DoD 6025.13-R

MILITARY HEALTH SYSTEM (MHS) CLINICAL QUALITY ASSURANCE (CQA) PROGRAM REGULATION

JUNE 11, 2004

ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

FOREWORD

11 JUN 2004

This Regulation is issued under the authority of Department of Defense Directive 6025.13, "Clinical Quality Assurance in the Military Health System," (reference (a)). It identifies the various components comprising the Department of Defense's efforts to ensure that beneficiaries receive quality care.

This Regulation applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the Department of Defense Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

The Regulation is effective immediately and is mandatory for use by all the Department of Defense Components.

Send recommended changes to this regulation to the following address:

Office of the Assistant Secretary of Defense (Health Affairs)
Director of Clinical and Program Policy
Skyline Five, Suite 810, 5111 Leesburg Pike
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William Winkenwerder, Jr., M.D.
Assistant Secretary of Defense
(Health Affairs)

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REFERENCES

(a) DoD Directive 6025.13, "Quality Assurance in the Military Health System," May 4, 2004
(b) DoD Directive 5154.24, "Armed Forces Institute of Pathology," October 3, 2001
(c) Sections 1346(b) and 2671-80(h) of title 28, United States Code
(d) Sections 801-940 (chapter 47), 1094, 1094a, 1096, 1102, 2731-2739 (chapter 163) of title 10, United States Code
(e) Sections 552 and 552a of title 5, United States Code
(f) Sections 11131 through 11152 of title 42, United States Code
(g) Joint Commission on Accreditation of Healthcare Organizations, "Accreditation Manual for Hospitals," Volumes 1 and II, current editions
(h) Joint Commission on Accreditation of Healthcare Organizations, "Ambulatory Healthcare Standards Manual," Volumes I and II, current editions
(i) Joint Commission on Accreditation of Healthcare Organizations, "Accreditation Manual for Health Care Networks," current edition
(j) Joint Commission on Accreditation of Healthcare Organizations, "Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services," current edition
(k) Commission on Accreditation of Rehabilitation Facilities (CARF), "Standards Manual for Organizations Serving People With Disabilities," current edition
(l) National Committee for Quality Assurance, "NCQA Standards for Accreditation and Review Guidelines," current edition
(m) DoD Instruction 6025.5, "Personal" Services Contracts for Health Care Providers," January 6, 1995
(n) DoD Instruction 1402.5, "Criminal History Background Checks On Individuals in Child Care Services," January 19, 1993
(o) DoD 5500.7-R, "Joint Ethics Regulation (JER), "August 1993
(p) Section 5536 of title 5, United States Code
(q) Sections 742 and 754 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001, Pub. L. 106-398
(r) DoD 8910.1-M, "DoD Procedures for Management of Information Requirements," June 30, 1998
(s) Title 45 of the Code of Federal Regulations, Part 60, "National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners" (Department of Health and Human Services (DHHS) regulations)
(t) DoD Instruction 1332.38, "Physical Disability Evaluation" November 14, 1996

(u) Title 45 of the Code of Federal Regulations, Part 61, "Health Care Fraud and Abuse Data Collection Program: Reporting of Final Adverse Actions"
(v) Section 7501-7543 (Chapter 75) of title 5, United States Code
(w) Part 209 of the Defense Federal Acquisition Regulation Supplement, 48 CFR

DL1. DEFINITIONS

DL1.1.1. Abeyance. The temporary assignment of a provider from clinical duties to non-clinical duties while an internal or external peer review or quality assurance investigation is conducted. It cannot exceed 30 days and is not considered an adverse privileging action.

DL1.1.2. Adverse Events. Occurrences or conditions associated with care or services when they cause unexpected harm to a patient during such care or services. These may be because of acts of commission or omission.

DL1.1.3. Adverse Privileging Action. Denying, suspending, restricting, reducing, or revocation of clinical privileges based upon misconduct, professional impairment, or lack of professional competence. The termination of professional staff appointment based upon conduct incompatible with continued professional staff membership may also result in an adverse privileging action.

DL1.1.4. Aggregate Statistical Information. An assembled collection of numerical facts and other information or data derived from various DoD health program activities. Names, social security numbers, or other specific information that would identify or reasonably lead to identification of individual healthcare providers, patients, or organizational entities below the Military Department level may not be included in aggregate statistical data, except that the Assistant Secretary of Defense (Health Affairs) (ASD(HA)) may authorize the release of aggregate statistical data at the Military Treatment Facility (MTF) (medical or dental) level as part of participation in national QA program activities

DL1.1.5. Approved Postgraduate Training. Postgraduate training program accredited by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association (AOA), or other similar entities regulating healthcare professional training programs

DL1.1.6. Clinical Privileging. The granting of permission and responsibility of a healthcare provider to provide specified or delineated healthcare within the scope of his or her license, certification, or registration. Clinical privileges define the scope and limits of practice for individual 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.

DL1.1.7. Credentials. The documents that constitute evidence of appropriate education, training, licensure, experience, and expertise of a healthcare practitioner.

DL1.1.8. Credentials Review. The credentials inspection and verification process conducted for healthcare practitioners 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.

DL1.1.9. Credentials, Verified. Documents confirming authenticity has been obtained from the primary (issuing) source by the Military Service or a representative of the Military Service. Confirmation, independent of the practitioner, is a key criterion. With respect to credentials that will never change, once verified, confirmation of authenticity with the primary source need not be repeated during subsequent credentials review. However, State licenses/certifications/registrations, NPDB/HIPDB/DPDB queries and current competency shall be verified at every granting and renewal of privileges.

DL1.1.10. Current Competence. The state of having adequate ability to perform the functions of a practitioner in a particular discipline as measured by meeting the following:

DL1.1.10.1. Authorized to practice a specified scope of care under a written plan of supervision at any time within the past 2 years; or, completed formal graduate professional education in a specified clinical specialty at any time within the past 2 years; or, privileged to practice a specified scope of care at any time within the past 2 years.

DL1.1.10.2. Actively pursued the practice of his or her discipline within the past 2 years by having encountered a sufficient number of clinical cases to represent a broad spectrum of the privileges requested; and,

DL1.1.10.3. Satisfactorily practiced the discipline as determined by the results of professional staff monitoring and evaluation of the quality and appropriateness of patient care.

DL1.1.11. Defense Practitioner Data Bank (DPDB). The automated information system maintained as part of the Risk Management and Adverse Actions Modules of the Centralized Credentials Quality Assurance System (CCQAS) and electronically monitored by the Department of Legal Medicine of the Armed Forces Institute of Pathology. It consists of data on the professional competence and conduct of licensed healthcare providers and malpractice cases involving the Department of Defense, including all filed and paid claims. It also includes cases in which disability system or

other payments are made because of personal injury or death of a member of a Uniformed Service caused by the failure of a practitioner(s) to meet the professional standard of care.

DL1.1.12. Denial of Privileges. Refusal to grant provider-requested privileges. This could occur at initial application for privileges or when renewal of privileges is requested. Denial of privileges because of professional incompetence or misconduct is reportable to the National Practitioner Data Bank (NPDB).

DL1.1.13. Department of Legal Medicine. The Department of Legal Medicine of the Armed Forces Institute of Pathology (AFIP) (reference (b)).

DL1.1.14. Feres-bared Cases. Cases of actual or alleged medical malpractice torts for which Federal court jurisdiction is not available under the Federal Tort Claims Act (reference (c)) based on the Supreme Court decision in Feres v. United States, 340 U.S. 135 (1950), (and/or similar cases) that the military disability system and other compensation programs, rather than tort litigation, provided the exclusive remedies for military members killed or injured incident to Military Service. Although payments under such military compensation programs that are a result of medical care are not malpractice payments under NPDB rules, this Regulation requires that they be reviewed for reporting to the DPDB. (NOTE: Although the "Feres doctrine" applies to all tort cases, not just medical malpractice cases, the term "Feres barred cases" in this Regulation refers only to actual or alleged torts involving medical malpractice.)

DL1.1.15. Healthcare Entity. A hospital, ambulatory health clinic, or dental clinic with an independent healthcare practitioner staff that provides healthcare to medical or dental patients and carries out professional staff review. The term also includes applicable professional staff components of each Military Department, as designated by the respective Surgeon General, that also perform peer reviews as part of the quality assurance and/or quality improvement program.

DL1.1.16. Healthcare Practitioner. Synonymous with "healthcare professional." Any physician, dentist, or healthcare practitioner of one of the professions whose members are required to possess a professional license or other similar authorization. These include DoD healthcare personnel who are physicians, dentists, registered nurses, practical nurses, physical therapists, podiatrists, optometrists, clinical dieticians, social workers, clinical pharmacists, clinical psychologists, occupational therapists, audiologists, speech pathologists, physician assistants, or any other person providing direct patient care as may be designated by the ASD(HA).

DL1.1.17. Healthcare Provider. Military (Active or Reserve component) and civilian personnel (Civil Service and providers working under contractual or similar arrangement) granted privileges to diagnose, initiate, alter, or terminate healthcare treatment regimens within the scope of his or her license, certification, or registration. This category includes physicians, dentists, nurse practitioners, nurse anesthetists, nurse midwives, physical therapists, podiatrists, optometrists, clinical dietitians, social workers, clinical pharmacists, clinical psychologists, occupational therapists, audiologists, speech pathologists, physician assistants, or any other person providing direct patient care as may be designated by the ASD(HA). This term is equivalent to Licensed Independent Practitioner (LIP). (See DL1.1.24.)

DL1.1.18. Healthcare Quality Assurance (QA) Program. Any activity performed before, on, or after the enactment of 10 U.S.C. 1102 (reference (d)) by or for the Department of Defense to assess the quality of medical care. This includes activities conducted by individuals, MTF committees, contractors, military medical departments, or DoD Agencies responsible for QA, credentials review and clinical privileging, infection control, patient care assessment (including review of treatment procedures, therapeutics, blood use, medication use), review of healthcare records, health resources management review, and risk management (RM) review.

DL1.1.19. Healthcare Trainee. Any resident, intern, or other healthcare practitioner in a formal healthcare training status.

DL1.1.20. Host State. The State in which off-base duties are or shall be performed.

DL1.1.21. Individual QA Action. A provider sanction, privileging action, or other activity on an individual healthcare provider intended to address a quality of healthcare matter. Such an action is based on processes structured by the QA program.

DL1.1.22. Intentional Unsafe Act. Any alleged or suspected act or omission of a provider, staff member, contractor, trainee, or volunteer pertaining to a patient involving 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.

DL1.1.23. License. A grant of permission by an official agency of a State, the District of Columbia, a Commonwealth, territory, or possession of the United States to provide healthcare within the scope of practice for a discipline. The stages of license are as follows:

DL1.1.23.1. Current. Active, not revoked, suspended, or lapsed in registration.

DL1.1.23.2. Valid. The issuing authority accepts, investigates, and acts upon quality assurance information, such as practitioner professional performance, conduct, and ethics of practice, regardless of the practitioner's military status or residency.

DL1.1.23.3. Unrestricted. Not subject to limitations on the scope of practice ordinarily granted all other applicants for similar specialty in the granting jurisdiction. An unrestricted license must allow the provider unabridged permission to practice in any civilian community in the jurisdiction of licensure without having to take any additional action on her/his license.

DL1.1.24. Licensed Independent Practitioner. Any individual permitted by law and by the organization to provide care, treatment and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. This term is equivalent to Healthcare Provider. (See DL1.1.17.)

DL1.1.25. Malpractice Payment. A monetary award under the authority of the Federal Tort Claims Act (reference (c)), the Military Claims Act (10 U.S.C. Chapter 163) (reference (d)), or the Foreign Claims Act (reference (d)) relating to the provision of healthcare services under the organizational responsibility of the Department of Defense.

DL1.1.26. Medical Readiness Training Certification. A process used to verify the preparation of healthcare providers for operational requirements. The commander's review and verification of individual, collective, and unit medical readiness training, education, and experiences is a critical element of the process.

DL1.1.27. Military Health System (MHS). The combination of military and civilian medical systems used to provide healthcare to DoD medical beneficiaries.

DL1.1.28. MHS Official Responsible. The Surgeon General, the TRICARE Lead Agent, the MTF Commander, or other official authorized by the ASD(HA) making the off-base duty assignment of the healthcare professional involved.

DL1.1.29. National Practitioner Data Bank (NPDB). The agency designed by the DHHS receiving and providing data on substandard clinical performance and conduct of physicians, dentists, and other licensed healthcare practitioners, including data on malpractice claims payment made on behalf of those practitioners.

DL1.1.30. Near Miss. Any process variation or error or other circumstance that could have resulted in harm to a patient but through chance or timely intervention did not reach the patient or did not harm the patient. Such events or circumstances have also been referred to as "close calls."

DL1.1.31. Network. The combination of the MTF and other civilian preferred providers (e.g., individuals, groups, hospitals, and clinics) who have agreed to accept the DoD and Uniformed Services beneficiaries enrolled in the regional managed care program authorized by the ASD(HA). Civilian networks' providers deliver healthcare at negotiated rates, adhere to provider agreements, and follow other requirements of the managed care program. Civilian network healthcare providers are independent contractors of the Government (or other independent entities having business arrangements with the Government).

DL1.1.32. Off-base Duties. Officially assigned professional duties performed at an authorized location outside a MTF and any military installation. Off-base duties include, but are not limited to, training or skill maintenance duties in non-DoD healthcare facilities, professional activities performed under the authority of the military-civilian health services partnership program under 10 U.S.C. 1096 (reference (d)), and telemedicine services involving a patient outside an MTF and any military installation. Off-base duties do not include participation in approved postgraduate training of physicians, or assigned professional duties performed in a Department of Veterans Affairs (DVA) or other Federal Government healthcare facility.

DL1.1.33. Other Authorizing Document

DL1.1.33.1. A mechanism, such as registration and certification, by which a State; the District of Columbia; or a Commonwealth, territory, or possession of the United States grants authority to provide healthcare in a specified discipline; or,

DL1.1.33.2. 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 a practitioner is professionally qualified to provide healthcare in a specified discipline; or

DL1.1.33.3. In the case where healthcare is provided in a foreign country by any person who is not a national of the United States, a grant of permission by an official agency of that foreign country for that person to provide healthcare in a specified discipline.

DL1.1.34. Privileges (Clinical). Permission to provide medical and other patient care services in the granting institution, within defined limits, based on the individual's education, professional license, experience, competence, ability, health, and judgment.

DL1.1.35. Potentially Compensable Event. An adverse event that occurs in the delivery of healthcare and services with resulting beneficiary injury. It includes any adverse event or outcome, with or without legal fault, in which the patient experiences any unintended or unexpected negative result.

DL1.1.36. Professional Impairment. A healthcare practitioner characteristic that may adversely affect the ability to render quality care. Professional impairment may include deficits in medical knowledge, expertise or judgment; unprofessional, unethical, or criminal conduct; and any medical condition that reduces or prevents the practitioner's ability to safely execute his or her responsibilities in providing healthcare.

DL1.1.37. Professional Review. A process that monitors, reviews, and evaluates the standard of care or quality of care given by a healthcare provider within a healthcare entity.

DL1.1.38. Professional Staff Appointment. Formal, written authorization to perform patient care accompanied by a delineation of authorized clinical privileges and a pledge to abide by the rules and regulations of the medical or dental staff.

DL1.1.38.1. Active Staff Appointment. Staff appointments granted to providers, according to the needs of the Government, who successfully complete the initial staff appointment period.

DL1.1.38.2. Initial Staff Appointment. The initial professional staff appointment granted to a provider when first assigned or employed by a DoD facility. The initial appointment for a period, not to exceed 12 months, is to allow the provider to demonstrate current clinical competence and compliance with the facility's policies, procedures, and bylaws.

DL1.1.39. QA Record. The proceedings, records, minutes, and reports that derive from healthcare QA program activities and are produced or compiled by the Department of Defense as part of a healthcare QA program. The term "medical QA Record" includes medical, mental health, and dental QA records, programs, activities, and information.

DL1.1.40. Reduction in Privileges. A portion of a provider's clinical privileges permanently removed. It may be based on misconduct, physical impairment, or other factors limiting a provider's capability. Reduction in privileges is reportable to the NPDB.

DL1.1.41. Reinstatement of Privileges. The revision of an adverse privileging action that restores all or a portion of the provider's clinical privileges. Reinstatement of privileges is reportable to the NPDB.

DL1.1.42. Restriction of Privileges. A temporary or permanent limit placed on all or a portion of the provider's clinical privileges so the provider is required to obtain concurrence before providing all or some specified healthcare procedures within the scope of his or her certification, license, or registration. The restriction may require some type of supervision. Restriction of privileges is reportable to the NPDB.

DL1.1.43. Revocation of Privileges. All clinical privileges of a healthcare provider permanently removed. In most cases, such action may be followed by action to terminate the provider's DoD service. Revocation of privileges is reportable to the NPDB.

DL1.1.44. Root Cause Analysis (RCA). A process for identifying the basic or contributing causal factors associated with actual adverse events and near misses. An RCA includes the following characteristics:

DL1.1.44.1. The review is interdisciplinary in nature with involvement of those closest to the process.

DL1.1.44.2. The analysis focuses primarily on systems and processes rather than individual performance.

DL1.1.44.3. The analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are identified.

DL1.1.44.4. The analysis identifies changes that may be made in systems and processes through either redesign or development of new processes or systems that may improve performance and may reduce the risk of actual adverse events or recurrence of near misses.

DL1.1.45. Sentinel Events. Unexpected occurrences involving death or serious physical or psychological injury or risk thereof.

DL1.1.46. Serious Adverse Events. Unexpected occurrences involving death or serious physical or psychological injury.

DL1.1.47. Significantly Involved Practitioners. Practitioners who (based on medical record entries) actively delivered care in primary or consultative roles during the episode(s) of care that gave rise to the allegation, regardless of the standard of care determination.

DL1.1.48. Standard of Care. Healthcare diagnostic or treatment judgments and actions of a provider generally accepted in the healthcare discipline or specialty involved as reasonable and appropriate.

DL1.1.49. State. Any of the 50 States, the District of Columbia, or a commonwealth, territory, or possession of the United States.

DL1.1.50. State Licensing Board. The entity or entities authorized under the applicable State law to issue licenses or other authorizing document such as certificate or registration to healthcare professionals.

DL1.1.51. Summary Suspension (or Summary of Action of Suspension of Privileges). The temporary removal of all or part of a provider's privileges, taken prior to the completion of due process procedures, based on peer assessment or command that the action is needed to protect patients or the integrity of the command resulting from cases involving the temporary removal from cases, professional or behavioral impairment or negligence. A summary suspension could continue until due process procedures are completed. Summary suspension of privileges within the Department of Defense is not reportable to the NPDB, unless the final action is reportable.

DL1.1.52. Supervision. The process of reviewing, observing, and accepting responsibility for assigned personnel. The types of supervision are as follows:

DL1.1.52.1. Indirect. The supervisor performs retrospective record review of selected records. Criteria used for review relate to quality of care, quality of documentation, and the authorized scope of practice.

DL1.1.52.2. Direct. The supervisor is involved in the decision-making process. This may be further subdivided as follows:

DL1.1.52.2.1. Verbal. The supervisor is contacted by phone or informal consultation before implementing or changing a regimen of care.

DL1.1.52.2.2. Physically Present. The supervisor is present physically through all or a portion of care.

DL1.1.53. Suspension of Privileges. The temporary removal of all or part of a provider's privileges resulting from incompetence, negligence, or unprofessional conduct after due process procedures are completed. Suspension of privileges is reportable to the NPDB. This term includes a summary suspension.

DL1.1.54. Temporary Assignment. For clinical practice this term refers to all clinical assignments other than permanent change of station.

DL1.1.55. Verification. Confirmation of authenticity obtained from the primary source by the MTF, a previous MTF, or a representative of the Military Service.

C1. CHAPTER 1

QUALITY ASSURANCE PROGRAM OVERVIEW

C1.1. PURPOSE

This Regulation implements the policy guidance concerning quality assurance in the MHS established in reference (a).

C1.2. APPLICABILITY

This Regulation applies to:

C1.2.1. The Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as the "DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

C1.2.1.1. DoD healthcare practitioners who are involved in the delivery of healthcare services to eligible beneficiaries.

C1.2.1.2. DoD MTFs.

C1.2.1.3. Groups of civilian-preferred providers under managed care support contracts to the Department of Defense, in health services regions throughout the MHS.

C1.2.1.4. DoD personnel who prepare and evaluate contract specifications and who select, procure, and administer networks of civilian preferred providers to deliver healthcare to eligible beneficiaries.

C1.3. RESPONSIBILITIES

C1.3.1. The Assistant Secretary of Defense for Health Affairs, under the Under Secretary of Defense for Personnel and Readiness, shall:

C1.3.1.1. Monitor the implementation of this Regulation to ensure consistent application across the MHS.

C1.3.1.2. Ensure all preferred provider healthcare contracts reflect the guidance set forth in this Regulation.

C1.3.1.3. Exercise authority to grant waivers to this Regulation in exceptional circumstances.

C1.3.2. The Secretaries of the Military Departments shall ensure compliance with this Regulation.

C1.4. MHS DEFINITION OF QUALITY IN HEALTHCARE

C1.4.1. Definition. Quality in Health Care is defined as "the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." More specifically the services provided will be safe, effective, patient-centered, timely, efficient, and equitable.

C1.4.2. Principles. The MHS emphasizes the following principles:

C1.4.2.1. Accountability. Is accountable to healthcare providers, military leadership and beneficiaries, and places an inherent value on the scientific measurement of individual and system performance characteristics, providing timely relevant feedback in a continuous fashion.

C1.4.2.2. Continuity of Care. Healthcare is provided by professionals whose commitment extends beyond the individual patient encounter or incident of healthcare delivery and encompasses a continuum of concern and care extending indefinitely.

C1.4.2.3. Quality Improvement. Employs strategies to continuously study and improve the processes and outcomes of providing healthcare services to meet the needs of individuals.

C1.4.2.4. Medical Readiness. Able to field a uniquely trained, equipped, and qualified team to meet the health needs of the fighting forces anytime, anywhere, and is capable of projecting military healthcare forces worldwide to advance our national security interests.

C1.5. QUALITY MANAGEMENT REVIEWS

To evaluate outcomes as a principal measure of quality and the relationship of outcomes to cost, the MHS utilizes Quality Management Reviews to do the following:

C1.5.1. Perform external comparisons of MHS outcomes with civilian benchmarks through participation in external organization quality measurement processes, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) ORYX Initiative.

C1.5.2. Perform internal comparisons between Regional and Service MTFs.

C1.5.3. Identify best clinical practice by finding those facilities with best cost and quality outcomes.

C1.5.4. Facilitate MHS-wide, Service, Regional, and MTF continuous quality improvement efforts.

C1.6. COMMUNICATION WITH PATIENTS

The Quality Assurance Program shall include procedures and standards to provide guidance to staff to ensure that in cases of unanticipated outcomes of care, including serious medical errors that cause harm to a patient, a qualified healthcare provider shall inform the patient or applicable family members. Information provided may not include medical QA records and information prohibited from disclosure by reference (d) and Chapter 2 of this Regulation. That information is provided as a matter of clinical policy and does not affect any rights or obligations in legal or administrative proceedings.

C2. CHAPTER 2

QUALITY ASSURANCE RECORDS CONFIDENTIALITY

C2.1. REQUIREMENT OF CONFIDENTIALITY

C2.1.1. Medical QA records created by or for the Department of Defense, as part of a medical QA program, are confidential and privileged. They may not be made available to any person under the "Freedom of Information Act" (5 U.S.C. 552, reference (e)). As a system of records, they are within the purview of the "Privacy Act" (Section 552a of reference (e)) and, therefore, the individual healthcare provider who is the subject of an individual QA action may be entitled to access to the records. With the exception of such a provider, the identities of third parties in the record; i.e., any person receiving healthcare services (patients) from the Department of Defense or any other person associated with the DoD QA program, shall be deleted from the record before any disclosure of the record is made outside the Department of Defense. This identity deletion requirement does not apply to disclosures under 5 U.S.C. 552a (reference (e)), but other deletion requirements under 5 U.S.C. 552a may apply in certain circumstances.

C2.1.2. No part of any medical QA record may be subject to discovery or admitted into evidence in any judicial or administrative proceeding, except in accordance with 10 U.S.C 1102 (reference (d)).

C2.1.3. A person who reviews or creates medical QA records for the Department of Defense or who participates in any proceeding that reviews or creates such records may not testify in any judicial or administrative proceeding on such records or on any finding, recommendation, evaluation, opinion, or action taken by such person or body for such records, except in accordance with 10 U.S.C. 1102 (reference (d)).

C2.1.4. A person or entity having possession of or access to medical QA records or testimony may not disclose the contents of such record or testimony in any manner or for any purpose, except in accordance with 10 U.S.C. 1102 (reference (d)).

C2.1.5. Any person who willfully discloses a medical QA record, other than as provided in 10 U.S.C. 1102 (reference (d)), knowing that such record is a medical QA record, shall be subject to adverse personnel action (to include, in appropriate cases, dismissal or separation), and may be liable for a fine of not more than $3,000 in the case of a first offense and not more than $20,000 in the case of a subsequent offense.

C2.1.6. Information on healthcare providers who are found to be incompetent, negligent, medically or psychiatrically impaired, or guilty of misconduct as defined in this Regulation shall be provided to Agencies specified in Chapter 5 of this Regulation.

C2.1.7. Information shall be submitted to the NPDB, as instituted by 42 U.S.C. 11131-11152 (reference (f)), in accordance with applicable law and this Regulation.

C2.1.8. Aggregate statistical information on results of DoD medical QA programs may be provided in response to written requests or as directed by the ASD(HA).

C2.1.9. As provided in 10 U.S.C. 1102 (reference (d)), a person who participates in or provides information to a person or body that reviews or creates medical QA records shall not be civilly liable for such participation or for providing such information if the participation or provision of information was in good faith, based on prevailing professional standards at the time the medical QA program activity took place.

C2.1.10. Nothing in this Chapter shall be construed as limiting access to the information in a record created and maintained outside a medical QA program, including a patient's medical records, on the grounds that the information was presented during meetings of a review body that are part of a healthcare QA program.

C2.2. STANDARDS FOR DISCLOSURE OF MEDICAL QA RECORDS

C2.2.1. QA records are protected from disclosure, except as described in paragraph C2.2.2., below. Those records include, but are not limited to, the data, testimony, and working documents of any MTF, DoD contractor, Military Department, or DoD Agency involved in monitoring, assessing, or documenting quality of healthcare.

C2.2.2. DoD QA Records may be authorized for disclosure or testimony to the following:

C2.2.2.1. A Federal Executive Agency, or private organization, if such medical QA record or testimony is needed by such Agency or organization to perform licensing or accreditation functions related to DoD healthcare facilities or to perform monitoring, required by law, of DoD healthcare facilities.

C2.2.2.2. An administrative or judicial proceeding commenced by a present or former DoD healthcare provider concerning the termination, suspension, reduction, restriction, or revocation of clinical privileges of such healthcare provider.

C2.2.2.3. A governmental board or Agency or a professional healthcare society or organization, if such medical QA record or testimony is needed by such board, Agency, society, or organization to perform licensing, credentialing, or the monitoring of professional standards of any healthcare provider who is, or was, a member or an employee of the Department of Defense.

C2.2.2.4. A hospital, medical center, or other institution that provides healthcare services, if such medical QA record or testimony is needed by such institution to assess the professional qualifications of any healthcare provider who is, or was, a member or employee of the Department of Defense and who has applied for, or has been granted, authority or employment to provide healthcare services in or on behalf of such institution.

C2.2.2.5. An officer, employee, or contractor of the Department of Defense who has need for such record or testimony to perform official duties.

C2.2.2.6. A criminal or civil law enforcement agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of such agency or instrumentality makes a written request that such record or testimony be provided for a purpose authorized by law.

C2.2.2.7. An administrative or judicial proceeding commenced by a criminal or civil law enforcement agency or instrumentality discussed in subparagraph C2.2.2.6., above, but only for the subject of such proceeding.

C2.2.3. Aggregate Statistical Information. Nothing in this Chapter shall be construed as authorizing or requiring the withholding from any person or entity aggregate statistical information on the results of DoD medical QA programs.

C2.2.4. Congressional Requests. Nothing in this Chapter shall be construed as authority to withhold any medical QA record from a committee of either House of Congress, any joint committee of Congress, or the General Accounting Office if such record pertains to any matter within their respective jurisdictions.

C3. CHAPTER 3

FACILITY STANDARDS

C3.1. ACCREDITATION

C3.1.1. All fixed hospitals and free-standing ambulatory clinics, including those providing care to DoD beneficiaries under various managed care support contracts, shall maintain accreditation by the JCAHO, under the "Accreditation Manual for Hospitals" (reference (g)) or the "Ambulatory Health Care Standards Manual" (reference (h)), or as a component of a network system approved by the Service under the "Accreditation Manual for Health Care Networks" (reference (i)), or through an accreditation source approved by the ASD(HA).

C3.1.2. Operational ambulatory clinics (those treating active duty personnel only) are exempt from the accreditation requirement. Each Military Service shall establish and implement comparable quality of care oversight mechanisms for those operational clinics under its cognizance.

C3.1.3. Hospital-sponsored alcoholism and drug dependence programs shall maintain accreditation under the standards contained in reference (g). All other Service-sponsored, free-standing alcoholism and drug dependence programs shall maintain accreditation through the "Accreditation Manual for Mental Health, Chemical Dependency, and Mental Retardation/Developmental Disabilities Services" (reference (j)) or the Commission on Accreditation of Rehabilitation Facilities (CARF) in the Standards Manual for Organizations Serving People With Disabilities" (reference (k)).

C3.1.4. All preferred provider networks shall maintain accreditation either through the JCAHO in reference (i) or through the National Committee on Quality Assurance (NCQA) in the "NCQA Standards for Accreditation and Review Guidelines" (reference (l)).

C3.1.5. All MTFs and networks listed in paragraphs C3.1.1., C3.1.3., and C3.1.4., above, shall attain and maintain accreditation. The ASD(HA) shall consider accreditation waivers on a case-by-case basis. Waiver requests shall specify patient volume statistics, provider specialty mix, ongoing performance, and alternate oversight mechanisms.

C3.1.6. Accreditation guidance is found in references (g) through (k) and shall not be duplicated in this Regulation. When appropriate, the ASD(HA) shall implement policy, direct procedures that exceed the standards of accrediting bodies, and issue implementing instructions.

C4. CHAPTER 4

CREDENTIALS AND CLINICAL PRIVILEGES

C4.1. LICENSING REQUIREMENT

C4.1.1. Statutory Requirement

C4.1.1.1. 10 USC 1094 (reference (d)) provides: "A person under the jurisdiction of the Secretary of a Military Department may not provide healthcare independently as a healthcare professional . . . unless the person has a current license to provide such care. In the case of a physician, the physician may not provide healthcare as a physician under this chapter unless the current license is an unrestricted license that is not subject to limitation on the scope of practice ordinarily granted to other physicians for a similar specialty by a jurisdiction that granted the license."

C4.1.1.2. The statute allows the Secretary of Defense to waive this requirement regarding any person in unusual circumstances, and directs the Secretary to prescribe by regulation the circumstances under which such a waiver may be granted. This authority and responsibility was delegated to the ASD(HA) by reference (a).

C4.1.1.3. Healthcare practitioners who do not possess a license or other authorizing document may practice only under a written plan of supervision with a licensed person of the same or a similar discipline.

C4.1.1.4. The statutory requirement is applicable to all healthcare practitioners practicing independently in military facilities or operational environments. This includes healthcare practitioners who are member of the Uniformed Services (Active and Reserve), Federal employees, volunteers (who are considered to be employees for certain purposes), and personal services contractors (under DoD Instruction 6025.5, reference (m)). The statutory requirement has no impact on non-personal services contractors in MTFs. Non-personal services contractor healthcare practitioners are required to maintain an unrestricted license in the State in which the MTF is located.

C4.1.2. Implementation of Licensure Requirement and Waiver Provision

C4.1.2.1. Any physician's license in a licensure category that restricts the physician to practice in a Federal facility or within some other confined limits does not comply with the requirement for an "unrestricted license." Unless waived, all physicians must have at least one current, valid, unrestricted license. Physicians may hold

additional licenses from States in licensure categories that have practice restrictions associated with military exemptions from certain fees or requirements as long as the physician also holds at least one license for which there are no limitations on the scope of practice. A physician without a full-scope license may not provide healthcare as a physician unless a waiver is granted under this Chapter.

C4.1.2.2. A licensure category that includes limitations on scope of practice shall not be considered for a waiver of the unrestricted license requirement unless it includes all the same requirements pertaining to clinical competency (e.g., education, training, national tests, continuing medical education, investigation, and sanction authority of the license board) as the full scope category and has no restrictions pertaining to clinical competency (e.g., practice under supervision). A waiver shall be considered only if the differences between the full scope license and limited scope license are solely of an administrative or financial nature.

C4.1.2.3. The statute permits a waiver of the unrestricted scope requirement only in "unusual circumstances." A waiver may be considered in cases in which the administrative or financial requirements applicable to the full scope license that are not applicable to the limited scope license are substantial and seek to achieve a State purpose clearly inapplicable to military physicians based on Federal policy, and thus are inharmonious with Federal policy. Examples of this would be a requirement that the physician reside in the State (Federal policy calling for worldwide service), pay a substantial amount into a medical injury compensation fund (Federal policy provides for medical injury compensation under Federal statutes), or maintain private malpractice liability insurance (Federal policy provides for malpractice liability through the U.S. Treasury). Among the situations not deemed to constitute an unusual circumstance are the following:

C4.1.2.3.1. A requirement to pay the standard license fee associated with an unrestricted license is not deemed an unusual circumstance and does not provide a basis to justify use of the waiver.

C4.1.2.3.2. In any case in which a physician holds a restricted license in more than one State and a waiver is not authorized for at least one of the restricted licenses (even if the waiver is authorized for at least one of the licenses), the physician is not eligible for a waiver. For example, if a physician has two State licenses, one with restrictions that would be removed through the payment of the standard license fee (see subparagraph C4.1.2.3.1., above) and one in a State listed in subparagraph C4.1.2.5. for which a waiver is authorized, the physician must obtain an unrestricted license in the first State by paying the standard license renewal fee. There are no unusual circumstances justifying use of the waiver authority in this example. The question has

arisen as to whether a waiver may be granted in this circumstance if the physician surrenders all licenses, except for the limited scope license in a State for which a waiver is granted. Physicians should not terminate a license just to avoid paying the fee for an unrestricted license. Some physicians may have legitimate reasons for surrendering multiple State licenses, which coincidentally make them eligible for a waiver.

C4.1.2.3.3. A physician's duties in a particular position being entirely administrative in nature and not involving the provision of patient care is not considered an unusual circumstance and thus does not provide a basis to justify use of the waiver.

C4.1.2.4. Waiver consideration is a two-step process.

C4.1.2.4.1. Step 1. The ASD(HA) shall determine, based on a review of a State's licensure requirements, that the standards outlined in subparagraphs C4.1.2.2. and C4.1.2.3., above, are met and identify the particular State administrative or financial requirements that may be considered for waiver. Requests for this determination may be made by a Surgeon General.

C4.1.2.4.2. Step 2. Individual healthcare practitioners who do not hold a full scope license in any State, but who hold a limited scope license in a State for which a waiver may be considered based on the step one determination may request a waiver from the Surgeon General of the Service involved. The request must include a justification for the waiver in the case of the individual physician. A waiver shall not be granted for longer than the applicable time period of licensure; a subsequent licensure renewal would require a new waiver. The Surgeons General shall submit to the ASD(HA) an annual account of the waivers granted and the applicable justifications.

C4.1.2.5. Waivers for Physicians. The following paragraphs indicate the status of respective State laws at the time of publication of this Regulation. Current State statutes should be consulted to ensure that there have been no intervening changes. The requirement for an "unrestricted license that is not subject to limitation on the scope of practice ordinarily granted" by the State may be waived for individual physicians who do not hold a full scope license, but who hold one of the following licenses:

C4.1.2.5.1. Colorado. Colorado requires every physician who holds or desires to obtain a Colorado medical license must maintain a certain level of professional liability coverage. A Federal civilian or military physician whose practice is limited solely to that required by his/her Federal/Military Agency is exempted from this requirement. Although the exclusive practice provision is a limitation on the scope

of practice, the requirement for an unrestricted license may be waived for a physician who obtains a Colorado license in a licensure category that exempts the physician from professional liability coverage. This requirement is unrelated to clinical competency and is inharmonious with Federal policy, under which professional liability is managed under the Federal Tort Claims Act (reference (c)).

C4.1.2.5.2. Florida. Florida requires that most physicians as a condition of licensure maintain a certain level of professional liability coverage and that all physicians contribute to the birth-related Neurological Injury Compensation Association (NICA), but exempt from this requirement physicians who practice "exclusively" as an officer or employee of the Federal Government. Although the exclusive practice provision is a limitation on the scope of practice, the requirement for an unrestricted license may be waived for a physician who obtains a Florida license in a licensure category that exempts the physician from the professional liability coverage and payment into the NICA risk pool requirement. The requirement is unrelated to clinical competency and is inharmonious with Federal policy, under which professional liability is managed under reference (c).

C4.1.2.5.3. Kansas. Kansas maintains a physician licensure category called a "federally active license," which requires compliance with all generally applicable State licensing requirements, except requirements for professional liability insurance and contributions to the State healthcare stabilization fund, and which limits licensees to practice in connection with official duties. Although this licensure category includes limits on the scope of practice, the requirement for an unrestricted license may be waived for a physician who obtains a Kansas "federally active license." This licensure category deviates from no standards pertaining to clinical competency and merely recognizes that the liability requirements are inharmonious with Federal policy, under which professional liability is managed under reference (c).

C4.1.2.5.4. Massachusetts. Massachusetts requires Massachusetts licensees who render any direct or indirect patient care in Massachusetts to maintain a certain level of professional malpractice liability insurance coverage, but exempts categories of licensees who do not provide direct or indirect patient care in Massachusetts or who do so only on behalf of Federal healthcare facilities. Although these licensure categories include limits on the scope of practice, the requirement for an unrestricted license may be waived for a physician who obtains a Massachusetts license in such licensure categories. These licensure categories deviate from no standards pertaining to clinical competency. The Massachusetts policy of exempting military physicians from the malpractice insurance requirement recognizes that the requirement is inharmonious with Federal policy, under which professional liability is managed under reference (c).

C4.1.2.5.5. Oregon. Oregon includes a licensure category called an "active military license," which is comparable to the generally issued "active" license, except that a military physician is exempt from the requirement to maintain an actual physician presence and medical practice in Oregon. The "active military license," however, limits the licensee to practice in connection with military duties. Although these licensure categories include limits on the scope of practice, the requirement for an unrestricted license may be waived for a physician who obtains an Oregon "active military license." This licensure category deviates from no standards pertaining to clinical competency and merely recognizes that Oregon's generally applicable physical presence requirement is inharmonious with Federal policy, which requires of military physicians worldwide requirements.

C4.1.2.5.6. Pennsylvania. Pennsylvania requires that in order to practice medicine "in the Commonwealth" of Pennsylvania, a physician must maintain, at the risk of revocation of license, particular levels of professional liability coverage and participate in a State liability contingency fund, Medical Professional Liability Catastrophe Loss Fund. These requirements are inapplicable to Federal medical personnel discharging official duties. When these requirements must be met before a physician may practice medicine other than in connection with official duties without risking license revocation, they reflect a limitation on the scope of practice. This limitation may be waived. The requirements for professional liability coverage and participation in the State liability contingency fund are unrelated to clinical competency and inharmonious with Federal policy, under which professional liability is managed under reference (c).

C4.1.2.6. Waivers for Physician Assistants (PAs). Given the unusual circumstances that require a PA and his or her supervising physician to be licensed in the same State, the ASD(HA) has exercised his authority to waive the license requirement for PAs who meet the criteria in subparagraphs C4.1.2.6.1. through C4.1.2.6.4. Since these are the identical criteria reviewed to determine if privileges are initially granted or renewed, any PA who has been granted privileges within the MHS by an authorized privileging authority shall be automatically granted a waiver. The waiver shall be documented in the CCQAS, with the date of the waiver reflecting the date that privileges were granted. At the time of privilege renewal, the criteria shall be reviewed again. If the criteria are not met, the waiver lapses, the request for renewal of privileges is withdrawn, and the individual must practice under a plan of supervision until such time as the criteria can be met. If the criteria are met, the waiver should automatically renew. If privileges are then renewed by the privileging authority, the waiver in the CCQAS shall be updated to reflect the date of the approved privileges. If for any reason the privileges are not approved by the privileging authority, the waiver

shall lapse, and the appropriate procedures for an adverse privileging action shall be initiated. A PA shall provide care under a formal plan of supervision unless he or she possesses both a waiver and clinical privileges. Monitoring for compliance with this process shall be via the standard unlicensed provider report in the CCQAS. This waiver is applicable to any MHS PA who is a member of a Uniformed Service (Active or Reserve), a civilian employee, a personal services contractor, or an authorized volunteer. It is not applicable to non-personal services contract personnel. The waiver criteria for qualified MHS PAs (including Reserve component PAs) are as follows:

C4.1.2.6.1. Has successfully completed an educational program for physician assistants accredited by the Accreditation Review Commission on Education for the Physician Assistant or, prior to 2001, by either the Committee on Allied Health Education and Accreditation, the Commission on Accreditation of Allied Health Education Programs;

C4.1.2.6.2. Has passed the PA National Certifying Examination administered by the National Commission on Certification of PAs;

C4.1.2.6.3. Has accumulated 100 approved hours of Continuing Medical Education every 2 years (after initial certification); and

C4.1.2.6.4. Achieves recertification with the National Commission on Certification of PAs every 6 years (after initial certification).

C4.1.2.7. Waivers For Other Categories of Healthcare Practitioners. The ASD(HA) shall establish waiver procedures for other categories of healthcare practitioners, as appropriate.

C4.2. PORTABILITY OF STATE LICENSURE FOR HEALTHCARE PROFESSIONALS

C4.2.1. General Provisions

C4.2.1.1. As directed by 10 U.S.C. 1094(d) (reference (d)), notwithstanding any State law regarding the licensure of healthcare professionals, a licensed healthcare professional who is a member of the Armed Forces may practice the member's profession in any State, regardless of whether the practice occurs in a healthcare facility of the Department of Defense, healthcare facility of the Veterans Administration, a civilian facility affiliated with the Department of Defense, or any other authorized location as long as the individual is practicing within the scope of Federal duties.

C4.2.1.2. The Military Departments and MHS officials responsible shall, prior to assigning licensed providers to off-base duties, follow the procedures established in this section to promote cooperation and good will with State licensing boards.

C4.2.2. Qualifications. To be eligible for assignment of off-base duties, the active duty healthcare professional shall have the following qualifications:

C4.2.2.1. The healthcare professional shall have a current, valid, and unrestricted license or other authorizing document such as certificate or registration, consistent with the requirements of this Chapter, which encompasses the professional activities involved in the off-base duty assignment.

C4.2.2.2. A healthcare professional shall not be assigned to off-base duties if there is an unresolved allegation which, if substantiated, would result in an adverse licensing or privileging action.

C4.2.2.3. The healthcare professional shall have current clinical competence to perform the professional duties assigned.

C4.2.2.4. In the case of physicians and other privileged providers, the healthcare professional shall have current clinical privileges granted and maintained in accordance with this Chapter, which encompass the professional duties assigned. Alternatively, if such duties are outside the scope of clinical privileges granted by the applicable privileging authority, the provider shall have clinical competence sufficient for such privileges.

C4.2.2.5. In the case of physicians, the following additional qualification requirements apply:

C4.2.2.5.1. The physician shall have completed at least 3 years of approved postgraduate training (including completion of PGY-3) or have achieved American Board of Medical Specialties (ABMS) or AOA specialty board certification.

C4.2.2.5.2. The physician shall have maintained current competence, in that if 10 years or more have passed since completion of the licensing examination, the physician must have ABMS/AOA specialty board certification.

C4.2.2.5.3. The physician shall be current with applicable continuing medical education requirements under the system established pursuant to 10 U.S.C. 1094a (reference (d)).

C4.2.2.6. In all cases in which the off-base duty shall be performed in a non-DoD healthcare facility, the healthcare professional shall follow the rules and by-laws of such facility, to the extent they are applicable to the professional.

C4.2.3. Coordination With State Licensing Boards

C4.2.3.1. Prior to an active duty healthcare professional performing off-base duties under the authority of 10 U.S.C. 1094(d) (reference (d)), the MHS official responsible shall notify the applicable licensing board of the host State of the duty assignment involved. Such notification shall include the name of the healthcare professional; the healthcare professional's State(s) of licensure; the location and expected duration of the off-base duty assignment; the scope of duties; the healthcare professional's commanding officer; and the MHS liaison official for the licensing board to contact with any questions or issues concerning the off-base duty assignment. The notification shall also reference 10 U.S.C. 1094(d) (reference (d)) and this Regulation as underlying authority and include a statement that the healthcare professional meets all qualification standards of paragraph C4.2.2.

C4.2.3.2. In cases in which the off-base duties involve the provision of healthcare services through telemedicine from an MTF and patients outside MTFs, subparagraph C4.2.3.1. shall not be applicable.

C4.2.3.3. The requirement of subparagraph C4.2.3.1. may, on a case-by-case basis, be waived by the MHS official responsible regarding off-base duties of non-physicians if the MHS official responsible determines that such requirement is not necessary in that case to promote cooperation and good will with the State licensing board concerned and such waiver is consistent with this section and guidance of the ASD(HA).

C4.2.4. Investigations and Reports. In the event of any allegation of misconduct on the part of the military healthcare professional arising from the healthcare professional's performance of the off-base duty assignment, the following requirements apply:

C4.2.4.1. MHS personnel shall, to the extent allowed by law, cooperate with authorized officials, if any, investigating the allegation on behalf of the host State licensing board, any other licensing board which has granted a license to the healthcare professional involved, and the non-DoD healthcare facility at which the military healthcare professional was performing the off-base duty assignment. Cooperation may include providing testimony and assisting in gathering evidence.

C4.2.4.2. Upon the referral by a State licensing board or authorized official of the non-DoD healthcare facility involved of such an allegation of misconduct to the MHS official responsible or designated MHS liaison official, or upon receipt of such an allegation from the person or entity making the allegation, or upon otherwise learning of such an allegation, the MHS official responsible shall ensure that the allegation is reviewed and, if it raises a substantive issue of misconduct, investigated.

C4.2.4.2.1. In the case of a privileged provider, if the results of the investigation indicate that the clinical privileges of the military provider should be revoked or restricted and/or reduced by the MHS privileging authority, such action shall be taken in accordance with applicable due process procedures. Adverse privileging actions shall be reported to the NPDB (see Chapter 10 of this Regulation) and the Federation of State Medical Boards and/or other appropriate authorities in accordance with applicable requirements.

C4.2.4.2.2. In the case of a healthcare professional other than a privileged provider, if the results of the investigation indicate that an action should be taken to revoke or restrict the authorized clinical activities of the healthcare professional, such action shall be taken in accordance with applicable due process procedures and shall be reported in accordance with applicable reporting requirements.

C4.2.4.2.3. If requested by the host-State licensing board or other appropriate State licensing board or by an authorized official of the non-DoD healthcare facility at which the off-base duty assignment was performed, the full results of the MHS investigation shall be provided to such board or authorized official as an exception to the general rule of confidentiality of medical quality assurance records under the authority of 10 U.S.C. 1102(c)(1)(C) or (D) (reference (d)). The provision of such results shall, however, be contingent upon the recipient agreeing to maintain the confidentiality of such medical quality assurance records in accordance with 10 U.S.C. 1102 (reference (d)).

C4.2.4.3. If the non-DoD facility at which the off-base duty was being performed withdraws approval for the military healthcare professional to continue to perform such duty, the off-base duty assignment shall be terminated. If the host-State licensing board requests that the off-base duty assignment be terminated, it shall be terminated, unless the ASD(HA) determines that such request is arbitrary or without foundation.

C4.2.5. Supplemental Agreements. MHS officials responsible are authorized to enter into memoranda of agreement or other appropriate arrangements consistent with

this section and other applicable law and DoD issuances to facilitate accomplishment of the purposes of this section.

C4.3. PRE-SELECTION CRITERIA FOR HEALTHCARE PRACTITIONERS

C4.3.1. Collection of Credentials. Credentials shall be collected and verified before the selection, employment, or contract of healthcare practitioners. Staff appointments and clinical privileges shall be granted to healthcare providers only after all the pre-selection criteria required have been verified through the primary source, unless otherwise specified in paragraph C4.3.2., below. Substantial errors of fact involving documents discovered before or after appointment can be the basis for non-selection or, after appointment, adverse action including separation and termination.

C4.3.2. Pre-selection Criteria. Evidence of the criteria listed below must be verified through the primary source and documented. Unless specified, secondary sources are supplementary and do not meet the requirement.

C4.3.2.1. Qualifying educational degree(s).

C4.3.2.2. Postgraduate training and fellowship for requested clinical privileges and/or scope of practice.

C4.3.2.3. State licenses, registration, certification, or other authorizing document. (A list of all healthcare licenses ever held shall be provided and an explanation of any licenses that are not current, have been voluntarily relinquished, or have been subjected to disciplinary action shall be attached.)

C4.3.2.4. A current report from the NPDB/Healthcare Integrity and Protection Data Bank (HIPDB) (see Chapter 10 of this Regulation) for all healthcare practitioners.

C4.3.2.5. Specialty board status, if applicable. (Board certification in medical board specialties shall be verified either through the primary source (the issuing body) or through the secondary source as described in reference (g).

C4.3.2.6. Chronological practice experience to account for all periods of time after graduation.

C4.3.2.7. A statement of the applicant's ability to perform his or her professional activities and proof of current professional competence (letters of recommendation from the program or training director and a recent description of scope

or practice and/or clinical privileges by the directors of the facility in which the applicant currently is practicing) as described in reference (g).

C4.3.2.8. Documentation of any medical malpractice claims, settlements, or judicial or administrative adjudication with a brief description of the facts of each case listed.

C4.3.2.9. Any history of adverse clinical privilege and/or disciplinary action by a hospital, State licensure board, or other civilian Government Agency. This shall include voluntary or involuntary termination of professional and/or medical staff membership or voluntary or involuntary suspension, reduction, restriction, or revocation of clinical privileges at a hospital or other healthcare delivery setting, and any resolved or open charges of misconduct, unethical practice, or substandard care.

C4.3.2.10. A statement of the applicant's health status, about his or her ability to provide healthcare. The statement must be confirmed as described in reference (g).

C4.3.2.11. Peer Interview Summary. Non-board certified physicians who allege to be specialists shall have two letters attesting their clinical competence by physicians certified in the specialty in which the non-board certified physicians are practicing. Those physicians who have not completed their initial period of qualification for board certification shall have two letters attesting their clinical competence from board-certified specialists who have current knowledge of their clinical practice. All other healthcare practitioners shall also have two letters attesting their clinical competence from board certified healthcare practitioners in their area of practice who have current knowledge of their clinical practice.

C4.3.2.12. Drug Enforcement Agency certificate (where applicable).

C4.3.2.13. Federal Bureau of Investigation background check and State criminal history repository checks, in accordance with DoD Instruction 1402.5 (reference (n)).

C4.3.2.14. A signed statement consenting to the inspection of records and documents pertinent to consideration of his or her request for accession or employment.

C4.3.2.15. A signed statement attesting to the accuracy of all information provided.

C4.4. CLINICAL PRIVILEGES AND APPOINTMENT TO THE MEDICAL AND/OR DENTAL STAFF

C4.4.1. The Military Services shall designate the privileging authorities for healthcare providers who are responsible for making decisions to diagnose, alter, or terminate a regimen of healthcare.

C4.4.2. Before providing care, healthcare providers shall be subject to review of licensure, relevant training and/or experience, current competence, and health status and shall be granted delineated clinical privileges with or without a medical staff appointment. Reappointment shall occur at least every 2 years.

C4.4.3. The NPDB/HIPDB/DPDB shall be queried for all healthcare practitioners before the granting or renewal of clinical privileges. (See Chapter 10 of this Regulation.)

C4.5. MEDICAL READINESS TRAINING CERTIFICATION

Pursuant to reference (a), the Services shall require Active and Reserve component healthcare providers to earn medical readiness certification that documents preparation for assignments involving military operations. The certification shall be reviewed and verified by the Medical Commander every 12 months. Noncompliance with the certification requirement may be the basis for adverse personnel actions, such as withholding of special pays, promotions, awards, or actions under the Uniform Code of Military Justice (UCMJ) (10 U.S.C. Chapter 47) (reference (d)).

C4.6. INTER-FACILITY CREDENTIALS TRANSFER AND PRIVILIGING

C4.6.1. When healthcare providers are assigned temporarily for clinical practice in a MTF the supplying MTF must convey all relevant credentials and privileging information to the gaining MTF. The receiving commander uses this information as a basis for assessing current clinical competence and making appropriate appointment and privileging decisions upon arrival at the gaining MTF. The Credentials Transfer Brief is the preferred mechanism to carry out this credentials transfer whenever its use can reasonably ensure the accurate transfer of credentials and privileging information. The privileging institution retains full responsibility and authority for making privileging decisions.

C4.6.2. The Credentials Transfer Brief is joined with the formal application for privileges and supplants sections of applicable Military Service forms containing

essentially like information. The Credentials Transfer Brief serves in the place of the documents normally kept in the Credentials File when making privileging decisions on temporarily assigned healthcare practitioners.

C4.6.3. After customary departmental review and recommendation, and consideration of the gaining facility's capability, MTF commanders may grant privileges based on the approved privilege list from the sending MTF by approving it with or without recommendations. The receiving facility's medical staff credentials function must ensure that all relevant information is considered, taking care to investigate additional information mentioned in subparagraphs C4.6.6.7., C4.6.6.9., and C4.6.6.10. on the Credentials Transfers Brief. The receiving facility may use its own customary forms or formats for notifying practitioners of their medical appointments and documenting same. Privileges applied for, but not granted due to facility-based limitations are not adverse privileging actions.

C4.6.4. Credentialing functions in MTFs shall accept healthcare practitioner performance appraisals on other Service's forms as their own.

C4.6.5. The Credentials Transfer Brief shall become invalid on the expiration of the professional staff appointment on which it is based. If the healthcare practitioner is assigned temporarily for several brief periods to the same location, it remains valid over the duration of the combined periods, providing the professional staff appointment at the sending MTF remains active. If other credentials have expired in the interim, telephonic or message confirmation of the renewal of the credential with the facility holding the Credentials File shall suffice; i.e., a new Credentials Transfer Brief is not required. A record of the telephone call or the message confirmation shall be maintained in the healthcare practitioner file at the gaining facility. The sending facility must keep an accurate record of all MTFs to which a Credentials Transfer Brief has been sent, to ensure updates on provider status are forwarded as required. The sending MTF shall provide a new Credentials Transfer Brief whenever the status of the provider's privileges changes (e.g., change from provisional to defined privileges, renewal of privileges, adverse privileging actions, etc.).

C4.6.6. Reporting elements for the Credentials Transfer Brief:

C4.6.6.1. Complete name, rank (or rating if Federal employee), corps, social security number, clinical specialty.

C4.6.6.2. List qualifying degree, internship, residency, fellowship, and other qualifying training, as appropriate. Include completion date of each and indicate presence/absence of primary source verification (PSV) in the Credentials File.

C4.6.6.3. List all currently held State licenses, registrations, and certifications; expiration date and PSV status of each.

C4.6.6.4. List all applicable specialty/board certifications and recertifications; expiration date and PSV status of each.

C4.6.6.5. List all applicable life support training (Basic Life Support, Advanced Cardiac Life Support, Advanced Trauma Life Support, Pediatric Advanced Life Support, Neonatal Advanced Life Support), and readiness certification training (when developed) and expiration date.

C4.6.6.6. State the type of appointment (provisional/defined (full)) currently held by the healthcare practitioner, and the expiration date. List privileges granted or summarize privileges and attach current privilege list(s). (See subparagraph C4.6.6.12., below, for guidance on Reserve or Guard units where appointments and privileges do not fully represent the capability of the healthcare practitioner.)

C4.6.6.7. List date of the most recent NPDB/HIPDB/DPDB query and indicate absence and/or presence of information in the report. If no query made, state so.

C4.6.6.8. Provide a statement of the nature or purpose of the temporary assignment and request performance appraisals, as appropriate.

C4.6.6.9. Provide a brief statement from an individual personally acquainted with the applicant's professional and clinical performance through observation or review to include quality assessment activities describing the applicant's actual clinical performance with respect to the privileges granted at the sending facility, the discharge of his or her professional obligations as a medical staff member, and his/her ethical performance. This person may be a training program director for new practitioners, or a peer from a prior or the current command. The statement may be taken from a current performance evaluation in the provider's Credentials File; however, the person making the statement must be asked whether or not additional relevant information exists pertaining to the elements above. (Relevant information is defined as information that reflects on the current clinical competence of the provider.) The paragraph must contain a statement indicating the presence and/or absence of other relevant information in the recommendation relating to the provider's competence for privileges as granted along with a means of direct contact with the person making the recommendation (name, title or position held, telephone, fax, etc.).

C4.6.6.10. Provide certification that the Credentials File was reviewed and is accurately reflected in the Credentials Transfer Brief as of (annotate the date). This paragraph must contain a statement indicating the presence/absence of other relevant information in the Credentials File. Of particular import is supplemental information accompanying PSV of training and licensure. Examples of other relevant information include, but are not limited to: delays in or extensions in training due to marginal performance, unprofessional conduct during training or in previous practice settings, investigations, investigations conducted or limitations imposed by State licensing boards, adverse actions, malpractice, etc.

C4.6.6.11. Provide the name, title, phone number and fax number of the designated point of contact at the sending facility.

C4.6.6.12. Paragraph(s) applicable to healthcare practitioners from Reserve or Guard components (as needed):

C4.6.6.12.1. Provide the current civilian position, place of employment or facility where privileges are held, and the clinical privileges held by the healthcare practitioner.

C4.6.6.12.2. If the healthcare practitioner is self employed, provide his or her office location.

C4.6.6.12.3. If privileges are held at several facilities, provide the name and location of the place or places where the majority of the practitioner's practice is conducted, and a list of the clinical privileges held that are applicable to the assignment prompting the use of the Credentials Transfer Brief.

C4.6.6.12.4. Additionally, include the address, business phone, and home telephone number where the healthcare practitioner can be reached prior to reporting for the assignment and the name of the MTF and dates of the last tour of clinical duty.

C4.6.6.13. Certifying signature by MTF commander and date. Electronic signatures shall be recognized.

C4.7. OFF-DUTY EMPLOYMENT BY DoD HEALTHCARE PRACTITIONERS

C4.7.1. General Provisions

C4.7.1.1. Commanders may, assuming the requirements of DoD 5500.7-R (reference (o)) and any applicable Service regulations are met, approve off-duty employment by DoD Healthcare Practitioners on active duty if the requirements of this section are met as well. When necessary to clarify questions of conduct and other ethical issues related to off-duty employment and compensation personnel should consult reference (o) and their Ethics Counselor.

C4.7.1.2. Although the requirements of this Section are directly applicable only to active duty and civilian healthcare practitioners the Military Services may also apply these requirements to other unlicensed technical and assistive healthcare personnel (e.g., x-ray technicians, nursing assistants) when appropriate.

C4.7.2. Commander's Responsibilities

C4.7.2.1. Commanders may authorize off-duty employment upon written request of healthcare practitioners when such activities do not interfere with provision of healthcare services or mission accomplishment. Commanders should consider factors such as hours per week, work site proximity, travel time, and impact on civilian communities and practitioners when reviewing such requests.

C4.7.2.2. Permission to engage in off-duty employment shall be documented in writing and may be withdrawn at any time by the commanding officer.

C4.7.2.3. Personnel enrolled in graduate training programs shall not be authorized to engage in off-duty employment.

C4.7.2.4. Commanders shall ensure the annual review of practitioner's compliance with applicable policy and regulatory guidance.

C4.7.3. Procedures for Requesting Authorization

C4.7.3.1. DoD healthcare practitioners desiring to engage in off-duty employment must submit a written request that includes:

C4.7.3.1.1. A statement of understanding of applicable DoD regulations.

C4.7.3.1.2. Written acceptance from the off-duty employer of the practitioner's availability, patients for whom services may be provided, compensation limitations, and contract restrictions.

C4.7.3.1.3. The impact on the civilian community and practitioners (e.g., statement from employer, local medical society, or practitioner's own assessment).

C4.7.3.2. Practitioners must certify their compliance annually with applicable policy and regulatory guidance, and whenever there is a change in off-duty employment status.

C4.7.3.3. Practitioners are responsible for complying with all requirements to practice in the civilian community, such as State licensure, Drug Enforcement Agency (DEA) certification, and medical malpractice coverage. The fee-waived DEA certification is only authorized for use in MTFs.

C4.7.3.4. DoD healthcare practitioners cannot be authorized TRICARE (formerly CHAMPUS) providers or be reimbursed for providing TRICARE services to DoD beneficiaries by virtue of 5 U.S.C. 5536 (reference (p)). This restriction does not apply to dental services provided to continental United States enrollees of the TRICARE Dental Program.

C4.7.4. Quality Management

C4.7.4.1. Commanders shall withdraw permission to engage in off-duty employment for all DoD healthcare practitioners at the beginning of any inquiry into potentially reportable actions of misconduct until the issues are resolved.

C4.7.4.2. Commanders shall ensure that the appropriate officials at all civilian places of employment are immediately notified whenever permission is withdrawn for practitioners to engage in off-duty employment.

C5. CHAPTER 5

CENTRALIZED CREDENTIALS QUALITY ASSURANCE SYSTEM (CCQAS)

C5.1. PURPOSE

C5.1.1. The CCQAS is a web-based, worldwide provider credential, RM and adverse privileging actions application that enables the MHS to manage clinicians' credentials and privileging actions, medical readiness training requirements, and RM.

C5.1.2. The CCQAS contains medical QA records created by or for the Department of Defense, as part of a medical QA program. Those records are confidential and privileged. Chapter 2 of this Regulation describes the protections afforded those records. All uses of CCQAS records are subject to the disclosure restrictions in Chapter 2.

C5.2. REPORTS TO THE CCQAS

The following actions, events, and circumstances shall be promptly reported to the CCQAS:

C5.2.1. Provider Credential records to include demographics; specialties; education and training; additional training, licenses and certifications; and eventually photographs.

C5.2.2. RM records to include every potentially compensable event, every claim filed (unless the claim provides insufficient information for RM review), every paid claim, and every case in which medical care may have contributed to the death or disability of an active duty member. Data elements shall include the tracking of ICD-9 and CPT4 codes, the place of care, and underlying event taxonomies (classification of types of events).

C5.2.3. Completed adverse privileging actions to include medical-legal actions associated with suspending, restricting, or revoking privileges; preliminary inquiries; investigations, UCMJ (reference (d)); peer review; and privileging authority decisions, as well as appeals thereof.

C5.2.4. DPDB records to include all DoD reports to the NPDB and HIPDB (Chapters 10 and 11) and every case in which medical care contributed to the death or disability of an active duty member or RC member in duty status.

C5.3. HEALTHCARE PROVIDERS INCLUDED IN THE CCQAS

The following list of healthcare providers, practitioners, and ancillary personnel have been identified as critical for credentials management and must be included in the CCQAS. Unless otherwise specified, the requirements apply to active duty (including trainees in Service programs, Service-sponsored training, or long-term civilian schooling (anyone counting against end strength)), Reserve component, Federal civilian, contractors and those providers working under resource sharing agreements.

C5.3.1. Physicians.

C5.3.2. Dentists.

C5.3.3. Nurse providers (Advanced Practice Nurses granted clinical privileges, Nurse Practitioners, Nurse Midwives, CRNAs, etc.).

C5.3.4. Physical therapists.

C5.3.5. Podiatrists.

C5.3.6. Optometrists.

C5.3.7. Clinical dieticians.

C5.3.8. Social workers.

C5.3.9. Clinical pharmacists.

C5.3.10. Clinical psychologists.

C5.3.11. Occupational therapists.

C5.3.12. Audiologists.

C5.3.13. Speech pathologists.

C5.3.14. Physician assistants.

C5.3.15. Chiropractors.

C5.3.16. Dental hygienists.

C5.3.17. Mental health counselors.

C5.3.18. Professional counselors.

C5.3.19. Marriage and family therapists.

C6. CHAPTER 6

QUALITY ASSURANCE REVIEW OF HEALTHCARE

C6.1. MEDICAL STAFF FUNCTIONS

The medical staff shall monitor and evaluate the quality and appropriateness of patient care and the clinical performance of all practitioners using the following methods:

C6.1.1. Meetings. Regularly scheduled meetings of clinical departments or services to consider findings from ongoing monitoring activities.

C6.1.2. Reviews. Surgical case review, audit of autopsy reports, anatomic pathology peer review, and invasive procedure review.

C6.1.2.1. Surgical Case Review. Regularly scheduled surgical case review shall be performed and include appropriate review of all surgical procedures performed in the operating room, all ambulatory surgery, and all major invasive diagnostic procedures; for example, bronchoscopy and colonoscopy.

C6.1.2.1.1. Pre-operative, post-operative, and pathologic diagnoses shall be compared and discrepancies evaluated.

C6.1.2.1.2. Each case in which no tissue or non-diagnostic specimens are removed shall be evaluated for the acceptability of or the need for the procedure.

C6.1.2.1.3. The pathologist(s) and medical staff shall develop a list of specimens that do not require tissue review; for example, those resulting from newborn circumcision; tooth extraction performed in a hospital operating room, when the anatomic name or anatomic number of each tooth, or fragment of each tooth, is recorded in the medical record; or cataract extraction. Cases requiring more intensive evaluation should be identified and specifically documented in committee minutes.

C6.1.2.1.4. When surgical case review consistently supports the justification and quality of individual surgical procedures, the review of an adequate sample of cases is acceptable. When sampling is employed, criteria that define appropriateness of or indications for surgery shall be defined and uniformly applied.

C6.1.2.1.5. All cases in which discrepancies have been identified shall be evaluated through peer review.

C6.1.2.1.6. When surgical case review is performed for practitioners who are not members of the department of surgery, department chiefs of the affected practitioners shall have access to MTF comparative data for procedures under review.

C6.1.2.2. Audit of Autopsy Reports. The pre-mortem and postmortem clinical diagnoses and the presumptive and final autopsy diagnoses shall be compared for all autopsies. Disagreement among them shall be evaluated.

C6.1.2.3. Audit of Anatomic Pathology Peer Review

C6.1.2.3.1. In the audit of anatomic pathology peer review, the tissue review shall be accomplished on the basis of routine, periodic, timely sampling of at least 10 percent of all surgical cases from which the tissue samples have been submitted; as close as is possible to 100 percent review should be sought.

C6.1.2.3.2. Peer review of all permanent tissue sections shall be accomplished in a timely manner, as befitting the respective individual clinical situation. Peer review of all frozen section diagnoses shall be done immediately in any case where major surgery or disfigurement is predicated upon that diagnosis. Where procedures are necessitated at a time when staffing does not exist for immediate peer review of frozen sections, a review of permanent sections shall be made as soon as possible and specifically noted in the audit report.

C6.1.2.4. Invasive Procedure Review. Invasive procedures with potential morbidity shall be reviewed for quality and appropriateness. Such procedures shall include endoscopies, invasive radiologic procedures, and cardiac catheterizations at a minimum. Review shall include comparison of pre- and post-procedure diagnosis and pathologic diagnosis; adverse or unexpected patient reactions and shall address patient notification of results.

C6.1.3. Blood Usage Review

C6.1.3.1. The appropriateness of all transfusions of blood and blood components shall be reviewed using clinically valid screening criteria. When blood usage review consistently supports the justification and appropriateness of blood use, the review of a random sample of cases is acceptable. (The justification and appropriateness of blood use shall be well documented and based on the screening criteria.) Evaluations shall include at least:

C6.1.3.1.1. Blood component use.

C6.1.3.1.2. Each confirmed transfusion reaction, to include clinical management. Possible transfusion reactions must be defined by the medical staff. Hemolytic transfusion reactions involving administration of blood or blood products having major blood group incompatibilities are JCAHO reviewable sentinel events. (See Chapter 7.)

C6.1.3.1.3. Justification for services. Evaluate cross-match-to-transfusion ratio; compare type and screen versus type and cross-match. Single unit transfusions need not be reviewed on a routine basis except where identified as a part of the monitoring and evaluation program. The director of the blood bank shall report any suspected overuse or problem to the appropriate hospital committee.

C6.1.3.1.4. Adequacy of medical staff-approved policies and procedures relating to the distribution, handling, use, and administration of blood and blood components. Policies and procedures shall be reviewed annually.

C6.1.3.1.5. Adequacy of ordering practices for blood and blood products.

C6.1.3.1.6. When sampling is used, all evaluations (see subparagraphs C6.1.3.1.1. through C6.1.3.1.5., above) must be accomplished. Sampling must be statistically representative of cases and departments or services.

C6.1.4. Drug Use Review

C6.1.4.1. This review is designed to evaluate prophylactic, therapeutic, and empiric use to ensure that all drugs, including antibiotics, are used in accordance with guidelines that address appropriateness, safety, and evaluation of effectiveness. Monitoring and evaluating shall be performed in cooperation with the pharmacy service, department of nursing, and other departments and services, as appropriate.

C6.1.4.2. To determine classes of drugs for review, consider whether the drugs are:

C6.1.4.2.1. Used in high volume.

C6.1.4.2.2. Known from medical literature (empiric studies) to pose a significant health risk.

C6.1.4.2.3. Known or are suspected to have a high incidence of adverse reactions with significant health risk.

C6.1.4.2.4. Known to cause or be suspected of causing drug interactions with significant health risk.

C6.1.4.2.5. Used in patients who may be at high risk for adverse reactions because of age, disability or metabolic characteristics.

C6.1.4.2.6. Known to be or are suspected of being especially addictive. Also consider any significant drug issues identified through the infection control program or other QA activities.

C6.1.4.3. Drug dispensing errors, drug administration errors, and untoward reactions associated with administered intravenous additive solutions shall be properly documented and routinely reviewed as a part of ongoing pharmacy and nursing quality assurance programs.

C6.1.4.4. Drug prescription errors by practitioners shall be documented and reviewed.

C6.1.5. Pharmacy and Therapeutics Monitoring. Pharmacy and therapeutics monitoring includes at least:

C6.1.5.1. The development or approval at least annually of policies and procedures relating to the selection, distribution, handling, use, and administration of drugs and diagnostic testing materials.

C6.1.5.2. Review of the drug formulary.

C6.1.5.3. Evaluation and approval of protocols for use of investigational drugs, as appropriate, in coordination with the clinical investigations committee.

C6.1.5.4. The definition and review of all significant untoward drug reactions.

C6.1.6. Medical Record Review. There shall be a system for selection of records for review at regularly scheduled intervals (no less frequently than every quarter).

C6.1.6.1. Inpatient Treatment Records (ITRs)

C6.1.6.1.1. A sample of records shall be reviewed for clinical pertinence; that is, the degree that the ITR reflects the diagnosis, results of diagnostic tests, therapy rendered, condition, and in-hospital progress of the patient, and condition of the patient at discharge. ITRs shall also be reviewed for timely completion. ITRs shall be considered complete when the required contents are assembled and signed.

C6.1.6.1.2. Sampling shall represent the full scope and practice of the MTF, reflect special attention to high-volume and high-risk diagnoses and procedures, and include a representative sample of all practitioners within a 12-month timeframe.

C6.1.6.2. Medical Record Delinquencies. At a minimum, the following delinquencies shall be identified:

C6.1.6.2.1. History and physical not done within 24 hours after admission.

C6.1.6.2.2. Operative report not dictated within 24 hours of the completion of surgery.

C6.1.6.2.3. Narrative summary not dictated within 4 working days of patient discharge.

C6.1.6.2.4. ITR cover sheet (worksheet) not completed within 4 working days of patient discharge.

C6.1.6.2.5. ITRs not completed within 30 days of discharge shall be attributed to either an individual or an institutional problem. Summation of medical record delinquencies data shall be reported on a quarterly basis to the QA or appropriate committee. Appropriate data shall be entered into the provider activity file.

C6.1.6.3. Outpatient Treatment Records (OTRs) and Health Records (HRECs). OTRs and HRECs shall be reviewed for clinical pertinence and completeness (appropriate documentation of visit or episode, including appropriate ICD9, CPT and E/M coding, up-to-date problem list, and diagnostic test results filed).

C6.2. ANESTHESIA REVIEW

This review includes all important aspects of anesthesia care in any department or service of the hospital, including surgical, obstetrical, emergency, ambulatory, and special procedure units. In addition to implementing appropriate professional or specialty standards; for example, the standards adopted by the American Society of

Anesthesiologists, clinically valid criteria shall be generated for at least the following indicators:

C6.2.1. Appropriateness of choice of anesthetic agent.

C6.2.2. Appropriateness of decision to reintubate.

C6.2.3. Appropriateness of length of stay in recovery room.

C6.2.4. Appropriateness of pre- and post-operative visit documentation.

C6.2.5. Anesthesia-related delays in surgery.

C6.2.6. Compliance with infection control policies and procedures.

C6.2.7. Anesthesia complications and management.

C6.3. EMERGENCY MEDICAL SERVICES (EMS)

Also, the quality and appropriateness of care in the major functions of the EMS shall be monitored and evaluated. Examples of indicators are:

C6.3.1. Adherence to protocols or criteria for handling emergencies.

C6.3.2. Review of culture results with patient follow-up to ensure appropriateness of therapy.

C6.3.3. Comparison of the final x-ray report with the initial interpretation by the emergency room physician.

C6.3.4. Review of ambulance records for appropriateness of treatment en route.

C6.3.5. Compliance with infection control policies and procedures.

C6.3.6. Review of referrals.

C6.4. AMBULATORY CARE

The commander shall designate the provider responsible for ensuring that QA activities are implemented. Indicators shall include at least:

C6.4.1. Appropriateness of diagnosis, treatment, and follow-up of frequently seen disease entities.

C6.4.2. Appropriateness of outpatient care provided pre- and post-hospitalization for patients with chronic illnesses.

C6.4.3. Follow-up of abnormal diagnostic tests.

C6.4.4. Availability of radiology, laboratory, and pharmacy services, and the availability of the results of such services in a timely manner.

C6.4.5. Control and monitoring of patients on anticoagulants.

C6.4.6. Compliance with infection control policies and procedures.

C6.4.7. Appropriateness of appointment scheduling (including backlogs) based on the patient's condition.

C6.4.8. Follow-up of patients referred to other facilities to determine that assessment was accomplished in a timely manner.

C6.4.9. Follow-up of the return of OTRs to the servicing MTF to include x-rays of patients referred to other facilities.

C6.5. SPECIAL CARE UNITS

A review of indicators shall include at least:

C6.5.1. Appropriateness of admission to the unit (defined by written criteria).

C6.5.2. Appropriateness of medications and treatment ordered and given.

C6.5.3. Appropriateness of request for consultations.

C6.5.4. Availability of necessary physician and supporting staff.

C6.5.5. Orientation and education programs.

C6.6. OTHER DEPARTMENTS AND SERVICES

There shall be ongoing review and evaluation of activities that are integral to the routine provision of patient care. Critical indicators and criteria, together with benchmarks or outside of established control limits, shall be developed by each department and service for the monitoring of patient care. Review and evaluation of preventive and occupational medicine services shall include activities integral to patient care and those that may impact on patient care or human health.

C6.7. ADVERSE OUTCOMES SCREENING

Adverse outcomes screening is a criteria-based monitoring of patient medical and dental records in order to identify adverse patient outcomes.

C6.7.1. The MTF shall develop active processes to screen inpatient dispositions (including all deaths) to identify any serious adverse events (see Chapter 7), potentially compensable events (see Chapter 8), and other adverse events or near misses (see Chapter 9).

C6.7.2. The organizational performance improvement coordinator shall ensure that each case identified through adverse outcomes screening is referred for appropriation actions, as outlined in Chapters 7 through 9 of this Regulation, and reported to the CCQAS, as required by Chapter 5.

C7. CHAPTER 7

SENTINEL EVENTS REVIEW AND REPORTING

C7.1. PURPOSES OF SENTINEL EVENT POLICY

C7.1.1. Sentinel Events are unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

C7.1.2. It is DoD policy to implement JCAHO recommendations for healthcare organization Sentinel Event Policies. JCAHO recommendations encompass both "JCAHO-Reviewable Sentinel Events" (see section C7.5.), for which the organization's analysis and response are reportable to the JCAHO as part of its accreditation activity, and other Sentinel Events, which, whether or not reviewable by the JCAHO, also signal the need for analysis and assessment of potential system improvements to avoid potential future Sentinel Events. This larger category of Sentinel Events is especially important in the MHS, where overall system management provides the opportunity for lessons learned from one event to benefit the entire system.

C7.1.3. The goals of the policy are four-fold:

C7.1.3.1. To have a positive impact in improving patient care and preventing sentinel events.

C7.1.3.2. To focus the attention of an organization that has experienced a sentinel event on understanding the causes that underlie the event, and on making changes in the organization's systems and processes to reduce the probability of such an event in the future.

C7.1.3.3. To increase the general knowledge about sentinel events, their causes, and strategies for prevention.

C7.1.3.4. To maintain the confidence of the public and the greater DoD community.

C7.1.4. The strategy of the Sentinel Event Policy is to engage the leadership and personnel of the MTF and MHS in reducing such events. When a sentinel event occurs

in a healthcare organization, it is necessary that appropriate individuals within the organization be aware of the event; investigate, and understand the causes that underlie the event; and make changes in the organization's systems and processes to reduce the probability of such an event in the future. The leaders are responsible for establishing processes for the identification, reporting, analysis, and prevention of sentinel events and for ensuring the consistent and effective implementation of a mechanism to accomplish these activities.

C7.1.5. Root Cause Analysis (RCA). The process used for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. An RCA focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that may decrease the possibility of such events in the future or determines after analysis that no such improvement opportunities exist.

C7.1.6. Action Plan. The product of the RCA is an action plan that identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

C7.2. MONITORING PROBLEM-PRONE AREAS

C7.2.1. MTFs shall collect data to monitor the performance of processes where sentinel events have already occurred or are prone to occur.

C7.2.1.1. Organizations select processes that are known to be high-risk, high-volume, problem-prone areas related to the care and services provided. This information is correlated with the listing of frequently occurring sentinel events published by the Joint Commission, the organization's risk-management data, or information about problem-prone processes generated by field-specific or professional organizations.

C7.2.1.2. Organizations select performance measures for processes that may jeopardize the safety of the individuals served or associated with sentinel events in similar health care organizations.

C7.2.2. Undesirable patterns or trends in performance and sentinel events are intensively analyzed.

C7.2.2.1. When the organization detects or suspects significant undesirable performance or variation it initiates intense analysis to determine where best to focus changes for improvement. The organization initiates intense analysis when the comparisons show that:

C7.2.2.1.1. Levels of performance, patterns, or trends vary significantly and undesirably from those expected.

C7.2.2.1.2. Performance varies significantly and undesirably from that of other organizations.

C7.2.2.1.3. Performance varies significantly and undesirably from recognized standards; or

C7.2.2.1.4. When a sentinel event has occurred.

C7.2.2.2. Intense analysis shall also occur for those topics chosen by the leaders as performance-improvement priorities or when undesirable variation occurs that changes the priorities. Intense analysis involves studying a process to learn in greater detail about how it is performed or how it operates.

C7.2.3. An RCA is mandatorily performed and an action plan developed when a sentinel event occurs that results in actual death or serious injury to the patient. MTFs should also consider, although it is not mandatory, conducting an RCA in cases of unexpected occurrences that created a risk of death or serious injury, but did not result in such injury.

C7.3. RCA AND ACTION PLANS

C7.3.1. An RCA has the following characteristics:

C7.3.1.1. The analysis focuses primarily on systems and processes, not individual performance.

C7.3.1.2. The analysis progresses from special causes in clinical processes to common causes in organizational processes.

C7.3.1.3. The analysis repeatedly digs deeper by asking "Why?" then, when answered, "Why?" again, and so on.

C7.3.1.4. The analysis identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of such events occurring in the future.

C7.3.1.5. The analysis is thorough, in that it includes:

C7.3.1.5.1. A determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence.

C7.3.1.5.2. Analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk.

C7.3.1.5.3. Inquiry into all areas appropriate to the specific type of event.

C7.3.1.5.4. Identification of risk points and their potential contributions to this type of event.

C7.3.1.5.5. A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

C7.3.1.6. The analysis is credible, in that it:

C7.3.1.6.1. Includes participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review.

C7.3.1.6.2. Is internally consistent, i.e., does not contradict itself or leave obvious questions unanswered.

C7.3.1.6.3. Provides an explanation for all findings of "not applicable" or "no problem;" and

C7.3.1.6.4. Includes consideration of any relevant literature.

C7.3.2. An action plan has the following characteristics:

C7.3.2.1. It identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes.

C7.3.2.2. Where improvement actions are planned, it identifies who is responsible for implementation, when the action shall be implemented (including any pilot testing), and how the effectiveness of the actions shall be evaluated.

C7.3.3. An RCA and Action Plan shall be completed within 45 days of the MTF becoming aware of the sentinel event, or other time period specified in current JCAHO standards.

C7.3.4. Copies of these RCAs and action plans will be forwarded to the DoD Patient Safety Center within 15 days of completion by the facility for the purpose of consolidation, analysis, and trending to develop lessons learned that can then be shared with the entire MHS. The data provided shall remove all identifying information concerning patients and individual healthcare providers. These copies shall be maintained as confidential quality assurance records in accordance with Chapter 2.

C7.4. JCAHO-REVIEWABLE SENTINEL EVENTS

C7.4.1. Under JCAHO standards, certain sentinel events are reviewable by the JCAHO as part of its accreditation activity. It is DoD policy to comply with JCAHO review procedures concerning the subset of sentinel events designated as reviewable by the JCAHO, and to report all such sentinel events to the JCAHO in accordance with JCAHO procedures.

C7.4.2. JCAHO-Reviewable Sentinel Events are the following:

C7.4.2.1. The event has resulted in an unanticipated death or major permanent loss of function, not primarily related to the natural course of the patient's illness or underlying condition. For this purpose, a major permanent loss of function is a sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. When major permanent loss of function cannot be immediately determined, it shall be determined when either the patient is discharged with continued loss of function, or 2 weeks have elapsed with persistent major loss of function, whichever occurs first.

C7.4.2.2. The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):

C7.4.2.2.1. Suicide of a patient in a setting where the patient receives around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center).

C7.4.2.2.2. Unanticipated death of a full-term infant.

C7.4.2.2.3. Infant abduction or discharge to the wrong family.

C7.4.2.2.4. Sexual assault. For this purpose, sexual assault is unconsented sexual contact involving a patient and another patient, staff member, or unknown perpetrator while being treated or on the premises of the health care facility, including oral, vaginal, or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. The sexual assault shall be determined to have occurred if the sexual contact was witnessed by any staff, is established by sufficient clinical evidence, or is admitted by the involved individual(s).

C7.4.2.2.5. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

C7.4.2.2.6. Surgery on the wrong patient or wrong body part, regardless of the magnitude of the procedure.

C7.4.2.2.7. Any additions to or deletions from this list as reflected by revised JCAHO standards.

C7.5. RESPONSIBILITY FOR SENTINEL EVENTS PROGRAM

The MTF Commander shall assign primary responsibility for implementation of this chapter to a senior physician on the staff of the MTF who is significantly involved in overall QA program activities. This responsibility shall be carried out in coordination with the facility patient safety manager.

C7.6. ASSESSMENT OF SENTINEL EVENTS PROGRAM

C7.6.1. To document the effective operation of the sentinel events program, including the conduct and submission of a root cause analysis on every sentinel event as provided in paragraph C7.2.3., the following procedure shall be followed with respect to compensable events arising from healthcare provided after July 1, 2004:

C7.6.1.1. Upon receiving notice of a malpractice case award or payment in excess of $100,000 associated with a serious adverse event, or notice under subparagraph C10.4.2.1. of a death or disability of a member of the Uniformed Services arising from the provision of medical care, the Surgeon General concerned shall notify the commander of the MTF or other treatment setting at which the event occurred.

C7.6.1.2. The commander receiving such notice shall promptly report to the Surgeon General whether a root cause analysis and action plan had been conducted and submitted in connection with the death or serious injury involved. The Surgeon General shall report the information to the AFIP and the DoD RM Committee.

C7.6.1.3. In the event that no root cause analysis had been performed and submitted, an appropriate analysis of the event shall be conducted and analysis shall be forwarded within 45 days.

C8. CHAPTER 8

RISK MANAGEMENT (RM)

C8.1. RM PROGRAM

An RM program provides for accident and injury prevention and the reduction of the cost of claims and other financial losses. It encompasses not only the reduction of financial loss to the Government, but the reduction of risk to patients presented for diagnosis and treatment, and to visitors, family, and MTF personnel. Events shall be reviewed that present patient risks although they may not present a risk of financial loss because of ineligibility, expiration of a statute of limitation, or fortuitous lack of damage. The overall effectiveness of the program shall be reviewed by the MTF Committee responsible for the QA program.

C8.2. RM PROGRAM IMPLEMENTATION

An RM program shall be implemented at every MTF.

C8.2.1. All serious actual adverse events, whether or not they are compensable, shall be promptly investigated by priority as established by the Risk Manager.

C8.2.2. A system shall be implemented that identifies all actual adverse events. An adverse event occurs when a patient suffers any unintended or unexpected negative result during patient care. Immediate action shall be taken to ensure that the patient is protected from additional injury and to mitigate the untoward effects of the event. The patient shall be informed by the primary provider of the effects of the event on his or her health and the prognosis.

C8.2.3. When an adverse event occurs, the person in charge of the activity where it occurred shall ensure that notification is prepared and submitted to the head of the department, service, or clinic within 24 hours of the occurrence. If death or life-threatening injury has occurred, the commander shall also be notified. Notification shall be forwarded to the risk manager as soon as possible, but in no case later than 48 hours.

C8.2.4. Reports of incidents occurring during weekends or holidays shall be submitted by 0800 the first normal workday. The report shall be factual and objective, giving full details in a concise manner. It shall not contain any analysis or speculations about the cause of the adverse event. The chief of the department, service, or clinic

concerned shall ensure that corrections and follow-up are made. Each adverse event that requires physician or dentist analysis and RM intervention shall be discussed with the chief of the department, service, or clinic concerned.

C8.2.5. RM documents are QA documents and accessible to authorized persons only. They shall never be placed in an individual treatment record.

C8.2.6. Additionally, all actual adverse events related to a patient's condition and treatment shall be entered on pertinent medical records. The entry should describe any evidence of patient injury and what action was taken for the patient. It should not conclude that an adverse event or accident occurred. Reports of other than patient care actual adverse events shall be reviewed by the safety officer. Such reports shall also be referred to other appropriate personnel.

C8.3. HANDLING OF MEDICAL RECORDS

In all cases of potentially compensable events (PCEs) or Federal tort claims, medical records shall be handled in accordance with Military Department procedures and in coordination with designated DoD legal counsel.

C8.4. RM COMMITTEE AND REPORTS

C8.4.1. A committee to perform RM functions shall be established. It shall be multidisciplinary, but consist of a majority of physicians, the risk manager, and the judge advocate/legal counsel.

C8.4.2. Committee minutes or reports shall summarize activities, to include problem trends with recommendations for resolving them, and the status of pending claims and actual adverse events. The minutes or reports shall be processed through the Committee responsible for the QA program. Sensitive information shall not be included in the minutes or reports, but shall be kept on file in the risk manager's office. Practitioner-specific findings shall be reported to the credentials committee.

C8.5. DESIGNATED RISK MANAGER

A risk manager shall be designated in writing at each MTF. The risk manager shall be an officer with the grade of O-4 or above or civilian equivalent, where possible. (The judge advocate and/or legal counsel shall not be the risk manager.) The risk manager shall have competence in RM standards and policy, general RM administration, basic

clinical disease processes, medical terminology, and accident prevention. Competence may be evidenced by appropriate education or by 1 year of practical experience in healthcare RM. The risk manager shall:

C8.5.1. Be a member of the committee that performs RM functions.

C8.5.2. Direct the RM program and report to the committee responsible for the QA program.

C8.5.3. Screen actual adverse events for determination whether or not they require physician analysis and RM intervention.

C8.5.4. Notify the judge advocate/legal counsel within 24 hours of identifying a PCE and coordinate further review and other actions pertinent to the claim or potential claim.

C8.5.5. Systematically analyzes internal hospital data sources (incident reports, medical records, patient care evaluation activities, patient complaints, and so forth) to identify problems and PCEs and determine if actual adverse events could have been avoided. Other reports, such as Inspector General reports, shall also be used, as authorized by applicable regulations.

C8.5.6. Maintain data including QA investigative reports on actual adverse events and claims. These data shall not be maintained by the patient's name. They should be maintained and cross-indexed by date, department or service, or type of event; for example, failure to diagnose cancer. Report appropriate information concerning medical malpractice claims and settlements.

C8.5.7. Coordinate with the QA coordinator.

C8.5.8. Instruct MTF personnel regarding RM policies and procedures.

C8.6. DESIGNATED SENIOR PHYSICIAN

A senior physician shall be designated in each MTF to provide professional medical consultation to the risk manager and judge advocate and/or legal counsel, as needed. For example, the senior physician shall:

C8.6.1. Assist the risk manager in analyzing actual adverse events.

C8.6.2. Provide consultation to the judge advocate and/or legal counsel before and during an investigation of the primary medical issues.

C8.6.3. Arrange reviews by qualified military and civilian medical specialists.

C8.7. PCE

C8.7.1. When an adverse event is determined to be a PCE by the risk manager after consultation with the judge advocate/legal counsel it shall be recorded with reports archived as support for possible future malpractice cases. In addition to the review, attributions, and disposition, the case shall be categorized as follows:

C8.7.1.1. Met standards of care.

C8.7.1.2. Standards of care not met.

C8.7.1.3. Indeterminate.

C8.7.2. The degree of injury or disability shall be graded as follows:

C8.7.2.1. Moderate. Examples include falls with laceration, appendectomy with a single postoperative episode of sepsis, healed forearm fracture with minor angulation, but full range of motion of wrist and elbow, incisional hernia, loss of one testicle, loss of a portion of a finger (other than index or thumb), and fracture of a tooth during anesthesia.

C8.7.2.2. Severe. Examples include a fall with resultant neurological injury, appendectomy with postoperative intra-abdominal abscess, healed forearm fracture with loss of motion in the wrist or elbow, myocardial infarction after surgery, evisceration, postoperative inadvertent retention of a foreign body, loss of one phalanx of a thumb or index finger, anesthetic-related cardiac or respiratory arrest, and loss of life other than in terminal illness.

C8.7.3. All PCEs shall be reported to the CCQAS in accordance with procedures established in Chapter 5.

C8.8. PRODUCTS LIABILITY CASES

In actual or potential products liability cases, the risk manager shall ensure that evidence is preserved.

C8.8.1. This includes actual adverse events in which medical equipment or appliances are involved in an unexpected injury, drug overdose, drug reaction, or an improper prescription. Every effort shall be made to preserve the actual equipment (for example, needles, sponges, supplies, drugs, or packages, along with relevant maintenance and purchase and manufacturer's literature).

C8.8.2. Where operating equipment is involved (for example, respirator, suctioning equipment, or equipment controlling the administration of intravenous fluids), the equipment shall be removed from service and inspected by a qualified Government employee to determine whether there has been a malfunction or a design flaw, and to decide whether an independent appraisal is necessary. The supplier and manufacturer shall be notified and provided an opportunity to inspect (while supervised by a qualified Government employee) the equipment and the actual parts involved. The judge advocate or legal counsel shall be notified prior to any inspection by Government employees, contractor, or supplier employees. The equipment shall not be returned to service prior to inspection except where, in the opinion of the commander, medical necessity requires immediate use. Any parts replaced in the equipment involved shall be secured by the chief, logistic division, for possible evidentiary use. All original maintenance and purchase records shall be secured and photographs taken of the equipment and actual parts involved.

C8.9. DEATH CASES

In cases involving death, immediate attention shall be given to whether an autopsy would aid in determining the role of a therapeutic misadventure as the cause of death. The autopsy should attempt to consider all life-shortening conditions present. Where necessary, consultation with the Armed Forces Medical Examiner is encouraged.

C8.10. ADVERSE EVENT REPORTING

Any adverse event involving significant morbidity or death shall be reported immediately to the next higher headquarters.

C8.11. MALPRACTICE CLAIM

The risk manager shall obtain from the judge advocate and/or legal counsel a copy of each claim alleging malpractice at the MTF.

C9. CHAPTER 9

DoD PATIENT SAFETY PROGRAM (DoD PSP)

C9.1. PURPOSE

C9.1.1. The DoD Patient Safety Program (DoD PSP) identifies and reports centrally actual and potential problems in medical systems and processes and implements effective actions to improve patient safety and healthcare quality throughout the MHS. The DoD PSP, to the extent practicable, emulates the system established for reporting, compilation, and analysis of errors in the provision of healthcare under the DVA healthcare system. The DoD PSP is operated consistent with reference (q).

C9.1.2. This Chapter prescribes procedures to be implemented in every MTF for a dedicated program for avoiding medical errors and improving patient safety that is focused on prevention, not punishment, and on improving medical systems and processes to overcome preventable errors. In its focus on prevention, the DoD PSP supplements the quality assurance reviews of sentinel events under Chapter 7 and potentially compensable events under Chapter 8. In contrast to those activities, DoD PSP activities can concentrate on system improvements.

C9.1.3. The DoD PSP includes the DoD Patient Safety Center (DoD PSC), the DoD Center for Education and Research in Patient Safety (DoD CERPS), and the Healthcare Team Coordination Program.

C9.1.4. Establishes a Patient Safety Executive Council (PSEC) to exercise oversight responsibility of the DoD PSP.

C9.1.5. Establishes a Patient Safety Planning and Coordination Committee (PSPCC) that includes representatives from the TRICARE Management Activity (TMA), the Military Departments, the DoD PSC, the Uniformed Services University of the Health Sciences (USUHS), and Health Affairs. The purpose of the PSPCC is to develop, promote, and support a comprehensive DoD PSP appropriate for the military health system mission(s). The PSPCC shall report to the PSEC.

C9.1.6. Complies with the requirements for confidentiality of medical QA records under Chapter 2 of this Regulation.

C9.2. RESPONSIBILITIES

C9.2.1. The Assistant Secretary of Defense for Health Affairs shall:

C9.2.1.1. Monitor the effectiveness of the DoD PSP and issue such additional guidance as needed.

C9.2.1.2. Grant exceptions to the requirements of this Chapter when indicated by unforeseen circumstances.

C9.2.1.3. Establish appropriate cooperative arrangements between the DoD PSP and the DVA and other patient safety initiatives of the Federal Government, State governments, and appropriate non-government organizations that may promote the mutual success of such activities. Any such cooperative arrangements shall maintain the confidentiality of records and information under Chapter 2 of this Regulation.

C9.2.1.4. Establish a PSEC that includes representatives of the Military Departments, the TMA, the AFIP, the DoD Office of General Counsel, the USUHS, and such other governmental entities as the ASD(HA) determines applicable. The Council shall review the reports from DoD PSC, patient safety initiatives in the Department of Defense, other Federal Agencies and the private sector, and other patient safety issues in the Department of Defense and report to the ASD(HA) no less than once a year on medical safety improvements and recommended policy changes.

C9.2.2. The Secretaries of the Military Departments shall:

C9.2.2.1. Authorize the Surgeons General of the respective Military Departments to participate fully in the DoD PSP, including initiatives to promote the objectives of the program, monitor for inappropriate use of information generated, and provide recommendations to the ASD(HA) for program improvements.

C9.2.2.2. Ensure adequate representation and participation of the Military Departments, assigning appropriate military personnel staff to the DoD PSC.

C9.2.3. The Director, Armed Forces Institute of Pathology shall establish and maintain the DoD PSC, which shall:

C9.2.3.1. Establish and maintain the DoD Patient Safety Registry (DoD PSR) (reference (b)) consistent with this Chapter.

C9.2.3.2. Make all de-identified information in the DoD PSR available to the ASD(HA), the Secretaries of the Military Departments, the Surgeons General, the Director of the TMA, the President of the USUHS, and the MTF Commanders.

C9.2.3.3. Review reports of adverse events, near misses, and RCAs; analyze the data; developing and executing action plans for addressing patterns of patient care errors; review and integrate processes for reducing errors and enhancing patient safety and create and distribute quarterly reports in accordance with paragraph C9.7.2. The execution of action plans shall be through the PSEC.

C9.2.3.4. Coordinate, promote, and perform research to support the DoD PSP and the HCTCP using information maintained by the DoD PSR.

C9.2.3.5. Have authority to contract with a qualified and objective external organization to manage the national patient safety database of the Department of Defense

C9.2.3.6. Provide, through the ASD(HA), to the Agency for Healthcare Research and Quality of the DHHS any reports that the ASD(HA) determines appropriate.

C9.2.3.7. Provide other support for an effective DoD PSP, including such other actions, as the ASD(HA) may direct.

C9.2.4. The Director, TRICARE Management Activity shall:

C9.2.4.1. Support the successful implementation of the DoD PSP.

C9.2.4.2. Establish and provide funding and oversight for the DoD PSC.

C9.2.4.3. Establish and support the HCTCP, a focused effort to improve systems and processes affecting the integration of multiple healthcare disciplines to produce effective communication, coordination, and teamwork in delivering quality healthcare. The HCTCP shall be implemented in phases in all fixed and combat casualty care organizations and in all medical specialty departments and areas. Phasing shall be coordinated through the PSEC to result in DoD-wide phasing at a rate of not less than ten organizations in each fiscal year (FY) and not less than one medical specialty department or area in each FY.

C9.2.4.4. Coordinate with other Federal Agencies on DoD PSP activities, including the DHHS and the Department of Homeland Security, on functions of the

Department of Defense affecting the non-DoD Uniformed Services, the DVA, and the Agency for Healthcare Research and Quality of DHHS.

C9.2.4.5. Monitor patient safety activities of State governments, and non-governmental organizations and include in quarterly reports, as appropriate.

C9.2.4.6. Establish two Centers of Excellence for the development, validation, proliferation, and sustainment of the HCTCP, one of which shall support all fixed military healthcare organizations, the other of which shall support all combat casualty care organizations.

C9.2.5. The President, Uniformed Services University of the Health Sciences, in the operation of education, training, clinical, and research programs of USUHS, shall promote the objectives of the DoD PSP, and establish and maintain the DoD CERPS. The DoD CERPS shall address DoD PSP educational needs and requirements at the undergraduate, postgraduate and staff levels of healthcare practitioners, with particular emphasis on the specific patient safety education and research needs of DoD beneficiaries, command, and administrative staff.

C9.3. MILITARY TREATMENT FACILITY PATIENT SAFETY PROGRAM (MTF PSP)

C9.3.1. Functions of the MTF PSP. The Commander of every MTF shall establish and implement a PSP consistent with this Chapter and applicable Service regulations. The administration of the MTF PSP shall be through a MTF Patient Safety Office or Directorate (MTFPSO/D), which shall function as an integral part of the QA and improvement process of the MTF. The MTFPSP shall have procedures and standards for the following activities:

C9.3.1.1. Receipt from clinical and administrative staff and patients or their families of reports of adverse events and near misses.

C9.3.1.2. Analysis or review of reports of adverse events and near misses, including preparation of written findings and recommendations on potential improvements in systems and processes to reduce the frequency and severity of medical errors.

C9.3.1.3. Prospective analysis and risk assessment.

C9.3.1.4. Prompt acknowledgement of reports received and timely feedback to staff making reports of actions planned to improve patient safety.

C9.3.1.5. Initiation of actions, through administrative staff, clinical staff and senior management, intended to improve patient safety with subsequent follow-up evaluation of their effectiveness.

C9.3.1.6. Compiling, maintaining, and using data to identify additional opportunities to improve patient safety.

C9.3.1.7. Submission of information and reports from the MTF to the DoD PSR in the DoD PSC at the AFIP.

C9.3.2. The MTF commander shall designate an individual as the Patient Safety Manager (PSM) to direct the MTF PSP and shall ensure that program activities receive interdisciplinary support from the MTF staff and other support necessary for an effective program. The PSM and other personnel designated by the MTF commander shall receive DoD PSP curriculum training from the DoD PSP.

C9.3.3. All clinical and administrative personnel shall be educated about the DoD PSP and the MTF-related activities, encouraged to report adverse events, sentinel events, and near misses, to support program activities, and be given periodic updates on its procedures and activities.

C9.3.4. Medical team programs emphasizing communication, coordination, and teamwork techniques shall be included in the overall education program.

C9.4. JOINT COMMISSION OF ACCREDITATION OF HEALTHCARE ORGANIZATION (JCAHO) STANDARDS

MTFs shall comply with current JCAHO Patient Safety Goals.

C9.5. CONDUCTING AN RCA

C9.5.1. The MTF shall include an RCA and action plan of all sentinel events that cause injury. (See Chapter 7.) The MTFs are encouraged to conduct RCAs on other adverse events and near misses that they deem necessary. With respect to near miss cases, consideration should especially be given to cases suggesting a potential for death or serious injury to a patient.

C9.5.2. The RCA and action plan shall include written findings regarding the underlying systems and processes involved in the event, including the identification of

actual and potential problems in those systems and processes, and recommendations for corrective action plans. The RCA and action plan shall be completed and approved by the MTF commander within 45 days of the MTF becoming aware of the sentinel event, or other time period specified in current JCAHO standards.

C9.5.3. The RCA and action plan shall be provided to the MTF official(s) with responsibility for the systems or processes involved so they may implement and evaluate the effectiveness of corrective actions.

C9.5.4. RCAs are conducted for improving medical systems and processes, not for personnel management. Although consideration of information discovered in the course of RCAs for personnel management matters is not prohibited, MTF commanders, credential, and/or privileging committees, medical malpractice claims peer review committees, and other entities charged with oversight of professional behavior and competence shall rely to the maximum extent practicable on information from other review systems and processes for those purposes. Limiting the use of MTF PSP information to improve systems and processes is essential for promoting maximum staff support for and participation in the MTF PSP.

C9.6. INTENTIONAL UNSAFE ACTS

C9.6.1. The investigation of and consideration of corrective actions on intentional unsafe acts are not within the primary authority or responsibility of the DoD PSP. If in the course of the activities of the PSP, information about intentional unsafe acts is revealed, the original report shall be referred to applicable command authorities. Primary authority to investigate and consider corrective actions on the matter shall be outside the DoD PSP.

C9.6.2. Findings of intentional unsafe acts that result from gross negligence or possible criminal activity shall be reported by the command authorities to the applicable military criminal investigative organization, and the Defense Criminal Investigative Service, Office of the Inspector General, Department of Defense.

C9.6.3. Some events meet the definitions of both "adverse events" and "intentional unsafe acts." When an event appears to be both an "adverse event" and an "intentional unsafe act," primary authority and responsibility is outside the DoD PSP. The DoD PSP shall proceed with a review, including an RCA, if applicable, of the systems and processes of the facility implicated in the actual or potential intentional unsafe act, but shall defer to the separate investigation and consideration on any matter of culpability of any person involved in the act.

C9.7. REPORTING TO THE DoD PSC

The manager of the MTFPSO/D shall submit regular reports (at least on a quarterly basis) to the DoD PSC, in accordance with guidance in Appendix 1.

C9.7.1. The report(s) shall include a numerical summary of all adverse events and near misses reported, copies of all mandatory RCAs completed during the reporting period and associated action plans; and a report on other actions taken by the MTF based on lessons learned under the MTF PSP. The MTFs are encouraged to submit all other RCAs.

C9.7.2. The data elements at Appendix 1 shall be used. Those elements may be changed by the ASD(HA) by memorandum.

C9.7.3. The reports and other information submitted to the DoD PSC shall not include names or other identifying information on patients, healthcare staff, or facilities. All information received by the DoD PSC shall be de-identified before entry into the registry.

C9.8. ADMINISTRATION OF THE DoD PSC

C9.8.1. The information reported to the DoD PSC shall be used exclusively for improving healthcare systems and processes that impact on medical errors and patient safety. DoD PSC information shall not be used for any adverse administrative, privileging or other personnel actions.

C9.8.2. Analysis of the de-identified information submitted to the DoD PSC shall be used to provide quarterly reports to the ASD(HA), the Secretaries of the Military Departments, the Surgeons General of the Military Departments, the Director of the TMA, the President of the USUHS, and each MTF commander. In coordination with the PSEC, information reported to the DoD PSC shall be used to develop and execute action plans for addressing patterns of actual or potential patient care errors and to promulgate patient safety standards for the Department of Defense.

C9.8.3. Confidentiality of Records and Information of the PSP. All records and information of the DoD PSP, including those at each MTF, at the DoD PSC, stored in the DoD PSR, and at all other levels of the Department of Defense, are medical QA records and are confidential under Chapter 2 of this Regulation. Aggregate statistical information at the DoD-wide, Service-wide or MTF levels may be provided consistent with that Chapter.

C9.9. INFORMATION REQUIREMENTS

The MTF PSP Reports required by this Regulation have been assigned Report Control Symbol DD-HA(M)2129, DoD PSR Near Misses and Adverse Events Reports in accordance with DoD 8910.1-M (reference (r)).

C10. CHAPTER 10

NATIONAL PRACTITIONER DATA BANK (NPDB)

C10.1. PURPOSE

C10.1.1. The Health Care Quality Improvement Act of 1986, as amended (reference (f)), established an alert system to facilitate a comprehensive review of healthcare practitioners' professional credentials and create a data bank of medical malpractice payments, adverse licensure actions, adverse clinical privilege actions, adverse professional membership actions and Medicare/Medicaid exclusion reports. This data bank, known as the National Practitioner Data Bank (NPDB) is governed by the regulations of DHHS (45 CFR Part 60, reference (s)).

C10.1.2. The Department of Defense is required to report to the NPDB medical malpractice payments; professional review actions that adversely affect a physician's or a dentist's, or other healthcare provider's clinical privileges for more than 30 days; and the acceptance of a healthcare provider's surrender or restriction of clinical privileges while under investigation for possible professional incompetence or improper professional conduct, or in return for not conducting an investigation or professional review action. Revisions to such actions must also be reported.

C10.1.3. This Chapter establishes requirements and procedures for DoD participation in the NPDB. It applies to all healthcare personnel who are in professions required to possess a license under Chapter 4.

C10.2. QUALITY OF CARE REVIEW OF POTENTIAL INSTANCES OF MEDICAL MALPRACTICE

C10.2.1. A quality of care review shall occur in every case involving a potential instance of medical malpractice. This includes every claim of alleged malpractice filed under the Federal Tort Claims Act (reference (c)), the Military Claims Act or the Foreign Claims Act (10 U.S.C. Chapter 163) (reference (d)) relating to healthcare provided by a DoD facility or provider. It also includes every report from a Medical Evaluation Board operating under DoD Instruction 1332.38 (reference (t)) of a case in which disability of a military member appears to have resulted from medical or dental care.

C10.2.2. Except in cases clearly lacking a substantive basis for evaluation, the quality of care review shall include a professional review of the care and an opinion as

to whether the standard of care was met or not met, an evaluation of any other processes and factors relating to the case, and a reasonable opportunity for the practitioners significantly involved to provide written comments. The opportunity for a significantly involved practitioner to provide written comments is not part of any formal proceeding or adverse action process and no due process procedures apply to this opportunity to comment.

C10.3. REPORTING PAID MALPRACTICE CASES

C10.3.1. A report shall be made to the NPDB in the name of the practitioner when a malpractice payment is made for the benefit of a healthcare practitioner.

C10.3.2. When a malpractice payment is made it is presumed to be made for the benefit of a healthcare practitioner. This presumption becomes conclusive 180 days after the Surgeon General concerned receives notice of such payment unless, prior to that date, the Surgeon General makes a final determination that the malpractice payment was not caused by the failure of any practitioner(s) significantly involved to meet the standard of care. Every effort must be made to provide adequate clinical and administrative resources to review these cases to prevent the required reporting of cases where, in fact, it is determined that the standard of care was indeed met, but that the determination exceeded the 180-day period.

C10.3.3. The process the Surgeon General uses for the final determination (referred in paragraph C10.3.2. with additional requirements established in section C10.5.) is as follows:

C10.3.3.1. The Surgeon General makes a preliminary determination whether the malpractice payment was or was not caused by the failure of one or more practitioners to meet the standard of care. The preliminary determination is based on the results of the quality assurance review referred to in section C10.2., available summary information concerning the disposition of the claim (whether an administrative settlement from the claims service involved, a litigation settlement obtained by the Department of Justice, or a litigation judgment), and information and comments provided by the involved providers.

C10.3.3.2. If the Surgeon General's preliminary decision is that the malpractice payment was not caused by the failure of any practitioner to meet the standard of care, the case file, including all relevant information, shall be forwarded for external peer review to the peer reviewer, external to the Department of Defense, designated by the ASD(HA). This includes cases in which the preliminary decision is

"system problems," instead of the failure of significantly involved practitioners to meet the professional standard of care, were responsible for the malpractice payment. The external peer reviewer shall provide to the Surgeon General an opinion on whether or not the standard of care was met for each involved provider and address the issue of causation. A copy of the report shall also be forwarded to the Department of Legal Medicine of the AFIP; including the reviewer's Curriculum Vitae and other pertinent information.

10.3.3.3. Based on the preliminary determination and the external peer review opinion, the Surgeon General shall make a final determination on whether or not the malpractice payment was caused by the failure of any practitioner to meet the standard of care. If the Surgeon General's final determination is that the malpractice payment was not caused by the failure of any practitioner to meet the standard of care, the presumption referred to in paragraph C10.3.2. is overcome and no report is made to the NPDB.

C10.3.3.4. In any case the 180-day period referred to in paragraph C10.3.2. expires without the Surgeon General concerned making a final determination that the malpractice payment was not caused by the failure of any practitioner(s) to meet the standard of care, a report shall be made in the name(s) of the significantly involved practitioner(s). If thereafter, the Surgeon General concerned makes a final determination that the malpractice payment was not caused by the failure of such practitioner(s) to meet the standard of care the report shall not be removed. It shall be amended by adding a comment that the Surgeon General determined that the malpractice payment was not caused by the failure of the practitioner to meet the standard of care.

C10.3.4. The Surgeons General shall provide quarterly to the DoD RM Committee for review, management information outlining the number of malpractice payments, the number and results of external peer review, the number of reports submitted to the NPDB, timeliness of the reports, any backlog, and any problems with reporting.

C10.4. REPORTING FERES-BARRED CASES TO THE DEFENSE PRACTITIONER DATA BANK (DPDB)

C10.4.1. When a determination is made that disability system or other payments shall be made because of personal injury or death of a member of a Uniformed Service caused by the failure of a practitioner to meet the professional standard of care, a report shall be entered by the Surgeon General into the disability sub-module of the Risk Management module of the CCQAS in the name of the practitioner.

C10.4.2. In any case of specific, credible evidence that a report should be made under paragraph C10.4.1., a presumption is created that a report is required. This presumption becomes conclusive in 180 days unless prior to that date the Surgeon General makes a final determination that the standard of care was met by the practitioner(s) significantly involved.

C10.4.2.1. Specific credible evidence exists when the following occur:

C10.4.2.1.1. A Medical Evaluation Board (MEB) reports to the Surgeon General concerned that a member whose medical impairments require referral to a Physical Evaluation Board under reference (t) may have incurred such impairments as a result of medical care provided in a MTF and such impairments are subsequently determined to require separation or retirement of the member because of physical disability. The 180-day period referred to in paragraph C10.4.2. begins on the date of such separation or retirement. The MEB shall report the case, together with full documentation, to the Surgeon General concerned. The senior medical officer of the MEB shall be responsible to ensure that cases covered by this paragraph are reported to the Surgeon General concerned.

C10.4.2.1.2. A medical examiner designated by the Armed Forces Medical Examiner under reference (b) determines that a member may have died as a result of medical care provided in a medical treatment facility and/or dental treatment facility and reports such determination to the Surgeon General concerned. The 180-day period discussed in paragraph C10.4.2. begins on the date of the medical examiner's report. The medical examiner shall report such determination, together with full documentation, to the Surgeon General concerned.

C10.4.2.2. A Surgeon General concerned otherwise becomes aware of circumstances indicating the probability that the disability system shall be utilized or other payments shall be made because of personal injury or death of a member of a Uniformed Service caused by the failure of a practitioner to meet the professional standard of care.

C10.4.3. The process for the Surgeon General to make the final determination discussed in paragraph C10.4.2. shall be comparable to the process established by paragraph C10.3.3. for malpractice payment cases (although the case file does not include tort claim information). The process shall include external peer review. Any report, when required, is made to the CCQAS (DPDB), rather than the NPDB. The additional requirements of section C10.5. shall also apply.

C10.4.4. During credentials and prospective clinical privileges evaluations of practitioners, MTF commanders shall review data concerning determinations of personal injury or death of a member of a Uniformed Service caused by the failure of a practitioner to meet the professional standard of care.

C10.5. ADDITIONAL REQUIREMENTS FOR PAYMENT CASE REPORTS

The following additional requirements apply to the reporting processes established under sections C10.3. and C10.4.

C10.5.1. When a healthcare trainee is a significantly involved practitioner subject to a report under section C10.3. or C10.4., the attending practitioner responsible (not the trainee) for the delivered care shall be reported to the NPDB and DPDB. If the Surgeon General makes a specific finding that the attending practitioner clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending practitioner, then the trainee (not the attending practitioner) shall be reported to the NPDB and DPDB.

C10.5.2. In general, responsibilities of a Surgeon General under sections C10.3., C10.4., and paragraph C10.5.1. may be delegated to one or more senior officers in the Surgeon General's chain of command. When the external peer review opinion is that the practitioner did not meet the standard of care, the authority to make a final decision may only be exercised by the Surgeon General and may not be delegated. Any such decision shall be reported to the ASD(HA).

C10.5.3. Confidentiality of External Peer Review Opinion. External peer review reports under sections C10.3. and C10.4. are confidential quality assurance records under reference (d) and Chapter 2 of this Regulation. The reports may be used and disclosed only as authorized therein.

C10.5.4. Each Surgeon General shall make an annual summary report to the Chairman of the Department of Legal Medicine of the AFIP, as directed by the ASD(HA), regarding determinations made under sections C10.3. and C10.4.

C10.6. REPORTS TO THE NPDB AND DPDB OF ADVERSE PRIVILEGING ACTIONS

Reports shall be made to the NPDB and the CCQAS (DPDB) in cases of adverse privileging actions in accordance with the following:

C10.6.1. The Surgeon General shall report to NPDB and the CCQAS (DPDB) all final adverse privileging actions consistent with the NPDB reporting. Reporting shall occur within 30 calendar days of the date of Surgeon General approves the adverse privileging action.

C10.6.2. The Surgeon General shall report adverse privileging actions taken against providers with alcohol and/or chemical-related impairments who do not self-refer into a rehabilitation program, or those who self-refer, but do not complete the rehabilitation program.

C10.6.3. The Surgeons General shall provide, at least annually to the DoD RM Committee for review, management information outlining the number of adverse privileging actions taken, the number reported to the NPDB, the timeliness of the reports, any backlog, and any problems with reporting.

C10.6.4. Practitioners shall have benefit of due process procedures for professional review activities under requirements of the Military Departments' regulations and healthcare entity professional staff by-laws in cases of adverse clinical privileging actions.

C10.6.5. Information on professional review actions or adverse privileging actions for healthcare practitioners shall be reported to the appropriate State licensing boards, professional boards, Federation of State Medical Boards, the NPDB, and the DPDB.

C10.6.6. Privileging actions resulting from a provider's medical disability that affects or could affect adversely the health or welfare of a patient or patients shall be reported to the NPDB.

C10.6.7. A practitioner who separates from active duty or whose business relationship with the Department of Defense ends, and whose clinical privileges are suspended at the time, shall be reported to the NPDB and appropriate State licensing boards. Clarifying or correcting notification of the NPDB and State licensing boards shall be made, if indicated, following completion of hearing procedures.

C10.7. QUERYING THE NPDB/HIPDB

The NPDB/HIPDB shall be queried during the accessioning process of healthcare providers, and at least every 24 months thereafter as part of the re-privileging process. The DPDB shall be queried at the time of renewal of privileges.

C10.8. OTHER REPORTS TO THE DPDB

The Surgeons General shall enter into the CCQAS (DPDB) such other information concerning malpractice claims and related activities as the ASD(HA) may direct.

C10.9. RESPONSIBILITIES

C10.9.1. The Military Services shall be responsible for the following:

C10.9.1.1. Healthcare entity clinical privileging and malpractice reports shall be forwarded, through intermediate and higher commands, to the Office of the Surgeon General (OTSG) via electronic entry of data elements into the CCQAS.

C10.9.1.2. The OTSG shall complete and send the appropriate electronic forms to the NPDB. The OTSG shall enter into the CCQAS all medical malpractice claims, both filed and paid, and all adverse actions for electronic monitoring by the Department of Legal Medicine of the AFIP.

C10.9.1.3. MTF commanders shall ensure that the NPDB has been queried during the initial credentialing for a healthcare provider and is queried at least every 24 months thereafter or whenever privileges are granted or changed. Information from those queries shall be given to all facilities to which the provider is ordered for either permanent or temporary duty during the 24 months.

C10.9.1.4. Permission shall be withdrawn from a provider who had previously been granted permission to engage in off-duty employment, and who is either appealing a decision to limit or suspend part or all of his or her clinical privileges or the decision to not fully restore clinical privileges. The provider shall be notified of such withdrawal. No new permission shall be granted during the appeal process. Additionally, the appropriate officials at the place of employment shall be notified that permission to engage in off-duty employment has been withdrawn.

C10.9.1.5. When a report is sent to the NPDB or the DPDB under this Chapter, a copy shall be provided to the healthcare professional, unless he or she cannot be located with reasonable effort.

C10.9.2. The AFIP (Department of Legal Medicine) shall electronically monitor and analyze the data reported to the CCQAS (DPDB).

C10.9.2.1. The DPDB shall consist of the risk management and adverse action modules of the CCQAS. Data maintained in the CCQAS and the DPDB are medical quality assurance records under 10 U.S.C.1102 (reference (d)) and shall be maintained confidential in accordance with Chapter 2 of this Regulation.

C10.9.2.2. The Department of Legal Medicine shall establish, maintain, and submit to the OASD(HA) on a regular basis or as requested, statistical information and reports on all available administrative or completed legal cases that arise from allegations of negligence in DoD MTFs or activities. Data describing adverse clinical privilege actions taken against military healthcare providers shall be, likewise, analyzed and reported to the OASD(HA). These reports shall consist of RM data and adverse clinical privilege action data and shall be shared with the DoD TRICARE Quality Council through the DoD RM Committee.

C10.9.2.3. The professional staff in the Department of Legal Medicine shall conduct analyses and research on DPDB data to assist the OASD(HA) in implementing policy changes designed to improve the quality of healthcare. The Department of Legal Medicine shall provide assistance in educational programs, reports, and publications that shall assist Federal healthcare providers in meeting continuing medical education requirements in RM and selected areas of quality improvement.

C10.9.2.4. The Department of Legal Medicine shall maintain a registry of closed malpractice files. This shall include all Standard Forms 95 and associated legal documents and medical (dental) records.

C10.9.2.5. The Department of Legal Medicine shall maintain a collaborative relationship with the U.S. Department of the Treasury, and obtain monthly paid claim information from the Financial Management Service, Judgment Fund Branch of the Treasury. The Department of Legal Medicine shall report to the three Offices of the Surgeon General as well as the interested legal parties within the Department of Defense and the Department of Justice.

C10.9.2.6. The Department of Legal Medicine shall monitor the reports performed by external review.

C10.9.2.7. The Department of Legal Medicine shall collaborate to the extent possible with other Federal Agencies and the private sector in order to obtain and develop appropriate civilian medical malpractice data for use by the Department of Defense.

C10.9.3. The DoD RM Committee shall be the primary oversight body of OASD(HA)/TMA for monitoring reporting of malpractice and adverse privileging actions to the NPDB and the DPDB.

C10.10. INFORMATION REQUIREMENTS

C10.10.1. Information reported to the NPDB shall be submitted through the Integrated Query and Reporting Service over the World Wide Web, which may be accessed at www.npdb.hipdb.com. Paper forms are no longer accepted for processing. Complete the below listed forms as appropriate: HRSA-529 (3/90), "Medical Malpractice Payment Report," HRSA-530 (3/90), "Adverse Action Report," or HRSA-531 (3/90), "Additional Information." Requests for information from the NPDB shall be by use of HRSA-532 (3/90), "Request for Information Disclosure," and/or HRSA-532-1 (3/90), "Request for Information Disclosure - Supplement."

C10.10.2. Reports to Department of Legal Medicine at the AFIP shall be submitted through electronic means via the CCQAS.

C11. CHAPTER 11

HEALTHCARE INTEGRITY AND PROTECTION DATA BANK (HIPDB)

C11.1. PURPOSE

C11.1.1. The HIPDB is a fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against healthcare providers, suppliers, or practitioners. The HIPDB is governed by the regulations of the DHHS (reference (u)).

C11.1.2. The Department of Defense is required by the statute to report to the HIPDB a broad range of "adverse actions" affecting DoD healthcare personnel, as well as the civilian provider community involved in TRICARE.

C11.2. REPORTS BY SURGEONS GENERAL OF THE MILITARY DEPARTMENTS

C11.2.1. Reporting Responsibility. The Surgeons General shall be responsible for reports regarding reportable adverse actions taken against healthcare providers, suppliers, or practitioners providing healthcare services to active duty members or any other MHS beneficiaries in MTFs or as part of any military unit.

C11.2.2. Reportable Adverse Actions. The following adverse actions taken against healthcare providers, suppliers, or practitioners are reportable:

C11.2.2.1. UCMJ Actions. Convictions under the UCMJ (reference (d)), as approved by the Court Martial convening authority, or final non-judicial punishment under the UCMJ, of a healthcare provider, supplier, or practitioner in a case in which the acts or omissions of the member convicted were related to the delivery of a healthcare item or service.

C11.2.2.2. Other Adjudicated Actions or Decisions. The following actions are reportable if they are against a healthcare provider, supplier, or practitioner based on acts or omissions that affect the payment, provision or delivery of a healthcare item or service:

C11.2.2.2.1. Adverse Personnel Actions Affecting Military Members. Any administrative action resulting in separation, reduction in grade, involuntary military occupational specialty reclassification, or other administrative action.

C11.2.2.2.2. Adverse Civilian Personnel Actions. Any adverse personnel action under Chapter 75 of title 5, United States Code (reference (v)).

C11.2.2.2.3. Contract Termination for Default. A contract termination for default taken by a MTF or medical command against a personal services or non-personal services contractor.

C11.2.2.3. Actions Not Included. Clinical privileging actions are excluded from the reporting requirement of this Chapter. Rather, such actions are reportable to the separate NPDB. (See Chapter 10 of this Regulation.)

C11.2.2.4. Reports to the HIPDB by the Surgeons General shall also be entered into the CCQAS to be electronically monitored by the Department of Legal Medicine of the AFIP. Data maintained by the Department of Legal Medicine concerning HIPDB reports are medical quality assurance records under 10 U.S.C. 1102 (reference (d)) and shall be maintained confidential in accordance with Chapter 2 of this Regulation.

C11.3. REPORTS BY THE DIRECTOR, TRICARE MANAGEMENT ACTIVITY

C11.3.1. Reporting Responsibility. The Director, TMA shall be responsible to report healthcare providers, suppliers, or practitioners excluded from participating in CHAMPUS/TRICARE.

C11.3.2. Reportable Adverse Actions

C11.3.2.1. Exclusions. Exclusion of any healthcare provider, supplier, or practitioner from CHAMPUS/TRICARE.

C11.3.2.2. Actions Not Included. Actions taken by TRICARE contractors concerning the establishment and operation of preferred provider networks are not reportable by the Director, TMA. However, they may be reportable by the contractor to the HIPDB.

C11.4. REPORTS CONCERNING CONTRACT DEBARMENTS AND SUSPENSIONS

C11.4.1. Reporting Responsibility. Designated debarring officials of the Military Departments and the Defense Logistics Agency shall report to the HIPDB any contract debarments or suspensions arising from any DoD healthcare program contracts with any healthcare provider, supplier or practitioner.

C11.4.2. Reportable Actions. Any contract debarment or suspension taken under Part 209 of the Defense Federal Acquisition Regulation Supplement (reference (w)) by a Military Department or the Defense Logistics Agency arising from any DoD healthcare program contract with any healthcare provider, supplier, or practitioner.

C11.5. COOPERATION REGARDING HIPDB REPORTS BY OTHER AGENCIES

The HIPDB also requires reports from licensing and certification agencies of adverse licensure and certification actions, Federal and State prosecutors of criminal convictions, and Federal and State attorneys and health plans of certain civil judgments (excluding medical malpractice judgments) against providers, suppliers and practitioners. The submission of such reports, including any such reports relating to the DoD healthcare program, are the responsibility of officials of the Department of Justice or other agencies or entities. In any such cases, it is the policy of the Department of Defense to cooperate, to the extent allowed by law, in the information collection and other processes involved in complying with the HIPDB reporting obligations.

C11.6. PROCEDURES

The DHHS Regulations (reference (u)) includes procedures for subjects of HIPDB reports to dispute the accuracy of reports. The DoD Components shall make reports to the HIPDB and review requests from subjects to modify such reports based on the standards contained in DHHS Regulations. Determinations by the Department of Defense on making reports or deciding whether to amend reports are made as a function of complying with regulatory requirements applicable to the Department of Defense. Such determinations are not due process proceedings for which the subject has any right of notice or participation beyond that if any which was provided or available in connection with the underlying adverse action being reported.

C11.7. EFFECTIVE DATE FOR REPORTING PURPOSES

The DHHS requires reporting of reportable actions occurring on or after August 21, 1996.

C11.8. METHODS AND PROCEDURES FOR REPORTS TO THE HIPDB

In filing reports with the HIPDB, the DoD Components shall follow the methods and procedures of the HIPDB. These procedures are outlined at www.bhpr.hrsa.gov/dqa.

AP1. APPENDIX 1

DoD ROOT CAUSE ANALYSIS (RCA) DATA ELEMENTS

DoD Root Cause Analysis (RCA) DATA ELEMENTS

1. **DoD Service** ☐ Army ☐ Navy ☐ Air Force
2. **Facility Size** ☐ Ambulatory (No beds) ☐ 1-50 Beds ☐ 51-100 Beds ☐ 101-200 Beds ☐ >200 Beds
3. **Location where event occurred** ***click on box*** Acute Care Unit; Hospital Room
4. **Facility Type** ☐ Teaching facility ☐ Non-teaching facility
5. **Event Type** ☐ Near Miss ☐ Actual Event ☐ Reportable Sentinel Event
6. **Safety Assessment Code (SAC) -**
   - ☐ Score based on "actual" outcome of this event
   - ☐ (Optional) Score based on "potential/risk thereof" outcome of this event
7. **Event Classification** ***click on box*** Assault
8. **Patient Information**
   Status: ☐ Active Duty ☐ Other
   Age: ☐ ***click on box*** Years Gender: ☐ Male ☐ Female
9. **Immediate Actions**
   There are a variety of actions that may need to be taken immediately following an event. If an action is not relevant or appropriate for this event just check the "N/A" option and move on to the next item.

   Provided immediate care/treatment to the individuals involved in the event (this includes patients, staff or visitors)
   ☐ Yes, Date: ☐ (ex. 15-MAR-03) ☐ No ☐ N/A
   Briefly describe the type of care/treatment that was provided:
   _____

   Made the situation safe and immediately prevented recurrence.
   ☐ Yes, Date: ☐ (ex. 15-MAR-03) ☐ No ☐ N/A
   Describe actions taken to make the situation safe and prevent recurrence:
   ☐

Physically removed specific equipment or supplies that malfunctioned.

Yes, Date: ____ (ex. 15-MAR-03) ☐ No ☐ N/A

Describe which items were removed and what interventions were taken (e.g. stored with evidence, sent to engineering for evaluation, contacted manufacturer) :

____

Notified Top Management (e.g., MTF Commander or equivalent)

☐ Yes, Date: ____ (ex. 15-MAR-03) ☐ No ☐ N/A

Who was notified: ____

Initial notification to the AFIP Patient Safety Center indicating a DoD or nation-wide "alert" may be necessary. (Note: An "alert" is a written bulletin that provides a "warning" or "heads up" to other facilities.)

☐ Yes, Date e-mailed: ____ (ex. 15-MAR-03) ☐ No ☐ N/A

10. Has this type of adverse event or near miss occurred before?

☐ Yes, Date ____ (ex. 15-MAR-03) ☐ No

If yes, were corrective actions developed and implemented? ☐ Yes ☐ No

If yes, describe previous actions: ____

Did previous actions have any effect on event? ☐ Yes ☐ No

If yes, ☐ Minimized the outcome or ☐ Contributed to reoccurrence

Describe the effect: ____

11. Resources. List the involved services/departments, information needed by the team
(e.g., policies, procedures, reports, regulations, medical records, committee minutes)

Information Needed	Service/Department	Responsible Team Member	Due Date

12. **Personnel Needed.** List those providing information to the team (e.g., interviewees)

Title	Date

13. **Understanding of Events.** What is the team's final interpretation of what actually happened - what was the sequence of events/factors – that ultimately resulted in the event or near miss.

Attach a copy of TapRoot *INCIDENT REPORT* ***and TapRoot*** *FINAL FLOW CHART*

14. **Root Cause/Contributing Factor Table.**
Each root cause/contributing factor displayed in the table must be addressed again in the action plan. Please document all areas reviewed in the ***JCAHO matrix.***

Attach a copy of TapRoot *ROOT CAUSE/ CONTRIBUTING FACTOR TABLE*

15. **RCA Team Plan Table.** Display and describe recommended actions resulting from this RCA. Develop one or more actions for each root cause/contributing factor previously identified in the root cause/contributing factor table.

It is anticipated that the RCA Advisor will be involved with the RCA Team and facility top management in determining the final close-out for each root cause/ contributing factor. In the event that top management does not concur with a proposed action developed by the RCA team, an alternative action will be developed and documented on the revised RCA plan.

Attach a copy of TapRoot *RCA TEAM ACTION PLAN TABLE*

16. **RCA Concurrence.** Note the names of the approving officials, and obtain signatures and dates of concurrence with the RCA Team Plan.

Final sign-off will include, at a minimum, the MTF Commander and the Risk Manager.

Name/Signature	Title	Date