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

BUMEDINST 6010.23A
BUMED-N10
15 Jul 2025

BUMED INSTRUCTION 6010.23A

From: Chief, Bureau of Medicine and Surgery

Subj: OPERATIONAL CLINICAL PATIENT SAFETY PROGRAM

Ref: (a) OPNAVINST 3500.39D
(b) DHA-PM 6025.13
(c) DoD Directive 6025.13 signed 29 August 2019
(d) 10 U.S.C.
(e) DHA-PI 6025.17
(f) National Defense Authorization Act
(g) OPNAVINST 5450.215F
(h) The Joint Commission Hospital Accreditation Standards - Current Edition (NOTAL)
(i) The Joint Commission Standards for Ambulatory Care - Current Edition (NOTAL)
(j) The Joint Commission Behavioral Health Standards - Current Edition (NOTAL)

Encl: (1) Confidentiality Statements for E-mails and Documents
(2) Clinical Patient Safety Related Terms and Definitions

1. Purpose. To establish policy, to assign responsibility, and to prescribe procedures for the operational clinical patient safety program in the Navy and Marine Corps, as authorized per references (a) through (c); reference (d), sections 1102 and 8077; reference (e); reference (f), sections 711 and 712 of fiscal year (FY) 2019, sections 742 and 754 of FY 2001, section 702 of FY 2017; and references (g) through (j). This instruction provides for the designation of healthcare patient safety managers to oversee implementation of the operational clinical patient safety program. The instruction augments reference (a) by implementing applications and requirements specific for oversight by Navy Medicine (NAVMED) personnel providing medical and dental treatment. The goal of the operational clinical patient safety program is to prevent harm to patients, visitors, and personnel; to mitigate risks related to process and system issues; to capture the events through the designated Department of Defense (DoD) electronic reporting system; and to implement process improvement strategies. This instruction is a complete revision and should be read in its entirety.

2. Cancellation. BUMEDINST 6010.23.

3. Scope and Applicability. This instruction applies to Navy and Marine Corps operational clinical patient safety services, regardless of platform type or installation. It is applicable to all privileged and non-privileged healthcare personnel (e.g., military, civilian, contractors, volunteer, and Reserve Components).

4. Background

a. The Secretary of the Navy (SECNAV) has policy oversight of the Clinical Quality Management (CQM) Program within the Department of the Navy (DON). The Chief, Bureau of Medicine and Surgery (BUMED), serves as the principal advisor to the SECNAV on all health and medical matters of the Navy and Marine Corps, including policy development relating to such matters. A strong operational clinical patient safety program is the key component of a comprehensive CQM program. This instruction outlines basic component activities, responsibilities, and functions key to a successful operational clinical patient safety program.

b. The DoD utilizes an electronic Web-based Joint Patient Safety Reporting (JPSR) System. This monitoring system captures information to identify, evaluate, and implement risk mitigation strategies to reduce the potential for harm. The operational clinical patient safety program focuses on creating a culture of safety that encourages reporting of errors and near misses, building teamwork though standardized training, and utilizing TeamSTEPPS™ tools, strategies, and techniques to enhance performance by applying solid problem-solving skills. Training, completed in a non-punitive interdisciplinary environment, focuses on process improvement activities to provide safe, high-quality patient care across the Naval enterprise.

5. Policy

a. DON ensures the operational clinical patient safety program adheres to safety, quality, and high reliability organization principles. Operational clinical patient safety program activities are designed to identify, analyze, evaluate, and control risk in any operational setting where NAVMED personnel deliver health care.

b. The information reported through the current electronic JPSR system will be used exclusively for improving healthcare systems and processes that have an impact on 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/SitePages/JPSR.aspx. The JPSR information will not be used for adverse administrative, privileging, disciplinary actions, or other personnel actions. The event may require other quality reviews separately from the patient safety review, as per reference (b).

c. In cases where possible disciplinary action could result, the command will conduct two separate and independent investigations. JPSR investigations may not be used in disciplinary proceedings. All records and information of the operational clinical patient safety program are

medical quality assurance (QA) records and are confidential under references (c) and (d), section 1102. Except as specifically authorized by instruction, operational clinical patient safety program records or information will not be disclosed unless authorized by references (c) and (d), section 1102 required by applicable authority, or authorized by Assistant Secretary of Defense Health Affairs (ASD(HA)). All QA documents will be designated as Medical QA Program documents, protected pursuant to reference (d), section 1102. Copies of QA documents, enclosures thereto and information therefrom, will only be released in accordance with the law. Enclosure (1) details recommended labeling of QA documents.

6. Roles and Responsibilities

a. Director, Clinical Operations, Policy, and Standards (BUMED-N10) and Chief Medical Officer (BUMED-N01CMO) must: Provide guidance for BUMED operational clinical patient safety program implementation to operational forces utilizing DoD, SECNAV, Chief Naval Officer (CNO), and Commandant of the Marine Corps (CMC) patient safety policies, per references (a) through (c); reference (d), sections 1102 and 8077; reference (e); reference (f), sections 711 and 712 of fiscal year (FY) 2019, sections 742 and 754 of FY 2001, section 702 of FY 2017; and references (g) through (j).

b. High Reliability and CQM (BUMED-N10G) must:

(1) Monitor implementation and coordination of the operational clinical patient safety program and provide consultation, educational support, and patient safety-related information to operational healthcare entities. Represent NAVMED in the Defense Health Agency (DHA) Patient Safety Program communications, including initiatives that promote the objectives of the program, monitor for applicability, and provide recommendations to the chief medical officer, Surgeon General of the Navy, CNO, CMC, and ASD(HA) for program improvement, interpretation of DoD instructions, and implementation to those operational commands and medical units under the direction and control of the Surgeon General of the Navy. Per reference (b), onsite surveys will be required to document compliance with applicable program requirements. BUMED in conjunction with the command and regional leadership, may participate in tracer-led quality assessment visits as part of the Surgeon General of the Navy medical oversight function.

(2) Serve as a resource to the operational military commands and medical units under the direction and control of the Surgeon General of the Navy, by providing options for patient safety program training and consultative services. BUMED-N10G will receive and review all comprehensive systematic root cause analyses, provide consultation on the completeness of the reports, abstract and trend data to identify system issues, provide feedback and recommendations for change.

(3) Support the CNO and the CMC commitment to continuously improving the quality of medical and dental care provided to DON members.

c. Fleet and Force Command Surgeons and Senior Medical Department Representatives must:

(1) Implement a patient safety program consistent with reference (b). The patient safety program, with its emphasis on process and system design, is an integral part of the risk reduction and performance improvement efforts of the organization and will function as an integral part of the NAVMED CQM program. The patient safety manager will report patient safety issues through the medical chain of command to assure that the senior leadership is aware of a serious event or trends.

(2) Designate an individual in writing as the patient safety manager to implement this program for operational units, per reference (b), and to provide point of contact information to BUMED-N10G and to Naval Medical Forces Atlantic, Naval Medical Forces Pacific, U.S. Fleet Forces Command, Naval Special Warfare Command, or Headquarters Marine Corps offices, as applicable.

(3) Ensure the patient safety program activities receive interdisciplinary support and implement:

(a) The patient safety event reporting system in the JPSR program.

(b) TeamSTEPPS™ training for all medical staff at least every 3 years.

(c) Track training in FLTMPS

(4) Ensure all clinical and administrative staff are educated about patient safety program and related activities; report patient related harm (e.g., adverse events), events designated as sentinel events by DHA Patient Safety Program, and near misses (e.g., close calls), per reference (b); support program activities; and are given periodic updates on its procedures and activities. The patient safety manager will be afforded annual educational opportunities commensurate with their responsibilities. All patient safety managers should participate and complete in the NAVMED Quality and Safety Leadership Academy course and the DHA-sponsored Professional Patient Safety Program course, if available.

(5) Provide guidance to staff in cases where a medical event causes unanticipated harm to a patient. The goal is for a qualified healthcare provider to inform the patient or legally designated representative of the facts as soon as the command is aware of the event. The Healthcare Resolution program, reference (e), 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. All staff must be aware that information disclosed may not include medical QA records such as the incident report or the review of the event or other information prohibited from disclosure under references (c) and (d), section 1102; and encourage staff to seek advice on disclosure from the command legal officer or risk manager prior to

disclosure if there are any questions about releasable information. Advise providers that the information is disclosed as a matter of clinical policy and does not affect any rights or obligations in legal and administrative proceedings.

(6) In conjunction with subparagraph 6c(5) of this instruction, advise the provider designated to communicate with the patient or designated family member to disclose only factual information known at the time of the discussion, to avoid speculation, and to discuss the patient care and options. The disclosure to the patient or representative is not a standard of care analysis, but a factual statement of outcome. Providers should be informed that in the event a patient asks if an investigation will be conducted or asks if they can obtain a copy of the investigation, the provider is to inform the patient that under the patient safety program, an investigation will be conducted to determine what, if any, corrective actions or improvements should be implemented. The patient and designated representative may submit a written statement for consideration into the QA investigation review process. However, since the purpose of the investigation is a safety analysis conducted under the QA Program, it will not be available to the patient. The provider will document that the patient or representative was advised of the injury and the patient's care options.

(7) Provide support and debriefing opportunities to staff involved in any medical event, regardless of harm to patient.

(8) Implement the TeamSTEPPS™ program, as directed by reference (b), into daily operations. Sites, per reference (b), will include TeamSTEPPS™ orientation and on the job training, and will sustain a cadre of instructors. TeamSTEPPS™ resources are on the Patient Safety Center for Data Integration Web site (https://info.health.mil/hco/clinicsup/patientsafety/PSLCHome/SitePages/PSAC.aspx).

7. Components of the Operational Clinical Patient Safety Program

a. DoD Reportable Events (RE)

(1) A DoD RE, per reference (b), is defined as any patient safety event resulting in death, permanent harm, or severe temporary harm, as per the Agency for Healthcare Research and Quality Harm Scale; is not primarily related to the natural course of the patient's illness or underlying condition; or meets The Joint Commission's sentinel event or the National Quality Forum's serious RE definitions and the Dental DoD RE definition. DoD REs could also include events identified by the Office of the ASD(HA) or the Surgeon General of the Navy, in alignment with strategic initiatives. Definitions can be found in enclosure (2).

(2) All sentinel events, as defined by reference (b), must be reported to BUMED-N10G within 5 working days of the discovery of the adverse event. Operational sites under the control of the Surgeon General of the Navy will report events through their chain of command to BUMED-N10G. Sentinel events are placed in the JPSR system and a phone call made to

BUMED-N10G regarding the event and the plan for review. All Navy and Marine Corps sites will complete the appropriate comprehensive systematic analysis and identify each page of the documents as QA information protected under section 1102 of Title 10, U.S. Code as per enclosure (1).

b. Evaluation and Reporting of Adverse Events or Near Misses. Following an adverse event, the immediate needs of the patient will be addressed to minimize further injury. The staff witnessing an adverse event or a near miss will preserve all evidence for subsequent analysis and provide a factual description of the event to the designated clinical team (e.g., risk manager and patient safety manager). The patient safety manager determines the priority and type of review required by applying the definitions and requirements of enclosure (2).

(1) Patient safety managers are encouraged to conduct performance improvement comprehensive systematic analyses on other adverse events and near misses as they deem necessary. Commands will submit these comprehensive systematic analyses to BUMED-N10G for review.

(2) The comprehensive systematic analysis 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 comprehensive systematic analysis (root cause analysis) and action plan will be completed and approved by the medical chain of command within 45 days of the date on which the report of the adverse event. The time frame is an accreditation requirement and codified in the DHA-Procedures Manual. Circumstances which preclude meeting the timeframe will be considered. A request for an extension waiver must be submitted to BUMED-N10G for evaluation and approval. This focuses on processes and system associated with the event.

(3) Guidance on conducting a comprehensive systematic analysis, use of reporting forms, and other pertinent patient safety information are available from the Patient Safety Center for Data Integration and resources: 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 will be submitted to the DHA Patient Safety Program inbox via e-mail: 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 operational clinical patient safety program. If in the course of the activities of the operational clinical patient safety program, information about intentional unsafe acts is revealed, the original report must 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. These include the initial notification done by e-mail or phone (that include the JPSR number, data and time of event, patient rank, description of the event and patient condition), and subsequent comprehensive systematic analysis (root cause analysis) documents, which will not include patient or staff identifiers.

e. Proactive Risk Assessments through Failure Mode and Effect Analysis. Proactive risk assessments provide the opportunity to reduce the likelihood of, or mitigate the impact of, future incidents that have the potential to result in injury, accident, or other loss to patients, visitors, staff, or assets. A proactive risk assessment is considered a performance improvement process protected under references (c) and (d), section 1102. Results of the proactive risk assessment will be forwarded to the chain of command and to BUMED-N10G for review and evaluation.

f. Food and Drug Administration (FDA) Class I recalls. Per reference (b), all patient safety managers will subscribe to the FDA Class I alerts on medical devices, medications, and other medically related products. 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 FDA safe medical device notification forms will be completed, per reference (b). BUMED-N10G will be notified of the event and device issue.

g. Supporting Urgent Response Across the Global Enterprise via Communicate, Anticipate, Identify, Resolve, Share. The Navy's Supporting Urgent Response Across the Global Enterprise is an external deep dive investigation used to determine causal factors in recurrent events or errors when the standard reviews and interventions have not been effective. A team of subject matter experts visit and review the program, interdependencies and progress to date, interview staff and observe staff workflow and processes before making further recommendations. A Supporting Urgent Response Across the Global Enterprise review may be triggered by the Surgeon General of the Navy, Naval Medical Forces Atlantic, Naval Medical Forces Pacific, U.S. Fleet Forces Command, U.S. Fleet Marine Forces units, U.S. Pacific Fleet, Naval Special Warfare Command, and operational leadership.

h. BUMED High Reliability Organization (HRO) Assessments of the Culture of Safety. Operational components must conduct annual assessments, and the results must be addressed in the operational annual quality summary report. The culture of safety focuses on reporting of events to include near misses, standard communication tools, patient safety huddles and reviews of health care processes and systems.

i. Ready Reliable Care. The DHA has adopted ready reliable care as the term for high reliability. Although NAVMED has not adopted the term ready reliable care for high reliability activities, the Surgeon General of the Navy has articulated an HRO approach that incorporates ready reliable care principles.

j. Annual Patient Safety Plan and Assessment. A patient safety plan and assessment are required from all sites under the operational control of the Surgeon General of the Navy.

Operational commands will develop and submit their plan and assessment annually through the chain of command to BUMED-N10G. The annual patient safety program plan assessment will include information on JPSR activities, efforts to reduce or mitigate harm, successful risk mitigation practices implemented following a sentinel event, other successful patient safety practices implemented, the number and type of actionable FDA alerts, and implementation of TeamSTEPPS™ tools.

k. Per reference (b), a potential compensable event (PCE) is a patient safety event that both reaches the patient (i.e., adverse event and no-harm event), and has a healthcare risk management assessment that determines that the event is likely to present a possible financial loss to the Federal Government (to include, but not limited to, a medical tort claim, an active duty disability payment, or an active duty death payment). Per reference (b), DoD REs are PCEs. The patient safety manager and team will review all JPSR events to determine if the harm category is accurate and will refer PCEs to risk management for further review and investigation.

l. The risk manager will refer claims that have not previously been captured in the JPSR system to the patient safety manager to ensure documentation in JPSR and to conduct an investigation or analysis to include PCEs that do not meet the definition of a DoD RE. PCEs referred to the patient safety manager must include identification as to whether or not the PCE is also a DoD RE.

m. The risk management PCE or QA investigation is separate from the patient safety comprehensive systematic analysis review, which focuses on process and system issues. The information is not shared during the investigations. Following completion of both investigations, identified system and process findings will be shared in the appropriate channels to promote organizational learning.

8. 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).

9. Confidentiality. All documents generated through professional review activities are protected as Medical QA Program documents, in accordance with reference (d), section 1102. These documents must not be released without proper authority. Further information is contained in enclosure (1).

10. Review and Effective Date. Per OPNAVINST 5215.17A, Performance, Plans, Analysis (BUMED-N5) will review this instruction annually around the anniversary of the issuance date to ensure applicability, currency, and consistency with Federal, DoD, SECNAV 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.

11. Information Management Control. The reports required in paragraphs 4b, 5b, 6b, and 7 accordance with enclosure (3) are exempt from reports control, per SECNAV M-5214.1 of December 2005, part IV, subparagraph 7k.

R. FREEDMAN
Acting

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/

CONFIDENTIALITY STATEMENTS FOR E-MAILS AND DOCUMENTS

1. QA Records. The term, medical QA program, means:

a. Any peer review activity carried out before, on, or after 14 November 1986, by or for the DoD to assess the quality of medical care, including activities conducted by individuals, military medical or dental treatment facility committees, or other review bodies responsible for QA credentials, infection control, patient care assessment (including treatment procedures, blood, drugs, and therapeutics), medical records, health resources management review, and identification and prevention of medical or dental incidents and risks, as defined in reference (d). section 1102.

b. The proceedings, records, minutes, and reports that emanate from QA program activities and are produced or compiled by the DoD as part of medical QA, as defined in reference (d), section 1102.

2. E-mail Labeling. Subject line: CUI 10 USC 1102 QA INFORMATION- EVENT P25-000/DoD RE-25-0000-000000.

3. E-mail Introduction: The requested information will be used for analysis of the event for the purpose of improving healthcare systems and processes that impact on medical errors and patient safety per BUMEDINST 6010.23A.

4. Footnote E-mail or QA Document. The information provided herein was obtained from records maintained as part of NAVMED's QA Program and is strictly confidential and privileged. No part of this information may be disclosed, subject to discovery, or admitted into evidence in any judicial or administrative proceeding, except as outlined in reference (d). section 1102.

CLINICAL PATIENT SAFETY RELATED TERMS AND DEFINITIONS

1. Accreditation. Process of review that allows healthcare organizations to demonstrate their ability to meet regulatory requirements and standards established by a recognized accrediting organization.

2. 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. See definition for patient safety event.

3. Agency for Healthcare Research and Quality Harm Scale

a. The Agency for Healthcare Research and Quality Harm Scale can be found in the Agency for Healthcare Research and Quality Common Formats - Hospital Version 2.0, and includes the assignment categories listed in subparagraphs 3a(1) through 3a(5) of this enclosure:

(1) No Harm. Event reached the patient, but no harm was evident.

(2) Mild Harm. Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, or increased length of stay.

(3) Moderate Harm. Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm.

(4) Severe Harm. Bodily or psychological injury (including pain or disfigurement) that interferes substantially with functional ability or quality of life.

(5) Death. In the absence of an applicable State statute or guidance under a Status of Forces Agreement, and for ships at sea where determination of death is at issue, death is defined as irreversible cessation of circulatory and respiratory functions or irreversible cessation of all brain functions, including the brain stem, termed “brain death”.

b. The harm scale defined by Agency for Healthcare Research and Quality Common Formats - Hospital Version 2.0, further delineates harm as:

(1) Temporary Harm. Expected to revert to approximately normal (i.e., patient’s baseline).

(2) Permanent Harm. Not expected to revert to approximately normal (i.e., patient’s baseline).

4. Communicate, Anticipate, Identify, Resolve, and Share Framework. Provides an event-response framework, utilizing existing tools and protocols as a means for DON military

personnel to identify patient safety events, hazards, or mishaps, to respond rapidly to eliminate or mitigate harm, and to share lessons learned across Navy Medicine. The framework is comprised of five critical phases to perform a thorough investigation with strong corrective actions: communicate, anticipate, identify, resolve, and share.

5. CQM. The integrated processes, both clinical and administrative, that provide the framework to objectively define, measure, assure, and improve the quality and safety of care received by beneficiaries. The CQM functional capability includes the programs: Patient Safety, Healthcare Risk Management, Credentialing and Privileging, Accreditation and Compliance, Clinical Measurement, and Clinical Quality Improvement.

6. Compliance. The ongoing process of meeting the legal, ethical, and professional standards applicable to a particular healthcare organization or provider.

7. Comprehensive Systematic Analysis. A comprehensive systematic analysis is a thorough, credible, and acceptable analysis following a patient safety event that seeks to identify system vulnerabilities so that they can be eliminated or mitigated in a sustainable manner to prevent reoccurrence. A root cause analysis is one type of comprehensive systematic analysis. Comprehensive systematic analyses can also be conducted for performance improvement purposes for those events that have the potential to be catastrophic. Guidelines subparagraphs 7a through 7e of this enclosure support the identification of causal factors in comprehensive systematic analyses:

a. Clearly show cause and effect relationships.

b. Use specifics and accurate descriptions of events.

c. Human errors must have a preceding cause.

d. Violations in procedure must have a proceeding cause.

e. Failure to act is only causal when there is a pre-existing duty to act.

8. Corrective Action Implementation Plan Report. The Corrective Action Implementation Plan Report describes the effectiveness of the corrective action after implementation. The Corrective Action Implementation Plan Report should include identified solutions, corrective actions implemented, and measures of effectiveness and sustainment to show that a corrective action has been implemented and is reducing or eliminating the risk of reoccurrence in a lasting way.

9. Data Monitoring. The systematic and ongoing collection, compilation, and organization of data pertaining to indicators for the quality and appropriateness of important aspects of care such that problems or opportunities to improve care can be identified.

10. Denominator. The part of a fraction that is below the line and that functions as the divisor of the numerator, the population at risk in the calculation of a rate or ratio.

11. Deviation. The action of departing from an established course or accepted standard; the amount by which a single measurement differs from a fixed value such as the mean.

12. DoD RE. Any patient safety event resulting in death, permanent harm, or severe temporary harm, as per the Agency for Healthcare Research and Quality's Harm Scale; or meeting The Joint Commission's sentinel event or the National Quality Forum's serious RE definitions. DoD REs require a comprehensive systematic analysis and follow-on Corrective Action Implementation Plan Report. The Joint Commission's sentinel event definition includes severe temporary harm: critical, potentially life-threatening harm lasting for a limited time with no permanent residual but requires transfer to a higher level of care or monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. The Joint Commission categorizes some event types as sentinel regardless of the magnitude of the outcome (e.g., harm).

13. Enterprise Risk Management. Provides a comprehensive framework for making risk management decisions to promote safe and reliable healthcare and to mitigate risks across the organization. Effective enterprise risk management practices are continuous in nature and support the journey to high reliability.

14. Event Reporting. The DoD Patient Safety Program captures the full range of patient safety events listed in reference (b), Volume 2, and all such events must be reported into the JPSR system to be used as opportunities to prevent harm. Any patient safety event that reaches the patient (e.g., adverse events and no harm events) must be reported to the appropriate Healthcare Risk Management Program for assessment. DoD REs also have reporting, notification, and analysis requirements beyond JPSR.

15. Failure Mode and 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.

16. Harm. Any physical or psychological injury or damage to the health of a person, including both temporary and permanent injury.

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

18. Healthcare Risk Management. Includes clinical and administrative activities, processes, and policies to identify, to monitor, to assess, to mitigate, and to prevent risks to the healthcare organization, patients, and staff. The healthcare risk manager addresses events that trigger the

need for a QA investigation initiated by a PCE or by a litigation claim. The risk manager investigations review the standard of care provided by individual staff in the delivery of healthcare services. The risk manager responsibility can be designated to the patient safety manager or can be designated to a separate individual.

19. HRO. NAVMED HRO operating model aligns with the three pillars of HRO: leadership engagement, culture of safety, and continuous process improvement. The model involved the establishment of HRO roles at each level of NAVMED, including echelons 2, 3, and 4 commands, which collectively comprise the HRO network.

20. Intentional Unsafe Act. Any alleged or suspected act or omission of a healthcare provider, staff member, contractor, trainee, or volunteer pertaining to a patient that involves a criminal act, a purposefully unsafe act, patient abuse, or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, disciplinary system, or administrative investigation.

21. Joint Commission Sentinel Event. A patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm.

22. JPSR System. JPSR is 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 QA investigation).

23. Medical QA Program. Any peer review activity carried out before, on, or after 14 November 1986 by or for the DoD to assess the quality of medical care, including activities conducted by individuals, military medical or dental treatment facility committees, or other review bodies responsible for QA, credentials, infection control, patient care assessment (including treatment procedures, blood, drugs, and therapeutics), medical records, health resources management review, and identification and prevention of medical or dental incidents and risks as defined in reference (d), section 1102.

24. Medical QA Record. The proceedings, records, minutes, and reports that emanate from QA program activities and are produced or compiled by the DoD as part of a medical QA program as defined in reference (d), section 1102.

25. National Quality Forum Serious RE. Largely preventable, grave errors, and events of concern to the public and healthcare providers that warrant careful investigation and should be targeted for mandatory public reporting. Includes both injuries caused by care management (rather than the underlying disease) and errors that occur from failure to follow standard care or institutional practices and policies.

26. Near miss event. Patient safety event that did not reach the patient (also known as "close call" or "good catch").

27. No harm event. Patient safety event that reached the patient but did not cause harm.

28. Patient Safety Event. A patient safety event is an incident or condition that could have resulted, or did result, in harm to a patient. A patient safety event can be but is not necessarily the result of a defective system or process design, a system or process breakdown, equipment failure or malfunction, or human error. Patient safety events include adverse events, no harm events, near miss events, and unsafe or hazardous conditions as defined in subparagraphs 28a through 28d of this enclosure:

a. Adverse event. Patient safety event that resulted in harm to the patient. The event may occur by the omission or commission of medical care.

b. No harm event. Patient safety event that reached the patient but did not cause harm.

c. Near miss event. Patient safety event that did not reach the patient (also known as "close call" or "good catch").

d. Unsafe or hazardous condition. A condition or a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

29. PCE. An adverse event that results in harm to a patient and presents a possible financial loss to the Federal Government (a malpractice claim or active duty death or active duty disability payment). All DoD REs are PCEs. All events that trigger a PCE will also be referred to the patient safety manager to ensure capture in the JPSR system and investigation or analysis, as defined in reference (b), Volume 2.

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

31. Proactive Risk Assessment. Process used to identify, to rate, and to prioritize risks or hazards. Based on a risk assessment, policies, procedures, and controls may be put into place to manage the risk as appropriate to the organization, with the intent of reducing risk to the lowest possible level. A form of proactive risk assessment is failure mode effect analysis: a systematic, proactive method for evaluating a process to identify where and how it might fail, to assess the relative impact of different failures, and to identify the parts of the process that are most in need of change.

32. Process. A goal-directed, interrelated series of actions, events, mechanisms, or steps. Processes should always be designed with flexibility in mind and the ability to periodically introduce controlled, measurable changes.

33. QA Investigation. 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 quality assurance investigation is used in all healthcare risk management activities, to include clinical adverse actions and is required in determining standard of care.

34. QA Records. Created by or for the DoD or DON, as part of a QA program, are confidential and privileged. Release of these records is governed by reference (d), section 1102.

35. Quality Healthcare. The degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Care that is evidence-based and provided in a technically and culturally competent manner with good communication and shared decision making as defined in the Institute of Medicine's Crossing the Quality Chasm: A New Health System for the 21st Century.

36. Rapid Process Improvement. A fast and effective approach to improve a process that usually takes a week or less, completed by the members of the process or value stream.

37. Root Cause Analysis. 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.

38. Supporting Urgent Response across the Global Enterprise via Communicate, Anticipate, Identify, Resolve, Share Framework. Supporting Urgent Response Across the Global Enterprise provides patient safety event investigation support to operational medicine leaders when requested. The prospective operating environments include any operational location where Navy healthcare providers serve. A Supporting Urgent Response Across the Global Enterprise via communicate, anticipate, identify, resolve, share framework team may be requested to assist in response to patient safety events, hazards, or near misses which resulted in or had the potential to result in, fatality, injury or illness to DON military personnel or degradation to mission readiness. A rapid response to a patient safety event, which can be initiated at the Naval Medical Forces Atlantic, Naval Medical Forces Pacific, operational military facility, or operational setting; the review and investigation are considered a QA effort, and the work product is confidential and privileged, per reference (d). Supporting Urgent Response Across the Global Enterprise is for process issues not resolved by routine investigation via a QA investigation, which is required for standard of care reviews.

39. TeamSTEPPS®. A teamwork system designed for health care professionals to help provide higher quality, safer patient care, and to create and sustain a culture of safety. TeamSTEPPS is an evidence-based framework to optimize team performance across the healthcare delivery system.

40. Unsafe or Hazardous Condition. A condition or a circumstance (other than a patient's own disease process or condition) that increases the probability of an adverse event.

41. Variation. An undesirable deviation from expected outcomes.