The Patient Safety Program

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATIN: MCHO-CL-Q.

1. History. This issue publishes a revision.

2. Purpose

   a. This regulation outlines the activities of the Army Medical Department (AMEDD) Patient Safety Program (PSP) to identify and centrally report actual and potential events as well as unsafe conditions in medical/dental systems and processes and to improve patient safety (PS) and healthcare quality throughout the AMEDD.

   b. This regulation supports Department of Defense Instruction (DODI) 6025.13, Army Regulation (AR) 40-68, and the requirements for confidentiality of medical quality assurance records under Title 10, United States Code (USC), Section 1102 (10 USC 1102).

3. Applicability. This regulation applies to personnel in all U.S. Army Medical Command (MEDCOM) installations and activities.

4. References. References are listed at Appendix A.

*This regulation supersedes MEDCOM Regulation 40-41, 8 May 2013.*
5. General

a. The MEDCOM PSP is the corporate program that uses leadership engagement, communication, teamwork, and data analyses to identify, evaluate, and execute process improvement initiatives to facilitate reduction in harm to beneficiaries.

b. The PSP establishes guidelines for every military treatment facility (MTF) and dental treatment facility (DTF) to execute a dedicated PSP as outlined in AR 40-68.

c. PS involves a variety of clinical and administrative activities that healthcare organizations undertake to identify, evaluate, and reduce the potential for harm to beneficiaries and to improve the quality of health and oral care. Effective health and dental care PS event reduction requires an integrated approach and a supportive environment in which patients, their Families, organization staff, and leaders can identify, manage, and learn from actual and potential risks.

d. A successful PSP facilitates a blame-free, interdisciplinary approach to decrease unanticipated adverse healthcare outcomes. MEDCOM is a partner in the Military Health System’s (MHS) Partnership for Patients Campaign and part of a broader national initiative that aims to reduce harm and improve care in health care facilities. The Clinical Performance Directorate (CPAD) has been tasked with aligning efforts of MTFs with Partnership for Patients (PfP) key aim to reduce harm and reducing readmissions caused by preventable patient concerns. The organizational focus is on continued learning about risks and mitigation strategies to reduce the chance of human error. The AMEDD fosters and supports an organizational environment that recognizes and acknowledges potential risks to PS and the occurrence of medical and dental care PS events. The PSP encourages event reporting in order to identify system or process failures and to enhance improvement strategies.

e. Military Health System (MHS) High Reliability Organization principles must be adopted at all levels of the enterprise and fundamental cultural changes will be required. Comprehensive assessment of quality and safety will drive to strengthen the connections between the purchased care and direct care systems, resulting in improved continuity, standardization, and a better patient care experience. A standardized performance management system will allow system-wide improvement in synchronizing the Services’ monitoring and management of MTFs and DTFs.

6. Responsibilities

a. The MEDCOM Clinical Performance Assurance Directorate (CPAD), PSP will-

   (1) Exercise broad oversight responsibility for development and implementation of the PSP as delegated by The Surgeon General (TSG).
(2) Represent TSG as a member of various committees and working groups sponsored by Office of the Assistant Secretary of Defense/Health Affairs, Department of Defense (DOD), and other healthcare agencies.

(3) In coordination with regional medical and dental patient safety officers (PSOs), provide guidance and assistance to the MTF medical patient safety manager (PSM) and DTF PSO in the development of his/her facility’s PSP.

(4) Educate and train PSMs and PSOs. Basic Patient Safety Manager’s Course is provided by the Defense Health Agency (DHA). CPAD PSP provides an Annual Patient Safety Training (APST), TeamSTEPPS Train the Trainer and Simulation Training, TapRooT Software and application training, and Patient Safety Reporting (PSR) Documentation and Reporting Training.

(5) Provide advice, assistance, and ongoing feedback to the PSMs and PSOs in identifying and categorizing PS events, conducting aggregate reviews and root cause analysis/analyses (RCA), and developing facility-specific Annual Patient Safety Action Plans.

(6) Implement standardized PS data collection, reporting, and metrics to monitor and evaluate program compliance and effectiveness.

(7) Align and integrate PS initiatives with relevant DOD and national PS and quality improvement programs, as appropriate.

(8) Establish the evidence-based Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™) as the AMEDD platform for training, implementation, skill building, and sustainment of teamwork initiatives. (Note: TeamSTEPPS™ is a public domain resource and is available at http://teamstepps.ahrq.gov/about-2cl3.htm)

(9) Provide regional and MTF/DTF-specific information and reports regarding PS events, RCA, action plans, and aggregate data to the facilities through the PSMs/PSOs and regional representatives.

(10) Provide opportunities for MTF/DTF lessons learned to be shared throughout the AMEDD.

b. Regional Health Command (RHC)/Regional Dental Command (RDC) commanders will-
(2) Develop and update their Regional Annual Patient Safety Plan.

(3) Communicate the Regional Patient Safety Plan to their MTFs/DTFs.

(4) Provide PSP support and guidance to supported MTFs/DTFs.

(5) Establish TeamSTEPPS™ as their platform for improving teamwork, empowering staff, improving communication, and improving patient safety within all facilities.

(6) Be responsible for review and utilization of the TeamSTEPPS™ Teamwork Perceptions Questionnaire (TTPQ) data for the region to drive proactive improvement actions.

(7) Ensure a balance between human and system accountability through the implementation of a Just Culture across the continuum of care. Encourage a systems approach to creating a safer patient environment by fostering trust, transparency, teamwork, and communication.

(8) Send a FDA Class 1 Recall regionally consolidated report within 5 business days of receipt of a Class 1 Medical Material Quality Control Messages (MMCQ) message to the MEDCOM CPAD at usarmy.jbsa.medcom.list.medcom-psc@mail.mil. This will include both positive and negative acknowledgement of purchase history through either Defense Medical Logistics Standard Support (DMLSS) and/or Government Purchase Card (GPC). Facilities acknowledging no purchase history and no product on hand have completed the task. If positive acknowledgement of product on hand, a Patient Safety Report number will be provided in the consolidated report. If positive acknowledgement for a medical device is received, a work order number will be provided in the consolidated report. The task for positive acknowledgement of product on hand will be completed when the PSR number or work order number have been submitted.

c. MTF and DTF Commanders will-

(1) Ensure the facility has a current, command approved Annual PSP Plan with data driven goals.

(2) Be responsible for effective implementation and compliance with the AMEDD PS policy as defined in this regulation.

(3) Establish TeamSTEPPS™ as their platform for improving teamwork, empowering staff, improving communication, and improving patient safety within all facilities.

(4) Role model TeamSTEPPS™ Leadership principles.
(5) Be responsible for data evaluation of the TeamSTEPPS™ Teamwork Perceptions Questionnaire (TTPQ).

(6) Utilize and integrate tools and strategies of TeamSTEPPS™ into facility processes.

(7) Empower staff to speak up for patient safety utilizing TeamSTEPPS™ tools.

(8) Ensure reporting of PS events, focusing on event prevention and systems improvement rather than punishment. Ensure a balance between human and system accountability through the implementation of a Just Culture across the continuum of care. Encourage a systems approach to creating a safer patient environment by fostering trust, transparency, teamwork, and communication.

(9) Ensure all sentinel events (SEs) (as defined by The Joint Commission (TJC) and MEDCOM behavioral health policy on suicides) are reported to the RHC/RDC and the MEDCOM CPAD PSP within 24 hours of identification using MEDCOM Form 732 (Sentinel Event Report Worksheet version 2015). In response to an SE, the MTF/DTF commander will designate and formally charter a team to conduct a thorough and credible RCA IAW current Root Cause Analysis (RCA) Reporting Requirements for Sentinel Events policy.

(10) Designate the PSM/PSO to manage the MTF/DTF organization-wide PSP.

(11) Provide the resources required to sustain a comprehensive, integrated PSP according to the provisions of this regulation.

(12) Ensure all assigned staff is educated on PSP components, roles, and responsibilities.

(13) Facilitate the education of MTF/DTF beneficiaries regarding their roles and responsibilities as partners in the health/dental care process, to include the identification of PS-related issues.

(14) Ensure the PSM/PSO and others designated by the commander receive PSP training through the DoD Basic Patient Safety Managers Course.

(15) Ensure acknowledgement, reporting, disposition and follow-up on MMCQ FDA Class I Recalls. Facilities will conduct a thorough review of purchases of the recalled product through Defense DMLSS and GPC. The facility will submit a purchase history and product on hand response to the respective facility acknowledging no purchase history and no product on hand have completed the task. If a positive acknowledgement of product on hand, a Patient Safety Report (PSR) will be generated and a PSR number will be submitted to the facility, within the suspense date.
(16) Support and actively engage an ongoing, proactive program for identifying PS risks and for reducing healthcare errors according to DODI 6025.13, AR 40-68, and MEDCOM guidance.

(17) Abide by The Joint Commission’s National Patient Safety Goals (NPSG’s) and “do not use” list of abbreviations in all forms of documentation.

(18) Identify all patients by the use of patient full name and date of birth.

   d. Department/service/clinic chiefs and management/ supervisory staff will-

(1) Support the facilities Annual PSP Plan: ensure all staff is educated on the plan.

(2) Ensure PS activities are implemented, monitored, and evaluated for effectiveness and actively participate in these processes.

(3) Support a culture at the department/service level that emphasizes cooperation, communication, and collaboration; ensures reporting of "near miss" and actual PS events; focuses on process rather than punishment; and works to improve medical systems and processes to promote PS.

(4) Role Model TeamSTEPPS™ leadership strategies.

(5) Utilize and integrate the tools and strategies of TeamSTEPPS™ into departmental processes.

(6) Utilize their departments TTPQ data proactively in their improvement plans.

(7) Empower staff to speak up for patient safety utilizing TeamSTEPPS™ tools.

(8) Department/service/clinic chiefs will ensure all PS events are closed within 45 days of the reported date.

(9) Facilitate orientation and ongoing education of all assigned staff regarding their roles and responsibilities in the PSP and TeamSTEPPS™.

(10) Ensure that staff members educate patients/family members on their roles and responsibilities related to the safe delivery of care.

(11) Ensure a balance between human and system accountability through the implementation of a safety culture across the continuum of care. Encourage a systems approach to creating a safer patient environment by fostering trust, transparency, teamwork, and communication. Cultures that support open communication in a "just•• culture environment are more likely to see high levels of improvement in patient safety.
(12) Encourage timely acknowledgement, reporting, disposition and follow-up on all MMQC FDA Class 1 Recalls. If a positive acknowledgement of product on hand, a Patient Safety Report (PSR) will be generated within 5 days. If a positive acknowledgement for a medical device, a work order number and PSR number will be generated within the suspense date. FDA Class 1 Recall MMQC responses, product on hand, PSR and work order numbers will be communicated immediately upon completion to the Quality Department.

e. PSMs/PSOs will-

(1) Be responsible for managing their organization's PSP by collaborating with leadership and staff to ensure the effective integration of PS initiatives within the organization. The PSM/PSO will be an integral part of the executive administrative team and will report PS issues directly to the command.

(2) Establish and maintain the facility Patient Safety Committee. This is to be a multidisciplinary committee as defined by AR 40-68.

(3) Collaborate with command team to develop the facilities Annual Patient Safety Plan.

(4) Incorporate TeamSTEPPS™ strategies in the Annual Patient Safety Plan.

(5) Utilize and integrate the tools and strategies of TeamSTEPPS™ into facility processes.

(6) Manage the PS reporting process from notification of an event though implementation of corrective actions.

(7) Role model TeamSTEPPS™ leadership strategies.

(8) Empower staff to speak up for safety utilizing TeamSTEPPS™ tools.

(9) Evaluate facility wide TTPQ data and develop proactive improvement objectives based on this data.

(10) Actively work to implement and sustain the TeamSTEPPS™ strategies and tools and promote effectiveness evaluation activities at the MTF/DTF.

(11) Support a safety culture that emphasizes cooperation, communication, and collaboration; ensures reporting of "near miss" and actual PS events; focuses on process improvement rather than individual punishment; and works to improve medical systems and processes to promote PS.
Encourage a systems approach to creating a safety culture that fosters trust, transparency, teamwork, and communication.

Actively partner with the facility’s safety manager to ensure a comprehensive, inclusive MTF/DTF safety culture.

Classify PS events according to current DHA Patient Safety Program guidelines.

Ensure all PS events are closed within 45 days of the report date.

Provide PSR and other patient safety data to MTF/DTF command team on a quarterly basis, at minimum.

Provide expertise, training, and guidance to staff members in the areas of PS principles, proactive risk assessment, data analysis, RCA, and concepts of TeamSTEPPS™.

Serve as the MTF/DTF liaison to the regional PSO and MEDCOM PSP.

Coordinate, facilitate, and/or educate all MTF/DTF assigned personnel on their roles and responsibilities in the PSP, to include NPSG's, reporting of all PS events, participating in MTF/DTF PS activities, and educating patients/families on facilitating the safe delivery of care.

Participate in all SE processes and ensure timely submission of the RCA through the regional PSO to MEDCOM PSP.

Facilitate a proactive risk assessment as required by TJC.

Collaborate with the facility Risk Manager on managing potentially compensable events.

Prepare data analysis and trending reports related to the facilities' Annual Patient Safety Plan and present at executive level committees.

Facilitate the utilization of PSR and other PS data in performance improvement initiatives.

All MTF and DTF personnel will-

Fully understand and take responsibility for their roles in the patient safety program.
(2) Actively participate in creating a safe environment for themselves, peers, patients; and families by meeting organizational and professional standards, abiding by the Joint Commissions NPSG’s, proactively mitigating unsafe conditions or situations.

(3) Report all unsafe conditions, near misses and adverse events.

(4) Understand their responsibility to be empowered to speak up for patient safety utilizing TeamSTEPPS™ tools and strategies.

(5) Utilize and integrate the tools and strategies of TeamSTEPPS™ into their practice.

(6) In response to a PS event, initiate immediate steps to ensure patient and staff safety and notify appropriate chain of command personnel. Secure any supplies/equipment that is part of the PS event "as is" without modifying their current condition or state and provide to the PSM/PSO. The PSM/PSO will coordinate with logistics, medical maintenance, or pharmacy to hold the supplies/equipment during the investigation.

(7) Educate patients/families in their roles and responsibilities to facilitate the safe delivery of care.

(8) Identify all patients by the use of patient full name and date of birth.

(9) Abide by TJC’s "do not use" list of abbreviations in all forms of documentation.
References

Section I
Required Publications

AR 40-68
Clinical Quality Management
http://arrmypubs.army.mil/epubs/40_Series_Collection_1.html
DOOM 6025.13

Medical Quality Assurance (MQA) and Clinical Quality Management in the
Military Health System (MHS)

Section II
Related Publications

AHRQ
http://www.ahrq.gov/

AHRQ Harm Scale

MHS Leadership Engagement Toolkit

Institute of Medicine Report #1
To Err is Human: Building a Safer Health System. Washington, DC: National
Academy Press (1999)
http://iom.nationalacademies.org/Reports/1999/To-Err-is-Human-Building-a-Safer-Health-System.aspx

Institute Of Medicine Report #2
Crossing the Quality Chasm: A New Health System for the 21st Century.
AHRQ Patient Safety Network (PSNet)

AHRQ TeamSTEPPS™ Implementation
http://teamstepps.ahrq.gov/about-2cl3.htm

MEDCOM OPORD 11-38
AMEDD-Wide Implementation of TeamSTEPPS™ 2011
https://www.gmo.amedd.army.mil/ptsafty/TeamSTEPPS.htm

Institute for Healthcare Improvement
http://www.ihi.org/Paques/default.aspx

National Patient Safety Foundation
http://www.npsf.org/

United States Code (USC), Title 10, Section 1102 (10 USC 1102)
Confidentiality of Medical Quality Assurance Records: Qualified Immunity for Participants

Comprehensive Accreditation Manual for Hospitals (CAMH)
https://www.jointcommission.org

Patient Safety Systems Chapter for the Hospital Program
http://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_proar_am

Section III
Prescribed Forms
This section contains no entries

Section IV
Referenced Forms
This section contains no entries.
Section V
MEDCOM Patient Safety Publications

MEDCOM Regulation 40-48
Fires Associated with the Performance of Surgical Procedures

MEDCOM Regulation 40-49 Surgical Counts

MEDCOM Regulation 40-54 Universal Protocol

MEDCOM Regulation 40-57
Trial of Labor for Patients Attempting Vaginal Birth After Previous Cesarean Delivery

MEDCOM Regulation 40-59
Standardization of Inpatient Falls Risk Assessment and Documentation Falls Prevention Program

OTSG/MEDCOM POLICY MEMO 13-050
Root Cause Analysis Reporting Requirements for Sentinel Events
OTSG/MEDCOM POLICY MEMO 13-052
Color-Coded Wristband Standardization for Patient Alerts

OTSG/MEDCOM POLICY MEMO 13-035
Privacy Act and Health Insurance Portability and Accountability Act (HIPPA) Privacy and Security Training

OTSG/MEDCOM POLICY MEMO 14-085
Prevention of Catheter Associated Urinary Tract Infections (CAUTI)
Glossary

Section 1
Abbreviations

AHRQ
Agency for Healthcare Research and Quality

AMEDD
Army Medical Department

AR
Army Regulation

CPAD
Clinical Performance Assurance Directorate

DoD
Department of Defense

DoDI
Department of Defense instruction

DHA
Department of Health Affairs

DTF
Dental Treatment Facility

MEDCOM
United States Army Medical Command

MHS
Military Health System

MTF
Medical Treatment Facility

OTSG
Office of The Surgeon General

PS
Patient Safety

PSM
Patient Safety Manager
MCHO-CP-A
SUBJECT: MEDCOM Regulation Memo 40-41

The proponent of this publication is the USAMEDCOM Quality Management Division. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, US Army Medical Command, ATTN: MCHO-Q, 2748 Worth Road, JBSA Fort Sam Houston, TX 78234-6010.

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