Department of Defense
MANUAL

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Incorporating Change 1, July 23, 2020

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 manual reissues DoD 6025.13-R (Reference (a)) as a DoD manual in accordance with the authority in DoD Directive (DoDD) 5124.02 (Reference (b)) and DoD Instruction (DoDI) 6025.13 (Reference (c)) and the guidance in DoDI 5025.01 (Reference (d)). It implements policy, assigns responsibilities, and provides procedures for managing DoD MQA and clinical quality management.

2. APPLICABILITY. This manual applies to:

a. OSD, the Military Departments, 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 DoD (referred to collectively in this manual as the "DoD Components").

b. Each DoD military treatment facility (MTF) of the uniformed services, medical or dental, and DoD healthcare providers, including United States Public Health Service personnel, volunteers, or other individuals authorized to provide or support the provision of healthcare services to eligible beneficiaries in MTFs.

c. Healthcare support contractors (HCSCs), designated providers (DPs), and overseas healthcare contractors consistent with their respective contracts as mandated by TRICARE guidance (available at the TRICARE Website at http://www.tricare.mil/tma/Policy.aspx).

3. RESPONSIBILITIES

a. Assistant Secretary of Defense for Health Affairs (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 (e)), the ASD(HA):

(1) Monitors the implementation of this manual to ensure consistent application across the MHS.

(2) Ensures that contracts for all HCSCs, DP contractors, overseas contractors, and civilian authorized provider agreements throughout the MHS reflect the applicable guidance set forth in this manual through contract language and TRICARE guidance (available at the TRICARE Website at http://www.tricare.mil/tma/Policy.aspx).

(3) Exercises authority, direction, and control over the Director, TRICARE Management Activity (TMA), in carrying out procedures in accordance with this manual.

(4) Exercises authority to grant waivers or exceptions, in accordance with law, to this manual in exceptional circumstances.

(5) Ensures that all advisory groups directed by this manual conform to DoD policies and procedures as required by DoDI 5105.04 (Reference (f)) and DoDI 5105.18 (Reference (g)).

b. Secretaries of the Military Departments and the Commander, Joint Task Force National Capital Region Medical (JTF CapMed). The Secretaries of the Military Departments and the Commander, JTF CapMed, oversee compliance with this manual within their respective areas of responsibility. The ASD(HA) shall establish and direct implementation of standards and procedures comparable to those in this Manual for all health care facilities under the control of a DoD organizational entity other than a Military Department.

4. PROCEDURES. See Enclosures 2 through 9.

5. RELEASABILITY. **Cleared for public release.** This manual s available on the Directives Division Website at https://www.esd.whs.mil/DD/.

6. SUMMARY OF CHANGE 1. The change to this issuance updates references and removes expiration language in accordance with current Chief Management Officer of the Department of Defense direction.

7. EFFECTIVE DATE. This manual is effective October 29, 2013.

Jessica Wright
Acting Under Secretary of Defense for
Personnel and Readiness

Enclosures
1. References
2. MQAPR Data Management and Use
3. Clinical Performance Measurement
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ENCLOSURE 1

REFERENCES

(a) DoD 6025.13-R, "Military Health System (MHS) Clinical Quality Assurance (CQA) Program Regulation," June 11, 2004 (hereby cancelled)
(b) DoD Directive 5124.02, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008
(c) DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011, as amended
(d) DoD Instruction 5025.01, "DoD Issuances Program," August 1, 2016, as amended
(e) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(f) DoD Instruction 5105.04, "Department of Defense Federal Advisory Committee Management Program," August 6, 2007
(g) DoD Instruction 5105.18, "DoD Intergovernmental and Intragovernmental Committee Management Program," July 10, 2009, as amended
(h) Title 10, United States Code
(i) DoD Manual 5400.07, "DoD Freedom Of Information Act (FOIA) Program," January 25, 2017
(j) Title 5, United States Code
(k) DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007
(l) Title 45, Code of Federal Regulations
(m) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DOD Health Care Programs," March 13, 2019
(n) Administrative Instruction 15, "OSD Records and Information Management Program," May 3, 2013, as amended
(o) Public Law 101-629, "Safe Medical Devices Act of 1990," November 28, 1990
(p) Office of Management and Budget, Office of Information and Regulatory Affairs, "Statistical Policy Working Paper 22 (Second version, 2005), Report on Statistical Disclosure Limitation Methodology," December 2005
(q) The Joint Commission, "Comprehensive Accreditation Manual for Hospitals (CAMH)," current edition available for purchase at http://www.jcrinc.com/Accreditation-Manuals/
(r) The Joint Commission, "Comprehensive Accreditation Manual for Ambulatory Care (CAMAC)," current edition available for purchase at http://www.jcrinc.com/Accreditation-Manuals/
(s) The Joint Commission, "Comprehensive Accreditation Manual for Home Health Care," current edition available for purchase at http://www.jcrinc.com/Accreditation-Manuals/
(t) The Joint Commission, "Comprehensive Accreditation Manual for Behavioral Health Care (CAMBHC)," current edition available for purchase at http://www.jcrinc.com/Accreditation-Manuals/
(u) Commission on Accreditation of Rehabilitation Facilities, "Behavioral Health Standards Manual," current edition available for purchase at

http://bookstore.carf.org/miva/merchant.mvc?Screen=PROD&Store_Code=CB&Product_Code=8612.11&Category_Code=2012-Behavioral-Health-Publications
(v) Accreditation Association for Ambulatory Health Care, "Accreditation Handbook for Ambulatory Health Care," current edition available for purchase at https://iweb.aaahc.org/eweb/dynamicpage.aspx?site=aaahc_site&webcode=COEPubSearch
(w) American Osteopathic Association Healthcare Facilities Accreditation Program, "Accreditation Requirements for Healthcare Facilities" current edition available for purchase at http://www.hfap.org/resources/manuals.aspx
(x) Title 32, Code of Federal Regulations
(y) DoD Instruction 6025.5, "Personal Services Contracts (PSCs) for Healthcare Providers (HCPs)," January 6, 1995
(z) Title 28, United States Code
(aa) DoD Instruction 1402.05, "Background Checks on Individuals in DoD Child Care Services Programs," September 11, 2015, as amended
(ab) Title 42, Code of Federal Regulations
(ac) American Telemedicine Association Website, "Telemedicine Standards & Guidelines,"[1]
(ad) American Telemedicine Association, "Practice Guidelines for Videoconferencing-Based Telemental Health,"[2] current edition
(ae) DoD 5500.7-R, "Joint Ethics Regulation (JER)," August 1, 1993, as amended
(af) Section 754 of Public Law 106-398, Patient Care Reporting and Management Systems," October 30, 2000
(ag) DoD Instruction 1332.18, "Disability Evaluation System (DES)," August 5, 2014, as amended
(ah) Title 48, Code of Federal Regulations
(ai) Section 721 of Public Law 104-201, "National Defense Authorization Act for Fiscal Year 1997," September 23, 1996
(aj) Section 11101 of Title 42, United States Code

[1] http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3311
[2] http://www.americantelemed.org/i4a/forms/form.cfm?id=24&pageid=3717&showTitle=1

ENCLOSURE 2

MQAPR DATA MANAGEMENT AND USE

1. GENERAL. This enclosure outlines the restrictions on the disclosure of MQA peer review (MQAPR) information and the circumstances and procedures for releasing such information. In particular, the enclosure covers the requirements for the release of aggregate statistical data, data sharing agreements (DSAs) for participating in quality improvement programs external to the DoD.

2. CONFIDENTIALITY AND DISCLOSURE OF MQAPR RECORDS

a. Confidentiality of Records

(1) MQAPR records created by or for the DoD as part of an MQA program are confidential and privileged. MQAPR records may not be disclosed to any person or entity, except as provided in section 1102(c) of Title 10, United States Code (U.S.C.) (Reference (h)).

(a) In accordance with section 1102(c) of Reference (h) and DoD Manual 5400.07 (Reference (i)), these records are exempt from the disclosure requirements in section 552 of Title 5, U.S.C. (Reference (j)).

(b) With the exception of the subject of an MQAPR action, the identity of any person receiving healthcare services from the DoD or the identity of any other person associated with DoD for purposes of an MQA program that is disclosed in an MQAPR record must be redacted before any disclosure is made outside of the DoD. This redaction requirement does not apply to the extent that disclosure of unredacted records is permitted by DoD 5400.11-R (Reference (k)).

(c) Information in MQAPR records may also contain protected health information (PHI) relating to a patient. The use of this PHI is authorized in accordance with Parts 160 and 164 of 45 Code of Federal Regulations (CFR) (Reference (l)), and DoD Manual 6025.18 (Reference (m)) as part of healthcare operations.

1. PHI contained in MQAPR records may also be released, pursuant to paragraph C7.4 of Reference (m), to other government agencies and outside entities that have been designated as part of the DoD MQA program. To be so designated, Reference (m) requires:

a. A written business associate agreement (BAA) between the DoD Component and the other entity.

b. A DSA restricting the further dissemination of the information.

2. Release of personally identifiable information (PII) and PHI to entities engaged in MQA activities but that have not been incorporated into part of the DoD MQA program is not authorized.

(2) Nothing in this enclosure limits access to information:

(a) In a record created and maintained outside an MQAPR program, including a patient's medical records, on the grounds that the information was presented during meetings of a review body and that the review body is part of a healthcare MQA program.

(b) That is part of the policies and procedures of an MTF or medical system headquarters on the grounds that the information was considered in an MQAPR program review.

(c) That is part of an MQA program but not part of a peer review activity under the MQA program.

b. Prohibition on Disclosure and Testimony

(1) No part of an MQAPR record may be subject to discovery or admitted into evidence in any judicial or administrative proceeding, except as provided in of section 1102(c) of Reference (h).

(2) A person who reviews or creates MQAPR records for the DoD or who participates in any proceeding that reviews or creates such records may not be permitted or required to testify in any judicial or administrative proceeding with respect to such records or with respect to any finding, recommendation, evaluation, opinion, or action taken by such person or body in connection with such records except as provided in section 1102 of Reference (h).

(3) A person or entity having possession of or access to MQAPR records or testimony may not disclose the contents of such record or testimony in any manner or for any purpose, except in accordance with section 1102(c) of Reference (h).

(4) Any person who willfully discloses an MQAPR record, other than in accordance with section 1102 of Reference (h), knowing that such record is an MQAPR record, will be subject to adverse personnel action (to include, in appropriate cases, dismissal or separation). He or she may be liable for a fine of not more than $3,000 in the case of a first offense and not more than $20,000 in the case of a subsequent offense.

(5) As provided in section 1102(g) of Reference (h), a person who participates in or provides information to a person or body that reviews or creates MQAPR records will not be civilly liable for such participation or for providing such information if the participation or provision of information was in good faith, based on prevailing professional standards at the time the clinical quality program peer review activity took place.

3. STANDARDS FOR DISCLOSURE OF MQAPR RECORDS

a. Protection of MQAPR Records. MQAPR records are protected from disclosure, except as described in paragraph 3b of this enclosure. For additional guidance regarding the disclosure of MQAPR records, the MTF legal counsel should be consulted. Regarding the disposition of MQAPR records, refer to Administrative Instruction 15 (Reference (n)), which includes procedures for the management and disposition of OSD records.

b. Authorized Disclosure and Testimony. Subject to paragraph (c)(2) of section 1102 of Reference (h), an MQAPR record may be disclosed and a person referred to in subsection (b) of section 1102 of Reference (h) may give testimony in connection with such records only:

(1) To a federal executive agency or private organization, if the MQAPR record or testimony is needed by the agency or organization to perform licensing or accreditation functions related to DoD healthcare facilities or to perform monitoring, required by law, of DoD healthcare facilities. An example of an authorized disclosure is the mandatory requirement in accordance with Public Law 101-629 (Reference (o)) to report to the Food and Drug Administration the details of fatal or serious adverse events relating to the use of a medical device.

(2) To an administrative or judicial proceeding commenced by a present or former DoD healthcare provider concerning the termination, suspension, or limitation of clinical privileges of the healthcare provider.

(3) To a governmental board or agency or a professional healthcare society or organization, if an MQAPR record or testimony is needed by such board, agency, society, or organization to perform licensing, credentialing, or the monitoring of professional standards with respect to any healthcare provider who is or was a member or an employee of the DoD. This includes reports to the National Practitioner Data Bank (NPDB) in accordance with Enclosure 9 of this manual.

(4) To a hospital, medical center, or other institution that provides healthcare services, if an MQAPR record or testimony is needed by the institution to assess the professional qualifications of any healthcare provider who is or was a member or employee of the DoD and who has applied for or has been granted authority or employment to provide healthcare services in or on behalf of the institution.

(5) To an officer, employee, or contractor of the DoD who has need for a record or testimony to perform official duties. Such official duties are not limited to MQA activities.

(6) To a criminal or civil law enforcement agency or instrumentality charged under applicable law with the protection of the public health or safety, if a qualified representative of the agency or instrumentality makes a written request that the record or testimony be provided for a purpose authorized by law.

(7) In an administrative or judicial proceeding commenced by a criminal or civil law enforcement agency or instrumentality referred to in paragraph 3b(6) of this enclosure, but only with respect to the subject of the proceeding.

c. Aggregate Statistical Information. This enclosure must not be misconstrued as authorizing or requiring the withholding from any person or entity aggregate statistical information regarding the results of DoD MQAPR programs.

d. Release Upon Congressional Request. This enclosure must not be misconstrued as an authority to withhold any MQAPR record from a committee of either house of Congress, any joint committee of Congress, or the Comptroller General, if the record pertains to any matter within their respective jurisdictions.

4. REQUIREMENTS FOR THE RELEASE OF AGGREGATE STATISTICAL DATA FOR MQA DATA TRANSPARENCY

a. Increasing Transparency. Initiatives to increase transparency to patients and the public of the quality of healthcare and the quality assurance (QA) program will be approved by the ASD(HA) and be in accordance with section 1102 of Reference (h).

(1) The MHS is committed to providing patient-centered and quality healthcare by providing MQAPR data in order to improve the services provided to all beneficiaries.

(2) The MHS will maintain readily available, transparent, and relevant MQAPR aggregate statistical data to provide to its beneficiaries, enrollees, and providers in an understandable manner.

(3) MHS healthcare MQAPR information may be released publically as aggregate statistical data. Aggregate statistical data derived from medical records and MQA, including MQAPR, information may be released outside of the DoD consistent with the requirements for the release of aggregate statistical information.

(4) In accordance with these requirements, aggregate statistical information on results of DoD clinical quality programs may be provided in response to written requests or as directed by the ASD(HA).

(5) Written requests received by MHS personnel for MQA data must be processed by utilizing the respective DoD Component Quality Management Leader as the primary point of contact. MTFs must work in close collaboration with their respective Service Quality Management Leader during clinical quality data collection, analysis, report writing, publication, and distribution.

(6) Individual event health care QA data may not be released by MHS. Health care QA data may be released publicly when stated as aggregate statistical data. Measures will be approved for release by the ASD(HA). Currently, the Healthcare Effectiveness Data and

Information Set (HEDIS®) measures and ORYX® performance measures are approved for such release, providing the data are released in a manner to meet the definition of aggregate statistical information and de-identified PHI in Reference (m).

b. Aggregate Statistical Information and Data. In accordance with Reference (m), section 1102 of Reference (h), and the Office of Management and Budget Statistical Policy Working Paper (Reference (q)), aggregate statistical data derived from medical records and MQA data may only be released outside of the DoD if adequate precautions are taken to protect the identity and privacy of the individual patients and providers involved. The measures must minimize the risk that a third party could use the information, alone or in combination with other reasonably available information, to identify an individual who is the subject of the information released.

c. Requirements for Ensuring Record Privacy. Although individual event MQAPR data may not be released, the data may be released publicly when stated as part of aggregate statistical data. Statistical measures will be approved for release by the ASD(HA).

(1) Requirements have been developed to ensure the privacy of the individual's health and treatment records as well as prevent the inadvertent release of information that would allow the identification of the individuals involved when the released information is combined with other publicly available data. These requirements are incorporated into the threshold rule adopted by the DoD.

(a) These requirements recognize that there may be instances when a third party possesses insider information or knowledge about a patient or individual provider based on a personal relationship (e.g., family, member, neighbor, close friend) with that patient or individual provider and that these persons may be able to add their insider knowledge to the information released by DoD to the general public, thereby identifying that individual as a member of the demographic grouping. However, absent this insider information, the requirements outlined in this section provide protections against others being able to positively identify a member of a demographic grouping.

(b) The HEDIS® measures and ORYX® performance measures are approved for release, providing the data are released as aggregate statistical information.

(c) The ASD(HA) will establish guidance regarding other releases of individual MTF aggregate MQAPR data. Aggregate statistical data derived from medical records and MQAPR data may be released outside of DoD when authorized under standards approved by the ASD(HA).

(2) The threshold rule as described in section D.2.b. of Reference (q), pertaining to the release of information from the MHS, is three. If the grouping of aggregated data includes several types of demographics, such as age, sex, race, active duty status, rank, or service, then the number of persons meeting all of the demographics in the grouping must be three or greater.

(a) For example, if DoD wants to release information relating to how many persons in a demographic grouping that did not receive aspirin within 30 minutes of presenting to the

emergency room (ER) with symptoms of acute myocardial infarction (AMI). Then, DoD wants its groupings to include those patients who possess the following demographics: age 50 or above, Caucasian male, currently on active duty, and who were treated within the MTF East Coast during the month of February for symptoms of AMI in the ER.

1. In this example the numerical data are being presented as a fraction with the numerator being the total of those persons in the entire demographic set that did not receive aspirin. The denominator is the entire number of persons who fit all the demographic fields. In order to release any information regarding how many persons did not receive aspirin, there must be three or more individuals who fit all of the demographics in that grouping, (i.e., three or more: 50 or above, Caucasian males, currently on active duty, who were treated within the MTF East Coast in the month of February, and who presented to the ER with symptoms of AMI).

2. If there are not at least three persons in this group then data may not be released. If the denominator contains too many demographic fields, the number may be too small for release. One or more demographic fields may have to be removed and then the aggregate statistical data on the subset of the original demographic fields could then be released. For example, if there were not three persons who met all of the demographics in the original example above but, there were three or more age 50 or above, Caucasian, males who were treated within the MTF East Coast during February with symptoms of AMI in the ER then, by removing the demographic requirement to be on active duty, this subset of the original demographic fields would be sufficiently large to release the aggregate statistical information.

(b) A denominator equal to three or more has been shown to provide reasonable assurances that the identity of any particular patient cannot be ascertained just by the grouping. When authorized by the ASD(HA), the Military Departments and MTFs may release aggregate statistical data having a denominator equal to three or more in a population or number of persons meeting all of the demographics in the grouping.

(3) Unless the threshold rule is met, the aggregate statistical data may not be released.

5. DSAs

a. DSA Required for Release of Patient-related Information. In addition to maintaining the confidentiality of PII of MHS providers and other DoD personnel involved in MQA programs, DoD is also required to establish safeguards to protect the privacy of patients' PHI in accordance with Reference (m). Among the required safeguards are DSAs. DSAs must be executed by outside parties who request access to patient data managed by TMA. DSAs obligate outside parties to maintain the confidentiality of patient-related data they receive from TMA.

b. Requesting a DSA. Prior to requesting access to MHS data managed by TMA, the requestor should obtain an approved DSA. To do so, requestor submits a Data Sharing Agreement Application (DSAA) to the Privacy Office. The Privacy Office reviews the DSAA for compliance with privacy and security regulations. If it approves the DSAA, the Privacy

Office provides a DSA for execution. Once the DSA is executed, the requestor may apply for data access to the MHS program office.

c. Reporting Data Breaches. If an actual or possible compromise of PII or PHI occurs as defined in Reference (k), the event must be treated as a breach and required breach response activities must be initiated. Such requirements have been established by Reference (k). Among other requirements, a breach must be reported to www.us-cert.gov within 1 hour of its discovery, and must be reported to the TMA Privacy Office within 24 hours via e-mail at http://www.tricare.mil/tma/privacy/breach.aspx.

ENCLOSURE 3

CLINICAL PERFORMANCE MEASUREMENT

1. CLINICAL PERFORMANCE MEASUREMENT PROGRAM. A performance measurement system for clinical quality must be implemented in every MTF as a dedicated program to confirm quality-of-care outcomes and identify opportunities for improvement. The main elements of the program are described in paragraphs 1a through 1c of this enclosure.

a. Accreditation and Certification. Accreditation guidance and standards that may be applicable in either the direct care system or the purchased care system are identified in The Joint Commission (TJC) standards, "Comprehensive Accreditation Manual for Hospitals" (Reference (q)), "Comprehensive Accreditation Manual for Ambulatory Care" (Reference (r)), "Comprehensive Accreditation Manual for Home Health Care" (Reference (s)), and "Comprehensive Accreditation Manual for Behavioral Healthcare" (Reference (t)). Additional applicable standards include the Commission on Accreditation of Rehabilitation Facilities standard, "Behavioral Health Standards Manual" (Reference (u)), the Accreditation Association for Ambulatory Healthcare standard, "Accreditation Handbook for Ambulatory Healthcare" (Reference (v)), and the American Osteopathic Association (AOA) Healthcare Facilities Accreditation Program standard (referred to as the "Accreditation Requirements for Healthcare Facilities" in this manual) (Reference (w)); or through an accreditation source approved by the ASD(HA). When appropriate, the ASD(HA) will direct the development of policy and procedures that exceed the standards of accrediting bodies and issue implementing instructions.

(1) Direct Care System

(a) Fixed MTFs and Freestanding Ambulatory Clinics. All fixed MTFs and freestanding ambulatory clinics must maintain accreditation by TJC under the applicable accreditation manual for hospitals as mandated by References (q), (r), (s), or (t), or through an accreditation source approved by the ASD(HA). In situations where formal agreements are established to provide care by military personnel in civilian or other healthcare facilities, the facilities must be accredited by TJC or an accreditation source approved by the ASD(HA).

(b) Accreditation Waivers. The ASD(HA) will consider accreditation waivers on a case-by-case basis. Waiver requests must include an overview of the facility (or facilities), the justification for the waiver, and a proposed implementation plan. The ASD(HA) will maintain a list of approved accreditation waivers and review the list annually.

(c) Exemption from Accreditation. Operational healthcare units (those treating only active duty personnel and Reserve Component members on duty status and that are not a component of an accredited MTF) are exempt from the accreditation requirement. The Military Services must each establish and implement comparable quality-of-care oversight mechanisms for operational healthcare units under their responsibility. At a minimum, the functions of credentialing, risk management, patient safety, and clinical performance improvement must be included in the quality-of-care mechanisms.

(d) Hospital-sponsored Alcoholism and Drug Dependence Programs. Hospital-sponsored alcoholism and drug dependence programs must maintain accreditation under the applicable hospital standards in accordance with Reference (q). All other Service-sponsored, freestanding alcoholism and drug dependence programs must maintain accreditation consistent with the standards contained in References (t) and (u).

(e) MTF Certification. All MTFs must maintain the appropriate nationally recognized certification for ancillary services such as blood banking, radiology and laboratory services, based on federal regulations and Military Service policies.

(2) Purchased Care System

(a) The HCSCs, DPs, and overseas healthcare contractors will ensure quality of care and services provided to TRICARE beneficiaries as mandated by their respective contract and consistent with TRICARE guidance.

(b) Healthcare organizations providing care in the United States to DoD beneficiaries in accordance with various managed care support contracts, must maintain accreditation by TJC pursuant to the applicable accreditation manual, or the AOA Healthcare Facilities Accreditation Program, or through an accreditation source approved by the ASD(HA).

(c) The ASD(HA) will consider accreditation waivers as described in paragraph 1a(1)(b) of this enclosure.

(d) Freestanding partial hospitalization programs, residential treatment centers, and substance use disorder rehabilitation facilities maintain accreditation as directed by the TRICARE Operations, Policy, and Reimbursement Manuals in accordance with part 199.6 of Title 32, CFR (Reference (x)).

(e) To allow for the significant cultural differences unique to the health practices of foreign countries outside the United States , quality oversight of host nation healthcare providers and institutions must be performed by the overseas contractor in accordance with the contract, all applicable TRICARE guidance, and generally accepted standards of practice in the local host nation.

b. Special Health Affairs (HA) or TMA Clinical Studies. DoD will commission studies to determine the outcome of care delivered to patient populations. These studies are recommended and prioritized by the scientific advisory panel. These studies will usually be carried out by external organizations and include national comparative data, as available. The study results are communicated across the MHS through the MHS Clinical Quality Forum (CQF) representatives. All performance improvement studies require the completion of the appropriate BAA and DSA, and must comply with section 552 of Reference (j). If the study uses or produces MQAPR data, the data must be managed consistent with the requirements in Enclosure 2 of this manual.

c. MHS Quality Programs and Initiatives

(1) MHS Participation in National Quality Programs. MHS participation in national quality programs and initiatives is based on mission priorities and the current healthcare environment. DoD Components, including all Military Services, work together to decide which quality programs the Military Services will participate in and to determine the resource responsibilities.

(2) National Quality Programs and Initiatives Participation Agreements. Participation in nationally recognized quality programs and initiatives requires the completion of the appropriate BAA and DSA and includes compliance with the privacy requirement as stated in Reference (i). In addition, the sharing of MQAPR data derived from these studies with external organizations must follow the requirements in Enclosure 2 of this manual, and must be approved by the ASD(HA).

(3) Clinical Quality Metrics. Clinical quality performance is measured by a variety of performance metrics which are linked to the strategic goals of the MHS. The performance metrics are defined by MHS leadership.

(4) Evidence-based Clinical Practice and Outcomes. Evidence-based data should be considered in the development of all clinical performance measures. The DoD and Veterans Health Administration develop and maintain evidence-based clinical practice guidelines that serve as the foundation for interagency population health promotion and condition management. The Department of the Army serves as the lead component for the evidence-based clinical practice guideline initiative.

(5) Patient Satisfaction Surveys. TMA conducts patient satisfaction surveys. These surveys encompass inpatient and outpatient care, and also evaluate support structures. Patient satisfaction surveys are conducted to evaluate satisfaction in both the direct and purchased care systems and to identify best practices and determine areas for improvement. Survey results are presented to MHS leadership, the Services, TRICARE regional offices, and TRICARE area offices.

(6) MHS CQF. The MHS CQF's responsibility is to assess and monitor the quality of healthcare provided to DoD beneficiaries. The CQF reports findings annually to the ASD(HA) and Congress and includes representatives from HA, TMA, TRICARE regional offices, the Services, and other DoD entities who oversee MHS quality of healthcare. The forum reports quarterly to the clinical proponency steering committee (CPSC) and as directed by the ASD(HA). Clinical quality issues may be presented to other leadership forums as directed by the TMA Chief Medical Officer (CMO). Recommendations presented to the clinical quality division by other leadership forums will be reviewed by the MHS CQF to determine their operational impact.

(7) Working Groups. Working groups chartered by the MHS CQF are established as required based on the identification of areas of need as identified by the forum members.

(a) With Service representation, the scientific advisory panel will annually commission studies of special populations that provide DoD with analyses of the outcome of care across the MHS to include private sector data for comparison purposes.

(b) With Service representation, the clinical measures steering panel will provide oversight of the MHS clinical quality measure initiatives and TJC ORYX® requirements.

2. RESPONSIBILITIES. Under the authority, direction, and control of the ASD(HA), the Director, TMA:

a. Supports the successful implementation of the DoD clinical quality program.

b. Provides funding and oversight, as needed, for the DoD clinical quality program.

c. Directs the TMA CMO to:

(1) Foster a culture of performance improvement that values transparency of data and information throughout the MHS.

(2) Provide direction and oversight to the DoD clinical quality program and MHS CQF.

(3) Chair the CPSC, which monitors the clinical quality program.

(4) Collaborate with other federal agencies on DoD clinical quality activities.

(5) Ensure the TRICARE regional offices and TRICARE area offices carry out clinical quality oversight of the purchased care system and work in close collaboration with the DoD Clinical Quality Division.

ENCLOSURE 4

CREDENTIALS AND CLINICAL PRIVILEGES

1. LICENSING REQUIREMENT

a. Statutory Requirement. Section 1094 of Reference (h) states that a person under the jurisdiction of the Secretary of a Military Department may not provide healthcare independently as a healthcare professional unless the person has a current license to provide such care. In the case of a physician, the physician may not provide healthcare as a physician in accordance with this enclosure unless the physician's current license is an unrestricted license that is not subject to limitation on the scope of practice ordinarily granted to other physicians for a similar specialty by the jurisdiction that granted the license.

(1) DoD HealthCare Provider. The statutory requirement is applicable to all DoD providers practicing independently in all care settings, to include healthcare providers who are members of the uniformed services (Active and Reserve), federal employees, volunteers (when considered to be employees), and personal services contractors consistent with DoDI 6025.5 (Reference (y)). The statutory requirement is fulfilled if licensed practical nurses and registered nurses are licensed in a State participating in the Nurse Licensure Compact.

(2) Healthcare Providers Required to Show Evidence of Licensing, Certification, or Registration. Occupational therapists whose service did not previously require licensure will have 2 years from the publication date of this manual to obtain licensure. Substance use disorder counselors may require certification or registration. Dieticians must be registered, and maintain current registration status and certification with the Commission on Dietetic Registration of the American Dietetic Association.

(3) Specific Licensing Requirements. Healthcare Providers Requiring Licensure (others may be added in the future as determined by the ASD(HA)) include:

(a) Advanced practice registered nurses (APN) (including certified nurse practitioner, certified nurse midwife , certified registered nurse anesthetist (CRNA)) (see paragraph 1b(7) of this enclosure for information about licensure waivers).

(b) Audiologists.

(c) Chiropractors.

(d) Clinical psychologists.

(e) Dental hygienists.

(f) Dentists.

(g) Licensed practical nurses or licensed vocational nurses and registered nurses.

(h) Marriage and family therapists.

(i) Mental health counselors.

(j) Pharmacists.

(k) Physical therapists.

(l) Physician assistants (PA) (see paragraph 1b(6) of this enclosure for information about licensure waivers).

(m) Physicians.

(n) Podiatrists.

(o) Licensed professional counselors.

(p) Occupational therapists.

(q) Optometrists.

(r) Social workers.

(s) Speech pathologists.

(4) Waiver Authority. Section 1094 of Reference (h) allows the Secretary of Defense to waive the requirements in paragraph 1b of this enclosure regarding any person in unusual circumstances, and prescribe by regulation the circumstances under which such a waiver may be granted. This authority and responsibility has been delegated to the ASD(HA) by Reference (c).

(5) Healthcare Providers Under a Written Plan of Supervision. Healthcare providers who do not possess a license or other authorizing document may practice only under a written plan of supervision with a licensed person of the same or a similar discipline.

b. Licensure Requirement and Waiver Provision

(1) Unrestricted License. Any provider's license, in a licensure category that restricts the provider to practice in a federal facility or within some other confined limits, does not comply with the requirement for an unrestricted license. All providers must have at least one current, valid, unrestricted license from a State; the District of Columbia; or a Commonwealth, territory, or possession of the United States. Exceptions for waivers are addressed in paragraph 1b(5) of this enclosure. Providers may hold additional licenses from States in licensure categories that have practice restrictions associated with military exemptions from certain fees or requirements as long as the provider also holds at least one license for which there are no limitations on the

scope of practice. A provider without an unrestricted license may not provide healthcare as a provider unless a waiver is granted in accordance with the terms of this enclosure.

(2) Waiver Related to Limitations on Scope of Practice. A licensure category that includes limitations on scope of practice will not be considered for a waiver of the unrestricted license requirement unless it includes all the same requirements pertaining to clinical competency (e.g., education, training, national tests, continuing medical education, investigation, and sanction authority of the license board) as the full scope category and has no restrictions pertaining to clinical competency (e.g., practice under supervision). A waiver will be considered only if the differences between the unrestricted and restricted license are solely of an administrative or financial nature.

(3) Waiver of the Unrestricted Scope Requirement. Section 1094 of Reference (h) permits a waiver of the unrestricted scope requirement only in unusual circumstances, and directs the Secretary to prescribe by regulation the circumstances under which such a waiver may be granted An unusual circumstance is one in which the State requirement is in conflict with federal policy. Examples would be a requirement that the physician reside in the State (federal policy calling for worldwide service), pay a substantial amount into a medical injury compensation fund (federal policy provides for medical injury compensation under federal statutes), or maintain private malpractice liability insurance (federal policy provides for malpractice liability through the U.S. Treasury).

(a) A requirement to pay the standard license fee associated with an unrestricted license is not an unusual circumstance and does not provide a basis to justify use of the waiver. If a physician has two or more State licenses, one with restrictions that would be removed through the payment of the standard license fee and others in States for which waivers are authorized, the physician must obtain an unrestricted license in the first State by paying the standard license renewal fee.

(b) A physician's duties in a particular position being entirely administrative in nature and not involving the provision of patient care is not considered an unusual circumstance and thus does not provide a basis to justify use of the waiver.

(4) Waiver Consideration Process

(a) Step 1. The ASD(HA) will determine, based on a review of a State's licensure requirements, which of the standards outlined in paragraphs 1b(2) and 1b(3) of this enclosure are met and will identify the particular State administrative or financial requirements that may be considered for waiver. Requests for this determination may be made by a Service Surgeon General (SG) on behalf of an individual healthcare provider or class of healthcare providers. The determinations made by ASD(HA) regarding particular State administrative or financial requirements that may be considered for waiver are posted at: http://www.health.mil/HAPolicies.aspx.

(b) Step 2. Individual healthcare providers who do not hold an unrestricted license in any State, but who hold a restricted license in a State for which a waiver may be considered

based on paragraph 1b(4)(a) of this enclosure, may request a waiver from the Service SG concerned. A waiver will not be granted for longer than the applicable time period of licensure; a subsequent licensure renewal would require a new waiver. The waiver must be documented in the Centralized Credentials Quality Assurance System (CCQAS), with the date of the waiver reflecting the expiration of the applicable time period of licensure. The Service SG must submit to the ASD(HA) an annual report of the waivers granted to individuals and the applicable justifications.

(5) Waivers for Physicians and Other Providers. Many States have requirements and restrictions for the licensing of military providers that limit the scope of practice. The requirement for an unrestricted license that is not subject to limitation on the scope of practice ordinarily granted by a State may be waived for individual providers who do not hold an unrestricted license.

(6) Waivers for PAs. Given the unusual circumstances that require a PA and his or her supervising physician to be licensed in the same State, the ASD(HA) has exercised the authority to waive the license requirement for PAs who meet the criteria in paragraphs 1b(6)(a) through 1b(6)(c) of this enclosure. Since these are the identical criteria reviewed to determine if privileges are initially granted or renewed, any PA who has been granted privileges within the MHS by an authorized privileging authority will be automatically granted a waiver. The waiver must be documented in CCQAS, with the date of the waiver reflecting the date that privileges were granted.

(a) At the time of privilege renewal, the criteria must be reviewed again. If the criteria are not met, the waiver will lapse, the request for renewal of privileges will be withdrawn, and the individual must practice under a formal plan of supervision until such time that the criteria can be met. If the criteria are met, the waiver should be renewed. If privileges are then renewed by the privileging authority, the waiver in CCQAS must be updated to reflect the date of the approved privileges. If for any reason the privileges are not approved by the privileging authority, the waiver will lapse and the appropriate procedures for an adverse privileging action must be initiated.

(b) A PA will provide care under a formal plan of supervision unless he or she possesses both a waiver and clinical privileges. The querying of the CCQAS will be the method used to monitor compliance with this process. This waiver is applicable to any MHS PA who is a member of a uniformed service (Active or Reserve), a civilian employee, a personal services contractor, or an authorized volunteer. It is not applicable to non-personal services contract personnel since they are required to meet the requirements of the state in which the MTF is located.

(c) The waiver criteria for qualified MHS PAs (including Reserve Component PAs) depend on whether the PA:

1. Has successfully completed an educational program for PAs accredited by the Accreditation Review Commission on Education for the PA or, prior to 2001, by either the

Committee on Allied Health Education and Accreditation or the Commission on Accreditation of Allied Health Education Programs.

2. Has passed the PA National Certifying Examination administered by the National Commission on Certification of PAs.

3. Achieves and maintains recertification with the National Commission on Certification of PAs.

(7) Waiver for an APN. Given the unusual circumstances that require an APN and his or her supervising or collaborating physician to be licensed in the same State or other State restrictions which may be impractical and not in the best interest of delivery of healthcare in the MHS, the ASD(HA) has exercised the authority to waive the license requirement for APNs who meet the criteria in paragraphs 1b(7)(a) through 1b(7)(c) of this enclosure. Since these requirements are the identical criteria reviewed to determine if privileges are initially granted or renewed, any APN who has been granted privileges within the MHS by an authorized privileging authority will be automatically granted a waiver. The waiver must be documented in CCQAS with the date of the waiver reflecting the date that privileges were granted.

(a) At the time of privilege renewal, the criteria must be reviewed again and the results of the review documented in CCQAS. If the criteria are not met, then the waiver lapses, the request for renewal of privileges will be withdrawn, and the individual must practice under a formal plan of supervision until such time that the criteria can be met. If the criteria are met, the waiver should be renewed. If privileges are then renewed by the privileging authority, the waiver in CCQAS must be updated to reflect the date of the approved privileges. If for any reason the privileges are not approved by the privileging authority, the waiver will lapse and the appropriate procedures for an adverse privileging action must be initiated.

(b) An APN will provide care under a formal plan of supervision unless he or she possesses both a waiver and clinical privileges. CCQAS will be utilized to monitor compliance with this process. This waiver is applicable to any MHS APN who is a member of a uniformed service (Active or Reserve), a civilian employee, a personal services contractor, or an authorized volunteer. It is not applicable to non-personal services contract personnel since they are required to meet the requirements of the state in which the MTF is located.

(c) The waiver criteria for qualified MHS APNs depends on if the APN:

1. Possesses a current, active, valid, and unrestricted license as a registered nurse and/or APN as required by the state issuing the license.

2. Has successfully completed an accredited educational program for advanced practice as a certified nurse practitioner, certified nurse midwife, CRNA, or certified clinical nurse specialist. Those completing their respective programs after December 31, 2001, must be educationally prepared at the master's level or above.

3. Has passed the national certifying examination for the specialty in question.

4. Has accumulated continuing education credit in accordance with the national certifying organization's requirement for certification or recertification.

5. Maintains certification or obtains recertification in accordance with the national certifying organization's stipulations.

(8) Waivers for Other Categories of Healthcare Providers. The ASD(HA) will establish waiver procedures for other categories of healthcare providers, as appropriate.

2. PORTABILITY OF STATE LICENSURE FOR HEALTHCARE PROVIDERS

a. General Provisions

(1) Section 1094(d) of Reference (h) mandates that, notwithstanding any law regarding the licensure of healthcare providers, a designated licensed individual provider may practice his or her profession in any location in any jurisdiction of the United States, regardless of where the provider or patient are located, so long as the practice is within the scope of authorized federal duties. For this purpose:

(a) A covered provider is one who is a member of the Military Services, civilian DoD employee, personal services contractor in accordance with section 1091 of Reference (h), or other health-care professional credentialed and privileged at a federal healthcare institution or location specially designated by the Secretary for this purpose.

(b) A jurisdiction of the United States is a State, the District of Columbia, or a Commonwealth, territory, or possession of the United States.

(2) Portability of State licensure does not apply to:

(a) Non-personal services contractor healthcare providers, whether on-base or off-base, unless specifically stated in the applicable contract and specifically approved by the ASD(HA).

(b) Non-DoD uniformed services personnel, employees, contractor personnel, volunteers, or other personnel of non-DoD agencies, unless specifically approved by the ASD(HA), or unless such personnel are properly detailed to DoD, in which case portability may apply to the same extent as to similar personnel of the DoD entity to which detailed.

(3) DoD Components must follow the procedures established in this section prior to assigning licensed individual providers to off-base duties to promote cooperation and goodwill with State licensing boards.

b. Qualifications

(1) To be eligible for assignment to off-base duties, the healthcare providers must:

(a) Have a current, valid, and unrestricted license or other authorizing document such as a certificate or registration, consistent with the requirements of this enclosure that encompasses the professional activities involved in the off-base duty assignment.

(b) Not be assigned to off-base duties if there is an unresolved allegation that, if substantiated, would result in an adverse licensing or privileging action.

(c) Have current clinical competence to perform the professional duties assigned.

(2) In the case of physicians and other privileged providers, the individual privileged provider must have current clinical privileges granted and maintained in accordance with this enclosure, which encompass the professional duties assigned. Alternatively, if such duties are outside the scope of clinical privileges granted by the applicable privileging authority, the individual privileged provider must have clinical competence sufficient to be granted such privileges by the civilian hospital or other entity responsible for privileges at the patient site.

(3) To be eligible for assignment to off-base duties, physicians must, additionally:

(a) Have completed at least 3 years of approved postgraduate training (including completion of postgraduate year 3) or have achieved American Board of Medical Specialties (ABMS) or AOA specialty board certification.

(b) Have maintained current competence, in that if 10 years or more have passed since completion of the licensing examination, the physician must have ABMS/AOA specialty board certification.

(c) Be current with applicable continuing medical education requirements under the system established pursuant to section 1094(a) of Reference (h).

(4) In all cases in which the off-base duty will be performed in a non-DoD healthcare facility, the healthcare provider must follow the rules and by-laws of such facility; to the extent they are applicable to the provider.

c. Coordination with State Licensing Boards

(1) Prior to a healthcare provider performing off-base duties pursuant to section 1094(d) of Reference (h), the DoD Component must notify the applicable licensing board of the host State of the duty assignment involved. Such notification will:

(a) Include:

1. Healthcare provider's name, State(s) of licensure, and commanding officer.

2. Location and expected duration of the off-base duty assignment.

3. Scope of duties.

4. MHS liaison official for the licensing board to contact with any questions or issues concerning the off-base duty assignment.

5. A statement that the healthcare provider meets all the qualification standards in paragraph 2b of this enclosure.

(b) Cite section 1094(d) of Reference (h) and this manual as its underlying authority.

(2) In cases in which the off-base duties involve the provision of healthcare services through telemedicine from an MTF and patients outside MTFs, paragraph 2c(1) of this enclosure will not be applicable.

(3) The requirement of paragraph 2c(1) of this enclosure regarding off-base duties of non-physicians may be waived by the MHS Service-level official responsible on a case-by-case basis if that official determines that such a requirement is not necessary to promote cooperation and goodwill with the State licensing board concerned and that such a waiver is consistent with this section and guidance of the ASD(HA).

d. Investigations and Reports. In the event of any allegation of misconduct on the part of the military healthcare provider arising from the healthcare provider's performance while on off-base duty assignment:

(1) MHS personnel must cooperate with authorized officials investigating the allegation on behalf of the host State licensing board, any other licensing board that has granted a license to the healthcare provider involved, and the non-DoD facility at which the DoD healthcare provider was performing the off-base duty assignment. Cooperation may include providing testimony and assisting in gathering evidence.

(2) Upon the referral of an allegation of misconduct to the MHS by a State licensing board or an official of the non-DoD healthcare facility involved, or upon receipt of an allegation from the person or entity making the allegation, or upon otherwise learning of the allegation, the MHS official responsible must make sure that the allegation is reviewed and, if it raises a substantive issue of misconduct, investigated.

(a) In the case of a privileged provider, if the results of the investigation indicate that the clinical privileges of the DoD privileged provider should be revoked or restricted by the MHS privileging authority; such action must be taken in accordance with applicable due process procedures. Adverse privileging actions must be reported to the NPDB and the Federation of State Medical Boards or other appropriate authorities in accordance with applicable requirements.

(b) In the case of an individual provider other than a privileged provider, if the results of the investigation indicate that an action should be taken to revoke or restrict the authorized clinical activities of the healthcare provider, this action must be taken in accordance with applicable due process procedures and must be reported using the appropriate reporting requirements.

(c) If requested by the host-State licensing board or other appropriate State licensing board or by an authorized official of the non-DoD facility at which the off-base duty assignment was performed, the full results of the MHS investigation must be provided to such board or authorized official as an exception to the general rule of confidentiality of MQAPR records pursuant to section 1102(c)(1)(C) and 1102(c)(1)(D) of Reference (h). The provision of the results will be contingent upon the recipient agreeing to maintain the confidentiality of the MQAPR records in accordance with section 1102 of Reference (h).

(3) If the non-DoD facility at which the off-base duty was being performed withdraws approval for the DoD healthcare provider to continue to perform such duty, the off-base duty assignment must be terminated. If the host-State licensing board requests that the off-base duty assignment be terminated, it must be terminated, unless the ASD(HA) determines that such request is arbitrary or without foundation.

e. Supplemental Agreements. The MHS officials responsible are authorized to enter into memorandums of agreement or other appropriate arrangements consistent with this section and other applicable law and DoD issuances to achieve the objectives of this section.

3. CREDENTIALS MANAGEMENT

a. Healthcare Providers. The healthcare providers listed in paragraph 1a(2) of this enclosure have been identified as critical for credentials management and must be included in the CCQAS. Unless otherwise specified, the requirements apply to active duty (including trainees in Service programs, Service-sponsored training, or long-term civilian schooling), Reserve Component members, federal civilian employees, contractors, volunteers, and those providers working under resource sharing agreements.

b. Pre-Selection Criteria. Credentials must be collected and verified before the selection, employment, or contract of healthcare providers. Staff appointments and clinical privileges will be considered only after all the pre-selection criteria required have been verified through the primary source, unless otherwise specified in paragraph 3c of this enclosure. Substantial errors of fact involving documents discovered before or after appointment can be the basis for non-selection or, after appointment, adverse action including separation and termination. Once appointed, all appropriate individual provider credentials must be entered into CCQAS.

c. Required Credentials. Credentialing decisions are based on:

(1) Evidence of the criteria listed in paragraphs 3c(1)(a) through 3c(1)(g) of this enclosure must be verified through primary source verification (PSV) and documented.

(a) Qualifying educational degree(s).

(b) Postgraduate training and fellowship for requested clinical privileges and scope of practice.

(c) Approved certificate by the Educational Commission for Foreign Medical Graduates for those graduates of foreign medical schools, other than approved schools in Canada.

(d) State licenses, registration, certification, or other authorizing document. A list of all healthcare licenses ever held must be provided with an attached explanation of any licenses that are not current or active; any challenges to licensure or registration; any voluntary or involuntary relinquishment of licenses; or any licenses that have been subjected to disciplinary action.

(e) Board certification, if applicable. Board certification in medical board specialties must be verified either through the primary source (the issuing body) or as described in Reference (q).

(f) Chronological practice experience and an accounting of all unexplained gaps in active practice or gaps in privileges back 10 years or to the date of qualifying degree.

(g) Documentation of any medical malpractice claims, settlements, or judicial or administrative adjudication with a brief description of the facts of each case listed. Documentation must include evidence of current or past malpractice coverage consistent with judiciary and judicial procedure as detailed in sections 1346(b) and 2671 through 2680(h) of Title 28, U.S.C. (Reference (z)).

(2) For the criteria listed in paragraphs 3c(1)(a) through 3c(1)(g) of this enclosure, secondary sources are supplementary and do not meet the requirement.

(3) In addition to the criteria listed in paragraphs 3c(1)(a) through 3c(1)(h) of this enclosure for PSV, the additional credentialing criteria are:

(a) A current report from the NPDB and Healthcare Integrity and Protection Data Bank (HIPDB) for each privileged provider.

(b) A statement of the applicant's ability to perform his or her professional activities and proof of current professional competence.

(c) Any history of adverse clinical privilege or disciplinary action by a hospital, State licensure board, or other civilian government agency. This will include voluntary or involuntary termination of professional and medical staff membership or voluntary or involuntary suspension, reduction, restriction, or revocation of clinical privileges at a hospital or other healthcare delivery setting, and any resolved or open charges of misconduct, unethical practice,

or substandard care. This will require query of the Department of Health and Human Services (DHHS) and the TRICARE sanction lists.

(d) A statement of the applicant's health status, about his or her ability to provide healthcare. The statement must be confirmed as described in TJC Comprehensive Accreditation Manual for Hospitals as described in Reference (q) or by another accreditation source approved by the ASD(HA).

(e) All healthcare providers must have two letters attesting to their clinical competency from healthcare providers of the same or similar specialty (e.g., letters of recommendation from the program or training director and a recent description of scope or practice or clinical privileges by the directors of the facility in which the applicant currently is practicing) as described in Reference (q). The period of time and/or the last time the individual had observed the provider's clinical practice should be included. If the provider is already working within the DoD MHS, clinical competency documentation may be in the Services' approved format (i.e., Performance Appraisal Report or Clinical Appraisal Report).

(f) Evidence of appropriate continuing education will be required for all healthcare providers in accordance with Service-specific guidance.

(g) A Drug Enforcement Agency (DEA) certificate, if eligible to obtain a DEA number, unless an exception approved by the ASD(HA) is applicable.

(h) A National Provider Identifier (where applicable).

(i) Federal Bureau of Investigation background check and State criminal history repository check, in accordance with Enclosure 5 of DoDI 1402.05 (Reference (aa)).

(j) A signed statement consenting to the inspection of records and documents pertinent to consideration of his or her request for accession or employment.

(k) A signed statement attesting to the accuracy of all information provided.

(l) A signed statement of agreement to follow the medical staff bylaws of the MTF.

4. CLINICAL PRIVILEGES AND APPOINTMENT TO THE MEDICAL OR DENTAL STAFF

a. Privileging Authority. The Secretaries of the Military Departments and the Commander, JTF CapMed have privileging authority in the MHS and designate the authorities at MTF levels for privileging providers who are responsible for making decisions to diagnose conditions and determine a regimen of healthcare.

b. Review of Credentials. Prior to providing care, all providers requiring privileges to practice must have their credentials and health status reviewed and clinical privileges must be

granted, regardless of whether or not they have a medical staff appointment. The following Privileging categories apply:

(1) Regular Privileges. Regular privileges may be granted for periods not to exceed 24 months.

(2) Supervised Privileges. A supervisor with regular privileges must be named and a plan of supervision developed and implemented. Providers with supervised privileges may not be appointed to the medical staff. Supervised privileges may be granted for periods not to exceed 24 months and do not allow the provider to practice independently.

(3) Temporary Privileges. Temporary privileges may not exceed 30 days. Granting of temporary privileges should occur infrequently and then only to fill pressing patient needs. Temporary privileges may be granted with or without a temporary appointment to the medical staff.

c. Medical Staff Appointment Status. Medical staff appointment status reflects the relationship of the provider to the medical or dental staff and the degree to which the provider participates in the activities of the medical or dental staff. There are four types of medical or dental staff appointment.

(1) Initial Appointment. An initial appointment is granted to an individual provider when he or she is first assigned or employed in a DoD MTF or when the provider has had a lapse of greater than 180 calendar days since having a medical or dental staff appointment in a DoD MTF. The initial appointment will not exceed 12 months. An initial appointment leads to an active or affiliate medical staff appointment and may be designated as such when granted (i.e., initial-active or initial-affiliate). When designated in this way, the appointment indicates the provider's responsibilities associated with that appointment.

(2) Active Appointment. An active appointment is granted to an individual provider exercising regular privileges who has completed an initial appointment period. Providers with active appointment fully participate in the activities and bylaws of the medical and dental staff. Active appointments will not exceed 24 months.

(3) Affiliate Appointment. Affiliate appointments may be granted to an individual provider exercising regular privileges who has completed an initial appointment period. Providers with affiliate appointments are not assigned organizational responsibilities of the medical or dental staff nor are they expected to be a full participant in activities of the medical or dental staff. Affiliate appointment is appropriate for consultants and individuals who are not assigned to the MTF, but who work part-time providing patient care. Affiliate appointment will not exceed 24 months.

(4) Temporary Appointment. A temporary appointment is granted in emergency situations when time constraints will not allow full credentials review but there are pressing patient care needs. This appointment is granted in conjunction with temporary privileges and will not exceed 30 calendar days.

d. Requirement to Query the NPDB and HIPDB. The NPDB and the HIPDB must be queried for all individual providers before granting, renewing, or modifying clinical privileges.

e. Documentation of Clinical Privileges. Clinical privileges granted to each individual provider must be documented in CCQAS.

5. INTER-FACILITY CREDENTIALS TRANSFER AND PRIVILEGING

a. Assigned Temporarily for Clinical Practice. When healthcare providers (including reservists) are assigned temporarily for clinical practice in an MTF, the supplying MTF must convey all relevant credentials and privileging information to the gaining MTF. The receiving commander uses this information as a basis for assessing current clinical competence and making appropriate appointment and privileging decisions upon arrival at the gaining MTF. The inter-facility credentials transfer brief (ICTB) is the preferred mechanism to carry out this credentials transfer whenever its use can reasonably ensure the accurate transfer of credentials and privileging information. The privileging institution retains full responsibility and authority for making privileging decisions.

b. ICTB and Formal Application. The ICTB is joined with the formal application for privileges and supplants sections of applicable Military Service forms containing similar essential information. The ICTB serves as the credentials file when making privileging decisions on temporarily assigned healthcare providers.

c. Granting Privileges. After customary departmental review and recommendation, and consideration of the gaining facility's capability, MTF commanders may grant privileges based on the approved privilege list from the sending MTF by approving it with or without recommendations. The receiving facility's medical staff credentialing functions must ensure that all relevant information is considered, taking care to investigate additional information regarding ICTB as detailed in paragraphs 5f(7), 5f(9), and 5f(10) of this enclosure. The receiving facility may use its own customary forms or formats for notifying providers of their medical appointments and documenting those appointments. Privileges applied for but not granted due to facility-based limitations are not adverse privileging actions.

d. Acceptance of Provider Performance Appraisals. Credentialing functions in MTFs will accept healthcare provider performance appraisals on other Service's forms as their own.

e. Invalidation of the ICTB. The ICTB will become invalid on the expiration of the professional privileges on which it is based. If the healthcare provider is assigned temporarily for several brief periods to the same location, it remains valid over the duration of the combined periods, providing the professional privileges at the sending MTF remains in effect. If other credentials have expired in the interim, confirmation of the renewal of the credential with the facility holding the credentials file will suffice (i.e., a new ICTB is not required). A record of the confirmation must be maintained in the healthcare provider's file at the gaining facility. The sending facility must keep an accurate record of all MTFs to which an ICTB has been sent to

ensure updates on provider status are forwarded as required. The sending MTF must provide a new ICTB whenever the status of the individual provider's privileges changes (e.g., change from provisional to defined privileges, renewal of privileges, adverse privileging actions).

f. Reporting Elements for the ICTB. Reporting elements for the ICTB must be acquired electronically from CCQAS and will include:

(1) The complete name, rank (or rating if federal employee), corps, social security number, and clinical specialty.

(2) The qualifying degree, internship, residency, fellowship, and other qualifying training, as appropriate. Include completion date of each and indicate the presence or absence of PSV in the credentials file.

(3) All currently held State licenses, registrations, and certifications, and the expiration date and PSV status of each.

(4) All applicable specialty or board certifications and re-certifications, and the expiration dates and PSV status of each.

(5) All applicable life support training (e.g., basic life support, advanced cardiac life support, advanced trauma life support, pediatric advanced life support, neonatal advanced life support), and expiration dates.

(6) The type of clinical privileges currently held by the healthcare provider and the expiration date. List privileges granted and attach current privilege list(s). Refer to paragraphs 5f(13)(a) through 5f(13)(d) of this enclosure for guidance on Reserve or Guard units where appointments and privileges do not fully represent the capability of the healthcare provider.

(7) A date of the most recent NPDB and HIPDB query and statement as to whether information was reported in response to the query.

(8) A statement of the nature or purpose of the temporary assignment and request performance appraisals, as appropriate.

(9) A brief statement from an individual who has observed the applicant's professional and clinical performance or who can describe the applicant's actual clinical performance with respect to the privileges granted at the sending facility, the discharge of his or her professional obligations as a medical staff member, and his or her ethical performance. This person may be a training program director for new providers, or a peer from a prior or current command. The statement may be taken from a current performance evaluation in the individual provider's credentials file. A statement indicating the presence or absence of other relevant information in the recommendation relating to the provider's competence for privileges as granted along with a means of direct contact with the person making the recommendation (e.g. name, title or position held, telephone, fax, e-mail) will be included.

(10) Certification that the credentials file was reviewed and is accurately reflected in the ICTB as of the date of the review. This paragraph must contain a statement indicating the presence or absence of other relevant information in the credentials file. Of particular importance is supplemental information accompanying PSV of training and licensure. Examples of other relevant information include, but are not limited to, delays in or extensions in training due to marginal performance, unprofessional conduct during training or in previous practice settings, investigations, limitations imposed by State licensing boards, adverse actions, and malpractice reports.

(11) The name, title, phone number, and fax number or e-mail address of the designated point of contact at the sending facility.

(12) The certifying signature by the MTF commander or appropriate agency official and date. Electronic signatures are acceptable.

(13) Paragraph(s) applicable to healthcare providers from Reserve or Guard components (as needed). This information should include:

(a) The current civilian position, place of employment or facility where privileges are held, and the clinical privileges held by the individual privileged provider.

(b) The provider's office location, if he or she is self-employed.

(c) If privileges are held at several facilities, the name and location of the place or places where the majority of the provider's practice is conducted, and a list of the clinical privileges held that are applicable to the assignment prompting the use of the ICTB.

(d) The address, business phone number, and home phone number where the provider can be reached prior to reporting for the assignment and the name of the MTF and dates of the last tour of clinical duty.

6. CREDENTIALS, PRIVILEGING, AND ADDITIONAL REQUIREMENTS FOR TELEMEDICINE

a. Clinical Privileging for Telemedicine Providers. For facilities that grant clinical privileges, the requirements for credentialing and granting of clinical privileges are modified such that the privileging authority of the facility where the patient is located (known as the "originating site") may choose to rely on the credentialing and privileging determinations of the facility where the provider is located (known as the "distant site") to make local privileging decisions. This is known as "privileging by proxy," and decisions must incorporate applicable telemedicine standards as identified in References (q), (r), (s), and (t) to include requirements of the originating site to make final privileging decisions. These modifications are conditional on the following:

(1) The originating and distant site facilities are accredited by TJC, the Accreditation Association for Ambulatory Healthcare, or other appropriate accrediting entity designated by the ASD(HA). Hospitals must meet the standards in Reference (q) for privileging by proxy.

(2) The distant site provider is privileged at the distant site facility to provide the identified services and is authorized to provide telemedicine services. The provider or the distant site facility must request of the originating site facility, permission to use the provider's current privileges to provide care to patients in the originating site. The request and a privileging decision must be appropriately documented at the originating site. The distant site facility must provide at a minimum a copy of the distant site provider's current list of credentials, privileges, and proof of HIPAA training in accordance with Reference (l).

(3) The originating site facility has evidence of periodic internal reviews of the distant site practitioner's performance of these privileges and receives such performance information, including all adverse events resulting from telemedicine services, for use in the periodic appraisals.

(4) The originating site will transmit performance information, including adverse event information and complaints from patients, other providers or staff to the distant site and the distant site will demonstrate use of this information in periodic performance reviews of the provider.

(5) The privileging authority of the originating site may choose to use the ICTB (or other credential transfer mechanism approved by ASD(HA)) as a source to rely upon the credentialing and privileging determinations of the distant site.

(6) If the distant site facility is not a MTF or Department of Veterans Affairs (VA) hospital, or otherwise does not have access to the ICTB (or other credential transfer mechanism approved by ASD(HA)), its medical staff credentialing and privileging process and standards at least meet the standards in Sections 482.12(a)(1) through 482.12(a)(7) and 482.22(a)(1) through 482.22(a)(2) of Title 42, CFR (Reference (ab)).

b. Additional Conditions. The use of an originating or distant site that is not an MTF or VA medical facility, but is an installation, armory, or other non-medical fixed DoD location, a DoD mobile telemedicine platform, or a civilian sector hospital, clinic, TRICARE contracted provider's office, or other location approved by ASD(HA) for this purpose is permissible unless restricted by the SG concerned, or Commander, JTF CapMed. Prior to engaging in telemedicine services, the applicable medical command(s) must ensure that with respect to originating and distant sites and the providers involved:

(1) Patients and providers are provided with a secure and private setting.

(2) Arrangements have been made for appropriate clinical support, including access by local emergency services, should the need arise.

(3) The facilities and providers meet applicable current telecommunication and technology guidelines of the American Telemedicine Association at www.americantelemed.org. Examples of such guidelines include the American Telemedicine Association "Telemedicine Standards & Guidelines" (Reference (ac)) and American Telemedicine "Practice Guidelines for Videoconferencing-Based Tele-mental Health" (Reference (ad)).

c. Alternative Arrangements. Alternatives to the requirements of section 6 of enclosure 4 require approval of ASD(HA).

7. OUTSIDE ("OFF-DUTY") EMPLOYMENT BY DoD HEALTHCARE PROVIDERS

a. General Provisions

(1) Commanders may, in accordance with DoD 5500.7-R (Reference (ae)) and applicable Service regulations, approve outside employment by DoD healthcare providers on active duty if all requirements of this section are met. To clarify questions of conduct and other ethical issues related to outside employment and compensation, personnel should consult Reference (aa) and their ethics counselor.

(2) Although the requirements of this section are directly applicable only to active duty and federal civilian healthcare providers, the Military Services may also apply these requirements to other unlicensed healthcare personnel who have received special training or education in a health-related field, which may include administration, direct provision of patient care, or ancillary services (e.g., x-ray technicians, nursing assistants).

b. Commander's Responsibilities

(1) Commanders may authorize outside employment upon written request of healthcare providers when such activities do not interfere with provision of healthcare services or mission accomplishment. Commanders should consider factors such as hours per week, work site proximity, travel time, and impact on civilian communities and providers when reviewing such requests.

(2) Permission to engage in outside employment must be documented in writing and may be withdrawn at any time by the commanding officer.

(3) Personnel enrolled in graduate training programs will not be authorized to engage in outside employment.

(4) Commanders will require the annual review of the healthcare provider's compliance with applicable policy and regulatory guidance.

c. Procedures for Requesting Authorization

(1) DoD healthcare providers desiring to engage in outside employment must submit a written request that includes:

(a) A statement of understanding of applicable DoD regulations.

(b) Written acceptance from the outside employer of the healthcare provider's availability and of any limitations on patients the provider may treat and payments for care rendered.

(c) The impact of outside employment on civilian community and healthcare providers (e.g., statement from employer, local medical society, or provider's own assessment).

(2) DoD healthcare providers must certify their compliance annually with applicable policy and regulatory guidance and whenever there is a change in outside employment status.

(3) DoD healthcare providers are responsible for complying with all requirements to practice in the civilian community such as State licensure, DEA certification, and medical malpractice coverage. The fee-waived DEA certification is not authorized for outside employment.

(4) DoD healthcare providers cannot be authorized TRICARE providers or be reimbursed for providing TRICARE services to DoD beneficiaries consistent with section 5536 of Reference (j). This restriction does not apply to dental services provided to TRICARE Dental Program enrollees in the continental United States. Section 5536 of Reference (j) does not prohibit DoD healthcare providers from becoming enrolled Medicare providers with regard to their off-duty employment and billing Medicare for their services.

d. Withdrawal of Authorization

(1) Commanders must withdraw permission to engage in outside employment for all DoD healthcare providers at the beginning of any inquiry into potentially reportable actions of misconduct until the issues are resolved.

(2) Permission must be withdrawn from a provider who had previously been granted permission to engage in outside employment and who is either appealing a decision to limit or suspend part or all of his or her clinical privileges or the decision to not fully restore clinical privileges. The provider must be notified of the withdrawal. No new permission will be granted during the appeal process. Additionally, the appropriate officials at the place of employment must be notified that permission to engage in outside employment has been withdrawn.

(3) Commanders must ensure that the appropriate officials at all civilian places of employment are immediately notified whenever permission is withdrawn for providers to engage in outside employment.

8. CREDENTIALING AND AUTHORIZATION OF PROVIDERS ON FOREIGN HUMANITARIAN MISSIONS. The military Senior Medical Department Representative (SMDR) assigned to a foreign humanitarian mission is responsible for monitoring the quality and safety of the medical care rendered by all providers participating in the DoD mission. The SMDR is required to review the credentials of all providers assigned to the DoD mission and to authorize those qualified providers to practice their specialties. The SMDR is the final authority on which healthcare providers participate in the DoD foreign humanitarian mission.

a. All DoD providers (Active Duty, Reserve Component, DoD civilian employee) as well as employees of DoD contractors carrying out contract work, will report as assigned with a current medical readiness certification and a complete ICTB for review and authorization by the SMDR. A Medical Readiness Certificate is not required if a Military service member was deployed through a Service-specific deployment program.

b. A host nation may require documentation or copies of medical school diplomas and state licenses as a condition for medical personnel practicing in that country. If required by a host nation, such documentation may be provided to the host nation. The host country should be requested to return the documents after review and or agree to protect the documents from further release.

c. If a copy of the ICTB is also provided to a host country, sensitive personal identifying information (e.g. Social Security number, date of birth, home address, and DEA number) will be redacted prior to release.

d. The Medical Director of a non-governmental organization (NGO) is responsible for providing appropriate information documentation verifying education, training, licensing, and current clinical competence to the SMDR for all its participating members when requesting authorization for the NGO to be a participant in the DoD humanitarian mission.

e. An NGO may be a cooperating party with a DoD humanitarian mission but not become part of the DoD mission if the NGO is not providing health care services in or on a DoD facility or platform (such as a field hospital or hospital ship), but rather is providing services independently, while receiving logistical support from DoD. In such cases, the SMDR is not responsible for verifying education, training, licensing, and current clinical competence of the NGOs members or monitoring their professional services, but will obtain assurance from the Medical Director of the NGO that the Medical Director accepts that responsibility. The SMDR will also ensure host nation officials have no misunderstanding regarding the relationship between DoD and the NGO with respect to the humanitarian mission.

f. All foreign providers (i.e., providers not licensed in any jurisdiction of the United States) will meet the credentialing and licensing standards of their respective country. A foreign provider's request for authorization to participate as part of a DoD humanitarian mission should include to the extent practicable supporting documentation of medical training, country certification or licensure, education, practice specialty, and current clinical competencies. A period of observed practice should ordinarily be performed to assess skill level prior to assignment of clinical duties.

g. Ensuring that all medical care provided as part of DoD foreign humanitarian missions meets applicable quality and safety standards is the responsibility of the assigned SMDRs. NGOs involved as a cooperating party, but not becoming a participant in the DoD humanitarian mission, are to accept comparable responsibilities. The role of the NGO as either a participant in the DoD humanitarian mission or a cooperating party with a DoD humanitarian mission should be clearly expressed in the MOU between DoD and the NGO for that mission.

ENCLOSURE 5

MANAGEMENT OF ADVERSE EVENT, NEAR MISS, OR UNSAFE CONDITION

1. OVERVIEW

a. When a patient experiences an unanticipated outcome or adverse event, near miss, or unsafe condition, QA, risk management, and patient safety subject matter specialists will collaborate to identify, analyze, and appropriately report these events. This integrated, collaborative relationship fosters organizational efforts to reduce risks to patients and improve the quality of care through fundamental principles and practices incorporated into healthcare delivery. Though QA, risk management, and patient safety personnel collaborate to reduce healthcare risk, each has distinct functions and activities as described in Enclosures 8 and 9 of this manual.

b. The management of adverse events, near misses, or unsafe conditions, is a component of the MHS clinical quality program for the DoD. The program encompasses identification and mitigation of risk to patients, family members, visitors, and staff as well as the oversight and review of the effectiveness of organizational risk reduction strategies. These programs will encompass the potential risk of liability for death or disability benefits to members of the uniformed services arising from possible substandard medical care, including that provided in operational healthcare units. MTFs must implement active systems and programs to reduce liability risks associated with actual or alleged medical malpractice and use those systems and programs to reinforce other MQA program activities.

2. IDENTIFICATION ADVERSE EVENT, NEAR MISS, OR UNSAFE CONDITION

a. Processes must be in place to identify all adverse events. Immediate action must be taken to make sure those patients, staff, and visitors are protected from additional injury and to minimize the effects of the event. All adverse events, near misses, or unsafe conditions, must be entered in the patient safety reporting system (PSR). Adverse events which meet the definition of a potentially compensable event (PCE) must also be entered in the PCE module of CCQAS.

b. A formal process must be established to identify, analyze, and report both individual and aggregate data associated with adverse events to the respective Service level and to the ASD(HA). Documentation, review, and analysis procedures must be established in Service policy documents.

3. DISCLOSURE OF AN ADVERSE EVENT

Patients are entitled to factual, complete information about the outcomes of diagnostic testing, medical procedures, and other healthcare interventions. This is true whether the results are expected or unanticipated. Prompt, compassionate, and honest communication with the patient and the patient's family following an adverse event or an unanticipated outcome is an essential component of quality healthcare.

Communication about the event should revolve around the known facts taken from the medical record and should avoid speculation or personal opinion. Proper disclosure does not suggest that the involved provider(s) have been negligent; it informs the patient or family that an unanticipated outcome has occurred, confirms the patient's current status, and identifies the ongoing plan of treatment.

a. Disclosure. The intent of disclosure is that the patient and, if appropriate, the patient's family will receive cogent, factual, event-related information, without attribution of blame or fault. Disclosure must be in a language and terms that are readily understood by the patient and family. If a language barrier exists between the provider and the patient or family, the MTF must arrange for an interpreter.

b. Informing the Patient. The patient must be informed that an adverse event or unanticipated outcome has occurred as soon as possible after the event is identified.

(1) The primary caregiver is the ideal individual to lead the initial disclosure communication with the patient and family.

(2) In instances where informing the patient is not possible or practical (i.e., provider has transferred to a new assignment), the primary provider's supervisor or a senior colleague should discuss the matter with the patient and family, as appropriate.

(3) The intent of these discussions is to have personal, candid communication with the patient and family. Should the patient or family request to have an attorney present during these communications, before consenting to the presence of other than family members, the provider must seek advice from MTF senior leadership, the risk manager (RM), and legal counsel, consistent with Service and DoD policy.

c. Full Disclosure. The intent of full disclosure is that healthcare providers should verify that the patient and family understand the facts and make certain timely and accurate documentation of those facts in the medical record. Full disclosure should include:

(1) Explanation of the effect of the adverse event on the patient's condition and prognosis.

(2) Provision of reliable information and facts associated with the adverse event avoiding all conjecture or personal opinion.

(3) Identification of the person(s) designated to provide the patient and family with additional information and how and when that communication will occur.

(4) Recommendations for further diagnostic and therapeutic interventions.

d. Service Policy Guidance. The Military Services must provide specific written policy guidance for disclosure to patients and their family members who have experienced adverse events, as directed by this manual. This guidance will also address correct procedures for

documentation in the medical record following an adverse event or unanticipated outcome. The Services must ensure that training on disclosure and documentation of adverse events is available to appropriate healthcare providers on a periodic basis.

4. REVIEW AND CLASSIFICATION OF AN ADVERSE EVENT, NEAR MISS, OR UNSAFE CONDITION. Every adverse event, near miss, or unsafe condition involving an MTF patient (active duty member or other beneficiary) must be reviewed. The RM, patient safety manager (PSM), senior clinical staff, and the MTF attorney (or Military Department legal office representative) will collaborate to determine the appropriate investigative process(es) for the event.

a. Adverse Event Investigation. All adverse events are investigated initially by both the Patient Safety Program (PSP) and by the risk management program personnel when there is evidence that individual healthcare provider issues are involved. The MTF attorney (or Military Department legal office representative) will be consulted when evaluating an adverse event as a PCE.

b. Events Requiring Both Patient Safety and Risk Management Investigation. When an adverse event results in concurrent review and analysis by both the PSM and the RM, the two investigations represent separate and distinct processes.

(1) All adverse events, near misses, or unsafe conditions, must be entered in the PSR. Adverse events which meet the definition of a PCE must also be entered in CCQAS. Events are entered into the PSR or CCQAS following the common definition sets for harm scale categories and event taxonomy descriptions included in this enclosure or detailed in the Glossary of this manual.

(2) All adverse events, to include PCEs, and the associated standard of care (SOC) determinations, must be independently entered into the PSR and the CCQAS risk management reporting system.

c. PCE Investigation. Every adverse event that resulted in harm to the patient and presents a possible financial loss to the Federal Government (i.e., a malpractice claim or death or disability payment) is considered a PCE. Every PCE must be investigated by both the PSM and the RM, and then promptly entered into the PCE module of CCQAS. The MTF must include in their assessment whether the SOC was met in relation to the adverse patient outcome and document findings in the PCE module of CCQAS. The MTF attorney (or Military Department legal office representative) will be consulted when evaluating an adverse event as a PCE.

d. Patient Safety and Risk Management Harm Scale Categories. All adverse events involving an MHS patient must be reviewed to determine whether harm to the patient occurred. Regardless of the level of harm that has occurred, all events must be documented as described in one of the nine harm scale categories defined in the Glossary. Harm scale categories for the PSR and the CCQAS risk management program are identical and are the required taxonomy for

documentation. However, because harm to the patient is a primary criterion in the identification of a PCE, only adverse events which involve harm scale categories 1 through 4 apply to PCEs.

e. Sentinel Event (SE) Identification. MTF personnel must actively identify SEs that occur in their facility, conduct a root cause analysis (RCA), and form a corrective action plan for each event. The results of the analysis and plan for each event must be reported through the Military Department concerned to the ASD(HA) within 24 hours of the facility learning of the event. In addition, each MTF must comply with TJC reporting requirements for those SE that are subject to review by the TJC. All SEs that meet the classification requirements and definition of a PCE must be documented in the PCE module of the CCQAS. To document the effective operation of the SE program, including the conduct and submission of an RCA on every SE event, the procedures in paragraphs 4e(1) through 4e(3) of this enclosure must be followed with respect to PCEs arising from healthcare provided.

(1) The Service-level RM, upon receiving notification of a malpractice case award or payment in excess of 500,000 dollars that is associated with a serious adverse event (PCE or SE) or notice of a death or disability of a member of the uniformed services arising from the provision of medical care must notify the respective Service SG. The Service SG concerned must report the information to the DoD Risk Management Committee via the Service-level RM.

(2) Each Service-level RM will determine whether an RCA or alternative quality analysis was completed by the MTF and will report whether an RCA, if completed, was reported to the DoD Patient Safety Center.

(3) In the event that no RCA or alternative quality analysis has been performed and submitted, a preliminary analysis of the event must be conducted and a report must be forwarded to the DoD Risk Management Committee by the Service-level RM within 45 days of receiving notice of the malpractice payment of 500,000 dollars or more. The report must include an explanation of why no RCA or alternate quality analysis was performed at the time of the event(s) that gave rise to the large malpractice payment and whether the SOC was met or not met.

5. ANALYSIS OF A PCE. PCE determination is based on the evidence of harm as described in this enclosure. Any event determined by the RM to meet the definition of harm scale categories 1 through 4 is to be identified and reported as a PCE in CCQAS. All PCEs must be fully investigated by the RM and documented in the PCE module (formally the incident module) of the CCQAS within 180 calendar days of the date of occurrence or initial identification.

a. PCE Documentation. Any adverse event that meets the definition of a PCE must be documented, tracked, reviewed, and analyzed to determine contributing causes and results of the investigation, and SOC must be documented in the PCE module of CCQAS within 180 days of identification of the occurrence. Any event determined to result in harm to a patient must be documented in the CCQAS.

(1) PCE documentation in the CCQAS must include the harm scale category (e.g., death, severe permanent harm, and permanent harm) defined in the Glossary, a description of the event type (e.g., accident, blood or blood products, healthcare associated infection), and the PCE Classification detailed in the Appendix to this enclosure.

(2) Information concerning the description of the PCE must be in enough detail to facilitate data tracking and trending at the MTF, Service, and DoD levels. PCE documentation in CCQAS must include documentation of both the SOC assessment and determination.

b. PCE Analysis. An analysis of the causes of the PCE provides an opportunity for organizational improvement to prevent the reoccurrence of the same or like event. Organizational changes that might follow a PCE investigation include, but are not limited to, simplifying and standardizing processes; reducing reliance on memory; introducing checklists, constraints, or forcing functions; eliminating medication names that look-alike and sound-alike; encouraging teamwork and better communication; and providing training programs.

(1) For every PCE, every claim for liability compensation in accordance with sections 1346(b) and 2671 through 2680 of Reference (z), or section 2733 or 2734 of Reference (h) alleging medical malpractice must be reported by the receiving claims office to the medical office designated by the Military Service concerned. Unless a review has already been completed and SOC properly documented, the MTF involved must review the healthcare provided and assess whether the 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) The PCE review process must commence within 30 days of PCE identification and be completed within 180 days. If the PCE involves an active duty Service member death, the 180 day process will include a determination of whether an NPDB reporting process review is required. Upon completion of the review process, each PCE, and the determination regarding whether SOC was met or not met, must be entered into the DoD PCE module of CCQAS to provide for review by the ASD(HA).

(3) Significantly involved providers must be identified and informed that a review of the PCE will be completed.

(4) Significantly involved providers must be afforded the opportunity to provide input in the PCE review process to the extent appropriate to ensure a full understanding of the facts regarding the care provided to the patient.

(5) An SOC review must be conducted on each of the significantly involved providers. The SOC investigation must include a professional review of the care and an opinion rendered as to whether or not the SOC was met for each significantly involved provider. In select circumstances SOC may be designated as indeterminate due to such factors as a lack of information, or incomplete medical records. For SOC “not met” or “indeterminate” opinions, the rationale for the decision will be documented.

(a) The SOC review considers any system issues as well as the clinical judgment, skills, knowledge, and experience of the providers in question. For performance improvement purposes, significantly involved providers should receive feedback regarding the SOC determination and the rationale for a determination of "not met" or "indeterminate."

(b) Recommendations for further action will be forwarded to the provider's clinical supervisor or department chair or to the QA department, as appropriate, for system and process improvement consideration.

(c) Other processes and factors which may have contributed to the adverse event should be addressed.

(6) The DoD PCE module of CCQAS must be utilized to document and track all PCEs. The details of the PCE, the specifics of the investigation, all significantly involved providers, and an SOC determination for each must be documented in CCQAS.

(7) MTFs must conduct an 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 must document the results of the SOC assessment in CCQAS. Service-level RMs, upon receiving notification of a disability or death of a member of the Military Services arising from the provision of medical care, must notify their respective Service SG. The Service SG concerned must report the information to the DoD Risk Management Committee through the Service-level RM. These events are to be documented in the CCQAS disability and PCE modules.

6. HEALTHCARE RESOLUTIONS PROGRAM

a. Purpose

(1) This section establishes MHS procedures for the promotion of organizational transparency and full disclosure following unanticipated or adverse outcomes of care. A healthcare resolutions program must be implemented within each MTF no later than 2 years following the publication of this manual. The requirements in this section do not supersede other requirements of this manual.

(2) Patients have a right to be fully informed regarding their health-related conditions including adverse events occurring in an MTF. An organized program of healthcare resolutions supports the evolution toward transparency within the MHS.

b. Procedures

(1) All licensed independent providers receive disclosure training by healthcare resolutions specialists. Disclosure training emphasizes that full transparency is practiced when there are unanticipated or adverse outcomes of care, treatment, or services. Transparency

involves the release and explanation of the medical facts of the case as documented in the medical record. Strict compliance must be maintained while protecting all MQAPR materials from inappropriate release, in accordance with section 1102 of Reference (h).

(2) The healthcare resolutions program does not take the place of legal or claims processes. Mediation and facilitation sessions are not considered formal resolutions of legal claims. Patients and families maintain any and all legal options. Healthcare resolutions specialists coordinate with MTF counsel on cases that may have legal implications, including potential claims against the government. However, counsel does not participate in mediation and facilitation sessions. Healthcare resolutions specialists advise MTF legal counsel, if notified, that a patient is represented by legal counsel or intends to file a claim against the government and refer any inquiries regarding legal issues or service of process to counsel, including any correspondence from legal counsel representing patients. Healthcare resolutions specialists disengage when and if claims are filed. If advised that a patient or family is represented by legal counsel but no claim has been filed, the healthcare resolutions specialist offers the patient or family an option to continue with the healthcare resolutions program or to proceed exclusively through the legal system with their attorney.

(3) Healthcare resolutions specialists report to senior command or management of the MTF and conduct appropriate periodic disclosure training for providers as well as case execution.

(4) Healthcare providers participate in disclosure training, refer cases to the attention of healthcare resolutions specialists, and participate in mediated sessions. Providers must be familiar with and observe guidelines regarding non-releasable information.

(5) Patient safety, risk management, and QA program officials support the Healthcare Resolutions Program. They accept case referrals from healthcare resolutions specialists and attend specific sessions arranged by healthcare resolutions specialists with patients and families who want to offer input to the formal case review process, having been advised that investigative results are not releasable. Patient safety, risk management, and QA program officials refrain from sharing information protected by section 1102 of Reference (h) with Healthcare Resolutions Specialists.

c. Principles and Practices of Healthcare Resolutions Specialists. Healthcare resolutions specialists incorporate multiple approaches to conflict management and dispute resolution, to include:

(1) Neutrality. To the extent permitted by MHS policy, promote a fair process which is objective, impartial, and free from conflict of interest.

(2) Conciliation. Listen impartially and attentively to assist patients in putting their problems into perspective. Listen to and informally research complaints.

(3) Facilitation. Encourage open communication between parties, and seek fair and equitable solutions to the situation.

(4) Coaching. Coach individuals at all levels on organizational behavior, communication strategies, and interpersonal communication; review policies, procedures, and systems pertinent to the case; assist and counsel parties to improve their communication skills, confront personal issues, handle emotions, etc.

(5) Informal Fact-finding. Fact-finding involves reviewing the medical record and speaking with involved patients and providers regarding the occurrence to gather information to facilitate the resolution process. Informal fact-finding does not interfere with any QA or litigation reports and does not seek the results of those proceedings.

(6) Referral. Refer to another department and resource when that department (e.g., Risk Management, Patient Safety) may be better able to resolve all or a portion of a case.

(7) Empowerment. Counsel patients and medical staff to recognize alternatives and to consider goals and objectives while balancing them against the goals and interests of the MHS.

(8) Mediation. Serve as an impartial third party who facilitates discussions between patients and providers, helping the parties focus on underlying issues and their needs and interests rather than on entitlements or rights-based positions.

(9) Ombudsman. Responds to patient complaints and works to achieve equitable solutions to patient concerns.

d. Referral Criteria. Referrals may be received from MTF leadership, MTF staff members, TRICARE beneficiaries, public websites, the office of the judge advocate general or other legal office, customer service, written correspondence received by the command, or any source other than information protected by section 1102 of Reference (h). Common referral issues include:

(1) Uncertainty about handling disclosure and patient communication.

(2) Unanticipated outcomes of care.

(3) Delayed diagnosis.

(4) Medical or medication errors.

(5) SEs, wrong site, or wrong patient procedures.

(6) Elevation of care caused by hospital or hospital acquired infections.

(7) Expected or unexpected deaths.

(8) Patient dissatisfaction with treatment outcomes or quality of care.

(9) Poor patient-provider interaction or communication.

(10) Appropriate patient disengagement without abandoning patient care.

(11) Follow up with patients who leave against medical advice.

(12) Adverse events to include near misses.

(13) Congressional inquiries involving quality of patient healthcare issues.

7. DoD RISK MANAGEMENT COMMITTEE

a. The DoD Risk Management Committee will be the primary oversight body of OASD(HA) and TMA for monitoring risk management processes and reporting of malpractice and adverse privileging actions to the NPDB.

b. The Committee includes representatives from HA, TMA, the Center for Legal Medicine, and each Service SG.

c. The Committee reports to the MHS CQF and to senior leadership via the CPSC and as directed by the ASD(HA). Risk management issues may be brought before other leadership forums as directed by the TMA CMO. Recommendations brought from other forums to the clinical quality management division at TMA will be reviewed by the DoD Risk Management Committee for operational impact, with subsequent recommendations made to the TMA CMO.

APPENDIX TO ENCLOSURE 5

PCE CLASSIFICATION

When an adverse event resulted in harm to the patient and presents a possible financial loss to the Federal Government (a malpractice claim or death or disability payment), it must be identified as a PCE and documented in the DoD PCE module of CCQAS. PCE documentation in the CCQAS must include the harm scale category (e.g., death, severe permanent harm, and permanent harm) defined in the Glossary, a description of the event type (e.g., accident, blood or blood products, healthcare associated infection), and the PCE Classification category identified in paragraphs a through o of this appendix.

a. Accident

b. Behavior

c. Blood or Blood Products

d. Clinical Process or Procedure

e. Fall

f. Healthcare Associated Infection

g. Lab Nonconformance

h. Maternity Care

i. Medical Device or Equipment/Product

j. Medication, IV Fluid, or Biologic (Includes Vaccine)

k. Neonatal Care

l. Nutrition

m. Oxygen, Gas, or Vapor

n. Resources or Organizational Management

o. Vascular Access Lines

ENCLOSURE 6

PATIENT'S RIGHT TO BE HEARD

1. GENERAL. This enclosure describes a patient's right to be heard in any QA program review of care provided by an MTF.

2. PATIENT'S OPPORTUNITY. Any patient, including any Service member, who believes he or she suffered a personal injury due to a perceived failure of an MTF to provide quality medical care must have the right to submit his or her concerns as part of a QA review of the care provided.

3. PROCEDURES

a. The MTF Commander or designee will ensure that the patient has notice of this opportunity and must advise the patient whether the opportunity must be through personal presentation or written presentation.

b. The opportunity provided in accordance with this enclosure may be provided in association with the healthcare resolutions program described in Enclosure 5 of this manual. However, the opportunity must be provided without regard to whether the healthcare resolutions program is involved and without regard to whether the patient has filed a claim for compensation or retained legal counsel.

c. A patient is entitled to the assistance of legal counsel of the patient's choosing not at government expense.

d. In the case of a patient's death or incapacitation, or if the patient is a child, the opportunity to submit concerns must be available to the next of kin or other close family member.

e. In any case in which a patient (or legal representative) submits concerns in accordance with this enclosure, those concerns must be considered as part of a QA review of the care provided. However, the results of any QA review are protected in accordance with section 1102 of Reference (h) and may not be disclosed to the patient or the patient's representative.

ENCLOSURE 7

CLINICAL ADVERSE ACTIONS

1. GENERAL. This enclosure describes the process and management of clinical adverse actions for privileged and non-privileged healthcare providers. All documents generated for the clinical adverse action process of peer review are protected in accordance with section 1102 of Reference (h). The documents must not be released without proper authority. Specifically, the purpose of clinical adverse actions is to protect patient safety, preserve the quality of healthcare, protect the integrity of the MHS, protect the rights of the involved healthcare provider, insure timely resolution of the issues, and insure timely reporting to regulatory entities when required.

2. MANAGING CLINICAL ADVERSE ACTIONS FOR INDIVIDUAL PRIVILEGED PROVIDERS

a. Upon discovery or notification to MTF leadership that a clinical adverse action may be indicated and continuing throughout the adverse action process, MTF leadership will consult with local legal authorities as appropriate and follow applicable personnel procedures so that due process proceedings, adequate notice, and fair hearing procedures are afforded to the involved provider.

b. When invoking an adverse action, the respective Service may place a healthcare provider into a period of abeyance for up to 30 calendar days while a QA investigation is conducted or the MTF Commander is reviewing the matter to decide whether or not to proceed with a clinical adverse action. The provider is notified in writing of the abeyance, the reason for abeyance, and the term of the abeyance (in calendar days). If the inquiry is not complete or the MTF Commander does not have adequate information to make a disposition on the provider's clinical practice within the 30 calendar-day abeyance, the abeyance will automatically become a summary suspension. A summary suspension is valid for 6 months. If an extension is required after 6 months, the MTF Commander must request Service-level approval to extend the summary suspension at 6 month intervals.

(1) An abeyance is not a reportable action, nor is it considered an adverse action the provider must self-report or disclose.

(2) The MTF Commander must withdraw any permission for the provider to engage in clinically-related outside employment from the initiation of an abeyance or summary suspension until all due process procedures are completed.

(3) The MTF credentials committee (CC) must inform (in writing) providers who separate from or end affiliation with the DoD while under an abeyance or an adverse action. The MTF CC must inform the provider of the implications of the provider's actions and their right to request that due process procedures be continued following their end of employment with the DoD. If the provider chooses to have the due process continued, he or she must send written

request to the office having responsibility for the case within 5 calendar days following his or her knowledge of the change in affiliation status.

c. An investigating officer must be an impartial peer of the provider under investigation (i.e., with similar education, training, clinical specialty and experience, but who has no personal or professional conflict of interest related to the investigation).

d. The MTF CC will convene and review the QA investigation findings and make an action recommendation to the MTF Commander. The MTF CC will be comprised of at least one member of the same clinical profession as the provider under review. The MTF CC participants must be fair and impartial. The provider under review does not have the right to attend this meeting; however he or she may provide written comments if desired. The MTF CC recommendations will be forwarded to the MTF Commander within 10 calendar days of committee review completion and may include:

(1) Reinstatement. The return of all regular clinical privileges.

(2) Monitoring and Evaluation (M&E). The documented plan of M&E must include clear expectations and measures of success that will be routinely reviewed throughout the period of M&E. This is neither an adverse action nor reportable to regulatory entities.

(3) Convening a Peer Review Panel. This action considers a potential clinical adverse action relating to the provider.

e. If the provider is a federal civilian employee, the MTF will keep the Civilian Personnel Office informed throughout the process. If the provider is a member of a contract group, the MTF Commander will keep the contracting officer informed throughout the process.

f. The MTF Commander has 10 calendar days from receipt of the MTF CC recommendations to make a determination on what action to take. The MTF Commander will forward his or her proposed action decision to a peer review panel for review, if the action is adverse in nature (i.e., restriction, reduction, revocation, or denial). The MTF Commander may reinstate the provider with an option to use a period of M&E.

g. The MTF Commander may place the provider in summary suspension while the due process continues. The provider is given written notice of the summary suspension. If the MTF Commander is forwarding a proposed adverse action to the peer review panel for review, the provider will receive written notification of the proposed action and be provided a copy of documentation that will be reviewed by the peer review panel. Summary suspension of privileges is not reportable to the NPDB unless the resultant action is reportable (e.g., the provider ends employment with DoD while in summary suspension and waives further due process rights). The final action is the suspension of privileges and this action is reported to the NPDB.

h. The peer review panel will be comprised of at least three clinical peers of the involved provider (similar clinical specialty, education, and training). If the MTF does not have three

peers available to conduct this review, it may be accomplished using peers from other MTFs, either in person or via video or teleconferencing. The provider may provide written comments to the peer review panel, but does not have the right to attend this meeting. The peer review panel should convene within 14 calendar days after receipt of the MTF Commander's determination, the QA investigation, and relevant evidence to make and forward a recommendation to the MTF CC. The recommendations may include:

(1) Reinstatement of privileges, which is the return of all, regular clinical privileges.

(2) Reinstatement of privileges with M&E, which is a well-defined, time-limited, well-documented plan of intensified peer review to confirm that a provider possesses the skill, knowledge, and ability to render safe and effective healthcare. The documented plan of M&E must include clear expectations and measures of success that will be routinely reviewed throughout the period of M&E. This is neither an adverse action nor reportable to regulatory entities.

(3) Restriction of privileges, which is a temporary or permanent limit placed on all or a portion of the provider's clinical privileges, so that the provider is required to obtain concurrence before providing all or some healthcare procedures within the scope of his or her certification, license, or registration. The restriction requires some form of supervision. Restriction of privileges is reportable to the NPDB. Restricted privileges will be recorded on the provider's privilege form(s).

(4) Reduction in privileges, which is the permanent removal of a portion of a provider's clinical privileges. Reduction of privileges is reportable to the NPDB.

(5) Revocation of privileges, which is the permanent removal of all of the provider's clinical privileges and the removal of the provider from all patient care duties. Revocation of privileges is reportable to the NPDB.

(6) Denial of privileges, which is the refusal to grant provider-requested clinical privileges. This may occur at initial application for privileges or when renewal of privileges is requested. Denial of privileges is reportable to the NPDB.

(7) Suspension of privileges, which is the temporary removal of all or part of a provider's privileges or the removal of the provider from all patient care duties. Suspension of privileges is reportable to the NPDB.

i. The MTF CC will reconvene within 10 calendar days to review the peer review panel findings and recommendations, and forward their final recommendation to the MTF Commander.

j. The MTF Commander will give written notification within 10 calendar days of receipt of the MTF CC final recommendation to the provider of his or her preliminary decision and the basis (allegations) for the action. If the preliminary action is to suspend, restrict, reduce, revoke, or deny the provider's privileges; then the MTF Commander must advise the provider in writing

of his or her right to a hearing and appeal rights. The provider must have access to all information considered by the MTF CC and the MTF Commander that resulted in the basis of the preliminary action.

k. The provider may request a hearing. The provider will be allowed not less than 10 and not more than 30 calendar days after receipt of the adverse action notification letter to request a hearing. The commander may extend this time period if appropriate. If the provider waives his or her right to a hearing, the right to appeal is also waived.

(1) If no written hearing request is received within the allotted time, the hearing and appeal rights are waived and the results are reported for final action. The MTF Commander will forward his or her decision through his or her respective Command to the Service level for final action by the Service SG. If the member is of a Service other than the Service of the MTF, the MTF Commander will notify the member's Service Office of the SG of the MTF Commander's final actions. The notification will include a copy of the case file. The adverse action process follows Service chain of command of the MTF. The Service SG responsible for the MTF taking the adverse action will make the final determination and direct reporting to the NPDB and other regulatory agencies, even if the provider is of a different Service.

(2) If the provider requested a hearing but fails to appear for the scheduled hearing, the MTF Commander may choose to proceed with the hearing or act on the provider's privileges as intended in the written notice of the preliminary decision.

l. The provider must receive a hearing notification. If the provider requests a hearing, the MTF Commander will give the provider written notification of the hearing proceedings within 10 calendar days of the provider's request. Written notice must include:

(1) The date, time, and location of the hearing, which must be no sooner than 30 calendar days from the date of the notification, but scheduled within 60 calendar days.

(2) A statement of the provider's right to be represented by counsel at their expense or to have another representative present. The legal or other representative may actively participate in the hearing, address the hearing committee, and question witnesses.

(3) A statement of the provider's right to be present, to present evidence, to call witnesses, and cross-examine witnesses.

(4) The names of the MTF's witnesses to be called to testify at the hearing. The provider will disclose the names and contact information for all witnesses testifying on his or her behalf no later than 15 calendar days before the scheduled hearing.

m. The provider may request in writing, a delay of the hearing for good reason. However, if the scheduled hearing is within 5 calendar days, no postponement will be granted by the MTF Commander unless there are extenuating circumstances.

n. There are specific requirements regarding the composition of the hearing committee. The hearing will be fair and impartial and will include a minimum of three privileged providers. At least one of the members will be a peer of the provider under review. To facilitate a fair hearing, members of the peer review panel and the QA investigator will not be a member of the hearing committee.

o. The MTF staff will arrange for a verbatim recording of the hearing proceedings. The hearing record will be given to the provider within 30 calendar days of hearing completion.

p. The hearing committee will provide a report of their findings on each allegation and their recommendation(s) for action to the MTF Commander. This report will be given to the provider within 30 calendar days of hearing completion.

q. After the provider has received the hearing record, including the hearing committee's findings and recommendations, he or she has 10 calendar days to submit a written statement of exceptions and corrections to the MTF Commander.

r. The MTF Commander will make a final decision within 10 calendar days of receipt of all hearing committee's findings and recommendation(s), and the provider's statement of exceptions and corrections. Although not bound by the hearing committee recommendation(s), the MTF Commander must provide rationale for taking a different action. The MTF Commander will provide written notification to the provider of the final decision, which will include:

(1) Final action and basis for such action. If the action is denial, restriction, reduction, suspension, or revocation, then the MTF Commander will provide a notification that the action is reportable to the NPDB and other regulatory agencies.

(2) A statement of the provider's right to appeal to the SG of the Service of the MTF.

s. Each provider has the right to appeal and may make a written appeal of the MTF Commander's final decision to the SG of the MTF's Service. The provider will submit a request for reconsideration within 10 calendar days to the MTF Commander. The commander will consider the request. If the MTF Commander does not grant the request for reconsideration, it will be forwarded as an appeal through the Command to the Service SG. The provider may request an extension for his or her written appeal for good cause. Extension is granted by the MTF Commander.

t. The Service SG's staff will coordinate the appeal process to include:

(1) Clinical peer review.

(2) Legal review of the due process procedures.

(3) Formal appeal committee process to review the clinical peer review, legal review, and make recommendation(s) to the Service SG. If the provider is a member of a different

Service, inclusion of a privileged provider from the member's Service on the appeal committee should be considered.

u. If the provider is a member of a different Service, a copy of all adverse action documents will be sent to the member's SG office for review and comment prior to the SG final action and report. The Service SG of the provider must review and provide comments within 30 calendar days. The Service member's SG will also be given an opportunity to append any NPDB report submitted by the reporting SG's office.

v. The SG will make the final decision in the case. The SG may make an alternate decision and will provide written rationale for the alternate decision. The SG will direct reporting to the NPDB and other regulatory agencies as necessary. The NPDB report will be submitted within 30 calendar days of the SG's final decision.

w. The provider will be given written notice of the SG's final decision.

x. When a provider is a member of a different Service from the one who took the clinical adverse action, the provider's Service SG's office will be notified of the final decision.

y. Adverse action documentation and record keeping must be maintained by the Service designated office. The DD Form 2499, "Health Care Provider Action Report" and official notification letters will be maintained in the provider's credentials file. After the clinical adverse action is complete, the Service will maintain an adverse action file in the CCQAS, with all mandatory data fields complete.

3. MANAGING CLINICAL ADVERSE ACTIONS FOR NON-PRIVILEGED PROVIDERS

a. Upon the discovery, or the notification to MTF leadership, that a clinical adverse action may be indicated, MTF leadership will consult with local legal authorities and follow applicable personnel system requirements so that due process proceedings, adequate notice, and fair hearing procedures are afforded to the involved provider.

b. Non-privileged providers who are licensed, certified, or registered by a State; the District of Columbia; or a commonwealth, territory, or possession of the United States are subject to this clinical adverse actions process. Reports of adverse actions for these providers will be to State licensing agencies and other agencies appropriate to the specialty of the provider. These actions are known as adverse practice actions.

c. A healthcare provider may be removed from patient care duties while a professional QA investigation is being conducted or while the MTF Commander is reviewing the matter to determine whether or not to proceed with a clinical adverse practice action. The non-privileged provider will be notified, in writing, that he or she has been removed from clinical practice and the reason for the removal. The MTF Commander must withdraw any permission for the provider to engage in clinically-related outside employment from initiation of the removal from patient care duties until all due process procedures are completed.

d. The QA investigation is initiated by the MTF Commander or as designated by the MTF Commander when needed to investigate any allegations of clinical incompetence, professional misconduct, or impairment. An investigating officer is appointed in writing and should be a peer of the provider (i.e., having similar clinical specialty, education, and training) under investigation. The purpose and scope of the QA investigation will be explicit in the written appointment. The investigating officer will submit a written report to the MTF CC for review.

e. The MTF CC will convene and review the QA investigation findings and make an action recommendation to the MTF Commander. The MTF CC will be comprised of at least one member of the same clinical profession as the provider under review. The MTF CC participants must be fair and impartial. The provider under review does not have the right to attend this meeting; however, he or she may provide written comments if desired. MTF CC recommendations will be forwarded to the MTF Commander within 10 calendar days of committee review completion and may include:

(1) Reinstatement of Clinical Practice. Return to clinical duties.

(2) Reinstatement of Clinical Practice with M&E. M&E is a well-defined, time-limited, well documented plan of intensified peer review to confirm a provider possesses the skill, knowledge, and ability to render safe and effective healthcare. The documented plan of M&E must include clear expectations and measures of success that will be routinely reviewed throughout the period of M&E. This is neither an adverse action nor reportable to regulatory entities.

(3) Convene a Peer Review Panel. This action would consider a potential clinical adverse action relating to the provider.

f. Federal civilian and contract providers may also be under review. If the provider is a federal civilian employee, the MTF will keep the civilian personnel office informed throughout the process. If the provider is a member of a contract group, the MTF will keep the contracting officer informed throughout the process.

g. The MTF Commander has 10 calendar days from receipt of the MTF CC recommendations to make a determination on what action to take. The MTF Commander will forward his or her proposed action decision to a peer review panel for review, if the action is adverse in nature (e.g., restriction, reduction, revocation, or denial). The MTF Commander may reinstate the provider with an option to use a period of M&E.

h. The peer review panel will be comprised of at least three clinical peers of the involved provider (i.e., similar clinical specialty, education, and training). If the MTF does not have three peers available to conduct this review, it may be accomplished using peers from other MTFs; either in person or via video or teleconferencing. The provider will receive written notification of the date of the peer review panel and be provided a copy of documentation that will be reviewed by the panel. The provider may provide written comments to the peer review panel, but does not have the right to attend this meeting. The peer review panel should convene within

14 calendar days after receipt of the MTF Commander's determination, the QA investigation, and relevant evidence to make and forward a recommendation to the MTF CC. The recommendations may include, in addition to those described in paragraph 4e of this enclosure:

(1) Restriction of clinical practice, which is a temporary or permanent limit placed on all or a portion of the provider's clinical practice, so that the provider is required to obtain concurrence before providing all or some clinical duties within the scope of his or her certification, license, or registration. The restriction requires some form of supervision. Restriction of practice is reportable to the appropriate regulatory agencies. Restricted practice will be recorded in the provider's competency assessment folder.

(2) Reduction of clinical practice, which is the permanent removal of a portion of a provider's clinical practice. Reduction of practice is reportable to the appropriate regulatory agencies.

(3) Removal of clinical practice, which is the permanent removal of all of the provider's clinical practice and removal of the provider from all patient care duties. Revocation of clinical practice is reportable to the appropriate regulatory agencies.

(4) Suspension of clinical practice, which is the temporary removal of all the provider's clinical practice and removal of the provider from all patient care duties. Suspension of clinical practice is reportable to the appropriate regulatory agencies.

i. The MTF CC will reconvene within 10 calendar days to review the peer review panel's findings and recommendations and then forward their final recommendation to the MTF Commander.

j. The MTF Commander has 10 calendar days from receipt of the MTF CC recommendations to make a determination on what action to take. The MTF Commander may reinstate the provider with an option to use a period of M&E.

k. The MTF Commander will give written notification within 10 calendar days of receipt of MTF CC final recommendation to the provider of his or her preliminary decision and the basis (or allegations) for the action. If the preliminary action is to suspend, restrict, reduce, or remove the provider's practice, the MTF Commander must advise the provider in writing of his or her right to a hearing and appeal rights. The provider must have access to all information considered by the MTF CC and the MTF Commander that resulted in the basis of the preliminary action.

l. The provider will be allowed not less than 10 and not more than 30 calendar days after receipt of the adverse action notification letter to request a hearing. The Commander may extend this time period if appropriate. If the provider waives his or her right to a hearing, the right to appeal is also waived.

(1) If no written hearing request is received within the allotted time, the hearing and appeal rights are waived. The MTF Commander will forward his or her decision through Command to Service level for final action by the Service SG. The adverse action process

follows Service chain of command responsible for the MTF. The SG responsible for the MTF taking the adverse action will make the final determination and direct reporting to state licensing boards and other regulatory agencies. The SG responsible for the MTF takes this action even if the provider is of a different Service.

(2) If the provider requested a hearing but fails to appear for the scheduled hearing, the MTF Commander may choose to proceed with the hearing or act on the provider's practice as intended in the written notice of the preliminary decision.

m. If the provider requests a hearing, the MTF Commander or designee will give the provider written notification of the hearing proceedings within 10 calendar days of the provider's request. Written notice will include items listed in paragraph 4k of this enclosure.

n. The hearing will be fair and impartial and will include a minimum of three providers. At least one of the members will be a peer of the provider under review. To facilitate a fair hearing, members of the peer review panel and the QA Investigator will not be a member of the hearing committee.

o. The MTF staff will arrange for a recording of the hearing proceedings. The hearing record will be given to the provider within 30 calendar days of hearing completion.

p. The hearing committee will provide a report of their findings on each allegation and their recommendation(s) for action to the MTF Commander. This report will be given to the provider within 30 calendar days of the hearing completion.

q. After the provider has received the hearing record, including the hearing committee's findings and recommendations, he or she has 10 calendar days to submit a written statement of exceptions and corrections to the MTF Commander.

r. The MTF Commander will make a final decision within 10 calendar days after receipt of all hearing documents and the provider's statement of exceptions and corrections. The MTF Commander is not bound by the hearing committee recommendation, but must provide rationale for taking a different action. The MTF Commander will provide written notification to the provider of the final decision, which will include:

(1) Final action and the basis for such action. If the action is restriction, reduction, or removal, then the written notification will include a statement notifying the provider that the action is reportable to all appropriate regulatory agencies.

(2) A notification of the provider's right to appeal to the SG of the Service of the MTF.

s. Each provider has the right to appeal. The provider may make a written appeal of the MTF Commander's final decision to the respective MTF's Service SG. The provider will submit a request for reconsideration within 10 calendar days to the MTF Commander. The MTF Commander will consider the request. If the MTF Commander does not grant the request for reconsideration, it will be forwarded as an appeal through the command to the Service SG. The

provider may request an extension for his or her written appeal for good cause. Extension is granted by the MTF Commander.

t. The SG's staff will coordinate the appeal process to include:

(1) Clinical peer review.

(2) Legal review of the due process procedures.

(3) A formal appeal committee process to review the clinical peer review and legal review, and make recommendation(s) to the Service SG. If the provider is a member of a different Service, inclusion of a peer provider from the member's Service on the appeal committee should be considered.

u. If the provider is a member of a different Service, a copy of all adverse action documents will be sent to the member's SG office for review and comment prior to the SG final action and report. The Service SG of the provider must review and provide comments within 30 calendar days. The Service member's SG will also be given an opportunity to append any regulatory agency report submitted by the reporting SG's office.

v. The SG will make the final decision in the case. The SG may make an alternate decision and will provide written rationale for the alternate decision. The SG will direct reporting to the appropriate regulatory agencies. The reports will be submitted within 30 calendar days of the SG's final decision.

w. The provider will be given written notice of the SG's final decision.

x. When a provider is a member of a different Service from the one who took the clinical adverse action, the provider's Service SG's office will be notified of the final decision.

y. Adverse action documentation and record keeping is maintained. All documentation created for the clinical adverse action will be maintained by the Service designated office. The provider's DD Form 2499 and official notification letters will be maintained in the provider's competency assessment folder. After the clinical adverse action is complete, the Service will maintain an adverse action file in CCQAS, with all mandatory data fields complete.

4. MANAGING IMPAIRED PROVIDERS

a. The identification and management of an impaired provider must facilitate the rehabilitation, rather than discipline, of the provider by offering assistance to retain and regain optimal professional functioning that is consistent with the delivery of quality healthcare.

b. Not with-standing the emphasis on rehabilitation in paragraph 4a of this enclosure, the Service SGs may initiate clinical adverse actions in cases where a provider does not self-refer,

fails to complete a rehabilitation program, or relapses after treatment. Any final adverse action must be reported to the NPDB, licensing boards, or other regulatory agency as appropriate.

ENCLOSURE 8

PSP

1. GENERAL

a. The DoD PSP seeks to promote a culture of safety to eliminate preventable patient harm by engaging, educating, and equipping patient-care teams to institutionalize evidences-based safe practices. Mandated according to section 754 of Public Law 106-398 (Reference (af)), the DoD PSP is a comprehensive program that provides products, services, and educational and training resources to help ensure the safe delivery of healthcare to patients. The guiding principles of the PSP include encouraging a standardized systems approach across the DoD to create a safer patient environment; promoting innovation and creativity while engaging leadership; fostering a culture of trust and transparency through communication, coordination and teamwork; and embracing of national initiatives deemed beneficial to the MHS.

b. The DoD PSP will be implemented in every MTF as a dedicated program for reducing harm due to medical errors and improving patient safety that is focused on prevention and on improving medical systems and processes to mitigate preventable errors. With a focus on prevention, the DoD PSP supports the clinical performance measurement program and the adverse event program. The administration of the MTF PSP must be through an MTF Patient Safety Office or Quality Management Program. The MTF PSP, with its emphasis on process and system design, must be an integral part of the risk reduction and performance improvement efforts of the MTF and must function as an integral part of the quality oversight of the MTF. The MTF PSM, designated by the MTF Commander and properly trained, is an integral part of the Executive Administrative team. Where resources permit, the MTF PSM and RM should not be the same person.

c. The DoD PSP is established under the Patient Safety Division within the TMA, Office of the Chief Medical Officer (OCMO).

d. The DoD PSP manages its operations through the Patient Safety Planning and Coordination Committee (PSPCC). The PSPCC is chaired by the Director, DoD PSP, and includes representatives from HA, the Military Departments, and the DoD PSP functional areas. The purpose of the PSPCC is to develop, promote, and support a comprehensively aligned PSP appropriate for the MHS mission(s).

e. The DoD PSP reports patient safety issues requiring senior leadership decisions to the MHS CQF and CPSC. The CPSC may recommend or direct patient safety policies and actions for implementation across the MHS. Patient safety issues may be brought before other leadership forums as directed by the TMA CMO. Recommendations brought from other forums to the DoD PSP will be reviewed by the PSPCC for operational impact and recommendations made to the MHS CQF and the TMA CMO.

f. The DoD PSP data are used exclusively for improving healthcare systems and processes that impact safe quality patient care. MQAPR data produced by the DoD PSP are handled in accordance with section 1102 of Reference (h).

2. PROGRAM OPERATIONS

a. The Patient Safety Analysis Center will:

(1) Collect, maintain, analyze, conduct research, and submit reports on patient safety data submitted from DoD MTFs.

(2) In conjunction with other federal agencies (e.g. VA), develop action plans and other tools designed to reduce harm due to medical errors and to enhance patient safety.

(3) Monitor patient safety activities of State governments, and NGOs and include in quarterly reports, as needed.

(4) Provide reports to various TMA quality activities (e.g., DoD Risk Management Committee, MHS CQF) and to the PSPCC for review and action as needed.

(5) Provide alerts, advisories, focused reviews, and other reports and publications.

(6) Work collaboratively with the VA to share and analyze data, alerts, and advisories, and develop action plans and other tools designed to reduce harm due to medical errors and enhance patient safety.

(7) Focus on the management and analysis of the data made available to the Patient Safety Analysis Center and report the data to the Service PSMs and the DoD PSP.

b. Education and Training: the Patient Safety Solutions Center will:

(1) Create unique programs of instruction to address the initial and ongoing learning needs of the MTF PSM.

(2) Promote usage of the Patient Safety Learning Center (PSLC), a secure online knowledge collaboration portal for DoD Patient Safety personnel. The PSLC facilitates the dissemination and active exchange of resources in support of the patient safety community.

(3) Establish Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™), an evidenced-based teamwork system, as the MHS platform for training, implementation, skill building, and sustainment of teamwork initiatives.

3. REPORTS AND INTERVENTION TECHNIQUES FOR MONITORING PROBLEM-PRONE AREAS

a. Patient Safety Reports

(1) Patient Safety Reports will be submitted to the Patient Safety Analysis Center. The data, information, and format will be in accordance with DoD PSP guidance.

(2) In order to facilitate timely and accurate reports and analysis, information submitted to the Patient Safety Analysis Center will include identification of the reporting MTF. All personal patient and individual provider information will be redacted before being sent to the Patient Safety Analysis Center.

b. PSR

(1) The DoD PSP has implemented the PSR, a standardized, automated reporting system which allows all users across each MTF the ability to report, aggregate, and analyze adverse events.

(2) All adverse events, near misses, or unsafe conditions must be reported to the PSR. Reporting into local MTF patient safety event or incidents reporting legacy systems must be discontinued.

c. Proactive Risk Assessment (PRA)

(1) Requirement to Complete a PRA. PRA is a process for the analysis and improvement of any at-risk system process. All MTFs will complete a PRA on a high-risk process in accordance with requirements established by their accrediting organization and individual Service guidance. PRAs may be conducted at any time and are appropriate for all processes. Medical facilities accredited by accrediting organizations other than TJC may be exempt from a PRA requirement, as determined by Service policy.

(2) PRA Submission

(a) All facilities must submit each PRA to the respective Service headquarters staff within 30 days of completion. The Service headquarters staff must forward all completed PRAs to the Patient Safety Analysis Center within 45 calendar days of receipt from the MTF. The reporting MTF will be fully identified and included on the PRA. Any requests for additional or clarifying information required from the MTF by the Patient Safety Analysis Center will be coordinated through the Service headquarters staff.

(b) PRA materials produced by MQAPR activities are not intended for public release and must be maintained as confidential MQAPR records.

d. RCA

(1) An RCA is used to identify the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of an SE. An RCA focuses on systems and processes, not individual performance.

(2) Patient Safety RCA data are used internally to DoD for improving healthcare systems and processes that impact quality and patient safety. At all levels of the DoD, information obtained through a Patient Safety RCA, to the greatest extent possible, will not be used in 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.

(3) An RCA must be completed by the MTF on all SEs, including TJC reviewable SEs, within 45 calendar days of the MTF becoming aware (i.e., discovery) of the SE. MTFs not accredited by TJC will complete RCAs on all SEs, including reviewable SEs, within 45 calendar days of the MTF becoming aware of the SE. Extensions for reviewable RCA completion by MTFs not accredited by TJC may be granted by the Service Headquarters PSP but will not ordinarily exceed 90 calendar days. RCAs conducted on non-reviewable SEs or other less serious events should be completed as soon as practicable or as dictated by the respective Service SG.

(4) RCA Submission

(a) Electronic or hard copies of RCAs from SEs should reach the Patient Safety Analysis Center not later than 45 days after discovery of the event. The data provided must not contain any identifying information related to the patient(s) or the individual healthcare provider(s). The reporting MTF identification will be included on the RCA. These copies must be maintained as confidential MQA records.

(b) Copies of additional updates or changes to the RCA (such as those required by TJC, intermediary or Service headquarters) will be forwarded through the Service headquarters staff to the Patient Safety Analysis Center within 30 days of completion. Any requests for additional or clarifying information required from the MTF by the Patient Safety Analysis Center will be coordinated through the Service headquarters staff.

e. Notification

(1) The DoD adopts TJC's list of reviewable SEs. MTFs not accredited by TJC must refer to TJC's list for information on reviewable SEs for urgent reporting to Service headquarters and the Patient Safety Analysis Center.

(2) All adverse events, including near misses and unsafe conditions will be reported within the PSR. Services will notify the TMA OCMO within 24 hours of the facility learning of a TJC reviewable SE or other SE involving serious harm to a patient. The Service headquarters staff will report such SEs occurring in accredited and non-accredited MTFs. Reports will be sent by e-mail. The report will include the event type or category, MTF identification, date of event discovery, brief summary of the event, date the RCA was chartered, the Service point of contact

and any unique identifiers or codes for the report. Since SEs that include harm to a patient would also meet the threshold for a PCE, these events also require manual entry into CCQAS, including identification as a SE and must include the harm scale category and type of event, using the taxonomy established in the appendix of this enclosure.

f. Intentional Unsafe Acts

(1) The investigation and consideration of corrective actions on intentional unsafe acts are not within the primary authority or responsibility of the DoD PSP. If in the course of the activities of the PSP information about intentional unsafe acts is revealed, the original report must be referred to applicable command authorities for criminal investigation and action as appropriate. Primary authority to investigate and consider corrective actions on the matter must be outside the DoD PSP.

(2) Some events meet the definitions of both "adverse events" and "intentional unsafe acts." When an event appears to be both an "adverse event" and an "intentional unsafe act," primary authority and responsibility is outside the DoD PSP. The DoD PSP must proceed with a review, including an RCA, if applicable, of the systems and processes of the MTF implicated in the actual or potential intentional unsafe act, but will defer to the separate investigation and consideration on any matter of responsibility of any person involved in the act.

ENCLOSURE 9

NPDB AND HIPDB

1. PURPOSE

a. The DHHS operates an alert system to facilitate a comprehensive review of healthcare providers' professional credentials. This system includes a data bank of medical malpractice payments, adverse licensure actions, adverse clinical privilege actions, adverse professional membership actions, and Medicare or Medicaid exclusion reports. This data bank, the NPDB, is governed by the regulations of DHHS in accordance with part 60 of Reference (l).

b. The HIPDB is governed by the regulations of DHHS in accordance with part 60 of Reference (l). The DoD and the civilian provider community involved in TRICARE are required by the statute to report to the HIPDB a broad range of adverse practice actions or adverse privileging actions.

2. REPORTING TO THE NPDB INFORMATION ON PAID MALPRACTICE CLAIMS AND COMPARABLE ACTIVE DUTY DEATH OR DISABILITY PAYMENT CASES

a. Malpractice Reports to the NPDB. Reports to the NPDB will be in the name of a healthcare provider each time a malpractice payment is made for the benefit of such provider. A payment will be considered to be made for the benefit of any provider significantly involved in the healthcare that was the basis for the malpractice payment unless, within 180 calendar days after the SG concerned receives notice of such payment, the SG has made a final determination that the malpractice payment was not caused by the failure of the provider to meet the SOC. The SG determination is non-delegable. If a determination has not been made within the 180-day time period, a report must immediately be made to the NPDB. The 180-day period will begin on the day the Military Department concerned first receives a report, through the Center for Legal Medicine, that the Department of the Treasury has notified the DoD of a paid claim.

b. Comparable Reports to the NPDB in Cases Involving Active Duty Members. Reports to the NPDB must also include instances in which a provider's failure to meet the SOC caused or contributed to the death or disability of a member of the uniformed services in accordance with DoDI 1332.18 (Reference (ag)).

(1) In every case in which a medical evaluation board (MEB) makes a referral to a physical evaluation board (PEB), the MEB approving official must identify and report to the MTF RM 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 MTF RM must, in consultation with the PEB liaison officer, monitor PEB disability decisions, and must 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 will be the subject of an SOC review and a report to the NPDB unless, within 180 calendar 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 provider to meet the SOC. The 180 calendar day period will begin on the day the RM receives confirmation of permanent disability awarded by the PEB.

c. Reports to the NPDB. Reports to the NPDB must include a report in the name of a healthcare provider each time a malpractice or comparable compensation payment is made for the benefit of such provider, as determined in accordance with Reference (c) and this section.

d. SOC Determinations. If a malpractice claim is paid, or a death or disability payment related to healthcare is awarded, the respective SG responsible for the MTF where the event occurred will ensure a thorough and unbiased review of the facts of the case to determine the SOC for the significantly involved healthcare provider(s). The process for the final determination is described in paragraphs 2d(1) through 2d(6) of this enclosure.

(1) The SG makes a preliminary determination whether the payment or award was or was not caused by the failure of one or more providers to meet the recognized SOC. The preliminary determination is based on the results of the professional peer review, all available information of a legal nature concerning the claim or award, and information and comments submitted by the involved providers. The preliminary determination is not an adverse action with respect to any provider and no due process procedures apply.

(2) If the SG's preliminary decision is that the significantly involved provider(s) met the recognized SOC, the case file, including all relevant information, must be forwarded to the medical peer review agency external to DoD as designated by the ASD(HA). This includes cases in which the SOC was decided to have not met recognized SOC but it was determined that the reason was due to causes not directly related to the significantly involved provider(s). The Service responsible for the MTF where the event occurred must request an external peer review for all significantly involved providers regardless of the civilian or military status or the branch of the Service of the significantly involved providers. The external medical peer review will render an SOC determination for each significantly involved provider and address the issue of causation. A copy of the external peer review report, the reviewer's curriculum vitae, and other pertinent information must be forwarded to the Center for Legal Medicine. The external peer review report is considered an MQA document in accordance with section 1102 of Reference (h); a copy of it must not be provided to the provider(s) whose care was reviewed.

(3) Based on the preliminary SOC determination, the external medical reviewer's opinion, and the facts of the case, the SG must render a final SOC determination. The SG responsible for the MTF where the event occurred will make the final determination for all significantly involved providers, regardless of their Service affiliation(s). If the SG determines that a provider in another Service will be reported to the NPDB, the member's SG office will be sent the case documents for review and comments prior to the submission of a report to the NPDB. The member's SG office must return the review and comments within 30 calendar days. The Service member's SG will also be given the opportunity to append comment to any regulatory agency report submitted by the reporting SG's office. If the Service SG of the MTF's

final determination is that the malpractice or death payment or disability award was not the result of a failure on the part of a provider to meet the SOC, no report is made to the NPDB.

(a) In any case in which there is a conflict between an external peer review opinion that the SOC was not met and the failure to meet the SOC caused the injury, and a final SG determination is that the SOC was met, the SG must promptly report, in memorandum, his or her determination to the DoD Risk Management Committee panel for review. The memorandum will explain the findings and the rationale for variance in the SOC determination. 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 the NPDB. This process applies to any case in which the external peer review SOC determination is that the SOC was not met, there were identified acts or omissions and injuries or illnesses, and the SG's determination was that the SOC was determined to have been met.

(b) Active duty death or disability payments that result from the failure of significantly involved provider(s) to meet the SOC are reportable to the NPDB. For the purposes of NPDB reporting, the dollar amount will be calculated by collecting the monthly disability for all relevant rated disabilities, multiplying the total by 12 to obtain the annual disability, multiplying the result by the percent disability associated with the medical harm, and multiplying that result by the annuity value calculated by the DoD Office of the Actuary. The total derived from this calculation equals disability annuity payment (comparable to claim payment and reported to NPDB). The annuity factors and life expectancies are published annually by the DoD Office of the Actuary and will be the reference for dollar amount determinations.

(c) As an alternative to the dollar amount calculation in paragraph 2d(3)(b) of this enclosure, in a case in which expected disability payments will be deferred because a member is retained on active duty, notwithstanding an unfit determination by a PEB, the NPDB report must be made with an amount determined by the SG concerned to be appropriate.

(4) When a significantly involved provider is a healthcare trainee, the attending provider responsible for the delivered care deemed to not have met the SOC (not the trainee) must be reported to the NPDB. If, however, the SG determines that the attending provider clearly met all reasonable standards of supervision and the trainee's act or omission was not reasonably foreseeable by the attending provider, the trainee (not the attending provider) must be reported to the NPDB.

(5) The SGs have no more than 180 calendar days from the date of notification of malpractice payment or death or disability payment to make a final SOC determination of the provider(s) significantly involved and to report to the NPDB, as appropriate, all significantly involved providers who have not been finally determined to have met the SOC. For malpractice payment cases, the 180-day period begins on the day the Military Department concerned first receives a report, through the Center for Legal Medicine, that the Department of the Treasury has notified the DoD of a paid claim. For active duty disability or death cases, the 180-day period begins on the day the SG (or official designated by the SG for this purpose) first receives a report that an expected disability or death payment involves a potential failure to meet the SOC. If no

final SOC decision has been made by the end of the 180-day period, all significantly involved providers in the case must be immediately reported to the NPDB. If a final SOC determination is made in the case and the finding is that the SOC was met, the SG must then submit an amendment to the report noting that the SG determined that the SOC was met; however, the report may not be withdrawn. The ASD(HA) has approval authority for any exceptions to the 180-day limit.

(6) The claim payment amount documented in the NPDB for each significantly involved provider will be the total amount of the claim divided by the number of significantly involved providers being reported.

e. Completion of NPDB Reporting Decision. Once the SG concerned has rendered a final decision whether or not the malpractice payment or death or disability award was caused by the failure of any significantly involved provider(s) to meet the SOC, the case can be closed. Upon closure of the malpractice case, the Service must update the CCQAS record and release it to the Center for Legal Medicine.

f. Notification of Result. When a report is made to the NPDB in accordance with this enclosure, a copy of the report must be provided to the healthcare provider in question unless, in spite of every reasonable effort on the part of the Service, he or she cannot be located. A copy of the NPDB report must also be forwarded to the State licensing board(s) or other certifying body of any reported providers. All reports must be documented in CCQAS.

g. Alternative Reporting Authority. The ASD(HA) may exercise any authority of the Secretary of a Military Department or an SG pursuant to this enclosure pertaining to reports to the NPDB to the extent the ASD(HA) determines necessary to implement this enclosure.

3. REPORTS TO THE NPDB OF ADVERSE ACTIONS. Clinical adverse actions taken consistent with the procedures in Enclosure 7 of this manual are reportable to the NPDB.

4. REPORTS TO THE HIPDB BY SGs OF THE MILITARY DEPARTMENTS

a. Reporting Responsibility. The SGs will be responsible for reports regarding reportable adverse actions taken against healthcare providers, suppliers, or providers providing healthcare services within the MHS.

b. Reportable Adverse Actions. The following adverse actions taken against healthcare providers, suppliers, or providers are reportable:

(1) Uniform Code of Military Justice (UCMJ) Actions. Convictions under chapter 47 of Reference (h), also known and referred to in this manual as "the UCMJ," as approved by the court martial convening authority, or final non-judicial punishment under the UCMJ, of a healthcare provider or supplier which the conduct involved was related to the delivery of a healthcare item or service.

(2) Other Adjudicated Actions or Decisions. The following actions are reportable if they are against a healthcare provider, supplier, or provider based on acts or omissions that affect the payment, provision, or delivery of a healthcare item or service:

(a) Adverse Personnel Actions Affecting Uniformed Services Members. Any administrative action resulting in separation, reduction in grade, involuntary military occupational specialty reclassification, or other administrative action.

(b) Adverse Civilian Personnel Actions. Any adverse personnel action as described in sections 7501 through 7543 of Reference (j).

(c) Contract Termination for Default. A contract termination for default taken by an MTF or medical command against a personal services or non-personal services contractor.

(3) Actions Not Included. Clinical privileging actions are excluded from the reporting requirement of this enclosure. Clinical privileging actions are reportable to the NPDB.

(4) Reports to the HIPDB. Reports to the HIPDB by the SG must also be entered into the CCQAS to be electronically monitored by the Center for Legal Medicine.

5. REPORTS TO THE HIPDB BY THE DIRECTOR, TMA

a. Reporting Responsibility. The Director, TMA, is responsible to report healthcare providers, suppliers, or providers excluded from participating in TRICARE.

b. Reportable Adverse Actions

(1) Exclusions. Exclusion of any healthcare provider or supplier from TRICARE in accordance with part 199.9 of Reference (x) and as displayed on the TMA Fraud and Abuse Website at http://www.tricare.mil/fraud/. The website provides a listing of TRICARE sanctioned providers.

(2) Actions Not Included. Actions taken by TRICARE contractors concerning the establishment and operation of preferred provider networks are not reportable by the Director, TMA. However, they may be reportable by the contractor to the HIPDB.

6. REPORTS TO THE HIPDB CONCERNING CONTRACT DEBARMENTS AND SUSPENSIONS

a. Reporting Responsibility. Designated debarring officials of the Military Departments and the Defense Logistics Agency must report to the HIPDB any contract debarments or suspensions arising from any DoD healthcare program contracts with any healthcare provider or supplier.

b. Reportable Actions. Any contract debarment or suspension taken regarding contractor qualifications in accordance with part 209 of Title 48, CFR (Reference (ah)) arising from any DoD healthcare program contract with any healthcare provider or supplier.

7. COOPERATION REGARDING HIPDB REPORTS BY OTHER AGENCIES. The HIPDB also requires reports from licensing and certification agencies of adverse licensure and certification actions, federal and State prosecutors of criminal convictions, and federal and State attorneys and health plans of certain civil judgments (excluding medical malpractice judgments) against providers, suppliers, and providers. DoD Components cooperate with other agencies in their reporting to the HIPDB.

8. HIPDB PROCEDURES

a. DoD Components make reports to the HIPDB and review requests from subjects to modify such reports based on the standards contained in part 61 of Reference (l). Determinations by the DoD on making reports or deciding whether to amend reports are made as a function of complying with regulatory requirements applicable to the DoD. Such determinations are not due process proceedings for which the subject has any right of notice or participation.

b. The DHHS requires reporting of reportable actions occurring on or after August 21, 1996.

c. In filing reports with the HIPDB, the DoD Components must follow the methods and procedures of the HIPDB. These procedures are outlined in regulations that can be accessed online at the DHHS HIPDB Website, http://www.npdb-hipdb.hrsa.gov.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ABMS	American Board of Medical Specialties
AMI	acute myocardial infarction
AOA	American Osteopathic Association
APN	advanced practice nurse
ASD(HA)	Assistant Secretary of Defense for Health Affairs
BAA	business associate agreement
CC	Credentials Committee
CCQAS	Centralized Credentials Quality Assurance System
CFR	Code of Federal Regulations
CMO	Chief Medical Officer
CPSC	Clinical Proponency Steering Committee
CQF	Clinical Quality Forum
CRNA	certified registered nurse anesthetist
DEA	Drug Enforcement Agency
DHHS	Department of Health and Human Services
DoDD	DoD directive
DoDI	DoD instruction
DP	Designated Provider
DSA	data sharing agreement
DSAA	data sharing agreement application
ER	emergency room
HA	Health Affairs
HCSC	health care support contractor
HEDIS®	Healthcare Effectiveness Data and Information Set
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIPDB	Healthcare Integrity and Protection Data Bank
ICTB	Inter-facility Credentials Transfer Brief
JTF CapMed	Joint Task Force National Capital Region Medical
M&E	monitoring and evaluation
MEB	medical evaluation board
MHS	Military Health System
MOU	memorandum of understanding
MQA	medical quality assurance

MQAPR	MQA peer review
MTF	military treatment facility
NGO	Non-governmental organization
NPDB	National Practitioner Data Bank
OCMO	Office of the Chief Medical Officer
PA	physician assistant
PCE	potentially compensable event
PEB	physical evaluation board
PHI	protected health information
PII	personally identifiable information
PRA	proactive risk assessment
PSLC	Patient Safety Learning Center
PSM	Patient Safety Manager
PSP	Patient Safety Program
PSPCC	Patient Safety Planning and Coordination Committee
PSR	patient safety reporting system
PSV	primary source verification
QA	quality assurance
RCA	root cause analysis
RM	risk manager
SE	sentinel event
SG	Surgeon General
SMDR	Senior Medical Department Representative
SOC	standard of care
TeamSTEPPS™	Team Strategies and Tools to Enhance Performance and Patient Safety
TJC	The Joint Commission
TMA	TRICARE Management Activity
UCMJ	Uniform Code of Military Justice
U.S.C.	United States Code
VA	Department of Veterans Affairs

PART II. DEFINITIONS

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

abeyance. The temporary assignment of 30 or fewer days of a provider from clinical duties to non-clinical duties while an internal or external peer review or QA investigation is conducted.

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.

adverse practice action. A limitation on the scope of practice of a non-privileged healthcare provider, including removal from patient care, based upon misconduct, impairment, or lack of professional competence that adversely affects the safe delivery of healthcare.

adverse privileging action. Denial, suspension, restriction, reduction, or revocation of clinical privileges based upon misconduct, impairment, or lack of professional competence that adversely affects the safe delivery of healthcare.

aggregate statistical data. A term applied to numerical data that constitute all of the data in pre-defined common demographic groupings. Aggregate statistical data are expressed in the form of a number, including whole numbers, fractions, or percentages, and are comprised of data from a population meeting all of the demographics in the grouping comprised of at least 3 individuals. Numerical data derived from records within the DoD CQM or MQA program must also be in such demographic groupings that the release of the information would not lead to the identification of the patient or the provider involved in providing care. Furthermore, the data must be "de-identified" as that term is used in chapter 8 of Reference (m). This specifically includes omission of the identifiers listed in paragraph C8.1.3.3 of chapter 8 of Reference (m) as they relate to the individuals involved. However, the term "de-identified data" does not include the geographic location or name of the treating facility or the time period covered for the care being reported upon. Thus aggregate statistical data does not require omission of the name of a particular MTF, prohibit reference to a group of MTFs by region or some other similar subdivision, or prohibit reference to a period of time such as month(s) or year(s). The HIPAA alternative standard for de-identification of PHI is identified in Reference (m) and involves obtaining a professional, documented opinion from a qualified statistician that the risk of re-identification is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify the individual who is a subject of the information.

approved postgraduate training. Postgraduate training program accredited by the Accreditation Council on Graduate Medical Education or the AOA, or other similar entities regulating healthcare provider training programs.

attorney work product doctrine. A doctrine whereby material prepared by an attorney in the anticipation of litigation may be protected from discovery. The attorney work product doctrine

applies to the notes, statements of witnesses, private memoranda, and mental impressions formed by the attorney.

authorized provider. A hospital or institutional provider, physician, or other individual professional provider, or other provider of services or supplies specifically authorized to provide benefits according to section 199.6 of Reference (x).

beneficiary. Any person eligible for benefits under the provisions of chapter 55 of Reference (h), which will generally include active duty Service members, retirees, certain reserve and national guard members, and eligible dependents and survivors.

board certified. A term applied to a physician or other healthcare provider who has passed an examination given by a professional specialty board and has been certified by that board as a specialist in that subject or discipline.

CCQAS. A database for managing a provider's credentials and privileges or scope of practice. This includes information on adverse privileging or practice actions, malpractice claims, and PCEs.

clinical adverse action. Action invoked against a healthcare provider with the result that the authority to practice clinically is adversely affected. A clinical adverse action is taken in response to a provider's acts or omissions (e.g., clinical incompetence, professional misconduct, or impairment) that may create a risk to patient safety, quality of healthcare, or the integrity of the MHS.

clinical privileges. Permission to provide medical and other patient care services in the granting institution, within defined limits, based on the individual's education, professional license, experience, competence, ability, health, and judgment.

clinical privileging. The granting of permission and responsibility of a healthcare provider to independently provide specified or delineated healthcare within the scope of his or her license, certification, or registration. Clinical privileges define the scope and limits of practice for individual providers and are based on the capability of the healthcare facility, licensure, relevant training and experience, current competence, health status, judgment, and peer and department head recommendations.

clinical quality management. A collection of programs that emphasize leadership, commitment to quality performance, regardless of the practice site (including operational platforms), a supportive organizational culture, and the evaluation of the effectiveness of clinical performance improvement activities. These activities include structured processes that design, measure, assess, and improve the healthcare status of beneficiaries and the quality of all healthcare services provided to them. Clinical quality management activities include clinical performance measurement and improvement, credentials and clinical privileging, risk management, adverse actions, and patient safety.

continuing medical education. Education beyond initial academic or professional preparation approved by an appropriate certifying professional organization that is relevant to the type of care or service delivered in an organization.

credentials. The documents that constitute evidence of appropriate education, training, licensure, experience, and expertise of a healthcare provider.

credentials review. The credentials inspection and verification process conducted for healthcare providers before selection for military service, employment, and procurement. The credentials review process is also conducted for healthcare providers before medical staff appointment and granting of clinical privileges, and is repeated at the time of reappointment and renewal of privileges.

current competence. The state of having adequate ability and up-to-date knowledge to perform the functions of a provider in a particular discipline, as measured by meeting three criteria.

The provider is authorized to practice a specified scope of care under a written plan of supervision at any time within the past 2 years, has completed formal graduate professional education in a specified clinical specialty at any time within the past 2 years, or has been privileged to practice a specified scope of care at any time within the past 2 years.

The provider has actively pursued the practice of his or her discipline within the past 2 years by having encountered a sufficient number of clinical cases to represent a broad spectrum of the privileges requested and that the individual has satisfactorily practiced the discipline as determined by the results of professional staff of M&E of the quality and appropriateness of patient care.

The provider possesses documented evidence of appropriate continued medical education to maintain the currency of his or her skills and knowledge in accordance with Service-specific guidance.

denial of privileges. Refusal to grant requested privileges to a provider, at the time of initial application or renewal, due to professional or clinical concerns, or due to facility-specific limitations. Denial of privileges due to professional incompetence or misconduct is an adverse privileging action that is reportable to the NPDB. Denial of privileges due to facility-related constraints is not an adverse privileging action and is not reported to the NPDB.

denominator. The part of a fraction that is below the line and that functions as the divisor of the numerator.

direct care system. Healthcare facilities and medical support organizations owned by the DoD and managed by the Services Surgeons General in accordance with applicable federal laws and regulations.

discovery. The date of awareness of an adverse event.

distant site. The location of the healthcare provider providing telemedicine services.

DP. Defined in section 721 of Public Law 104-201 (Reference (ai)).

DSA. Agreement between the DoD and the recipient of MHS data that establishes the permitted uses and disclosures of the data released. DSAs are used to control the release of patient- and provider-related information (other than releasable aggregate statistical information in accordance with Enclosure 2 of this manual).

equitable. Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

evidence-based clinical practice guidelines. Systematically developed disease or diagnosis-based statements to assist care givers and patient decisions about appropriate preventative actions and care for specific clinical conditions or circumstances.

fraction. A numerical representation (as ¾, ⅝, or 3.234) indicating the quotient of two numbers.

harm scale categories. The MHS has defined nine categories related to the level of harm to the patient who suffers an adverse event for purposes of the required documentation in the PSR and CCQAS. The nine harm scale categories include:

(1) Category 1: Death. Death at the time of the assessment.

(2) Category 2: Severe Permanent Harm. Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with the functional ability or quality of life. Prognosis at the time of assessment.

(3) Category 3: Permanent Harm. Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at the time of assessment.

(4) Category 4: Temporary Harm. Bodily or psychological injury, but likely not permanent. Prognosis at the time of assessment.

(5) Category 5: Additional Treatment. Injury limited to additional intervention during admission or encounter or increased length of stay, but no other injury. Treatment since discovery, or expected treatment in future as a direct result of event.

(6) Category 6: Emotional Distress or Inconvenience. Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and imaging studies). Distress or inconvenience since discovery, or expected in the future as a direct result of event.

(7) Category 7: No Harm. Event reached patient, but no harm was evident.

(8) Category 8: Near Miss. Any process variation or error or other circumstance that could have resulted in harm to a patient but through chance or timely intervention did not reach the patient.

(9) Category 9: Unsafe Condition. Potential event. Any circumstance that increases the probability of an adverse event.

HCSC. Entities under contract to DoD to manage or administer the provision of healthcare in accordance with the authority in chapter 55 of Reference (h).

healthcare provider. Defined according to section 1102 of Reference (h).

healthcare trainee. Any resident, intern, or other healthcare provider in a formal healthcare training status.

HIPDB. The data bank operated by DHHS containing information on fraud, abuse and certain other misconduct by healthcare providers and suppliers. The HIPDB is a fraud and abuse data collection program for the reporting and disclosure of certain final adverse actions taken against healthcare providers and others.

host State. The State in which off-base duties are or will be performed.

impaired provider. A provider who is unable to practice clinically with reasonable skill and safety because of physical or mental illness, including deterioration through the aging process or loss of motor skills, or excessive use or abuse of drugs, including alcohol.

individual QA action. A provider sanction, privileging action, or other activity on an individual healthcare provider intended to address a quality of healthcare matter. Such an action is based on processes structured by the QA program.

intentional unsafe act. An intentional action by a person harming or creating a risk of harm to one's self or to another person.

JTF-CapMed. The command with temporary authority over MTFs in the National Capital Region. For purposes of this Manual, the term includes a DoD component that succeeds JTF-CapMed with respect to this authority.

Joint. Connotes activities, operations, organizations, etc., in which elements of two or more Military Departments participate.

license. A grant of permission by an official agency of a State; the District of Columbia; or a commonwealth, territory, or possession of the United States to provide healthcare within the scope of practice for a discipline. A current license is one that is active, not revoked, suspended, or lapsed in registration. A valid license is one in which the issuing authority accepts, investigates, and acts upon QA information, such as provider professional performance, conduct, and ethics of practice, regardless of the provider's military status or residency. An unrestricted

license is one that is not subject to limitations on the scope of practice ordinarily granted all other applicants for similar specialty in the granting jurisdiction. An unrestricted license must allow the provider unabridged permission to practice in any civilian community in the jurisdiction of licensure without having to take any additional action on her or his license.

licensed independent practitioner. Defined Reference (q).

malpractice payment. A monetary award in accordance with Reference (z), chapter 163 ("Military Claims") of Reference (h), or as specified in sections 2734 through 2736 of Reference (h)) relating to the provision of healthcare services under the organizational responsibility of the DoD.

medical staff appointment. Formal, written authorization to perform patient care accompanied by a delineation of authorized clinical privileges and a pledge to abide by the rules and regulations of the medical or dental staff. There are four types of medical staff appointments.

Active staff appointments are granted to providers, according to the needs of the government, who successfully complete the initial staff appointment period.

Initial staff appointments are the initial professional staff appointment granted to a provider when first assigned or employed by a DoD facility. The initial appointment for a period of no more than 12 months is to allow the provider to demonstrate current clinical competence and compliance with the facility's policies, procedures, and bylaws.

Affiliate staff appointments are granted to a provider exercising regular privileges and meeting all qualifications for medical staff membership. This applies after successful completion of the initial appointment period when, due to conditions of employment, the provider is neither assigned organizational responsibilities of the medical or dental staff nor expected to fully participate in activities of the medical or dental staff.

Temporary staff appointments are granted to a provider in emergency or disaster situations when there are urgent beneficiary care needs, but the time constraints will not allow full credentials review.

MHS. The combination of military and civilian medical and dental programs, personnel, facilities, and other assets operating pursuant to chapter 55 of Reference (h) that provides healthcare to DoD healthcare beneficiaries.

MHS CQF. The MHS forum that reports to the ASD(HA)/TMA with oversight responsibility for clinical quality programs across the MHS. The committee includes representatives from HA, TMA, and the Services.

monitoring and evaluation. A well-defined, time-limited, well documented plan of intensified peer review to confirm a provider possesses the skill, knowledge, and ability to render safe and effective healthcare.

MQAPR Record. A record described in subsection (a) of section 1102 of Reference (h).

MTF. A DoD hospital or clinic operated to provide healthcare to active duty Service members or other DoD beneficiaries.

NPDB. The national data repository of actions against healthcare providers and reports of malpractice payments managed by the DHHS in accordance with section 11101 of Title 42, U.S.C. (Reference (aj)).

National Provider Identifier. A nationally applicable identifier issued by the government and required by individuals, groups, or organizations that provide medical or other health services or supplies.

near miss. Any process variation, error, or other circumstance that could have resulted in harm to a patient but through chance or timely intervention did not reach the patient.

numerator. The part of a fraction that is above the line and signifies the number to be divided by the denominator.

off-base duties. Officially assigned professional duties performed at an authorized location outside an MTF and any military installation. Off-base duties include, but are not limited to, training or skill maintenance duties in non-DoD healthcare facilities, professional activities performed under the authority of the military-civilian health services partnership program under section 1096 of Reference (h), and telemedicine services involving a patient outside an MTF and any military installation. Off-base duties do not include participation in approved postgraduate training of physicians, or assigned professional duties performed in a VA or other Federal Government healthcare facility.

operational healthcare units. Those deployable units that while at home station are treating only active duty personnel and Reserve Component members on duty status and not a component of an accredited MTF.

originating site. The location of the patient receiving telemedicine services.

ORYX®. An initiative developed by TJC to integrate outcome and other performance measures into the accreditation process for hospitals and home healthcare organizations.

other authorizing document. A mechanism, such as registration and certification, by which a State; the District of Columbia; or a Commonwealth, territory, or possession of the United States grants authority to provide healthcare in a specified discipline. In specialties not licensed and where the requirements of the granting authority for registration or certification are highly variable, the validation by a national organization that a provider is professionally qualified to provide healthcare in a specified discipline. In the case where healthcare is provided in a foreign country by any person who is not a national of the United States, a grant of permission by an official agency of that foreign country for that person to provide healthcare in a specified discipline.

patient-centered. Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

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 death or disability payment).

peer review. Any assessment of the quality of medical care carried out by a healthcare professional, including any such assessment of professional performance, any patient safety program root cause analysis or report, or any other such assessment carried out by a healthcare professional under provisions of this manual.

peer review panel. MTF panel comprised of at least three clinical peers of the involved provider (similar clinical specialty, education, and training).

performance improvement. The continuous study and adaptation of a healthcare organization's functions, structure, and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals, populations, and other users of services.

personally identifiable information. As defined in Reference (k).

plan of supervision. An approved arrangement to provide supervision, specific to a practitioner, which includes: the scope of care permitted, level of supervision, identity of supervisor, evaluation criteria, and frequency of evaluation.

professional impairment. A healthcare provider characteristic that may adversely affect the ability to render quality care. Professional impairment may include deficits in medical knowledge, expertise, or judgment; unprofessional, unethical, or criminal conduct; and any medical condition that reduces or prevents the provider's ability to safely execute his or her responsibilities in providing healthcare.

protected health information. As defined in Reference (m).

provider. Individuals, groups, or organizations that provide medical or other health services or supplies.

provider credentials file. A file containing pertinent information regarding an individual privileged provider to include credentialing and privileging documents, permanent performance data, medical practice reviews, continuing health education documentation, and information related to permanent adverse privileging actions.

purchased care system. Civilian providers (including individuals, groups, hospitals, and clinics) who have agreed to accept the DoD and uniformed services beneficiaries enrolled in the regional managed care program authorized by the ASD(HA). Providers in the purchased care system deliver healthcare at negotiated rates, adhere to provider agreements, and follow other requirements of the managed care program.

reduction in privileges. A portion of a provider's clinical privileges permanently removed. It may be based on misconduct, physical impairment, or other factors limiting a provider's capability. Reduction in privileges is reportable to the NPDB.

regular privileges. Permission to independently provide medical and other patient care services.

reinstatement of privileges. The revision of an adverse privileging action that restores all or a portion of the provider's clinical privileges. Reinstatement of privileges is reportable to the NPDB.

restriction of privileges. A temporary or permanent limit placed on all or a portion of a provider's clinical privileges. The restriction may require some type of supervision. Restriction of privileges is reportable to the NPDB.

revocation of privileges. All clinical privileges of a healthcare provider are permanently removed. In most cases, such action may be followed by action to terminate the provider's DoD service. Revocation of privileges is reportable to the NPDB.

RCA. A 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 outcomes measures. The analysis focuses primarily on systems and processes rather than individual performance.

SE. 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.

significantly involved providers. 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. Healthcare diagnostic or treatment judgments and actions of a provider generally accepted in the healthcare discipline or specialty involved as reasonable and appropriate.

summary suspension. The temporary removal of all or part of a provider's privileges, taken prior to the completion of due process procedures, based on peer assessment and command determination that the action is needed to protect patients or the integrity of the command. A summary suspension could continue until due process procedures are completed. Summary suspension of privileges within the DoD is not reportable to the NPDB, unless the final action is reportable. The period of summary suspension will not exceed 180 calendar days.

supervised privileges. Supervised privileges are those privileges granted to healthcare providers who do not meet the requirements for independent practice because they lack the necessary

licensure or certification; however, all educational requirements have been met (e.g., a physician who has completed an internship, but is not yet licensed).

supervision. The process of reviewing, observing, and accepting responsibility for assigned personnel. The types of supervision are:

indirect. The supervisor performs retrospective record review of selected records. Criteria used for review relate to quality of care, quality of documentation, and the authorized scope of practice.

direct. The supervisor is involved in the decision-making process.

verbal. The supervisor is contacted by phone or informal consultation before implementing or changing a regimen of care.

suspension. The temporary removal of all or part of a provider's privileges resulting from incompetence, negligence, or unprofessional conduct after due process procedures are completed. Suspension of privileges is reportable to the NPDB.

tele-mental health. The provision of mental healthcare services using an interactive telecommunications system between a healthcare provider and patient in different locations.

temporary privileges. Granted in situations when time constraints will not allow full credentials review.

threshold rule. As defined in Reference (q).

unsafe condition. Potential event. Any circumstance that increases the probability of an adverse event.

verification of credentials. Documents confirming authenticity has been obtained from the primary (issuing) source by the Military Service or a representative of the Military Service.