If the individual is a contract employee, a copy of the Privileging Authority decision letter will also be provided to the Contracting Officer and COR.

(14) Non-Appeal of the Privileging Authority's Decision of Clinical Adverse Action

(a) If an individual waives their right to appeal the Privileging Authority's decision, either in writing or by failing to appeal in a timely manner, the Privileging Authority will prepare a memorandum to the Report Authority, stating that the appeal was waived. The memorandum should also include a recommendation as to whether or not the clinical adverse action should be reported to the NPDB, state(s) of licensure, and any other applicable certifying/regulatory agencies (identify those appropriate to the case). Along with the memorandum to the Report Authority, the full and complete MQAR will be sent (in writing by certified return receipt requested mail or secure electronic delivery with confirmation of receipt) to DHA/Service Headquarters' HRM Program to facilitate legal review. If the legal review reveals any due process concerns, the DHA/Service Headquarters' HRM Program has the authority to return the case to the Privileging Authority for corrective actions.

(b) The Report Authority makes the final decision and directs reporting, as appropriate, to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. In cases where a report was made for summary suspension lasting greater than 30 days, the type of report to the NPDB will in most circumstances be a Revision-to-Action Report pursuant to Reference (q). Reference (q) directs the form and content of all reports to the NPDB.

(c) The Report Authority will forward a copy of any report for a member of the Reserve Components to the respective National Guard or Reserve Component Surgeon's office.

(d) In cases in which the Report Authority is not the Service SG of the uniformed Service healthcare provider being reported, the Report Authority will ensure the SG concerned is

notified of any report. Likewise, if a Service SG is reporting a uniformed Service healthcare provider, the Service SG will ensure the DHA Report Authority and the DHA Headquarters' HRM Program are notified of any report.

(15) Appeal of the Privileging Authority's Decision of Clinical Adverse Action

(a) Each individual has the right to written appeal of the Privileging Authority's decision to the Report Authority.

(b) The individual must submit their written appeal to the Privileging Authority no later than 10 calendar days from receipt of the Privileging Authority's decision.

(c) The individual may request an extension for their written appeal for good cause. Extension is granted by the Privileging Authority. The Privileging Authority's decision remains in effect during the appeal process.

(d) The Privileging Authority will have 14 calendar days to provide a written decision on the appeal. If the Privileging Authority denies (partial or complete) the appeal, the appeal will be promptly forwarded to the DHA/Service Headquarters' HRM Program, via the DHA Market/Intermediate Headquarters, for the appeal review process. The Privileging Authority may respond, and offer rebuttal evidence, to any issues raised in the individual's appeal. Any delays encountered by the Privileging Authority must be noted in the documentation forwarded.

(e) The forwarded appellate review record must include:

1. The complete peer review hearing panel record (i.e., the full and complete case file to date), the peer review hearing panel's recommendation to the Privileging Authority, and the Privileging Authority's proposed decision for action.

2. Any appeal request and supporting documentation.

3. The Privileging Authority's decision regarding the appeal request.

4. A written legal sufficiency review of the due process procedures.

(f) Upon receipt of the appellate review record from the Privileging Authority, the DHA/Service Headquarters' HRM Program will arrange for a clinical peer review of the appellate request, if one was not done by the Privileging Authority to decide on the appeal, and arrange for a healthcare professional appropriate panel as per Enclosure 2. The healthcare professional appropriate panel will review the entire appellate review record, the clinical peer review of the appeal, and make a written recommendation to the Report Authority for whether or not to uphold the appeal or to take the clinical adverse action.

(g) The Report Authority reviews the appellate review record and the healthcare professional appropriate panel recommendation, makes the decision, and directs any reporting, as appropriate, to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

1. The Report Authority, as the appeal authority, can overturn, uphold, or modify the decision of the Privileging Authority without returning the case to the Privileging Authority for further due process. The rationale for the decision will be provided in writing to the Privileging Authority and the healthcare provider. If the Report Authority appeal decision is for a more severe action than the Privileging Authority decision, the case must be returned or remanded back to the Privileging Authority with guidance for further due process.

a. A copy of the any report for a member of the Reserve Components will be forwarded to their respective National Guard or Reserve Component Surgeon's office.

b. If the individual is a federal civilian employee, a copy of the decision letter will also be provided to the servicing civilian personnel office. If the individual is a contract employee, a copy of the Report Authority decision letter will also be provided to the Contracting Officer and COR.

2. In cases in which the Report Authority is not the Service SG of the uniformed Service healthcare provider being reported, the Report Authority will ensure the SG concerned is notified of any report. Likewise, if a Service SG is reporting a uniformed Service healthcare provider, the Service SG will ensure the DHA Report Authority and the DHA Headquarters' HRM Program are notified of any report.

3. The Privileging Authority will advise appropriate department, service, unit, or clinic chiefs of the decision. A copy of this notice will be placed in JCCQAS in both the provider credential record in a Section 1102 of Reference (t) protected document folder and in the adverse action module. For providers not registered in JCCQAS, a JCCQAS credentials record must be established. Annotation will be made in the provider's activity file or competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review or competency assessments.

q. Clinical Adverse Action Reporting

(1) A Report Authority is solely responsible for reporting summary suspension exceeding 30 calendar days, clinical adverse actions taken, Correction Reports, Revision-to-Action Reports, and Void Reports to the NPDB in accordance with Reference (q), with subsequent notification to state(s) of licensure, and other applicable certifying/regulatory agencies.

(2) NPDB reports shall be made consistent with the NPDB regulations and guidelines. Report Authorities ensure reports to the NPDB are submitted within 30 calendar days of their adverse action and/or appeal decision, to include those reports required for summary suspension

exceeding 30 calendar days. The DHA/Service Headquarters' HRM Program maintains the electronic and paper adverse action files to ensure accessibility and prepare responses to official requests for information (e.g., state license boards, privileging entities).

(3) Report Authorities ensure reports to state(s) of licensure, and other applicable certifying/regulatory agencies, are submitted within 30 calendar days of their adverse action and/or appeal decision, to include those reports required for summary suspension exceeding 30 calendar days. The DHA/Service Headquarters' HRM Program maintains the electronic and paper adverse action files to ensure accessibility and prepare responses to official requests for information (e.g., state license boards, privileging entities).

(4) With regard to privileged providers, notification of the NPDB report is then sent to state(s) of licensure, the Federation of State Medical Boards (for physicians), the American Association of Dental Examiners (for dentists), and any other applicable certifying/regulatory agencies. Reports concerning deceased providers must be submitted to the NPDB because a fraudulent provider could assume the identity of the deceased provider. When submitting a report on a deceased provider, indicate that the provider is deceased in the appropriate data field.

(5) With regard to non-privileged providers, clinical adverse actions are reported to state(s) of licensure and other applicable certifying/regulatory agencies (e.g., the National Council of State Boards of Nursing for clinical nurses), and to the NPDB as appropriate.

(6) A copy of any NPDB, state(s) of licensure, or other applicable certifying/regulatory agency report for a member of the Reserve Components will be forwarded to their respective National Guard or Reserve Component Surgeon's office as appropriate for their branch of Service.

(7) In cases in which the Report Authority is not the Service SG of the uniformed Service healthcare provider being reported, the respective Service SG and Service Headquarters' HRM Program will receive notification of any report. Likewise, if a Service SG is reporting a uniformed Service healthcare provider, the DHA Report Authority and DHA Headquarters' HRM Program will receive notification of any report.

(8) Replies are sent from the DHA/Service Headquarters' HRM Program directly to the civilian medical facilities, credentialing agencies, or other medical entities on requests for official requests for information regarding completed clinical adverse actions after they are reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

(9) Report Authorities provide their decision or appeal action, with rationale, and in writing to the respective Privileging Authority, via the DHA Market/Intermediate Headquarters, and also to the individual.

r. Clinical Adverse Action Documentation/Record Keeping

(1) Clinical adverse action electronic documentation will be recorded in JCCQAS in both the credentials record and the adverse action module, to include the DD Form 2499,

“Healthcare Provider Action Report” and official notification letters. For providers not registered in JCCQAS, a JCCQAS credentials record must be established. Annotation will be made in the provider’s activity file/competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review/competency assessments. Once clinical adverse actions that are reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies by the DHA Director or Service SG are entered into the JCCQAS adverse action module (completing all required data fields), the record is released to the DHA Headquarters’ HRM Program (Medical Legal Office).

(2) If the individual requires a mandatory PCS (e.g., overseas return), all paper documentation is forwarded by certified return receipt requested mail to the gaining Privileging Authority.

(3) The Healthcare Risk Manager will maintain the complete clinical adverse action case record for actions taken for a minimum of 10 years from the date of the final action. The Healthcare Risk Manager will then forward the case file to DHA Headquarters HRM Program (Medical Legal Office) for archiving. All DoD completed clinical adverse action case records shall be maintained by the DHA Headquarters HRM Program (Medical Legal Office) for archiving.

(4) When MTFs close, the closing MTF forwards all archived and pending cases to the DHA Headquarters’ HRM Program (Medical Legal Office), who assumes responsibility for managing the case records.

3. CRIMINAL CONVICTIONS RELATED TO HEALTHCARE AND OTHER ADJUDICATED ACTIONS OR DECISIONS

a. Background. Prior to May 2013, criminal actions and other adjudicated actions or decisions related to healthcare were reported to the Health Integrity Protection Data Bank (HIPDB). The HIPDB merged with the NPDB, and information previously collected and disclosed through the HIPDB is now collected and disclosed through the NPDB. This applies to active duty, civil service, personal service contract personnel, National Guard, and Reserve personnel. Non-personal services contract personnel are not employees of the Federal Government; however, if a non-personal services contract employee who commits an offense that meets the requirement for reporting to the NPDB, the respective Report Authority shall report the non-personal services contract employee in the same manner as it reports all other providers.

b. Reporting Responsibility. The Report Authority directs the reporting of healthcare providers to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies, regarding reportable criminal actions and other adjudicated actions or decisions related to, or could adversely affect, healthcare.

c. Reportable Criminal Convictions and Other Adjudicated Actions or Decisions. The following addresses reportable criminal convictions and other adjudicated actions or decisions

taken against healthcare providers and suppliers (individuals who furnish, whether directly or indirectly, healthcare services, supplies, items, or ancillary services regardless of licensure, certification, or registration status) who deliver healthcare services to DoD beneficiaries.

(1) Judicial and Non-Judicial UCMJ Actions:

(a) Include both convictions under Chapter 47 of Reference (t), also known and referred to in this manual as “the UCMJ,” as approved by a court martial convening authority, and final non-judicial punishment under the UCMJ, related to the delivery of a healthcare item or service.

(b) Include, but are not limited to, actions involving the following offenses when related to the delivery of a healthcare item or service, or could negatively affect the provision of healthcare:

1. Fraud or misrepresentation involving application for initial, active, modification, or renewal of credentials, staff appointment, and privileges. This includes, but is not limited to, failure to disclose any sanction issued by a licensing or regulatory agency in a timely manner (within seven calendar days), any ongoing investigations by a licensing or regulatory agency, falsifying credentials, forging signatures on peer reference letters, and other intentional acts or omissions meant to deceive the credentialing and privileging process.

2. Theft of government or personal property.

3. Drug offenses to include illegal use, possession, or distribution of controlled substances; diversion of narcotics; self-prescribing; or other improper prescribing of controlled medications.

4. Reporting to or performing clinical duties (to include being on call or otherwise on duty) while under the influence of alcohol or drugs.

5. Alcohol or drug abuse.

6. Acts of sexual abuse, sexual assault, sexual harassment or sexual exploitation.

7. Engagement in a sexual or other inappropriate relationship with a patient that violates professional boundaries.

8. Assault of patients or staff or engagement in threatening behavior.

9. Other acts or omissions for which the healthcare provider is formally disciplined.

(2) Other healthcare-related criminal convictions by civilian federal, state, or local authorities are reported as per Reference (q). Consult with servicing healthcare legal counsel for additional guidance.

(3) Other Reportable Adjudicated Actions or Decisions

(a) Certain Patient Safety Events Affecting Active Duty Service Members. Any DoD RE or patient safety event involving an active duty Service member that is at high risk for becoming a disability or death payment will be considered by Report Authorities for an NPDB Report as an “other adjudicated action or decision” if there is expected to be a significant time lapse prior to such payment being made. For example, an active duty Service member harmed by a DoD RE or patient safety event who remained on active duty and could not receive a disability or death payment until a future date.

(b) Adverse Personnel Actions Affecting Uniformed Services Members. These actions include any administrative action resulting in separation, reduction in grade, involuntary military occupational specialty reclassification, or other administrative action in which the individual is given notice and an opportunity to be heard. Other adjudicated actions or decisions, based on a Service’s quality force management disciplinary tools, may meet criteria for reporting if the uniformed Service member is afforded sufficient due process (e.g., appropriate notice, an opportunity to be heard, and an appeal right). The hallmark for reporting these is the availability of a due process mechanism, regardless of whether the uniformed Service member elects to use the due process mechanism.

(c) Adverse Civilian Personnel Actions. Any adverse civilian personnel action as described in Reference (w), is reportable. Given due process concerns, adverse disciplinary actions include suspension of more than 14 calendar days, removal from federal employment, and change to a lower grade based on disciplinary procedures. Actions, such as furlough without pay, reduction in grade, or removal based on performance, are not reportable, unless related to the delivery of healthcare. Resignations in lieu of removal are not reportable, unless related to the delivery of healthcare.

(d) Certain Contracting Actions. Reportable actions include:

1. A contract termination for default taken by an MTF/Service against a personal services or non-personal services contractor based on acts or omissions negatively impacting the delivery of healthcare.

2. Terminations of personal services contract employees with the contractor related to concerns regarding suspected misconduct, impairment, incompetence, or any conduct (acts or omissions) that adversely affects, or could adversely affect, the health or welfare of a patient.

(4) Reporting Process to the NPDB, State(s) of Licensure, and Other Applicable Certifying/Regulatory Agencies

(a) Privileging Authorities are responsible for identifying criminal convictions related to, or could adversely affect, healthcare, and adjudicated actions or decision actions that meet criteria for reporting to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. The servicing healthcare legal counsel may assist the Privileging

Authority with identification of cases appropriate for reporting, and will review the file for legal sufficiency and documents the review in writing. The case file is forwarded to the DHA/Service Headquarters' HRM Program, through the respective DHA Market/Intermediate Headquarters, for the respective Report Authority.

(b) For federal civilians, local civilian personnel offices and the servicing healthcare legal counsel must be notified.

(c) For personal services contractors, Contracting Officers, CORs, and the servicing healthcare legal counsel must be notified.

(d) In coordination with the servicing healthcare legal counsel, and prior to forwarding the action for possible reporting, the Privileging Authority will notify the individual, in writing, of the adverse effect the misconduct or other act or omission had or could have had on the provision of a healthcare item or service and that the recommendation to report the action to the NPDB will be forwarded to the Report Authority for final determination and reporting to the NPDB, as appropriate. The individual will also be notified that they may submit a written statement within 14 calendar days regarding the recommended reporting of the misconduct. The individual's written statement, if submitted, will be included in the reporting recommendation package to the Report Authority.

(e) Required in the documentation forwarded to the Report Authority are the finalized criminal action documents (such as the court-martial convening authority's order and the completed non-judicial punishment paperwork), Standard Form 50 for civilian employees, other requirements of the state(s) of licensure or other applicable certifying/regulatory agencies, documentation to support the action which may include the DD Form 2499, "Health Care Practitioner Action Report", the Privileging Authority's report recommendation, the healthcare servicing legal counsel written review, and the individual's written statement (if submitted) or a memorandum reflecting that the individual declined to submit a statement.

(f) The Report Authority reviews the case file and decides whether to report; if the decision is to report, the Report Authority will direct a designee to submit reports, as appropriate, to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies. The designee will also provide written notification of the decision, rationale, and the report, to the individual and the Privileging Authority. Similarly, appropriate Report Authorities of the DHA, Service SGs and Reserve Components, to include the Guard, will be notified as well.

(g) Misconduct warranting a potential clinical adverse action will follow the clinical adverse action due process procedures discussed in this enclosure. It is possible that acts or omissions by an individual may result in multiple reports (i.e., clinical adverse action, criminal conviction, and administrative action).

(h) If the criminal conviction related to healthcare or other adjudicated action or decision is appealed or set aside, the reporting process continues, regardless of the status of the appellate process. The Report Authority may direct reporting, regardless of the appeal status. If the criminal conviction or other adjudicated action or decision is overturned or modified on

appeal after the individual had been reported to the NPDB, a Revision-to Action Report (or a Void Report if the action or decision was vacated) is submitted to the NPDB. A copy of the Revision-to-Action (or Void) Report is also sent to state(s) of licensure and other applicable certifying/regulatory agencies. Privileging Authorities will submit such requests for revising or voiding a NPDB report to their Report Authority.

(i) Reports involving deceased healthcare providers must be submitted to the NPDB because a fraudulent provider could assume the identity of a deceased provider. When submitting a report on a deceased provider, indicate that the provider is deceased in the appropriate data field.

(j) Criminal convictions related to healthcare and other adjudicated actions or decisions reported to the NPDB will be entered into the JCCQAS adverse action module, completing all required data fields, and then released to DHA Headquarters' HRM Program (Medical Legal Office).

ENCLOSURE 4

IMPAIRED HEALTHCARE PROVIDER PROGRAM (IHPP)

1. GENERAL OVERVIEW

a. The IHPP is designed to provide support, assistance, and coordination or advocacy for rehabilitation of healthcare providers who suffer from a condition that adversely affects, or could adversely affect, the safety or welfare of a patient. Identification and management of an impaired healthcare provider must facilitate rehabilitation of the provider by offering assistance to retain and regain optimal professional functioning consistent with the delivery of quality healthcare. An impaired healthcare provider is one who is under evaluation for or is diagnosed with impairment associated with substance use/abuse, or a medical/mental health condition.

b. Notwithstanding the emphasis on rehabilitation in this enclosure, clinical adverse action due process may need to be initiated in cases in which a healthcare 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 rehabilitation program, or relapses after treatment. If a clinical adverse action is taken against the provider, it must be reported to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies as appropriate. Healthcare providers undergoing clinical adverse action due process will be provided services and support in accordance with this manual.

c. Privileging Authorities ensure they have a structured IHPP, or comparably titled program, to address the multidisciplinary needs of their military, civilian, and personnel services contract healthcare providers with substance use/abuse, or medical/mental health conditions. This program is not applicable to non-personal services and independent contractors. For Privileging Authorities without the resources to have an IHPP of their own, they will ensure affiliation with such a program to support their providers.

2. OBJECTIVES OF THE IHPP

a. Promote the well-being of healthcare providers and minimize factors that contribute to impairment.

b. Identify impaired healthcare providers as early as possible to promote recovery and ensure PS.

c. Recommend reasonable accommodations regarding the clinical practice of impaired healthcare providers.

d. Ensure treatment, or other appropriate remedial actions, and subsequent return to clinical practice (when feasible) for impaired healthcare providers who have been successfully rehabilitated/treated.

e. Provide ongoing monitoring of rehabilitated healthcare providers.

f. Ensure compliance with Reference (x) for uniformed Service members when a mental status evaluation is recommended. For civilian General Schedule (GS) employees, ensure compliance with applicable provisions, such as Reference (y), as amended, Reference (z), as well as Subpart C of Reference (aa), when a mental status evaluation is recommended. ADA requirements are implemented by the Equal Employment Opportunity Commission's ADA enforcement guidance at Reference (z). In addition, for GS providers, consult with the servicing labor law office.

3. IHPP COMMITTEE. The IHPP is a subcommittee of the Credentials Committee/Function that serves to ensure effective assistance by advocating and coordinating for treatment and rehabilitation, and to aid impaired healthcare providers in retaining or regaining optimal professional functioning. The committee members, including the chairperson, will be appointed by the respective Privileging Authority and should, at a minimum include:

a. Composition

(1) Representatives from Mental or Behavioral Health, may include a healthcare provider who specializes in substance use disorders (e.g., a Clinical Consultant, Clinical Director, or substance use disorder provider).

(2) Representatives from Nursing (e.g., a Clinical Nurse Specialist, if available).

(3) A recovered and stable (no relapse) impaired staff member of comparable position with at least 2 years in recovery, if available.

(4) The GME Director or a Program Director when there are enrollees from the GME Program.

b. Functions. The IHPP will meet as needed to accomplish the following functions:

(1) Recommend a plan for management of impaired healthcare providers to the Privileging Authority.

(2) Design a staff development plan that incorporates elements of prevention, education on recognition, and reporting of healthcare provider impairment and well-being issues.

(3) Recommend procedures for management of impaired healthcare providers. Recommendations will be consistent with all requirements contained in Reference (x) when a mental status evaluation is considered for a uniformed Service member, regardless of the reason for the evaluation. For civilian employee GS healthcare providers, recommendations will be consistent with Reference (y), Reference (z), as well as Subpart C of Reference (aa), regardless of the reason for the evaluation. In addition, GS healthcare providers are recommended to consult with the servicing civilian personnel/labor relations office.

(4) Ensure evaluation of any healthcare provider who self-refers or is reported for possible impairment.

(5) Recommendations for healthcare providers will be forwarded through the Credentials Committee/Function to the Privileging Authority.

(6) Monitor the progress of impaired healthcare providers during treatment, and through the complete aftercare phase. Successful completion of the IHPP requires that the healthcare provider has successfully participated in a period of ongoing monitoring to the predetermined end date.

(7) Recommend an individualized plan for the gradual return to full clinical privileges/practice for each impaired healthcare provider who has completed treatment. For impaired providers who are retiring or separating from federal service while still enrolled in an IHPP, the IHPP will address whether to recommend full reinstatement of clinical privileges/practice (in other words, if the provider has successfully completed the program) or continuation of the monitored status by state(s) licensing board(s), if appropriate (e.g., substance use/abuse).

(8) The IHPP Chairperson may request the Department Chief (or equivalent), or the Supervisor, or both to attend the meeting if this direct participation is deemed beneficial to the individual in question.

(9) The IHPP will review input, and statements of progress and recommendations, from the healthcare provider's treating provider (substance use disorder clinical staff for substance use/abuse), Supervisor, and Department Chief (or equivalent), to develop their recommendation for the Privileging Authority, through the Credentials Committee/Function.

(10) The IHPP recommends appropriate duty limitation or separation from Service as a result of the medical condition or disorder, or as a result of the recommendation(s) from a Medical Evaluation Board (MEB), Physical Evaluation Board (PEB), or Integrated Disability Evaluation System (IDES). The IHPP also ensures that the Credentialing Committee/Function receives notification of any MEB, PEB or IDES recommendations for impact on the healthcare provider's privileges or scope of practice. The IHPP coordinates with the Credentialing Committee/Function for their final recommendation for modification of a provider's privileges/practice to the Privileging Authority. This should not be considered a clinical adverse action but may require reporting of the long term impairment to state(s) of licensure and other applicable certifying/regulatory agencies.

(11) Provide a monthly status update summary to the Credentials Committee/Function (or Chair if meetings held less frequently). Status update summaries will include the IHPP assessment of continued impact of impairment on the healthcare provider's privileges/practice, and any other relevant matters for leadership awareness. The Credentials Committee/Function (or Chair as appropriate) forwards the summary, with comment if indicated, to the Privileging Authority. In the case of chronic conditions, and with Privileging Authority approval, status update summaries can be reduced from monthly to quarterly.

c. IHPP Chairperson Role and Responsibilities

(1) The IHPP Chair will ensure that all assigned committee members receive an orientation to the duties and responsibilities of this committee, including the requirement for compliance in accordance with References (u), Section 1102 of Reference (t), and Reference (v), for all healthcare provider discussions and associated documents.

(2) The IHPP Chair supports the Privileging Authority's written notification to DHA/Service Headquarters' HRM Program through the DHA Market/Intermediate Headquarters. Notification will also be given to the individual's respective Service chain of command. Enrollment in the IHPP may also require notification to the Report Authority to report to this provider's state(s) of licensure.

(3) Prior to a provider's PCS or transfer, the IHPP Chair provides recommendations to the Privileging Authority, through the Credentials Committee/Function (or Chairperson), as to whether the gaining Privileging Authority should maintain the provider in the IHPP for continuation of program support and monitoring. While it is usually helpful for the healthcare provider to complete all phases of the IHPP at the provider's current unit of assignment, this may not be feasible or appropriate. The IHPP Chair supports the Privileging Authority's written notification to the gaining Privileging Authority and the individual's respective Service chain of command.

(4) The IHPP Chair will have, and document, a discussion with the individual healthcare provider to advise compliance with any requirement to self-report enrollment into the IHPP to the provider's state(s) of licensure.

4. IMPAIRED HEALTHCARE PROVIDER INDIVIDUAL RESPONSIBILITIES

- a. Provide requested information to the IHPP in a timely fashion.
- b. Follow up with their state licensing board(s) with respect to notification of participation in the IHPP Program and any other requirements with respect to their state(s) of license.
- c. Be an active participant in the IHPP, their prescribed treatment or rehabilitation program.
- d. Be informed that failure to comply with these obligations could result in a disenrollment in the IHPP, in other personnel administrative or disciplinary action, or in initiation of clinical adverse action due process, as appropriate.

5. MANAGEMENT OF HEALTHCARE PROVIDERS IMPAIRED BY SUBSTANCE USE/ABUSE OR MEDICAL/MENTAL HEALTH CONDITIONS

- a. Any healthcare provider involved in the delivery of healthcare who is known or suspected of having acute or chronic substance use/abuse or a medical/mental health condition that

adversely affects, or could adversely affect, the safety or welfare of a patient will be reported to the provider's Supervisor, Department Chief (or equivalent), the Chief of the Medical Staff, and the IHPP Chair.

b. Any healthcare provider who recognizes that a potential or actual impairment exists may self-report to the IHPP. The provider may also submit a written request to the Credentials Committee/Function to modify all or part of their privileges/practice along with documentation from their treating provider. Managing a provider who self-reports is considered a personnel administrative action, not a clinical adverse action. However, a request for modification of privileges to avoid initiation of clinical adverse action due process is not permitted.

(1) A healthcare provider may self-report substance use/abuse; however, if there is evidence of drug diversion, use of illegal drugs, conduct that adversely affects, or could adversely affect, the safety or welfare of a patient, clinical adverse action due process will be initiated. In addition, any suspected loss of drugs or drug diversion should be immediately reported to the supporting military law enforcement investigative agency.

(2) Healthcare providers who fail to self-report and seek treatment for an impairment of which they are aware exists and that has or potentially has impacted their ability to perform their clinical duties, may be subject to a clinical adverse action. In such cases, the Credentials Committee/Function, supported by consultation with at least the provider's senior corps representative and supervisor, reviews the facts of the case with the servicing healthcare legal counsel. The servicing legal office advises on possible criminal violations related to impairments and is consulted prior to questioning the provider. See Enclosure 3 for management and reporting of clinical adverse action due process, and for when concurrent with misconduct.

c. The IHPP will request:

(1) A statement of diagnosis, prognosis, compliance with treatment, and implications for privileges/practice. The impaired healthcare provider will request their treating provider to send this information to the IHPP.

(2) A statement from the healthcare provider's clinical supervisor concerning current clinical performance and the ability to safely execute clinical responsibilities in providing or supervising the delivery of healthcare. The statement shall include the results of a retrospective FPPE review of the provider's clinical care during the period prior to self-disclosure of impairment. In the case of substance use/abuse, the IHPP will coordinate with the Substance Use Disorder Clinical Director, or senior substance use disorder provider as appropriate, for the appropriate rehabilitation program and resources necessary for treatment.

d. The voluntary modification of privileges/practice in conjunction with impairment self-disclosure is not to be construed as a clinical adverse action. If the Privileging Authority decides to initiate clinical adverse action due process due to other extenuating circumstances, they will follow the clinical adverse action due process as outlined in this manual.

e. Status update reports from the healthcare provider's treating provider, rehabilitation program if enrolled, and clinical supervisor to the IHPP will be requested at least monthly, pursuant to valid HIPAA compliant authorization. For chronic conditions, and with Privileging Authority approval, the IHPP Chair may reduce the frequency of these update reports from monthly to quarterly. These reports are also required at the time of privilege(s)/practice appraisal and evaluation, privilege renewal, or if a change occurs in the health of the impaired provider. These reports will be maintained in a secure file pursuant to the protections of Section 1102 of Reference (t) and Reference (ab) as a part of the IHPP minutes.

f. The IHPP will provide monthly status update summaries to the Privileging Authority, through the Credentials Committee/Function (or the Chair if meetings held less frequently). Status update summaries will include the IHPP assessment on continued impact of the impairment on the healthcare provider's privileges/practice, and any other relevant matters for leadership awareness. The Credentials Committee/Function (or Chair as appropriate) forwards the summary, with comment if indicated, to the Privileging Authority. In the case of chronic conditions, and with Privileging Authority approval, status update summaries can be reduced from monthly to quarterly.

(1) When a healthcare provider recovers, separates, or retires, the IHPP Chair will coordinate with the Credentialing Committee/Function in a similar manner with a final IHPP report.

(2) Healthcare providers who are returned to practice subsequent to a clinical adverse action related to substance use/abuse shall have a period of FPPE with a monitoring and evaluation plan to include random substance use testing as recommended by their treating provider and in consultation with servicing legal counsel. In consultation with the treating provider, the IHPP should strongly consider recommending to the Credentials Committee/Function a period of at least 3 months for an FPPE monitoring and evaluation plan for providers with mild to moderate substance abuse disorder, and a period of at least 6 months to 1 year for an FPPE monitoring and evaluation plan for providers with a moderate to severe substance abuse disorder.

g. The Privileging Authority will forward to the DHA/Service Headquarters' HRM Program, through the DHA Market/Intermediate Headquarters, recommendation(s) to the Report Authority regarding reporting to state(s) of licensure, those impaired healthcare providers who are ending affiliation with the MHS and require continued monitoring. Providers with impairment due to substance use/abuse and who do not successfully complete the rehabilitation program in which they are enrolled, will be reported to respective state(s) of licensure and other applicable certifying/regulatory agencies as appropriate.

h. Temporary conditions that affect a healthcare provider's privilege(s)/practice (e.g., broken arm or leg, brief illness, pregnancy, or other short-term conditions) are noted on an official duty limiting condition report for uniformed Service members, signed medical statement for others. Documentation should include a brief explanation regarding the prognosis and how the medical condition limits or affects the healthcare provider's clinical practice (e.g., cannot operate with a broken finger, should not deliver babies with a broken arm, temporary nerve damage, or loss of

strength). The duty limiting condition report or medical statement should also specify, to a reasonable degree of medical certainty, the length of time the condition is expected to last. This duty limiting condition report/statement should immediately be brought to the attention of the impaired healthcare provider's Supervisor for appropriate management of healthcare service delivery operations. Should a temporary condition become chronic, the Supervisor will discuss the situation with the IHPP Chair for potential enrollment in the IHPP. Temporary conditions impacting civilian healthcare providers are handled in accordance with applicable civilian personnel regulations. Temporary conditions of a contract healthcare provider are handled in accordance with the terms of the contract.

i. Healthcare providers who are undergoing treatment or evaluation for temporary medical/mental health conditions not requiring a medical board, or who have potentially communicable diseases that may impact their ability to provide safe patient care, may be reassigned to non-direct patient care activities. Because each case may be slightly different from the next, and due to the complexity of such cases, each case should be independently considered in context (e.g., infectious disease specialists should be consulted for healthcare providers with potentially communicable diseases). In cases specifically involving infection with the Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), or the Human Immunodeficiency Virus (HIV), case-by-case evaluation will be according to the current Society for Healthcare Epidemiology of America (SHEA)'s "SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus" (<http://www.shea-online.org/index.php/practice-resources>). If temporary administrative reassignment occurs, it is non-adverse and non-reportable. The healthcare provider's ability to safely resume patient care activities must be evaluated at regular intervals. For civilian employees, consult with the servicing civilian personnel office. For contractors, consult with the servicing Contracting Officer and COR.

6. NATIONAL GUARD AND RESERVE MEMBERS. Should information arise that indicates the National Guard or Reserve member is impaired (as described in this enclosure), the Privileging Authority will notify the appropriate National Guard/Reserve member's chain of command. If on the other hand, the National Guard/Reserve member's chain of command becomes aware of the impairment first, they will notify the respective Privileging Authority under whom the provider holds privileges/practices.

7. HEALTHCARE PROVIDERS WITH INFECTIOUS DISEASES. Healthcare providers with certain infectious diseases (e.g., infection with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus) will be managed in accordance with Paragraph 5.i. of this enclosure.

ENCLOSURE 5

POTENTIALLY COMPENSABLE EVENTS, ACTIVE DUTY DEATH, ACTIVE DUTY
DISABILITY, AND MEDICAL TORT CLAIMS

1. BACKGROUND

a. The Chief of the Medical Staff, along with the rest of the CQM team and other SMEs, collaborate to identify and analyze PS events that reach the patient (adverse and no harm events), for risk mitigation (both immediate and future) and appropriate reporting. This integrated collaborative relationship fosters organizational efforts to reduce risks to patients and improve the quality of care utilizing high reliability principles and practices.

b. HRM and PS each have distinct roles (as described in this manual) for the identification, analysis, and mitigation of risks involving adverse and no-harm events; however, they collaboratively manage both individual and aggregated adverse and no-harm event trend data, corrective action plans (mitigation strategies), sharing organizational lessons learned, and process improvement activities. HRM reports both individual and aggregated adverse and no-harm event trends to local, DHA Market/Intermediate Headquarters, DHA/Service Headquarters, and to the DoD RMWG as directed.

2. POTENTIALLY COMPENSABLE EVENTS (PCE)

a. Overview

(1) CQM teams must have formal, structured, collaborative processes in place to identify, analyze, and mitigate risks involving PS events in such a way that promotes a fair and just culture. PS and HRM each have distinct roles involving PS events that reach patients; however, they collaboratively manage trend data (both individual and aggregated) for collective learning and process improvement.

(2) PCEs are those PS events that both a) reach the patient (i.e., adverse and no-harm events), and b) have 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 of this manual.

(3) PCE review procedures assist with analysis of both individual and system clinical performance for risk mitigation, learning, and process improvement. Deliverables required from PCE reviews include both standard of care (SOC) determinations and system process reviews.

b. PCE Review

(1) Immediate action must be taken to ensure patients, staff, and visitors are protected from additional injury and to mitigate the adverse impact of adverse and no-harm events.

(a) The Healthcare Risk Manager, in coordination with the Chief of the Medical Staff, other appropriate clinical leadership, and the servicing healthcare legal counsel, assess whether or not the adverse or no-harm event is likely to present a possible financial loss to the Federal Government. If so, a PCE review will be completed.

(b) All DoD Reportable Events (DoD REs) require PCE review procedures, as do all filed (or paid) medical tort claims and active duty death or disability payments related to the delivery of healthcare, and adverse and no-harm patient safety events determined to present a possible financial loss to the government. Summary suspension and initiation of clinical adverse action due process procedures will be considered with the initiation of every PCE SOC review. Documentation by the Privileging Authority regarding the decision for or against summary suspension will be kept with the full and complete PCE case file.

(c) The Healthcare Risk Manager, and other CQM team members, will secure and preserve all relevant physical evidence related to the PCE immediately (or as soon as possible) after the event with all appropriate physical, technical, and administrative safeguards. Evidence may include, but is not limited to, medical records, telephone consults, radiology reports, exams, films, recordings, fetal monitor strips, and ancillary recordings from medical monitoring devices such as anesthesia, cardiac monitors, and other related data.

(2) All PCEs must be referred to the Patient Safety Manager to ensure capture in the Joint Patient Safety Reporting (JPSR) system and PS event management as per Enclosure 2 in Volume 2 of this manual.

(a) All PS events must be entered into the JPSR system to be analyzed for opportunities to prevent harm, and will be classified according to the current Agency for Healthcare Research and Quality (AHRQ) harm scale and JPSR taxonomy.

(b) The Healthcare Risk Manager, Patient Safety Manager, and senior clinical staff will collaborate to determine the appropriate investigative process(es) for the event. The servicing healthcare legal counsel will be consulted.

(c) When both a PS Comprehensive System Analysis (CSA) and a PCE review are required on a given adverse or no-harm event concurrently, the two analyses are separate and distinct processes. While information cannot be shared during the course of either the CSA or the PCE review, following the completion of both investigations the two programs collaborate on their analyses of the system and process findings for organizational learning.

(d) The Privileging Authority, or any higher headquarters, may direct a facility-level analysis of any PS event.

(3) If directed by the Privileging Authority, or designee, the HRM Program will notify the Healthcare Resolutions Program for support in the disclosure of adverse and no-harm events (including DoD REs) to the patient as per Reference (ac).

(4) The Healthcare Risk Manager will commence the PCE review within 30 calendar days, and complete it within 180 calendar days, of notification of the event.

(5) Every PCE review will identify significantly involved providers (SIPs), conduct a SOC review on each SIP, and analyze both systems and processes involved in the care of the patient that may have contributed to the PCE. The peer reviewer must be an appropriate clinical peer to the individual under review. If no such individual is on staff under the Privileging Authority, they may reach to DHA Market/Intermediate Headquarters, with subsequent reach to DHA/Service Headquarters' HRM Program, as appropriate, to coordinate or obtain the services of such an individual.

(a) The Healthcare Risk Manager will assist the Chief of the Medical Staff, or designee, to notify the healthcare provider(s) in writing when they have been identified as a SIP in a PCE, and that a SOC review will be conducted. Reasonable attempts will be made to notify the provider in writing. If the Healthcare Risk Manager is unable to notify the SIP, all attempts will be documented in the PCE file.

(b) The PCE review must include a peer SOC review. PCE peer SOC reviews are based on the standard of care of healthcare delivery at the time of the adverse or no-harm event, and will include an opinion and a basis for that opinion as to whether the SOC was "met" or "not met" for each SIP. In rare circumstances, SOC may be designated as "indeterminate" due to such factors as a lack of information or incomplete medical records, which render the SOC reviewer unable to determine the SOC. A DHA-approved SOC review template will be used for PCE SOC reviews.

(c) SIPs must be afforded the opportunity to provide a statement for the PCE review, to the extent appropriate per the servicing healthcare legal counsel, to ensure a full understanding of the facts regarding the care provided to the patient. The Healthcare Risk Manager will request a written memorandum from each SIP for the PCE review. This memorandum must be protected in accordance with Section 1102 of Reference (t). SIPs may review medical records and relevant clinical documentation to assist them in writing the memorandum for purposes of the PCE review.

(6) The PCE review will include an analysis of both system and process issues in addition to the SOC review(s).

(7) The Healthcare Risk Manager will enter the PCE into the JCCQAS risk management module, completing all required data fields, within 180 calendar days of PCE notification. Until there is an approved electronic database for scanning and uploading PCE documents, the Healthcare Risk Manager will maintain a paper or electronic copy of all PCE documents, as well as entering the case into the PCE module in JCCQAS.

(8) The entire PCE review case file, which must include the SOC review and any recommendations, will be forwarded to the Chief of the Medical Staff for appropriate action:

(a) For additional procedures regarding a PCE review case file related to payment to an active duty Service member for a medical condition(s) which may have been caused or contributed to as a result of healthcare provided by the MHS, please see Paragraph 6.a. in this enclosure.

(b) For additional procedures regarding a PCE review case file related to active duty deaths associated with healthcare provided by the MHS and resulting in death benefit payments, please see Paragraph 6.b. in this enclosure.

(c) For additional procedures regarding a PCE review case file related to medical tort claims, please see Paragraph 7. in this enclosure.

(d) For all other PCE review case files related to DoD REs and to PS adverse and no-harm events determined to present a risk of financial loss to the government, these will be forwarded to the Credentials Committee/Function for review.

(9) If SOC was found to be met these other PCE review case files related to DoD REs and to PS adverse and no-harm events determined to present a risk of financial loss to the government, the Credentials Committee/Function will re-assess the risk for a potential future active duty death or disability payment to be made, and if high, then the full and complete PCE review MQAR must be forwarded to the DHA/Service Headquarters' HRM Program (through appropriate DHA Market/Intermediate Headquarters) and then to the civilian peer review agency external to the DoD, as designated by the ASD(HA).

(a) The external reviewer's curriculum vitae, and other pertinent information from the external review (such as current supporting literature used in the external peer SOC report) must be provided with the external peer SOC report by the external peer review agency.

(b) The external peer review report is considered a MQAR in accordance with Section 1102 of Reference (t). The external peer SOC review will not be given to the healthcare provider under review.

(c) DHA/Service Headquarters' HRM Program shall ensure that reviewers at all levels, including the external review, are provided a full and complete PCE review MQAR. All reviewers should base their determinations on the same information contained in the record.

1. A full and complete PCE review MQAR includes all relevant information (medical records, all clinical reports, images, and process/system findings), and information and comments submitted by the SIPs.

2. When new information is obtained that is material and relevant to the determination, it must be added to the record.

(d) In instances in which the external SOC review has determined that a SIP met SOC, no further review is required and the matter may be closed with notification to the local Privileging Authority, who subsequently notifies the SIP in writing.

(10) If SOC not met was found by either the PCE SOC review or by the external civilian peer review agency for these other PCE review case files related to DoD REs and to PS adverse and no-harm events determined to present a risk of financial loss to the government, the Credentials Committee/Function will provide a written review of the case for the Privileging Authority and will include:

(a) An analysis of whether or not the deviation from SOC caused or contributed to the patient safety event.

(b) A recommendation as to whether or not initiation of clinical adverse action due process procedures is indicated.

(c) An FPPE with monitoring and evaluation plan that will include at least an assessment of provider performance regarding care related to the PCE as well as identification of system issues that led to increased vulnerability for a patient safety event.

(d) A re-assessment of the risk for an active duty death or disability payment, and if high, a recommendation for whether or not an “other adjudicated action or decision” report to the NPDB should be made prior to any death or disability payment having been made.

(11) The Privileging Authority reviews the Credentials Committee/Function written review for these SOC not met reviews PCEs related to DoD REs, and to PS adverse and no-harm events determined to present a risk of financial loss to the government, and evaluates the assessments and actions recommended within. Specifically they must:

(a) Concur or dissent on any recommendation to initiate clinical adverse action due process procedures (with subsequent initiation as per Enclosure 3 of this Volume). Documentation of this decision will be kept with the full and complete PCE case file.

(b) Concur or dissent on any re-assessment for there being high risk for an active duty death or disability payment, warranting an “other adjudicated action or decision” report to the NPDB.

1. If the Privileging Authority proposed decision is to not recommend an “other adjudicated action” report to the NPDB, state(s) of licensure, and other applicable certifying or regulatory agencies, they will notify the SIP in writing and will ensure the full and complete PCE review MQAR is forwarded to the DHA/Service Headquarters’ HRM Program (through the appropriate DHA Market/Intermediate Headquarters) to ensure completion of the JCCQAS record and ensure that DHA Headquarters’ HRM Program/Medical Legal Office receives it (in JCCQAS this is “release to DoD” function) for archiving.

2. If the Privileging Authority proposed decision is to recommend an “other adjudicated action” report to the NPDB, state(s) of licensure, or other applicable certifying or regulatory agencies, each SIP subject to such a report shall be notified in writing, delivered in person when possible, otherwise to be notified by certified return receipt requested mail, or secure electronic system with confirmation of receipt; and will be afforded the opportunity to request an appeal of that decision. An appeal will be requested in a timely manner and not to exceed 30 days from the date of notification of the proposed decision. The SIP’s appeal will include the opportunity to submit a statement and supporting documents to address care they provided. The SIP is to be provided a redacted copy of the SOC review to develop their appeal. The SIP will be deemed to waive the right of appeal if a request for an appeal or documents are not submitted within 30 days of notification of the proposed decision.

(12) The full and complete PCE review SOC not met case files of these DoD REs and PS adverse and no-harm events determined to present a risk of financial loss to the government, are forwarded, along with all documentation relating to the Privileging Authority’s proposed decision and any appeal documentation, to the DHA/Service Headquarters’ HRM Program (through the appropriate DHA Market/Intermediate Headquarters). The DHA/Service Headquarters’ HRM Program will convene a healthcare professional appropriate panel as per Enclosure 2. The healthcare professional appropriate panel will review the entire PCE review MQAR (with both SOC reviews as applicable), make a written reporting recommendation regarding the SOC determination for each SIP with inclusion of an analysis with the presumption that the deviation in SOC caused or contributed to the member’s disabling condition unless the evidence clearly established that there was no causal or contributing relationship, as well as a recommendation for whether an “other adjudicated action” NPDB report is indicated.

(13) When the Report Authority decision is to not make an “other adjudicated action” NPDB report, the full and complete PCE review MQAR will be forwarded to the DHA/Service Headquarters’ HRM Program (through the appropriate DHA Market/Intermediate Headquarters) to ensure completion of the JCCQAS record and ensure that DHA Headquarters’ HRM Program/Medical Legal Office receives it (in JCCQAS this is “release to DoD” function) for archiving. Documentation of the decision will be kept with the full and complete PCE review MQAR. DHA/Service Headquarters’ HRM Program will notify the local Privileging Authority who notifies each SIP in writing. Documentation of the Report Authority’s decision is appropriately maintained in the provider’s JCCQAS credentials record (and securely maintained training records as appropriate, e.g., GME programs).

(14) When the Report Authority decision is for an “other adjudicated action” NPDB report (i.e., SOC not met, and the deviation of SOC caused or contributed to the disability or death, and that re-assessment of risk for an active duty death or disability payment is high), an “other adjudicated action” report to the NPDB, state(s) of licensure, and applicable certifying/regulatory agencies is made even though the amount of the death or disability payment is not known; when the death or disability payment becomes known at a later date, a Revision-to-Action Report is made to include the payment information. The case can then be closed and archived by the DHA Headquarter’s HRM Program/Medical Legal Office.

(a) The DHA/Service Headquarter's HRM Program will notify the local Privileging Authority, with a copy to the DHA Market/Intermediate Headquarters. In addition, a summary identifying system and process opportunities for improvement for organizational learning purposes will be provided for each case.

(b) The DHA/Service Headquarter's HRM Program will provide to each reported SIP a copy of the Provider Overview from JCCQAS as well as a copy of any report directed by the Report Authority to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies (the Department of Health and Human Services also provides the SIP a copy of the NPDB report). All NPDB reports must be documented in the JCCQAS provider credential record in Section 1102 of Reference (t) protected document folder, and in the appropriate JCCQAS Risk Management module. For providers not registered in JCCQAS, a JCCQAS credentials record must be established. Annotation will be made in the provider's activity file or competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review or competency assessments. The DHA/Service Headquarters' HRM Program will respond to those individuals who dispute such reports.

(c) When the SIP reported to the NPDB is a healthcare trainee, a copy of the NPDB report is uploaded to the SIP's JCCQAS credentials record. A JCCQAS credentials record must be established if one does not already exist. A copy of the NPDB report is also provided to the Training Program Director to be maintained securely in the training record (e.g., GME programs). If the training record is not maintained securely, then annotation is made in the competency or training record (e.g., enlisted training programs) that a JCCQAS credentials record exists and is to be reviewed in future competency or training assessments. If the healthcare trainee completes the training program, Healthcare Risk Managers will ensure the JCCQAS credentials record is transferred to the healthcare trainee's gaining Privileging Authority (may be in collaboration with the Medical Staff Professional (MSP)/Medical Staff Manager (MSM) in the Credentialing and Privileging Program).

(15) When a PCE review is completed/closed, the Chief of the Medical Staff will coordinate with other senior clinical leadership as appropriate to ensure PS collaboration for clinical lessons learned regarding system and process improvement action(s) for clinically relevant staff, affected units, and the organization at large.

(16) When a PCE review is completed, SIPs involved in PCE review procedures associated with active duty death or disability payments or those DoD REs and PS adverse and no-harm events determined to present a risk of financial loss to the government in which SOC met, may be given redacted peer SOC reviews for performance improvement purposes only, and to be given only after the SIP has provided a written memorandum based on their review of medical records and relevant clinical documentation. This is not an opportunity to share MQAP information maintained in accordance with Section 1102 of Reference (t) with the SIP regarding any NPDB, state(s) of licensure, or other applicable certifying/regulatory agency reporting decisions.

(a) The Healthcare Risk Manager will redact the SOC peer reviewer's name and other identifying information before providing it to the SIP.

(b) If a SIP did not provide a written response, they will only receive a memorandum of the result of the review.

(10) For purposes of claims adjudication, information protected by Section 1102 of Reference (t) may be shared with legal staff adjudicating medical tort claims. In turn, there may be a need for the attorney to share information with a SIP that is protected by Section 1102 of Reference (t) solely to aid in evaluating the merits of the claim. This is not an opportunity to provide such information to a SIP to aid the SIP in providing a response for possible reporting actions.

6. ACTIVE DUTY DISABILITY/DEATH REVIEW USING PCE REVIEW PROCEDURES

a. Active Duty Disability Review Using PCE Review Procedures

(1) In every case in which the Medical Evaluation Board (MEB) makes a referral to the Physical Evaluation Board (PEB), the MEB convening authority or Chief of the Medical Staff will establish a process to identify those cases requiring PCE review procedures, i.e., those cases in which the medical condition(s) under review by the Disability Evaluation System (DES) may have been caused or contributed to as a result of healthcare provided by the MHS. Healthcare Risk Managers will establish a process to obtain the MEB screening documents and clinical summaries in appropriate cases to assist with this process to determine which active duty disability cases may be associated with healthcare. All PS events discovered in this process must be reported and evaluated in accordance with Volume 2 in this manual.

(2) The Chief of the Medical Staff, the Healthcare Risk Manager, and other clinical leadership as appropriate, will ensure both the identification of active duty disability cases requiring PCE review, and that the complete PCE review process is conducted for each identified case as outlined in Paragraph 5. of this enclosure. To aid identification of cases, the Healthcare Risk Manager, Physical Evaluation Board Liaison Officer (PEBLO) and convening authority for the MEB will work collaboratively to identify those active duty disability cases that meet criteria for PCE review and potential NPDB, state(s) of licensure, or other applicable certifying/regulatory agency reporting.

(3) The PEBLO will monitor the PEB disability decisions and provide the PEB disability award (payment) decisions to the Healthcare Risk Manager. Initiation of the PCE review process is not dependent on the disability award being available, rather it shall begin as the Chief of the Medical Staff, the Healthcare Risk Manager, and other clinical leadership as appropriate, identify the cases appropriate for review.

(4) The Healthcare Risk Manager will forward the full and complete active duty disability PCE review Medical Quality Assurance Record (MQAR) (paper or electronic case file including SOC reviews, relevant medical records, other clinical evidence, provider(s) statements, etc.), and release the JCCQAS disability event, to the DHA/Service Headquarters' HRM Program, through the respective DHA Market/Intermediate Headquarters. Forward of the PCE

review MQAR and release in JCCQAS will occur within 30 calendar days of notification of the disability payment for every disability case identified for review and potential reporting.

(5) The DHA/Service Headquarters' HRM Program will ensure every active duty disability PCE review has an objective peer SOC review for each SIP. If SOC not met, the peer SOC review will include a determination that the failure to meet SOC either caused or contributed to the condition for which the disability award was granted, or that the evidence clearly establishes that there was no causal relationship.

(6) If the PCE peer SOC review finds that any SIP(s) met the SOC, then the DHA/Service Headquarters' HRM Program must forward the active duty disability full and complete PCE review MQAR to the civilian peer review agency external to DoD, as designated by the ASD(HA).

(a) The external reviewer's curriculum vitae, and other pertinent information from the external review (such as current supporting literature used in the external peer SOC report) must be provided with the external peer SOC report by the external peer review agency.

(b) The external peer review report is considered a MQAR in accordance with Section 1102 of Reference (t). The external peer SOC review will not be given to the healthcare provider under review.

(7) DHA/Service Headquarters' HRM Program shall ensure that reviewers at all levels, including the external review, are provided a full and complete PCE review MQAR. All reviewers should base their determinations on the same information contained in the record.

(a) A full and complete PCE review MQAR includes all relevant information (medical records, all clinical reports, images, and process/system findings), and information and comments submitted by the SIPs.

(b) When new information is obtained that is material and relevant to the determination, it must be added to the record.

(8) In instances in which the external SOC review has determined that a SIP met SOC, no further review is required and the matter may be closed with notification to the local Privileging Authority, who subsequently notifies the SIP in writing.

(9) In instances in which either the initial PCE peer review or the external agency peer review determined any SIP failed to meet the SOC, DHA/Service Headquarters' HRM Program will convene a healthcare professional appropriate panel as per Enclosure 2. The healthcare professional appropriate panel will review the entire PCE review MQAR (with both SOC reviews), make a written reporting recommendation regarding the SOC determination for each SIP with inclusion of an analysis with the presumption that the deviation in SOC caused or contributed to the member's disabling condition unless the evidence clearly established that there was no causal or contributing relationship.

(10) When the Report Authority decision is SOC not met, the deviation of SOC caused or contributed to the disability, and that a report is indicated, then the NPDB report will be made. For cases in which the disability award is not known, see procedures in Paragraph 5.b. in this enclosure; if the disability award becomes known at a later date, a Revision-to-Action Report is made to include the payment information.

(11) A report to the NPDB is required, unless, within 180 calendar days from disability payment notification to the DHA/Service Headquarters' HRM Program, the Report Authority has made a final SOC determination that the disability was not caused or contributed to by the failure of a healthcare provider to meet the SOC.

(12) If no final decision has been made by the Report Authority by the end of this 180 calendar day period, all SIPs in the case must be immediately reported to the NPDB. Such a report by the Report Authority is not discretionary. The ASD(HA) has waiver approval authority for any exceptions to this 180 calendar day limit. Route such requests to ASD(HA) for an exception through the DHA/Service Headquarters' HRM Program.

(13) If a final SOC determination is made after the 180 calendar day period and the finding is that the SIPs met SOC or that the deviation from SOC did not cause or contribute to the disability, the Report Authority must then submit a Revision-to-Action Report to the NPDB stating that a determination was made that the provider met the SOC. Similar corrections will be sent to state(s) of licensure and other applicable certifying/regulatory agencies.

(14) For each case involving a SIP who is a uniformed Service member and is being reported to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies, the Report Authority will notify the respective Service SG. Service Report Authorities notify the DHA Report Authority if the SIP also holds privileges/practices in an MTF.

(15) When a SIP is a healthcare trainee, the attending or supervising healthcare provider responsible for the delivered care that caused or contributed to the disability and is deemed to not have met the SOC must be reported (not the trainee). If, however, the Report Authority determines that the attending or supervising healthcare provider clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending or supervising healthcare provider, the trainee (not the attending or supervising healthcare provider) would be reported. A trainee is defined as any resident, intern, or other healthcare provider in a formal healthcare training status.

(16) For the purposes of NPDB reporting for active duty disability SOC not met, for each SIP the payment reported will be the total disability annuity payment for the disability condition for which SOC was not met (comparable to a claim payment). The dollar amount reported is calculated by multiplying the total monthly disability payment by 12 to obtain the total annual disability payment, then multiplying the total annual disability payment by the percent of the payment attributed to the condition(s) for which SOC not met, and finally multiplying that result by the annuity value calculated by the DoD Office of the Actuary. The annuity factors and life expectancies are published annually by the DoD Office of the Actuary and will be the reference for dollar amount determinations. In cases in which the expected

disability payments will be deferred because a member is retained on active duty, notwithstanding an unfit determination by a PEB, DHA/Service Headquarters' HRM Program will confer with the appropriate servicing legal counsel. (Example: a person with 50 percent total disability, has a 45 percent disability condition related to SOC not met and a 5 percent additional disability condition. The total annual disability payment would be multiplied by 0.90 (90 percent) because 90 percent of the total disability payment (45/50 x 100 percent) is attributed to the condition for which SOC not met. Then, this 90 percent of total annual disability payment number, would be multiplied by the annuity value and the resulting final product would be the reported payment.)

(17) Once the Report Authority has made a final decision and report has been submitted, the case can be closed.

(a) The DHA/Service Headquarters' HRM Program will provide written notification to the Privileging Authority of each SIP, with a copy to the DHA Market/Intermediate Headquarters.

1. Notification will include the final SOC determination and whether or not a report will be made to the NPDB, state(s) of licensure, and applicable certifying/regulatory agencies.

2. In addition, a summary identifying system and process opportunities for improvement for organizational learning purposes will be provided for each case.

(b) The DHA/Service Headquarters' HRM Program must complete the JCCQAS disability case record and ensure the DHA Headquarters' HRM Program/Medical Legal Office receives it (in JCCQAS this is "release to DoD" function). The DHA Headquarters' HRM Program/Medical Legal Office archives a complete copy of the active duty disability PCE review MQAR. Maintaining the case is necessary for future responses to requests for information regarding SIP reports to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies.

(c) The DHA/Service Headquarters' HRM Program will provide a copy of the Provider Overview from JCCQAS to each SIP.

(d) The DHA/Service Headquarters' HRM Program will provide a copy to the reported SIP of any report directed by the Report Authority to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies (the Department of Health and Human Services also provides the SIP a copy of the NPDB report). All NPDB reports must be documented in the JCCQAS provider credential record in Section 1102 of Reference (t) protected document folder, and in the appropriate JCCQAS Risk Management module. For providers not registered in JCCQAS, a JCCQAS credentials record must be established. Annotation will be made in the provider's activity file or competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review or competency assessments. The DHA/Service Headquarters' HRM Program will respond to those individuals who dispute such reports.

(e) When the SIP reported to the NPDB is a healthcare trainee, a copy of the NPDB report is uploaded to the SIP's JCCQAS credentials record. A JCCQAS credentials record must be established if one does not already exist. A copy of the NPDB report is also provided to the Training Program Director to be maintained securely in the training record (e.g., GME programs). If the training record is not maintained securely, then annotation is made in the competency or training record (e.g., enlisted training programs) that a JCCQAS credentials record exists and is to be reviewed in future competency or training assessments. If the healthcare trainee completes the training program, Healthcare Risk Managers will ensure the JCCQAS credentials record is transferred to the healthcare trainee's gaining Privileging Authority (may be in collaboration with the Medical Staff Professional (MSP)/Medical Staff Manager (MSM) in the Credentialing and Privileging Program).

(f) DHA/Service Headquarters' HRM Program will ensure each healthcare provider identified as a SIP is notified in writing when the Report Authority decision for that provider is for not being significantly involved and removed from the case. Documentation is appropriately maintained in the provider's JCCQAS credentials record (and securely maintained training records as appropriate, e.g., GME programs). This documentation is not adverse.

b. Active Duty Death Review Using PCE Review Procedures

(1) The DHA/Service Headquarters' HRM Program and other designees will receive and review the Active Duty Casualty Notification Report and request a review from Privileging Authorities (through the DHA Market/Intermediate Headquarters) associated with an active duty death.

(2) The Chief of the Medical Staff will establish a process to identify those cases requiring PCE review procedures, i.e., those deaths which may have been caused or contributed to as a result of healthcare provided by the MHS. The Healthcare Risk Manager, Chief of the Medical Staff, or appropriate CQM clinical leadership (to include PS) will review each active duty death to determine if an adverse event has occurred. All active duty deaths associated with healthcare and resulting in death benefit payments must be reviewed to identify those requiring PCE review procedures, SOC determination on each SIP, and for the potential for reporting. All active duty deaths that meet the definition of a DoD RE must be reported as per Volume 2 of this manual, and reviewed using PCE procedures outlined in Paragraph 5. of this enclosure.

(3) The Healthcare Risk Manager will change the classification in JCCQAS from PCE to active duty death, if appropriate, and forward the full and complete active duty death PCE review MQAR (paper or electronic case file including SOC reviews, relevant medical records, other clinical evidence, provider(s) statements, etc.), and release the JCCQAS death event to the DHA/Service Headquarters' HRM Program, through the DHA Market/Intermediate HQ, within 180 calendar days of identification of the active duty death.

(4) The DHA/Service Headquarters' HRM Program will ensure every such active duty death PCE review has an objective peer SOC review for each SIP and a determination as to whether the failure to meet the SOC either contributed to or caused the death for which a death payment was granted.

(5) If the PCE review peer SOC review finds that any SIP(s) met the SOC, then the DHA/Service Headquarters' HRM Program must forward the active duty death full and complete PCE review MQAR to the civilian peer review agency external to DoD, as designated by the ASD(HA).

(a) The external reviewer's curriculum vitae, and other pertinent information from the external review (such as current supporting literature used in the external peer SOC report) must be provided with the external peer SOC report by the external peer review agency.

(b) The external peer review report is considered a MQAR in accordance with Section 1102 of Reference (t). The external peer SOC review will not be given to the healthcare provider under review.

(6) DHA/Service Headquarters' HRM Program shall ensure that reviewers at all levels, including the external review, are provided a full and complete PCE review Medical Quality Assurance Record (MQAR). All reviewers should base their determinations on the same information contained in the record.

(a) A full and complete PCE review MQAR includes all relevant information (medical records, all clinical reports, images, and process/system findings), and information and comments submitted by the SIPs.

(b) When new information is obtained that is material and relevant to the determination, it must be added to the record.

(7) In instances in which the external review panel has determined that the SIP met SOC, no further review is required and the matter may be closed with notification to the Privileging Authority, who subsequently notifies the SIP in writing.

(8) In instances in which the initial active duty death PCE peer review or the external agency peer review determined any SIP failed to meet the SOC, the DHA/Service Headquarters' HRM Program will convene a healthcare professional appropriate panel as per Enclosure 2. The healthcare professional appropriate panel will review the entire PCE review MQAR (with both SOC reviews), make a written reporting recommendation regarding the SOC determination for each SIP with inclusion of an analysis with the presumption that the deviation in SOC caused or contributed to the member's death unless the evidence clearly established that there was no causal or contributing relationship.

(9) A report to the NPDB is required, unless, within 180 calendar days from the date of death (or, if later, the date the event was first identified as adverse and requiring PCE review procedures), the Report Authority has made a final SOC determination that the death was not caused or contributed to by the failure of a healthcare provider to meet the SOC.

(10) If no final decision has been made by the Report Authority by the end of this 180 calendar day period, all SIPs in the case must be immediately reported to the NPDB. Such a

report by the Report Authority is not discretionary. The ASD(HA) has waiver approval authority for any exceptions to this 180 calendar day limit. Route such requests for an exception through the DHA/Service Headquarters' HRM Program.

(11) If a final SOC determination is made after the 180 calendar day period and the finding is that the SIPs met SOC, or that the deviation from SOC did not cause or contribute to the death, the Report Authority must then submit a Revision-to-Action Report to the NPDB stating a determination was made that the healthcare provider met the SOC. Similar corrections will be sent to state(s) of licensure and other applicable certifying/regulatory agencies.

(12) For each case involving a SIP who is a uniformed Service healthcare provider and is being reported to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies, the Report Authority will notify the respective Service SG. Service Report Authorities will notify the DHA Report Authority if the SIP also holds privileges/practices in an MTF.

(13) When a SIP is a healthcare trainee, the attending or supervising healthcare provider responsible for the delivered care that cause or contributed to the death and is deemed to not have met the SOC must be reported (not the trainee). If, however, the Report Authority determines that the attending or supervising healthcare provider clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending or supervising healthcare provider, the trainee (not the attending or supervising healthcare provider) must be reported to the NPDB. A trainee is defined as any resident, intern, or other healthcare provider in a formal healthcare training status.

(14) For the purposes of NPDB reporting for active duty death SOC not met, the dollar amount reported will be the active duty death payment.

(15) Once the Report Authority has made a final decision and report has been submitted, the case can be closed.

(a) The DHA/Service Headquarters' HRM Program will provide written notification to the Privileging Authority of each SIP, with a copy to the DHA Market/Intermediate Headquarters.

1. Notification will include the final SOC determination and whether or not a report will be made to the NPDB, state(s) of licensure, and applicable certifying/regulatory agencies.

2. In addition, a summary identifying system and process opportunities for improvement for organizational learning purposes will be provided for each case.

(b) The DHA/Service Headquarters' HRM Program must complete the JCCQAS death case record and ensure the DHA Headquarters' HRM Program/Medical Legal Office receives it (in JCCQAS this is "release to DoD" function). The DHA Headquarters' HRM Program/Medical Legal Office archives a full and complete copy of the active duty death PCE review MQAR. Maintaining the case is necessary for future responses to requests for

information regarding SIP reports to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies.

(c) The DHA/Service Headquarters' HRM Program will provide a copy of the Provider Overview from JCCQAS to each SIP.

(d) The DHA/Service Headquarters' HRM Program will provide a copy to the reported SIP of any report directed by the Report Authority to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies (the Department of Health and Human Service also provides the SIP a copy of the NPDB report). All NPDB reports must be documented in the JCCQAS provider credential record in a Section 1102 of Reference (t) protected document folder, and in the appropriate JCCQAS Risk Management module. For providers not registered in JCCQAS, a JCCQAS record must be established. Annotation will be made in the provider's activity file or competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review or competency assessments. The DHA/Service Headquarters' HRM Program will respond to those individuals who dispute NPDB reports.

(e) When the SIP reported to the NPDB is a healthcare trainee, a copy of the NPDB report is uploaded to the SIP's JCCQAS credentials record in a Section 1102 of Reference (t) protected document folder. A JCCQAS credentials record must be established if one does not already exist. A copy of the NPDB report is also provided to the Training Program Director to be maintained securely in the training record (e.g., GME programs). If the training record is not maintained securely, then annotation is made in the competency or training record (e.g., enlisted training programs) that a JCCQAS credentials record exists and is to be reviewed in future competency or training assessments. If the healthcare trainee completes the training program, Healthcare Risk Managers will ensure the JCCQAS credentials record is transferred to the healthcare trainee's gaining Privileging Authority (may be in collaboration with the MSP/MSM in the Credentialing and Privileging Program).

(f) The DHA/Service Headquarters' HRM Program will ensure each healthcare provider identified as a SIP is notified in writing when the Report Authority decision is for not being significantly involved and removed from the case. Documentation is appropriately maintained in the provider's JCCQAS credentials record (and securely maintained training records as appropriate, e.g., GME programs). This documentation is not adverse.

7. MEDICAL TORT CLAIMS

a. When Healthcare Risk Managers are notified that a medical tort claim has been filed, regardless of whether or not payment has been made, a review will be done for an associated PCE MQAR.

(1) If a PCE MQAR exists, the Healthcare Risk Manager will change the classification in JCCQAS to a medical tort claim, and forward the full and complete PCE MQAR (clinical evidence, medical records, list of SIPs and their SOC reviews, memos for record, and other

documents) to the DHA/Service Headquarters' HRM Program, through the respective DHA Market/Intermediate Headquarters.

(2) If no PCE MQAR exists, the complete PCE review process will be initiated as outlined in Paragraph 5. of this enclosure. These claims are maintained and tracked in the JCCQAS Risk Management Module.

b. The DHA Headquarters' HRM Program/Medical Legal Office will notify the respective DHA Market/Intermediate Headquarters and Healthcare Risk Manager of a paid medical tort claim to include the payment disposition for each claim. As provided in the NPDB regulations (Subpart 60.7 of Reference (p)), "A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred." NPDB reports of malpractice payments (and the comparable reports concerning active duty disability or death) are not clinical adverse actions regarding SIPs, and due process procedures do not apply to decisions to report such payments. (If clinical adverse action warranted, please refer to Enclosure 3.)

(1) This financial information must be recorded in the JCCQAS medical tort claim file.

(2) If not already forwarded, the Healthcare Risk Manager must forward the full and complete medical tort claim MQAR to the DHA/Service Headquarters' HRM Program, via the respective DHA Market/Intermediate Headquarters, within 15 calendar days of payment notification. The JCCQAS medical tort claim file must also be released to the DHA Headquarters HRM Program/Medical Legal Office.

(3) All SIPs will be notified of their involvement in the medical tort claim and afforded the opportunity to submit a statement and supporting documents to address their care prior to the Report Authority's final SOC determination and decision for NPDB reporting. Reasonable effort will be made to give each SIP written notice. For those cases in which the healthcare provider is unable to be located, Healthcare Risk Managers will document attempts to notify the SIP in the case MQAR.

c. The DHA/Service Headquarters' HRM Program will ensure every paid medical tort claim has an objective peer SOC review for each SIP.

d. If the peer SOC review finds that any SIP(s) met the SOC, then the DHA/Service Headquarters' HRM Program must forward the full and complete medical tort claim MQAR to the civilian peer review agency external to DoD, as designated by the ASD(HA).

(1) The external reviewer's curriculum vitae, and other pertinent information from the external review (such as current supporting literature used in the external peer SOC report), must be provided in the external peer SOC report by the external peer review agency.

(2) The external peer review report is considered an MQAR in accordance with Section 1102 of Reference (t). The external peer SOC review will not be given to the healthcare provider under review.

e. The DHA/Service Headquarters' HRM Program will ensure that reviewers at all levels, including the external review, are provided a full and complete medical tort claim MQAR. All reviewers should base their determinations on the same information contained in the record.

(1) A full and complete medical tort claim MQAR includes all relevant information (medical records, all clinical reports, images, and process/system findings), and information and comments submitted by the SIPs.

(2) When new information is obtained that is material and relevant to the determination, it must be added to the record.

f. In instances in which the external review agency determined that the SIP met SOC, no further review is required and the matter may be closed with notification to the respective Privileging Authority, who subsequently notifies the SIP in writing.

g. In instances in which the initial PCE or paid medical tort claim peer review or the external agency peer review determined any SIP failed to meet the SOC, the DHA/Service Headquarters' HRM Program will convene a healthcare professional appropriate panel as per Enclosure 2. The healthcare professional appropriate panel will review the full and complete medical tort claim MQAR (with both SOC reviews), and make a written reporting recommendation regarding the SOC determination for each SIP. (The panel does not provide an analysis as to whether the deviation in SOC caused or contributed to the claim payment.)

h. The legal offices conducting adjudication of medical tort claims will provide information concerning the amount of the settlement or judgment, and the basis (rationale) as available, as well as identify (to the extent possible) those healthcare personnel whose conduct was influential on the decision to settle or render judgment. The information provided may be considered by the panel and the Report Authority; however, it shall not be further released without prior permission from the authoring legal office to ensure that any applicable privilege is not waived.

i. Reports to the NPDB are required when a claim payment was made and the Report Authority determines that a SIP did not meet the SOC. Reports concerning deceased practitioners must be submitted to the NPDB because a fraudulent practitioner could assume the identity of a deceased practitioner. When submitting a report on a deceased practitioner, indicate that the practitioner is deceased in the appropriate data field.

j. A report to the NPDB is required, unless, within 180 calendar days from the paid medical tort claim notification to DHA/Service Headquarters' HRM Program Lead (or designee), the Report Authority has made a final SOC determination that each SIP met SOC.

k. If no final decision has been made by the Report Authority by the end of this 180-day period, all SIPs in the case must be immediately reported to the NPDB. Such a report by the Report Authority is not discretionary. The ASD(HA) has waiver approval authority for any exceptions to this 180-day limit. Route such requests for an exception through the DHA/Service Headquarters' HRM Program.

l. If a final SOC determination is made after the 180-day period and the finding is that the SIPs met SOC, the Report Authority must then submit a Revision-to-Action Report to the NPDB stating a determination was made that the healthcare provider met the SOC. Similar corrections will be sent to state(s) of licensure and other applicable certifying/regulatory agencies.

m. For each case involving a SIP who is a uniformed Service healthcare provider and is being reported to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies, the Report Authority will notify the respective Service SG. Service Report Authorities will notify the DHA Report Authority if the SIP also holds privileges/practices in an MTF.

n. When a SIP is a healthcare trainee, the attending or supervising healthcare provider responsible for the delivered care deemed to not have met the SOC (not the trainee) must be reported to the NPDB. If, however, the Report Authority determines that the attending or supervising healthcare provider clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending or supervising healthcare provider, the trainee (not the attending or supervising healthcare provider) must be reported to the NPDB. A trainee is defined as any resident, intern, or other healthcare provider in a formal healthcare training status.

o. For the purposes of NPDB reporting for paid medical tort claims, the dollar amount reported will be the total claim amount.

p. Once the Report Authority has made a final decision and the report has been submitted, the case can be closed.

(1) The DHA/Service Headquarters' HRM Program will provide written notification to the Privileging Authority of each SIP, with a copy to the DHA Market/Intermediate Headquarters.

(a) Notification will include the final SOC determination and whether or not a report will be made to the NPDB, state(s) of licensure, and other applicable certifying/regulatory agencies.

(b) In addition, a summary identifying system and process opportunities for improvement for organizational learning purposes will be provided for each case.

(2) The DHA/Service Headquarters' HRM Program must complete the JCCQAS medical tort claim record and ensure the DHA Headquarters' HRM Program/Medical Legal Office receives it (in JCCQAS this is "release to DoD" function). The DHA Headquarters' HRM Program/Medical Legal Office archives a full and complete copy of the paid medical tort claim MQAR. Maintaining the case is necessary for future responses to requests for information regarding SIP reports to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies.

(3) The DHA/Service Headquarters' HRM Program will provide a copy of the Provider Overview from JCCQAS to each SIP.

(4) The DHA/Service Headquarters' HRM Program will provide a copy to the reported SIP of any report directed by the Report Authority to the NPDB, state(s) of licensure, or other applicable certifying/regulatory agencies (the Department of Health and Human Service also provides the SIP a copy of the NPDB report). All NPDB reports must be documented in the appropriate JCCQAS provider credential record in a Section 1102 of Reference (t) protected medical tort claim case file document folder. For providers not registered in JCCQAS, a JCCQAS record must be established. Annotation will be made in the provider's activity file or competency folder that a JCCQAS credentials record exists and is to be reviewed in future peer review or competency assessments. The DHA/Service Headquarters' HRM Program will respond to those individuals who dispute NPDB reports.

(5) When the SIP reported to the NPDB is a healthcare trainee, a copy of the NPDB report is uploaded to the SIP's JCCQAS credentials record in a Section 1102 of Reference (t) protected document folder. A JCCQAS credentials record must be established if one does not already exist. A copy of the NPDB report is also provided to the Training Program Director to be maintained securely in the training record (e.g., GME programs). If the training record is not maintained securely, then annotation is made in the competency/training record (e.g., enlisted training programs) that a JCCQAS credentials record exists and is to be reviewed in future competency or training assessments. If the healthcare trainee completes the training program, Healthcare Risk Managers will ensure the JCCQAS credentials record is transferred to the healthcare trainee's gaining Privileging Authority (may be in collaboration with the MSP/MSM in the Credentialing and Privileging Program).

(6) The DHA/Service Headquarters' HRM Program will ensure each healthcare provider identified as a SIP is notified in writing when the Report Authority decision is for not being significantly involved and removed from the case. Documentation is appropriately maintained in the provider's JCCQAS credentials record (and securely maintained training record as appropriate, e.g., GME programs). This documentation is not adverse.

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 dietitian 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.