

Department of Defense INSTRUCTION

NUMBER 6025.13 February 17, 2011

USD(P&R)

SUBJECT: Medical Quality Assurance (MQA) and Clinical Quality Management in the

Military Health System (MHS)

References: See Enclosure 1

1. PURPOSE. This Instruction:

- a. Reissues DoD Directive (DoDD) 6025.13 (Reference (a)) as a DoD Instruction (DoDI) in accordance with the authority in DoDD 5124.02 (Reference (b)).
- b. Establishes DoD policy on issues related to MQA programs and clinical quality management activities.

2. APPLICABILITY. This Instruction applies to:

- a. OSD, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").
- b. DoD military treatment facilities (MTFs), medical or dental, and DoD healthcare practitioners who are involved in the delivery of healthcare services to eligible beneficiaries.
- c. Civilian preferred providers under managed care support contracts to the Department of Defense in health services regions throughout MHS.

3. <u>DEFINITIONS</u>. See Glossary.

- 4. <u>POLICY</u>. It is DoD policy that:
- a. MHS shall maintain active and effective organizational structures, management emphasis, and program activities to ensure quality in healthcare throughout MHS. Clinical quality management activities include clinical performance measurement and improvement, credentials and clinical privileging, risk management (RM), adverse actions, and patient safety.
- b. MQA records and information created by or for the Department of Defense as part of an MQA program are confidential and privileged in accordance with section 1102 of title 10, United States Code (U.S.C.) (Reference (c)). Disclosures of such records and information shall occur only as authorized by section 1102 of Reference (c).
- c. The Department of Defense shall implement medical management procedures in accordance with DoDI 6025.20 (Reference (d)) to ensure that healthcare services provided in MTFs or by non-DoD providers at DoD expense are necessary and appropriate.
- 5. RESPONSIBILITIES. See Enclosure 2.
- 6. PROCEDURES. See Enclosure 3.
- 7. <u>INFORMATION REQUIREMENTS</u>. The Centralized Credentials Quality Assurance System (CCQAS) referred to in section 3 of Enclosure 3 is included in the public information collection for the Defense Medical Human Resources System Internet, which is assigned Office of Management and Budget Control Number 0720-0041. CCQAS has also been assigned Report Control Symbol DD-HA(AR)2415 in accordance with DoD 8910.1-M (Reference (e)).
- 8. <u>RELEASABILITY</u>. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at http://www.dtic.mil/whs/directives.
- 9. <u>EFFECTIVE DATE</u>. This Instruction is effective upon its publication to the DoD issuances Website.

Clifford L. Stanley
Under Secretary of Defense
(Personnel and Readiness)

Enclosures

- 1. References
- 2. Responsibilities3. Procedures

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 6025.13, "Medical Quality Assurance (MQA) in the Military Health System (MHS)," May 4, 2004 (hereby cancelled)
- (b) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
- (c) Sections 1094, 1102, 2733, and 2734 and chapters 47¹ and 55 of title 10, United States Code
- (d) DoD Instruction 6025.20, "Medical Management (MM) Programs in the Direct Care System (DCS) and Remote Areas," January 5, 2006
- (e) DoD 8910.1-M, "Department of Defense Procedures for Management of Information Requirements," June 30, 1998
- (f) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," June 4, 2008
- (g) Sections 1346b and 2671-2680 of title 28, United States Code
- (h) Sections 11131-11152 and 1320a-7e of title 42, United States Code
- (i) DoD Instruction 1332.38, "Physical Disability Evaluation," November 14, 1996

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¹ Chapter 47 is also known as "The Uniform Code of Military Justice."

ENCLOSURE 2

RESPONSIBILITIES

- 1. <u>ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS (ASD(HA))</u>. The ASD(HA), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness and in accordance with DoDD 5136.01 (Reference (f)), shall:
 - a. Develop supporting guidance as necessary to implement this Instruction.
- b. Oversee the implementation of this Instruction to ensure consistent application across MHS.
- c. Exercise authority to grant waivers or exceptions, in accordance with law, to this Instruction in exceptional circumstances.
- d. Exercise any authority of the Secretary of a Military Department or a surgeon general (SG) pursuant to this Instruction pertaining to reports to the National Practitioner Data Bank (NPDB) to the extent the ASD(HA) determines necessary to implement this Instruction.
- 2. <u>DIRECTOR</u>, <u>TRICARE MANAGEMENT ACTIVITY (TMA)</u>. The Director, TMA, under the authority, direction, and control of the USD(P&R), through the ASD(HA), shall establish in TRICARE regulations, contracts, and regulatory guidance appropriate standards for quality assurance in TRICARE provider networks consistent with Reference (f).
- 3. <u>SECRETARIES OF THE MILITARY DEPARTMENTS</u>. The Secretaries of the Military Departments shall ensure that the procedures in Enclosure 3 are implemented within their respective Departments, including standard-of-care (SOC) determinations by the SGs and the reporting of those determinations.
- 4. <u>COMMANDER, JOINT TASK FORCE NATIONAL CAPITAL REGION MEDICAL (JTF CapMed)</u>. The Commander, JTF CapMed, shall establish and implement procedures, approved by the ASD(HA), for ensuring the application of standards comparable to MQA standards to all healthcare provided in accordance with his or her authority as Commander, JTF CapMed.

ENCLOSURE 3

PROCEDURES

- 1. <u>ACCREDITATION</u>. All fixed MTFs, as well as hospitals and other facilities used by managed care support contractors, shall meet or exceed the standards of appropriate external accrediting bodies. This includes accreditation of all hospitals by The Joint Commission (TJC) and participation, as directed by the ASD(HA), in all TJC quality management programs. Alternatively, for fixed MTFs or facilities used by managed care support contractors, the ASD(HA) may approve a different accreditation source. Operational healthcare units (not a component of an accredited MTF) are exempt from the accreditation requirement. The Military Services shall each establish and implement comparable quality-of-care oversight mechanisms for operational healthcare units under their cognizance. At a minimum, the functions of credentialing, RM, patient safety, and clinical performance improvement shall be included in the quality-of-care oversight mechanisms.
- 2. <u>CREDENTIALS AND CLINICAL PRIVILEGES</u>. Individual provider credentials and qualifications shall be carefully evaluated before allowing involvement in patient care.
- a. Staff appointments and clinical privileges shall be granted to healthcare providers only after all pre-selection criteria have been verified.
- b. Licensed healthcare practitioners shall have and maintain a current, valid, and unrestricted license or other authorizing document, in accordance with the issuing authority, before practicing within the defined scope of practice for like specialties. Licensing shall comply with section 1094 of Reference (c). Authority to waive the license requirement is vested with the ASD(HA) and shall be used only to address extraordinary circumstances and in accordance with section 1094 of Reference (c).
- c. Each MTF shall implement processes and procedures for managing and reporting clinical adverse actions to protect patients and enhance the quality of care.
- 3. <u>CCQAS</u>. CCQAS shall collect, track, and report required provider data for DoD Component credentialing and granting of clinical privileges, and for Component RM and adverse privileging actions. All required data shall be promptly documented and available in the CCQAS for review by the ASD(HA).
- 4. <u>MQA REVIEWS</u>. MTFs shall conduct regular, systematic, and comprehensive reviews of the quality of healthcare provided in their facilities. Resources that may be used for carrying out these reviews include accreditation standards, national consensus measures, evidence-based clinical practice standards, and medical management guidelines.

- 5. <u>SENTINEL EVENTS</u>. MTFs shall actively identify sentinel events that occur in their facilities, conduct a root cause analysis, and form a corrective action plan for each event. The results of the analysis and plan for each event shall be promptly reported through the Military Department concerned to the ASD(HA) or designee. In addition, each MTF shall comply with TJC reporting requirements for those sentinel events that are subject to TJC review.
- 6. <u>RM</u>. MTFs shall implement active RM systems and programs to reduce liability associated with actual or alleged medical malpractice, and shall use those systems and programs to reinforce other MQA program activities. RM programs shall encompass identification and mitigation of risk to patients, family members, visitors, and staff, as well as oversight and review of the effectiveness of organizational risk reduction strategies. RM programs shall encompass the potential risk of liability for death or disability benefits to members of the Military Services arising from possible substandard medical care, including that provided in a field environment.
- a. Every unexpected adverse patient outcome or event that meets the criteria for identification as a potential compensable event (PCE) shall be reviewed and promptly documented in the CCQAS. MTF shall assess whether SOC was met in relation to the adverse patient outcome.
 - b. As part of the identification of every PCE:
- (1) Receiving claims offices shall report every claim for liability compensation in accordance with sections 1346b and 2671-2680 of title 28, U.S.C. (Reference (g)), or section 2733 or 2734 of Reference (c), that alleges medical malpractice to the medical office designated by the Military Department concerned. The MTFs involved shall review the healthcare provided if they have not already done so and assess whether SOC was met in all cases in which sufficient information is provided with the claim to allow identification of the patient and healthcare involved.
- (2) MTFs shall conduct a SOC review and assessment of every unexpected adverse patient outcome, and identify every PCE, involving a member of the Military Services that suggests a potential disability separation or retirement of the Service member as a result of the unexpected adverse patient outcome. MTFs shall document the results of the SOC assessment in the CCQAS. Service-level risk managers, upon receiving notification of a disability or death of a member of the Military Services arising from the provision of medical care, shall notify their respective SGs. The SG concerned shall report the information to the DoD RM Committee through the Service-level risk manager. These events are to be documented in the CCQAS disability and/or PCE modules.
- c. MTFs shall promptly report information concerning every PCE, claim, and SOC assessment in the CCQAS.

- 7. <u>PATIENT SAFETY</u>. MTFs shall participate in the DoD Patient Safety Program (PSP) to identify and report actual and potential problems in medical systems and processes and to implement effective actions to improve patient safety and healthcare quality throughout MHS. PSPs shall focus on systems and procedures, and complement other MQA program activities.
- 8. NPDB AND HEALTHCARE INTEGRITY AND PROTECTION DATA BANK (HIPDB). MTFs, or other Service component, shall query NPDB and HIPDB for information on all healthcare practitioners before granting or renewing clinical privileges, and shall report to NPDB and HIPDB in accordance with sections 11131-11152 and 1320a-7e of title 42, U.S.C. (Reference (h)).
- a. Reports to NPDB shall include a report in the name of a healthcare practitioner each time a malpractice payment is made, for the benefit of such practitioner.
- (1) A payment shall be considered to be made for the benefit of any practitioner significantly involved in the healthcare that was the basis for the malpractice payment unless, within 180 days after the SG concerned receives notice of such payment, the SG has made a final determination, following external peer review, that the malpractice payment was not caused by the failure of such practitioner to meet SOC. This SG determination is nondelegable. If such determination has not been made within the 180-day time period, a report shall immediately be made to NPDB. The 180-day period shall begin on the day the Military Department concerned first receives a report through the Center for Legal Medicine, its organizational successor, or other designated entity that the Department of the Treasury has notified the Department of Defense of a paid claim.
- (2) In any case in which there is a conflict between an external peer review opinion that SOC was not met and the failure to meet SOC caused the injury, and a final SG determination that SOC was met, the SG shall immediately report, in memorandum, his or her determination to the DoD RM Committee panel for review. The memorandum shall explain the findings and the rationale for variance in SOC determinations. The panel will review both the external peer review and the SG determination, and will send, via memorandum, a report stating that the panel either agrees with the SG's determination or recommends that the SG reconsider the final determination and report the provider(s) to NPDB. This process applies to any case in which the external peer review SOC determination is "Not Met" with causation (acts or omissions and injuries or illnesses), and the SG's determination is "Met."
- b. Reports to NPDB shall also include instances in which a practitioner's failure to meet SOC caused or contributed to the death or disability, separation, or retirement of a member of the Military Services in accordance with DoDI 1332.38 (Reference (i)).
- (1) In every case in which a medical evaluation board (MEB) makes a referral to a physical evaluation board (PEB), the MEB approving official shall identify and report to the facility risk manager every instance in which the condition that is the subject of the referral may have been incurred or aggravated as a result of MTF-provided medical care.

- (2) The facility risk manager shall, in consultation with the PEB liaison officer, monitor PEB disability decisions, and shall report to the SG concerned (or to the official designated by the SG to receive such reports) every case identified that results in a PEB determination to separate or retire a Service member due to physical disability. Every such case shall be the subject of a SOC review and a report to NPDB unless, within 180 days, the SG has made a final, nondelegable determination, following external peer review, that the disability was not caused in whole or in part by the failure of a practitioner to meet SOC. The 180-day period shall begin on the day of the risk manager's report to the SG.
- c. Reports to HIPDB shall be made based on acts or omissions that affect the payment, provision, or delivery of a healthcare item or service, to include actions pursuant to chapter 47 of Reference (c) (also known as "The Uniform Code of Military Justice"), other administrative actions, adverse civilian personnel actions, or contract termination for default.
 - d. All reports to NPDB or HIPDB shall also be documented in the CCQAS.
- 9. <u>TRANSPARENCY</u>. The Military Departments and MTFs shall implement applicable initiatives approved by the ASD(HA) to increase transparency to patients and the public of the quality of healthcare and the quality assurance program. All such initiatives shall be in accordance with section 1102 of Reference (c).

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA) Assistant Secretary of Defense for Health Affairs

CCQAS Centralized Credentials Quality Assurance System

DoDD DoD Directive
DoDI DoD Instruction

HIPDB Healthcare Integrity and Protection Data Bank

JTF CapMed Joint Task Force National Capital Region Medical

MEB medical evaluation board
MHS Military Health System
MQA medical quality assurance
MTF military treatment facility

NPDB National Practitioner Data Bank

PCE potential compensable event PEB physical evaluation board PSP patient safety program

RM risk management

SG surgeon general SOC standard of care

TJC The Joint Commission

TMA TRICARE Management Activity

U.S.C. United States Code

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

<u>MHS</u>. Consists of the DoD medical and dental programs, personnel, facilities, and other assets operating pursuant to chapter 55 of Reference (c) by which the Department of Defense provides healthcare services and support:

To the Military Services during military operations.

Under TRICARE to members of the Military Services, their family members, and others entitled to DoD medical care.

MQA program. Defined in section 1102 of Reference (c).

MQA record. Defined in section 1102 of Reference (c).

<u>PCE</u>. An adverse event that results in harm to a patient and presents a possible financial loss to the Federal Government (a malpractice claim or death or disability payment). All PCEs shall be fully investigated by the risk manager and documented in the DoD PCE module of the CCQAS within 180 calendar days of the date of occurrence or initial identification. Any event determined to result in harm to a patient shall be documented in the CCQAS according to the DoD PSP reporting harm scale categories e.g. death, severe permanent harm, permanent harm. All PCEs shall be documented in the CCQAS with descriptions identical to the DoD PSP reporting categories of event types e.g. accident, blood/blood products, healthcare associated infection.

<u>quality in healthcare</u>. The degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

<u>sentinel event</u>. An unexpected occurrence involving death or serious physical or psychological injury or risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

<u>TJC</u>. An independent, not-for-profit organization that is a standards-setting and accrediting body in healthcare. TJC accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.