DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

BUMEDINST 6010.13A
BUMED-N10
22 Jan 2026

BUMED INSTRUCTION 6010.13A

From: Chief, Bureau of Medicine and Surgery

Subj: MEDICAL QUALITY ASSURANCE PROGRAM AND CLINICAL QUALITY MANAGEMENT PROGRAM

Ref: See Enclosure (1)

Encl: (1) References
(2) Glossary - Definitions
(3) Credentials and Clinical Privileges
(4) Adverse Event Reporting Requirements
(5) Clinical Adverse Actions
(6) Joint Patient Safety Program
(7) Healthcare Resolutions Program
(8) Healthcare Risk Management Program
(9) Patient's Right to Be Heard

1. Purpose. To establish Bureau of Medicine and Surgery (BUMED) policy, assign responsibility, and prescribe procedures for operational Medical Quality Assurance (MQA) and Clinical Quality Management (CQM) in the Navy and Marine Corps. This instruction assigns responsibility and prescribes procedures for complying with references (a) through (t). This instruction is guided by MQA and CQM strategy elements and supported by CQM functions and programs. This instruction affirms the Department of the Navy's (DON) unwavering commitment to the delivery of quality health care by Navy Medicine (NAVMED) personnel. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. BUMEDINST 6010.13.

3. Scope and Applicability. This instruction applies to Navy and Marine Corps operational clinical healthcare services, regardless of platform type or installation. It is applicable to all Active duty and Reserve healthcare providers, privileged, non-privileged, and unlicensed staff who work under a scope of practice or are supervised (directly or indirectly) by a licensed health care provider (e.g., corpsman, independent duty corpsman).

4. Background. The Secretary of the Navy (SECNAV) has policy oversight of the MQA and CQM programs within the DON. The Surgeon General of the Navy serves as the principal advisor to SECNAV on all health and medical matters of the Navy and Marine Corps, including policy development relating to such matters per reference (a). Chief of Naval Operations (CNO) and the Commandant of the Marine Corps (CMC) are committed to continuously improving the

quality of medical and dental care provided to all DON personnel regardless of assignment. MQA and CQM provide an organized structure for an integrated framework of programs to objectively define, measure, assure, and improve the quality of health care in any operational setting where NAVMED personnel deliver health care.

5. Policy. DON ensures all active duty, Reserve, and civilian medical, dental, and contract personnel under the operational control of the Surgeon General of the Navy, will participate in ongoing monitoring and evaluation processes designed to assess the quality and appropriateness of the services provided in any operational setting where NAVMED personnel deliver health care.

6. Roles and Responsibilities

a. Director, Clinical Operations, Policy, and Standards (BUMED-N10) and Chief Medical Officer (BUMED-N01CMO) will provide guidance for BUMED MQA and CQM program implementation to include operational forces utilizing Department of War (DOW), SECNAV, Chief of Naval Operations, and Commandant of Marine Corps MQA and CQM policies.

b. High Reliability and Clinical Quality Management (BUMED-N10G) will:

(1) Monitor implementation and coordination of MQA and CQM programs and provide consultation, education support, and MQA and CQM-related information regarding credentials and privileging, healthcare risk management, clinical quality improvement, and clinical quality measurement.

(2) Provide technical support and assistance for MQA and CQM-related issues and for entering information into the various programs used to track and to monitor credentials and privileges, adverse event reporting, clinical adverse actions, risk management, and patient safety reports.

(3) Ensure the protection of MQA records, as they are confidential and privileged and may not be disclosed to any person or entity, except as provided in reference (b). These records are exempt from the disclosure requirements of the Freedom of Information Act. The Surgeon General of the Navy is the release authority for any disclosures of MQA records. Any person who willfully discloses an MQA record will be subject to adverse personnel action (to include in appropriate cases, dismissal, or separation). They may also be subject to fines of no more than $3,000 in the case of a first offense and not more than $20,000 in the case of a subsequent offense. An unauthorized willful disclosure of MQA records must be reported to BUMED-N10G.

(4) Provide support to operational, readiness, and training units and NAVMED operational clinical communities with analysis of data and assistance with improvement, and with spread and scale of improvement.

(5) Ensure individuals responsible for MQA and CQM program management are afforded educational opportunities commensurate with their responsibilities.

(6) Monitor quality performance metrics.

(7) Conduct annual review of program effectiveness with revision as necessary.

c. Director, Health Services, Headquarters Marine Corps, on behalf of the Surgeon General of the Navy, will ensure implementation of program policies, processes, and procedures as set forth in this instruction by medical personnel assigned to Marine Corps operational forces.

d. Fleet and Force Command Surgeons (with the support of BUMED-N10G) will:

(1) Implement effective, flexible, integrated, and comprehensive MQA and CQM programs, incorporating applicable elements of references (c), (f) through (m), and enclosures (1) through (8).

(2) Use existing credentialing and privileging processes to ensure that operational medical department providers comply with this instruction.

(3) Use provider-specific results of MQA and CQM monitoring activities to support credentials review and privileging activities, per references (f), (g), and (m).

(4) Identify resources needed to maintain and preferably exceed acceptable standards of patient care service.

(5) Implement and coordinate MQA and CQM assist visits as required to maintain optimal MQA and CQM programs.

(6) Conduct annual assessment of preceding calendar year TYCOM quality assurance programs, to include any patient safety program recommendations.

7. Clinical Quality Management Program Components

a. Monitoring and evaluation to include:

(1) Ongoing, planned, and systematic information collection to identify opportunities to improve patient care services, clinical performance, and support service processes.

(2) Comprehensive monitoring activities encompassing all aspects of patient care services provided by the clinical and support services, trainee groups not permitted to practice independently, and administrative staff.

(3) Predetermined written criteria that reflect current knowledge and clinical experience to evaluate services provided and to identify, to assess, and to decrease risk of harm for patients and staff.

b. Routine MQA program-related documentation must be maintained in a secure location for a period of five years before disposal. MQA inquiries and medical records related to a potentially compensable event and Manual of the Judge Advocate General (JAGMAN) investigations must be maintained in a secure location for a minimum of five years or as long as needed thereafter.

c. Communicate important MQA information to effect sound clinical and management decision-making at all levels of the organization.

d. Integrate, track, and trend MQA information to identify significant patterns or processes, which may need in-depth review, addressed by clinical quality improvement and TeamSTEPPS™ techniques or other interventions.

8. Reporting Requirements. Forward one copy of any healthcare quality assurance investigation, command investigation, or litigation-report in which the adequacy of medical care is an issue or that involve potential claims, permanent disability, or death to BUMED N10G by certified mail or other secure electronic format. Primary filing method for any healthcare risk management, quality, or patient safety investigation must use a numerical system that does not include any personal identifiers (e.g., N23-0002).

9. Confidentiality

a. MQA records generated through professional review activities are protected per reference (b). These documents must not be released without proper authority from the Surgeon General of the Navy.

b. Litigation reports are protected under the attorney client privilege and are not quality assurance documents. Per reference (k), litigation reports will not contain quality assurance information or records protected under reference (b). Judge Advocate General Office of the Navy is the release authority for all litigation reports.

c. Aside from the subject of an MQA program action, the identity of any person receiving healthcare services from the DOW or the identity of any other person associated with the DOW for purposes of an MQA that is disclosed in an MQA record must be redacted per reference (b) before any disclosure is made outside of the DOW.

d. Information in an MQA record may also contain protected health information relating to a patient. The use of this protected health information is authorized per reference (s).

Protected health information contained in an MQA record may also be released, pursuant to reference (s), section 4.4.d, to other Government agencies and outside entities that have been designated as part of the DOW MQA program. To be so designated, reference (s) requires:

(1) A written business associate agreement between the DOW Component and the other entity.

(2) A direct support agreement restricting further dissemination of the information. Litigation reports are protected under the attorney client privilege and are not quality assurance documents.

10. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the DON Assistant for Administration, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-InformationManagement/Approved%20Record%20Schedules/Forms/AllItems.aspx.

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact the local records manager or the OPNAV Records Management Program (DNS-16).

11. Review and Effective Date. Per OPNAVINST 5215.17A, BUMED-N10G will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, DOW, Secretary of the Navy and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

D. K. VIA

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, https://www.med.navy.mil/Directives/

REFERENCES

(a) OPNAVINST 5450.215G
(b) 10 U.S.C. §1102
(c) OPNAVINST 6320.7B
(d) OPNAVINST 5102.1E
(e) DoD Instruction 6025.13 of 26 July 2023
(f) DHA-Procedures Manual 6025.13
(g) BUMEDINST 6010.17D
(h) BUMEDINST 6010.18C
(i) BUMEDINST 6010.21
(j) BUMEDINST 6010.23A
(k) JAGINST 5800.7G
(l) BUMEDINST 5830.1C
(m) BUMEDINST 6010.30
(n) BUMEDINST 6220.9B
(o) SECNAVINST 5720.42G
(p) SECNAVINST 5211.5F
(q) DHA-PI 6025.17
(r) SECNAVINST 1920.6D
(s) DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health care Programs, 13 March 2019
(t) SECNAVINST 12752.1A

DEFINITIONS

1. Active Duty Death. An adverse event resulting in the death of an active duty member when the medical care provided may have caused or contributed to the death.

2. Active Duty Disability. An adverse event resulting in a medical injury or condition to an active duty member that prevents the member from performing their duties and requires referral to the Physical Evaluation Board for disability determination.

3. Adverse Event. Unintended occurrences or conditions associated with care or services that reach the patient and that may result in harm to the patient. These may be because of acts of commission or omission.

4. Aggregate Statistical Data. Numerical data that constitute all of the data in pre-defined common demographic groupings, expressed in the form of a number and comprised of data from a population meeting all of the demographics in the grouping comprised of at least three individuals. Numerical data derived from medical quality assurance and clinical quality management (CQM) program records must also be in such demographic groupings that the release of the information would not lead to the identification of the patient or the provider involved in providing care.

5. Approved Postgraduate Training. Training program accredited by the Accreditation Council on Graduate Medical Education (GME), the American Osteopathic Association (AOA), or other similar entities regulating health care provider training programs.

6. Attorney Work Product. Material prepared by an attorney in the course of legal representation, especially in anticipation of litigation. Applies to notes, statements of witnesses, private memoranda, and mental impressions formed by the attorney. Work product is privileged and is exempt from discovery.

7. Board Certified. A term applied to a physician or other healthcare provider who has passed an examination given by a professional specialty board and has been certified by that board as a specialist in that subject or discipline.

8. Centralized Credentials Quality Assurance System. DOW electronic database that documents healthcare risk management activities (e.g., potentially compensable events, active duty death, active duty disability, malpractice claims, clinical adverse actions, and reporting actions (e.g., National Practitioner Data Bank, state(s) of licensure, and regulatory agencies and professional organizations) and credentialing and privileging requirements.

9. Chain of Custody and Chain of Evidence. A rule of evidence in a legal proceeding requiring custody of a piece of evidence, such as a piece of malfunctioning equipment alleged to have

caused an injury, to be continuously documented from the time of the incident until its introduction into evidence. The chain of custody includes identification of each custodian and each transfer of custody.

10. Claim. A written demand for payment based on an allegation of negligence causing personal injury, death, or property damage to a patient. Standard Form 95 is generally used to present claims against the United States for injuries, death, or damages caused by negligent acts or omissions by Federal employees occurring within the scope of Federal employment under the Federal Tort Claims Act (FTCA) or Military Claims Act (MCA).

11. Clinical Adverse Action. Action invoked against a healthcare provider, privileged or not, with the result that the authority to practice clinically is adversely affected. Adversely affected privilege(s) or practice are the result of a due process professional review action based on evidence of misconduct, impairment, incompetence, or any conduct that adversely affects, or could adversely affect the health or welfare of a patient, and that leads to the inability of a provider to exercise their privilege(s) or practice with their own independent judgment.

12. Clinical Privileges. 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.

13. Clinical Privileging. The granting of permission and responsibility of a healthcare provider to independently provide specified or delineated healthcare within the scope of their 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.

14. Clinical Quality Management (CQM). The integrated processes, both clinical and administrative, that provides the framework to objectively define, measure, assess, and improve the quality and safety of care received by beneficiaries. CQM programs include clinical performance measurement and improvement, credentials and clinical privileging, healthcare risk management, clinical adverse actions, and patient safety.

15. Command Investigation. A tool that gathers, analyzes, and records relevant information about an incident or event of primary interest to the command. Not protected as either attorney work product or quality assurance information.

16. Concise Incident Analysis (CIA). A succinct, yet systematic way to analyze no or low harm incidents.

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

18. Credentials. Documents that constitute evidence of appropriate education, training, licensure, experience, and expertise of a healthcare provider.

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

20. Data Sharing Agreement. Agreement between the DOW and the recipient of Military Health System data that establishes the permitted uses and disclosure of the data released. Data sharing agreements are used to control the release of patient and provider related information.

21. DOW Reportable Events. Any patient safety event resulting in death, permanent harm, or severe temporary harm which includes the Joint Commission's sentinel events and the National Quality Forum's serious reportable events.

22. Failure Modes Effect Analysis. Method used to minimize likelihood of failure in a system. Focuses on identifying the origins of process or product failure and taking preventive action based on this analysis.

23. Federal Tort Claims Act (FTCA). A Federal law (sections 2671 through 2680 of Title 28, U.S. Code) that allows individuals who are injured or whose property is damaged by the wrongful or negligent act of a Federal employee acting within his or her official duties to file a claim with the government for reimbursement of injuries or damage.

24. Freedom of Information Act. A Federal law (section 552 or Title 5, U.S. Code) that provides persons with a right to access Federal agency records, unless such records are exempt from disclosure.

25. Harm. Injury suffered as the result of an adverse event or unanticipated outcome.

26. Intentionally Unsafe Act. An intentional action by a person harming or creating a risk of harm to oneself or to another person.

27. Investigation. Systematic inquiry for ascertaining facts.

28. Joint Patient Safety Reporting (JPSR) System. An event reporting system for patient-related events regardless of level of harm. It also captures near misses and unsafe conditions related to medical care and documents the level of harm to the patient. The level of harm will dictate the type of further quality investigation that may be required (e.g., root cause analysis or quality assurance investigation).

29. License. A grant of permission by an official agency of a State, the District of Columbia, or a commonwealth, territory, or possession of the United States to provide healthcare within the scope of practice for a discipline. Healthcare providers in the MHS must have and maintain an active, current, valid, and unrestricted license or other authorizing documents to practice independently. A valid license is one in which the issuing authority accepts, investigates, and acts upon quality assurance information, such as provider professional performance, conduct, and ethics of practice, regardless of the provider's military status or residency.

30. Litigation Report. Investigation of an incident or event that resulted in or potentially could result in a claim or civil litigation against the Navy for personal injury or death caused by the negligent act or omission of Federal employees acting within the scope of their employment. Litigation reports are conducted under the supervision of an attorney and are completed per JAGMAN, chapter 2.

31. Malpractice Payment. Monetary award per FTCA or MCA relating to the provision of healthcare services under the organizational responsibility of the DOW.

32. JAGINST 5800.7G. A Navy publication that contains regulations of DON that are issued under the authority of Federal law. Provides guidance on military justice, administrative investigations, complaints of wrong, and other legal topics.

33. Negligence. Failure to use the degree of care a reasonably prudent person would use under similar circumstances. Negligence may be an act of omission, commission, or both.

34. Payment in Kind. Active Duty Death Gratuity payment or Active Duty Disability payment.

35. Peer Review. Any assessment of the quality of medical care carried out by a healthcare professional, including any such assessment of professional performance, any patient safety program root cause analysis or report, or any other similar activity prescribed by DOW or DON regulations. Process used for purposes of employment, appointment, reappointment, privileging, or corrective action.

36. Personally Identifiable Information. Data that could potentially identify a specific individual. Any information used to distinguish one person from another or for de-anonymizing anonymous data can be considered personally identifiable information.

37. Potentially Compensable Event. An adverse event that results in harm to a patient and presents a possible financial loss to the Federal Government (e.g., a malpractice claim or active duty death or active duty disability payment).

38. Protected Health Information. Information about health status, provision of health care, or payment for healthcare that can be linked to a specific individual.

39. Quality Assurance Investigation (QAI). Inquiry into facts and circumstances surrounding an incident or event involving the delivery of medical care to assist in identifying opportunities to improve patient care services, clinical performance, and support service processes. A QAI is used in all healthcare risk management activities, to include clinical adverse actions and is required in determining standard of care.

40. Quality Assurance (QA) Records. QA records created by or for the DOW or the Department of the Navy as part of a QA program are confidential and privileged. Includes proceedings, records, minutes, and reports that emanate from quality assurance program activities. Release of these records are governed by Federal law, reference (b).

41. Quality Improvement. A structured activity to introduce fundamental changes to achieve higher levels of performance. It represents the introduction of beneficial change.

42. Quality Planning. An organizational process involving a series of universal steps:

a. Identifying the customers.

b. Determining the needs and expectation of customers.

c. Developing product and process features which respond to customer needs.

d. Developing process which are consistently able to produce those product and process features.

e. Implementing the resulting plans.

43. Root Cause Analysis (RCA) also known as Comprehensive Systematic Analysis (CSA). Systematic process for identifying the causal and contributory factors associated with adverse events and near misses which includes the development of corrective action plans and outcome measures. The analysis focuses primarily on systems and processes rather than individual performance.

44. Scope of Practice. Professional activities a health professional is authorized to perform under the laws of the state in which the health professional is licensed.

45. Significantly Involved Provider. Providers who 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.

47. Specialty Review. Unbiased, impartial review of the clinical standard of care performed by an appropriate clinical peer.

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.

49. Supporting Urgent Response Across the Global Enterprise (SURGE). A rapid response to a patient safety event, which can be initiated at the BUMED, regional or operational level; the review and investigation are considered a quality assurance effort and the work product is protected under reference (b). SURGE is for process issues not resolved by routine investigation vice a QAI, which is required for standard of care reviews.

50. Tort. A civil wrong, not including a breach of contract, for which the injured party is entitled to compensation.

51. Transparency. The release and explanation of the medical facts of the case as documented in the medical record.

CREDENTIALING AND PRIVILEGING

1. General Overview. The credentialing and privileging process incorporates high reliability organization guiding principles, with emphasis on full evaluation of individual healthcare provider credentials and qualifications before allowing involvement in patient care.

a. Standardizes and directs the credentialing and privileging process for the DON healthcare providers regardless of where they are assigned in order to facilitate provider movement between fixed facilities and operational components.

b. Addresses the responsibility of clinical leaders to manage the scope of a provider's independent practice and the requirements for oversight of non-privileged providers.

c. Requires active duty and Reserve Component licensed independent providers to request the broadest scope of clinical privileges commensurate with their professional qualifications and level of current competence. Those who fail to maintain qualifications, including but not limited to, an unrestricted license, or those who do not request such privileges are subject to processing for separation for cause under references (r) and (t).

d. Provides a mechanism for privileged and non-privileged provider involvement in the credentialing and privileging process.

2. Scope and Core Responsibilities

a. Privileging Authority

(1) Privileging within the military medical treatment facilities is governed by reference (f).

(2) Privileging within the operational forces of the DON is governed by reference (m).

(a) The designated Privileging Authority for practitioners assigned to non-clinical (e.g., administrative) billets, who wish to request privileges in order to maintain clinical competency, is the CO of the health care facility where such health care services are performed. Providers assigned to non-clinical billets are encouraged to maintain clinical competency whenever possible.

(b) Privileging authorities may not grant medical staff appointments or clinical privileges to themselves, but may grant medical staff appointments to their executive officers. The Privileging Authority must always be the next higher level in the chain of command than the position of the individual requesting privileges. For example, a Privileging Authority cannot grant privileges to their incoming relief (i.e., successor).

b. Fleet and Force Command Surgeons will:

(1) Provide a mechanism for medical or dental staff involvement in the credentialing and privileging process. This function will be performed by providers appointed by the privileging authorities designated from among the privileged licensed independent providers under their cognizance.

(2) Establish mechanisms to ensure individual providers function within the scope of clinical privileges granted.

(3) Ensure the clinical performance and professionalism of all assigned health care providers is measured, periodically assessed, and documented at intervals not to exceed 8 months per ongoing professional practice evaluation (OPPE) requirements outlined in this policy. Performance Appraisal Reports and Clinical Appraisal Reports for privileged providers and clinical support staff registered nurses, dental hygienists, and certified athletic trainers, respectively, must be produced at intervals not to exceed 2 years.

(4) Maintain a Credentials Record on all healthcare providers (whether holding a staff appointment with privileges, practicing under a plan of supervision, or working under a scope of practice).

(5) Follow FPPE and OPPE policies, directives to ensure current clinical competency of providers.

(6) Grant clinical privileges to licensed independent providers using standardized, specialty-specific privileges contained in the DOW CCQAS Master Privilege Listing.

(7) Immediately remove healthcare providers whose clinical incompetence, professional misconduct, or impairment may adversely affect their ability to provide safe, quality patient care from direct patient care activities under the provisions of references (f) and (m).

(8) Investigate, without delay, allegations of clinical incompetence (e.g., deficits in medical knowledge, expertise, or judgment); professional misconduct (i.e., unprofessional, unethical, or criminal conduct), or impairment (e.g., medical conditions, mental health conditions, or alcohol abuse, drug abuse, or dependence), including reportable misconduct, per references (f) and (m).

(9) Impaired providers (i.e., those with medical or mental health conditions, alcohol abuse, drug abuse, or dependence) must have their clinical practice reviewed by the Medical Executive Committee or medical staff leadership, per references (f) and (m).

c. Navy Medicine department healthcare providers (Active and Reserve Components).

(1) Navy Medicine department licensed independent providers are required to request Core privileges regardless of assignment. Core privileges, as promulgated in the CCQAS Master Privilege Listing, constitute the expected baseline scope of care for a fully trained and currently competent practitioner of a specific healthcare specialty.

(2) Supervised privileges are not authorized for healthcare providers who are deployed or assigned to an operational platform, except as granted by a formal plan of supervision approved by the Privileging Authority.

3. Procedures

a. Licensure, certification, or registration is a condition of employment and applies in all healthcare settings, including deployment and assignments in foreign countries. Other procedures are listed in subparagraphs 3a(1) and 3a(2).

(1) Healthcare providers must have at least one current, valid, active, and unrestricted license. Additional licenses held by a provider must be in good standing, whether they are inactive, expired, or limit the provider's practice to a military setting. Providers in the Military Health System may not have one active license and another currently suspended or in a probationary status.

(2) Healthcare providers who fail to maintain compliance with licensing, certification, or registration requirements in accordance with references (f) and (m) will be removed immediately from patient care. Such providers may be subject to personnel actions (e.g., as a condition for employment, failure to keep licensure by being late on fee payment may prompt disciplinary personnel actions), clinical adverse actions (e.g., any adverse action taken by the state authority may prompt a quality assurance investigation), or both, which may lead to National Practitioner Data Bank and other applicable certifying or regulatory agency reporting. Privileging Authorities should consult with servicing operational health law counsel, Office of the General Council (BUMED-N01L) prior to initiating any action.

b. Credentialing and privileging requirements are addressed in references (f) and (m).

ADVERSE EVENTS REPORTING REQUIREMENTS: POTENTIALLY COMPENSABLE EVENTS, ACTIVE DUTY DEATH, ACTIVE DUTY DISABILITY, AND MEDICAL TORT CLAIMS

1. Every adverse event involving a patient receiving healthcare services in an operational environment that resulted in actual harm, must be reviewed as a potentially compensable event (PCE). BUMED-N10G, the operational clinical risk manager, the operational patient safety manager, the appropriate privileging authority representative, the appropriate senior medical representative, and BUMED-N01L will collaborate to determine the appropriate investigative process or processes and reporting requirements for adverse events based on the type of event as well as the level and duration of actual harm to the patient. Certain adverse events may trigger multiple reports.

a. Adverse Event Investigation. All adverse events are investigated initially by both the operational patient safety manager and operational clinical risk manager when there is evidence that individual health care provider issues are involved.

b. Joint Patient Safety Reporting (JPSR) System. All adverse events, near misses, or unsafe conditions that affect or could affect patients must be reported to the JPSR upon identification.

c. RCA also known as CSA. Is used to identify the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event (SE). Both analysis focuses on systems and process, not individual performance. Both are quality assurance documents and cannot be used in any other investigation.

d. SE. A patient safety event (i.e., not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent or severe temporary harm. Such events are "sentinel" because they signal the need for immediate investigation and response.

(1) Navy healthcare personnel must actively identify SEs that occur, conduct an RCA or CIA, and form a corrective action plan for each event. SEs must be reported to BUMED within 24 hours of discovery. BUMED will determine if higher level notification is required.

(2) All SE occurrences must be processed as a PCE.

2. Potentially Compensable Events

a. Overview

(1) Clinical quality management teams must have formal, structured, and collaborative processes in place to identify, to analyze, and to mitigate risks involving patient safety (PS) events in such a way that promotes a fair and just culture. PS and healthcare risk management

(HRM) each have distinct roles involving PS events that reach patients; however, they collaboratively manage trend data (both individual and aggregated) for collective learning and process improvement.

(a) BUMED-N10G, the operational clinical risk manager, the operational patient safety manager, the appropriate privileging authority representatives, the appropriate senior medical representative, and BUMED-N01L will collaborate to assess whether the event is likely to present a possible financial loss to the Federal Government. If so, a PCE review will be completed.

(b) All DOW reportable events require PCE review procedures, as do all filed (or paid) medical tort claims, active duty death, or active duty disability payments related to the delivery of healthcare. PCE review case files determined to present a risk of financial loss to the government will be forwarded to the Privileging Authority Medical Executive Committee (MEC), or medical staff leadership as part of the PCE quality review.

b. PCE review procedures assist with analysis of both individual and system clinical performance for risk mitigation, learning, and process improvement. The PCE review will include an analysis of both system and process issues in addition to the standard of care (SOC) review(s).

(1) The PCE review will commence within 30 calendar days of the event notification, and be completed within 180 calendar days. If the PCE involves an active duty Service Member death, the 180-day process will include a determination of whether medical care caused or contributed to the death. PCEs will be entered into the DOW Centralized Credentials Quality Assurance System (CCQAS) risk management module.

(2) Every PCE review will identify significantly involved providers (SIP), conduct an SOC review on each SIP, and analyze both systems and processes involved in the care of the patient that may have contributed to the PCE.

(a) Reasonable attempts will be made to notify the provider in writing when they have been identified as a SIP in a PCE, and that an SOC review will be conducted. If unable to notify the SIP, all notification attempts will be documented in the PCE file.

(b) PCE peer SOC reviews are based on the SOC of healthcare delivery at the time of the event and will include an opinion and a basis for that opinion as to whether the SOC was "met" or "not met" for each SIP.

(c) SIPs must be afforded the opportunity to provide a statement for the PCE review, to the extent appropriate to ensure a full understanding of the facts regarding the care provided to the patient. SIPs may review medical records and relevant clinical documentation to assist them

in writing a statement or memorandum for purposes of the PCE review. Only SIPs who provide a written response will be given a redacted copy of the SOC review at the conclusion of the review.

(3) The MEC will review PCE SOC for each SIP to determine whether or not a SIP should undergo remediation (Focused Professional Practice Evaluation or Monitoring) or have their privileges or practice placed in summary suspension for a possible clinical adverse action. Documentation by the privileging authority regarding decision for or against a summary suspension will be kept in the PCE case file.

c. All PCEs will be reviewed and analyzed to determine contributing causes.

(1) The results of the PCE review determines what, if any, further additional reviews are necessary and whether the event will be reclassified as an Active Duty Disability or an Active Duty Death.

(2) PCEs serious enough to warrant convening a litigation investigation will be identified as JAGMANs, or if an SF 95 (claim for damage, injury or death) or medical malpractice payment notification is received, update in the CCQAS database to a tort.

d. The PCE review process includes a review of the SIP's credentials to determine if further credentials intervention is required (e.g., Focused Professional Practice Evaluation, monitoring, or adverse action).

(1) Results of the initial investigation and SOC will be documented in CCQAS.

(2) If it is determined that no further investigation is warranted, sufficient information to identify the date and location of the event, the involved patient, and a statement indicating the date of that determination will be entered into CCQAS.

3. Active Duty Disability

a. In cases where a Medical Evaluation Board makes a referral to the Physical Evaluation Board, and a determination is made that the medical condition under review by the Disability Evaluation System may have been caused by or contributed to the healthcare provided, the adverse event will be identified initially as a PCE and subsequently reclassified as an Active Duty Disability.

b. Completion and forwarding of all pertinent documents, to include the full and complete PCE review Medical Quality Assurance Record, including SOC reviews, relevant medical records, other clinical evidence, and provider(s) statements to BUMED-N10G, will occur within 30 calendar days of notification of the disability payment.

4. Active Duty Death. PCE reviews that identify an active-duty death which may have been caused by or contributed to the healthcare provided will be initially identified as a PCE. Upon identifying that medical care contributed to the death, the PCE will be reclassified as an Active Duty Death.

5. Paid Malpractice Claims/Military Medical Claims Acts. When notified that a medical claim (e.g., Federal Tort Claims Act or Military Claims Act) has been filed, a review will be conducted for an associated PCE. If a PCE already exists, the case will be reclassified as a Claim. If no PCE exists, a review will be completed, initially classified as a PCE, and subsequently reclassified as a claim.

6. National Practitioner Data Bank Reporting. The National Practitioner Data Bank review and reporting process applies to all Active Duty Death, Active Duty Disability, or paid claims.

7. Disclosure of an Adverse Event. Patients are entitled to factual, complete information about the outcomes of diagnostic testing, medical procedures, and other healthcare interventions. This is true whether the results are expected or unanticipated. Prompt, compassionate, and honest communication with the patient and the patient's family following an adverse event or an unanticipated outcome is an essential component of quality healthcare. Communication about the event should revolve around the known facts taken from the medical record and avoid speculation or personal opinions. Proper disclosure does not suggest that the involved provider(s) have been negligent; it informs the patient or family that an unanticipated outcome has occurred, confirms the patient's current health status, and identifies the ongoing plan of treatment. Refer all questions to the Health Care Resolutions Program specialist. See enclosure (6) of this instruction for further information on the Health Care Resolutions Program.

a. Disclosure. The intent of disclosure is that the patient and, if appropriate, the patient's family will receive cogent, factual, event-related information, without attribution of blame or fault. The disclosure must be in a language and terms that are readily understood by the patient and family. If a language barrier exists between the provider and the patient or family, arrangements for an interpreter are required.

b. Informing the Patient. The patient must be informed that an adverse event or unanticipated outcome has occurred as soon as possible after the event is identified.

(1) The primary caregiver is the ideal individual to lead the initial disclosure communication with the patient and family as appropriate.

(2) In instances where informing the patient is not possible or practical (e.g., provider has transferred to a new assignment), the primary provider's supervisor or a senior colleague should discuss the matter with the patient and family, as appropriate.

(3) The intent of these discussions is to have personal, candid communication with the patient and family. Should the patient or family request to have an attorney present during these communications, before consenting to the presence of personnel other than family members, the provider must seek advice from senior leadership and legal counsel, consistent with Service and DOW policy.

c. Full Disclosure. The intent of full disclosure is that healthcare providers should verify that the patient and family understand the facts and make certain timely and accurate documentation of those facts in the medical record. Full disclosure should include:

(1) Explanation of the effect of the adverse event on the patient's condition and prognosis.

(2) Provision of reliable information and facts associated with the adverse event avoiding all conjecture or personal opinions.

(3) Identification of the person(s) designated to provide the patient and family with additional information, and how and when that communication will occur.

(4) Recommendations for further diagnostic and therapeutic interventions.

d. Service Policy Guidance. Reference (q) provides specific written policy guidance for disclosure to patients and their family members who have experienced adverse events. This guidance also addresses correct procedures for documentation in the medical record following an adverse event or unanticipated outcome. The filing of an event report or the findings from the Quality Assurance Investigation are not documented in the medical record. The provider documents that discussion was held with the patient and the plan of action or options for the patient's case.

8. Special interest adverse events such as Congressional inquiries as well as inquiries from the CNO, the CMC, or the Naval Safety Center will also be documented in CCQAS, and any completed investigations will be forwarded to BUMED-N10G.

9. Adverse events that occur due to an intentionally unsafe act are investigated and reported by the appropriate law enforcement agency.

10. Federal Drug Administration Class 1 recalls will be investigated, and a Safe Medical Devices report will be submitted if there is an impact on patient care or safety.

11. To standardize the adverse event review process across the Military Health System, Defense Health Agency forms and templates can be accessed at https://info.health.mil/hco/clinicsup/quality/HRM/AdverseEventsLibrary/Forms/AllItems.aspx.

CLINICAL ADVERSE ACTION GUIDANCE

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

2. Basic Principles and Guidance

a. Clinical adverse action procedures are Medical Quality Assurance Program activities.

b. Clinical adverse action process is not a disciplinary tool. Concerns for suspected misconduct, impairment, incompetence, or any conduct related to the delivery of healthcare and services that adversely affect, or could adversely affect, the health or welfare of a patient, or staff member, are the basis for a clinical adverse action.

c. Conduct that violates local, state, or Federal law; the Uniform Code of Military Justice (or other military regulations); or those civil judgments against a healthcare provider, when related to the delivery of healthcare items or services, may be the basis for reporting to the National Practitioner Data Bank (NPDB), state(s) of licensure, and other applicable certifying or regulatory agencies. Consultation with the servicing Staff Judge Advocate or servicing healthcare legal counsel is required to ensure proper military or civilian procedures are followed.

3. Managing Clinical Adverse Privileging Actions for Privileged Providers

a. Adverse action can only be taken by the authorized Privileging Authority.

b. Upon discovery or notification to leadership that a clinical adverse action may be indicated and throughout the adverse action process, leadership will consult with servicing operational health law counsel and follow applicable procedures, so that due process proceedings, adequate notice, and fair peer hearing procedures are afforded to the involved individual.

c. The Privileging Authority initiating a clinical adverse privileging action will notify all privileging authorities (i.e., DOW and civilian) under whom the individual holds privileges and the respective Service for uniformed Service Members.

d. All decisions must be warranted by the findings of fact and comply with the due process procedures in reference (f), volume 3, enclosure (3).

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

f. Any voluntary surrender of clinical privileges or failure to renew clinical privileges, while under investigation, is reportable to the NPDB.

g. Individuals who separate from or end affiliation with the MHS while in summary suspension or follow-on clinical adverse action due process procedures, have the right to request continued due process to include a hearing. The request must be submitted in writing by the individual to the Privileging Authority, or designee, within 5 calendar days following their knowledge of the change in affiliation status. If the individual fails to submit the request for this right, it is considered waived.

h. If the individual waives the right to further due process, the actions listed in subparagraphs 3h(1) through 3h(3) will be taken:

(1) The Quality Assurance Investigation (QAI) will be completed, and the report of investigation forwarded to the respective Credentials Committee for review. The Credentials Committee will then recommend a final action to the Privileging Authority.

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

(3) Clinical adverse action decisions are reported in accordance with reference (f), volume 3, enclosure (3).

4. Managing Clinical Adverse Practice Actions for Non-Privileged Providers

a. Adverse action can only be taken by the authorized Privileging Authority.

b. Upon the discovery or notification to leadership that a clinical adverse action may be indicated, leadership will consult with servicing operational health law counsel and follow applicable procedures so that due process proceedings, adequate notice, and fair peer hearing procedures are afforded to the involved individual.

c. Non-privileged providers who are licensed, certified, or registered by a state; the District of Columbia; or a commonwealth, territory, or possession of the United States are subject to this clinical adverse actions process. Reports of adverse actions for providers will be to state licensing agencies and other agencies appropriate to the specialty of the provider. These actions are known as adverse practice actions.

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

e. All decisions must be warranted by the findings of fact and comply with the due process procedures in reference (f), volume 3, enclosure (3).

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

g. If the individual waives the right to further due process, the actions listed in subparagraphs 4g(1) through 4g(3) will be taken:

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

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

(3) Clinical adverse action decisions are reported per reference (h) and enclosure (3).

5. Clinical Adverse Action Due Process

a. Summary Suspension

(1) A Privileging Authority may put all or a portion of an individual's privilege(s) or practice into summary suspension on the basis of concerns regarding suspected misconduct, impairment, incompetence, or any other conduct that adversely affects, or could adversely affect, the health or welfare of a patient or staff member. Summary suspension is an administrative status pending the completion of due process procedures.

(2) The individual will be notified in writing on the day clinical privilege(s) or practice are placed in summary suspension, conveying the basis for the action, the initiation of a QAI, the review of the QAI by the Credentials Committee, and the Credentials Committee recommendation for the proposed decision by the Privileging Authority. The notification will include the consequences of separating from or ending affiliation with the MHS, while under summary suspension.

(3) Summary suspensions of privileged providers that remain in effect for more than 30 calendar days are reportable to the NPDB and state(s) of licensure.

b. QAI Procedures

(1) The Privileging Authority initiates the QAI and appoints the investigating officer (IO) in writing; the purpose and scope of the QAI will be explicit in the letter. The QAI IO must be an appropriate clinical peer to the individual under review. The QAI IO must consult with the operational servicing health law counsel prior to beginning the investigation, follow the guidance of counsel, and provide counsel with a draft report for review prior to final submission.

(2) The content of the QAI report must include the requirements in reference (f), volume 3, enclosure (3).

(3) The individual will be provided a redacted copy of the QAI report (without the enclosures) and given 15 calendar days to submit a written statement, if desired, to the Credentials Committee for consideration.

c. Full Due Process Procedures to include Credentials Committee Review, Legal Sufficiency Review, Proposed Privileging Authority Decision, Peer Review Hearing Request and Procedures, Final Legal Sufficiency Review, Privileging Authority Decision, and Appeal Process are provided in reference (f), volume 3, enclosure (3).

6. Criminal Convictions and Government Administrative Actions Related to Healthcare

a. Actions involving acts of professional misconduct or other acts or omissions for which a healthcare provider is formally disciplined will be reported to the NPDB in cases where the conduct had or could have adversely affected the delivery of a healthcare item or service. Personnel (i.e., active duty, Reserve, civil service and personal service contractors) in any position or assignment providing healthcare services, whether in direct patient care or in support of the delivery of healthcare, are subject to reporting. Reporting of healthcare providers is not exclusive to those individuals who are licensed, certified, registered or privileged.

b. Reportable actions include judicial (courts-martial) and non-judicial (Article 15 hearings) Uniform Code of Military Justice actions, adverse personnel action affecting uniformed Service Members (e.g., administrative separation) and adverse civilian personnel actions not involving probationary employees. See reference (f), volume 3, enclosure (3) for additional guidance.

7. Impaired Healthcare Provider Program (IHPP)

a. The IHPP is designed to provide support, assistance, and coordination or advocacy for rehabilitation of healthcare providers who have a condition that adversely affects or could adversely affect the safety or welfare of a patient. The identification and management of an

impaired provider must facilitate the rehabilitation of the provider by offering assistance to retain and to regain optimal professional functioning consistent with the delivery of quality healthcare. An impaired healthcare provider is one who is under evaluation for or is diagnosed with an impairment associated with substance use, substance abuse, or a medical or mental health condition.

b. Notwithstanding the emphasis on rehabilitation in reference (f), volume 3, and enclosure (4), clinical adverse action due process may need to be initiated in cases where a healthcare provider who is, or may be, impaired does not self-refer, lacks insight or willingness to address their condition or be compliant with treatment, fails to complete a rehabilitation program, or relapses after treatment. If a clinical adverse action is taken against the provider, it must be reported to the NPDB, state(s) of licensure, and other applicable certifying or regulatory agencies as appropriate. Healthcare providers undergoing clinical adverse action due process will be provided services and support per reference (f), volume 3 and enclosure (4).

c. Privileging authorities without the resources to have an IHPP of their own will ensure affiliation with such a program to support their providers.

JOINT PATIENT SAFETY PROGRAM

1. General

a. All active duty, reserve, and civilian medical, dental, volunteers, and contract personnel under the operational control of the Surgeon General of the Navy, will participate in ongoing clinical Patient Safety Program (PSP) activities designed to identify, to analyze, to evaluate, and to mitigate process and system failures in any setting where Navy Medicine personnel deliver health care.

b. The DOW utilizes an electronic Web-based Joint Patient Safety Reporting (JPSR) system that allows anonymous reporting. This system is available to multiple DOW entities. The system accepts patient safety-related events, which may or may not reach the patient and which may or may not have harmed the patient. Examples include those identified as sentinel events, adverse events, and near misses (i.e., close calls) and unsafe conditions.

c. The information reported through the current electronic JPSR system will be used exclusively for improving health care systems and processes that impact medical errors and patient safety; no legacy systems are authorized. An authorized JPSR offline reporting form is available during times of system outage at https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SiteAssets/SitePages/JPSR/20180509_JPSR_Offline%20Report%20Form.pdf.

d. The JPSR PSP information must not be used for adverse administrative, privileging, or other personnel actions including disciplinary action. The event may require other quality reviews separate from the patient safety review as per reference (f). Information from the JPSR investigations may be not be used in disciplinary proceedings.

e. All records and information of the PSP are medical quality assurance records and are confidential under reference (b). Except as specifically authorized by instruction, PSP records or information will not be disclosed unless authorized by reference (b), required by applicable authority, or authorized by the Assistant Secretary of Defense for Health Affairs. All Quality Assurance documents will be designated as Medical Quality Assurance Program documents, protected pursuant to reference (b). Copies of this document, enclosures thereto, and information therefrom will only be released in accordance with the law.

f. The PSP focuses on creating a culture of safety that encourages reporting of errors or near misses (realizing the majority of errors are caused by system failures), building teamwork though standardized training, utilizing TeamSTEPPS™ communication techniques, and applying solid problem-solving skills. All of this is done in a non-punitive interdisciplinary environment that focuses on process improvement activities to provide safe, high-quality patient care across the entire Naval enterprise.

g. The basic component activities, responsibilities, and functions key to a successful clinical PSP are addressed:

(1) The PSP is an integral part of the Navy Medicine Clinical Quality Management program. The Patient Safety Manager or responsible department head is part of the administrative team and will report patient safety issues through the administrative medical chain of command and operational chain of command as appropriate.

(2) Designate an individual as the Patient Safety Manager to implement this program for U.S. Fleet Forces Command (USFFC), Naval Specialty Warfare (NSW) and Fleet Marine Forces (FMF) units and operational units, and provide point of contact information to BUMED-N10G and the Atlantic and Pacific points of contact as applicable. The Patient Safety Manager will be afforded annual educational opportunities commensurate with their responsibilities, with formal training being military or civilian-sponsored and in person or virtual.

(3) Ensure the PSP activities receive interdisciplinary support for an effective program.

(4) Monitor JPSR submissions, and track and trend the data. Provide leadership with periodic updates on its procedures and activities.

(5) Provide guidance to staff in cases where a medical event causes unanticipated harm to a patient. A qualified healthcare provider will inform the patient or applicable family member (if designated) of the facts as soon as the command is aware of the event and the patient or family member is able to understand the discussion.

(6) Staff can utilize the Healthcare Resolutions program that can provide advice and support to the staff for this process. Designate the attending physician or clinician most closely involved in the care of the patient to manage the discussion. Further information on the Healthcare Resolutions program can be found in enclosure (6) of this instruction.

(7) Provide support and debriefing opportunities to staff involved in the medical event which caused patient harm, if needed.

2. Components of the PSP

a. DOW Reportable Events (DOW REs)

(1) A DOW RE, per reference (f), is broadly defined as any patient safety (PS) event resulting in death, permanent harm, or severe temporary harm, as per the Agency for Healthcare Research and Quality Harm Scale; and is not primarily related to the natural course of the patient's illness or underlying condition or meets The Joint Commission's (TJC) sentinel event or the National Quality Forum's serious reportable event definitions and the DOW RE definition.

DOW REs could also include events identified by the Office of the Assistant Secretary of Defense for Health Affairs or Defense Health Agency (DHA) leadership in alignment with Military Health System strategic initiatives.

(2) For sites not accredited by TJC, the list of TJC events are considered DOW REs and require mandatory reporting to BUMED-N10G (see reference (f) for the list of DOW REs). Please Note: This list may change based upon organizational focus. DOW REs may qualify as potentially compensable events and require referral and collaboration with BUMED-N10G for a quality standard of care investigation. DOW REs require a CSA, RCA or CIA and a follow-on Corrective Action Implementation Plan Report.

(3) All sentinel events, as defined by reference (f), will be reported to BUMED-N10G within five working days of the discovery of the adverse event. Sites under the operational control of Surgeon General of the Navy, including medical and dental treatment units, will report events through their chain of command to BUMED-N10G. All Navy sites will complete the appropriate comprehensive systematic analysis and identify each page of the documents as quality assurance information protected under reference (b).

b. Evaluation and reporting of adverse events. Following an adverse event, the immediate needs of the patient will be addressed to minimize further injury. The staff witnessing an adverse event will preserve all evidence for subsequent analysis and provide a factual description of the event to the designated clinical team (e.g., team leader, Risk Management representative, and Patient Safety Manager). The Patient Safety Manager determines the priority and type of review required by applying the definitions and requirements of enclosure (3).

(1) Patient Safety Managers are encouraged to conduct performance improvement CSAs, RCAs, or CIAs on other adverse events and near misses as they deem necessary. Commands will submit these CSAs, RCAs, or CIAs to BUMED-N10G for review.

(2) The CSA, RCA, or CIA and action plan will 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 or CIA and action plan should be completed and approved by the commander within 45 days of the date on which the Patient Safety Manager reported the adverse event. A request for an extension waiver must be submitted to BUMED-N10B.

(3) Guidance on conducting a CSA, RCA, or CIA, reporting forms, and other pertinent PS information is available from the Patient Safety Analysis Center whose resources can be found at: https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/PSAC.aspx. The Patient Safety Analysis Center information is housed at the Patient Safety Learning Center site. Access requests to this site should be submitted to the DHA Patient Safety Program inbox at: DHA.PatientSafety@health.mil.

c. Referral of information concerning intentional unsafe acts. The investigation and consideration of intentional unsafe acts are not within the primary authority or responsibility of the PSP. If in the course of the activities of the PSP, information about intentional unsafe acts is revealed, the original report will be referred to appropriate command authority. The Patient Safety Manager proceeds with a review of systems and processes involved in the event but defers to the separate investigation and consideration with respect to any matter of culpability of any person involved in the act. The criminal investigation will take priority in the review process.

d. Reports submitted to BUMED-N10G. No patient or staff identifiers will be included in the initial notification and subsequent CSA, RCA, or CIA documents.

e. TeamSTEPPS™. Sites under the operational control of Surgeon General of the Navy, including medical and dental treatment units from USFFC, NSW, and the FMF, will implement the TeamSTEPPS™ program as directed by reference (f) into daily operations, and include TeamSTEPPS™ training as part of the program requirements. DHA offers the TeamSTEPPS Train-the-Trainer course.

f. Food and Drug Administration (FDA) Class I recalls. Per reference (f), all Patient Safety Managers will subscribe to the FDA class I alerts on medical devices, medications, and other medically-related products. Unit Staff will work through their designated logistic communication units for replacements and additional notifications. Any Class I recall item directly affecting a patient will be placed in the JPSR system and appropriate DOW and FDA safe medical device notification forms will be completed per reference (f).

HEALTHCARE RESOLUTIONS PROGRAM

Please Note**:** This enclosure is included as informational guidance on how the Healthcare Resolutions Program functions and make healthcare professionals aware of these functions. The Healthcare Resolutions Program is a hospital based program, and patients (regardless of where their care is delivered) and their family have a right to seek out a healthcare resolution specialist, if they so desire.

1. Purpose

a. To provide guidance, to assign responsibilities, and to prescribe procedures for the Healthcare Resolutions Program as part of the MHS commitment to transparency, as described in reference (q).

b. To implement DOW and DHA policies on issues related to the management and disclosure of adverse, unexpected or unanticipated events, clinical conflict, and healthcare provider resiliency and support.

c. To recognize that patients, and when appropriate, family members or healthcare proxies, be fully informed of adverse, unanticipated, or unexpected events that occur during the provision of healthcare services.

d. To facilitate the patient's right to be heard in any quality assurance program review of the quality of care.

2. Procedures

a. All licensed independent providers receive disclosure training by healthcare resolutions specialists at a minimum of every 2 years. Disclosure training emphasizes that full transparency is practiced when there are unanticipated or adverse outcomes of care, treatment, or services. Transparency involves the release and explanation of the medical facts of the case as documented in the medical record. Strict compliance must be maintained while protecting all Medical Quality Assurance program records materials from inappropriate release, in accordance with reference (b).

b. The Healthcare Resolutions Program does not take the place of legal or claims processes. Mediation and facilitation sessions are not considered formal resolutions of legal claims. Patients and families maintain any and all legal options. Healthcare resolutions specialists:

(1) Coordinate with legal counsel on cases that may have legal implications, including potential claims against the government. However, counsel does not participate in mediation or facilitation sessions.

(2) Advise legal counsel, if notified, that a patient is represented by legal counsel or intends to file a claim against the government and refer any inquiries regarding legal issues or service of process to counsel, including any correspondence from legal counsel representing patients.

(3) Disengage when, and if, claims are filed. If advised that a patient or family is represented by legal counsel, but no claim has been filed, the healthcare resolutions specialist will offer the patient or family an option to continue with the Healthcare Resolutions Program or to proceed exclusively through the legal system with their attorney.

c. Healthcare resolutions specialists report to senior command and conduct appropriate periodic disclosure training for providers as well as case execution.

d. Healthcare providers participate in disclosure training, refer cases to the attention of healthcare resolutions specialists, and participate in mediated sessions. Providers must be familiar with and observe guidelines regarding non-releasable information.

e. Patient safety, risk management, and quality assurance (QA) program officials support the Healthcare Resolutions Program. They accept case referrals from healthcare resolutions specialists and attend specific sessions arranged by healthcare resolutions specialists with patients and families who want to offer input to the formal case review process, having been advised that investigative results are not releasable. Patient safety, risk management, and QA program officials refrain from sharing information protected by reference (b) with healthcare resolutions specialists.

3. Principles and Practices of Healthcare Resolutions Specialists. Healthcare resolutions specialists incorporate multiple approaches to clinical conflict management and dispute resolution, to include:

a. Neutrality. To the extent permitted by MHS policy, promote a fair process which is objective, impartial, and free from conflict of interest.

b. Conciliation. Listen impartially and attentively to assist patients in putting their problems into perspective. Listen to and informally research complaints.

c. Facilitation. Encourage open communication between parties and seek fair and equitable solutions to the situation.

d. Coaching. Coach individuals at all levels on organizational behavior, communication strategies, and interpersonal communication; review policies, procedures, and systems pertinent to the case; assist and counsel parties to improve their communication skills; and confront personal issues, handle emotions, etc.

e. Informal Fact-finding. Fact-finding involves reviewing the medical record and speaking with involved patients and providers regarding the occurrence to gather information to facilitate the resolution process. Informal fact-finding does not interfere with any QA or litigation reports and does not seek the results of those proceedings.

f. Referral. Refer to another department and resource when that department (e.g., Risk Management, Patient Safety) may be better able to resolve all or a portion of a case.

g. Empowerment. Counsel patients and medical staff to recognize alternatives and to consider goals and objectives while balancing them against the goals and interests of the MHS.

h. Mediation. Serve as an impartial third party who facilitates discussions between patients and providers, helping the parties focus on underlying issues and their needs and interests rather than on entitlements or rights-based positions.

i. Ombudsman. Responds to patient complaints and works to achieve equitable solutions to patient concerns.

4. Referral Criteria. Referrals may be received from leadership, staff members, TRICARE beneficiaries, public websites, the Office of the Judge Advocate General or other legal office, customer service, written correspondence received by the command, or any source other than information protected by reference (b). Common referral issues include:

a. Uncertainty about handling disclosure and patient communication.

b. Unanticipated outcomes of care.

c. Delayed diagnosis.

d. Medical or medication errors.

e. Sentinel events, wrong site, or wrong patient procedures.

f. Elevation of care caused by hospital or hospital acquired infections.

g. Expected or unexpected deaths.

h. Patient dissatisfaction with treatment outcomes or quality of care.

i. Poor patient-provider interaction or communication.

j. Appropriate patient disengagement without abandoning patient care.

k. Follow up with patients who leave against medical advice.

l. Adverse events to include near misses.

m. Congressional inquiries involving quality of patient healthcare issues.

5. Healthcare Provider Resiliency and Support. Appropriate support services, such as peer support programs, must be offered to all involved healthcare providers after an adverse, unexpected, or unanticipated event. This program is separate from the event investigation and does not involve case analysis or review of medical records or documentation, and does not interfere with quality assurance or legal processes. The peer support program is intended to provide psychological first aid and assist with restoring clinical confidence.

HEALTHCARE RISK MANAGEMENT PROGRAM COMPONENTS

1. An effective Healthcare Risk Management (HRM) Program includes components to identify and to mitigate risk to patients and staff. This includes oversight and review of the effectiveness of organizational risk reduction strategies per accrediting bodies such as Joint Commission (or comparable accreditation) of providers, per reference (f).

2. HRM implements active systems and programs to reduce liability risks associated with actual or alleged medical malpractice, preventable injuries (special cause variation), and to minimize or to mitigate claim severity, while contributing to the organization's mission of providing quality care to patients.

3. HRM utilizes processes to identify adverse events. Immediate action must be taken to protect patients, staff, and visitors from additional injury and to minimize the effects of adverse events. Immediate actions can include the sequestration of applicable equipment for evaluation, a safety stand down if required, and a staff debrief on the situation to obtain critical information. All adverse events, near misses, and unsafe conditions must be entered in the Joint Patient Safety Reporting (JPSR) system. Adverse events that meet the definition of a potentially compensable event (PCE) must be entered in the PCE module of the DOW Centralized Credentials Quality Assurance System (CCQAS) and:

a. Disclose adverse events to the patient and, if appropriate, to the patient's family. Disclosures include factual, event-related information, without attribution of blame or fault, and must be in a language and terms that are readily understood by the patient and family. Disclosure and care-related discussions never include quality assurance information protected under reference (b).

b. Promote organizational transparency and full disclosure following unanticipated or adverse outcomes of care, using the healthcare resolution program, per reference (q).

4. HRM is an essential part of a high reliability program and provides the basis for promoting safe and effective delivery of healthcare. An effective program is dependent on the unique characteristics of the individual healthcare activity, and requires senior medical administration commitment, support, and sufficient resources to manage risk management activities.

5. Reporting Requirements. One copy of any healthcare command investigation or litigation report in which the adequacy of medical care is an issue or that involve potential claims, permanent disability or death must be provided to BUMED-N10G which will enter the PCE or tort claim information into CCQAS. Enclosure (3) identifies the various Adverse Events Reports Requirements. Primary filing method for any healthcare risk management, quality, or patient safety investigation must use a numerical system that does not include any personal patient identifiers (e.g., NQA25-001).

6. Tort Claims. The HRM Program will review and process all paid claims under the control of the Surgeon General of the Navy, to include beneficiary and active duty claims plus active duty death and disability cases without a claim filed. Active duty members are permitted to file claims under the Military Claims Act for personal injury or death caused by the medical malpractice of a DOW healthcare provider for medical treatment provided at a medical treatment facility. OJAG adjudicates these claims, and commands are required to conduct litigation reports in support of Navy claims attorneys. The quality assurance review process for paid Medical Claims Act claims, to include a determination of the standard of care for significantly involved providers and the reporting of the significantly involved providers to the National Practitioner Data Bank, remains the same for these cases as well as other Medical Claims Act claims and Federal Tort Claims Act cases.

7. Command Investigations. A tool to gather, analyze, and record relevant information about an incident or event of primary interest to the command and higher leadership; quality assurance information is not included. Command investigations are not to be used to inquire into incidents that have resulted or are likely to result in claims or civil litigation for damage to real or personal property or personal injury caused by Navy personnel acting within the scope of employment. Command investigations are not privileged, are releasable under the Freedom of Information Act per reference (p) and may be used for disciplinary purposes. Command investigations may be used to inquire into:

a. Significant property loss, or destruction.

b. Incidents in which a member of the naval Service, as a result of misconduct, incurs a disease or injury that may result in permanent disability or physical inability to perform duty for a period exceeding 24 hours (distinguished from a period of hospitalization for evaluation or observation).

c. Deaths of military personnel apparently caused by suicide or under other unusual circumstances.

8. Quality Assurance Investigations. Evaluates the facts and circumstances in the care of a patient and assist in identifying opportunities to improve health care services. These investigations are conducted separately from a litigation report. QAIs are protected from disclosure per reference (b). All documents generated will be appropriately labeled as “1102 protected” and may only be released as permitted by law.

a. An investigator, who is appropriate to the healthcare under review, will be assigned in writing. The investigator will conduct in-person interviews of all significantly involved providers and review medical records. Appropriate specialty reviews will be obtained for all specialties involved in the medical care provided.

b. QAIs will use the same format as litigation reports and will include:

(1) Findings of fact

(2) Opinions

(3) Recommendations

(4) Medical Records

(5) Specialty Reviews

c. QAIs will be signed by the investigating officer and endorsed by the command where the care being reviewed took place. The QAI will be documented in the Risk Management Module of CCQAS. When a QAI finds that medical care contributed to the harm the patient experienced, a copy with command endorsement will be forwarded to BUMED HRM program manager upon completion of the QAI.

9. Litigation-Report Investigation. Used to investigate an incident or event that has or may result in a claim or civil litigation for damage to real or personal property, personal injury or death caused by Navy personnel acting within the scope of their employment. The primary purpose of a litigation report is to document facts and evidence to protect the legal interests of the Navy and the Federal Government. Litigation reports are protected from disclosure under the attorney work product and attorney-client privileges. To maintain these privileges, the litigation-report investigation must be conducted under the direction and supervision of a supervisory judge advocate. The report will be marked on every page: "FOR OFFICIAL USE ONLY; LITIGATION/ATTORNEY WORK PRODUCT." An advance copy will be sent to the Office of the Judge Advocate General (Claims Office). Waiting until endorsement has been obtained before providing a copy of the investigation is neither required nor desired as the facts of the incident must be made known to the cognizant claims personnel for use in adjudicating the claim properly. A copy of the investigation will be provided to the Surgeon General of the Navy, attention BUMED-N10G at the same time it is forwarded to OJAG. OJAG is the release authority for all litigation reports.

PATIENT'S RIGHT TO BE HEARD

1. General. This enclosure describes a patient's right to be heard in any QA program review of care provided by a MHS healthcare provider.

2. Patient's Opportunity. Any patient, including any Service member, who believes they have suffered a personal injury due to a perceived failure of an MHS healthcare provider to provide quality medical care has the right to submit their concerns in writing as part of a QA review of the care provided. The requirement that a patient's concerns be written will ensure inclusion of the patient's input throughout the MQAP review procedures; this includes but is not limited to those described in reference (f). This written requirement does not include the complaint and grievance procedures handled by Healthcare Resolutions and Patient Experience staff (e.g. Patient Advocacy or Patient Relations).

3. Procedures

a. The patient must be given notice of this opportunity and advised the opportunity must be through written presentation.

b. The opportunity provided per this enclosure may be provided in association with the Healthcare Resolutions Program described in enclosure (6) of this instruction. However, the opportunity must be provided without regard to whether the Healthcare Resolutions Program is involved and without regard to whether the patient has filed a claim for compensation or retained legal counsel.

c. A patient is entitled to the assistance of legal counsel of the patient's choosing not at government expense. However, legal counsel does not participate in healthcare resolutions processes.

d. In the case of a patient's death or incapacitation, or if the patient is a minor, the opportunity to submit concerns must be available to the next of kin or other close family member.

e. In any case in which a patient (or legal representative) submits concerns in accordance with this enclosure, those concerns must be considered as part of a QA review of the care provided. However, the results of any QA review are protected per reference (b) and may not be disclosed to the patient or the patient's representative.