Report No. D-2007-054 February 20, 2007

Inspector General
United States Department of Defense

Quality Assurance in the DoD Healthcare System

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Acronyms

ASD(HA)	Assistant Secretary of Defense (Health Affairs)
BUMED	Bureau of Medicine and Surgery
CCQAS	Centralized Credentials and Quality Assurance System
MHS	Military Health System
MTF	Military Treatment Facility
PCE	Potentially Compensable Event
PSP	Patient Safety Program
PEBLO	Physical Evaluation Board Liaison Officer

INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
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February 20, 2007

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (FINANCIAL MANAGEMENT AND COMPTROLLER)
NAVAL INSPECTOR GENERAL
AUDITOR GENERAL, DEPARTMENT OF THE ARMY

SUBJECT: Report on Quality Assurance in the DoD Healthcare System (Report No. D-2007-054)

We are providing this report for review and comment. We considered comments from the Assistant Secretary of Defense (Health Affairs), the Army, the Navy, and the Air Force when preparing the final report.

DoD Directive 7650.3 requires that all recommendations be resolved promptly. Comments from the Assistant Secretary of Defense (Health Affairs) were responsive. Comments from the Army Surgeon General were responsive, except for Recommendation 2.d. Comments from the Navy Surgeon General were responsive, except for Recommendation 2.c. which we considered partially responsive. Comments from the Air Force Surgeon General were responsive. We request additional comments from the Army Surgeon General on Recommendation 2.d. and from the Navy Surgeon General on Recommendation 2.c. by March 20, 2007.

If possible, please send management comments in electronic format (Adobe Acrobat file only) to Audyorktown@dodig.mil. Copies of the management comments must contain the actual signature of the authorizing official. We cannot accept the / Signed / symbol in place of the actual signature. If you arrange to send classified comments electronically, they must be sent over the SECRET Internet Protocol Router Network (SIPRNET).

We appreciate the courtesies extended to the staff. Questions should be directed to Michael A. Joseph at (757) 872-4801, extension 223 or Mr. Timothy J. Tonkovic at 757-872-4763. See Appendix H for the report distribution. The team members are listed inside the back cover.

By direction of the Deputy Inspector General for Auditing:

Wanda A. Scott

Wanda A. Scott
Assistant Inspector General
Readiness and Operations Support

Department of Defense Office of Inspector General

Report No. D-2007-054 **February 20, 2007**
(Project No. D2005-D000LF-0147)

Quality Assurance in the DoD Healthcare System

Executive Summary

Who Should Read This Report and Why? Policymakers, healthcare managers, healthcare providers, patient safety, and risk managers should read this report to become aware of issues related to complete and timely reporting of medical incidents in the military healthcare system.

Background. Medical quality assurance is a comprehensive process used to monitor and evaluate the quality and appropriateness of patient care and the clinical performance of all practitioners in the military health system. Two components of a medical quality assurance program are patient safety and risk management. Patient safety programs identify actual and potential problems in medical systems and processes whereas risk management programs help prevent accidents and injuries and reduce the cost of claims and risk of other financial losses.

Medical quality assurance also includes managing and reporting medical incidents. Medical incidents include near miss and adverse events. Adverse events occur when a beneficiary of the military health system experiences unexpected harm. Some adverse events are potentially compensable and can result in a paid claim to a dependent or retiree or the disability retirement or separation of an active duty member.

Results. The Deputy Assistant Secretary of Defense (Clinical and Program Policy) requested the audit because of concerns that the military healthcare system does not provide full visibility over the quality assurance process DoD uses to report medical incidents.

We visited seven military treatment facilities in the military health system. Each maintained certification from the Joint Commission on Accreditation of Healthcare Organizations and had active and ongoing programs for patient safety and risk management. In spite of these programs, healthcare managers in the health system did not have sufficient visibility of medical incident events. To improve the system, we recommend that the Assistant Secretary of Defense for Health Affairs and the Military Departments revise their regulations on quality assurance, require uniform use of the information system DoD uses to track risk management, and establish a link between patient safety and risk management for medical incidents deemed potentially compensable events. Such improved guidance as well as consistent implementation and reporting from the patient safety and risk management programs will help military health system managers monitor and improve the quality of medical care in the military health system and mitigate the risk of financial loss. See the Finding section of the report for the detailed recommendations.

As DoD moves toward increased joint operations, the ability of the military health system to share and compare data is critical. The quality assurance program is another

opportunity to improve joint operations by providing military health system managers with accurate and timely visibility of all medical incidents involving active duty members, retirees, and dependents.

Management Comments and Audit Response. The Assistant Secretary of Defense (Health Affairs) concurred with the audit finding and conclusions and stated that his office is revising DoD Regulation 6025.13, "Clinical Quality Assurance in the Military Health System," June 11, 2004. The Assistant Secretary stated that he would incorporate the recommendations into the revised DoD Regulation 6025.13, and that the revision would be closely coordinated with the Military Departments. The Assistant Secretary of the Army (Manpower and Reserve Affairs), the Army Surgeon General, the Assistant Secretary of the Navy (Manpower and Reserve Affairs), the Chief, Bureau of Medicine and Surgery, and the Air Force Surgeon General generally concurred with the recommendations addressed to them.

The Army Surgeon General did not agree with the recommendation to establish a quality assurance focal point for the centralized reporting of functional area reviews. The Army Surgeon General also stated that functional area reviews are outdated and that DoD requirements for tracking and comparing functional area results should be predicated on current accrediting agency performance improvement processes. We support the ASD(HA) efforts to revise this section of the Regulation, because functional area reviews are a critical part of a successful quality assurance program. We maintain that functional area review results should be centralized in one location in military treatment facilities to assist in comparing and analyzing quality assurance information in a timely manner.

The Chief, Bureau of Medicine and Surgery stated that he would advise commanding officers of military treatment facilities to refer those Physical Evaluation Board cases where medical care is called into question to the risk manager. The intent of the recommendation was to make sure that the Medical Evaluation Board approving officials identify and report all Medical Evaluation Board cases, including those not submitted to Physical Evaluation Boards, to military treatment facility risk managers for further evaluation. We maintain that Medical Evaluation Board cases, where medical care is questioned, should be identified and reported to the military treatment facility risk manager.

We request that the Army Surgeon General provide additional comments on the establishment of a quality assurance focal point in each military treatment facility. We request that the Chief, Bureau of Medicine and Surgery provide additional comments clarifying the Navy's position on submitting all active duty Medical Evaluation Board cases to a military treatment facility risk manager. We request the Army and Navy comments on the final report by March 20, 2007.

See the Finding section for a discussion of management comments on the recommendations. See Appendix B for a discussion of management comments on the Background and Finding sections of the report and for a discussion of unsolicited comments on the recommendations. See the Management Comments section of the report for the complete text of the comments.

Table of Contents

Background

The Deputy Assistant Secretary of Defense (Clinical and Program Policy) requested the audit. He was concerned that the military health system (MHS) does not provide full visibility over the quality assurance processes for reporting medical incidents.

Military Health System. DoD strives to provide world-class medical care to beneficiaries at 70 hospitals as well as numerous medical and dental clinics, technically called military treatment facilities or MTFs. For this report, the term MTF includes only hospitals. More than 132,000 MHS personnel serve about 9.2 million beneficiaries throughout the world. DoD spent about $37 billion in FY 2006 on its health system. The mission of the MHS is to enhance DoD and our Nation's security by providing health support for the full range of military operations and sustaining the health of eligible beneficiaries.

Medical quality assurance is a comprehensive process that the MHS uses to monitor and evaluate the quality and appropriateness of patient care as well as the clinical performance of practitioners. Quality assurance in the MHS also includes reporting and managing medical incidents through programs for patient safety and risk management. Both of those programs focus on preventing and reducing medical incidents in the MHS. In this report, we define medical incidents as near miss or adverse events. See Appendix G for a glossary of near miss and adverse events as well as other terminology that people use in the quality assurance, patient safety, and risk management processes.

Incident Reporting. The patient safety program (PSP) at each MTF identifies and centrally reports problems in medical systems and processes and then implements actions that will improve patient safety throughout the MHS. DoD requires that each MTF PSP have procedures and standards in place for receiving medical incident reports from clinical staff, administrative staff, and patients or their families. In the MTFs, PSP personnel evaluate medical incidents to determine how and why they occurred. Patient safety personnel work closely with risk management personnel.

Risk management personnel evaluate adverse events and determine whether they are potentially compensable events (PCEs). A PCE occurs when a beneficiary experiences any unintended or unexpected negative outcome. A PCE requires a determination for standards of care and degree of injury. A standards of care determination is a decision about whether a healthcare provider's diagnosis, treatment judgment, and actions were reasonable and appropriate within their healthcare discipline or specialty. Risk management programs help reduce the liability of the Government by archiving information on PCEs as support for the possible defense of future malpractice cases.

Medical Malpractice Claims. DoD dependents and retirees have 2 years after an incident occurs or after harm is recognized to file a malpractice claim with a Service legal office. Military Department legal offices may deny or settle a claim. If denied, the DoD dependent or retiree can refile a claim within 6 months with the Department of Justice. Military Department personnel in the Offices of the Surgeons General are required to enter claims, both filed and paid, into the

Centralized Credentials Quality Assurance System (CCQAS) that the Department of Legal Medicine monitors. In addition to tracking and trending medical malpractice claims, the Department of Legal Medicine at the Armed Forces Institute of Pathology consults, educates, and researches those DoD matters relating to medical and legal quality assurance and risk management.

By statute, active duty members cannot receive compensation from the Government for financial claims and lawsuits because of the Feres Doctrine. The Feres Doctrine is based on the 1950 Supreme Court decision, *Feres v. United States*. The exclusive remedies for active duty members killed or injured during military service, including injuries that result from medical care, are the military disability system and other compensation programs run by the Department of Veteran Affairs.

MTF Accreditation. The Joint Commission on Accreditation of Healthcare Organizations surveys and accredits the 70 MTFs. The Joint Commission on Accreditation of Healthcare Organizations is an accrediting organization that provides a set of standards that measure the quality of healthcare in the United States and around the world.

DoD Policies and Procedures

DoD Directive 6025.13, "Medical Quality Assurance (MQA) in the Military Health System (MHS)," May 4, 2004, (the Directive), establishes policy for DoD on issues related to medical quality assurance programs and activities. The Directive states that the MHS must maintain active and effective organizational structures, management emphasis, and program activities that will assure quality healthcare throughout the MHS.

The Directive authorizes DoD Regulation 6025.13-R, "Military Health System (MHS) Clinical Quality Assurance (CQA) Program Regulation," June 11, 2004, (the Regulation). The Regulation implements policy guidance established in the Directive. It requires that commanders implement programs for patient safety and risk management in the MTFs and use quality assurance reviews for evaluating beneficiary care outcomes as a principal measure of quality.

See the Finding section of the report for the Military Departments' guidance and procedures.

Objective

The overall objective of the audit was to evaluate the completeness, effectiveness, and performance of the quality assurance processes that involve reportable medical incidents. We focused our audit on whether healthcare managers had visibility over medical incidents that occur in MTFs. We also assessed the management control program as it related to the audit objective. See Appendix A for a discussion of the scope and methodology as well as prior coverage.

Limited Patient Safety and Risk Management Reviews. Although we focused this audit on the visibility of medical incidents within the MHS, we verified the adequacy of the programs for patient safety and risk management on a limited basis at the seven MTFs visited. See Appendix A for the scope of the audit.

Our limited review of the programs for patient safety and risk management showed that the MTFs visited have programs that are active and ongoing. Opportunities exist (see the Finding section) to improve the quality assurance program for the MHS through identifying and reporting medical incidents.

Review of Internal Controls

DoD Instruction 5010.40, "Manager's Internal Control (MIC) Program Procedures," January 4, 2006, requires DoD organizations to implement a comprehensive system of management controls that provide reasonable assurance that programs are operating as intended and to evaluate the adequacy of the controls.

Scope of the Review of the Management Control Program. We reviewed the adequacy of the management controls related to the Military Departments' quality assurance programs. We focused on program guidance and the procedures for identifying and reporting medical incidents. Finally, we determined whether the self-evaluation of management controls adequately met the requirements and intent of DoD Instruction 5010.40.

Adequacy of Management Controls. For the MTFs visited, a weakness exists in quality assurance programs as DoD Instruction 5010.40 defines. Management controls that would ensure consistent implementation and uniform reporting of quality assurance information to senior DoD managers of the MHS did not exist. Because of the limited number of MTFs visited and because MTFs were accredited, we did not make a judgment on the materiality of the weakness identified.

Implementation of the recommendations will help to deliver safe and effective healthcare to DoD beneficiaries. We will provide a copy of the report to the senior official responsible for management controls within the TRICARE Management Activity and the Military Departments.

Management's Self-Evaluation. The Office of the Assistant Secretary of Defense (Health Affairs) [ASD(HA)] did not identify quality assurance, risk management, or patient safety as assessable units. The Army and Navy Surgeons General identified the subject areas as assessable units. The Navy reported no material weaknesses, and the Army has reviews scheduled in future years. The Air Force Surgeon General did not identify the subject areas as assessable units.

Other Matters of Interest

Public Law 105-174 (May 1, 1998) required that the Secretary of Defense appoint an independent panel of experts to evaluate measures that the then Acting ASD(HA) and Surgeons General took to improve the quality of care in the MHS. The panel's report, "DoD Healthcare Quality Initiatives Review," undated (the Panel report), presents 4 general and 44 specific recommendations for improving quality relative to 9 initiatives. One of the general recommendations directs DoD to implement a Unified Military Medical Command for managing an error reduction and safety program that is based on root cause analysis and system process redesign. The panel also recommended that DoD install robust, comprehensive data systems that can measure and monitor quality outcomes, use of resources, and healthcare costs. DoD implemented some of the panel's recommendations and incorporated them into the Directive and the Regulation. See Appendix F for a summary of the panel's recommendations.

Implementation of the DoD Quality Assurance Program

As part of its overall effort to improve the safety and quality of healthcare provided to beneficiaries, the DoD MHS maintains active programs for patient safety and risk management. Each of the seven MTFs visited had Joint Commission on Accreditation of Healthcare Organizations certification. However, MHS managers did not have sufficient visibility over medical incidents. To improve visibility over medical incidents:

- the ASD(HA) and the Military Departments should revise quality assurance guidance, and the Military Departments should implement the revised DoD Regulation;
- the ASD(HA) and the Military Departments should require use of the risk management module of the CCQAS for complete and timely reporting of all PCE and claim information; and,
- the ASD(HA) should establish an interface between the Patient Safety Reporting System and the CCQAS to facilitate exchange of information on medical incidents that are determined potential compensable events.

Improved guidance as well as consistent implementation and reporting from the programs for patient safety and risk management will help MHS managers monitor and improve the quality of medical care in the MHS and mitigate the risk of financial loss.

Quality Assurance Guidance

The seven MTFs visited maintained active programs for patient safety and risk management; however, guidance on quality assurance needs improvement. The Regulation needs to be revised in several areas. Improvements to the Regulation should require:

- that the risk management process identify any PCE;
- that risk managers report to the Surgeons General any compensable disability retirement or separation resulting from medical malpractice;
- that information necessary to monitor and oversee the PSP is available to ASD(HA) healthcare managers;
- that functional area review information is available to accommodate comparisons and trends throughout the MHS; and,
- use of clear and descriptive terminology for categorizing, identifying, and reporting medical incidents.

Improved and consistently applied guidance will help improve the quality of medical care throughout the MHS.

Identifying Potentially Compensable Events. DoD needs guidance that will help risk managers identify all PCEs. The Regulation defines a PCE as:

> An adverse event that occurs in the delivery of healthcare and services with resulting beneficiary injury. It includes any adverse event or outcome, with or without legal fault, in which the patient experiences any unintended or unexpected negative result.

When adverse events are determined a PCE, the risk manager must initiate a standards of care determination to make sure a healthcare provider's diagnosis, treatment judgments, and actions were reasonable and appropriate. Guidance can be improved by (1) requiring legal counsels participate in determining a PCE; (2) including all active duty adverse events when determining a PCE, and (3) identifying alleged and suspected active duty adverse events through the Medical Evaluation Board process.

The MHS needs legal office participation and coordination with risk management when risk managers evaluate adverse events as potentially compensable. Procedures in the Regulation and Military Department guidance for classifying and determining PCEs were inconsistent, and the guidance was not clear about whether DoD intended involvement of legal counsel during or after an event is determined to be potentially compensable. The Regulation should be consistent and require that risk managers consult with the MTF legal office when evaluating adverse events as potentially compensable. See "Legal Counsel Participation in PCE Determinations" in Appendix C for additional details.

Guidance is needed requiring that risk managers include all active duty adverse events when determining a PCE. The Feres Doctrine bars active duty members from receiving compensation from financial claims and lawsuits that may arise because of an adverse event. The Regulation does not include military disability retirement and separation benefits resulting from an active duty adverse event as another form of compensation that should be considered in a PCE determination. Risk management personnel did not always consider active duty adverse events when making PCE determinations because they did not consider active duty disability retirements and separations as a form of financial compensation. As a result, active duty adverse events that risk managers did not initially identify as potentially compensable could go unidentified and unreported.

Guidance is also needed to help identify any alleged or suspected active duty adverse events during the Medical Evaluation Board process. The Medical Evaluation Board documents an active duty member's medical status and provides MTFs with a final opportunity for identifying possible active duty adverse events and PCEs that went unreported when the active duty member initially received treatment. The active duty adverse event may have occurred at the same MTF where the Medical Evaluation Board is located or at another MTF. Medical Evaluation Board personnel are not required to identify alleged or suspected adverse events. Additionally, the Medical Evaluation Board is not required to notify risk managers of a suspected adverse event for patient safety review or evaluation as a PCE. As a result, active duty adverse events that cause

a disability would remain unreported and would not receive the level of oversight or visibility consistent with DoD quality assurance initiatives. See "Identification of Alleged or Suspected Active Duty Adverse Events During the Medical Evaluation Board Process" in Appendix C for additional details.

Appendix D shows the process flow for evaluating active duty medical events and discusses two opportunities for reporting possible active duty adverse events to the risk manager. Those opportunities for reporting include an active duty member's interaction with the Physical Evaluation Board Liaison Officer (PEBLO) and identification of active duty adverse events by the Medical Evaluation Board. The PEBLO is an advocate for active duty members in the disability evaluation system and someone who can be alert to allegations that the active duty member might make because of medical care provided in the MHS. The approving official for the Medical Evaluation Board is a commanding officer or designated physician, independent of the Board, who reviews medical documentation related to medical disability cases and acts on Board findings and recommendations. Approved cases go to Military Department Physical Evaluation Boards, which determine fitness for duty and, if necessary, disability retirement or separation. Both the PEBLO and the approving official for the Medical Evaluation Board are in positions to identify and report allegations or suspicions of active duty adverse events to MTF patient safety and risk managers for validation and PCE determination.

Reporting Medical Malpractice to the Surgeons General. Of the seven MTFs visited, none could demonstrate that they were reporting compensable disability retirements or separations caused by medical malpractice to the Surgeons General. After a Physical Evaluation Board reaches a decision on an active duty compensable disability retirement or separation resulting from medical malpractice, the Regulation requires the senior medical officer of the Medical Evaluation Board to report the decision to the Surgeon General. Personnel involved in the Medical Evaluation Board process stated that they were unaware of the reporting requirement to the Surgeons General. MTF personnel were unable to determine the number of reportable compensable disability retirements or separations because they did not identify medical malpractice cases during the medical evaluation process.

Risk managers, instead of senior medical officers of the Medical Evaluation Boards, should report compensable disability retirement or separations that result from medical malpractice to the Surgeon General. The risk manager oversees PCEs, has access to information to identify and link medical malpractice cases to disability cases, and is in the best position to report compensable disability malpractice events to the Surgeon General. The senior medical officer may not be involved with the risk management program, may not be aware of alleged or suspected adverse events, and is normally not involved after the Medical Evaluation Board completes its medical evaluation.

Guidance from the Army and Air Force did not identify reporting compensable disability retirement or separation cases that resulted from medical malpractice to the Surgeons General. Bureau of Medicine and Surgery (BUMED) Instruction 6010.18A, "Participation in the National Practitioner Data Bank," February 13, 2003, requires that the Physical Evaluation Board report to the Surgeon General any case of an active duty member whose medical impairment

may have been incurred by medical care. The Navy Surgeon General did not receive any reports of active duty members because the Physical Evaluation Board did not determine that any impairment was a result of medical care.

Requiring that risk managers monitor active duty medical malpractice cases, link those cases to retirement and separation decisions, and report those cases to the Offices of the Surgeons General would help to identify adverse events for active duty members.

Patient Safety Program. Guidance is needed to make sure that ASD(HA) healthcare managers have the information necessary for establishing and coordinating joint patient safety activities. MHS personnel cannot view or access detailed medical incidents above the Offices of the Surgeons General level. Detailed medical incident information would help MHS personnel identify and trend medical information on situations that place patients at risk in the MHS as well as identify areas for improving the MHS.

The Regulation states that monthly summary reports and other information submitted to the Patient Safety Center must not include names or other identifying information on patients, healthcare staff, or MTFs. However, a healthcare manager in the Office of the ASD(HA) stated that to maintain oversight of the DoD PSP, visibility beyond summarized and de-identified information is necessary to heighten awareness and enhance visibility of patient safety activities.

MTF monthly summary reports include only categorized numerical summaries of the patient safety events, which the Patient Safety Center uses to centrally develop, promote, and manage its patient safety database. Monthly summary reports categorize near miss, actual, and sentinel events into reporting categories and subcategories.

The categories briefly describe the type of event, and the subcategories further describe the event. For example, a "delay in treatment" incident may be further subcategorized as "delayed test results." No identifying details other than near miss and "actual" event numerical summaries for each category or subcategory are available on the monthly summary reports. Except for sentinel events, detailed information cannot be matched to a specific event or MTF where the event occurred. ASD(HA) healthcare managers receive detailed information that identify sentinel events. Healthcare managers in the Office of the ASD(HA) should determine and convey to the Military Departments the detailed information that will help to adequately monitor the DoD Patient Safety Program. The Office of the ASD(HA) should revise the Regulation so that Office of the ASD(HA) healthcare managers have access to information necessary to monitor and provide comprehensive oversight of the DoD PSP.

Functional Area Reviews. Guidance should make sure that ASD(HA) healthcare managers can compare functional area review results throughout the MHS. At the time of our review, none of the MTFs visited established oversight for reporting functional area reviews or designated a focal point to compile the results of the reviews. Uniform reviews of functional areas help quality improvement efforts because uniformity allows comparison with civilian benchmarks, comparisons between regions and Military Department MTFs, and identification of best clinical practices.

The Regulation requires that MTF personnel perform 14 functional area reviews and provides specific criteria for those reviews. We reviewed 13 of the 14 specific clinical functional areas and reviewed 67 elements that comprise criteria for the 13 reviews. Because it was included in our review of the programs for patient safety and risk management for each MTF, we did not include the adverse outcome screening functional area. Examples of functional areas include medical staff functions such as reviews of surgical cases, blood usage, drug usage, as well as emergency departments, and special care units. At each MTF visited, we relied on documentation that MTF personnel provided to determine whether they included each functional area review element. We did not determine the validity of the results of the functional area reviews for each MTF or the frequency of the reviews.

At the seven MTFs, medical staff and quality assurance personnel stated that they were not aware of the functional area reviews the Regulation requires. We met with physicians and nurses as well as patient safety, risk management, and other personnel to determine if they completed elements related to the 13 functional areas. In some cases, MTF departments may have completed a review that matched a specific element, but no one person in the MTF knew if the required reviews were completed. Throughout the seven MTFs visited, little consistency existed in supporting documentation, how MTF personnel performed the reviews, or how MTF personnel complied with the requirements of the Regulation.

The Regulation requires that the MHS quality assurance program include functional area reviews that monitor and evaluate the quality and appropriateness of patient care, the clinical performance of all physicians, and the performance of medical departments throughout the MTFs. However, the Regulation does not specify the content, frequency, or format of reviews, or require a centralized focal point for compiling and reporting the results of a functional area review. Additionally, Military Department guidance did not comprehensively identify the functional areas or provide the same level of detail as specified in the Regulation. The Air Force is the only Military Department that expanded on the functional areas and included some of the same specific elements as the Regulation. See "Functional Area Reviews" in Appendix C for additional details and Appendix E for the 13 functional areas and the 67 elements.

Inconsistent Terminology. The MHS needs clear and descriptive terminology for categorizing, identifying, and reporting medical incidents. The Regulation, the DoD Patient Safety Center, and the Military Departments each define near miss, adverse and sentinel events, and PCEs differently, and the terminology needs to be clarified. Depending on the definition used, some near miss and adverse events are interchangeable and may result in under- or over-reporting throughout the MHS. Confusion can also occur with identifying sentinel events, depending on the definition used. Finally, cases with potential financial risk to the Government will not be uniformly identified because of inconsistent PCE definitions for the Military Departments and because no difference exists in the Regulation's definition of an adverse event and PCE. The MHS needs clear, concise, and consistent terminology so medical incidents are categorized in the same way, reported uniformly, and not used interchangeably. The "Quality Assurance Terminology" section of Appendix C provides further discussion on the differences for definitions as well as explanations of how medical incidents may be under- or over-reported.

Use of the Centralized Credentials and Quality Assurance System Risk Management Module for Reporting PCEs and Claims Information

ASD(HA) and the Military Departments can improve visibility over PCE and claim information by using CCQAS. The risk management module of CCQAS is a Web-based, worldwide application that helps manage PCEs, as well as filed, and paid medical malpractice claims and disability claims.

Use of CCQAS. The MHS did not have complete visibility over PCEs and medical malpractice claim information, in part, because CCQAS use varied among Military Departments. The Regulation requires that MTF risk management personnel promptly report every PCE in CCQAS, and that personnel in the Offices of the Surgeons General report every medical malpractice claim, both filed and paid, into CCQAS. The Regulation also requires that every case in which medical care may have contributed to the death or disability of an active duty member be promptly reported in CCQAS. Although not required to do so, some MTF risk managers also entered filed and paid claims. The table below shows the varying degrees of use of CCQAS at the seven MTFs.

MTF Use of CCQAS Risk Management Module

	MTF Entering Data for		
MTF Location	**PCEs**	**Filed Claims**	**Paid Claims**
Tripler Army Medical Center, Hawaii	**Yes***	**Yes***	**Yes**
Darnall Army Community Hospital, Texas	**Yes**	**Yes***	**Yes**
Portsmouth Naval Medical Center, Virginia	**No**	**Yes***	**No**
Naval Hospital Jacksonville, Florida	**Yes***	**Yes***	**No**
Naval Hospital Camp Pendleton, California	**No**	**No**	**No**
Wilford Hall Medical Center, Texas	**No**	**Yes**	**Yes***
96th Medical Group, Eglin Air Force Base, Florida	**No**	**No**	**No**

***MTFs did not enter all PCEs, filed, or paid claims selected for review into the system.**

At each MTF, we selected a limited number of PCEs and claims and determined if risk managers entered required information into CCQAS. For the PCEs we selected for review, the risk manager at Darnall Army Community Hospital entered the events into CCQAS. Risk managers at Tripler Army Medical Center and Naval Hospital Jacksonville entered some of the PCEs, and the remaining risk managers at the MTFs did not enter PCE information.

Although the Regulation states that personnel in the Offices of the Surgeons General must enter claim information, some risk managers were also entering claim information at the MTF level. For the filed claims we selected, risk

managers at Wilford Hall Medical Center entered all of the filed claims into CCQAS. At Tripler Army Medical Center, Darnall Army Community Hospital, Portsmouth Naval Medical Center, and Naval Hospital Jacksonville, risk managers reported some of the filed claims and, at the remaining two, risk managers did not report any filed claims.

For the paid claims selected, risk managers at Darnall Army Community Hospital and Tripler Army Medical Center entered paid claims into CCQAS. The risk manager at Wilford Hall Medical Center entered some of the paid claims. At the remaining four locations, risk managers did not enter paid claim information into the system.

Finally, the Surgeons General did not enter information into the disability submodule of CCQAS for compensable active duty medical malpractice cases. As discussed earlier, none of the MTFs visited were aware of the requirement for Medical Evaluation Boards to identify and report cases of compensable active duty medical malpractice to the Offices of the Surgeons General. To improve visibility of PCEs and medical malpractice claims, MHS healthcare managers should consistently use CCQAS.

Inconsistencies in the CCQAS Risk Management Module. For those MTFs using the CCQAS risk management module, inconsistencies existed when reporting PCEs, filed, and paid claims as well as disability claims. The risk management module contains four submodules: the incident management, the JAGMAN, the claims management, and the disability management submodule. Although two of the Military Departments have already adapted the incident and JAGMAN submodules to report PCEs, the submodules were not developed for this purpose.

Incident Management Submodule. Inconsistent and incomplete use of the incident and JAGMAN submodules for CCQAS prevented full visibility of PCEs across the MHS. Although the Regulation does not specify where to report PCEs in the system, the Army and Navy tried to use the incident and JAGMAN submodules as a method to record PCEs in CCQAS. The Army modified the incident management submodule of CCQAS to assist Army MTF personnel with documenting the facts and findings associated with incidents identified as PCEs. The Navy developed the JAGMAN submodule, which assists Navy MTF personnel in documenting the facts and findings from investigations convened at Navy MTFs. As of August 2006, the Air Force had not adapted and did not use the incident submodule of CCQAS to enter PCE information. The Air Force MTFs we visited report PCEs to the Air Force Surgeon General outside of CCQAS.

The Army and Navy submodules capture many of the same types of information in CCQAS. However, the Army and Navy data field names were not consistent within the submodules. Additionally, completion of some data fields is optional in one Military Department and required by another. Because of Military Department business rules, only Army and Navy MTFs and their respective Offices of the Surgeons General, can see PCE information. Army and Navy PCE information is not visible to other Military Departments or to ASD(HA)

healthcare managers. Additionally, the Military Departments have stated the incident submodule does not include all data fields necessary for risk managers to manage PCEs.

Claims Management and Disability Management Submodules. Inconsistent and incomplete use of the Claims Management and Disability Management submodules of CCQAS does not facilitate joint analysis of filed and paid medical malpractice and disability claims across the MHS. The Claims Management and Disability Management submodules of CCQAS help personnel record malpractice and disability claims involving their MTFs. The submodules enable MTFs to record details about incidents underlying medical malpractice claims as well as dates and assessments made during the processing of a claim. To fit their respective needs, each Military Department altered the submodules. Although many of the fields are the same, no consistency exists among the Military Departments in which fields are mandatory to populate. Additionally, ASD(HA) healthcare managers cannot oversee filed and paid medical malpractice claims and disability claims until after the Offices of the Surgeons General complete their review and release the information to the Department of Legal Medicine. The legal and administrative processes associated with management and closure of medical malpractice claims in DoD can be lengthy.

Closing Paid Claims. The Navy needs to determine why its percentage of filed and paid claims reported to the Department of Legal Medicine was significantly lower than the Army and the Air Force. The CCQAS claims and disability submodules include historical claim information from Military Department legacy systems. CCQAS also includes the current claim information at the MTF level as well. MTF risk managers must input paid claims and then electronically release information to the Offices of the Surgeons General through CCQAS. The Offices of the Surgeons General complete their review and electronically release filed and paid claims by way of CCQAS to the Department of Legal Medicine at the Armed Forces Institute of Pathology for analysis and review. As of June 2006, the Army released 4,873 of 5,472 claims (89 percent) to the Department of Legal Medicine and the Air Force released 2,355 of 2,822 claims (83 percent). However, the Navy released only 144 of 1,489 claims (10 percent). The Surgeon General of the Navy should review and validate its inventory of claim information, determine those claims eligible for release as required by the Regulation, and submit those claims in a timely manner to the Department of Legal Medicine.

To ensure the MHS has complete and timely visibility over PCEs and all claim information, the Office of the ASD(HA) and the Military Departments should assess whether the information captured in the risk management submodules contains information that can help management facilitate MHS-wide analysis. The Office of the ASD(HA) should also require standard risk management modules that can help track and trend PCEs, filed, and paid claims as well as disability claims. In addition, the Military Departments should use uniform data fields to input information. Consistent information and real-time access to open claim information in CCQAS will enable healthcare managers for the ASD(HA) to have complete and timely visibility of PCEs, and medical malpractice and disability claims. Complete and up-to-date information will also let healthcare managers identify trends and monitor healthcare in the MHS.

Patient Safety and Risk Management Reporting

The MHS does not have a method for linking patient safety and risk management events that are determined to be PCEs. As a result, healthcare managers for the ASD(HA) cannot follow the life cycle of a medical malpractice or disability claim.

Patient Safety Program. The Regulation requires that MTFs, through participation in a PSP, identify and report actual and potential problems in medical systems and processes and implement effective actions that will improve patient safety and healthcare quality throughout the MHS. Specifically, the objectives of the PSP are to improve coordination of patient safety activities across the Military Departments, develop an analysis plan for patient safety data to uncover opportunities for improvement in the MHS, create a culture of trust in reporting medical errors, and increase patient awareness and involvement in patient safety initiatives. The PSP also maintains oversight of the Patient Safety Center reporting system.

Risk Management Program. DoD Directive 6025.13 requires that MTFs implement active systems and programs for risk management that will reduce liability risks associated with actual or alleged cases of medical malpractice and use those systems and programs to reinforce other medical quality assurance program activities. Army Regulation 40-68, "Clinical Quality Management," February 26, 2004, emphasizes collaboration among organizational staff members who are responsible for risk management, patient safety, and MTF safety as well as occupational health and integrating these processes to avoid redundancies. BUMED Instruction 6010.21, "Risk Management Program," October 29, 1996, requires that risk management programs be as standard as possible. Air Force Instruction 44-119, "Clinical Performance Improvement," June 4, 2001, requires that a coordinated approach to improving patient care requires an intensive, integrated, and collaborative systems approach by all disciplines in the MTF and that every effort must be made to jointly plan and carry out performance improvement and risk management programs and activities.

Interfacing Patient Safety and Risk Management Information. In FY 2007, 9 of the 70 MTFs will began using an automated patient safety system for reporting near miss and adverse events. The system will provide more consistency in reporting MTF medical incidents. The system will not, however, provide visibility of detailed information above the Offices of the Surgeons General. To oversee the DoD PSP, information other than summary statistics by MTF is necessary at the ASD(HA) level. Such oversight will enable quality assurance personnel to share information related to error prevention and quality improvement throughout the MHS. Patient safety and risk management for the MTFs are important components of an MTF quality assurance program. However, programs for patient safety and risk management also use two different reporting systems that do not interface or link patient safety events that are later determined to be potentially compensable. Not linking events prevents visibility over medical incidents that are initially recognized as adverse events, through the process that may lead to a medical malpractice or disability claim.

An automated interface that links information from the patient safety program to the risk management program would allow DoD to track the life cycle of a medical incident from identification of the event in the PSP to recognition of the event as a PCE in the risk management system. An automated interface would also enable healthcare managers for the ASD(HA) to reconcile patient safety events to filed medical malpractice claims or disability claims in the risk management program.

Conclusion

The medical quality assurance program in DoD provides services that help deliver safe and effective healthcare to beneficiaries. The program helps healthcare managers make informed decisions about quality assurance. Opportunities exist for improving the oversight and reporting of medical events in the MHS. The ASD(HA) and the Military Departments should provide complete and consistent guidance for identifying, categorizing, reporting, and monitoring the life cycle of medical incidents in both the patient safety and risk management programs. Additionally, the MHS needs consistent and uniform functional area reviews that will provide specific and meaningful comparisons with benchmarks for the MTFs, for the Military Departments, and for civilian hospitals.

In 1998, Public Law 105-174 required appointment of an independent panel to evaluate measures taken to improve the quality of care provided by the MHS. In its report, the panel recommended that DoD reestablish the Quality Management Report to aid in early identification of MHS compliance problems. The panel further states in their report that the Quality Management Report should be reestablished and improved as a:

> . . . comprehensive information product for communicating with and educating leadership . . .on the status of quality in the MHS; and, as a vehicle to facilitate meaningful, specific comparisons among the Services, the Federal agencies, and the civilian healthcare sector, especially in the risk management and patient safety arena.

The Office of the ASD(HA) reestablished the annual Quality Management Report that discusses the quality of health care furnished under the DoD MHS. The quality management report must discuss the quality of healthcare measured from statistical and customer satisfaction factors that the ASD(HA) determines to be appropriate. Implementation of the recommendations will better enable healthcare managers at all levels to compare and trend patient safety and risk management information. Implementation of the recommendations should also provide more in-depth information to healthcare managers in the Office of the ASD(HA) for management and oversight of the programs for MHS patient safety and risk management.

As DoD moves toward increased joint operations, the ability of the MHS to both share and compare data becomes more critical. The quality assurance program is another opportunity to improve joint operations by providing healthcare managers complete and timely visibility of all medical incidents involving active duty members, retirees, and dependents.

Management Comments on the Finding and Audit Response

In addition to commenting on the recommendations, the ASD(HA), the Assistant Secretary of the Army (Manpower and Reserve Affairs), the Army Surgeon General, the Assistant Secretary of the Navy (Manpower and Reserve Affairs), and the Chief, Bureau of Medicine and Surgery commented on the finding. We revised sections of the report because of some of the management comments. Unsolicited comments on recommendations and comments related to the background and finding are discussed in Appendix B.

Recommendations, Management Comments, and Audit Response

1. We recommend that the Assistant Secretary of Defense (Health Affairs):

a. Revise DoD Regulation 6025.13-R to require that:

(1) Military Department legal office representatives participate when evaluating any adverse event as potentially compensable events at military treatment facilities.

(2) Risk management personnel consider all adverse events for active duty members when making determinations for potentially compensable events.

(3) The Physical Evaluation Board Liaison Officer report to the risk manager at each military treatment facility any allegation of injury from active duty members that may have occurred as a result of medical care provided in the military health system.

(4) Approving officials of a Medical Evaluation Board, as part of the Medical Evaluation Board approval process, identify and report to the risk manager any instance of suspected active duty adverse events.

(5) The risk manager, rather than the senior medical officer, monitor Physical Evaluation Board disability decisions and report to the Surgeon General any separation or retirement that was the result of medical malpractice.

(6) Specific medical incident information necessary to monitor the DoD Patient Safety Program is available to healthcare managers. Such information should, at a minimum, provide healthcare managers for the Assistant Secretary of Defense (Health Affairs) visibility of actual and potential problems in the military health system.

(7) Military treatment facilities consistently document with uniform content and standard format the results of functional area reviews. To develop the content, format and frequency of reports, healthcare

managers for the Assistant Secretary of Defense (Health Affairs) should coordinate with Military Department healthcare managers.

(8) The Military Departments identify and establish a centralized quality assurance focal point in each military treatment facility to ensure that all elements of functional area reviews are performed and consolidated.

(9) Healthcare managers for the Assistant Secretary of Defense (Health Affairs) and the Military Departments develop uniform reporting standards and consistent terminology for near misses, adverse/actual events, sentinel events, and potentially compensable events.

b. Require consistent and comprehensive use of the risk management submodules of the Centralized Credentials and Quality Assurance System for the Military Departments. Consistent and comprehensive use should include full and timely reporting of potentially compensable events, open and paid claims as well as active duty disability claims.

c. Develop a list of uniform data fields that are mandatory to populate in the risk management submodules of the Centralized Credentials and Quality Assurance System. Healthcare managers for the Assistant Secretary of Defense (Health Affairs) should determine the information in the risk management submodules that can help management facilitate military health system wide analysis and if the incident submodule is an adequate tool for reporting information on potentially compensable events.

d. Establish an interface between the Patient Safety Reporting System and the Centralized Credentials and Quality Assurance System to facilitate the exchange of information on medical incidents determined to be potentially compensable events.

ASD(HA) Comments. The ASD(HA) concurred with comments on the findings and conclusions detailed in the draft report concerning the Department's quality assurance procedures for identifying and reporting medical incidents. The ASD(HA) also concurred with our recommendations and stated that the recommendations would help strengthen DoD oversight processes. Specifically, the ASD(HA) stated that the Office of the Deputy Assistant Secretary for Clinical and Program Policy is currently revising DoD Regulation 6025.13, in coordination with the Military Departments, and plans to incorporate the Inspector General, DoD, recommendations into the revision. The ASD(HA) stated that an interface between patient safety and risk management systems would be appropriate when the related policies, business processes, and functional requirements are changed. The ASD(HA) also stated that a review of functional area requirements is ongoing and that consistent terminology will be developed. Finally, the ASD(HA) recommended that Recommendation 1.d. be changed to establish an interface that allows a unidirectional flow of data between the Patient Safety Reporting system and CCQAS. The ASD(HA) also made similar comments on the finding text supporting the interface recommendation.

Audit Response. We consider the ASD(HA) comments and planned actions responsive. The ASD(HA) incorporation of the recommendations into the

Regulation revision should result in consistent implementation of the DoD patient safety and risk management programs. The ASD(HA) comment that the revision is being closely coordinated with the Military Departments is encouraging. A forum that includes personnel responsible for the patient safety and risk management programs in DoD helps achieve a consensus of improvements that are needed. The revised Regulation should assist healthcare managers at all levels in monitoring and improving the quality assurance program in the MHS. Although we accept the ASD(HA) proposal to use a unidirectional interface as fully responsive to our recommendation, we did not change Recommendation 1.d. or the body of the report because the recommendation as stated provides the ASD(HA) with the flexibility to establish the best solution for an interface and determine the data targeted for exchange.

Military Department Comments. Although not required, the Army Surgeon General and the Air Force Surgeon General commented on Recommendation 1. We considered the comments but did not revise the recommendation based on the comments. See Appendix B for a discussion of the Army Surgeon General and Air Force Surgeon General comments on Recommendation 1.

2. We recommend that the Surgeons General of the Military Departments revise and update quality assurance regulations and instructions consistent with a revised DoD Regulation 6025.13-R. In the interim, the Military Departments should:

a. Require that risk management personnel:

(1) Include adverse events for active duty members when making potentially compensable event determinations.

(2) Monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

b. Establish procedures that require Physical Evaluation Board Liaison Officers report active duty member allegations of injury resulting from medical care to the military treatment facility risk manager for evaluation as a potentially compensable event.

c. Establish procedures requiring that approving officials of Medical Evaluation Boards identify and report any instances of possible active duty adverse events to the risk manager for a military treatment facility.

d. Establish a central quality assurance focal point in each military treatment facility to oversee the centralized reporting of functional area reviews.

Army Comments. The Army Surgeon General concurred with all of Recommendation 2., except for Recommendation 2.d. The Assistant Secretary of the Army (Manpower and Reserve Affairs) concurred with the response provided by the Army Surgeon General. Specifically, for Recommendation 2.a.(1) and 2.a.(2), the Army Surgeon General stated that Army Regulation 40-68 already requires that active duty adverse events be included in PCE determinations and

that risk managers monitor the Physical Evaluation Board disability decisions and report to the Surgeon General. The Army Surgeon General will clearly state this requirement in the revision to Army Regulation 40-68. The Army Surgeon General also stated that medical care that may have caused an injury may have occurred at a different MTF than the one where the Medical Evaluation Board case is presented. For Recommendation 2.b., the Army Surgeon General agreed to work with the patient administration division to require PEBLO reporting of active duty member allegations of injury to the MTF risk manager. On Recommendation 2.c., the Army Surgeon General stated he will emphasize procedures for Medical Evaluation Board approving officials to report active duty adverse events to risk managers.

The Army Surgeon General nonconcurred with Recommendation 2.d. to establish a central quality assurance focal point in each MTF. The Army Surgeon General stated that functional area reviews are outdated and overly prescriptive and that the current level of detail should be deleted from the Regulation. The Army Surgeon General also stated that DoD requirements for tracking and comparing functional area results should be predicated on current accrediting agency performance improvement processes. Additionally, the Army Surgeon General stated that if a central focal point is needed for other reasons, it already exists at each MTF in the quality management office.

Audit Response. The Army Surgeon General comments on Recommendations 2.a., 2.b., and 2.c. are fully responsive. We recognize that active duty adverse events may have occurred at the same MTF where the Medical Evaluation Board is located or at another MTF. We also recognize that the event may have happened many years before the Medical Evaluation Board and Physical Evaluation Board process occurs. It may be necessary for the MTF and the Surgeon General risk manager to coordinate a review of the event. The revised Regulation should assist MTF risk managers and other healthcare personnel in tracking the complete life cycle of an adverse event. Time delays may occur in the Medical and Physical Evaluation Board process which further supports the need for comprehensive and complete reporting of all adverse events.

The Army Surgeon General comments on Recommendation 2.d. are not responsive; therefore we request that the Army Surgeon General reconsider his position. We agree that some of the functional area review requirements may not be up-to-date and may be subject to further change. We support the ASD(HA) efforts to revise this section of the Regulation, because we maintain that functional area reviews are a critical part of a successful quality assurance program. This condition does not invalidate the recommendation, which will allow complete and consistent reporting of functional area review results.

We disagree with the Army Surgeon General statement that the quality management office is the central focal point for functional area reviews. To complete the reviews and assist in comparing quality assurance information, the functional area review results should be centralized in one location at the MTF. Under the current process, we had to request copies of the functional area reviews from multiple locations within each MTF visited. We also had to meet with personnel from numerous clinical departments and other medical support areas to obtain documentation related to functional area reviews. We request that the

Army Surgeon General provide additional comments to Recommendation 2.d. on the establishment of a quality assurance focal point in each MTF.

Navy Comments. The Assistant Secretary of the Navy (Manpower and Reserve Affairs), forwarded detailed comments from the Chief, Bureau of Medicine and Surgery, who is also the Navy Surgeon General. The Navy Surgeon General concurred with all of Recommendation 2. Specifically, the Navy Surgeon General agreed to update the BUMED quality assurance regulations consistent with a revised Regulation. For Recommendation 2.a.(1), the Navy Surgeon General stated that risk managers currently evaluate all adverse event reports regardless of patient status and that he would define a process to assist MTF risk managers in identifying active duty adverse event reports. For Recommendation 2.a.(2), the Navy Surgeon General will also align BUMED's policies with the revised Regulation for MTF risk managers to monitor Physical Evaluation Board disability decisions and provide guidance to them to identify cases requiring monitoring and additional investigation, but expressed concern with the length of time that it currently takes to go through the Medical Evaluation Board and Physical Evaluation Board process.

On Recommendation 2.b., the Navy Surgeon General will advise commanding officers to direct the PEBLO at each MTF to report active duty concerns to the MTF risk manager. For Recommendation 2.c., the Navy Surgeon General stated that he would advise MTF commanding officers to refer any Physical Evaluation Board cases where medical care is called into question to the MTF risk manager for further evaluation. The Navy Surgeon General agreed with Recommendation 2.d. to establish a central quality assurance focal point in each MTF to oversee the centralized reporting of functional area reviews. Finally, the Navy Surgeon General agreed to advise MTFs to establish a process to assure that the results of required reviews are communicated to leadership personnel.

Audit Response. We consider the Navy Surgeon General response to Recommendations 2.a.(1), 2.a(2), 2.b., 2.d. to be fully responsive. Although the Navy Surgeon General stated that risk managers evaluate all adverse patient events, we found that the risk manager at one Navy MTF did not always consider active duty adverse events when making PCE determinations. The Navy Surgeon General proposed interim action to define a process to assist the MTF risk manager in identifying active duty adverse events will strengthen current requirements. The Navy Surgeon General also raised a legitimate concern with the length of time between an episode of care or treatment and when the active duty member may enter the Medical and Physical Evaluation Board process. Those concerns further support the need for comprehensive identification and tracking of all active duty adverse events.

The Navy Surgeon General comments on Recommendation 2.c. are partially responsive. We request that the Navy Surgeon General clarify the Navy's position regarding MTF commanding officers referring Physical Evaluation Board cases to risk managers for further evaluation. Commanding officers may delegate Medical Evaluation Board approving authority to another individual and not participate in the Medical Evaluation Board process. We emphasize that Medical Evaluation Board approving officials, not commanding officers, should identify and report all cases where medical care is called into question to the MTF risk manager, including those not forwarded to Physical Evaluation Boards. We

request that the Navy Surgeon General explain how cases that are not forwarded to Physical Evaluation Boards will be handled and clarify who should identify and report cases to the MTF risk manager.

Air Force Comments. The Air Force Surgeon General concurred with the recommendations. On Recommendation 2.a.(1), the Air Force Surgeon General agreed that the identification and analysis of PCEs on all beneficiaries is an important patient safety and risk management process and that early legal participation is vital for preventing financial loss. The Air Force Surgeon General also stated that the Air Force Medical Service proposes to include PCEs and the results of its medical incident investigations in a CCQAS PCE module, but explained that CCQAS does not currently have the capability to capture PCEs and that PCEs are only visible at the MTF level. The Air Force Surgeon General stated that to fully support the recommendation, DoD must develop a PCE tab in the CCQAS risk management module that includes an appropriate workflow process of the events.

On Recommendations 2.a.(2)., 2.b., and 2.c., the Air Force Surgeon General stated that active duty adverse events that lead to Medical or Physical Evaluation Board actions should be reported to the MTF risk manager. The Air Force Surgeon General stated that to implement the recommendation, the revised Regulation must require change in Air Force policy for identifying possible medical malpractice events within the medical evaluation process. The Air Force Surgeon General also agreed with Recommendation 2.d. and stated that functional area reviews vary by MTF, measure clinical performance, and are monitored by the Joint Commission on Accreditation of Hospital Organizations. The Air Force Medical Service will centrally collect and consolidate the functional area reviews required by accreditation agencies, as well as any additional review required by DoD.

Audit Response. We consider the Air Force Surgeon General response to be fully responsive. We note the Air Force Surgeon General comment regarding the DoD development of a PCE tab in CCQAS. In Recommendation 1.c., we asked that ASD(HA) determine whether the incident submodule is an adequate tool for reporting information on PCEs. If necessary, the ASD(HA) should provide the resources to upgrade CCQAS submodule capabilities that will assist the ASD(HA) and the Military Departments in MHS-wide analysis of PCEs.

ASD(HA) Comments. Although not required, the ASD(HA) commented on Recommendation 2. See Appendix B for a discussion of the ASD(HA) comments.

3. We recommend that the Surgeon General of the Navy review and validate its inventory of claim information, determine those claims eligible for release as required by the Regulation, and submit those claims in a timely manner to the Department of Legal Medicine.

Management Comments. The Navy Surgeon General concurred with the recommendation and agreed to validate the inventory of paid claims and submit those claims to the Department of Legal Medicine at the Armed Forces Institute of Pathology. The Navy Surgeon General stated that since November 2006, BUMED has released additional claim information to the Department of Legal

Medicine; however, cases remain to be validated. Although not required to respond, the ASD(HA) also concurred with the recommendation.

Appendix A. Scope and Methodology

As requested by the Deputy Assistant Secretary of Defense (Clinical and Program Policy), the audit focused on visibility over the quality assurance process used to report medical incidents in the MHS. We reviewed DoD and Military Department policies and guidance from 1977 through 2004 relating to quality assurance, risk management, and patient safety procedures in the MHS. We also reviewed *Feres v. United States*, which determined that, under the Federal Tort Claims Act, the United States is not liable for injuries to active duty members of the armed forces sustained on active duty and not on furlough and resulting from the negligence of others in the armed forces. We also reviewed Military Department comments on the then draft DoD Directive 6025.13 and the then draft DoD Regulation 6025.13-R.

From May 2005 through June 2006, we met with representatives from the TRICARE Management Activity, the Armed Forces Institute of Pathology Department of Legal Medicine and Patient Safety Center, the Offices of the Surgeons General, and seven MTFs. At those locations, we obtained background information and summary information on quality assurance programs as well as open, closed, pending, and denied medical malpractice claims. We also met with personnel from the Army Claims Service, the Army Legal Services Agency, the Department of the Navy Office of the Judge Advocate General, and the Air Force General Counsel to the Surgeon General. At those locations, we documented the process for handling medical malpractice claims.

We also obtained summary information on medical disability retirements from the Army Physical Disability Agency, the Navy Physical Evaluation Board, and the Air Force Physical Disability Division. We documented the process for medical disability active duty retirements or separations.

To determine the MTFs that we would visit, we obtained summaries of MHS Standard Inpatient Data Records and the total number of dispositions by diagnostic related group for FY 2002. The FY 2002 information was the most readily available at the start of the audit. Using that information, we developed a compilation of total MTF enrollment populations, total dispositions, total number of obstetric dispositions (because of the high risk/high cost potential of malpractice claims), the type of facility, and the inpatient bed capacity. Using that information, we selected one medical center and one hospital at an Army, Navy, and Air Force location for review. We also selected a Navy hospital at a Marine Corps base. We limited our review to MTFs in the United States.

At the selected MTFs, we reviewed the programs for quality assurance, patient safety, and risk management and assessed the reporting of medical incident information. We did not assess the effectiveness of the quality assurance program within the MTF. As part of our limited quality assurance review, we analyzed compliance of each MTF with 13 functional areas and the 67 elements supporting the reviews. We did not determine the validity of the results or how often personnel addressed each element and accepted the format and information provided by MTF personnel. We also met with TRICARE Management Activity personnel to discuss the history, training, and capabilities of CCQAS.

We performed limited verification of the programs for patient safety and risk management. We assessed the programs for compliance with the requirements stated in the Regulation. We obtained lists of near miss, adverse, sentinel, and PCEs for 2004 and 2005. We also obtained listings of medical malpractice claims and potential product liability events for 2004 and 2005. For each category, we selected one or two events to determine the type of analysis conducted and if risk managers took action on the events. We also discussed the flow of information once an adverse or sentinel event occurs but did not verify the accuracy of the information reported. We reviewed reports on near miss, adverse and sentinel events, and actions taken to improve patient safety. We did not determine the validity and quality of the reviews but whether risk managers and patient safety personnel reviewed and initiated action if appropriate. We also documented the training curriculum used for educating clinical and administrative personnel about PSP activities.

We also reviewed policies and procedures for risk management and reviewed how risk managers identify and report PCE and claim information. We determined if risk managers investigated adverse events and PCEs and if they initiated action to mitigate unexpected effects of the event and protect the patient from additional injury. We also determined if risk managers reported PCEs, medical malpractice, and disability claims information. We met with personnel to discuss the Medical Evaluation Board process. We did not try to identify active duty compensable medical malpractice cases during our review.

We reviewed meeting minutes of the various hospital and departmental committees from January 2004 through September 2005. We reviewed guidance on the Military Departments' Disability Evaluation System. We also discussed with legal personnel their involvement in the identification of PCEs.

We performed the audit from May 2005 through August 2006 in accordance with generally accepted government auditing standards.

Use of Computer Processed Data. We used computer-processed data obtained from the Defense Manpower Data Center and the Standard Inpatient Data Records system to establish workloads at MTFs, but we did not evaluate the accuracy of the data. We also used limited information from the CCQAS system. We did not perform a formal reliability assessment of the CCQAS computer-processed data. However, we tested reliability of the data for each PCE and medical malpractice claim we selected at the MTF level.

We also obtained the number of paid and closed claims from the Military Departments and the Department of Legal Medicine. We did not establish reliability of the data because we did not evaluate the details of the paid and closed claims.

Government Accountability Office High Risk Area. The Government Accountability Office (GAO) has identified several high-risk areas in DoD. This report provides coverage of DoD strategic human capital management, which has been identified as a high-risk area.

Prior Coverage

Since 2001, the GAO and the DoD Inspector General (DoD IG) issued two reports related to quality assurance in the MHS. Unrestricted GAO reports can be accessed over the Internet at http://www.gao.gov/. Unrestricted DoD IG reports can be accessed at http://www.dodig.osd.mil/audit/reports.

GAO

GAO Report No. GAO-06-362, "Improved Oversight Needed to Ensure Consistent and Timely Outcomes for Reserve and Active Duty Service Members," March 2006

DoD IG

DoD IG Report No. D-2001-037, "Collection and Reporting of Patient Safety Data Within the Military Health System," January 29, 2001

Appendix B. Discussion of Management Comments on Background and Finding and Unsolicited Comments on Recommendations*

The ASD(HA), the Assistant Secretary of the Army (Manpower and Reserve Affairs), the Army Surgeon General, the Assistant Secretary of the Navy (Manpower and Reserve Affairs) and the Navy Surgeon General, provided comments on the Background and Finding sections of the report. The ASD(HA), the Army Surgeon General, and the Air Force Surgeon General also provided unsolicited comments on the recommendations. The additional comments and our responses that were not addressed at the end of the finding are shown below.

Incident Reporting (page 1). We stated that risk management programs help reduce the Government's liability by archiving PCE information for the possible defense of future malpractice cases. The Navy Surgeon General stated that PCEs are tracked to identify individual MTF or Navy-wide process and system issues and that PCE information helps to reduce future litigation by implementing risk reduction strategies. The Navy Surgeon General also stated that each PCE is unique and that they have very limited evidentiary value in defense of future specific malpractice claims.

Audit Response. The Regulation states that, when risk management determines that an adverse event is a PCE and after consulting with the judge advocate/legal counsel, the adverse event should be recorded with reports archived as support for possible future malpractice cases. We agree with the Navy Surgeon General that each PCE is unique; however, the information archived in relation to a PCE has value by providing support related to possible litigation. A PCE may result in filing a medical malpractice claim. Information that documents the facts of a patient's illness, their diagnosis, and treatment, is important for anticipated claims and legal actions and for risk management efforts to properly review such claims. Additionally, information related to active duty PCEs is also important, especially when active duty members have transferred to different duty locations.

Reporting Medical Malpractice to the Surgeons General (page 7). The Army Surgeon General and Navy Surgeon General provided comments. The Army Surgeon General stated that our comment regarding senior medical officer involvement with the risk management program is incorrect. The Army Surgeon General also stated that our comment that Army guidance did not address reporting of compensable disability retirement cases is incorrect. The Army Surgeon General stated that Army Regulation 40-68 addresses the review and reporting of incidents involving active duty service members, including Medical Evaluation Board cases. The Navy Surgeon General stated that BUMED has processed and released completed disability claim information to Armed Forces

* We considered comments on recommendations that were not addressed to the organizations as unsolicited.

Institute of Pathology and stated that the illustration at Appendix D does not include the transfer of final Physical Evaluation Board information from the PEBLO to the MTF risk manager.

Audit Response. We agree with the Army Surgeon General comment about senior medical officer involvement and revised the statement in the finding on page 7. We disagree with the Army Surgeon General comments regarding the reporting of compensable disability retirement or separation cases that result from medical malpractice. The references provided by the Army Surgeon General do not address reporting to his office after a disability or separation occurs.

The Navy Surgeon General comment that the Navy has processed and released completed disability claims to the Armed Forces Institute of Pathology Department of Legal Medicine is noted. As addressed in the finding, none of the Navy MTFs visited could demonstrate that they were reporting compensable disability retirements or separations caused by medical malpractice to BUMED. Additionally, the illustration located at Appendix D only shows opportunities to identify active duty adverse events, not the process for reporting those events.

Inconsistencies in the CCQAS Risk Management Module (page 11). The Army Surgeon General stated that his staff uses the risk management module of CCQAS and encourages improvements to the module. The Army modified the incident submodule of CCQAS to assist Army MTF personnel in documenting incidents identified as PCEs and stated that the functionality of the risk management module is in need of extensive upgrade.

The Navy Surgeon General stated that individual Navy MTFs do not enter paid claims in CCQAS and provided a brief description of the process BUMED uses before submitting completed claims to the Armed Forces Institute of Pathology. The Navy Surgeon General also stated that there are four submodules in the CCQAS risk management module: the JAGMAN, claims, disability, and incident submodules. The Navy Surgeon General stated that the JAGMAN is not an incident-reporting module and that BUMED did not agree with allowing Armed Forces Institute of Pathology access to data in the JAGMAN submodule prior to the completion of the review process.

Audit Response. The Regulation requires that MTF risk management personnel promptly report every PCE in CCQAS, and that personnel in the Offices of the Surgeons General report every medical malpractice claim, both filed and paid, into CCQAS. The intent of our discussion was to point out inconsistencies in the reporting of claim information in CCQAS and to show opportunities for improving the visibility of PCE and claim information. During the audit, we found that Offices of the Surgeons General personnel received claim payment information from the respective Military Department Judge Advocate General, and in some cases, forwarded that information to the MTF where the PCE originated. We also found examples where personnel in the Judge Advocate General's office submitted claim payment information to the MTF. We maintain that CCQAS should contain information that assists the ASD(HA) and the Military Departments in MHS-wide analysis of PCEs and related claim information. Consistent information and uniform use of CCQAS should provide complete and timely oversight of PCEs, medical malpractice, and disability claims. As a result of the Navy comments, we revised page 10 of the finding to

clarify the requirements of the Regulation. Military Department involvement with revisions to the Regulation should improve the timeliness and visibility of PCE and paid claim information.

In response to the Navy Surgeon General's comments, we did not recommend that the Armed Forces Institute of Pathology be able to view or access information in the JAGMAN submodule. We stated that consistency does not exist among the Military Departments in fields that are mandatory to populate the claims and disability submodules. We also stated that access is not available to ASD(HA) healthcare managers for filed and paid medical malpractice claims and disability claims until the Surgeons General complete their review and release the information to the Department of Legal Medicine. Rather than provide complete access to the JAGMAN, our intention was for senior healthcare managers to develop uniform data requirements to facilitate MHS-wide analysis. This is consistent with the Regulation that requires the Offices of the Surgeons General to enter into the CCQAS all medical malpractice claims, both filed and paid, and all adverse actions for electronic monitoring by the Department of Legal Medicine of the Armed Forces Institute of Pathology. Finally, we revised page 11 of the finding to acknowledge that there are four risk management submodules.

ASD(HA) Comments on Patient Safety and Risk Management Reporting (page 13). The ASD(HA) recommended that we change the text of the report to reflect a change in the deployment date for the Patient Safety Reporting system. We modified the final report to show that the Patient Safety Reporting system will not deploy until FY 2007.

Unsolicited Comments on Recommendations and Related Comments on Supporting Details in the Finding. This section addresses management comments on recommendations not made to them. Additionally, it addresses management comments on the finding that are directly related to a recommendation.

Army Surgeon General Unsolicited Comments. The Army Surgeon General concurred with Recommendation 1.a.(2)., 1.a.(3)., 1.a.(4)., and 1.a.(9). On Recommendation 1.a.(1), the Army Surgeon General stated that an experienced risk manager or physician can independently determine whether an adverse event is potentially compensable, and that legal counsel is not always necessary. On Recommendation 1.a.(5), the Army Surgeon General stated that both the risk manager and senior medical officer have a responsibility to identify and report compensable disability decisions to the Surgeon General. The Army Surgeon General also commented on Recommendation 1.a.(6), stating that more detailed medical incident information required for healthcare managers to monitor the DoD Patient Safety Program may result in decreased MTF reporting. The Army Surgeon General is concerned that monitoring the more detailed information may lead to actions that are perceived by the MTF as punitive.

On Recommendation 1.a.(7) and 1.a.(8). the Army Surgeon General nonconcurred and stated that the Regulation's requirements for functional area reviews are outdated and overly prescriptive. The current level of detail for the functional areas should not be included in the Regulation because accrediting requirements change more frequently than the Regulation. The Army Surgeon General also

stated that DoD requirements for tracking and comparing functional areas should be predicated on the performance improvement processes of the current accrediting agency.

On Recommendations 1.b. and 1.c., the Army Surgeon General stated that to ensure the consistent use of the CCQAS risk management submodules, DoD must devote personnel and funding resources for additional CCQAS development. The Army Surgeon General also stated that all Army MTFs are now using the module. On Recommendation 1.d., the Army Surgeon General concurred and commented that the deployment date for the pilot sites for the Patient Safety Reporting system had been delayed to March 2007. The Army Surgeon General supports the recommendation to link the patient safety and risk management systems for limited data exchange.

Audit Response. Although we agree that some adverse events are obviously PCEs, Recommendation 1.a.(1). would require risk managers and legal counsel to consider and evaluate all adverse events. We recognize that existing Army guidance requires legal consultation in the determination of PCEs, but DoD Regulation 6025.13 provides conflicting guidance on legal consultation. We agree with the Army requirement and maintain that legal counsel provides further insight into the legal merit of an adverse event for those cases that may not have been considered a PCE by a risk manager.

For Recommendation 1.a.(7), we agree that some of the functional area review requirements may not be up-to-date and may be subject to further change. This condition does not invalidate the recommendation, which will allow complete and consistent reporting of functional area review results. We support the ASD(HA) efforts to revise this section of the Regulation, because we consider that functional area reviews are a critical part of a successful quality assurance program. Close coordination on the revisions to the Regulation should provide the Military Departments with the opportunity to share their concerns on the currency of accreditation standards, uniform content, and format of the reviews. We continue to maintain that functional area consistency and completeness among the Military Departments will enhance the DoD ability to track and compare functional area review results with military and civilian benchmarks.

Regarding the Army Surgeon General comments on Recommendations 1.b. and 1.c. and related statements in the finding, we requested that ASD(HA) determine whether the incident submodule is an adequate tool for reporting information on PCEs. We also recognized that the Army modified the incident submodule of CCQAS to assist Army MTF personnel in documenting incidents identified as PCEs. We emphasize that CCQAS should contain information that assists the ASD(HA) and the Military Departments in MHS-wide analysis of PCEs and that the ASD(HA) should provide the resources necessary to accomplish this task. As stated in the report, the consistent use of CCQAS varied among the Army MTFs visited. We revised page 13 of the finding to acknowledge the change in the deployment date of the Patient Safety Reporting system.

Navy Surgeon General Unsolicited Comments. Although the Navy Surgeon General did not comment on the recommendation, he commented on details of the finding that support Recommendation 1. Related to Recommendation 1.a.(1), the Navy Surgeon General stated that reviewing and

screening incident reports is a clinical oversight responsibility and not a legal function. The Navy Surgeon General stated that Navy MTF risk managers screen cases and refer those that meet the criteria for a legal investigation to the Office of the Judge Advocate General for legal advice and expertise.

Related to Recommendation 1.a.(6), the Navy Surgeon General stated that the DoD PSP was established as a non-punitive reporting program to gain information about processes and systems and that identification of specific facilities beyond Navy identification adds nothing to the analysis at the MHS level. The Navy Surgeon General did not agree with the statement that "visibility beyond summarized and de-identifed information is necessary" for maintaining oversight of the DoD PSP.

Related to Recommendations 1.a.(9), 1.b., and 1.c., the Navy Surgeon General stated that the CCQAS risk management module is the appropriate venue for reporting claims and PCEs. The Navy Surgeon General stated that there is no official DoD PCE module and that BUMED does not support recording incident information into CCQAS. The Navy Surgeon General cited the need for standard PCE definitions, definitions of critical elements that trigger a PCE review, designation of a PCE tracking module; and use of the Patient Safety Reporting system for incident reporting instead of the CCQAS incident submodule currently used by the Army for PCE identification.

For Recommendation 1.d., the Navy Surgeon General disagreed on establishing an interface between the patient safety reporting system and CCQAS. The Navy Surgeon General stated that the CCQAS risk management module is a claims database and not an incident reporting system like the patient safety system. The Navy Surgeon General stated that DoD is engaged in an acquisition process to purchase a commercial product for a Patient Safety Reporting system that will provide a standardized event reporting system for the Military Departments for near miss and actual events.

Audit Response. As discussed in our response to the Army's concern with Recommendation 1.a.1., we maintain that consultation with legal counsel is necessary in PCE determinations.

On Recommendation 1.a.(6), the Regulation states that the ASD(HA) shall monitor the effectiveness of the DoD PSP. The Navy Surgeon General agreed that the new Patient Safety Reporting system will allow visibility of numerical summary information. As discussed in the finding, a healthcare manager stated that, to maintain oversight of the DoD PSP, visibility beyond summarized and de-identified information is necessary to heighten awareness and enhance visibility of patient safety activities across the MHS. The Military Departments and OASD(HA) should continue to coordinate on revising the Regulation to determine the information necessary to heighten awareness and enhance visibility of patient safety activities.

The Navy Surgeon General comments on reporting claims and PCEs in the CCQAS risk management module are similar to the Army and Air Force comments. The Navy Surgeon General is correct in his statement that DoD needs to establish criteria and guidance for determining what incidents should be considered as PCEs. The ASD(HA) stated that the revision of the Regulation is

being closely coordinated with the Military Departments. The Navy Surgeon General comments should be considered by the ASD(HA) in the revision of the Regulation. Close coordination with the Military Departments is necessary to ensure that business process changes include a PCE submodule in CCQAS. On Recommendation 1.a.(9), Military Department coordination on a revised Regulation should assist the ASD(HA) in developing a PCE definition that can be uniformly applied across the MHS.

Discussions on a draft of this report with BUMED risk management personnel revealed concerns with establishing an interface between the patient safety and risk management systems. Public Law 109-41, "The Patient Safety and Quality Improvement Act of 2005," provides legal privilege and confidentiality protections to information that is reported by health care providers to patient safety organizations. As of January 2007, the ASD(HA) had not received implementing guidance from the Department of Health and Human Services. As a result, the ASD(HA) could not determine how or when the public law would be implemented in DoD MTFs. We recognize that patient safety and risk management information must be separated to support the MHSs non-punitive patient safety culture. However, as discussed in the audit responses to ASD(HA) comments on Recommendation 1.d., the recommendation provides the flexibility for ASD(HA) to establish the best solution for linking targeted data fields from the patient safety program to the risk management program. DoD needs the capability to track the life cycle of medical incidents. The ASD(HA) suggested a unidirectional interface. We suggest that BUMED coordinate with the ASD(HA) to determine the best solution for establishing a link and determining the data targeted for exchange.

Air Force Unsolicited Comments. On Recommendation 1.a.(6)., the Air Force Surgeon General concurred and stated that the Air Force Medical Service will comply and provide medical incident and adverse event information, as required, for MHS-wide visibility of events. On Recommendation 1.b., the Air Force Surgeon General stated that the Air Force Medical Service will implement policy to use a PCE module in CCQAS when that capability is developed. For Recommendation 1.d., the Air Force Surgeon General stated that the Patient Safety and Quality Improvement Act of 2005 and other organizations do not support an interface between patient safety reporting and risk management systems. The Air Force Surgeon General stated that a culture of safety should be established, one which supports an open atmosphere for reporting and correcting errors. An interface between the patient safety system and the CCQAS risk management system will have a profoundly negative effect on the Air Force's efforts to build a safety culture, which fosters reporting of near miss and adverse events.

Audit Response. Regarding the Air Force Surgeon General comments on Recommendation 1.b., the Regulation requires CCQAS to be used to report PCEs, and filed, paid, and disability claims. We acknowledge that the Regulation did not specify where to report PCEs in the CCQAS risk management submodule and that there is not an official PCE submodule. However, the Army and Navy are using the incident and JAGMAN submodules as a method to record PCEs in CCQAS. As discussed earlier in our response to the Army, we asked ASD(HA) to determine if the incident submodule is an adequate tool for reporting information on PCEs. The ASD(HA) concurred and agreed to implement the

recommendation in the revised Regulation. The Air Force should coordinate closely with ASD(HA) personnel on using the CCQAS risk management submodule for reporting PCEs.

The Air Force had similar concerns to the Navy's about establishing an interface between CCQAS and the patient safety reporting system. See our response to the Navy Surgeon General comments on Recommendation 1.d.

ASD(HA) Comments on Recommendation 2. The ASD(HA) stated that the revisions to the Regulation would require both MTF leadership and the personnel involved with the Medical Evaluation Board process to identify allegations of injury to active duty members relating to medical care. The ASD(HA) stated that processes would be specified in the Regulation to:

- identify and investigate adverse medical events involving active duty members when they occurred;
- ensure active duty adverse event cases are held in the risk management system for long term visibility;
- establish procedures requiring approving officials of Medical Evaluation Boards to identify and report any instances of possible active duty adverse events to the risk manager;
- use the Physical Evaluation Board process (through the PEBLO) to report any allegations from an active duty member whose disability could be the result of an adverse event that occurred in an MTF; and,
- establish a process to report the date of a disability determination for an active duty service member because of an adverse event.

The Regulation's revision is being closely coordinated with the Military Departments.

Audit Response. We agree with the ASD(HA) comments.

Functional Area Reviews (page 33). The Navy Surgeon General stated that BUMED quality assurance guidance required many reviews that are now obsolete and are no longer valid requirements. The Navy Surgeon General stated that Navy MTFs are required to be accredited with the Joint Commission on Accreditation of Healthcare Organizations and must meet requirements that include pertinent functional areas.

Audit Response. We acknowledge the Navy Surgeon General comments that BUMED required reviews are now obsolete and that the reviews may no longer be valid requirements. We adjusted page 34 of Appendix C to reflect their concern in reference to their instruction. See our response to the Army regarding Recommendation 1.a.7. about the requirements to meet standards of the Joint Commission on Accreditation of Healthcare Organizations for further discussion on this issue.

Sentinel Events (page 35). The Navy Surgeon General also stated that its MTFs use the Joint Commission on Accreditation of Healthcare Organizations' definition for sentinel events, to include incidents involving serious psychological injury.

Audit Response. We acknowledge the Navy's use of the Joint Commission on Accreditation of Healthcare Organizations definition for reviewable sentinel events, however, as discussed in Appendix C, DoD 6025.13-Regulation defines sentinel events differently than the requirements of the DoD Patient Safety Center summary reports. Close coordination with the Military Departments on the revisions to the Regulation should alleviate the concerns about consistent terminology.

Appendix C. Additional Information Related to Quality Assurance Guidance

The following sections provide additional information related to the Finding.

Legal Counsel Participation in PCE Determinations. The Regulation states that risk managers should record PCEs after consulting with the MTF legal counsel, which would include legal counsel input as part of the determination process. Conversely, the Regulation also requires that the risk manager notify the MTF legal counsel within 24 hours of identifying a PCE. This requirement indicates that events are not subject to legal review because the PCE determination was made before the legal office was notified.

Military Department guidance and MTF implementation is inconsistent regarding legal review of events as compensable. Army Regulation 40-68 requires that risk managers and patient safety managers review adverse events in conjunction with the hospital attorney and clinical advisor when making a PCE determination. Despite the Army regulation, risk management personnel at one Army MTF determined that some adverse events were not potentially compensable and did not include the events in the meetings of the risk management committee that the hospital attorney attended. Navy and Air Force guidance did not require legal review. None of the Navy and Air Force MTFs visited involved legal personnel until after PCE determinations were made.

Identification of Alleged or Suspected Active Duty Adverse Events During the Medical Evaluation Board Process. Risk managers at the seven MTFs visited had no way of knowing how many active duty disability cases resulted from adverse events. Army Regulation 40-68, "Clinical Quality Management," February 26, 2004, requires review of any adverse event, including Medical Evaluation Board cases involving death or injury to a soldier, to determine if the cases might be PCEs. However, the Army does not require that a Medical Evaluation Board report to the risk manager any suspected adverse events, and none were reported. Guidance for the Navy and Air Force does not discuss reporting suspected adverse events as part of the Medical Evaluation Board process nor does it require review of Medical Evaluation Board cases to determine if the cases were PCEs. As a result, unidentified cases continue to go unreported.

Functional Area Reviews. Differences in information used to support functional area reviews consistently surfaced throughout the reviews of the 13 functional areas at the MTFs, and little consistency existed in the reviews. The Regulation should require a reporting format that includes frequency and content for the functional area reviews. The Regulation should require, and Military Departments should establish, focal points at the MTFs who can ensure that each element of the review is completed and consolidated. Finally, the Military Departments should comply with the review requirements of the Regulation.

Each of the Military Departments handled performance of functional area reviews differently. Army Regulation 40-68 requires completion of process improvement

functions on six functional areas identified in the Regulation. The Navy requires that MTFs have programs that continually monitor the quality and appropriateness of healthcare. BUMED Instruction 6010.13, "Quality Assurance Program," August 19, 1991, further identifies reviews in seven of the functional areas cited in the Regulation. Risk management personnel at BUMED stated that the requirement is obsolete and the reviews are no longer valid requirements. Air Force guidance requires reviews of high-risk, high-volume, problem-prone processes, and identifies seven of the Regulation's functional areas.

The functional area reviews consistently mentioned in Military Departments' guidance were surgical case, blood usage, drug use, medical record, and reviews of other departments or services that MTFs identified. In addition to the five reviews cited earlier, the Army included reviews of autopsy reports, the Navy included pharmacy and therapeutics monitoring and invasive procedure reviews, while the Air Force included reviews of autopsy reports and invasive procedures. Following are examples of what we found at the MTFs visited.

At one MTF, documentation for the elements was in multiple sources at multiple locations within the MTF. Personnel involved with quality improvement stated that the review elements for the Special Care Unit are actually addressed in command morning reports, annual competency training checklists, intensive care unit educational history reports, and peer reviews of healthcare provider records.

At another MTF, clinical personnel located nursing utilization resource summaries. That documentation supported Special Care Unit reviews throughout the MTF as well as MTF orientation and education programs. We verified that those items discussed each of the elements. The MTF did not, however, provide documentation on other elements that the Regulation requires for completing the functional area review.

MTF personnel at a third location could not provide documentation to support their review of the Special Care Unit. Personnel provided documentation indicating that the periodic performance record review completed on each physician in the MTF **may** (emphasis added) include a patient who was in a special care unit. We do not agree that those types of records satisfy the intent of a review of a special care unit. The record review did not specifically discuss all of the elements the Regulation identifies for a review of special care units. Additionally, because the documentation supported a review of the physician and not the unit, a review may or may not discuss the care of a patient within that special care unit. The MTF did not provide any other documentation that would support the review.

Quality Assurance Terminology. Clear and descriptive terminology is necessary for categorizing, identifying, and reporting medical incidents. Differences follow for the following terms: near miss, adverse, and sentinel event and PCEs.

Near Miss Events. The Regulation defines a near miss event as "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 **or did not harm** (emphasis added) the patient." The Patient Safety Center and the Military Departments define a near miss as any process variation or error that

could have resulted in harm to a patient, a visitor, or staff, but through chance or timely intervention **did not reach** (emphasis added) the patient. The definition in the Regulation would include incidents that reached, but did not harm, the patient such as medication errors with no subsequent harm or patient falls without injury as near misses. Because the incident reached the patient, the Patient Safety Center and Military Departments would report those examples as an adverse event. Under the Regulation, more events are near miss events while fewer are near miss events under the Patient Safety Center and Military Department definition. Comparisons of events across the MHS will not be accurate until personnel report events based on similar definitions.

Adverse Events. The Regulation defines an adverse event as "occurrences or conditions associated with care or service when they cause unexpected harm to a patient during such care or services." The Patient Safety Center uses the term "actual event" and defines it as an occurrence or condition associated with the provision of healthcare or services that may or **may not** (emphasis added) result in harm to the patient/beneficiary. A confusion or difference in reportable information can occur because events such as medication errors and patient falls reported as near misses according to DoD guidance are reportable as adverse events under the Patient Safety Center and Military Department definition even when there is no harm or permanent effect on the patient.

The Army defines an adverse event in the same way that the Patient Safety Center defines an actual event, and the Air Force is consistent in both terminology and definition. However, BUMED Instructions 6010.21 and 6010.23, "Participation in the Military Health System Patient Safety Program," December 18, 2002, define adverse events differently. One instruction implements the Regulation's definition while the other BUMED instruction defines an adverse event using the Patient Safety Center definition for actual event. The inconsistencies lead to fewer adverse events being identified under the Regulation while more adverse events are identified using the Patient Safety Center definition.

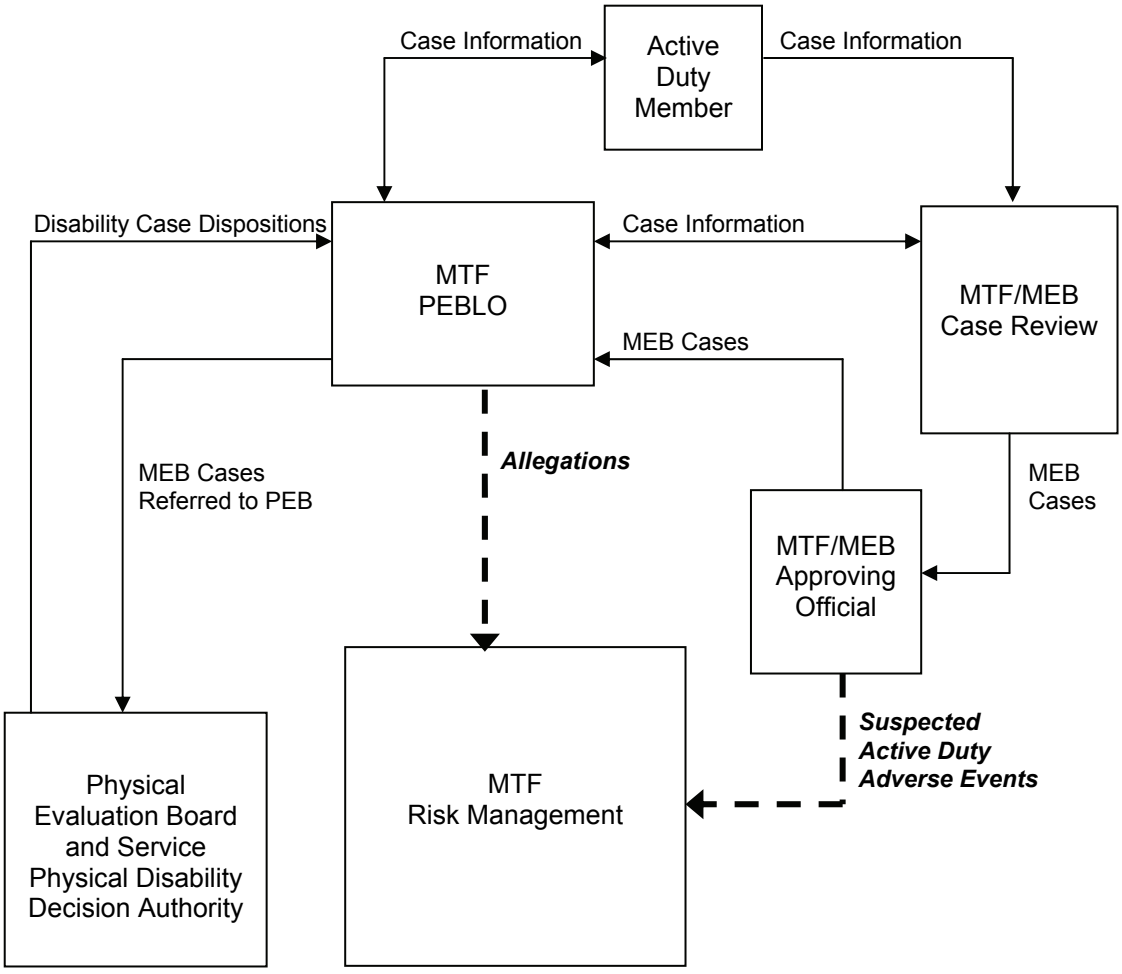
Sentinel Events. The Regulation defines sentinel events as "unexpected occurrences involving death or serious physical or psychological injury or risk thereof." Guidance from the Military Departments mirrors the DoD Regulation. However, the definition that the Patient Safety Center uses does not include serious psychological injury as a sentinel event. Sentinel events classified as serious psychological injury at the MTF may not be reported as sentinel events in Patient Safety Center summary reports.

Potentially Compensable Event. The Regulation defines a PCE as "an adverse event that occurs in the delivery of healthcare and services with resulting beneficiary injury. It includes any adverse event or outcome, with or without legal fault, in which the patient experiences any unintended or unexpected negative result." The Army definition is consistent with the Regulation. The Navy's definition of a PCE is more descriptive than the one in the Regulation and the Army regulation. BUMED Instruction 6010.13 states that a PCE is any event or outcome that occurs during medical or dental care in which the patient does not improve, suffers injury, or suffers illness of severity greater than ordinarily experienced by patients with similar procedures or illnesses. The Air Force does not clearly define PCEs in its guidance.

Essentially, no difference exists in the Regulation between the definitions of an adverse event and a PCE. Inconsistent definitions and use can cause different interpretations. An adverse event with "unexpected harm" and a PCE with "resulting beneficiary injury" mean the same thing. By definition, all adverse events are PCEs. During our review, we were advised that DoD did not intend to identify all adverse events as potentially compensable and that DoD should evaluate each event separately to determine financial risk. Establishing uniform and clear definitions should eliminate confusion on categorizing events as well as how and when events are reportable.

Appendix D. Opportunities to Identify Active Duty Adverse Events

The following illustration shows the flow of information when military personnel are referred for medical evaluation at an MTF. The illustration shows initiation of the case through disposition by the Military Department's Physical Evaluation Board and Physical Disability Decision Authority. We identified two opportunities within the medical evaluation process to isolate active duty adverse events that may have gone unreported when the active duty member received treatment at an MTF. The PEBLO and the Medical Evaluation Boards (MEB) approving official can report alleged and suspected medical incidents to the risk manager in conjunction with their medical evaluation duties. The risk manager, as the MTF focal point for making PCE determinations and entering the event into CCQAS, can notify the patient safety manager of previously unidentified events to review for improvements to patient safety at the MTF. The spaced dark-dashes from the PEBLO and approving official show opportunities for identifying possible adverse events during the medical evaluation process.



Appendix E. Functional Area Reviews

The Regulation requires medical staffs to monitor and evaluate the quality and appropriateness of patient care and clinical performance by completing regularly scheduled quality assurance reviews and meetings. The table below lists 13 of the 14 functional area reviews and the 67 elements that we reviewed at the seven MTFs visited. We did not review the "adverse outcomes screening" functional area because we included those elements in our review of patient safety and risk management.

Functional Areas and Elements for Review		
Functional Area	**Regulation Reference**	**Element for Review**
1. Surgical Case Reviews	C6.1.2.1.	Regularly scheduled surgical case review shall be performed and include appropriate review of all surgical procedures performed in the operating room, all ambulatory surgery, and all major invasive diagnostic procedures.
	C6.1.2.1.1.	Pre-operative, post-operative, and pathologic diagnoses shall be compared and discrepancies evaluated.
	C6.1.2.1.2.	Each case in which no tissue or non-diagnostic specimens are removed shall be evaluated for the acceptability of or the need for the procedure.
	C6.1.2.1.3.	List of tissue samples not reviewed, for example, those resulting from newborn circumcision or cataract extraction. Cases requiring more intensive evaluation should be identified and specifically documented in committee minutes.
	C6.1.2.1.4.	When sampling is employed, criteria that define appropriateness of or indications for surgery shall be defined and uniformly applied.
	C6.1.2.1.5.	All cases in which discrepancies have been identified shall be evaluated through peer review.
	C6.1.2.1.6.	Surgical case review of practitioners who are not members of the department of surgery.
2. Autopsy Case Reviews	C6.1.2.2.	The pre-mortem and postmortem clinical diagnoses and the presumptive and final autopsy diagnoses shall be compared for all autopsies. Disagreements among them shall be evaluated.
3. Anatomic Pathology Peer Reviews	C6.1.2.3.1.	At least 10 percent of all surgical cases from which the tissue samples have been submitted; as close as is possible to 100 percent review should be sought.
	C6.1.2.3.2.	Review of all permanent tissue sections shall be accomplished in a timely manner, as befitting the respective individual clinical situation.

Functional Area	Regulation Reference	Element for Review
4. Invasive Procedure Reviews	C6.1.2.4.	Invasive procedures shall be reviewed for quality and appropriateness. Review shall include comparison of pre- and post-procedure diagnosis and pathologic diagnosis; adverse or unexpected patient reactions and shall address patient notification of results.
5. Blood Usage Reviews	C6.1.3.1.1.	Review of blood component use.
	C6.1.3.1.2.	Review each confirmed transfusion reactions, to include clinical management. Possible transfusion reactions must be defined by medical staff.
	C6.1.3.1.3.	Evaluate cross-match-to-transfusion ratio; compare type and screen versus type and cross-match, and any suspected overuse.
	C6.1.3.1.4.	Adequacy of medical staff-approved policies and procedures relating to the distribution, handling, use, and administration of blood and blood components. Policies and procedures shall be reviewed annually.
	C6.1.3.1.5.	Adequacy of ordering practices for blood and blood products.
	C6.1.3.1.6.	Sampling must be statistically representative of cases and departments or services.
6. Drug Use Reviews	C6.1.4.1.	Evaluate prophylactic, therapeutic, and empiric use to ensure that all drugs are used in accordance with guidelines that address appropriateness, safety, and evaluation of effectiveness.
	C6.1.4.2.1.	High volume use.
	C6.1.4.2.2.	Identified from literature as a significant health risk.
	C6.1.4.2.3.	Known or suspected of high incidence of adverse reactions.
	C6.1.4.2.4.	Known or suspected to cause drug interactions.
	C6.1.4.2.5.	Used in patients at higher risk of adverse reactions.
	C6.1.4.2.6.	Medications known to be addictive or have significant drug issues identified through infection control and quality assurance activities.
	C6.1.4.3.	Drug dispensing errors, drug administration errors, and untoward reactions associated with administered intravenous additive solutions shall be properly documented and routinely reviewed through pharmacy and nursing quality assurance programs.
	C6.1.4.4.	Drug prescription errors documented and reviewed**.**

Functional Area	Regulation Reference	Element for Review
7. Pharmacy and Therapeutics Reviews	C6.1.5.1.	The development or approval at least annually of policies and procedures relating to the selection, distribution, handling, use, and administration of drugs, and diagnostic testing materials.
	C6.1.5.2.	Review of the drug formulary.
	C6.1.5.3.	Evaluation and approval of protocols for use of investigational drugs, as appropriate, in coordination with the clinical investigations committee.
	C6.1.5.4.	Definition and review of all significant untoward drug reactions.
8. Medical Records Review	C6.1.6.	There shall be a system for selection of records for review at regularly scheduled intervals (no less frequently than every quarter).
	C6.1.6.1.1.	A sample of records shall be reviewed for clinical pertinence; that is, the degree that the Inpatient Treatment Record reflects the diagnosis, results of diagnostic tests, therapy rendered, condition, and in-hospital progress of the patient, and condition of the patient at discharge. Inpatient Treatment Records shall also be reviewed for timely completion.
	C6.1.6.1.2.	Sampling shall represent the full scope of the MTF, reflect special attention to high-volume and high-risk diagnoses and procedures, and include a representative sample of all practitioners within a 12-month timeframe.
	C6.1.6.2.1.	History and Physical not completed within 24 hours after admission.
	C6.1.6.2.2.	Operative Report not dictated within 24 hours of surgery.
	C6.1.6.2.3.	Narrative Summary not dictated within 4 working days of patient discharge.
	C6.1.6.2.4.	Cover Sheet not completed within 4 working days of patient discharge.
	C6.1.6.2.5.	Inpatient Treatment Records not completed within 30 days of discharge shall be attributed to either an individual or an institutional problem. Summation of medical record delinquencies data shall be reported on a quarterly basis to the QA or appropriate committee. Appropriate data shall be entered into the provider activity file.
	C6.1.6.3.	Outpatient Treatment Records and Health Records shall be reviewed for clinical pertinence and completeness.
9. Anesthesia Review	C6.2.1.	Appropriateness of choice of anesthetic agent.
	C6.2.2.	Appropriateness of decision to reintubate.
	C6.2.3.	Appropriateness of length of stay in recovery room.
	C6.2.4.	Appropriateness of pre- and post-operative visit documentation.

Functional Area	Regulation Reference	Element for Review
9. Anesthesia Review (continued)	C6.2.5.	Anesthesia-related delays in surgery.
	C6.2.6.	Compliance with infection control policies and procedures.
	C6.2.7.	Anesthesia complications and management.
10. Emergency Medical Services (EMS)*	C6.3.1.	Adherence to protocols or criteria for handling emergencies.
	C6.3.2.	Review of culture results with patient follow-up to ensure appropriateness of therapy.
	C6.3.3.	Comparison of the final x-ray report with the initial interpretation by the emergency room physician.
	C6.3.4.	Review of ambulance records for appropriateness of treatment en route.
	C6.3.5.	Compliance with infection control policies and procedures.
	C6.3.6.	Review of referrals.
*EMS elements are examples of indicators to monitor and evaluate the quality of care.		
11. Ambulatory Care	C.6.4.1.	Appropriateness of diagnosis, treatment, and follow-up of frequently seen disease entities.
	C.6.4.2.	Appropriateness of outpatient care provided pre-and post-hospitalization for patients with chronic illnesses.
	C.6.4.3.	Follow-up of abnormal diagnostic tests.
	C.6.4.4.	Availability of radiology, laboratory, and pharmacy services, and the availability of the results of such services in a timely manner.
	C6.4.5.	Control and monitoring of patients on anticoagulants.
	C.6.4.6.	Compliance with infection control policies and procedures.
	C.6.4.7.	Appropriateness of appointment scheduling (including backlogs) based on the patient's condition.
	C6.4.8.	Follow-up of patients referred to other facilities to determine that assessment was accomplished in a timely manner.
	C6.4.9.	Follow-up of the return of outpatient treatment records to the servicing MTF to include x-rays of patients referred to other facilities.
12. Special Care Units	C6.5.1.	Appropriateness of admission to the unit (defined by written criteria).
	C6.5.2.	Appropriateness of medications and treatment ordered and given.
	C6.5.3.	Appropriateness of request for consultations.
	C6.5.4.	Availability of necessary physician and supporting staff.
	C6.5.5.	Orientation and education programs.
13. Other Departments and Services	C6.6.	Review and evaluation of other activities integral to provision of patient care.

Appendix F. Summary of Recommendations from the DoD Healthcare Quality Initiatives Report

The Healthcare Quality Initiatives Review Panel developed four general recommendations to improve quality in the MHS in response to quality improvement initiatives proposed by the then Acting ASD(HA).

- Implement a Unified Military Medical Command to achieve stability and uniformity of healthcare processes and resource acquisition and manage an error reduction and safety program based on root cause analysis, system process redesign, responsive resource management, and provider education.

- Achieve comparability of oversight and accountability across the TRICARE spectrum including both the direct care and purchased care components.

- Expand and refine credentials management for all healthcare professionals in the MHS to: enhance oversight, accountability, and career management (especially education) for such personnel; and support implementation of and develop experience with a centralized federal interagency credentials repository.

- Install robust and comprehensive data systems capable of measuring and monitoring quality outcomes, resource utilization, and healthcare costs.

Additionally, they developed 44 specific recommendations to improve quality in the MHS. The following seven recommendations relate to this report.

- Improve the DoD Risk Management Program by using an integrated tri-Service process to address cases, perform analysis, and provide coordination with external agency peer review and the Armed Forces Institute of Pathology Department of Legal Medicine.

- Improve timeliness of reporting to the National Practitioner Data Bank and eliminate associated backlogs in reporting.

- Require a uniform comprehensive process for identification and reporting of practitioners not meeting the standard of care in claims by active duty Service members (Feres Doctrine cases).

- Refine CCQAS to interface with other federal agency platforms, include meaningful, relevant, supportive clinical data; offer programmed and ad hoc capabilities for generating reports so that various levels of oversight and management can better manage personnel.

- Re-establish and improve the Quality Management Report as a vehicle to facilitate meaningful, specific comparisons among the Services, the Federal agencies, and the civilian healthcare sector, especially in the risk management and patient safety arena.

- Promulgate a definition of "quality" concerning MHS and TRICARE healthcare and related services that can be used to identify and position data and automation support initiatives in the future. Incorporate the definition into DoD Directive 6025.13, "Clinical Quality Management Program in the Military Healthcare System."

- Update DoD Directive 6025.13, "Clinical Quality Management in the Military Health Services System," and include a definition of quality for TRICARE clinical healthcare and related services to orient current and future measurement initiatives.

As a result of the panel's recommendations, DoD published DoD Directive 6025.13, "Medical Quality Assurance (MQA) in the Military Health System (MHS), May 4, 2004, and DoD 6025.13-R, "Military Health System (MHS) Clinical Quality Assurance (CQA) Program Regulation," June 11, 2004. DoD incorporated some of the panel's recommendations into the Directive and Regulation and implemented some of them in the MHS to improve overall quality management.

Appendix G. Glossary

The definitions that follow are frequently used by quality management, risk management, and patient safety personnel. The definitions are in DoD Regulation 6025.13-R and DoD Manual 6015.1, "Glossary on Healthcare Terminology," January 1999. The definitions may be changed based on revisions to the Regulation.

Actual Event is an occurrence or condition associated with providing healthcare or services that may or may not result in harm to the patient or beneficiary. Actual events may be the result of a commission or omission. Incidents such as patient falls or improper administration of medications are actual events even if there is no harm or permanent effect on the patient. (Patient Safety Center definition).

Adverse Event is an occurrence or condition associated with care or services when they cause unexpected harm to a patient during such care or services. Adverse events may be acts of commission or omission.

Armed Forces Institute of Pathology is a tri-Service agency that consults, educates, and researches in the field of pathology.

Joint Commission on Accreditation of Healthcare Organizations is a private, not-for-profit organization with representatives from the American College of Surgeons, American College of Physicians, American Hospital Association, American Medical Association, and American Dental Association. The purpose of the organization is to establish standards for operating of health facilities and services, conduct surveys, and determine accreditation status of medical facilities.

Medical Evaluation Board is a board convened at an MTF to report about the health and physical status of a member of the Armed Forces. The board recommends further evaluation and treatment or, as appropriate, renders an opinion about the future health status and related needs of the member.

Near Miss is 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 or did not harm the patient. Such events or circumstances are sometimes referred to as "close calls."

Physical Evaluation Board is a board that provides three stages of review for a Service member who has been referred by a Medical Evaluation Board of an MTF that believes that the member's physical condition raises questions about his or her ability to perform the duties of his or her office, grade, rank, or rating.

Potentially Compensable Event (PCE) is an adverse event that occurs during the delivery of healthcare and services and that results in injury to the beneficiary. A PCE includes any adverse event or outcome, with or without legal fault, in which the patient experiences any unintended or unexpected negative result.

Sentinel Events are unexpected occurrences involving death or serious physical or psychological injury or risk thereof.

Appendix H. Report Distribution

Office of the Secretary of Defense

Under Secretary of Defense (Comptroller)/Chief Financial Officer
    Deputy Chief Financial Officer
    Deputy Comptroller (Program/Budget)
Under Secretary of Defense for Personnel and Readiness
Assistant Secretary of Defense (Health Affairs)
General Counsel

Department of the Army

Assistant Secretary of the Army (Financial Management and Comptroller)
Auditor General, Department of the Army

Department of the Navy

Assistant Secretary of the Navy (Manpower and Reserve Affairs)
Naval Inspector General
Auditor General, Department of the Navy

Department of the Air Force

Assistant Secretary of the Air Force (Financial Management and Comptroller)
Auditor General, Department of the Air Force

Non-Defense Federal Organization

Office of Management and Budget

Congressional Committees and Subcommittees, Chairman and Ranking Minority Member

Senate Committee on Appropriations
Senate Subcommittee on Defense, Committee on Appropriations
Senate Committee on Armed Services
Senate Committee on Homeland Security and Governmental Affairs
House Committee on Appropriations
House Subcommittee on Defense, Committee on Appropriations
House Committee on Armed Services
House Committee on Oversight and Government Reform

Assistant Secretary of Defense (Health Affairs) Comments

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

OCT 3 0 2006

MEMORANDUM FOR DEPARTMENT OF DEFENSE INSPECTOR GENERAL
DIRECTOR, READINESS AND OPERATIONS
SUPPORT

SUBJECT: Report on Quality Assurance in the Department of Defense Healthcare System (D2005-D000LF-0147)

Thank you for the opportunity to review and provide comments on the draft report, "Quality Assurance in the DoD Healthcare System" (D2005-D000LF-0147), dated September 28, 2006.

I concur with comments to the findings and conclusions detailed in the draft report concerning the Department's quality assurance procedures for identifying and reporting medical incidents. I am appreciative of the Department of Defense Inspector General's (DoD IG) efforts to review this matter. I believe your recommendations will help strengthen our oversight processes.

The Deputy Assistant Secretary of Defense for Clinical and Program Policy is currently undertaking the revision of DoD 6025.13-R, "Military Health System Clinical Quality Assurance Program Regulation." The DoD IG recommendations will be incorporated into the reissuance. This effort is being closely coordinated with the military Services.

My points of contact on this issue are COL Gary Matteson (functional) at 703.681.1703 x5215 and Gunther Zimmerman (Audit Liaison) at (703) 681-3492, extension 4065.

William Winkenwerder, Jr., MD

Attachments:
As stated

DoD IG DRAFT REPORT–DATED SEPTEMBER 28, 2006
(D2005-D000LF-0147)
Agency Comments on Draft Report "Quality Assurance in the DoD Health System"

DEPARTMENT OF DEFENSE COMMENTS

Recommendation 1: We recommend that the Assistant Secretary of Defense (Health Affairs):

a. Revise DoD Regulation 6025.13-R to require that.

(1) Military Department legal office representatives participate when evaluating any adverse event as potentially compensable events at military treatment facilities.

(2) Risk management personnel consider all adverse events for active duty members when making determinations for potentially compensable events.

(3) The Physical Evaluation Board Liaison Officer report to the risk manager at each Military Treatment Facility any allegations of injury from active duty members that may have occurred as a result of medial care provided in the military health system.

(4) Approving officials of a Medical Evaluation Board as part of the Medical Evaluation Board approval process, identify and report to the risk manager any instance of suspected active duty adverse events.

(5) The risk manager, rather than the senior medical officer, monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

(6) Specific medical incident information necessary to monitor the DoD Patient Safety Program is available to healthcare managers. Such information should, at a minimum, provide healthcare managers for the Assistant Secretary of Defense (Health Affairs) visibility of actual and potential problems in the military health system.

(7) Military treatment facilities consistently document with uniform content and standard format the results of functional area reviews. To develop the content, format and frequency of reports, healthcare managers for the Assistant Secretary of Defense (Health Affairs) should coordinate with Military Department healthcare managers.

(8) The Military Departments identify and establish a centralized quality assurance focal point in each Military Treatment Facility to ensure that all elements of functional area reviews are performed and consolidated.

(9) Healthcare managers for the Assistant Secretary of Defense (Health Affairs) and the Military Departments develop uniform reporting standards and consistent terminology for near misses/actual events, sentinel events, and potentially compensable events.

b. Require consistent and comprehensive use of the risk management submodules of the Centralized Credentials and Quality Assurance System for all Military Departments. Consistent and comprehensive use should include full and timely reporting of potentially compensable events, open and paid claims as well as active duty claims.

c. Develop a list of uniform data fields that are mandatory to populate in the risk management submodules of the Centralized Credentials and Quality Assurance System. Healthcare managers for the Assistant Secretary of Defense (Health Affairs) should determine the information in the risk management submodules that can help management facilitate military health system wide analysis and if the incident submodule is an adequate tool for reporting information on potentially compensable events.

d. Establish an interface between the Patient Safety Reporting System and the Centralized Credentials and Quality Assurance System to facilitate the exchange of information on medical incidents determined to be potentially compensable events.

OASD (HA) RESPONSE: The Office of the Deputy Assistant Secretary for Clinical and Program Policy is currently in the midst of a revision of DoD Regulation 6025.13 "Clinical Quality Assurance in the Military Health System". The DoD IG recommendations are being incorporated into that process. Once the related policies, business processes, and functional requirements are changed to support the exchange of information on medical incidents determined to be potentially compensable events, an interface between Patient Safety and Risk Management systems would be appropriate. Consistent terminology will be developed and a review of the functional area reviews is occurring.

Recommendation 2: We recommend that the Surgeons General of the Military Departments revise and update quality assurance regulations and instructions consistent with a revised DoD Regulation 6025.13-R. In the interim, the Military Departments should:

a. Require that risk management personnel:

(1) Include adverse events for active duty members when making potentially compensable event determinations.

(2) Monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

b. Establish procedures that require Physical Evaluation Board Liaison Officers report any active duty member allegations of injury as a result from medical care to the Military Treatment Facility risk manager for evaluation as a potentially compensable event.

c. Establish procedures requiring that approving officials of Medical Evaluation Boards identify and report any instances of possible active duty adverse events to the risk manager for a Military Treatment Facility.

d. Establish a central quality assurance focal point in each Military Treatment Facility to oversee the centralized reporting of functional area reviews.

OASD(HA) Response:

Concur. In our revision of the regulation we will require both Military Treatment Facility leadership and officials involved with the Medical Evaluation Board process, identify allegations of injury as a result of medical care to active duty Service members (ADSM). Because definitive Medical Evaluation Board/Physical Evaluation Board actions may not take place until years after an adverse event, and may not take place in the Military Treatment Facility where the adverse medical event occurred, processes will be specified in the regulation to insure that the Services:

a. Identify and ensure prompt investigation of adverse medical events involving active duty service members at the time of the adverse event occurrence.
b. Hold ADSM cases potentially representing medical malpractice in long-term Risk Management visibility.
c. Establish procedures requiring that approving officials of Medical Evaluation Boards identify and report any instances of possible active duty adverse events to the risk manager for a Military Treatment Facility.
d. Provide a mechanism by which the Physical Evaluation Board process (Physical Evaluation Board Liaison Officers are well-positioned for this function) report any allegations from an ADSM that the disability being considered is possibly related to an adverse event occurring during care in a Military Treatment Facility.
e. Establish processes for notification of the date of a disability determination on an ADSM alleging disability due to an adverse medical event in an Military Treatment Facility. This date would be analogous to a paid medical malpractice

claim in terms of triggering steps leading to reporting to the Defense Practitioners Data Bank in cases where standard of care is determined not to have been met.

Recommendation 3: We recommend that the Surgeon General of the Navy review and validate its inventory of claim information, determine those claims eligible for release as required by the Regulation, and submit those claims in a timely manner to the Department of Legal Medicine.

OASD(HA) Response:
Concur

Final Report Reference

Revised page 13

DoD IG DRAFT REPORT – DATED SEPTEMBER 28, 2006
(D2005-D000LF-0147)
Agency Comments on Draft Report "Quality Assurance in the DoD Health System"

DEPARTMENT OF DEFENSE COMMENTS

TECHNICAL COMMENTS:

Current: Pg 13, bottom paragraph

In October 2006, 9 of the 70 Military Treatment Facilities begin using an automated patient safety system for reporting near miss and adverse events.

HA Response:, change October 2006 to FY07. Delays in Systems Qualification Testing of the electronic application will move initial deployment to second quarter FY07.

Current: Pg 14, first full paragraph

An automated interface that links information from the patient safety program to the risk management program would provide DoD a capability to track the life cycle of a medical incident from identification of the event in the Patient Safety Program to
recognition of the event as a Potentially Compensable Event in the risk management system.

HA Response: Change "An automated interface that links information…" to "An automated, unidirectional interface that links targeted data fields from the Patient Safety program to the ….."

Current: Pg 16, item d.

Establish an interface between the Patient Safety Reporting System and the Centralized Credentials and Quality Assurance System to facilitate the exchange of information on medical incidents determined to be potentially compensable events.

HA Response: Change "Establish an interface between the …." to "Establish an interface with unidirectional flow of data between the…."

Department of the Army Comments

DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT SECRETARY
MANPOWER AND RESERVE AFFAIRS
111 ARMY PENTAGON
WASHINGTON DC 20310-0111

SAMR

DEC 21 2006

MEMORANDUM FOR DOD INSPECTOR GENERAL, ATTN: DIRECTOR, READINESS AND OPERATIONS SUPPORT, 400 ARMY NAVY DRIVE, ALRLINGTON, VA 22202-4704

SUBJECT: Reply to Draft Audit Report on Quality Assurance in the Department of Defense (DoD) Healthcare System (Project D2005-D000LF-0147)

1. Reference memorandum, DASG-HPS, Office of the Surgeon General, 14 November 2006, subject as above.

2. I concur with the Office of the Surgeon General (OTSG) response to the audit conducted by the DoD Inspector General on Quality Assurance in the DoD Healthcare System.

3. Colonel Thomas is the Secretariat point of contact. He can be reached at (703) 697-2044, or by e-mail: richard.thomas@hqda.army.mil.

21 Dec 06

RONALD J. JAMES
Assistant Secretary of the Army
(Manpower and Reserve Affairs)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

14 NOV 2006

DASG-HPS

MEMORANDUM THRU ACTING ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)

FOR DOD INSPECTOR GENERAL, ATTN: DIRECTOR, READINESS AND OPERATIONS SUPPORT, 400 ARMY NAVY DRIVE, ARLINGTON, VA 22202-4704

SUBJECT: Reply to Draft Audit Report on Quality Assurance in the DoD Healthcare System (Project D2005-D000LF-0147)

1. We appreciate the opportunity to comment on your report. Our comments are enclosed.

2. Our point of contact is COL Doreen M. Lounsbery, MC, Deputy Chief, Quality Management Division, DSN 471-6195 or commercial (210)-221-6195; Ms. Donna Wright, Risk Manager, Quality Management Division DSN 471-6195 or commercial (210)-221-6195; or Mr. deWayne Beers, Internal Review and Audit Compliance Office, DSN 471-8148 or commercial (210) 221-8148.

FOR THE SURGEON GENERAL:

Encl

Gale S. POLLOCK
Major General
Deputy Surgeon General

Final Report Reference

OTSG / MEDCOM Command Reply to DOD Inspector General Report on
Quality Assurance in the DOD Healthcare System
Project D2005-D000LF-0147

1. The following are comments regarding the body of the report:

a. Page 5, Implementation of the DoD Quality Assurance Program, second bullet: Army Regulation 40-68 and MEDCOM policy already require the use of the risk management module of CCQAS. All Army MTFs are now using this module.

b. Page 5, Quality Assurance Guidance, fourth bullet: The functional area review requirements in DoD 6015.13-R are based upon Joint Commission on Accreditation of Healthcare Organization standards from 10-15 years ago. They need to be deleted from the regulation as recommended when this regulation was last revised. Specific measures should not be included in the regulation as accrediting requirements change more frequently than the regulation. Current, relevant measures that DoD wishes to follow centrally are better determined on an annual or semi-annual basis.

c. Page 7, first full paragraph regarding Appendix C: Does not address a common situation with Medical Evaluation Boards (MEB). The care that may have caused an injury is often received at one MTF and the MEB done at another. These may even cross service lines.

d. Page 7, the second paragraph under Medical Malpractice Reporting to the Surgeons General: States that the senior medical officer is not involved with the risk management program. That is generally incorrect. The senior medical officer is usually the Deputy Commander for Clinical Services and he/she also has responsibility for risk management.

Revised page 7

e. Page 7, last paragraph states that "Guidance from the Army and Air Force did not address reporting compensable disability retirement or separation cases that result from medical malpractice to the Surgeons General." This is incorrect. Paragraphs 13-2.c, 13-4.a (1), and 13-4b(1) of AR 40-68 all address the review and reporting of incidents involving active duty service members, including medical board cases.

f. Page 8, Functional area reviews. Non-concur with doing these as they are outdated and overly prescriptive. This level of detail should be deleted from the regulation (see 1b above). If comparison is to be made between the MHS and civilian benchmarks, the metrics must be contemporary. DoD requirements for tracking, trending, and comparison should be predicated on current accrediting agency performance improvement processes. The detail, which is subject to change, should be contained in the established standards of these agencies, not in the DoD regulation.

g. Pages 10-12 on CCQAS. Army Medical Department risk management staff use and encourage the improvement of the risk management module of CCQAS. The functionality of this application is in need of extensive upgrade.

Enclosure - Page 1

Final Report Reference

OTSG / MEDCOM Command Reply to DOD Inspector General Report on
Quality Assurance in the DOD Healthcare System
Project D2005-D000LF-0147

Revised page 13

h. Page 13-14, Linking Patient Safety and Risk Management Information. The first sentence is incorrect. The patient safety system has not been initiated at any MTFs to date. The estimated deployment at the pilot sites is now March 07. Army concurs with the recommendation to link the systems for limited data exchange.

2. Though not required, we offer the following comments regarding recommendations directed to the Assistant Secretary of Defense (Health Affairs). DODIG recommended that the Assistant Secretary of Defense (Health Affairs):

a. Revise DoD Regulation 6025.13-R to require that:

(1) Military Department legal office representatives participate when evaluating any adverse event as potentially compensable events at military treatment facilities.

Response: Concur, with comment. It is not always necessary. Some events are evident without the input of the legal advisor. An experienced risk manager or physician can independently make that determination.

(2) Risk management personnel consider all adverse events for active duty members when making determinations for potentially compensable events.

Response: Concur. Army regulation currently addresses this requirement.

(3) The Physical Evaluation Board Liaison Officer reports to the risk manager at each military treatment facility any allegation of injury from active duty members that may have occurred as a result of medical care provided in the military health system.

Response: Concur.

(4) Approving officials of a Medical Evaluation Board, as part of the Medical Evaluation Board approval process, identify and report to the risk manager any instance of suspected active duty adverse events.

Response: Concur.

(5) The risk manager, rather than the senior medical officer, monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

Enclosure - Page 2

OTSG / MEDCOM Command Reply to DOD Inspector General Report on
Quality Assurance in the DOD Healthcare System
Project D2005-D000LF-0147

Response: Concur, with comment. Both the risk manager and senior medical officer have a responsibility to identify and report these cases.

(6) Specific medical incident information necessary to monitor the DoD Patient Safety Program is available to healthcare managers. Such information should, at a minimum, provide healthcare managers for the Assistant Secretary of Defense (Health Affairs) visibility of actual and potential problems in the military health system.

Response: Concur, with comment. The more detailed the information that is required at higher levels of DoD may decrease the MTF reporting, if this leads to actions that are perceived to be punitive.

(7) Military treatment facilities consistently document with uniform content and standard format the results of functional area reviews. To develop the content, format and frequency of reports, healthcare managers for the Assistant Secretary of Defense (Health Affairs) should coordinate with Military Department healthcare managers.

Response: Non-concur. The functional area review requirements in DoD 6015.13-R are based upon Joint Commission on Accreditation of Healthcare Organization standards from 10-15 years ago. Specific measures should not be included in the regulation as accrediting requirements change more frequently than the regulation. Current, relevant measures that DoD wishes to follow centrally are better determined on an annual or semi-annual basis. Functional area reviews are outdated and overly prescriptive. This level of detail should be deleted from the regulation. If comparison is to be made between the MHS and civilian benchmarks, the metrics must be contemporary. DoD requirements for tracking, trending, and comparison should be predicated on current accrediting agency performance improvement processes. The detail, which is subject to change, should be contained in the established standards of these agencies, not in the DoD regulation.

(8) The Military Departments identify and establish a centralized quality assurance focal point in each military treatment facility to ensure that all elements of functional area reviews are performed and consolidated.

Response: Non-concur. See response in paragraph 2.a.(7) above.

(9) Healthcare managers for the Assistant Secretary of Defense (Health Affairs) and the Military Departments develop uniform reporting standards and consistent terminology for near misses, adverse/actual events, sentinel events, and potentially compensable events.

Response: Concur.

b. Require consistent and comprehensive use of the risk management sub modules of the Centralized Credentials and Quality Assurance System for the Military Departments. Consistent and comprehensive use should include full and timely reporting of potentially compensable events, open and paid claims as well as active duty disability claims.

Response: Concur, with comment: DoD must devote CCQAS development resources (personnel and funding) to make this happen.

c. Develop a list of uniform data fields that are mandatory to populate in the risk management sub modules of the Centralized Credentials and Quality Assurance System. Healthcare managers for the Assistant Secretary of Defense (Health Affairs) should determine the information in the risk management sub modules that can help management facilitate military health system wide analysis and if the incident sub module is an adequate tool for reporting information on potentially compensable events.

Response: Concur, with comment: DoD must devote CCQAS development resources (personnel and funding) to make this happen.

d. Establish an interface between the Patient Safety Reporting System and the Centralized Credentials and Quality Assurance System to facilitate the exchange of information on medical incidents determined to be potentially compensable events.

Response: Concur.

3. DODIG recommend that the Surgeons General of the Military Departments revise and update quality assurance regulations and instructions consistent with a revised DoD Regulation 6025.13-R. In the interim, the Military Departments should:

a. Require that risk management personnel:

(1) Include adverse events for active duty members when making potentially compensable event determinations.

Response: Concur. AR 40-68 already requires this.

(2) Monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

OTSG / MEDCOM Command Reply to DOD Inspector General Report on
Quality Assurance in the DOD Healthcare System
Project D2005-D000LF-0147

Response: Concur. AR 40-68 already addresses this, but it will be stated more clearly in the revision of the regulation which we will ~~be~~ published within the next 3 months.

b. Establish procedures that require Physical Evaluation Board Liaison Officers report active duty member allegations of injury resulting from medical care to the military treatment facility risk manager for evaluation as a potentially compensable event.

Response: Concur. Will work with Patient Administration Division to incorporate this into the PEBLO processes and appropriate regulations.

c. Establish procedures requiring that approving officials of Medical Evaluation Boards identify and report any instances of possible active duty adverse events to the risk manager for a military treatment facility.

Response: Concur. Same comment as 3a(2), above.

d. Establish a central quality assurance focal point in each military treatment facility to oversee the centralized reporting of functional area reviews.

Response: Non-concur. The functional area review requirements in DoD 6015.13-R are based upon Joint Commission on Accreditation of Healthcare Organization standards from 10-15 years ago. Specific measures should not be included in the regulation as accrediting requirements change more frequently than the regulation. Current, relevant measures that DoD wishes to follow centrally are better determined on an annual or semi-annual basis. Functional area reviews are outdated and overly prescriptive. This level of detail should be deleted from the regulation. If comparison is to be made between the MHS and civilian benchmarks, the metrics must be contemporary. DoD requirements for tracking, trending, and comparison should be predicated on current accrediting agency performance improvement processes. The detail, which is subject to change, should be contained in the established standards of these agencies, not in the DoD regulation. If a central focal point is needed for other reasons, it already exists at each MTF. It is the Quality Management office.

4. DODIG recommends that the Surgeon General of the Navy review and validate its inventory of claim information, determine those claims eligible for release as required by the Regulation, and submit those claims in a timely manner to the Department of Legal Medicine.

Response: Not-applicable, as this recommendation was addressed to Navy.

5. POCs for this command reply are COL Doreen M. Lounsbery, MC, Deputy Chief, Quality Management Divison and Ms. Donna Wright, Risk Manager.

Department of the Navy Comments

DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
1000 NAVY PENTAGON
WASHINGTON, D.C. 20350-1000

NOV 28 06

MEMORANDUM FOR INSPECTOR GENERAL

SUBJECT: Quality Assurance in the Department of Defense (DoD) Healthcare System

Department of the Navy (DON) has reviewed the draft report on Quality Assurance in the DoD Healthcare System. DON non-concurs with some of the DoD Inspector General audit team's recommendations. Specific DON comments from the Bureau of Medicine and Surgery are provided at attachment 1.

My point of contact in this matter is LCDR Karen Leahy, MSC, USN, Special Assistant for Health Affairs, Office of the Assistant Secretary of the Navy (Manpower & Reserve Affairs) at 703-693-0238 or Karen.leahy@navy.mil.

William A. Navas, Jr.
Assistant Secretary of the Navy
(Manpower and Reserve Affairs)

Attachment:
As stated

cc:
Chief, Bureau of Medicine and Surgery

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

IN REPLY REFER TO

5890
Ser M3/06UN093-000451
3 Nov 06

From: Chief, Bureau of Medicine of Surgery
To: Department of Defense, Inspector General

Subj: RESPONSE TO DODIG AUDIT SERVICE DRAFT REPORT QUALITY ASSURANCE IN THE DOD HEALTHCARE SYSTEM (PROJECT NO. D2005-D000LF-0147)

Encl: (1) Navy Medicine Clarification and Comments
(2) Navy Medicine Response to Recommendations

1. I have reviewed the DoDIG Audit Service draft report and your recommendations. In response to the draft report, I have identified statements within the report with which I do not concur. Enclosure (1) provides clarification on these statements and includes rationale, interim plans, and alternative solutions for Navy Medicine's Quality Assurance/Risk Management Program.

2. Trending of issues does not require individual Medical Treatment Facility identification. Whether this approach will ultimately affect the protected status of our quality assurance (QA) documentation will require further legal review.

3. Standardizing our internal processes would certainly benefit our enterprise. We do not, at this time, inspect the QA reporting processes, but will explore incorporating this into our Medical Inspector General visits.

4. In response to recommendations on pages 15 through 17, my comments, interim plans of action, and alternative solutions are provided as enclosure (2).

5. My point of contact for Navy Medicine's Risk Management Program is Ms. Carmen Birk, who may be contacted at (202) 762-3081.

C. S. HUNTER
Acting

Navy Medicine Clarification & Comments
for DoDIG Audit Service Draft Report
Quality Assurance in the DoD Healthcare system
(Project No. D 2005-D000LF-0147)

Page 1, Para 5 - Background

DoD IG Recommendation: Risk Management programs help reduce the liability of the government by archiving PCE information as support for the possible defense of future malpractice cases.

Navy Clarification: PCEs are tracked and trended in order to identify individual MTF or Navy-wide process and system issues. The information gleaned from the PCEs at the local or system level help reduce future litigation by implementation of risk reduction strategies. Since each PCE is unique they have very limited evidentiary value in defense of future specific malpractice claims.

Page 5, Para 3 - Implementation of the DoD Quality Assurance Program

Navy Comment: Concur: The CCQAS Risk Management module is the appropriate venue for reporting claims and potential compensable events (PCEs) - not incident information. To achieve full benefit from the CCQAS RM module we need: (1) development of standard definitions regarding PCEs. (As noted in Appendix B p. 24, it was not DoD's intention to include all adverse events as PCEs); (2) definition of critical elements that trigger a PCE review; (3) development or designation of the module to track PCEs (preferably the JAGMAN Module); and (4) utilization of the Patient Safety Reporting (PSR) System for the incident reporting system vice the CCQAS RM incident report submodule utilized by the Army to identify PCE's for investigation and monitoring.

Navy Interim Process: Navy will use the JAGMAN Module for PCEs. The JAGMAN Module was developed to mirror the Claims Module and to track and trend PCEs (litigation reports without a SF 95 and AD cases referred to the PEB for evaluation). The information in the module can be transferred to the claims and/or disability module efficiently since the data fields are similar once the SF 95 is filed or the disability payment is confirmed.

Page 5, Para 4

DoD IG Recommendation: ASD/HA should establish an interface between the Patient Safety Reporting System and the CCQAS to facilitate the exchange of information for medical incidents determined as potentially compensable events.

Navy Comment: Non-concur.

Navy Process: The CCQAS RM module is a claims database, not a quality assurance (QA) incident reporting system (like the PSR system). Navy does not include QA documents in its Litigation Reports. Incident reports are QA documents protected under the 10 U.S.C. 1102 regulation.

Navy Alternative: DoD is engaged in the acquisition process to purchase a commercial product for a PSR system that will provide a standardized event reporting system for all three services for both near miss and actual events. PSR reports will be available to Risk Managers (RM) and Patient Safety (PS) Managers. Using the PSR system will conserve personnel and monetary resources and achieve the desired goal, as well as, respect the legal policy differences between services. The time and effort spent on creating an interface to transfer information between the COTS Reporting System and CCQAS RM Module could be better used to enhance CCQAS. In addition, the direct connection between the event reporting system and the Claims Module will have a negative impact on the non-punitive PS culture we are trying to achieve. Navy promotes the PS Program (PSP) as a non-punitive system. Cultural change is measured by levels of increased reporting. Direct linking of the two systems will have a chilling effect on the efforts to increase reporting.

Enclosure (1)

Final Report Reference

Page 6 - Quality Assurance Guidance - Identification of Potentially Compensable Events (PCE)

Navy Comment: The definition of PCE and the critical elements needs to be clarified. There is no official DoD PCE module identified in CCQAS. The MTF incident reporting system includes the safety assessment scoring for determining the severity of the injury and identifying the type of investigation required for either active duty or dependents. Both types of reports are forwarded to BUMED RM for processing. The information from the investigations of the PCEs are placed into the JAGMAN Module. Once a disability claim is paid, the case is moved to the Disability Module.

Page 7 - Medical Malpractice Reporting to the Surgeons General

Navy Clarification: BUMED has processed and released completed disability claims to AFIP Legal Medicine. Case information has come from other sources vice from the PEB and MEB processes mentioned in the instruction.

Navy Comment: Appendix C diagram does not include the transfer of final PEB information from the PLEBO to the MTF RM.

Page 8, Para 3 - Patient Safety Program "…visibility beyond summarized and de-identified information is necessary."

Navy Comment: Nonconcur. The DoD PSP was established as a non-punitive reporting program to gain information about process and system issues. For purposes of tracking and trending MHS process and system issues and the aggregation of data, the identification of specific facilities beyond service identification adds nothing to analysis at the MHS level. Currently, there is no centralized event reporting system. As a result, DoD PSP has visibility of numerical summary information and detailed root cause analyses and individual mediation event reports. All reports have service identification and demographic information. The PSR system will allow visibility of de-identified individual event information at the service and headquarters level once released from the MTF. The respective Surgeons General have responsibility for quality oversight of their individual commands, thus the data going forward is de-identified for the purposes of tracking and trending and is consistent with the DoD regulations.

Page 9 - Inconsistent Terminology

Navy Comment: Concur: BUMED will align policies with the revised 6025.13-R.

Page 10 - Use of CCQAS RM for Reporting PCEs and Claims Information

Navy Clarification of Table Data: Individual Navy MTFs do not enter paid claims into CCQAS, BUMED does. BUMED receives paid claims information from the Judge Advocate General (OJAG). This initiates the NPDB review process. MTFs have had access to the CCQAS RM Module since July 2004. MTFs enter disability cases in the JAGMAN Module. BUMED moves the case to the Disability Module once the PEB determination has been made. BUMED releases completed cases to AFIP Legal Medicine.

Revised page 10

Page 11 - Inconsistencies in the CCQAS RM Module - Accessing Pending Claims and PCEs

Navy Correction: There are 4 submodules in the CCQAS Risk Management Module: the JAGMAN, Claims, Disability and Incident Modules. The JAGMAN Module is not an incident reporting module. As noted previously, the Incident and the JAGMAN Modules were developed to address service specific needs.

Revised page 11

Navy Comment: Nonconcur with requirement to allow AFIP to view or access data in the JAGMAN Module prior to the completion of the review process. Final summary data that is of significance to AFIP Legal Medicine is not available until after case reviews have been completed. The module was developed for service-specific needs not for MHS reviews. Entries in the module are work-in-progress where the analysis of an event evolves. The status of a case changes upon receipt of paid claim

Final Report Reference

information or disability information. Navy's PCE investigations are considered attorney/client work product. Release and use of this information prior to settlement or judgement is restricted. After claims have been settled and entries in the module completed, claims are released to AFIP Legal Medicine for analysis. AFIP Legal Medicine sees all released claims with all data completed. To release data prematurely would create unreliable statistics.

Page 13, Para 4 - Patient Safety and Risk Management Reporting

Navy Comments: Nonconcur. As previously stated, the PSR system will be available to PS managers and RMs. This initial information will allow them to decide the type of investigations needed. The information required for claims processing is more in-depth than that provided in the incident report. Linking the databases will have an adverse effect upon the culture of safety that we are trying to achieve.

Appendix B – Additional Information Related to Quality Assurance Guidance

Page 21, Para 2 - Legal Counsel Participation in PCE Determinations

Navy Response: Nonconcur. Review and screening of incident reports is a clinical oversight, not legal function. RM will screen cases and refer those that meet the criteria for a legal investigation to the JAG for their legal advice and expertise. This process allows for the most appropriate and efficient use of scarce legal resources.

Revised page 34

Page 22, Para 3 – Functional Area Reviews

Navy Clarification: Navy's QA instruction required many reviews that are now obsolete, given the electronic computer systems and databases, and are no longer valid requirements. In addition, MTFs are required to be JCAHO accredited and must meet the current accreditation requirements that include the pertinent functional areas.

Navy Comment: Sentinel Event reporting: MTFs utilize the JCAHO definition for reviewable sentinel events so those that fall into "serious psychological "injury would be included.

Navy Medicine Response to Recommendations
to DoDIG Audit Service Draft Report
Quality Assurance in the DoD Healthcare System
(Project No. D 2005-D000LF-0147)

Page 16, Para 2

DoD IG Recommendation: Revise and update the quality assurance regulations and instructions consistent with a revised DoD 6025.13-R.

Navy Response: Concur. Revision will be made to the applicable BUMED instructions after receipt of a signed revision of the DoD 6025.13-R.

Timeline: 180 days.

Page 16, Para 2a

DoD IG Recommendation: Implement interim processes. Require that risk management personnel:

(1) Include adverse events for active duty members when making potentially compensable event determinations.

Navy Response: Concur. Risk Managers (RM) currently evaluate all adverse event reports regardless of patient status. Any quality of care or process issues are evaluated in real time for improvement purposes.

Interim Process: BUMED will define the process to assist the MTF RM in identifying active duty (adverse) event reports that will generate a separate investigation. The results of that investigation will be placed in the JAGMAN module of CCQAS for follow up to determine if the service member receives a disability payment. Once the disability payment has been confirmed, the case information will be transferred to the disability module. As noted in Appendix B (page 24), DoD did not intend that every adverse event be considered a potential compensable event.

Timeline: 90 days.

(2) Monitor Physical Evaluation Board disability decisions and report to the Surgeon General any retirement and separation that was the result of medical malpractice.

DoD IG Recommendation: Recommend changing the term "malpractice" to "negligence". This term will be more analogous to the federal tort claim process.

Navy Response: Concur. BUMED will align policies with revised DoD 6025.13-R.

Interim Process: BUMED will provide guidance to MTF RMs to identify cases requiring monitoring and additional investigation.

Possible Limitations: The disability process has a long tail compared to the claims process. The disability process, when utilized, does not begin until an average of 18 months following either the initial episode of care or treatment for a previous episode of care now affecting fitness for duty. The 18 months does not include the time for the MEB and PEB evaluations, which are frequently backlogged due to increased caseload due to Global War on Terrorism.

Timeline: 90 days.

Enclosure (2)

Page 16 Para 2b:

DoD IG Recommendation: Establish procedures that require Physical Evaluation Board Liaison Officers (PEBLO) report active duty member allegations of injury resulting from medical care to the military treatment facility risk manager for evaluation as a potentially compensable event.

Navy Response: Concur: BUMED will advise the COs to direct the PEBLO at each MTF to report active duty member concerns involving their care to the command risk manager. This information will be processed in the same manner as other concerns involving quality of care.

Timeline: 90 days.

Page 16, Para 2c:

DoD IG Recommendation: Establish procedures requiring that approving officials of Medical Evaluation Boards identify and report any instances of possible active duty adverse events to the risk manager for a military treatment facility.

Navy Response: Concur: BUMED will advise MTF COs to refer any cases referred to the PEB where medical care is called into question to the MTF RM for further evaluation.

Timeline: 90 days.

Page 16, Para 2d:

DoD IG Recommendation: Establish a central quality assurance focal point in each military treatment facility to oversee the centralized reporting of functional area reviews.

Navy Response: Concur: BUMED will align service policy with the revised DoD 6025.13 regulation.

Interim Process: BUMED will advise MTFs that they must a have a process in place to assure that the results of required reviews are processed through the communication chain to leadership.

Timeline: 90 days.

Page 16, Para 3:

DoD IG Recommendations: Validate the inventory of paid claims eligible for release as required by the regulation and submit those claims to the AFIP Legal Medicine.

Navy Response: Concur: Navy has conducted an initial inventory of cases eligible for release to AFIP Legal Medicine, which includes 1308 cases in the claims module. Of these, 636 cases have payment information. Navy has validated and released 264 (42%) of these cases to AFIP Legal Medicine. We anticipate that the remaining cases will be released within 180 days.

Timeline: 180 days.

Department of the Air Force

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

2 November 2006

MEMORANDUM FOR DEPUTY INSPECTOR GENERAL FOR AUDITING, DOD INSPECTOR GENERAL

FROM: HQ USAF/SG
1780 Air Force Pentagon
Washington DC 20330-1780

SUBJECT: Report on Quality Assurance in the DoD Healthcare System (Project D2005-D000LF-0147)

This is in reply to your memorandum requesting the Assistant Secretary of the Air Force (Financial Management and Comptroller) to provide Air Force Medical Service (AFMS) comments on subject report.

The AFMS concurs that revised DoD quality assurance guidance is necessary to facilitate effective patient safety and healthcare risk management programs within the military services. The AFMS participated in a DoD working group in August 2006 to begin revision of such guidance. A new Air Force Instruction (AFI) will follow the revised DoD policy within 180 days to implement the new requirements. In the meantime, the AFMS has submitted a new policy (AFI 44-119) for publication, which complies with current DoD 6025.13-R requirements.

Any questions should be directed to my point of contact Ms. Meghan Snide, AFMOA/SGOC, (202) 767-4137, or meghan.snide@pentagon.af.mil.

JAMES G. ROUDEBUSH
Lieutenant General, USAF, MC, CFS
Surgeon General

Attachment:
Recommendations

SG DOC: 06-0315

Comments on Report on Quality Assurance in the DoD Healthcare System

RECOMMENDATION: MTF risk management process identify any potential compensable event (PCE) and include adverse events for active duty members when making PCE determinations.

CONCUR: The identification and analysis of PCEs on all beneficiaries is an important patient safety and risk management process. Early legal participation is vital for financial loss prevention. Currently Air Force policy requires military treatment facilities to identify and review incidents with poor or unanticipated clinical outcomes, which may result in financial loss. In addition to identification of PCEs, the AFMS has a robust review process called the Medical Incident Investigation (MII). The MII includes a team of clinical experts (not from the MTF where the incident occurred), which investigates the incident, reports the findings, and presents performance improvement recommendations to the Commander. The MII team prepares a formal report and briefs the findings/recommendation to the Office of the Surgeon General. The AFMS will include PCEs and MII incidents in the Centralized Credentials Quality Assurance System (CCQAS) PCE module; this will improve the visibility of incidents. Currently, CCQAS does not have the capability to capture PCEs in the risk management module and these events are only visible to the MTF. To fully support the DoDIG recommendation, DoD must develop a PCE tab in the CCQAS risk management module including an appropriate workflow process across the medical-legal offices, and service-level visibility of the events. This will allow MTFs to appropriately enter PCE, collaborate event review with legal services, and facilitate service-level involvement with risk reduction activities.

RECOMMENDATION: 1) Monitor Physical Evaluation Board (PEB) disability decision and report to the Surgeon General any retirement and separation that was the result of medical malpractice. 2) Establish procedures that require Physical Evaluation Board Liaison Officers (PEBLO) report active duty member allegations of injury resulting from medical care to the MTF risk manager for evaluation as a potentially compensable event. 3) Establish procedures requiring that approving officials of Medical Evaluation Boards (MEB) identify and report any instance of possible active duty adverse events to the MTF risk manager.

CONCUR: These three recommendations are centric to the MEB and PEB functions and require coordinated procedures between Line of the Air Force and Medical Offices. We concur adverse events involving active duty members that lead to MEB and PEB actions should be reported to the MTF risk manager for appropriate review and reporting. The current Air Force MEB and PEB process is administered and monitored by the Air Force Personnel Center and patient administration functions. To implement DoD IG recommendations, the revised DoD quality assurance regulation must require change in Service policy (AFI 41-210 and 44-119) to identify adverse events and possible medical malpractice within the medical evaluation process and forward that information via the PEBLO to the MTF risk manager. The MTF risk manager

will then enter the events (PCEs) into CCQAS and forward them to the Surgeon General's Office. This will facilitate full visibility and review from the MTF through the Surgeon General's Office to Health Affairs.

RECOMMENDATION: Specific medical incident information necessary to monitor the DoD Patient Safety Program is available to healthcare managers…to provide the Assistant Secretary of Defense (Health Affairs) visibility of actual and potential problems in the military health system.

CONCUR: AFMS will comply and provide medical incident/adverse event information, as required, for military health system-wide visibility of events. Following the revision of the DoD regulation, the AFMS will implement within 180 days via a new AFMS instruction.

RECOMMENDATION: MTFs consistently document with uniform content and standard format the results of functional area reviews. The content, format, and frequency of reports should be coordinated between Health Affairs and military department. Additionally, the military services shall identify and establish an MTF centralized quality assurance focal point to ensure all elements of functional area reviews are performed and consolidated.

CONCUR: Functional area reviews measure clinical performance and are monitored by the Joint Commission of Accreditation of Hospital Organizations (JCAHO) and Accreditation Association for Ambulatory Health Care (AAAHC). Since the functional areas are based upon high-risk processes, they may vary from one MTF to another. The AFMS will centrally collect and consolidate the reviews required by the accreditation agencies, as well as any additional reviews required by DoD.

RECOMMENDATION: MTFs will consistently utilize risk management modules of CCQAS for full and timely reporting of PCEs, open and paid malpractice claims, as well as active duty disability claims.

CONCUR: AFI 44-119 requires MTFs to utilize CCQAS risk management module for malpractice claims and reported active duty disability payments when associated with the medical malpractice. Currently CCQAS does not have a PCE module, when that capability is developed, the AFMS will implement policy to meet this requirement.

RECOMMENDATION: Establish an interface between the Patient Safety Reporting System and CCQAS to facilitate the exchange of information on medical incidents determined to be potentially compensable events.

NONCONCUR: The Patient Safety and Quality Improvement Act of 2005 and organizations such as the Institute of Medicine (IOM), Agency for Healthcare Research and Quality (AHRQ), and the National Patient Safety Foundation (NPSF) do not support an interface with patient safety reporting and risk management systems. The Patient Safety and Quality Improvement Act of 2005 proposes patient safety work products are "for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize

patient risk…and analyze information for reporting to a patient safety organization." Furthermore, the Act states patient safety products shall not be "admitted in a professional disciplinary proceedings against a provider, or subject to discover in connection with civil or administrative proceedings…the entity maintains patient safety work products separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product." Many risk management products (i.e. medical malpractice claim documents) are utilized in such proceedings against medical providers, and therefore must be kept separate and apart from patient safety products/information. According to the IOM, a "culture of blame" is the top barrier to implementing a patient safety system. A culture of safety should be established, one which supports an open atmosphere for reporting and addressing errors. Interfacing the patient safety reporting system and the risk management system (CCQAS) will have a profoundly negative affect on our efforts to build a safety culture which fosters reporting of near miss and adverse events to learn and use each event as an opportunity to improve.

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