



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

BUMEDINST 6010.23
BUMED-M3M22
18 Dec 2002

BUMED INSTRUCTION 6010.23

From: Chief, Bureau of Medicine and Surgery
To: Ships and Stations Having Medical Department Personnel

Subj: PARTICIPATION IN THE MILITARY HEALTH SYSTEM PATIENT SAFETY PROGRAM (MHSPSP)

Ref: (a) Floyd D. Spence National Defense Authorization Act, sections 742 and 754 for FY 01
(b) DOD Instruction 6025.17 of 16 Aug 01
(c) OPNAVINST 3500.39A/Marine Corps Order 3500.27A
(d) Title 10, USC, section 1102
(e) DOD Directive 6040.37 of 9 Jul 96
(f) Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Manuals Applicable to Health Care, current editions

Encl: (1) Sample Appointment Memo for a Quality Assurance Inquiry
(2) Confidentiality Statements for Sentinel Event Related Documents
(3) Patient Safety Program Definitions

- 1. Purpose.** To establish Bureau of Medicine and Surgery (BUMED) policy, assign responsibility, and prescribe procedures for complying with references (a) and (b). This instruction augments reference (c) by implementing applications and requirements specific to Navy Medicine medical and dental treatment facilities (MTFs and DTFs) per references (a) through (f) and enclosures (1) and (2). Enclosure (3) is a list of patient safety program definitions.
- 2. Background.** Reference (b) establishes the broad parameters for monitoring and improving the medical and dental health care provided to our beneficiaries. This monitoring includes identifying, evaluating, and reducing the potential for harm. The Department of Veterans Affairs (VA) has developed a system for reporting, compiling, and analyzing situations that lead to the identification of actual or potential patient harm. Department of Defense (DOD) health entities are to emulate this system to the extent that is practical. Effectively promoting patient safety focuses on creating strong incentives to disclose the errors made or observed (realizing the majority of errors are caused by system failures), as well as building teamwork, communication, and problem-solving skills. All of this is done in a non-punitive interdisciplinary environment.
- 3. Applicability.** Applies to all shore-based commands providing medical and dental services, including BUMED activities under the command or support of BUMED. All individuals providing care or participating in the health care delivery system are responsible for supporting the Patient Safety Program (PSP).

4. Policy. The goal of the PSP is to prevent injuries to patients, visitors, and personnel and to minimize the negative consequences of injuries that do occur. This is accomplished through the identification, reporting, and intensive analysis of sentinel events, adverse events, and close calls. The information reported through the PSP shall be used exclusively for improving health care systems and processes that impact on medical errors and patient safety. PSP information shall not be used for any adverse administrative, privileging, or other personnel actions including disciplinary action. In cases where possible disciplinary action could result, the command will conduct two separate and independent investigations. No information from these PSP investigations may be used in disciplinary proceedings. All records and information of the PSP are medical quality assurance (QA) records and are confidential under references (d) and (e). Except as specifically authorized by instruction, PSP records or information shall not be disclosed unless authorized by references (d) and (e), required by applicable authority, or authorized by Assistant Secretary of Defense (Health Affairs) (ASD(HA)). All QA documents shall be designated as such using the wording recommended in enclosure (2).

5. Responsibilities

a. Chief, BUMED shall:

(1) Participate fully in the MHSPSP, including initiatives to promote the objectives of the program, monitor for inappropriate use of information generated, and provide recommendations to the ASD(HA) for program improvement, interpretation of DOD instructions, and implementation guidance to the field.

(2) Assign appropriate military personnel to the Armed Forces Institute of Pathology (AFIP) in support of the MHSPSP to ensure adequate representation and participation of Navy Medicine.

(3) Serve as a resource to the military MTFs and DTFs by providing PSP training opportunities as well as consultative services through BUMED, Risk Management (RM) (BUMED-M3M22). BUMED RM will receive and review all root cause analyses (RCA), provide consultation to the field on the completeness of the report, abstract and trend data to identify system issues, and provide feedback to the field on the system issues identified and recommendations for changes.

b. Commanding officers of all shore-based treatment facilities shall:

(1) Establish and implement a PSP consistent with reference (b). The PSP, with its emphasis on process and system design, is an integral part of the risk reduction and performance improvement efforts of the facility and shall function as an integral part of the QA process of the facility. The patient safety manager (PSM) shall be part of the administrative team and should report patient safety issues directly to the facility commander or executive officer.

(2) Designate an individual as the PSM to implement this program in the MTF or DTF per reference (b), and this instruction, and provide point of contact information to BUMED RM and the Deputy Chief Dental Operations Support (BUMED-M3D) for DTFs.

(3) Ensure the PSP activities receive interdisciplinary support from the MTF and DTF staff as well as other support necessary for an effective program.

(4) Ensure all clinical and administrative staff: are educated about the MTF and DTF PSP and facility related activities; are encouraged to report adverse events, sentinel events, and close calls using the MTF and DTF reporting systems; support program activities; and are given periodic updates on its procedures and activities. The PSM should be afforded annual educational opportunities commensurate with their responsibilities; formal training may be military or civilian sponsored. The program will be sufficient in scope to enable effective program oversight.

(5) Provide guidance to staff in cases where a medical event causes unanticipated harm to a patient. The goal is for a qualified health care provider to 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 (pain controlled). Designate (in most cases) the attending physician or clinician most closely involved in the care of the patient to manage the discussion. Remind providers that information disclosed may not include medical QA records and other information prohibited from disclosure under reference (e) and encourage them to seek advice on disclosure from the command legal officer or risk manager prior to disclosure if they have any questions about what information is releasable. 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 paragraph 5b(5) above, 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 about what may have happened and to discuss the patient's care and options for care. The disclosure to the patient or family is not meant to be a standard of care analysis, but a factual statement of outcome. Additionally, an expression of sorrow or concern for the patient and family does not equate to admission of negligence. Providers should be informed that if the patient should ask if an investigation will be conducted, or ask if they can obtain a copy of the investigation, they should inform the patient that under the PSP an investigation will be conducted to determine what, if any, corrective actions or improvements should be implemented. However, since the purpose of the investigation is a safety analysis conducted under the QA Program that Congress has mandated, the information gathered is protected under QA regulations and will not be available to the patient. The provider will document that the patient or family member was advised of the injury and the patient's care options at that point.

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

c. All active duty, Reserves, civilians, and contractors (all employees) involved in the health care delivery process, shall use the command's reporting mechanisms to report actual or potential unsafe conditions or processes, support systems redesigns resulting from safety issues, and assist fellow employees with maintaining safe practices.

6. Components of the PSP

a. JCAHO sentinel event reporting. All sentinel events, as defined by JCAHO, occurring in JCAHO-accredited facilities, must be reported to JCAHO and BUMED RM. All Navy MTFs will notify JCAHO and BUMED RM of the sentinel event within 5 working days of the adverse event or of becoming aware of the event. All Navy MTFs will identify the review process documents, including each page of the RCA form, as a QA activity protected under 10 USC 1102 using the language noted in enclosure (2). The completed RCA and action plan, consistent with JCAHO policy and time limits, shall be made available to JCAHO with a copy forwarded to BUMED RM. BUMED RM will forward the RCA to the Military Health System Patient Safety Center (MHSPSC). Refer to enclosure (1) for a sample appointment memo for a QA inquiry.

b. Evaluation and reporting of "other" adverse events, close calls, or near misses. Following an adverse event, the immediate needs of the patient will be addressed to minimize injury. The employee witnessing an adverse event or a close call will preserve all evidence for subsequent analysis and provide a factual description of the event to the designated clinical team (e.g., team leader, RM representative, and PSM). The PSM determines the priority and type of review required by applying the safety assessment code (SAC) matrix, per reference (b).

(1) SAC matrix is established by pairing the severity of the adverse event with the probability of recurrence rating, resulting in a SAC score of 1, 2, or 3. MTFs and DTFs are required to complete an RCA and action plan of adverse events scored as a category 3. All category 3 RCAs will be sent to BUMED RM for review and analysis. PSMs are encouraged to conduct RCAs on other adverse events and close calls they deem necessary or as required by JCAHO standards (intensive reviews). Commands are encouraged to submit these RCAs to BUMED RM for review.

(2) RCA and action plan should include written findings regarding the underlying systems and processes involved in the event, including the identification of actual and potential problems in those systems and processes, and recommendations for corrective action plans. The RCA and action plan shall be completed and approved by the MTF or DTF commander within 45 days of the date on which the PSM becomes aware of the adverse event.

(3) A quarterly aggregate review may be performed in lieu of an individual event RCA for certain types of more common adverse events or close calls, which are not SAC 3s. Examples of events suitable for aggregate reviews include falls and medication events not included in the JCAHO standards requiring intensive review.

(4) Guidance on conducting an RCA, reporting forms, and other pertinent patient safety information is available from BUMED RM and the MHSPS Web site at www.afip.org/PSC/index.html.

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 shall be referred to appropriate command authority. The PSM proceeds with a review of systems and processes of the facility implicated in the actual or potential intentional unsafe act (but defers to the separate investigation and consideration with respect to any matter of culpability of any person involved in the act).

d. Reporting to the MHSPSC. All reports shall be submitted to BUMED RM per reference (b). Names or other identifying information on patients or health care providers shall not be included. BUMED RM will submit all required reports to MHSPSC.

e. Health Care Team Coordination Program (HCTCP). The MTF and DTF PSP shall include implementation of the HCTCP as directed by the DOD Patient Safety Council.

f. Failure Mode and Effects Analysis (FMEA). JCAHO accredited programs shall implement a program to reduce the risks of adverse events and other medical and health care events by conducting proactive risk assessment activities using FMEA. The frequency of conducting the FMEA must meet the current JCAHO requirements. Results of the FMEA will be forwarded to BUMED RM for review and evaluation. FMEA is optional for non-accredited entities.

7. Action. This instruction is effective immediately.



K. L. MARTIN
Vice Chief

Available at: <http://navymedicine.med.navy.mil/instructions/external/external.htm>

SAMPLE APPOINTMENT MEMO FOR A
QUALITY ASSURANCE INQUIRY

MEMORANDUM

From: (Commanding Officer)
To: (Name and Rank of Designated Individual)

Subj: APPOINTMENT AS SENIOR INVESTIGATOR FOR A QUALITY ASSURANCE
INQUIRY

1. You are hereby appointed senior investigator for a Quality Assurance inquiry into the care provided to _____ (name) on _____ (date). You will be assisted by:

_____ (Name)

_____ (Name)

2. Preliminary information indicates that the patient _____ (name) had the following experience (describe event). _____
_____. From the information available at this time, this event meets the criteria for a sentinel event.

3. Therefore, special timelines are appropriate and the use of an appropriate root cause analysis tool for recording and reporting your results is required. Your final report is due in the _____ (name of office) on _____ (date). The office of _____ (name of office) will contact you on _____ (date) for a status report, if the report has not already been provided. Your report will be distributed to the responsible director(s) and will be placed on the Executive Committee of the Medical Staff agenda for the _____ (date) meeting.

4. We ask that your analysis include the use of appropriate quality tools, such as a flow diagram. This tool can be used to clarify the current process, develop a modified process, or convey to all concerned the proper procedures to be followed in the future.

5. Please note that documents and records created pursuant to this order are Quality Assurance materials, which are confidential and privileged under 10 USC 1102.

6. If you have any questions during your review, please contact _____ (name) in the _____ (name of office) at _____ (telephone number).

CONFIDENTIALITY STATEMENTS FOR
SENTINEL EVENT RELATED DOCUMENTS

1. Include the following statements on Sentinel Event related documents including appointment letters to JCAHO and the root cause analysis document.

a. Place the following statement on the bottom of each page of the root cause analysis report form:

Do not release. Confidential and privileged Quality Assurance material under 10 USC 1102.

b. Place the following statement in the body of the appoint letter authorizing the investigation:

Documents and records created pursuant to this order are Quality Assurance materials, which are confidential and privileged under 10 USC 1102.

c. Place the following statement in the body of the letter forwarding a completed root cause analysis to JCAHO:

This root cause analysis was produced as a part of this facility's Quality Assurance program, and is strictly confidential and privileged. No part may be disclosed, subject to discovery or admitted into evidence in any judicial or administrative proceeding, except under 10 USC 1102.

2. If you have any questions regarding the contents of this enclosure, contact the BUMED Risk Manager at (202) 762-3081 or DSN 762-3081.

PATIENT SAFETY PROGRAM DEFINITIONS

1. Adverse Events. Occurrences or conditions associated with care or services provided that cause unexpected harm to a patient during such care or services. These may be due to acts of commission or omission. Adverse events do not include intentional unsafe acts.
2. Sentinel Events. As defined by JCAHO, sentinel events are unexpected occurrences involving death or serious physical or psychological injury or risk thereof.
3. Close Calls. An event or situation that could have resulted in harm to a patient, if it had reached the patient. Such events have also been referred to as "near misses."
4. Intentional Unsafe Act. Any alleged or suspected act or omission of a 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. This also includes cases of negligence, which rise to the level of criminal negligence.
5. Root Cause Analysis (RCA). A process for identifying the basic or contributing causal factors associated with adverse events and close calls. An RCA includes the following characteristics:
 - a. The review is interdisciplinary in nature with involvement of those closest to the process.
 - b. The analysis focuses primarily on systems and processes rather than individual performance.
 - c. The analysis digs deeper by asking "what" and "why" until all aspects of the process are reviewed and all contributing factors are identified.
 - d. The analysis identifies changes that may be made in systems and processes through either redesign or development of new processes or systems that may improve performance and may reduce the risk of adverse events or recurrence of close calls.
6. Aggregate Review. The process of analyzing recurring incidents, events, or close calls (such as medication errors) for trends and patterns to use for process improvement.
7. Health Care Team Coordination Program (HCTCP). The HCTCP was written into the National Defense Authorization Act for FY 01, section 754, and requires team training in the emergency departments with expansion to a new medical specialty on an annual basis. In addition, training is required for the combat casualty care organizations.
8. Failure Mode and Effects Analysis (FMEA). FMEA is a tool used to conduct a proactive risk assessment of a facility defined critical process. The VA National Center for Patient Safety has modified the traditional FMEA by combining the detectability and criticality steps into an algorithm presented as a decision tree.