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

Canc: Jul 2017
IN REPLY REFER TO
BUMEDNOTE 6010
BUMED-M3B5
20 Jul 2016

BUMED NOTICE 6010

From: Chief, Bureau of Medicine and Surgery

Subj: POTENTIALLY COMPENSABLE EVENTS REPORTING COMPLIANCE

Ref: (a) DoD Manual 6025.13 of 29 October 2013
(b) 10 U.S.C. §1102
(c) BUMEDINST 6010.21

Encl: (1) Patient Safety Reporting Harm Scale (Based on Agency for Healthcare Research and Quality Common Formats 1.2)
(2) Definitions
(3) Patient Safety Reporting System Classification Categories

1. Purpose. Per reference (a), it is Department of Defense (DoD) policy that adverse events, which meet the definition of a potentially compensable event (PCE), must be entered into the PCE module of the Centralized Credentials Quality Assurance System (CCQAS) within 30 days of identification of the occurrence and be completed within 180 days. This policy provides additional guidance to ensure compliance with this DoD requirement.

2. Scope. This instruction applies to all Budget Submitting Office (BSO) 18 activities inside and outside the continental United States, Navy Medicine echelon 3 activities, and all medical treatment facilities (MTF) as the sourcing commands for active component, BSO-18 Augmented Platforms.

3. Background. A PCE is defined as an adverse event that results in harm to the patient and presents a possible financial loss to the Federal Government (i.e., malpractice claim, death, or disability payment). All PCEs must be documented, tracked, reviewed, and analyzed to determine contributing causes. Results of the investigation and standard of care (SOC) must be documented in CCQAS. Harm scale categories (enclosure (1)) for the Patient Safety Reporting (PSR) system and CCQAS Risk Management program are identical and are the required taxonomy for identifying and documenting adverse events.

4. Action

a. Adverse events require an initial quality review to determine if they meet the definition of a PCE. If determined to be a PCE within the harm scale categories of mild to severe harm as stated in enclosure (1), the facility review must include a SOC evaluation. While all PCEs by definition represent a potential financial loss, not all are serious enough to warrant further investigation (i.e., a quality of care review or litigation report).

Using the NAVMED 6010/1, Potentially Compensable Event Determination Worksheet, the Risk Manager (RM), Patient Safety Manager (PSM), and senior clinical staff will collaborate, and consult with the MTF attorney as needed, to determine the appropriate investigative process(es) for the adverse event based on the level and duration of actual harm to the patient.

b. PCE documentation must be in enough detail to ensure a full understanding of the facts regarding care provided to the patient, including:

(1) Event Identifier/PCE Identification Number per enclosure (2)

(2) Identification of the patient

(3) Initial diagnosis

(4) PSR classification type (see enclosure (3))

(5) Summary and review of healthcare provided, to include an opinion as to whether or not the SOC was met for each significantly involved provider. In cases where the SOC is indeterminate due to a lack of information/incomplete medical records or cases where the SOC is determined to not have been met, the rationale for these opinions will be documented.

(6) Identification of all significantly involved providers who must be afforded the opportunity to provide input as to their role in the event. Input requested is pursuant to the quality assurance (QA) process involving peer review and is therefore protected from release per reference (b). All requests for information, along with the provider's input, must be clearly identified as QA protected material regardless of method used to procure the information (hardcopy or electronic).

c. RM will be alerted to all cases involving active duty (AD) members where medical care is called into question. If the initial SOC evaluation determines that medical care contributed to an AD member's death or disability, a quality assurance investigation (QAI) documenting the adverse event is required. The completed QAI is forwarded to the Bureau of Medicine and Surgery and must be documented in the risk management module of CCQAS.

d. When an adverse event results in concurrent review and analysis by both the PSM and RM, the two investigations represent separate and distinct processes and must be entered into both PSR and CCQAS.

e. PCE reviews are done as part of the medical quality assurance (MQA) process and are confidential and privileged. MQA records may not be disclosed to any person or entity, except as provided in reference (b).

5. This policy is effective the date signed and remains in effect until incorporated as a change into reference (c).

6. Forms. The NAVMED 6010/1, Potentially Compensable Event Determination Worksheet is available at: http://www.med.navy.mil/directives/Pages/NAVMEDForms.aspx.

C. FORREST FAISON III

Releasability and distribution:
This notice is cleared for public release and is available electronically only via the Navy Medicine Web site at: http://www.med.navy.mil/directives/Pages/default.aspx

# PATIENT SAFETY REPORTING SYSTEM HARM SCALE (BASED ON AGENCY FOR HEALTHCARE RESEARCH AND QUALITY COMMON FORMATS 1.2)

| Harm Scale | Definition |
|---|---|
| Death | Dead from event. |
| Severe Harm | Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life. |
| Moderate Harm | Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm. |
| Mild Harm | Bodily or psychological injury resulting in minimal symptoms, loss of function, or injury limited to additional treatment, monitoring and/or length of stay. |
| No Harm | Reached patient, but no harm was evident. |
| Near Miss - did not reach patient | Event occurred, but was caught and corrected before reaching the patient. |
| Unsafe Condition - potential event | Conditions are present that could result in a patient safety event. |

## DEFINITIONS

AD Death – Active Duty Death - An adverse event resulting in the death of an AD member where there is a question of whether or not medical care may have contributed to the death.

AD Disability – Active Duty Disability - An adverse event that results in an AD member being referred to the Physical Evaluation Board (PEB) and the PEB awards a disability settlement/payment.

Adverse Event – Unintended occurrences or conditions associated with care or services that reach the patient and that may or may not result in harm to the patient. These may be because of acts of commission or omission.

CCQAS – Centralized Credential Quality Assurance System - Electronic system that documents AD Death, AD Disability, PCEs, and torts.

Event Identifier – Facility assigned unique tracking indicator used to identify an entry in the RM module of CCQAS that does not include personally identifiable information or protected health information (Example PCE-16-01 would be the first PCE at the facility for 2016). Do not file any QA information by patient or provider name.

Litigation Report – Used to investigate an incident or event that may potentially result in claims or civil litigation against the Navy for personal injury or death caused by Navy personnel acting within the scope of their employment. Litigation Reports are done per Manual of the Judge Advocate General Chapter II.

Malpractice payment – A monetary award relating to the provision of healthcare services under the organizational responsibility of the Department of Defense.

PCE – Potentially Compensable Event - An adverse event that results in harm to a patient and presents a possible financial loss to the Federal Government (a malpractice claim, death, or disability payment).

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

PII – 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 PII.

PSR – Patient Safety Reporting system - A standardized, automated reporting system which allows all users across each military treatment facility the ability to report, aggregate, and analyze adverse events. Focuses on systems and processes.

QAI – Quality Assurance Investigation - Used to investigate and document facts for an incident or event involving an AD member where personal injury or death may have resulted due to the medical care provided. QAI can also be done on any event, but cannot be used for litigation work. QAI includes SOC determinations and follows the litigation report format.

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.

Sentinel Event - 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 any of the following:

- Death
- Permanent harm
- Severe temporary harm

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 SOC determination.

SOC – 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.

**PATIENT SAFETY REPORTING SYSTEM CLASSIFICATION CATEGORIES**

Care Management Events
Environmental Events
Patient Protection Events
Potential Criminal Events
Product or Device Events
Surgical or Invasive Procedures or Anesthesia Events

NOTE: These correspond to the revised "Event Type" in the Military Health System Patient Safety Reporting System.